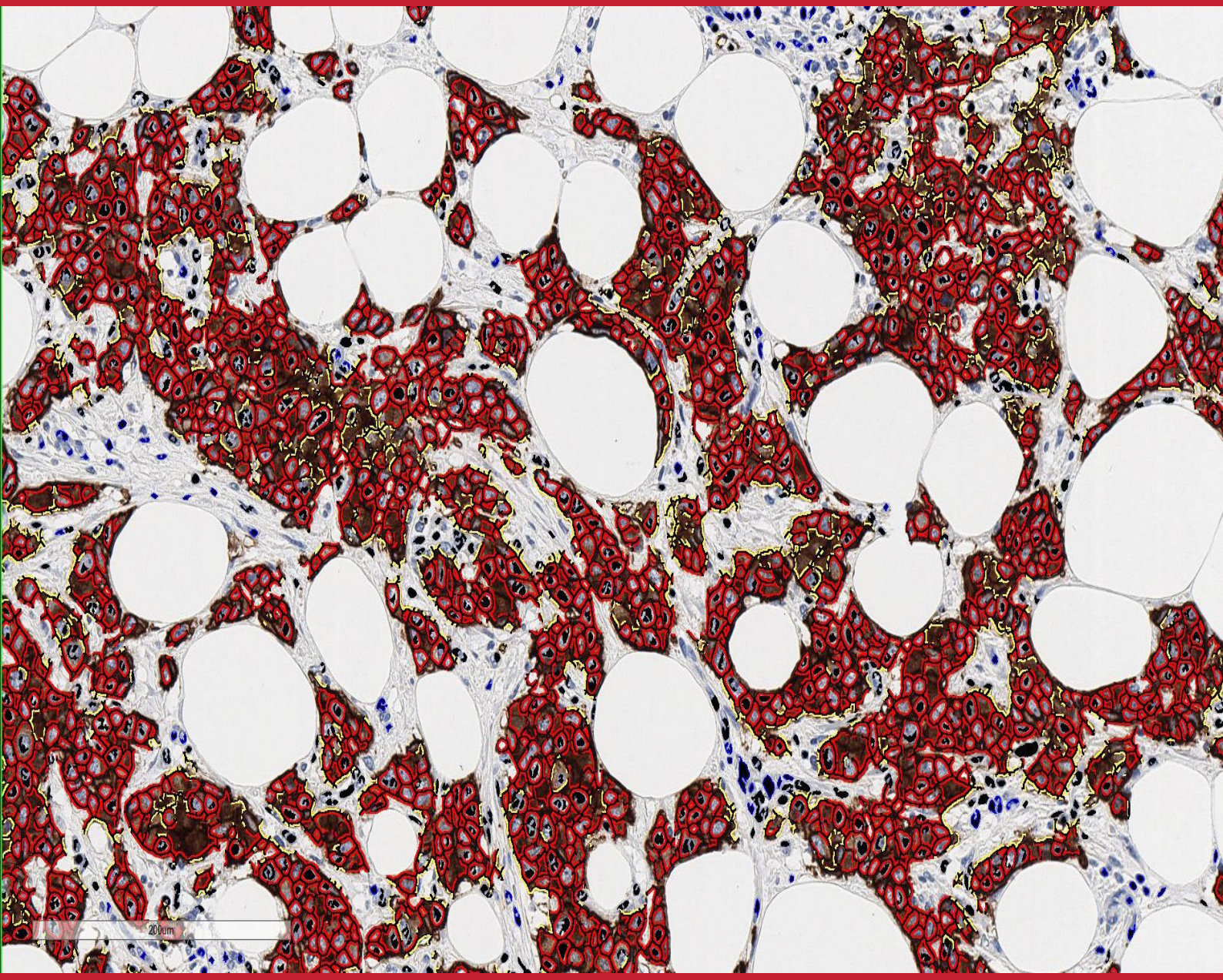
IRE

ISTITUTO NAZIONALE TUMORI

REGINA ELENA

ISTITUTO DI RICOVERO E CURA A CARATTERE SCIENTIFICO



Scientific Report 2020

Computational image analysis for HER-2 immunohistochemistry (IHC) of high-resolution whole slide images (WSI) of human breast carcinoma tissue. Image analysis algorithm detects positive cell membranes for a target chromogen and quantifies their intensity. Cell identification result overlaid on the IHC staining image. Cells staining classified as 0 (blue), 1+ (yellow), 2+ (orange) and 3+ (red) is based on positive staining intensity. The high-resolution WSI were acquired with Leica APERIO AT2 Scan.

Courtesy of Dr. Enzo Gallo

Acknowledgments "The Editorial Organization of this Scientific Report was created by Dr. Martina Ferrazzano, member of IRE Grant Office"

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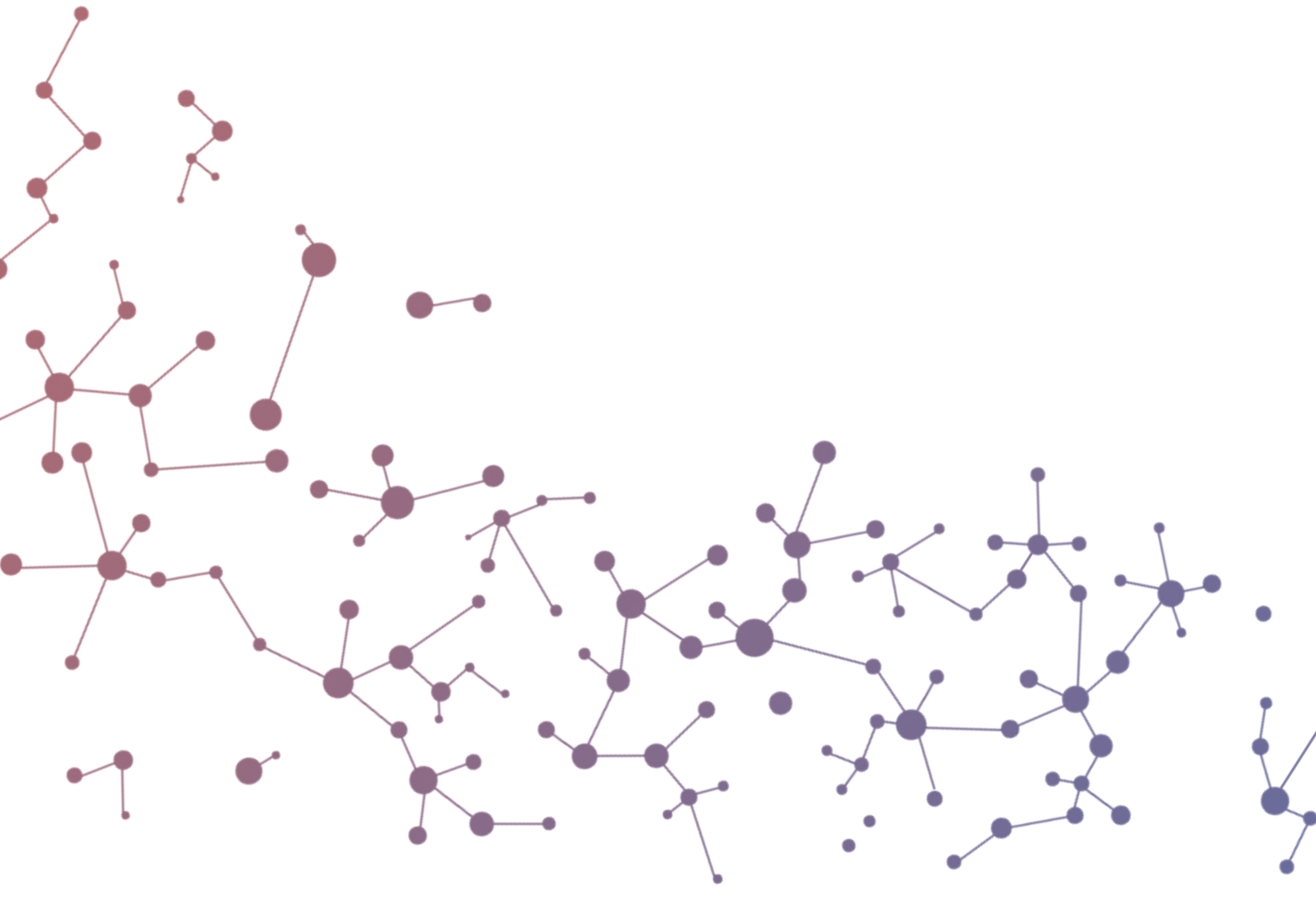
Introduction and IFO Organization



CEO IFO Message
Dr. Francesco Ripa Di Meana

Dear Readers,

In the Scientific Report 2019, I had mentioned in my welcome speech the first wave of the COVID-19 Pandemic, which had already broken out at the time of publication. This major event surely marked 2020, not only because of the pain and misery it caused due to the number of lives lost, but also because it stimulated the scientific medical community to respond to the global emergency in a timely and innovative manner.

By introducing this Scientific Report today, I can confirm that experiencing the extraordinary times of the pandemic not only did it not hinder the development of the Regina Elena National Cancer Institute but allowed for great progress to take place both in health care and in research. However, at the same time, the COVID-19 pandemic placed our organizational structure under great stress, and this gave us the opportunity to rethink our organizational models in view of a permanent integration between clinicians and researchers. Our response to the pandemic promoted better collaboration between the two institutes IRE and ISG, between our laboratories and other research centers, giving way to numerous innovative projects investigating the spread of the pandemic both on cancer patients at our Institute and on health care professionals.

As far as health care assistance is concerned, it seems that we were able to maintain an outstanding level of performance, even during in the most difficult phases of the corona virus, regarding production capacity, especially concerning surgery, which saw the operating block permanently in operation, never leaving or delaying surgery for any of our patients treated before, during and after the infectious wave.

This result was achieved by having made our hospital Covid-free after implementing control measures for hospital staff and patients, tracing each individual case and the people they encountered in a thorough and timely manner (thanks to our microbiology laboratory that processed hundreds of nasal swabs daily) as well as by adopting behavioral and organizational procedures that made it possible to limit each source of outbreak. Agreements made with other hospitals that had suspended their oncological surgery activities made it possible to always keep the productivity of our operating block to a maximum. The need to keep our patients closely monitored due to obligated distancing or because of fear of catching covid that kept patients away from the hospital led to innovative activities such as call centers, telemedicine services, remote medicine and pharmaceutical delivery to patients at a distance, thus offering continuity of care to patients in difficulty. We will cherish these innovative services even after this pandemic. Finally, the last days of 2020 saw the vaccination campaign kick-off.

The flourishing research initiatives during this first year of the pandemic were also exciting to see. Activities increased up to 20% in areas already ongoing, and on projects specifically aimed at studying the impact of Covid on fragile patients and

health care staff. Indeed, the opportunity to develop our NGS capabilities, both from a technological and organizational perspective, and going beyond patient profiling activities and active participation in studies on virus variants was important. Establishing a unit dedicated to Phase 4 completed a global offer for clinical trials in all its phases, enabling IRE to compete as a platform available to profit and non-profit scientific research (it is useful to remember that in the middle of the pandemic we presented the self-certification for phase 1 non-profit research).

During 2020, the OECI site-visit took place for certifying IRE as a Comprehensive Cancer Center. Preparing for the 'site visit' and implementing measures that complied with the final recommendations, certainly represented an important and further incentive for improvement.

In addition to this new 'chapter', our collaboration with the University of La Sapienza and IRCCS Bambino Gesù was re-launched in the post-pandemic phase on precision medicine projects and cell therapies, and on providing new technologies for diagnosis and treatment.

Finally, I would like to highlight how the investment made by our Strategic Directorate in assigning organizational and professional positions in hospital management contributed significantly towards building the image of our Institute, which considerably strengthened IFO as a specialist cancer centre. In fact, it helped IFO focus more on specialized care services offered by the Regional and National Health Care Network. We have also defined a virtual catalogue better guiding users and stakeholders, consequently increasing transparency as well as trust between clinicians and patients.

This introduction to the Scientific Report 2020 represents one of the last deeds of my term as General Director of IFO. I believe my mandate focused on building a more solid institutional and organizational foundation, based on the values of quality, innovation and patient centrality, which will serve for re-launching IRE in an era where the field of Oncology holds much promise.

Therefore, I would like to thank all the hospital staff with whom I have shared these years with and wish the Regina Elena Cancer Institute all my best for a successful and fruitful future, to which I hope to have contributed.

General Director of Istituti Fisioterapici Ospitalieri (IFO)

Dr. Francesco Ripa di Meana

Scientific Director IRE Message
Prof. Gennaro Ciliberto

Dear Readers,

The year 2020 will be remembered by all for the COVID-19 pandemic. The first wave spread all over the country starting at the end of February and severely hit the northern regions of Lombardia, Veneto, Piemonte and Emilia Romagna. Our country payed an extremely heavy death toll due to the myriad number of deaths. The entire national health care service was placed under stress, our personal life changed with the strict measures of social distancing, commercial and work activities were subjected to strict lock downs, the entire Italian economy plunged into crisis.

The first pandemic wave decreased its strength at the beginning of Summer, most likely due to the severe lock down measures that were implemented from March to May, but was then followed by a more prominent and more diffused second wave starting in September. As a matter of fact, at the time of writing this welcome speech in April 2021, we are still experiencing an elevated spread of the virus, also in large part linked to the emergence of more infectious variants, with dozens of thousands of newly infected people and hundreds of deaths occurring every day. Our hope at the moment lies in the vaccination campaign that aims to reach herd immunity later this year.

Our Institute responded to this new situation by implementing a series of measures directed at ensuring the status of a COVID-free clinical center as well as to allow our cancer patients to gain access to the necessary continuity and intensity of our health care services. Thanks to everybody at our hospital, we quickly resumed the same level of clinical performance of pre-pandemic times in a short time frame and even improved the efficiency of administrative activities with introducing the opportunity of "smart working" whenever possible.

From a research perspective, our laboratories never closed not even during the initial months of the pandemic. A good level of activity was maintained at all times and this resumed full speed in the period of May-June. I would like thank all our scientists who dedicated their time to maintaining these research activities under very difficult conditions. Overall, our scientific productivity even increased in the year 2020 with roughly 20% more publications than the previous year. This was also in part due to the spontaneous interest of our researchers towards the biology of Sars-CoV-2 and COVID-19 which led to publishing several papers on this new topic, especially in relationship to the impact of COVID-19 in oncology.

To briefly summarize the main scientific achievements our Institute reached in 2020 have been the following:

1. Published more than 350 peer-reviewed papers for a total of more than 2000 total Impact Factor
2. Published 30 papers with an IF above 10
3. Obtained 26 grants and 5 fellowships for a total economic value of more than 3 Million euros
4. Obtained the approval by our Ethics Committee of more than 130 new Clinical Studies
5. Filed four new patent applications
6. Obtained a grant from the Ministry of Economic Development (MISE) for the enhancement of the Technology Transfer Office.
7. Obtained formal approval for a research project by the Institute Soka Gakkai to study the impact of COVID-19 in fragile patients (mainly cancer patients): project COMETA
8. Completed the procedures of stabilization of the Personale di Ricerca Sanitaria (Piramide dei ricercatori)
9. Carried out the second meeting (in a virtual mode) of the International Scientific Advisory Board (ISAB) in November
10. Obtained administrative approval of the Strategic Plan of Research for years 2020-2022.

This long list of our main achievements is testimony to the high level of commitment that our Institute has dedicated towards excellence together with our resilient researchers, administrative support staff have shown under the difficult environmental situation we are experiencing in these years.

Gennaro Ciliberto

Scientific Director ISG Message

Prof. Aldo Morrone

Dear Readers,

The year 2020 has been one of the most challenging I have ever experienced in my life. We all have faced the devastating and dramatic explosion of COVID19 pandemic that affected severely our daily life as a single person and as a people community.

Since our sister Institutions, Regina Elena and San Gallicano, deliver public care for fragile subjects, as those affected by cancer, dermatological and viral diseases we have been actively involved as front line for fighting COVID19. While the pandemic has significantly halted most of the research activities both clinically and experimentally, it has concomitantly instigated an unprecedented spirit of collaboration within the international scientific community that has been pivotal for limiting the impact of COVID19. This collaborative spirit has pervasively flowed into the research activities of our institutes leading to the activation of intramural multidisciplinary teams that have reshaped significantly our care delivery.

COVID19 has also increased disparities that have exacerbated unsolved social issues regarding migration and homeless people. I feel very proud to say that we, as a scientific community of both institutions, devoted extraordinary efforts to monitor and protect this fragile population. The related scientific programmes are running in collaboration with almsgiver of the Pope, with Binario95, with Caritas, with Medicina Solidale and Rome Municipality. As we are public institutions in which patient care is profoundly impacted by the research activities of our laboratories, we have strongly contributed to understand how COVID19 affects more severely fragile people than those in healthy conditions.

The current year will hopefully see Olympic Games taking place in Tokyo during summer. We are proudly collaborating with the Fencing and Pararowing national teams to monitor closely their training activities in preparation for Tokyo. The collaborative research project named Serena brings together our sister institutions with the Universities of Milan and Trento and lasts as soon as the athletes will leave to Tokyo.

Despite vaccination is having a tremendous and positive impact on COVID19 pandemic this will not end within months but it will last for years both as viral diffusion due to the increased number of variants and for the long COVID19 impact on people who have previously experienced COVID19 infection. We need to be ready for both challenges and to serve as operative arms of both Minister of Health and Regione Lazio. We must also be aware that every time we deliver care, we also spread novel knowledge derived from our active research activities.

Looking forward to collaborating and learning from all of you

Prof. Aldo Morrone

Scientific Director

San Gallicano Institute

IFO Chief Medical Officer Message
Dr.Branka Vujovic

Dear Readers,

I have been the Chief Medical Officer of IRCCS IFO since 2017. This past year, I have been completely dedicated to improving the organization of the Institute. The spread of the new Coronavirus is probably one of the greatest health crises of our modern era, a revolution that has claimed too many innocent lives , leading to a social and health crisis which has forced us to change many organizational health care routines that had been in use for a long time.

The urgent need to adjust processes, not only regarding legislative stimulus, has allowed to re-analyze the health care pathways with placing greater attention on all patients who are potentially more vulnerable to the SARS-Cov-2. Recent studies show that cancer patients are more likely to develop severe infection and die from COVID-19. The Istituti Fisioterapici Ospitalieri (IFO) is made up of two Scientific research Institutes for hospitalization and care that are completely dedicated to frail patients. Given that we are a NON COVID facility, means that greater focus is placed towards ensuring the safety and health of our patients and staff.

The new organizational asset, gradually implemented, has resulted in a series of measures taken to protect staff and patients. New operating instructions for information/training and specific entrances for gaining access to the Institute for patients, staff and providers, have been implemented as well as actions taken to support cancer patients, including those at home. Communication strategies have also been impacted by the changes implemented: new channels have been enhanced or created to provide guidance and support, as well as greater sensitivity to hand hygiene and the proper use of PPE.

The post-pandemic legacy will allow IFO to continue to improve their growth in taking in care of their patients, which remains the main focus. The renewal process, to date, consists of health care and psychological support services for patients and family members (ParlaConNoi-MiPrendoCuraDiTe), telemedicine activities (such as television/teleconsultation) to ensure follow-up pathways and professional development webinars for staff. We even take care of our patients by having extended our Institute's boundaries towards territorial initiatives such as delivering medicine directly to our patients homes – with an established treatment plan and stable conditions - and offer free nasal swab testing for all cancer patients in the Lazio Region.

In 2020, the Health Directorate also participated in research projects together with the Scientific Directors IRE and ISG that aimed at studying this pandemic from multiple perspectives. In particular, we contributed to the management of a multi-center project which was approved by the Ethics Committee entitled: "Development of approaches and metrics to assess the impact and improve outcomes of patients with fragility in the covid-19 era". This project aimed at studying the impact of infection on the compliance of fragile patients to therapies, hospital management of fragile patients and how the virus can modify the immune system of fragile subjects within oncological and immunocompromised patients.

For the future, it is essential for the Institute to remain and continue on this solid pathway, especially with regard to mapping risk analysis so that we can provide effective and safe services. In addition, I can already anticipate that together with the Scientific Directions in 2021, we will be at the forefront of vaccinating all our health workers, patients and all those people who, in accordance with the rules of the national vaccination campaigns, choose our Institute as their vaccinating center Overcoming this crisis, therefore becomes an opportunity for IFO to put its projects into practice and reinforce the innovations implemented so far, as well as to remain a safe and a regional reference point for the diagnosis and treatment of all types of cancers.

Yours sincerely, Dr. Branka Vujovic

IFO Administrative Director

Dr. Laura Figorilli from 03/05/2021 Acting CEO

Office of the Administrative Director

The Administrative Director manages and coordinates the administrative activities of the entire Institute, and attentively considers the independence of each department and operating unit (UOCs and UOSDs). Further responsibilities include: facilitating the strategic planning process along with establishing actions in order to verify efficiency, effectiveness and quality of the administrative activities of the Institute.

The Administrative Director works side by side with the General Director in the administrative, financial and organizational management of the Institute, to ensure that all the necessary administrative interventions are implemented in order that all the structures within the Institute carry out the activities. The Administrative Director is also responsible for guaranteeing transparency and the regularity of all administrative activities, as well as approving deliberative acts that are proposed by the Departmental Directors (UOCs and UOSDs) which are then finally adopted by the General Director

The Office of the Administrative Director deals with all the technical/ administrative activities supporting health care services as well as research matters concerning both Scientific Directions.

The Administrative Director:

- As a member of the Strategic Management, plays an active part in IFO's decision-making processes, such as establishing strategies for corporate development and innovation programs, setting priorities and allocating resources to the various corporate functional areas;
- Ensures the integration and harmonization of administrative procedures for all the organizational structures of the institute, as well as leads the activities of the administrative organizational structures, promoting innovation and development;
- Works closely with the Chief Medical Office towards developing new forms of integration between clinical and research areas;
- Collaborates with the regional structures involved in the various business processes;
- Cooperates with other health care structures within the territory for developing and producing a synergistic network for the healthcare system.

In 2020, the Administrative Direction was also involved in managing the covid pandemic within the Institute. In March 2020, approximately 200 agile workstations were activated to ensure the safety of all our employees who could work from home, accelerating a process that would have taken years to complete. We also worked towards recruiting necessary personnel for the new lines of activities that arose due to covid.

Additional COVID-19 accomplishments:

- Setting up screening check points for external visitors
- Strengthening the capacity of the microbiology and virology laboratories
- Establishing a vaccination hub
- The ABS Office temporarily supplied the laboratories with all the necessary equipment for carrying out their activities which involved testing molecular nasal swabs and virus sequencing.
- Through the Human Resources Department all the necessary information was provided for the staff to take advantage of the benefits made available by the Italian government.16

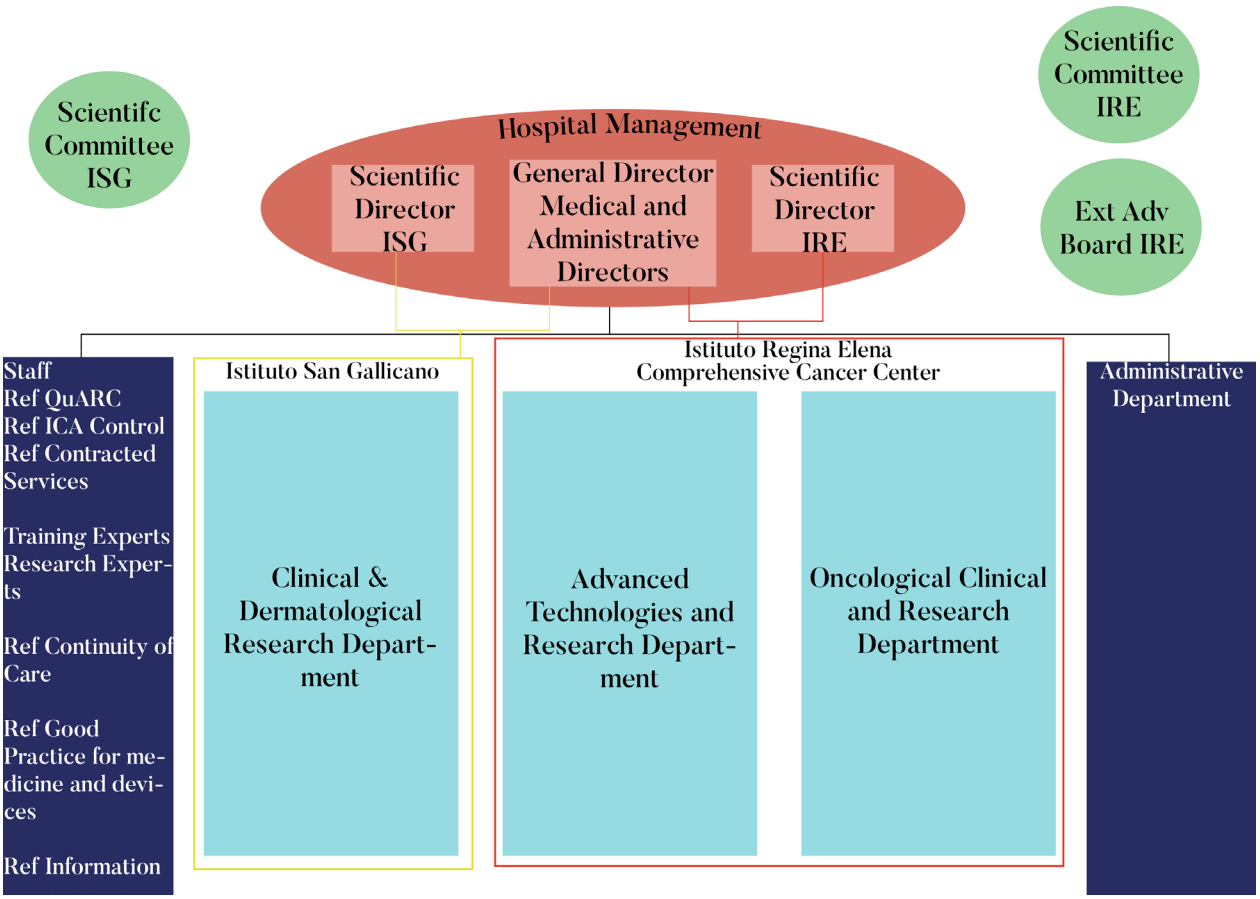
- IT services quickly created a telemedicine/teleassistance platform available for all IFO outpatient clinics.

Yours sincerely, Dr. Laura Figorilli.

Staff

Nicoletta Avitabile
Santina Paola Cocuzza

Organization chart of Istituti Fisioterapici Ospitalieri - IFO



Press Office & Public Relations

Head: Dr. Lorella Salce

Staff

Simona Barbato, press officer, science communicator, content editor

Francesco Bianchini, social media referent, video maker

Daniela Renna, administrative collaborator, corporate identity referent

Mauro Di Giovanni, photographer

Ivana Zardin, photographer

Press Office Activities

- Communication strategy and plan
- Covid-19 crisis communications
- Corporate identity and brand communication;
- Public Relation
- Media relations management: press releases, press conferences;
- Website: managing content, updating press section and news;
- Managing TV, radio and press interviews;
- New media communication (Facebook, Twitter, Youtube, Instagram, Linked-in, Telegram);
- Digital press review

Annual Activities Report

Press releases	44
Press agency launches	200
Mass media presences	1530 (newspaper, magazine, radio, TV)
Internal communication items (news, mail everyone, closed-circuit TV, poster, brochures, pamphlets, leaflets, info-graphics, signage)	500
Facebook (13.570 follower)	705 post; 2.85 million views
Youtube	153 videos posted, 14.143 hours watched, 400.000 views
Twitter (1.471 follower)	745 tweet; 980 mentions; 960 retweet; 840.000 views
Instagram (1.570 follower)	185 post; 140.000 views
Linked-in (5.026 follower)	415 post; 235.000 views
Telegram	240 post, 28.000 views, 164 subscribers

Some of the Campaigns of 2020

- World Cancer Day campaign for promotion public awareness. February
- International HPV Awareness Day campaign. March
- Fundraising campaign "la forza dei più Fragili" April
- 5x1000 campaign for the collection of the 5 per thousand tax option from taxpayers (a governmental initiative whereby for every thousand paid by a taxpayer). May to September
- The European Researchers' Night on-line event:

a. Facebook Webinar: Pandemics & Vaccines, is a sustainable future in our hands?
b. Videos on scientific research topics November

Awards

- III "La Rosa d'Oro" National Journalism Award winner. September
- Smartphone d'Oro, PASocial award for digital public communication – December

COVID-19 Crisis Communication

During the months of pandemic, the Communication, Press and External Relations Office of IRCCS IFO Regina Elena and San Gallicano, played a decisive and synergy role with the apical management, crisis unit and communication offices of the other institutions, as well as representing a solid link between institution and citizenship, strategic direction and internal staff.

A series of information actions has been fully and comprehensively activated to cover three areas of intervention:

1. Convey good behavioral norms and a new culture of being a user/operator inside the hospital, in order to reduce infections;

2. Provide clear and correct news, procedures and data to unravel doubts about the new virus;

3. Counter disinformation, propaganda and misinformation.

Our Institutes are characterized by being research and care centers in oncology and dermatology, they mainly deal: cancer patients, dermatologists, chronic and rare.

A seven-day/seven operational working group ensured timely and timely communication on analogue, digital and multimedia channels. Digital channels have once again proved strategic and useful, without detracting from traditional channels. Only in the field of coronavirus, on social media, we have obtained a total of 2 million and 270 thousand views.

Education and Training Unit

Head: Dr. Tiziana Lavalle

The IFO, as a Healthcare Company, has been identified by AGENAS (National Agency) as provider no. 1270 for Continuing Medical Education (CME) both for residential methodologies (RES), since June 2018, for field training methodologies (FSC) and now for ADL (at distance learning) or e-learning. The I.F.O. has an Education Area "Raffaele Bastianelli", which houses 3 classrooms, respectively of 199, 90, 50 seats and the Training Service is made up of 1 manager and 4 collaborators, two with a health-care profile, two with an administrative profile.

The Budget made available to the Training Service was € 380,000, to be used for internal and external training events, internships and for the management of the activities supporting training events in the Education Area "Raffaele Bastianelli".

In 2020, the Company Training Plan (PFA) was approved with resolution no. training events, to which were added the events gradually created as business needs. Cause the SARS-Cov-2 pandemia, the training activities were suspended and many courses were transformed in video-call briefings.

In 2020 has been concluded no. 20 CME accredited events, of which 18 scheduled with a single edition. These events took place at the "Raffaele Bastianelli" Education Area, at the Patient's Library computer room and other Meeting Rooms for small groups.

Many educational activities has been performed without CME credits, using on site and bed side teaching:

- Safety behaviors in care, diagnosis and treatments during COVID-19 pandemia;
- Prevention of COVID-19 disease and use of PPE;
- Safety and Hygiene of hands;

and using online tutorials:

- How to do a nasal swab;
- How to dress and undress PPE.

The Training Service of IFO managed, cooperating with the Scientific Direction, internship and fellowship for 22 students of 5 Universities.

Quality, Accreditation, clinical Risk management (QuARC) Unit

Head Dr. Assunta De Luca

Mission

To improve the integration between health care professionals involved in patient care, assistance, research and the administrative side contributing to a better understanding of the improvement initiatives ensuring "quality" of care and patient "safety".

In particular, the QuARC Unit:

- Defines the areas for elaborating Protocols, Procedures, Operating Instructions according to Evidence Based criteria;
- Coordinates the study groups set up for the elaboration and dissemination of shared responsibility tools based on Quality Management System (QMS)
- Adopts and implements the clinical risk management process for medical, nursing, technical health, rehabilitation, research and support (administrative) activities with the involvement of health care and nonhealth professionals;
- Contributes to the verification and evaluation of the Quality System in accordance with the UNI EN ISO 9001 Certification and other Accreditations processes such as OECI, JACIE etc;
- Proposes organizational models aimed at preventing clinical risk.

Resources

The QuARC Unit is made up of a medical hygienist, a nursing coordinator with proven experience in quality and clinical risk management, a nurse dedicated to the management of healthcare-acquired infections (HAis) and an administrative expert in the management of the incident-related reporting information system (SIMES) and monitoring adverse events and all administrative support activities in the Unit.

The QuARC Unit is dedicated to implementing a culture of QUALITY and the correct management of the CLINICAL RISKS throughout the "IFO network for quality and safety of care" composed by "reference persons" for each unit/service at IFO (clinical, research and administrative).

Main Activities 2020

The UNI EN ISO 9001 certification and accreditation: Upholding the requirements as an IRCCS and oncological and dermatological certified body.

Improved the Clinical Risk Management System through Implementing good practices issued by the Ministry of Health, Applying recommendations through procedures and workplace directives, also deriving from international and European bodies.

This activity has been implemented by establishing the Quality Management, Accreditation and Clinical Risk Committee (CoQuarc).

During 2020 the clinical risk activities at IFO strongly focused on the more fragile patients. For this reason, the goal in upholding our Institute as a NON COVID body has been priority

ensuring the safety of patients and providers. Managing the pandemic has determined, the need to create new protocols/procedures/operational instructions on an organizational level as well as the creation of dedicated pathways for patient, staff and provider access, updating what was already in place limiting access to IFO without neglecting our Institute's mission in providing care and psychological support to both patients and their families (ParlaConNoi, miPrendoCuraDiTe, telemedicine activities). In order to limit unnecessary access to our Institute, a drug delivery system to the homes of our oncology patients has been set up in accordance with their therapeutic treatment plan thus extending our services beyond the walls of IFO.

For healthcare personnel, IFO has set up regular training and educational activities through webinars, tutorials and other informative/training tools.

The Control Committee for Healthcare Associated Infections (CC-ICA), which operates on the general indications set out in the Institute's annual plan and in accordance with the regional guidelines to identify and implement planned activities, in relation to the prevention and control of healthcare-related infections at IFO. In fact, this is one of our main priorities for controlling and managing clinical risk. This activity involves incorporating measures into the Corporate Plan for controlling hospital infections through numerous actions to be implemented in accordance with the regional plans:

- active surveillance both prior hospitalization and in the preoperative preparation phase in terms of epidemiological indicators, based on quarterly reports regarding the number and type of infections/colonizations for "health alert germs" distributed by each ward, and relative frequencies of antibiotic resistance profiles, the type of antimicrobial used, consumption in DDD (Defined Daily Dose) and relative costs.

- management indicators regarding the ICA surveillance system, which includes evaluating the adherence of healthcare personnel with respect to specific indications (procedures/operational instructions) (e.g.: executing active surveillance swabs for certain types of patients; adopting additional precautions in case of patients with infection).

- Continuous training of healthcare personnel in applying specific procedures in order to improve active surveillance for certain types of patients at risk of infection

- Corporate Antimicrobial Stewardship Program (ASPs) is a team composed of an infectivologist, pharmacist, an expert in resuscitation with expertise in ICA, a hematologist with expertise in ICA, a microbiologist and 20 "physicians in charge of the responsible use of antimicrobials" which aim to involve all departments and services at IFO more closely.

Pharmacovigilance

Head: Dr. Felice Musicco

Staff

Angela Frazzetto, Pharmacist
Annamaria Di Filippo, Pharmacist,
Agnese Persichetti, Clinician
Chiara Fulgenzio, Pharmacist

Mission

- Supporting and promoting reports of suspected drug adverse reactions (ADR); Activities in clinical wards to promote ADR reporting with doctors, nurses, technicians, etc.
- Monitoring safety of medicines: collect, assess, report, and analyze adverse events
- Registering and updating ADR reports in the National Network of Pharmacovigilance (Rete Nazionale di Farmacovigilanza RNF- AIFA) also in collaboration with QPPV of Pharmaceutical Industry and the Lazio GLASS pharmacovigilance regional group
- Review of research study protocols, pharmacovigilance section
- Reporting ADR in research studies as Registered PV person in EMA for IFO
- Member of the Lazio Regional Panel for Pharmacovigilance
- Member of the Lazio Regional Committee for Drug Uses

Clinical Activities

- Number of ADR reports registered in RNF: 63 reactions in 2020 (14 serious)
- Drug safety information to doctors: highlight and internal transmission of alerts published by regulatory agencies (EMA, AIFA)
- ospital reports, guidelines, procedures:

    a. Participation in OECI and other certification activities
    b. Procedures for Pharmacovigilance in interventional and observational studies

Research Activities

- Preparation and review of the pharmacovigilance section in interventional and observational study protocols; collaboration in writing of DSUR;

- Principal Investigator Observational studies “Nivolumab and Pembrolizumab in real life in advanced metastatic melanoma: observational study about effectiveness and safety” and “Palbocilib nel trattamento del carcinoma mammario: Real World Data e indicatori di farmacoutilizzazione” and studio “S.U.R.E (Sicurezza Utilizzo Rituximab Ematologia): Studio osservazionale prospettico multicentrico su sicurezza ed efficacia di rituximab originatore o biosimilare nei pazienti che accedono ai Servizi di Ematologia del SSN”

- Cancer drugs for solid tumors approved by the EMA since 2014: an overview of pivotal clinical trials R Lasala, A Logreco, A Romagnoli, F Santoleri, F Musicco, A Costantini

- European journal of clinical pharmacology 76 (6), 843-850 2020

- Anti-PD-1 immunotherapy in advanced metastatic melanoma: State of the art and future challenges (vol 240, 117093, 2020) RS Moreira, J Bicker, F Musicco, A Persichetti, AMPT Pereira LIFE SCIENCES 245 2020

Office of Research Administration

Head: Dr. Ottavio Latini

Staff

Giovanni Cavallotti
Maria Assunta Fonsi
Giuseppina Gioffrè
Annalisa Marini
Samantha Mengarelli
Catia Minutiello

Mission

The Research Administration Office (SAR) provides administrative support to the Scientific Directorates and researchers of the Regina Elena Institute and the San Gallicano Institute by carrying out the following activities:

- Approve/ modify/disapprove protocols of paperwork and storing all documents electronically;
- Prepare administrative procedures for creating and establishing research agreements, managing all expenses relating to funding from the Ministry of Health (Ricerca Corrente) and research funding from specific targeted projects (Ricerca Finalizzata) and related reporting;
- Create administrative procedures for drafting conventions regarding clinical trials and projects approved by the Ethics Committee and related reporting;
- Coordinate Conto Capitale Grant funding measures;
- Prepare administrative procedures for employing research collaborators and administrative support staff through flexible contracts funded by research grants;
- Manage reimbursement of various types of expenditures for both permanent and non-permanent staff (missions, publications, staff development courses, etc.);

This office is under the supervision of the Administrative Director of the Institute where it carries out all assigned tasks as well as liaising with the Human Resources Unit, Economic Resources Unit, the Decision Making Acts

Department, Occupational Medicine, in addition to the various Project Managers of specific targeted funded projects.

Activities

During 2020 the SAR dealt with managing the administrative and economical aspects of public and private research projects funded by the Regina Elena Institute (IRE).

The SAR handled the administrative and accounting procedures of all expenses concerning Ricerca Corrente 2020 funding (€ 3.156.389,57) for IRE and prepared the economic report for Ricerca Corrente 2019 funding (€3.743.955,58). This office also handled Ricerca Finalizzata funding for a total of € 3.424.462.

In the same period, the SAR Office was appointed Coordinator of the Conto Capitale procedures and responsible for following up on all the procedures between the Services involved making sure all steps in process are done accurately. In particular, during 2020 SAR worked to prepare the appropriate documentation for the budget adjustments, for the intermediate or final financial reports of 6 "Conto Capitale" projects, realized with grants of Italian Ministry of Health, relating to the funding Calls of years 2010, 2014-2015, 2016, 2018. The SAR office has assisted the

Scientific Direction in the Agreement procedures about grant of the "Conto Capitale" 2019 call with submission of n° 2 projects.

The SAR office also signed the provision of onerous agreements (within the scope of approved projects) and free of charge license agreements. During 2020 the SAR continued to manage projects from previous years, handled more than 150 projects and supported new projects in regards to budgets and new applications. For all the funded projects listed above, the SAR office followed through with all the administrative procedures concerning related expenditure.

In summary, during the 2020 the following activity were performed:

1. Reforming, analyzing and implementing a recruitment legislative framework;
2. Stabilization of Personnel with a subordinate TD Contract, for Research and Support (L. 205/2017, art. 1, Section from 422 to 434).

Goods and Services Acquisition Unit

Head: Dr. Gianluca Moretti

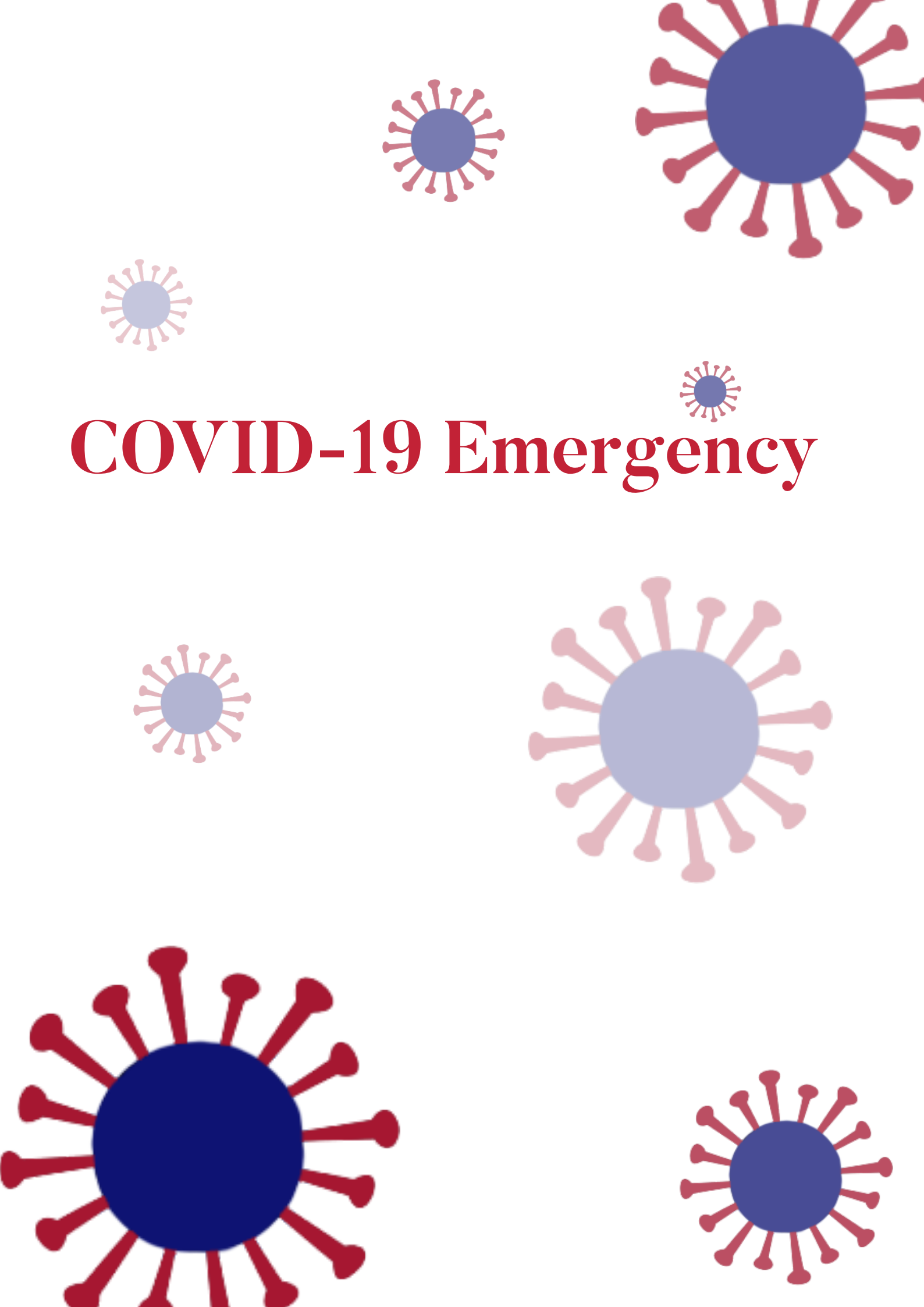
Staff

Cristina Corsi
Zoe Tonda
Carol Scioscia
Giovanna Surace
Gabriella Ingrosso
Anita Fiumara
Giovanni Ricci
Fabrizio Gatto
Tiziana Chiari
Massimiliano Romano
Angela De Simone
Antonio De Paolis
Domenico Fiorillo
Gianluca Murru
Piera Brugnoli
Barbara Filipponi
Emanuela Miceli

The Goods and Services Acquisition Unit deals with procurement for the hospital's needs regarding medical devices, drugs, reagents, laboratory materials, laboratory equipment.

The staff is organized into four different purchasing areas: medical devices; drugs, reagents and laboratory materials; economics and an independent purchasing section dedicated to research. This section deals with purchases for "current and finalized" research. It is financed by public and private bodies and by the European Union. About one thousand procurement procedures are carried out every year

COVID-19 Emergency



Reorganization of Istituti Fisioterapici Ospitalieri, an oncological and dermatological clinical and research center, to face the coronavirus health emergency: adopted measures and metrics of success to achieve and keep a COVID-19-free status

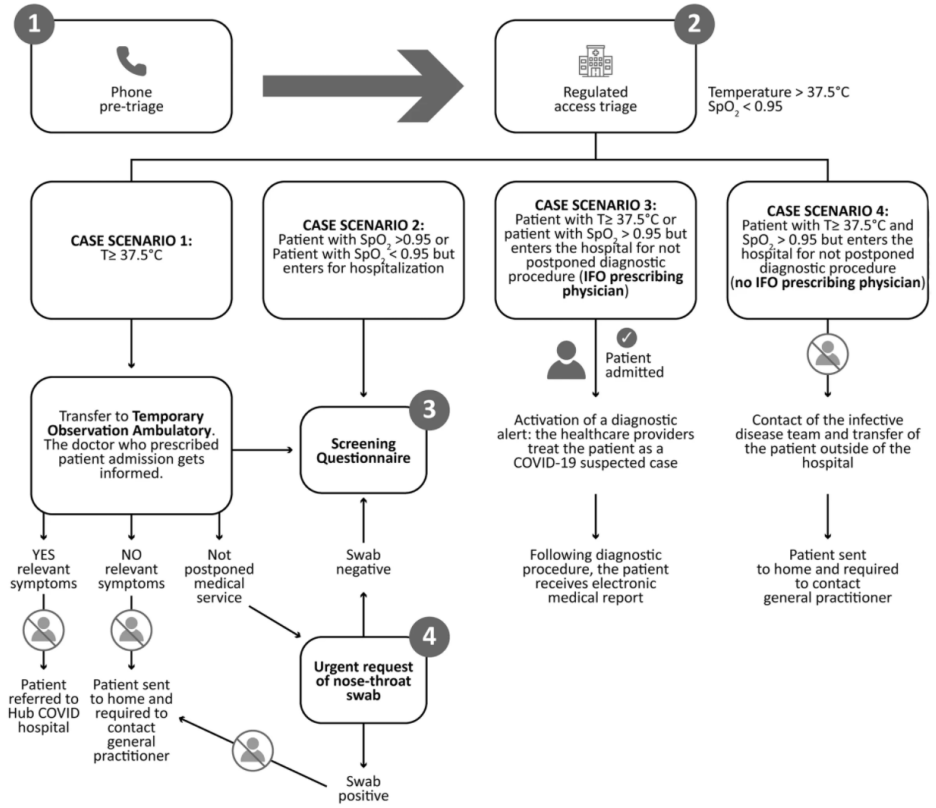
Assunta De Luca, Francesco Ripa di Meana, Branka Vujovic, Aldo Morrone, Chiara Degirolamo, Gennaro Ciliberto & Tiziana Lavalle

The spread of SARS-CoV-2 has forced a reorganization of the Institute asset in order to better protect fragile patients and avoid compromising the continuity of care and therefore the results of therapies.

Since the beginning of the COVID-19 outbreak in Italy, we designed institutional protocols and internal guidelines early on to guarantee cancer treatment for our patients while minimizing COVID-19-related risks ensuring a safe environment for care providers. The first measure was the activation of a Crisis Unit, chaired by the Medical Director and including the main representatives of different units involved in the virus containment, that consisted in meeting once a week to discuss the current clinical scenario, and updating institutional protocols and internal guidelines through a shared decision-making process. The weekly meeting of the Crisis Unit was organized more frequently when needed until 30 May 2020 when institutional activities were fully restored. Afterwards, the meetings, held via a web-based conference platform, were attended every 14 days.

Protective and organizational measures have been implemented to provide healthcare professionals with the necessary training needed against the spread of the virus, including prevention, containment measures and hygiene recommendations: use of personal protective equipment (PPE), wearing PPE equipment in healthcare settings, PPE disposal in bio-hazard containers, use of screening questionnaires for patients admitted to hospital.

Further measures to preserve safety of our employees have been also implemented, including the use of smart working via a dedicated platform developed upon the healthcare emergency. Until 18 May 2020, about 250 employees were currently on smart working. Residential meetings were replaced by video conferences.



The COMETA Project

Developing approaches and metrics to assess impact and improve outcomes for patients with frailty in the COVID-19 era

The COVID-19 pandemic, due to the SARS-CoV-2 virus, started at the end of December 2019 in the Chinese province of Hubei and has spread to countries around the world, including Italy, which still is living the third wave of pandemic spreading throughout Italy.

Recent studies indicate very serious outcomes in cancer patients with SARS-Cov2 infection, and the lethality rate can increase up to 25% in these patients. The development of the cancer itself and surgical procedures, radiation therapy, and/or systemic treatments can lead to immune suppression, thereby increasing the risk of SARS-Cov-2 infection. The negative impact of COVID-19 has been seen in a broad spectrum of cancers. Some recent studies highlight that cancer patients are more likely to develop a severe infection and die from COVID-19 disease. However, although cancer itself may be a risk factor for COVID-19 infection and disease evolution, prospective epidemiological data need to be collected to have a detailed review of how many Italian patients with neoplastic disease are also infected with SARS-Cov-2.

The virus causes a multi-organ disease in some cases fatal. In addition to the direct effects of the COVID-19 pandemic in terms of lethality and mortality, we expect to observe a wide range of indirect impacts on the health status of the general population and, even more, on frail patients such as cancer patients. This may result in decreased adherence to pharmacological treatment, as well as cancellation of already scheduled laboratory and instrumental tests. In addition, disease-related factors in these patients may contribute to the level of host immunocompetence and vulnerability to viral agents including SARS-CoV-2.

Based on these consideration in the 2020 we have pursued the following objectives:

1) to assess the direct and indirect impact of the COVID-19 epidemic on frail patients in terms of adherence to treatment protocols

2) further develop non-COVID status in non-COVID centers and in mixed-mode centers. This in order to provide the most appropriate level of care and ensure safety to all patients, while ensuring the continuation of health care activities also by implementing Telemedicine tools with "user friendly" interfaces on multimedia communication

3) to perform a biobank serial collection and storage of oro-pharyngeal swabs and blood samples to evaluate: a) the serum levels of anti-SARS-Cov-2 (Abs) antibodies (IgG/IgM/IgA); b) the profile of virus mutations in the infected population; c) specific biological alterations such as acquired or innate immune response; d) the presence of specific circulating biomarkers.

In the 2020 the participating centers have gone through a radical and incredibly rapid reorganization of the management of frail oncologic patients among which also the free telemedicine oncology consulting service. We have pursued collection of biological materials from frail patients with or without SARS-CoV-2 infection useful to study how different mutational variants of the virus may result in different clinical outcomes also through specific biological alterations such as acquired or innate immune response or identify/validate circulating biomarkers.

The project is funded by the 8×1000 of the Italian Buddhist Institute Soka Gakkai.

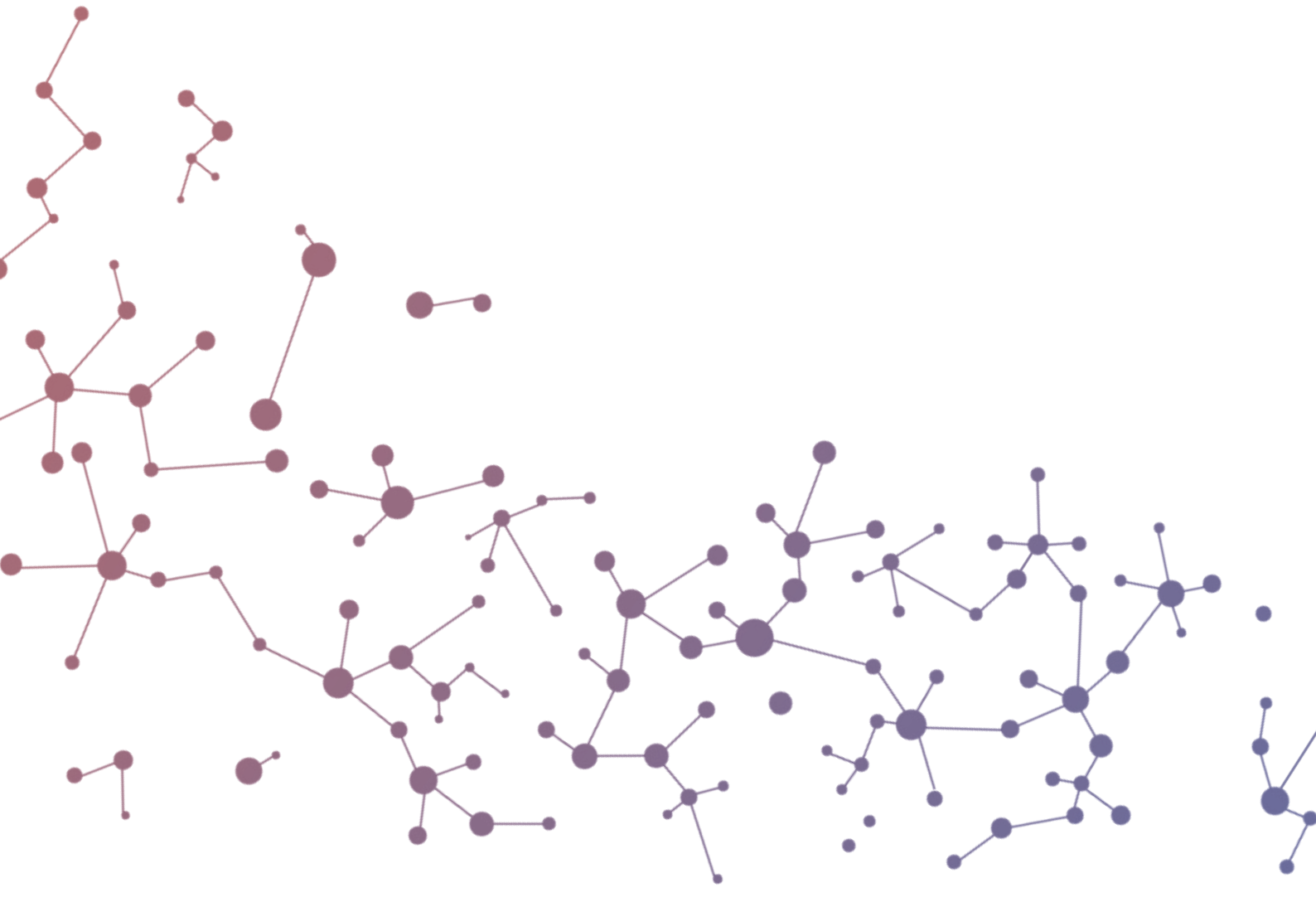
V-DAY

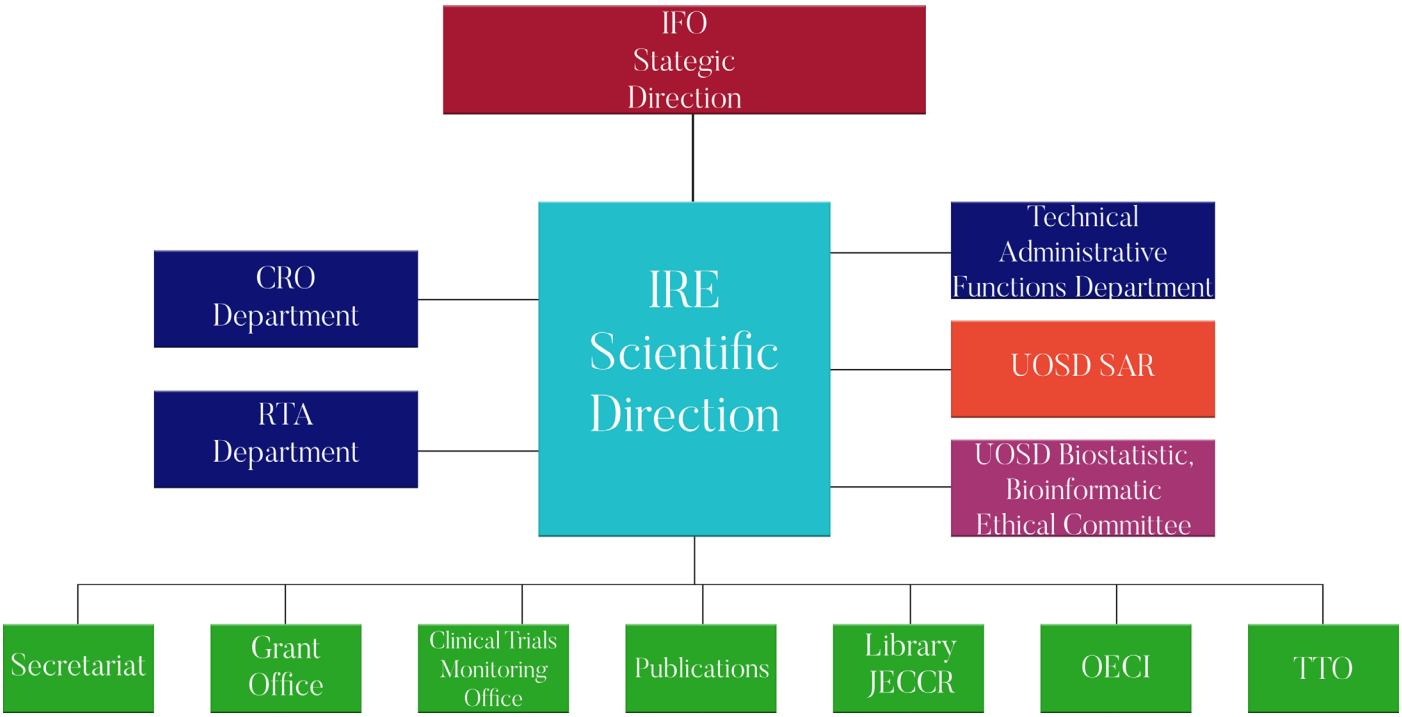
"These last days of 2020 project us into an extraordinary era. Today is for all of us a historic day, we're starting to vaccinate 36 IFO operators against COVID-19. I renew the appeal as a Director, as a physician and as a person who cares the oncological and dermatological patients: everyone get vaccine, is a duty to yourself and to others"

These are the CEO Francesco Ripa Di Meana's words on 29th December 2020, the V-Day of the Institute.

On December 29th Dr. La Malfa withdraw at "Istituto Spallanzani" the first doses of vaccine anti-COVID Pfizer – Biontech. The names of the first vaccinated are: Dr. Ornella Di Bella sanitary Direction physician, Dr. Camilla Casodi vaccinating nurse, Dr. Luigi Toma infectious disease specialist, Dr. Mariagrazia Loira nursing coordinator and reception manager, Dr. Ester Forastiere head of Anesthesia, Intensive Care Unit.

Scientific Directorate




IFO
Stategic
Direction
IRE
Scientific
Direction
CRO
Department
RTA
Department
Technical
Administrative
Functions Department
UOSD SAR
UOSD Biostatistic,
Bioinformatic
Ethical Committee
Secretariat
Grant
Office
Clinical Trials
Monitoring
Office
Publications
Library
JECCR
OECI
TTO

IRE Scientific Directorate

Staff

Prof. Gennaro Ciliberto, Scientific Director
Carmela Matrascia, Scientific Direction Secretariat
Tania Merlino, Scientific Direction Secretariat
Pina Gioffrè, Scientific Direction Secretariat
Federica Falcioni, Clinical Trials Office
Cecilia Fagioli, Clinical Trials Office
Martina Ferrazzano, Grant Office
Samantha Mengarelli, Grant Office
Marco Canfora, IT

There is an organizational structure specifically for research and development in oncology which culminates in the office of the Scientific Director

The Scientific Director to accomplish his goals 1s supported by the Scientific Directorate Offices:

Secretariat

The Secretariat office handle administrative documents for fund management: purchases, payments, missions, reimbursements, collaboration agreements between various entities, fellowships, self-employments and frequencies for various reasons. Collaborate with the organization of scientific events, seminars, national conferences and travels organization. Supports the Scientific Director organizing meeting. In the Scientific office is active a linguistic revision service and official documents translation. This office proceed to protocol official institutional documents and authorization request from research personnel with the Folium Protocol.

Grant Office

The activities of the IRE GO are: communication, promotion, support and centralization of project submission procedures. The GO manages and coordinates all project submission activities with the aim of promoting productivity and competitiveness of research. Every year on average the GO supports and coordinates more than 100 applications to competitive grants, Furthermore, the GO helps coordinating the generation of the yearly report of research productivity to the Ministry of Health.

Clinical Trials Monitoring Office

Provides support during the activation, management, reporting and data processing of clinical trials; manages IRE clinical database trials/SMART clinical trials platform; generates the yearly report of clinical research activity (number of active clinical trials, number of patients involved, etc.) to the Ministry of Health (Research Workflow).

Publications Office

The publications office collaborates with the Library, in the initial phase of manuscript submission, provides support to researches with a continuous monitoring, manages the manuscripts information by giving bureaucratic-administrative and economic information. The publications office invites researchers to deposit the raw-data linked to publications eligibility for the ministerial funding and guides the researchers to use a scientific integrity analysis service to avoid falsification and plagiarism

Library

Head: Dr. Gaetana Cognetti Interim head from March 2020 Dr. Francesca Servoli

Staff

Domenico Verbicaro
Virginia Scarinci, Fellow

Mission

Aim of the Library is to guarantee easy access to updated scientific documentation, most on electronic support. Apart from acting as a library, it should also be considered a knowledge Centre which facilitates access to relevant documentation in order to favour the best clinical practices and the choices of patients. The Knowledge Centre aims to contribute health information literacy also promoting the exchange of information between different professional areas.

Location

The Library is located near the main entrance of the Institute and offers a multimedia room with 15 computers. The Patient Library is located, since 2005, in a dedicated room providing quality information through professional staff and civil service volunteers using booklets for patients, scientific databases and trusted health portals.

Services

- The Library offers its services to the medical staff. The Library supports research activities by offering scientific information, documentation and education.

- The Library supports the institutional clinical staff offering: consultation of the main biomedical databases; document delivery through interlibrary exchange system, NILDE (in 2020 total borrowing 122, total lending 55); document delivery through other systems (total 340); organization of training courses; the librarian staff also offers support to the bibliographic searches, systematic reviews and meta-analyses. The main activities of the library consists of managing: monographs and periodicals following international standards and updating of national union catalogues; reference desk also through the personalized service “Book a

librarian", tailored courses on demand by the users (30 meetings online and 20 meetings in presence in 2020). In 2020, thanks also to the Bibliosan Network, the Library subscribed electronic resources: thousands of online journals, databases as Embase, Scopus, Web of Science, Journal Citation Reports, BMJ BestPractice, Cochrane Library, Faculty 1000, Cinahl, etc.

- Inventory and accommodation of the library's paper heritage.
- In 2020 the multimedia room of the Library was booked 15 times for training courses.
- The Patient Library offers information, using-booklets, databases and quality websites. Patients and their relatives can also use the multimedia room with Internet connection. There is also a Library for recreational reading. Since 2005 about 2220 patients and their relatives visited the Library. In 2020, due to the pandemic situation, Patient Library was closed to the public from March to December. The requests of patients and family members were processed online.

Research activities

The Library is involved in various research and educational activity and participates in library networks.

As far as information literacy is concerned, the library, due to the COVID-19 emergency, of the 4 scheduled courses, was able to organize only one CME course on scientific documentation (RefWorks); the participants were 10. The Library staff is involved in the teaching and tutorship of the course. The Library promoted knowledge of Bibliosan's resources through webinars.

The Library is involved in OECI Improvement Plan on patient involvement and empowerment, concerning humanization of the care, communication and information. The Library staff participated in the virtual audit for OECI accreditation and designation on December 2020.

The Library is involved in IFO Institutional Working Group for Patient's Centrality and. In 2018 Ethics Committee approved INFO RP - An observational study of information prescription in Italy. Patients will be directed to the consultation of information at the Patient Library, with prescription pads signed by the medical staff of the Endocrinology Unit. This study is still ongoing.

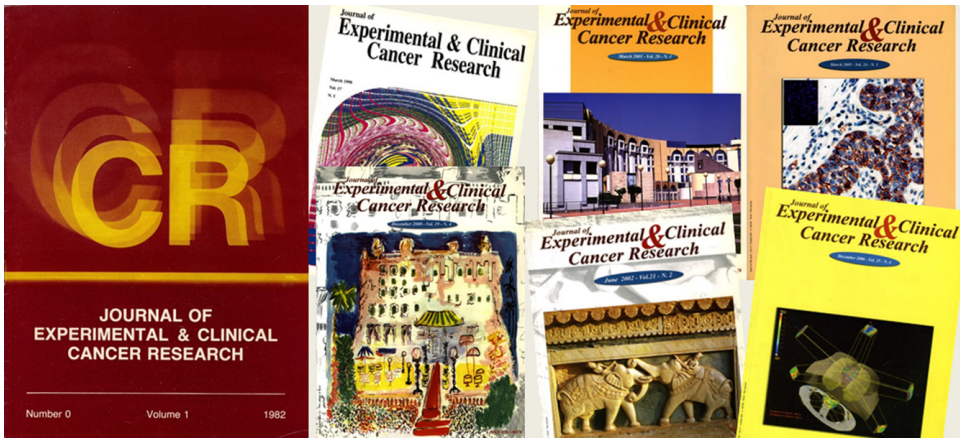
The Library staff participates in the working group for the reporting of the Institute's scientific activity, required annually by the Italian Ministry of Health, and manages the institutional archive of publications.

All Library activities have been automated using electronic shared systems. In particular, the Library participates in the following networks:

1. National Library Service (SBN) - the Library's books are catalogued following the MeSH (Medical Subject Headings) and the National Library of Medicine (NLM) Classification;
2. Network Inter-Library Document Exchange (NILDE) - document delivery service for exchanging scientific articles.
3. National Union Catalog of Periodicals (ACNP) for the cataloguing and management on the web of the periodicals;
4. Library Network of Biomedical Research Institutes (Bibliosan).

Journal of Experimental & Clinical Cancer Research

Editor-in-chief: Dr. Mauro Castelli, PhD



Editorial Staff:

Deputy Editor: Dr. Giovanni Blandino, MD, PhD
Assistant Editor: Dr. Silvia Di Agostino, PhD
Assistant Editor: Dr. Sara Donzelli, PhD
Managing Editor: Dr. Alice Castelli, PhD

Journal of Experimental & Clinical Cancer Research (JECCR) is the official scientific journal of the "Regina Elena" National Cancer Institute since 1986 which publishes manuscripts regarding significant advances in basic cancer research and offers a translational bridge from the laboratory to the clinic.

The most important aims are to open new roads for the understanding, prevention, diagnosis and treatment of cancer and to share the scientific results with the international scientific community.

JECCR has led its editorial activity by maintaining its partnership with the publisher BioMed Central - Springer Nature in London.

Thanks to its "open access" version, JECCR improved its performance in terms of rapid publication of the articles, better widespread all scientific results and higher visibility in the scientific community confirming its position in the 1st quartile among International Oncology Journals

In 2020 JECCR has launched a new Special Issue regarding the latest highlights on the role of hypoxia in all aspects of tumor progression, including therapy resistance and metastases in light of the 2019 Nobel Prize in Medicine.

The main accomplishments achieved by JECCR in 2020 are:

- Impact Factor 7.068;
- 1570578 downloads;
- 2861 submissions;
- 271 accepted papers;
- 257 published papers;

Most of submitted and published articles in the last years comes from International Oncology Institutes and Universities worldwide.

Moreover in this year, the "Journal of Experimental & Clinical Cancer Research" has reinforced its visibility in the international scientific community sharing the latest articles and collections by Social Media.

JECCR online website: https://jeccr.biomedcentral.com/

Top 5 JECCR publication most cited in 2020

1. Exosomal circRNA-100338 promotes hepatocellular carcinoma metastasis via enhancing invasiveness and angiogenesis

By: Huang, Xiu-Yan; Huang, Zi-Li; Huang, Jin; et al.

Volume: 39 Issue: 1 Article Number: 20 Published: JAN 23 2020 Times Cited: 27

2.Circular RNA circRHOBTB3 acts as a sponge for miR-654-3p inhibiting gastric cancer growth

By: Deng, Guangxu; Mou, Tingyu; He, Jiayong; et al.

Volume: 39 Issue: 1 Article Number: 1Published: JAN 13 2020 Times Cited: 26

3.MiR-199a-modified exosomes from adipose tissue-derived mesenchymal stem cells improve hepatocellular carcinoma chemosensitivity through mTOR pathway

By: Lou, Guohua; Chen, Liang; Xia, Caixia; et al.

Volume: 39 Issue: 1 Article Number: 4 Published: JAN 2 2020 Times Cited: 16

4.Genetic and pharmacological targeting of A2a receptor improves function of anti-mesothelin CAR T cells

By: Masoumi, Elham; Jafarzadeh, Leila; Mirzaei, Hamid Reza; et al.

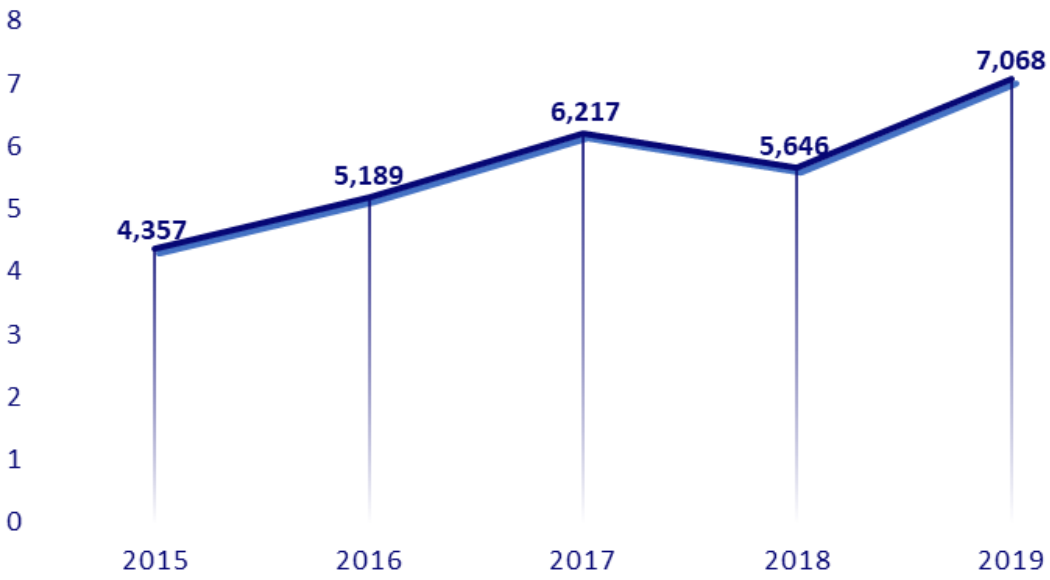
Volume: 39 Issue: 1 Article Number: 49 Published: MAR 10 2020 Times Cited: 14

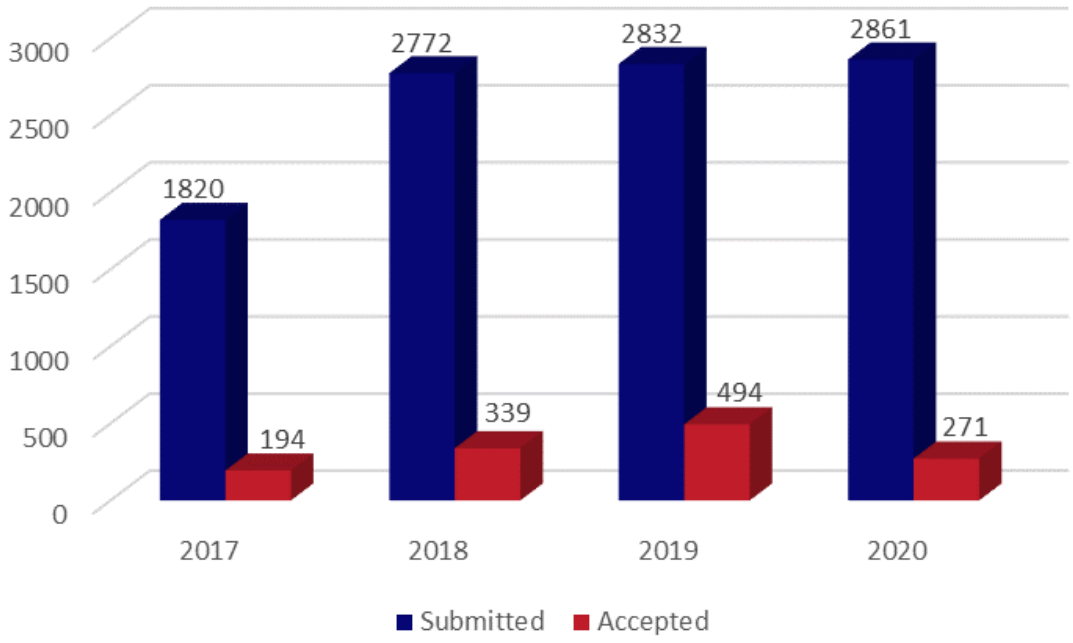
5.Regulation of heterogeneous cancer-associated fibroblasts: the molecular pathology of activated signaling pathways

By: Yoshida, Go J.

Volume: 39 Issue: 1 Article Number: 112 Published: JUN 16 2020 Times Cited: 13

IMPACT FACTOR

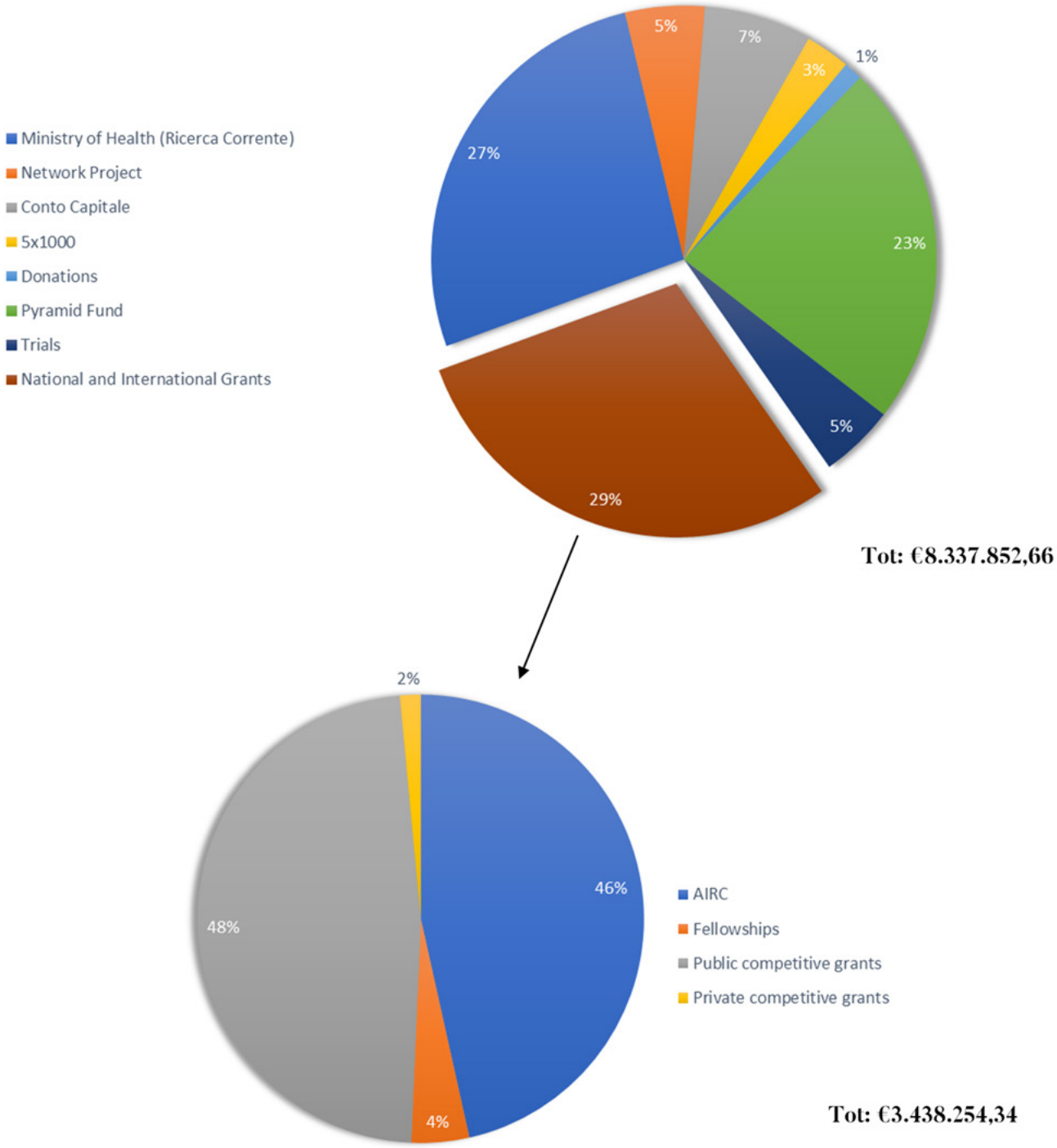




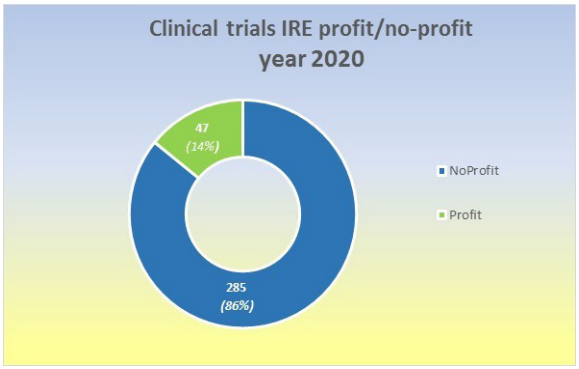
IRE Scientific Productivity Years 2005 - 2020

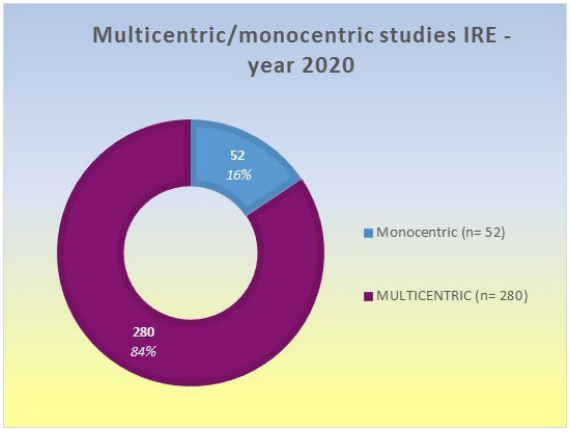
**From 2019 the criteria to indicate the productivity of the institute was changed, in fact the normalization refers to the values of the new quartiles that measures the prestige of a journal that, in particular for the Oncology category, have undergone an average increase of 25%. This means that journals in the Oncology category receive less IFN in the years following 2018.*

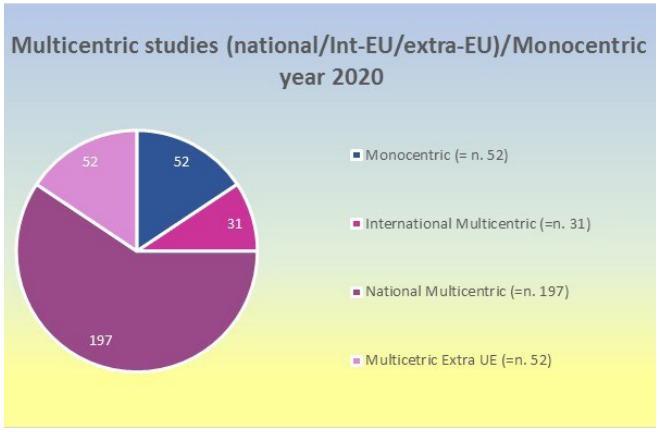
Distribution of the Main Funding Sources Supporting IRE Research

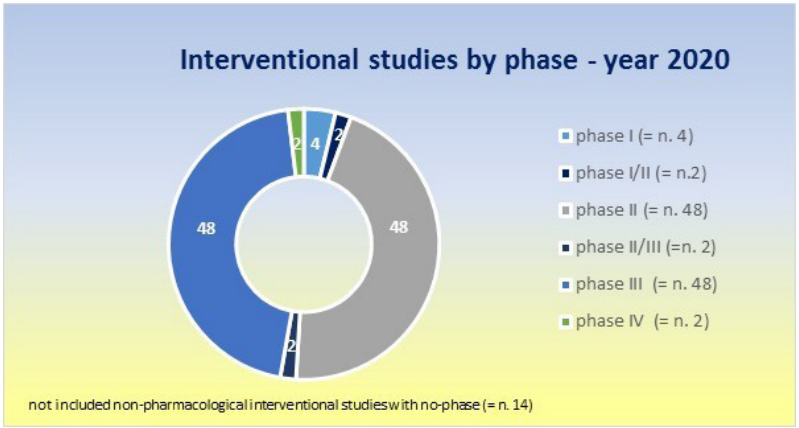


Clinical Trials









Technology Transfer Office

Staff

Gianluca Moretti
Emanuela Miceli
Giuseppe Campanella
Samantha Mengarelli

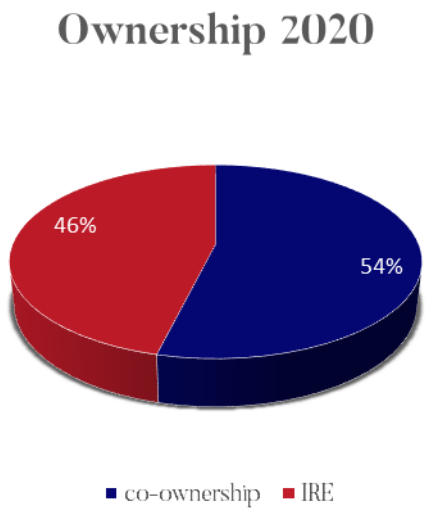
Mission

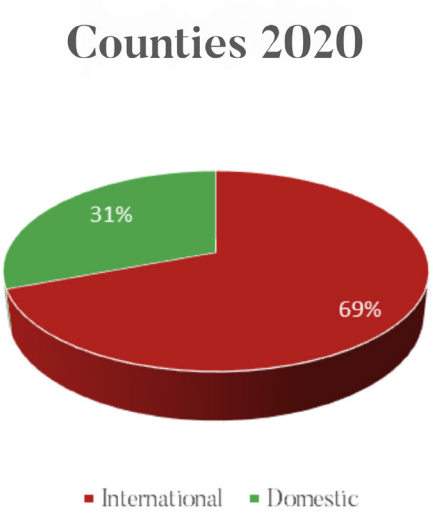
The Technology Transfer Office (TTO) operates within the Scientific Directorates and cooperates with the IFO Patent Committee established by resolution no. 725 of 01.08.2016.

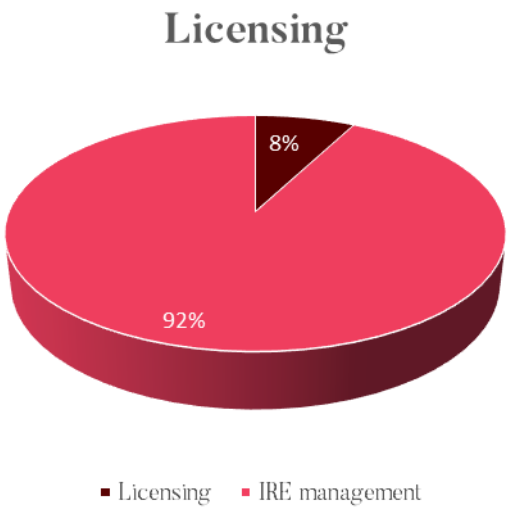
The TTO brings together the researchers' inventive proposals, promotes their protection and technology transfer. To this end, it assists and supports researchers in the management of intellectual property, from the start of the patenting process to external licensing or, alternatively, to commercial exploitation.

Patents

The Patent Portfolio of the Istituto Regina Elena in 2020 was composed of 13 international patent families that have been divided into two main categories: a) fully owned by the Institute and b) with co-ownership with other institutes. Some of these patents have already been allowed to be issued in several countries and others are still under examination. The patent portfolio mainly protects the discovery of new prognostic and/or predictive biomarkers, but also nanotechnologies for better drug deliverv.







OECI

Staff

Giuseppina Caolo
Annunziata Di Turi

Mission

The OECI staff coordinates the entire accreditation process of the Institute, in all its phases: from Application and Preliminary Designation, to Self Assessment, Peer Review Visit, Improvement Action Plan, Final Designation and Follow up Report.

During the whole process the staff takes care of collecting documentation, writing reports and organising the site visit. It also receives and collects official documentation from the headquarters in Brussels.

Staff keep in touch with the OECI European coordinators of Bruxelles and with the other Italian IRCCS participating in the accreditation process.

In addition, the staff participated in the creation of the hospital cancer registry, requested by OECI, which it now manages, registering all new IRE patients from the three main sites (breast, lung and colon) in line with the population cancer registry of the Lazio Region.

Research Strategic Plan

The main research goal of the IRCCS Regina Elena National Cancer Institute is the translational management of cancer patients (PRESa in carico Traslazionale del paziente Oncologico - PRESTO). What does this mean? It means that the cancer patient is always placed at the center of our research objectives and with this focus, we aim to understand the distinct alterations of patients' tumors within the perspective of personalized and precision medicine; and then to transfer our research results to the patients' bedside in order to provide rapid answers to their health needs through scientific and technological innovation.

Today, providing care to cancer patients is essentially based on having several vital contributing facilities. IRE has therefore armed itself with a series of indispensable tools, from a modern and equipped biobank storing tissue and liquid samples deriving from cancer patients up to a number of the most recent technologies for "omics" analysis as well as for surgery such as robotic surgery, stereotactic radiotherapy, imaging and so non. Our Institute is the only facility in Lazio where these facilities combined with the necessary expertise (know how) are all physically concentrated in the same logistic area and dedicated to cancer patients' care. This allows us to apply all the standards of the state-of-the art modern medicine to implement a more personalized approach towards the patient, not only considering their clinical characteristics, but also the expression of molecular determinants which are increasingly fundamental in improving diagnostic, prognostic, predictive and therapeutic performance.

It is now crucial to manage cancer patients by evaluating the expression of molecular biomarkers with cutting-edge "omics" technologies that allow to stratify patients that are able to respond or not to certain types of therapies. Even if it appears to be more challenging at first, obtaining knowledge, understanding and clinical management of these parameters provides us with an unquestionable advantage and together with the results generated can drastically improve the clinical picture (survival and quality of life) of the patient. By applying this modern approach towards cancer patient care it is also essential to increase the number of early diagnoses, which are now often possible due to the very high resolution in diagnostic imaging equipment provides, thus avoiding falling into making frequent errors in over-diagnosis and over-treatment.

The future of cancer care and patient medical records will therefore have to contain, in addition to the results of routine investigation, also a series of metadata (genomics, transcriptomics, metabolomics, proteomics, microbiomics, radiomics, etc.) that concern the molecular aspects of single neoplasms which provide the basis for an advanced prognostic / predictive / therapeutic approach. The objective is to obtain a personalized clinical report capable of highlighting the biological and clinical relevance of each identified molecular alteration. In fact, these methodologies allow identifying therapies and clinical studies that include potentially effective drugs (targeted therapy, immunotherapies and experimental therapies) that are best for each individual patient.

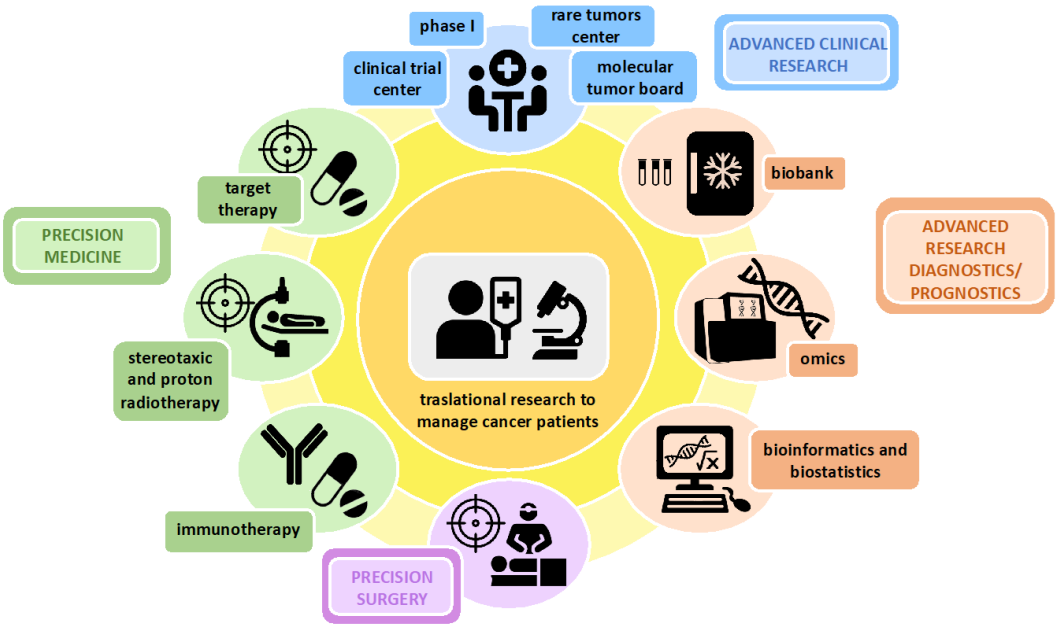
It is therefore important that the data provided by the most modern technologies are managed by a multidisciplinary team that includes not only oncologists, but also biotechnologists, molecular biologists, geneticists, pathologists, biostatistics, bioinformatics, etc.

PRESTO is summarized in the diagram above (Fig1). It is divided into four macro-areas which are highlighted by distinct colors: advanced diagnostic / prognostic research (in Orange), precision surgery (in Purple), precision medicine (in Green) and advanced clinical research (in Blue).

In the following sections the features of each macro-area will be described as well as short and long-term objectives. All together these sections constitute the elements of the research strategy, represent the research footprint of the institute and characterize its specificity in the context our national clinical cancer research.

It has to be pointed out that Regina Elena National Cancer Institute works in close collaboration within national and international networks, in first instance is one of the founders of the largest

organization of clinical research cancer centers in Italy called Alliance Against Cancer (Alleanza Contro il Cancro -ACC). Furthermore, it is member of OECI, the Organization of European Cancer Institute where it has been given the highest level of accreditation as comprehensive cancer center, and finally has established strategic collaborations with prestigious research centers outside Italy such as the Weizmann Institute in Israel. All these network collaborations help the realization of the strategic plan but we have decided not to specifically mention them in the following sections



Ministry of Health - Research Lines

In accordance with the priorities indicated by the "Programma Nazionale della Ricerca Sanitaria" every three years the Ministry of Health (MOH) aprroves the research activities of the IRCCS. This had to be the conclusion year for our active research lines, but, due to sanitary emergency, the MOH extended for another year the active research lines.

In the years 2018 - 2021 our Instite has five research lines, and the MOH intriduced a sixth "COVID specific" line.

Line 1: Cancer Prevention and Early Detection

Coordinators of the scientific report: R. Falcioni - V. Stigliano

The mission of this Line is the identification and elucidation of the mechanisms that contribute to the risk of developing cancer, the characterization and validation of new biomarkers of susceptibility to cancer, and the development of methodologies capable of increasingly anticipating the diagnosis of cancer in subjects and/or populations at risk. Primary prevention intervenes on healthy subjects and is based on the identification of risk factors, the assessment of exposure to these factors and their modification. Secondary prevention intervenes on sick people, identifies the disease at an early stage, asymptomatic, susceptible to immediate and effective therapeutic intervention. The advent of advanced technologies, genetic characterization and molecular classification, make the prognostic stratification of tumors and early detection of cancer increasingly possible. The perspective of this Line is therefore to carry out research activities aimed at educating new diagnostic and/or behavioural procedures aimed at cancer prevention, improvement of health status and cancer control. At present, the existence of innovative molecular and instrumental diagnostic techniques makes it possible to make an early diagnosis of the tumor and to define the molecular characteristics that influence the therapeutic approach and prognosis. Fundamental elements for the success of the Line are: (A) access to biological materials from subjects predisposed to the onset of tumors due to hereditary family causes, or environmental factors; (B) multidisciplinary experimental approaches that take into account bio-molecular, epidemiological, nutritional, virological, radiodiagnostic, endoscopic, clinical and surgical expertise.

Line 2: Cancer Immunotherapy

Coordinators of the scientific report: A. Venuti - V. Ferraresi

The "Cancer Immunotherapy" line includes the activity of translational pre-clinical and clinical research, aimed at: improving the knowledge of anticancer immunological mechanisms; immunoevasion processes including those mediated by the microenvironment; optimizing the generation of vaccines, engineered T cells and the use of new molecules and immunomodulating strategies. Research is also based on the characterization of tumor-specific antigens and the analysis of the molecular/immune profile (immunoprofiling) of the individual patient. Finally, this Line is designed to identify new combination approaches to optimize therapy and better manage associated toxicity. It is increasingly evident that all anti-neoplastic therapies require activation of the host immune system to be effective, as historically demonstrated for CT and RT. Cancer immunotherapy represents the fourth approach to cancer treatment, together with surgery, RT and CT/biological therapy. It is a therapy that instructs and/or reactivates the cells of the immune system so that they can recognize and eliminate cancer cells. Tumors alter the immunocompetence of the host, triggering phenomena of immune resistance, in particular the functions of tumor-specific T-cells. Since many immunological checkpoints are triggered by receptor and ligand interactions, effective immunotherapies based on blocking these interactions by antibodies have developed.

The identification of predictive biomarkers of response to immunotherapy is a further fundamental information to direct the clinician towards a personalized treatment. The characterization of tumor antigens has made it possible to conceive therapeutic vaccines but the need to design more effective vaccination therapies remains. At the same time, the molecular study of TCR allowed to engineer T cells with anti-tumor activity to be reinfused in the patient, although of problematic clinical applicability. Therapies with checkpoint inhibitors are effective but the identification of predictive response biomarkers is critical to select the patients most likely to benefit by limiting side effects. Fundamental elements for the success of the line are the biobanks and the use of samples from subjects at risk of cancer due to genetic, dietary, behavioural, environmental and occupational causes, and the multidisciplinary approach that includes biomolecular, immunological, virological, epidemiological, nutritional, radiodiagnostic, clinical and surgical expertise.

Line 3: Personalized and Precision medicine in Oncology

Coordinators of the scientific report: P. Giacomini - F. Marchesi

The knowledge of the molecular mechanisms involved in tumor pathogenesis and progression has allowed the development of innovative therapies based on the use of agents able to specifically interfere with the cell pathways responsible for the growth, survival and progression of cancer cells. This approach has been defined as personalised medicine as well as precision medicine, if a precise interaction/correlation between the administered drug and the presence of its molecular target in the tumour can be identified. The line "Personalized Medicine and Precision in Oncology" deals with research activities that aim, in the pre-clinical and clinical field, to..: 1) Identify the prognostic and/or predictive relevance of genetic and epigenetic alterations of the tumour that can be exploited as potential therapeutic targets; 2) Study the role of intra-tumour heterogeneity in the response to molecular target agents; 3) Develop methods of analysis to follow the molecular evolution of tumours both in tissues and in the blood (e.g. The rationale of this line of research lies in the fact that identifying the possible mechanisms of primary and acquired resistance; 4) systematically biobank cancer samples and longitudinal biological fluids using standardized and reproducible methods; 5) develop clinical trials with molecular target drugs in patient populations identified by suitable biomarkers. The rationale of this line of research lies in the fact that identifying the biological alterations of individual neoplasms makes it possible to use targeted and effective therapies. Therefore, studies will be conducted to: (i) implement personalised therapy protocols in patients with progressive/metastatic disease; (ii) identify markers of intrinsic and acquired resistance to molecular target drugs; (iii) identify new diagnostic strategies for early diagnosis and prevention, and for anticipating/redirecting relapse/progression; (iv) identify new therapeutic strategies to block the processes of tumour invasion, progression and metastasis; (v) facilitate the transversal repositioning and use (drug repositioning/repurposing) of known drugs; (vi) identify new molecular target drugs; (vii) rapidly apply and transfer the above to clinical practice in oncology, acquiring innovative know-how and technologies where necessary.

Line 4: Innovative Approaches and Technologies in Diagnostics and Therapies

Coordinators of the scientific report: G. Simone - A. Vidiri

This Line bases its assumptions on the use of innovative diagnostic approaches and technologies, functional imaging and/or molecular methodologies, and the effectiveness of minimally invasive and multimodal/integrated treatments that now represent the standard therapeutic approach for many types of cancer. Technological advances in bio-molecular research, imaging, minimally invasive surgery, radiotherapy and new oncological target therapies require increasing efforts towards a more accurate diagnosis and more personalized therapy. The integration of synergistic

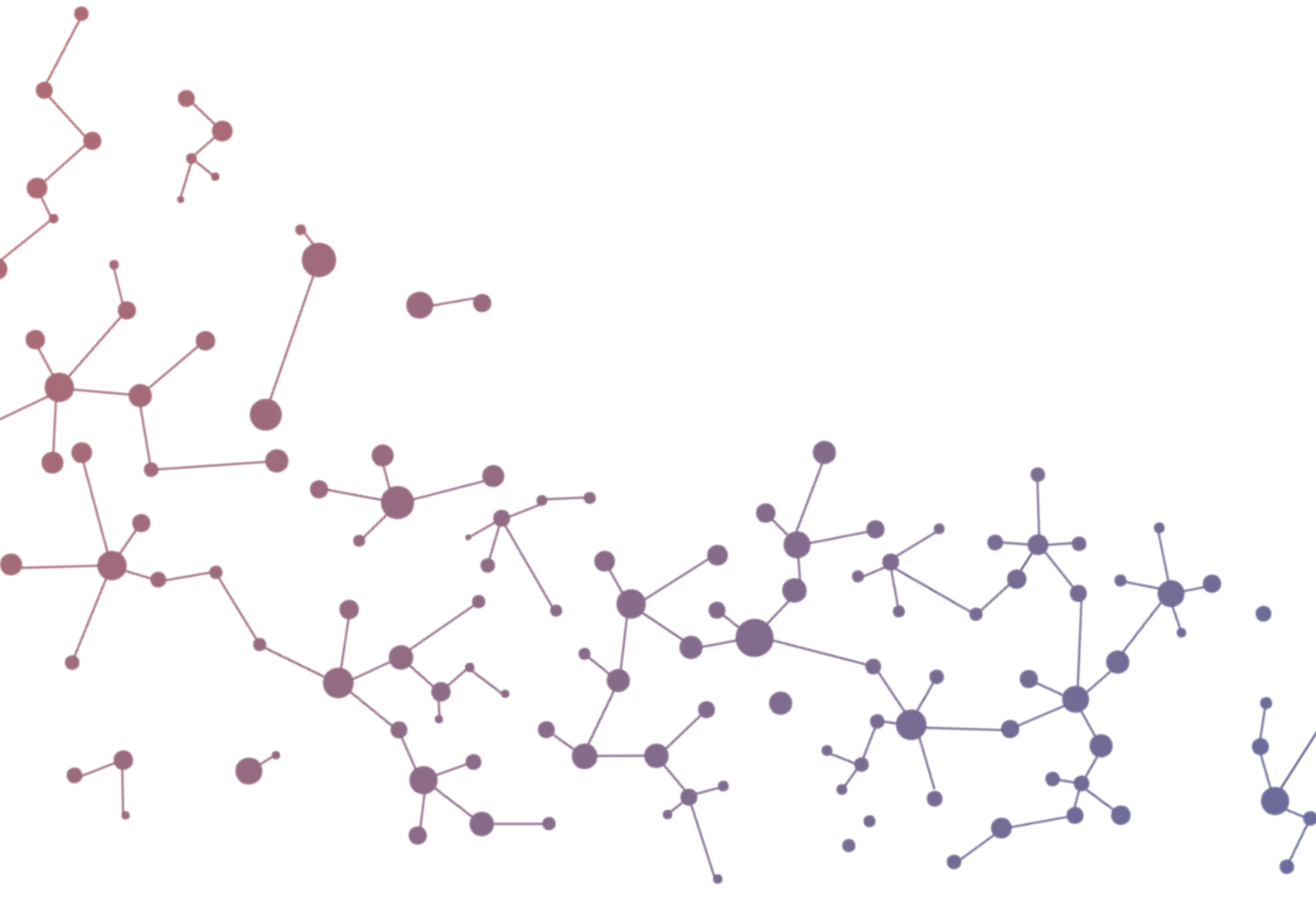
and complementary skills (molecular biology and pathological anatomy, endoscopy, surgery, radiotherapy, radiology, nuclear medicine and medical physics) is the pivot for the improvement of diagnosis and treatment both for the most common tumors (e.g. colorectal, lung, breast and prostate) and for rarer tumors (e.g. melanoma, head-neck, thyroid, pancreas, soft tissue sarcomas, hepatocarcinomas). IRE translational research teams will allow the integration of clinical information with the parameters extracted from biomedical images and functional analysis at cellular and molecular level, allowing a more appropriate customization of treatment. The study of new preclinical models (primary tumor cultures, 3D cell growth models, xenopatients, innovative animal models of tumor disease, development of models for drug repurposing), preclinical and clinical validation of innovative diagnostic tools (genomic tests), proteomics, metabolomics in tissues and/or biological fluids, development of new models for target identification through genetic manipulation with CRISPS/Cas9 technology), development of new combined therapeutic approaches (surgery, radiation, nanoparticles, ultrasound, heat, etc.).) taking into account clinically available advanced technologies (robotic and minimally invasive surgery, focal therapies, radiotherapy, radiosurgery and SBRT, medical-nuclear therapy, radiomics) will allow to identify new prognostic/predictive biomarkers and to test innovative therapeutic approaches for personalised therapy, a goal for translational research.

Line 5: Quality of Life of the Neoplastic Patient

Coordinators of the scientific report: A. Pace - M.G. Paggi

This Line is oriented to the study of quality of life (QoL), rehabilitation, drug-induced toxicity and gender medicine of the cancer patient. The outcomes of oncological disease and cancer treatments and their influence on QoL will be studied with particular attention to fragile (elderly) populations, long survivors and the role of gender medicine. Patient-based evaluation tools and oncological rehabilitation strategies oriented to the recovery of complex disabilities will be studied. Research in this area aims to identify the pathophysiological mechanisms of toxicity and to define therapeutic strategies for prevention. The toxicities induced by radiotherapy treatments, in particular on the Central Nervous System and those on the Peripheral Nervous System induced by numerous anticancer drugs, require clinical studies to identify risk factors and drug trials for prevention and therapeutic purposes. Oncological rehabilitation, aimed at the recovery of motor, functional, psychological and social disabilities as a result of oncological disease and its treatments, represents a field of research of great interest that requires the definition of appropriate multidimensional assessment tools and the testing of multidisciplinary models of care aimed at the treatment of complex disabilities (cognitive functions, fertility, sexuality, fatigue). The increase in the effectiveness of cancer treatments and the increase in the number of long term cancer treatments help to make the issues of quality of life and cancer rehabilitation critical. Measuring the impact of treatments on QoL requires a better definition of patient-based tools for monitoring QoL and the impact of treatments, particularly in fragile populations. The interest in these outcome measures is linked both to the issue of patient centrality and to the evident limits of traditional end-points (PFS, OS-toxicity) in clinical trials. All the studies described above will also be analysed and interpreted from a gender perspective, taking into account not only sex but many gender-related variables. The Research Line will also develop experiments in the field of palliative and supportive care with the aim of promoting guidelines and recommendations for treatment in the advanced stages of illness and at the end of life.

Overseeing Committee



Control and Verification Board

Head: Prof. Paolo Marchetti

Staff

Prof. Antonio Addis
Prof. Stefano Alemà
Prof. Alfonso Celotto
Prof. Pier Giorgio Natali

Mission

Article 4 of the Regional Law N. 2/2006 legislates that leadership and guidelines functions are a responsibility of the Control and Verification Board (Consiglio di Indirizzo e Verifica - C.I.V.). The board consists of five members selected according to their expertise. The Board's chief officer is appointed by the Regional President and the Ministry of Health jointly. Three members are elected by the Regional President and one more is chosen by the Ministry of Health. They remain in office for five years.

I.F.O.'s present Control and Verification Board has been appointed by the Ministry of Health and Lazio Regional President through protocol 1546 of 19 February 2019 and Regional Decree N. T00146 of 12 June 2019. With resolution N. 604 of 2 July 2019 I.F.O. accepted and transposed the appointment of the Board.

The Control and Verification Board determines the direction and objectives of the Institute's activities on an annual and multi-annual basis and verifies all activities carried out and the results achieved by each Department.

Ethical Committee

Chairman

Prof. Francesco D'Agostino, Expert in Bioethics

Vice Chairman

Prof. Agata Amato Mangiameli, Expert in Legal Matters

Secretary

Anna D'Ambrosio

Technical scientific secretariat

Diana Giannarelli
Maria Cecilia Ciacchella
Barbara Matrascia
Federica Struglia

Members

Clinicians: Prof. Stefano Calvieri, Prof. Vito Fenicia, Dr. Teresa Gamucci, Dr. Carlo Garufi.
General Medicine: Dr. Mario Falconi
Pedriatician: Dr. Raffaele Cozza

Biostatistics: Prof. Annarita Vestri

Pharmacologist: Prof. Lucia Negri

Pharmacists: Dr. Antonia Marina la Malfa, Dr. Silvia Murachelli, Dr. Nicoletta Onori

Genetist: Prof. Giovanni Neri

Volonteer Representative: Elisabetta Iannelli, Lawyer

Health Areas Representative: Dr. Laura Iacorossi

IRE Scientific Director: Prof. Gennaro Ciliberto

ISG Scientific Director: Prof. Aldo Morrone

IFO Chief Medical Officer: Dr. Branka Vujovic

Bietti Foud. Scientific Director: Dr. Monica Varano

Bietti Foud. Chief Medical Officer: Dr. Amalia Allocca

Clinical Engineer: Ing. Giuseppe Navanteri

Nutrition Expert: Prof. Giorgio Calabrese

Nutrition Expert: Prof. Giorgio Calabrese

The Central Ethical Commitee IRCCS Lazio expresses its opinion on trials to be managed in Regina Elena National Cancer Institute, San Gallicano Dermatological Institute and G.B. Bietti Foundation for ophthalmology.

During years 2020 the Central Ethical Commitee IRCCS Lazio examined and expressed its opinion on 154 studies including clinical trial protocols, observational studies and research projects, 240 substantial amendments.

Relatively to these items the ethics committee analysed ethical and scientific aspects, the adequacy of the investigators and the structures involved and, above all, the methods and documents to be used to inform patients and obtain their informed consent.

The Ethical Committee meetings are held monthly and, if necessary and urgent, the opinion of their members on a particular case such as the use of drugs not commercially available is obtained by mail

Technical Scientific Committee (CTS)

The CTS is an advisory and a supporting body for the clinical and research activities of the Institute and is chaired by the Scientific Director of IRE. According to Regional Law 2/2006 art. 9, is composed of ten other members appointed by the Board of Directors. The CTS is informed in advance of the scientific objectives by the Scientific Director.

Members of the CTS:

Prof. Gennaro Ciliberto
Scientific Director and CTS President

Dr. Roberto Biagini
Head of Orthopaedics Unit

Prof. GianLuca Grazi
Head of Hepato Biliary Pancreatic Surgery Unit

Prof. Gerry Melino
"Tor Vergata" University of Rome

Dott.ssa Paola Nisticò
Head of Immunology and Immunotherapy Unit

Dr. Sandro Pignata
"Fondazione Pascale" National Cancer Institute

Prof. Giuseppe Sanguineti
Head of Radiotherapy Unit

Dr. Branka Vujovic
Medical Director

Dr. Patrizia Vici
Head of Medical Oncology 2 Unit

Dr. Antonello Vidiri
Head of Radiology Unit

Dr. Maurizio Fanciulli
Head of SAFU Unit

Dr. Paolo Di Ridolfi
Nurse Coordinator

ISAB

Second Meeting of the International Scientific Advisory Board of the Regina Elena Institute

On Nov 4th, 2020 the second meeting of the International Scientific Advisory Board of the Regina Elena Institute took place. Due to the diffusion of the Sars-Cov-2 Pandemic the meeting was organized in a virtual format.

All designated members of the committee participated:

Prof. Andrew V. Biankin
Regius Professor of Surgery
Director, Wolfson Wohl Cancer Research Centre,
University of Glasgow

Prof. Andrés Cervantes
Professor of Medicine at the University of Valencia
Head of the Department of Medical Oncology at the Hospital Clínico Universitario de Valencia
General Director of the Biomedical Research Institute INCLIVA
Biomedical Research institute INCLIVA
University of Valencia

Prof. Pierre-Alain Clavien
Chairman of Department of Surgery & Transplantation
University Hospital of Zurich, Switzerland

Prof. Vincent Gregoire
Vincent GREGOIRE, MD, PhD, Hon FRCR (IE), Hon FRCR (UK)
Département de Radiothérapie - Radiation Oncology Department
Centre Léon Bérard - Léon Bérard Cancer Center

Dr. Francesco M. Marincola
Chief Scientific Director
Refuge Biotechnologies, Inc.
Menlo Park, California, US

Prof. Amanda Psyrri
Chief of Medical Oncology and Assistant Professor of Medicine
Institution Attikon University Hospital Department Medical Oncology Dept.

Prof. Henning Walczak, PhD
Institute for Biochemistry I, Medical Faculty,
University of Cologne, Cologne, Germany.

Prof. Anne Willis
Professor A E Willis OBE
Director, Medical Research Council Toxicology Unit
MRC Toxicology Unit

It was a full day meeting with the morning dedicated to individual presentations, while the afternoon was organized as a breakdown into four subgroups each one dedicated to the four pillars of Strategic Plan of Research of the Institute, namely

1. Advanced Diagnostics Research;

2. Precision Surgery;
3. Precision Medicine;
4. Advanced Clinical Research.

Here below is a summary of the main feedback points received from ISAB members

"*Over the last two years there has been excellent progress against the recommendations made by the SAB at the previous meeting. There is a very sound clinical and basic science research strategy which allows the Institute to move forward and achieve its full potential. In particular an excellent clinical appointment has been made. This will allow a full development of the clinical strategy and the recruitment of a high-profile leader in the field will ensure that the Institute will have increased international visibility and this in turn will increase patient numbers. Moreover, much of bioscience research carried out at IRE is excellent. It is commendable that the Institute has been set up to allow multidisciplinary research with a strong degree of integration between basic and clinical sciences as this will ensure direct translation basic research such that it impacts on clinical outcomes.*

The Strategic Plan plays to the strengths of IRE, with substantial development of diagnostic capacity and capability, delivering cutting edge technology for the benefit of cancer patients. In particular, the analysis and aggregation of patient data has been enhanced and is world class. This key element, coupled with biobanking will enhance research endeavours and enable translation of discoveries to real impact. The richness of clinical data integrated with diagnostic and -omic datasets will attract investment from industry beyond clinical trials, which this capability is already beginning to attract.

The area of precision surgery is particularly innovative. The discovery and development of prognostic markers, and markers predictive of benefit from surgical resections is a vital strategy for contemporary health systems. Better selecting patients for the most appropriate procedure improves outcomes and curbs morbidity, mortality and cost through avoiding major operative procedures for patients who will not benefit from them.

Establishing a molecular tumour board is a great achievement. These can be challenging, and although many centres claim to do it, few have actually achieved what IRE is doing. The embedding of expertise from the diagnostic and analytic capacity IRE now possesses was an important strategic move.

In summary, the ISAB were impressed with the progress made, with almost all of the objectives sought in the strategic plan achieved, or well on track to do so in the near future. IRE is well-positioned to achieve its goal to be an internationally recognised centre of excellence."

Biostatistic and Bioinformatic Unit

Head: Dr. Diana Giannarelli, Biostatistician

Staff

Anna D'Ambrosio, Ethical Committee Secretary
Cecilia Ciacchella, Administrative Unit
Barbara Matrascia, Administrative Unit
Federica Struglia,Administrative Unit
Marco Canfora, Clinical Informatics
Andrea Sacconi, Bioinformatic
Matteo Pallocca, Bioinformatic
Eleonora Sperandio, Bioinformatic
Francesca Sperati, Biostatistician
Isabella Sperduti, Biostatistician
Irene Terrenato, Biostatistician
Silvia Cartolano, Research Nurse
Giulia Costantini, Research Nurse
Ilaria Farina, Research Nurse
Stefano Pacilli, Research Nurse
Valerio Basile, Biologist
Silvia Bastucci, Study Coordinator
Elisabetta Bozzoli, Study Coordinator
Arabella Bufalo, Study Coordinator
Viviana Cangiano, Study Coordinator
Barbara Conforti, Study Coordinator
Marianna Ferrara, Study Coordinator
Paola Franzoso, Study Coordinator
Marianna Introna, Study Coordinator
Vittoria Iorio, Study Coordinator
Katia Messana, Study Coordinator
Francesca Nardozza, Study Coordinator
Agnese Provenziani, Study Coordinator
Alessandra Zambardi, Study Coordinator
Ashanti Zampa, Study Coordinator
Alessandro Zennaro, Study Coordinator

Mission

The Unit includes the Clinical Trial Center (CTC) and the Biostatistic and Bioinformatic Unit.

The main objectives of CTC are:

- To promote clinical trialmanagement according to GCP and quality standard
- To support researchers in clinical trial start-up and conduct
- To empower 'no-profit' research and the role of IRE as sponsor
- To monitor clinical trials coverage of different therapeutics area
- To attract profit clinical trials and private investment

Its core consists of

1. Ethical Committee Scientific Technical Office
    a. monthly meeting organization
    b. meeting minute
    c. budget and agreementnegotiation
    d. authorizationprocess
    e. ncome management
2. Study Coordinators
    a. support researchers along all study phases from Site Qualification Visit to Study Closure in the fully respect of trial protocolandprocedures according to GCP
3. Research Nurses
    a. support Medical Doctors during patients visits and treatments (blood samples, vital signs, drug administration time, PRO, questionnaires, drug contability, phone contacts...)

4. Research Biologist
    a. - process blood samples according to quality standard procedures

The CTC has strict relationships with

5. Clinical Trial Monitoring
    a. through SMART cloud platform to control trial status and patients accrual
6. Institutional Review Board (CISC)
    a. internal studies evaluation
7. Translational Coordinators
    a. to improve 'from lab to bed' research and studies
8. Epidemiology and Tumor Registries
    a. to evaluate study feasibility in terms of patients
9. Hospital Pharmacy
    a. to manage drug supply and contability
10. Pharmacovigilance
    a. to report Adverse Events according to EUDRAVigilance standard
11. Biobank and Clinical Pathology
    a. to manage samples according to high quality standard

The Biostatistical and Bioinformatic Unit gives statistical advice for the protocol design related to observational and experimental studies. It is a support for the researchers in study design choice, randomization procedures identification, sample size calculation and Case Report Form definition.

Furthermore, the staff performs statistical analysis of clinical and laboratory data and develops new technique ofdata analysis, as required from the always increasing complexity of available information. It performs also systematic reviews and meta-analysis on clinically relevant aspects.

The Computer Science section of the Unit develops and implements databases and web apps related to clinical trial and research projects as well as particular pathologies.The Clinical Informatics department is working on a cloud eCRF/DB based on REDCap, a platform employed by thousands of clinical researchers worldwide.

The Bioinformatic section of the Unit coordinates all the activities pertaining -omics and Big Data analysis in the institute. It provides a unique platform of discussion for all the bioinformaticians in IRE, bridges the communication from data scientist to the Information Technology department for High Performance Computing analysis of Next Generation Sequencing and other -omics data such as Nanostring.

Research Activities

The Biostatistic and Bioinformatic Unit implements the most advanced statistical and methodological techniques to analyze data arrays. Along with the basic ways of analyzing data

multivariate approaches are followed using available softwares as SPSS, Medcalc, Comprehensive Meta-analysis, PASS, NCSS and specific routines developed in R environment. Data coming from our single center and multicenter studies are formally checked together with investigators and strategies are constantly discussed. Our support starts with the study design and sample size determination using the most appropriate and innovative clinical trial design, and goes on focusing on protocol development and randomization scheme. During the study we support the investigators with interim analysis and database management. When writing the paper we perform the analysis and discuss the interpretation of results. Our activity includes systematic reviews and meta-analysis as well as the most recent techniques of analysis as propensity score and network meta-analysis. In collaboration we study the possibility of reducing high-dimensional data to develop models for interpreting prognostic and predictive role of factors.

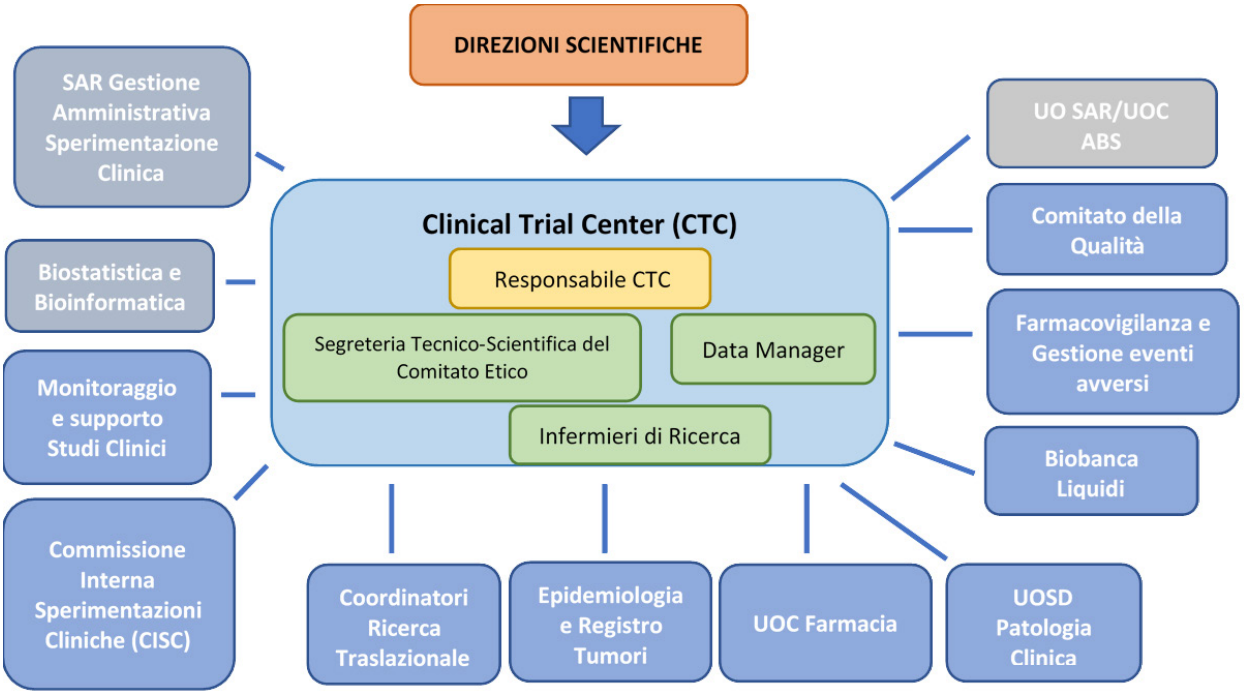
The Bioinformatic department started recently employing virtualization techniques such as Docker and Nextflowon High Performance Computing platforms in order to ensure total result reproducibility. During 2020 a "virtual machine recipe" was implemented with the basic toolbox needed for NGS data analysis. It also acts as a coordinating hub for many working groups of Alliance Against Cancer, such as ACC-Bioinformatics WP6 on Clinical Reporting and the data analysis of ACC-Immunotherapy.

IFO - Clinical Trial Center

The CTC was established by Decree No. 308 dated 24 April 2018 and subsequently amended with Decree No. 602 dated 06 August 2018. The components of both the CTC and External Units is shown in Figure 8. The CTC performs the following functions:

- Coordinates and monitors the functional activities regarding the management of clinical trials within the IFO, acting as a qualified reference point;
- Guarantees greater control of the clinical trials to the Scientific Directions of Regina Elena and San Gallicano Institutes and IFOs Medical Office;
- Particular supports in the spontaneous non-profit research;
- Interacts with the Departments involved in experimental research activities, coordinating the activities of the experiments aimed at:

1. Providing administrative, managerial, methodological and statistical services to researchers for the conception, design, planning, start-up phase, conduction, analysis and reporting of clinical studies so that these activities are carried out in compliance with the Good Clinical Practice (GCP) and the protocols;
2. Supporting the management of authorization procedures as well as the conduction and financial reports of clinical studies;
3. Promoting, in profit and non-profit research, the professional development of all participating researchers in terms of compliance with GCPs and regulatory aspects;
4. Guaranteeing quality control of studies (experimental and observational studies) with profit and non-profit study promoters;
5. Supporting monitoring of information regarding the feasibility of studies in terms of potentially enrolled patients;
6. Increasing the synergistic collaboration between researchers involved in the studies;
7. Evaluating the experiments proposed by researchers at IFO, for which IFO takes on the role of Promoter, and monitors the progress of the approved studies;
8. Identifying areas of great strategic interest for the Institute and propose initiatives necessary for promoting clinical trial projects in these areas



BioBank - BBIRE

Head: Prof. Gennaro Ciliberto

Coordinator

Dr. Laura Conti, MD, PhD. Head of Clinical Pathology and Cancer Biobank Unit

Staff BBIRE T

Prof. Edoardo Pescarmona, MD
Head of Pathology Unit
Dr. Mirella Marino, Quality Assurance
Dr. Simona di Martino, PhD Biologist
Dr. Valentina Laquintana, Biologist
Claudia Bonomo Technician

Staff BBIRE - LB

Dr. Giovanni Cigliana, Quality Assurance
Dr. Chiara Mandoj, Biologist
Dr. Giulia Orlandi, Biologist
Mustapha Haoui, Technician
Tommaso Mancuso, Technician

BBIRE is involved in a growing number of Institution projects (44 projects), and as a member of the European research network of Biobanks and Biomolecular Resources (BBMRI-ERIC) participates with European groups (EORTC- European Organisation for Research and Treatment of Cancer) to large-scale multicentre projects.

Also, BBIRE is involved in the ACC network and the primary objective of the Pathology and Biobanking Working Group is represented by the organization of a shared preanalytical workflow to obtain uniform quality of the biological samples, mainly tissue sample

Tumor Tissue BioBank IRE

DEPARTMENT	PATHOLOGY	PATIENTS	SAMPLE PRESERVATION MODE						
			TUMOR TISSUE CRYOPRESERVATION	NOT TUMOR TISSUE CRYOPRESERVATION	TUMOR TISSUE OCT	NOT TUMOR TISSUE OCT	NGS	FFPE	TOTAL
ORTHOPEDIC SURGERY	Sarcoma	146	1344	720	47	8	36	73	2228
THORACIC SURGERY	Thymoma	36	323	68	11	4		35	441
	Lung tumors	228	1153	972	80	45	120	171	2541
	Mesothelioma	2	8	0	1	0		1	10
	Lymphoma	10	48	8	2	1		11	70
	Pleural effusion	43	0	0	0	0	21	0	0
	Peripheral blood (pleural effusion)	25	0	0	0	0		0	0
SURGERY A/PLASTIC SURGERY	Breast cancer	109	519	439	25	15		106	961
GYNECOLOGICAL SURGERY	Uterine cancer	122	855	236	27	3		84	1205
	Ovarian cancer	48	823	26	13	3		37	902
	Ovarian cancer + peritoneal washing	41	494	95	19	3		34	645
	Peritoneal washing	21	0	0	0	0		0	0
	Uterine carcinosarcoma	6	77	17	7	0		6	107
UROLOGY SURGERY	Renal Cancer	99	855	357	38	12		88	1350
	Bladder Cancer	59	483	248	22	13		53	819
NEURO SURGERY	Brain cancer	29	126	5	2	1	10	29	173
HEPATOBILIARY SURGERY	Colon cancer	86	432	302	24	16	23	78	875
	Colon cancer/hepatic metastasis	6	76	63	0	0		7	146
	Hepatic metastasis	34	190	129	5	2		20	346
	Stomach cancer	14	55	33	7	5		12	112
	Liver cancer	24	208	92	13	0		19	332
	Pancreas cancer	33	161	64	10	4		25	264
	Gist	2	18	0	1	0		2	21
	Retroperitoneal sarcoma	6	118	32	2	1		5	158
	Cholangiocarcinoma	9	75	46	1	1		10	133
	Biliary tract cancer	4	8	0	1	1		3	13
	Melanoma	1	8	4	0	0	1	1	13
OTOLARYNGOLOGY SURGERY	Head and neck cancer	12	56	15	4	0		3	78
OTHERS	Metastasis (melanoma)	21	115	4	6	0	21	18	164
Total		1276	8628	3975	368	138	232	931	14107

Body Fluids BioBank IRE

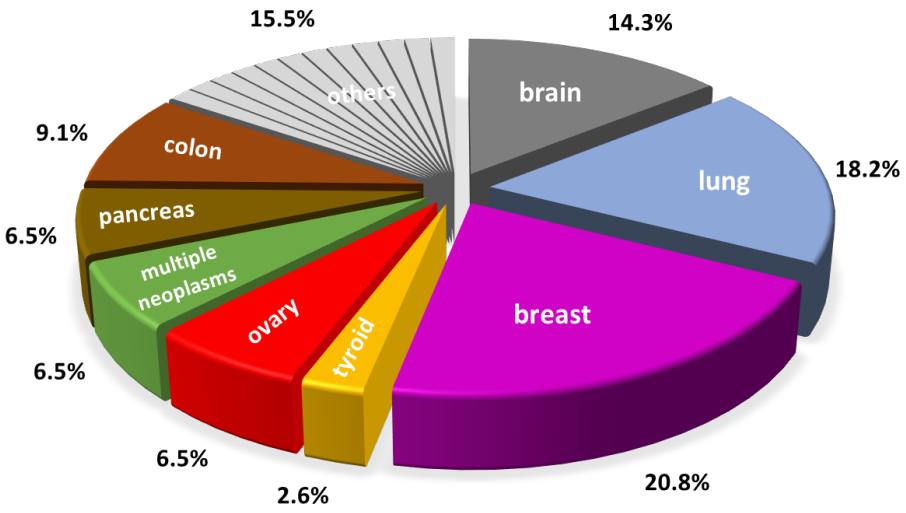
DEPARTMENT	PATHOLOGY	PATIENTS	WITHDRAWALS	SAMPLE ALIQUOT (-500µL)				2mL*	1mL	
				Whole Blood	Plasma EDTA	Plasma Citrate	Serum	Plasma EDTA	PBMC	TOTAL
ORTHOPEDIC SURGERY	Sarcoma	603	1675	3336	8069	998	6942	3267	-	22612
THORACIC SURGERY	Thymoma	26	26	52	195	13	102	20	-	382
	Lung cancer	205	205	410	970	-	803	426		2609
	Lymphoma	4	4	8	26	-	16	6		56
MEDICAL ONCOLOGY 2	Breast cancer	69	71	141	327	201	483	15	-	1167
GYNECOLOGICAL SURGERY/ BTO (Ovarian Tissue Biobank)	Uterine cancer	314	320	638	438	956	1339	931	-	4302
	Ovarian cancer	75	75	150	473	222	350	135		1330
	Various									
RADIOTHERAPY	Prostate/ Oropharynx/ Breast cancer	169	596	1192	2908	-	2682	1471	-	8253
MEDICAL ONCOLOGY 1/2	Lung cancer (ACC LUNG)	27	48	143	-	-	7	311	57	518
NEURONCOLOGY/ NEURO SURGERY	Brain cancer	74	93	186	295	266	389	232	-	1368
		112	117	234	568	-	477	269		1548
ENDOCRINOLOGY	Medullary thyroid cancer	18	18	36	4	-	-	34	-	74
MED. ONCOLOGY/ PLASTIC SURGERY	Melanoma	67	144	286	541	6	622	549	-	2004
GASTROENTEROLOGY	Hereditary colon cancer	200	200	400	114	-	-	397	-	911
HEPATOBILIARY SURGERY	Colon/Stomach /Liver cancer	17	18	36	27	51	74	47	-	235
MTB	Various	26	38	76	42	9	82	153	5	367
TRANSFUSION M.	Healthy donor	59	105	210	82	303	455	208	-	1258
TOTAL		2065	3753	7534	15079	3025	14823	8471	62	48994

Molecular Tumor Board - MTB

The Molecular Tumor Board (MTB) at the Regina Elena National Cancer Institute (IRE) is active since September 2018. During the last year, our MTB consolidated its reputation within Regione Lazio by stably expressing recommendations for the treatment of complex, intramural but also external, clinical cases. Particularly, during 2020, 22 MTB sessions, at 15-day intervals, have been made. Overall, 23 neoplastic patients bearing common (e.g. lung, colorectal, breast carcinomas) or rare (e.g. sarcomas) cancers with no therapeutic options left have been analyzed. In all cases, after a revision of the clinical history and the available genomic data, the MTB requested additional molecular testing, most often based on massive parallel sequencing. Next Generation Sequencing (NGS) was carried out in-house by small targeted panels (e.g. 50 genes) and genome-wide (Whole Exome Sequencing, WES) approaches, or by outsourcing from prime International NGS Service Providers (e.g. Foundation Medicine). Particular care was exercised in selecting the analyte (or analyte combination) most suitable for each individual patient. Either or both tissue and circulating DNA (tDNA and ctDNA) were used to investigate the genomic profile of patients, often through the implementation of serial blood drawings and/or, when ethically acceptable, tissue re-biopsy. Digital PCR (dPCR) custom assays were designed, validated and deployed when no commercial solutions were available in order to confirm the presence of a specific tumor alteration. Immunohistochemistry (e.g. PD-L1 status) and in situ hybridization (e.g. FGFR1 amplification or ROS1 fusion) were also requested and applied in some cases. All the collected data were integrated as orthogonal confirmatory measures and/or evaluated as self-standing assays. Non-standard assays were backed up by (and integrated with) CE-IVD testing whenever possible. In 14 cases (61%), at least one peculiar molecular alteration associated with a potential, additional tumor vulnerability was identified. Following MTB case review, a non-standard targeted therapy (mostly OncoKB levels 3A and 3B) was recommended for 11 patients (48%). In 2 colorectal cancer patients identification of EGFR mutations strongly suggested the discontinuation of the ongoing standard line of therapy.

It is important to acknowledge that all the costs associated with supplemental genomic analyses were entirely covered by the Regina Elena Institute. None of the patients was requested to pay, or incurred in any disbursement for any kind of molecular testing, or for the purchase and administration of the selected drugs. In specific situations, when applicable, the MTB entertained a collaborative effort with the Italian National and local Health Authorities to obtain special permits and economical support finalized to free drug administration. Additional collaborative efforts are in progress to extend the MTB approach.

81 pts
have been
discussed



45/81 **(55.6%)** pts showed ≥1 actionable mutation

29/45 **(64.4%)** pts have received therapeutic recommendations

19/29 **(65.5%)** started recommended therapy

IRE
ISTITUTO NAZIONALE TUMORI
REGINA ELENA

Participation to National and International Networks

Alleanza Contro il Cancro - ACC

The IRCCS Regina Elena National Cancer Research (IRE) is one of the founder members of Alliance Against Cancer (ACC), the largest Italian organization for cancer research, that was established in 2002 by the Italian Ministry of Health as a network of six high standard institutes for comprehensive cancer patient care and research (IRCCS).

The primary aim of ACC is to promote the network among oncologic institutes pursuing mainly clinical and translational research in order to bring state of the art diagnostics and advanced therapeutics to patient care.

In addition to the aims of translational medicine, ACC also fosters research through international collaborative networks of excellence, such as Transcan ACC is one of the funding agencies in this European network that coordinates translational research projects that are selected by means of high standard evaluation procedures.

The Association is currently made up of 26 Comprehensive Cancer Center, AIMaC, Italian Sarcoma Group, CNAO Foundation and the Istituto Superiore di Sanità.

Actually, eleven Working Groups (WGs) that deal with the main types of cancer (Colon, Breast, Lung, Glioblastoma, Melanoma and Sarcoma) and clinical research (Genomics, Pathological Anatomy and Biobanks, Oncohematology, Immunotherapy and Radiomics) are active in the ACC. These are collaborative groups formed by the best national reference experts who deal with programming clinical research and optimizing the use of new drugs for each individual tumor pathology. The IRE Institute participate to all WGs with the participation of pre-clinical and clinical representative.

Working Group	Pre-clinical representative	Clinical representative
Colon	A. Biroccio	M. Maugeri Saccà
Glioblastoma	M. Paggi	A. Pace
Immunotherapy	P. Nisticò	V. Ferraresi
Breast	G. Blandino	P. Vici
Melanoma	P. Giacomini	V. Ferraresi
Sarcoma	R. Falcioni	V. Ferraresi
Lung	P. Nisticò	M. Maugeri Saccà
Oncohematology	M. Fanciulli	F. Marchesi
	Wet Lab	Bioinfo
Genomics	S. Buglioni	M. Pallocca
Anatomo Pathology	S. Di Martino	E. Pescarmona
Radiomics		A. Vidiri

EATRIS

A-IATRIS, Association Italian Advanced Translational Research Infrastructure, is a network of institutions of excellence on the national scene able to make specific and complementary contributions in the area of translational medicine. A-IATRIS represents the Italian node of EATRIS (European Advanced Translational Research Infrastructure in Medicine).

EATRIS is designed to bridge the gaps and deficits in the panorama of European translational medicine. Its objectives for EATRIS are:

- To support the process of translating research results into innovative strategies aimed at the prevention, diagnosis and treatment of diseases of particular health and economic importance for European member states;
- To build a beWer space in which the flow of information between basic research and clinical observations is bi directional

EORTC

European Organization for Research and Treatment of Cancer Is an independent, non-profit cancer research organization, its mission is to coordinate and conduct international translational and clinical research to improve the standard of cancer treatment for patients

EURACAN

The management of rare cancers poses significant diagnostic challenges, sometimes having major consequences for patients' quality of life and outcome. Inappropriate management of these patients may also result in an increase risk of relapse, and even death. In order to solve these issues, EURACAN was established in year 2016

EURACAN acts as a virtual network connecting patients and expert healthcare professionals across Europe. The aim is to tackle these complex and rare cancers that require highly specialized treatment and concentrated knowledge and resources.

More than 300 rare cancers have been identified. EURACAN covers all rare adult solid tumor cancers, grouping them into 10 domains:

1. Connective tissue (sarcomas)*
2. Female genital organs and placenta
3. Male genital organs and urinary tract*
4. Neuroendocrine system*
5. Digestive tract*
6. Endocrine organs*
7. Head and neck
8. Torax*
9. Skin and eye melanoma*
10. Brain and spinal cord*

*Domains where the Istituto Regina Elena has been an accredited Euracan Member since year 2016

OECI

The "Organization of European Cancer Institutes" is a nongovernmental, no-profit legal Entity established in 1979 to promote greater cooperation among European Cancer Centres and Institutes with the following Aims:

- Create a critical mass of knowledge and skills that can identify and share new and improved models of care
- Improve the quality of cancer care and translational research
- Improve the quality of life for cancer patients
- Provide a path of continuous improvement in order to homogenize the care of cancer patients according to shared
- Achieve high European standards and quality levels.
- Facilitate the development of European multi-centre studies and the use of EU research funds

With time OECI has grown to include more than 100 Cancer Institution mainly in Europe but also in other Continents. The OECI aims to promote efficient partnership, reduce fragmentation and increase competitiveness amongst European cancer centres and institutes. This goal is being achieved by promoting and enhancing the concept of "comprehensiveness" and "multidisciplinarity", supporting quality in cancer care and dynamically working in crosscut expertise by involving our Working Groups, our Members and promoting synergies with other cancer Organisations.

OECI, on September 10, 2015, has certified that IRE meets the quality standards for cancer treatment and research and has therefore awarded to IRE the qualification of Comprehensive Cancer Centre, namely an Institute with the combination of characteristics such as translational research, multidisciplinary, continuous improvement of care, the production of guidelines and diagnostic-therapeutic pathways, continuous training and centrality

Year 2019 has to be remembered as the year in which for the first time the annual meeting of OECI called "Oncology Days" has been held in Italy. The meeting was held in Bari from June 19 to June 21. All Italian OECI Members, including IRE contributed to the organization of the program. A dedicated roundtable session with the title: The OECI Italian Institutions Network Alliance Against Cancer (ACC), A Country Based Model took place as a central event in the meeting

In Year 2019 IRE has applied to undergo a new OECI Accreditation and Designation Programme. Upon approval of the IRE application on June 5, 2019, a self-assessment period started that was completed in January 2020. A provisional Accreditation as Comprehensive Cancer Center has been assigned as well as in March 2020 a GO decision was communicated and a peer review visit planned for May 12 and 13. Unfortunately that date was cancelled due to the COVID-19 pandemic and at the time of writing this report it has not yet been rescheduled

UICC

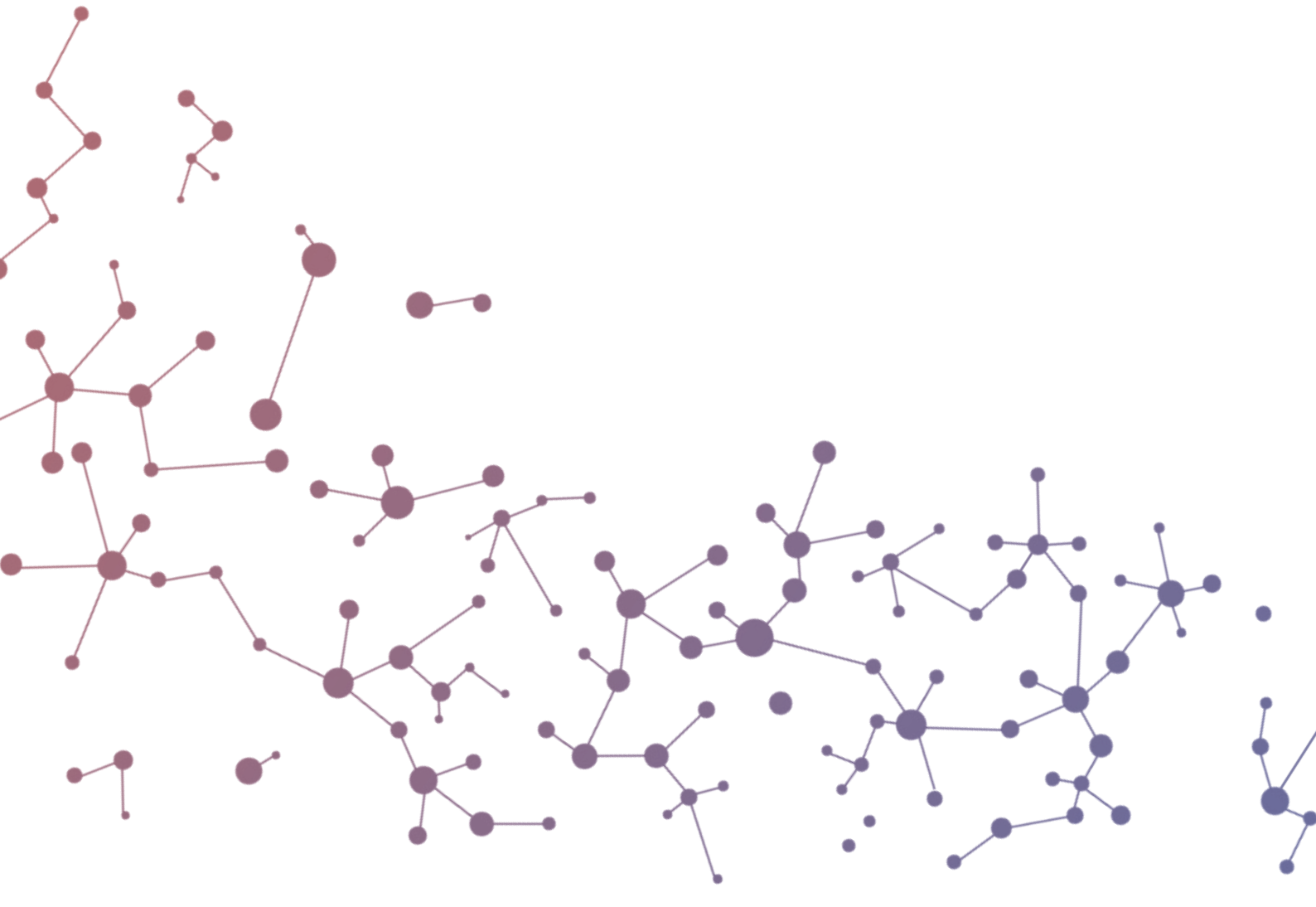
The Union far International Cancer Control's (UICC) rapidly increasing membership base of over 1000 organizations in more than 160 countries, represents the world's major cancer societies, ministries of health and patient groups and includes influential policy makers, researchers and experts in cancer prevention and control. UICC also boasts more than 50 strategic partners

Weizmann Institute

In 2020 the IRE has established a collaboration with the Weizmann Institute of Science (WIS) in Rehovot, Israel. These two institutes have called an internal research grant for collaborative research between an IRE PI and a WIS PI. This grant will support the research for two years with €25.000,00 per year. This first edition was won by the team Yarden – Bagnato and Krizhanovsky – Bossi

מכון ויצמן למדע
WEIZMANN INSTITUTE OF SCIENCE

Translational Research Interest Groups



Genomics

By Dr. Patrizio Giacomini

The IRE Working Group (WG) Genomics is a multidisciplinary group spanning in expertise from basic-translational approaches to clinical Next Generation Sequencing (NGS). Although NGS is our main focus, members of the group implement many ancillary nucleic-acid-based methods for research and advanced diagnostics. Biologists, Biotechnologists, Bioinformaticians, Pathologists and Clinical Pathologists provide the WG Genomics with a solid biotech core, but all the activities (from study design to patient enrollment and treatment, through data collection and analysis) build on the strong contributions of medical oncologists, radiologists, surgeons, and Biostatisticians. Integrative approaches are being carried out including radiogenomics, liquid biopsies, whole-genome and single-cell sequencing, big data interrogation, model building and clinical trial design. The goal is to harmonize diverse skills and institutional needs into a common finalized effort (see figure).

Achievements

During 2020, clinical NGS panels of increasing complexity have been employed to reflect the expansion of the druggable genome. In parallel, we have witnessed a considerable increase in the number of NGS-based diagnostic tests performed, as follows: 1120 patients (colorectal, lung, thyroid, gastric carcinomas, brain tumors, sarcoma and melanoma), 780 of whom displayed pathogenetic or likely pathogenetic alterations, and 670 had targetable or potentially targetable alterations either in the standard of care setting or in the context of ongoing clinical trials. More in general, rather than adopting the one-size-fits-all scheme so common to commercial outsourcing models, we find it most useful to tailor different NGS solutions for different clinical-pathological patient groups.

The Genomics WG entertains a close collaboration with the institutional BioBank. Whether occurring in the context of standard of care, or during a clinical trial, we do our best to biobank tissue, blood, and other body fluids for future reference, molecular 'second look', and retrospective analysis.

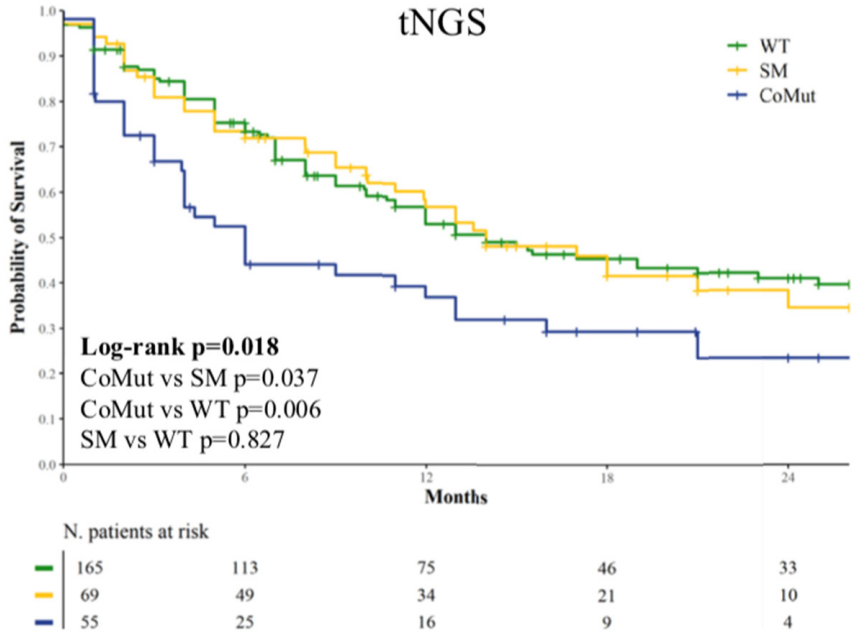
The WG Genomics includes members of our Genetic Testing Unit, focusing on the most frequent Hereditary Cancer syndromes (HCS) such as the Lynch syndrome (LS), the Peutz-Jeghers syndrome (PJS), the Juvenile polyposis syndrome (JPS), The Cowden syndrome (CS) the Hereditary Breast and Ovary Cancer syndrome (HBOC), APC-associated polyposis and MUTYH-associated polyposis (AAP and MAP), and the Multiple Endocrine Neoplasia syndrome type 1 and type 2 (MEN1 and MEN2). Molecular testing is performed in the framework of genetic interview/counseling through the activities of our outpatient's clinics. Moreover, a substantial fraction of cases are referred from other institutions all over the country. During 2020, testing 375 probands resulted in the discovery of 67 affected patients, e.g. we have further optimized the affected/tested percentage of our testing, which attests to an improved clinical-molecular integration in our multidisciplinare HCS unit.

Hereditary Cancer testing allows an in-depth cancer risk assessment for each patient, leading to improvements in health outcomes of both carriers and family members.

During 2020, the throughput of our advanced genomics facilities has been considerably expanded through the purchase of new equipment and personnel training/acquisition. This has resulted in an improved support to research projects and, most importantly, to the Molecular Tumor Board. To this end, during 2020, we have carried out 6 WES analyses, and have greatly streamlined and automatized bioinformatic support. This has resulted in both more accurate data for research purposes and an extension in our ability to investigate rare cancers and uncover unsuspected vulnerabilities in fragile patients.

Research Activities

Several studies are ongoing to identify epigenetic mechanisms involved in tumor transformation, including miRNA signatures in melanoma, head and neck cancer, and hematological malignancies. Recently, members of the Genomic Translational Group have reported that KEAP1-driven co-mutations make lung adenocarcinoma unresponsive to immunotherapy despite high Tumor Mutational Burden (Fig. ...). This study helps to explain why our ability to predict the efficacy of this important class of therapeutic agents has lagged behind.



A specific combination of mutations impairs immune checkpoint blockade in lung carcinoma. Patients whose tumors hosts co-mutations (blue line) have a short overall survival compared to patients whose tumors either lack the selected set of mutations (WT, green line) or have a single mutation (SM, yellow). From Marinelli et al. Ann. Oncol. https://doi.org/10.1016/j.annonc.2020.08.2105

Non Coding RNAs (NCR)

By Dr. Giovanni Blandino

Recent studies have revealed that about 901X1 of the eukaryotic genome is transcribed. Interestingly, only 1-2% of these transcripts encode for proteins, the majority are transcribed as non-coding RNAs (ncRNAs).

During the past few years ncRNAs, previously thought as transcriptional junk, have become a research goldmine. The functions of ncRNAs are likely diverse, and their underlying mechanisms are just beginning to be understood. For sure ncRNAs are important regulatory molecules of many cellular processes in development and diseases, among which cancer, and have been identified as the key gene expression regulators.

The NCR group is mainly focused on three classes of ncRNA: microRNAs (miRNAs) long-non-coding RNAs (lncRNAs) and circular RNAs (circRNAs).

MiRNAs are small single-stranded molecules (20-24 nt) that derive from transcripts with distinctive hairpin structures. The hairpin is processed into mature miRNA by two endonucleases, Drosha and Dicer, and forms the RNA induced silencing complex (RISC). The miRNAs will pair with complementary sequences on target mRNAs transcripts through the 3'UTR, leading to gene silencing of the target.

LncRNAs are non-protein coding transcripts >200 nt in length that have been shown to control every level of the multi-level regulated gene expression pathway. For example, they are implicated in post-transcriptional gene regulation through controlling protein synthesis, RNA maturation and transport, the amount of available functional miRNAs, and in transcriptional gene silencing through regulating the chromatin structure.

CircRNAs are a large class of endogenous RNAs formed by exon skipping or back-splicing events as covalently closed loops, which are expressed abundantly in mammalian cells. CircRNAs can regulate transcription, RNA splicing and, as for lncRNAs, they can function as miRNA sponges.

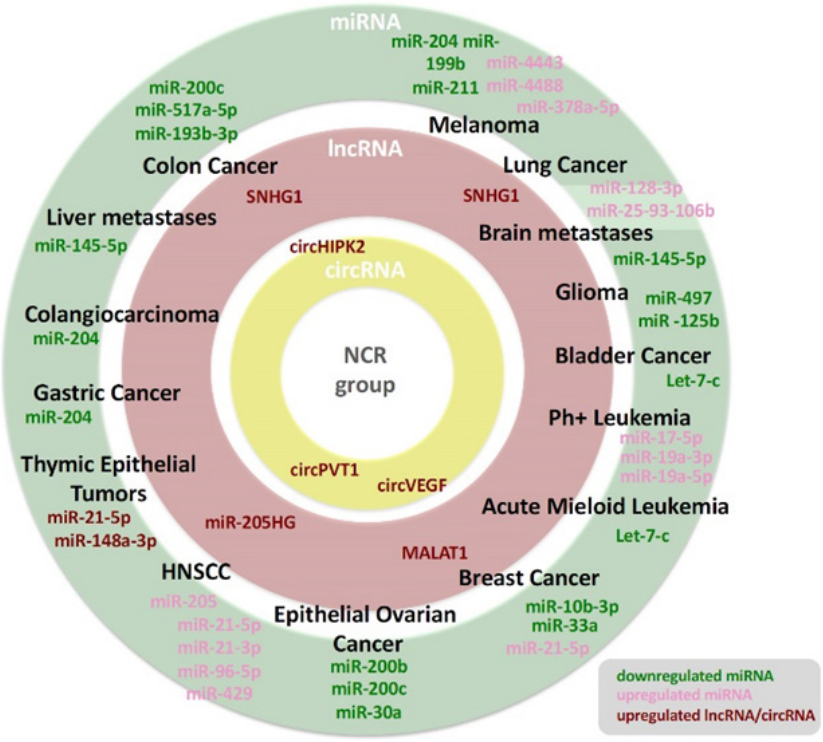
The studies conducted by the NCR group are based on two principal approaches: a) one of more basic research approach that is intent to discovery the molecular mechanisms at the basis of rniRNAs, lnRNAs and circRNAs deregulation and functions in cancer cells; b) the other one is based on translational research approaches aimed to identify, by genome-wide screening, rniRNA, lncRNAs and circRNAs deregulated in tissue and liquid biopsies derived from cancer patients of our Institute, in way to discovery novel molecular biomarkers with clinical-prognostic impact and to develop innovative and more effective therapeutic approaches.

The research activity of NCR group, conducted in the last years, allowed to the identification of an intricate network between the three different classes of non coding factors in several cancer types (Figure). Moreover, several studies focused on circulating ncRNAs in cancer patients, underling their promising use as novel powerful biomarkers. The obtained results lead to a deeper understanding of the molecular pathways involved in tumorigenesis and represent the basis for the identification of novel powerful biomarkers.

In the last year the research activiyt of the group led to the possibility of patenting new biomarkers such as miRNA and circRNA.

In particular 3 projects led to the filing of 3 patents:

1. The identification of a 4 miRNAs signature associated with the occurence of relapse in patients with head and neck cancers.
2. The identification of a circRNA as a biomarker involved in the recurrence of breast tumors, in particular TNBC.
3. The identification of a miRNA signature as biomarkers for the development of mucositis. A project in collaboration with the San Gallicano Institute.


miRNA
miR-204 miR-199b
miR-4443
miR-211
miR-4488
miR-200c
miR-517a-5p
miR-193b-3p
miR-378a-5p
Melanoma
lncRNA
Colon Cancer
Lung Cancer
SNHG1
SNHG1
miR-128-3p
miR-25-93-106b
Liver metastases
miR-145-5p
circHIPK2
Brain metastases
miR-145-5p
circRNA
Glioma
miR-497
miR -125b
Colangiocarcinoma
miR-204
NCR group
Bladder Cancer
Let-7-c
Gastric Cancer
miR-204
Ph+ Leukemia
miR-17-5p
miR-19a-3p
miR-19a-5p
Thymic Epithelial Tumors
circPVT1
circVEGF
Acute Mieloid Leukemia
miR-21-5p
miR-148a-3p
miR-205HG
Let-7-c
MALAT1
HNSCC
Breast Cancer
miR-205
miR-21-5p
miR-21-3p
miR-96-5p
miR-429
Epithelial Ovarian Cancer
miR-10b-3p
miR-33a
miR-21-5p
miR-200b
miR-200c
miR-30a
downregulated miRNA
upregulated miRNA
upregulated lncRNA/circRNA

Melanoma (Joint IRE - ISG)

By Dr. Emilia Migliano and Dr. Patrizio Giacomini

During year 2020, the group has built on a pre-existing collaborative network and has strenghthened the interactions among the Melanoma Disease Management Team, the institutional Melanoma 4P project, and work in the context of Alliance Against Cancer (ACC).

Organization

The Melanoma DMT convenes on Tuesdays to discuss the most crotical clinical cases, but is also a forum for the dissemination of the ongoing clinical and clinical-translational projects and ideas. Melanoma 4P stands for Precision, Predictive, Personalized and Participated.

During 2020, we have been able to enrol in this study 97 more patients, 68 from the cohort at early stages, and 29 from the late-stage cohort. The total numbers of enrolled patients is now 149 (since May 2019) which demonstrates our commitment to make precision oncology available to an expanding coohrt of high-risk patients. The project is run under the supervision of Professors Gennaro Ciliberto and Aldo Morrone, Scientific Directors of the Regina Elena National Cancer Institute and S. Gallicano Dermatological Institutes, respectively. Collaboration of our twin Institutes is a plus enabling Melanoma 4P to span from prevention and Dermatology to Medical and Molecular Oncology in a single uninterrupted flowchart.

Achievements

During 2020, a joint initiative of the Regina Elena and S, Gallicano Institutes has met with success. The application of a young investigator from ISG (fully supported by a team of young promising investigators from IRE) has been funded by the Ministry of Health to investigate the role of radiomics and radiogenomics in the context of checkpoint treatment. Hopefully, this new project will help to establish novel routines for our patients. We expect that combining tissue genomics,liquid biopsies, and radiomics (medical imaging texture) features, it will be possible to describe melanoma in more detail. Concepts such as genomic profiling, ctDNA relapse, and medical imaging texture are likely to become important independent variables guiding melanoma management in the next future. We do expect that response to checkpoint blockade may be predicted and monitored, sparing unnecessary toxic regimens to 'resistant' patients, and optimizing dosages and schedules for susceptible patients. This new project is fully synergistic with Melanoma 4P and several ongoing clinical activities. IRE and ISG are aso active in a project on melanoma organoid s that is carried out under the egida of Alliance Against Cancer (ACC). In this study, we will establish short term 3D cultures of melanoma explants and will determine in a multi-institutional context, how these can help to address the long vexing question of the tumor immune environment in patients undergoing checkpoint blockade therapy. In addition, the group is active in a variety of other projects that are not desfcribed here in the interest of space, but aim at the characterization and better knowledge of major transduction pathways, drugs, and miRNA profiling. Finally, the two Pathology groups at ISG and IRE are fully collaborating to bring innovative molecular diagnostics (e.g. NGS panels of ever increasing complexity) into the diagnostic routine, providing an important 'backbone' to all other activities.

Rare Tumors

By Dr. Virginia Ferraresi

Tumors are for definition considered rare when incidence is less than 6 cases in 100.000 people per year, but altogether rare tumors account for approximately 25%, of all cancers (approximately 18% solid rare cancers and 7% rare hematological diseases). Rare tumors are almost invariably associated with 5-year overall survival rates globally less than 50% as compared to 65% in common cancers. This overall worse prognosis is substantially linked to the limited medical expertise and the lack of evidence-based treatment guidelines that ultimately result from low frequency with scanty tissue banks and registries, few clinical trials, misdiagnosis (both clinical and pathological) and delayed diagnosis, all of which are serious obstacles to clinical decisions.

The estimates of incidence, prevalence and survival of rare cancers in Italy are based on the pool of the AIRTUM cancer registries (years 2000-2010) and it was estimated that about 360.000 people were diagnosed with new cancers in Italy in 2011, with an annual incidence rate of about 200 rare cancers per 100,000 corresponding to about 89,0000 new diagnoses annually.

With a yearly admittance of 1,000 new cases and 3,000 total patients being followed per year, IRCCS Regina Elena represents one recognized center for the diagnosis and treatment of rare solid tumors.

Over the past 10 years, IFO played an active role in the collaborative efforts of the national network on rare tumors (Rete Tumori Rari, RTR). Since 2016 IFO are involved in EURACAN (EUropean network for Rare Adult solid CANcer) and have become a European Referral Center for eight rare tumors (soft tissue, viscerae and bone sarcomas, rare neoplasm of the male genital organs, and of the urinary tract, neuroendocrine tumors, rare neoplasm if the digestive tract, rare neoplasm of endocrine organs, rare neoplasm of the thorax, rare neoplasm of the skin and eye melanoma, rare neoplasm of the brain and spinal cords). Main objectives of EURACAN are to improve the quality of care of all European patients affected with rare cancers enabling a major improvement in the access to centers of excellence for diagnosis and treatment and unifying the availability of optimal clinical practices in the EU by centralizing knowledge and experience, medical research, training, and resources. A European Collaborative Platform and a Clinical Patient Management System (CPMS) are actually in development in order to discuss and to share clinical cases of patients with rare tumors all over the European centers of the network. In 2019, IFO domain leaders have been involved in virtual meetings and asked to participate in panel of experts

Our Institute is actively involved in International collaboration and revision of specific guidelines of various type of rare tumors and is engaged in national and international clinical trials. Since 2018, the Rare Tumors Translational Group has been participating in the European trial ARCAGEN (EORTC-SPECTA) whose aim is to perform a molecular characterization of rare cancers on retrospective and prospective biological samples. Retrospective cases have been collected and the accrual of prospective cases is actively ongoing.

In 2020, IRE became one of the 9 EURACAN and OECI Italian national cancer institutes of project Rarity. The project is sponsored and funded by Alliance Against Cancer (ACC) and aims at initiating the Italian part of the EURACAN registry (STARTER project).

Clinical cases of rare tumors having access to our institute are discussed in meeting, scheduled on weekly or biweekly basis, by dedicated multidisciplinary disease management teams in order to assure an adequate clinical, radiological and pathological assessment leading to a correct diagnosis and an appropriate treatment inside or outside national or international experimental trials.

A dedicated group of data managers is actively involved in the prospective registration of all case

of rare tumors accessing to our Institute on a database including all relevant clinical information and follow up updates. For some rare tum or s (for example soft tissue and bone sarcomas) a regular process of institutional biobanking of blood and pathologic specimens is ongoing.

In 2020, integrate care pathways in rare tumors have been further elaborated in order to assure timely taking charge of the patients. In order to facilitate the access of patients with rare tumors and diseases and to offer them dedicated diagnostic and therapeutic pathways, in December 2020 a helpdesk has been activated. It is coordinated by a doctor, a nurse and an administrative employee and will guide patients through paths that can facilitate quick access to facilities dedicated to individual rare tumors.

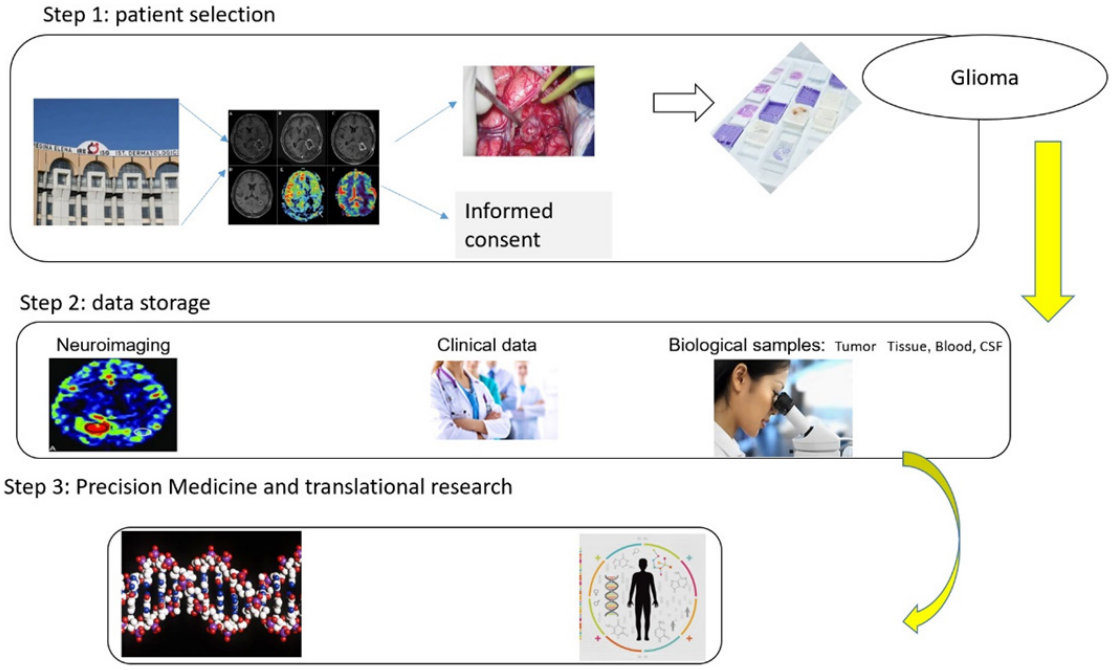
Increasing emphasis is moreover given to the collaboration with basic researchers to identify, as for more common cancers, molecular diagnostic, prognostic or predictive biomarkers and regular translational meetings, under the supervision of our Scientific Direction, are organized on bimonthly basis.

Finally, in June 2020 a departmental Unit on Sarcomas and Rare Tumors was activated. The unit is specifically addressed to the diagnosis, clinical management and translational research in patients with sarcoma and will be responsible for coordinating the activities on Rare Tumors in the Institute and in the EURACAN project.

EURACAN Network distribution

Brain Tumors

By Dr. Veronica Villani



Despite standard multimodality treatment including surgical ablation followed by radiotherapy plus concomitant and adjuvant chemotherapy with temozolomide, the prognosis of malignant gliomas remains unsatisfactory. Median survival in Glioblastoma Multiforme (GBM) patients is of 14.6 months and the average 5-years survival rate is less than 9.8%, with very few cases of long-term survivor, thus justifying the research on novel more effective therapies. The understanding of the molecular mechanisms of Glioma tumors has significantly evolved over the last decade and translational programs based on a large clinicobiological database are required to improve our understanding of GB biology, potentially facilitating the development of personalized and specifically targeted therapies and research applications. Successful biomaterial collection is a key requirement for the application of contemporary methodologies for the validation of candidate prognostic factors, discovery of new biomarkers and clinical implementation of precision medicine (eg, target therapies and immunotherapies).

Recent progress has been made possible by using advanced molecular analysis of brain tissue specimens systematically collected and stored in tissue repositories, including bioinformatics analysis of molecular data and integration with clinical information.

In the last years , the Regina Elena Cancer Institute promoted the Glioma Translatonal Group through multidisciplimnary collaboration between clinicians and researchers.

The primary aim of this collaborative group was to create a joint repository of tumor tissue, blood and CSF samples developing and mantaining a neuroncological biobank.

Collection and storage of biospecimens are offered to all patients undergoing surgery or submitted to neuroncological treatments including those obtained not only at disease onset but also at recurrence. In general, brain tumor patients are followed longitudinally from diagnosis throughout their disease course. An imaging repository is annexed to the clinical data and specimens that include MRI studies following a standardized protocol with pre- and postcontrast T1, T2, diffusion and non-morphological sequences.

With tissue specimens and pertinent clinical information the database has a role in both clinical and research development: at an individual level a personalized approach to precision medicine

allows direct patient treatment

At present, several translational studies are ongoing:

- Radiomic imaging studies are under development to align patterns in MR images with molecular and clinical features (Glioma Project);
- In the framework of glioma's group, Next generation sequencing in glioma patients for identification of potential target therapy:NGS panels assessment such as Ion-AmpliSeq (Thermo Fisher Scientific) to identify either the presence of point variants and fusion genes or variations in the number of gene copies with a panel of 50 genes that are recognized to have a key role in tumour development, with the aim to identify potential therapeutic target . Also for In order to dissect the microenvironment heterogeneity of our samples, we started applying whole transcriptome sequencing (RNA-seq) on a subset casuistry of the Glioma Project.
- To investigate if circulating miRNAs could mirror the mutational status of IDH1 we explored, through genome-wide methodologies, the miRNA expression profile in serum samples of a discovery cohort of IDH1 mutant and IDH1wt glioma patients. We found, on the basis of prognostic value and IDH1 status, a serum signature of 10 miRNAs with a promising diagnostic and prognostic value as non-invasive tool to stratify gliomas according to IDH1 status and useful to complement the molecular analyses routinely carried out on formalin-fixed paraffin-embedded tissue biopsies.

Translational approach and the development of dedicated biobank are critical to promote translational researches in neuroncology

Immunotherapy

By Dr. Paola Nisticò

Over the past few years, novel anticancer immunotherapy strategies, such as immune checkpoint inhibitors (ICI) and adoptive T-cell therapies, have shown remarkable clinical success across several tumor types, generating a wave of optimism in the oncology field. However, the durable regression of the disease achieved by immunotherapy approaches is currently limited to a subset of patients. The variability in patient response to cancer immunotherapies is due to the dynamic and complex nature of anticancer immunity, the existence of multiple immune-regulatory receptors/ligands and the heterogeneity in immunological composition, localization and function of the tumor immune microenvironment (TIME) cells.

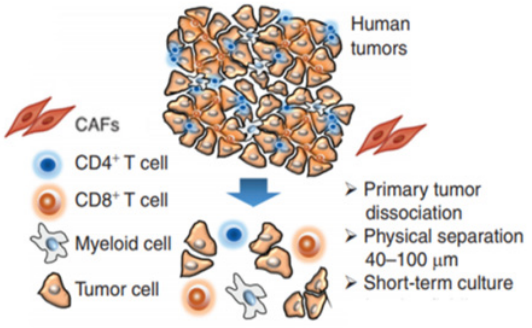
The group is developing a platform comprising of bioinformatics workflows and models that will stem from patient multi-omics integration. This asset will be exploited in future studies to guide optimal selection of best immunotherapeutic strategies for NSCLC patients, also in the framework of ongoing Alliance Against Cancer (ACC) network clinical trials.

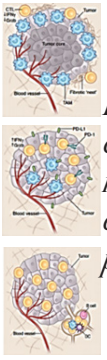
In particular, several lines of actions have been pursued:

- In the framework of the ACC Network, we have applied multi-omics platforms (RNAseq, NanoString, HLA typing, TCR-Seq, Whole Exome Sequencing) and deconvolution algorithms to identify biomarkers of response in ICI treated NSCLC patients.
- We posit to identify mechanisms of resistance in ICI non responder patients to design strategies to stimulate a non-immunogenic microenvironment TIME, e.g. radiotherapy.

CAR T-cell therapy is based on the administration of genetically modified T-lymphocytes specifically redirected to the tumor target by the expression on the lymphocyte cell surface of Chimeric Antigen Receptors (CARs). This therapy has been particularly effective in the context of B-cell lymphoproliferative diseases, while in other hematological malignancies and in solid tumors, so far, the efficacy has been much more limited. CAR T-cells therapy remains a challenge in solid tumors due to the presence of a TIME that may act as a physical barrier hampering CAR T-cell trafficking. The group is involved in a research project promoted by the Ministry of Health and developed under the aegis of Alliance Against Cancer. In particular, we are focused on the development of different strategies aiming at modulating the immunosuppressive elements to overcome the inhibition exerted by TIME to CAR T-cell therapy. The group currently carries out the following tasks :

- By bioinformatics methods and Machine Learning techniques we identified CAF-specific RNA signatures responsible of immune exclusion as putative target of CAR T
- We delivered oncolytic viruses in a murine model of head and neck cancer to support CAR T-cell penetration.
- We have planned to identify innovative biomarkers to predict CAR T-cell therapeutic response in human sarcomas





Identification of tumor microenvironment components participating to ICI resistance, focusing on cancer associated fibroblasts (CAF), extracellular matrix (ECM) and immune cell presence and localization

Artificial Intelligence (AI) and Imaging

By Dr. Matteo Pallocca

Precision Medicine is now a common practice and an established diagnostic paradigm, revolutionizing therapeutic approaches thanks to novel multidisciplinary schemes. One pillar of these new techniques is Artificial Intelligence (AI), the umbrella world defining all the computational techniques able to mimic or reproduce intelligent behaviors, such as language, pattern recognition, or classification. These techniques are able to provide novel models of prediction and prognosis to our patients in order to enable a new era of High-Resolution, other than Precision, Medicine.

Mission

With the purpose to give a basic framework and round table of discussion to all the several units dealing with structured and unstructured data in the Institute, the Scientific Direction prompted the creation of the Interdepartmental group of Artificial Intelligence and Imaging. The final aim is also to accelerate the Digitalization process of several data types and the employment of complex AI models on biomedical data.

The team is interdisciplinary in nature and comprises Bioinformaticians, Radiologists, Medical Physicists, Engineers, Medical Doctors, Biologists, Physics, Statisticians, and Experts in Scientific Communication.

Regarding unstructured data, Images are the bulkiest and largest set of data generated in a research hospital setting. Radiological data, for instance, are born digital, but they do need to undergo several in silico processing steps in order to extract modeling-ready numeric features. Furthermore, the Pathology Department of a cancer center processes thousands of Immunohistochemistry slides via human analysis and data curation. Now, the automated digitalization of said images enables an unprecedented power to reanalyze with novel techniques and algorithms hundreds of patient slides altogether and to overcome the intrinsic inter-operator human variability.

When it comes to structured data, -omics are the bread and butter of many diagnostic Units, with Next Generation Sequencing being applied to thousands of patients (ref. Genomics group), along with several other facilities such as Lipidomics and Metabolomics. The future of AI in Precision Medicine lies in multi-omics integration, with its numerous technical challenges due to data heterogeneity and batch effect distribution.

Novel synergies among Units

During the first months, the main focus of the AI and Imaging group has been the presentation of several modeling and analysis activities among Units that have been physically and strategically separated, such as Radiology/Medical Physics with the Genomics/Bioinformatics department.

For instance, the Radiology unit and the Medical Physics Laboratory shared their experience on Radiomics analysis of oropharyngeal squamous cell carcinomas and Head and Neck cancer. These projects were strongly related to AI not only for the feature extraction methods but also for the Machine Learning models employed on imaging features that exhibited a classification accuracy of over 90% for benign/malignant parotid lesions. Another joint-venture ongoing with the Galeazzi Orthopaedic Institute is focused on the Texture Analysis of Rare Tumor lesions, with the intent to better separate benign from malignant lesions from the TC and RM data.

Furthermore, during 2020 the interaction between the Digital Pathology and the Bioinformatics

group enabled the expansion of the implementation of the Aperio AT2 System for digitalization with the GENIE tool for automatized segmentation of digitalized slides. This tool enables to train the macro-regions of interests of each slide, to then apply the Aperio scoring algorithms to identify immunohistochemical staining specific to each cell in every region (such as tumor, stroma, etc).

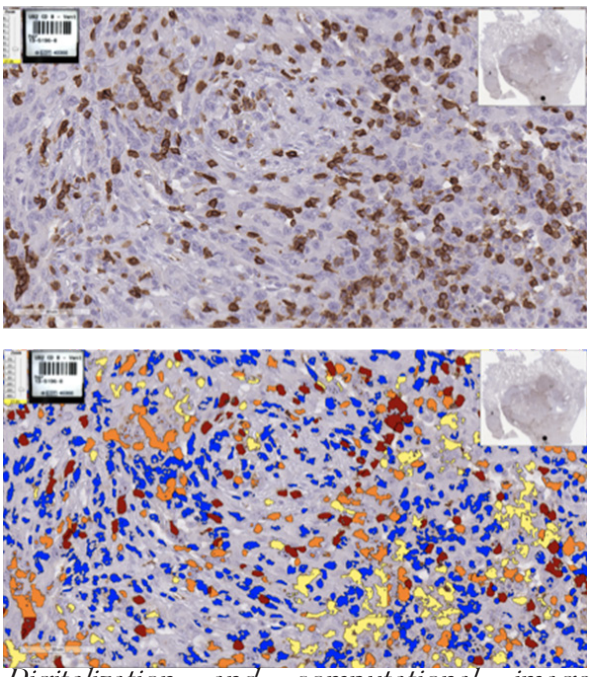
This system enabled to accelerate two projects already in place employing Digital Pathology: a digitalization effort on PD-L1 staining on Head and Neck Cancer and another casuistry of Non-Small Cell Lung Cancer treated with Immuno-Checkpoint inhibitors stained with PD-L1 and other CD* immunological markers, with the intent to define a novel predictive immunoscore (ref. Immunology Unit).

The Lung Radiogenomic Pilot

The first project stemmed from the AI & Imaging group pertains a complete multi-omic profiling of a casuistry of 150 Non-Small Cell Lung Cancer Patients who underwent surgery in our Thoracic Surgery department. These patients have pre-surgery TC scans from our Radiology Unit, complete oncogene sequencing from the Pathology, and clinical data annotation concerning treatments, progression events, and comorbidities such as smoking. This multi-omics integrative analysis will enable to shear light on how molecular mechanisms such as somatic mutations influence imaging data and whether a combined radiogenomic model improves biomarker modeling for prognostic and predictive endpoints.

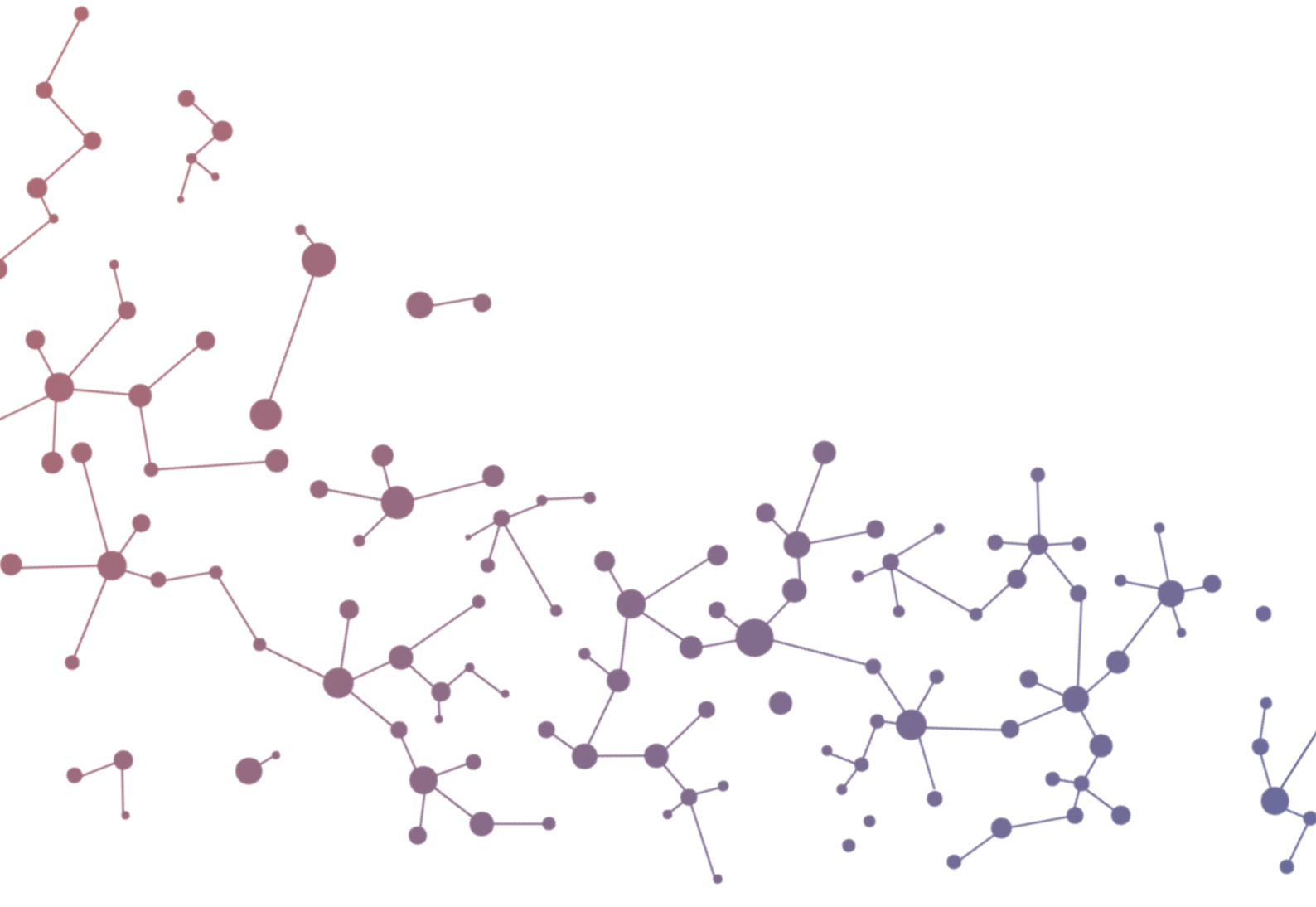
Components

Matteo Pallocca (coordination, Bioinformatics)
Eleonora Sperandio (Bioinformatics)
Simona Marzi (Medical Physics)
Francesca Piludu (Radiology)
Vincenzo Anelli (Radiology)
Alessio Annovazzi (Nuclear Medicine)
Antonello Vidiri (Radiology)
Enzo Gallo (Digital Pathology)
Edoardo Pescarmona (Pathology)
Simona Di Martino (Biobank)
Laura Conti (Biobank)
Irene Terrenato (Biostatistics)
Diana Giannarelli (Biostatistics)
Paola Nisticò (Immunology)
Giovanni Blandino (Epigenomics)
Maurizio Fanciulli (Genomics)
Roberto Biagini (Surgery)
Giuseppe Sanguineti (Radiotherapy)
Lorella Salce (Communication)
Eriseld Krasniqi (Oncology)
Rosa Sciuto (Nuclear Medicine)



Digitalization and computational image analysis of CD8 staining in Non-Small Cell Lung Cancer in Digital Pathology

Disease Specific Units



Breast Unit

Coordinator: Prof. Roy De Vita, MD

Mission

To offer an integrated and quality program to guarantee the care of patients with a diagnosis of suspected or ascertained breast cancer in the various phases of diagnostic confirmation and therapy, in order to improve the continuity of care, consistent with the lines guide based on the available evidence and with the most current scientific research lines.

All patients will be offered the same entry possibilities into clinical trials that may be underway at the Institute for each individual case.

- The program also aims to:
- Improve waiting times for the therapeutic diagnostic process, by setting company standards;
- Improve the information and communication aspects with the patient,
- Optimize and monitor the quality levels of the care provided, through the identification of process and outcome indicators and the development of a data collection and analysis system.

Moreover the program intends to consolidate the relationships with voluntary associations through systematic participation, scientific dissemination initiatives, with the General Practitioners Association and with the Medical Association of Rome.

The program also implements the systematic data collection for patient monitoring using the EUSOMA software and according with EUSOMA requirements and standards in order to be able to compete at European level.

Clinical Activities

A. The program is divided into the following phases:
B. Organization of activities: the assistance model
C. Patient access
D. Diagnostic phase: diagnostic therapeutic evaluation of the multidisciplinary team
E. Therapeutic phase
F. Follow-up
G. Advanced treatment of cancer

Research Activities

Developing strategies for permanent professional training and information addressed to the citizens are part of the scientific/informative activities of the Breast Unit

HPV Unit

Coordinator: Dr. Aldo Venuti, MD

Mission

Main mission is to formalize an organizational model of a "unified and coordinated space" in which originate jointly initiatives related to the topic of HPV This organizational model is a tool to inform, train and network both patients and health workers involved in HPV-related pathologies, from gynecological area to the skin, comprising ENT, urological and proctologic diseases. Finally, HPV-Unit is organized to deliver HPV vaccines to women and men.

Clinical Activities

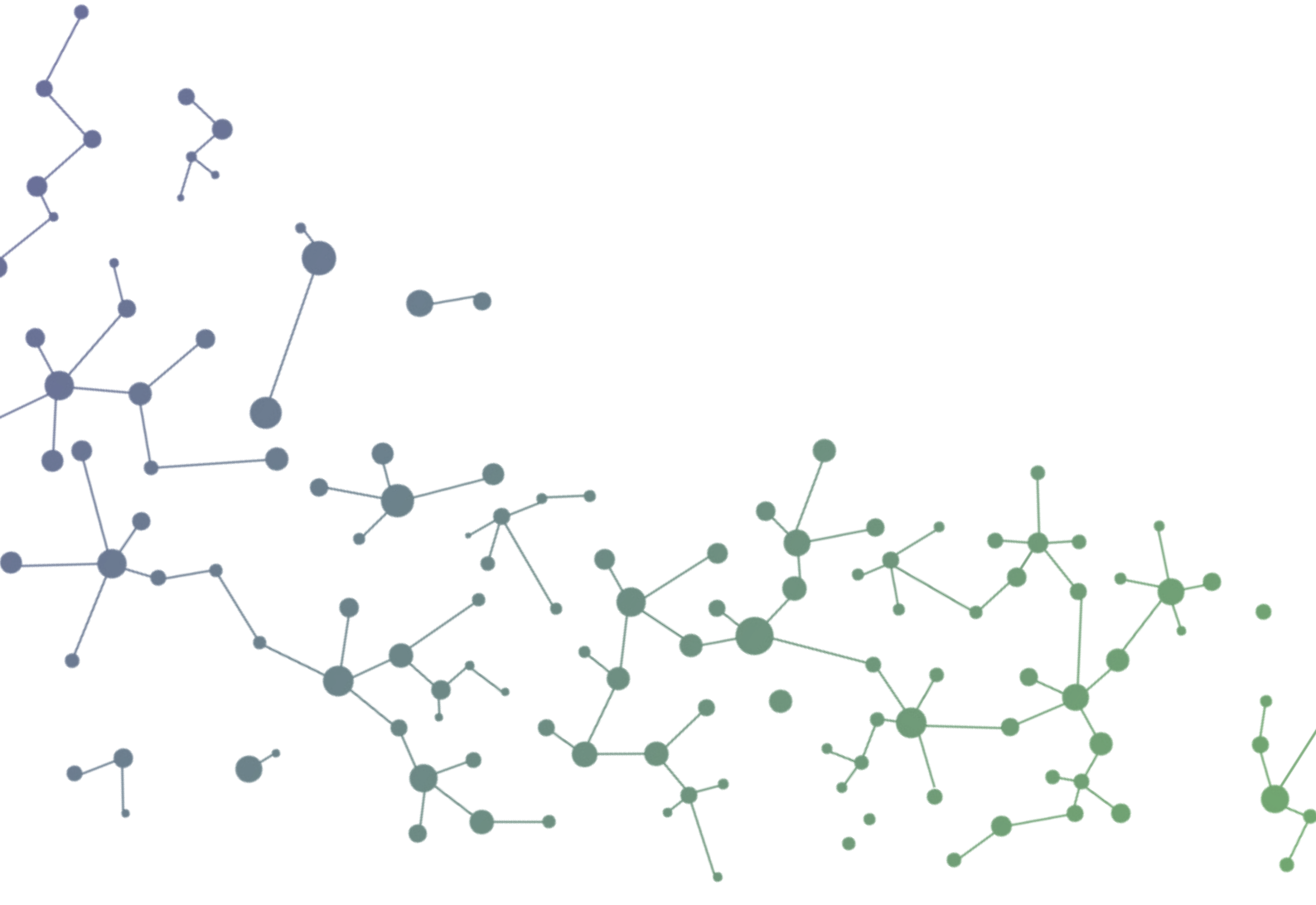
HPV UNIT is involved in second level diagnosis of virus-associated cancers, detecting HPV, EBV and polyomavirus in skin, oral cavity, and genital/perianal areas. Main activity was focused on coordinating diagnostic interventions by clinical interpretation of molecular data from assay tests, advice in evaluation of clinical cases by clinical teams, outpatients counseling and advising in preventive actions like individual screening or HPV vaccination. Specific clinical activities of HPV-Unit are: HPV vaccination to women as adjuvant therapy after conization; HPV vaccination to adult men as prevention of HPV-associated cancer and as adjuvant therapy after treatments for condiloma. HPV-Unit/IRE is coordinating Center for a large multicentric (V503-049) study on HPV vaccine safety and effectiveness on prevention of oral cancer. 37 patients were enrolled according to the Experimental Protocol and a three-year follow-up was started.

Research Activities

Part of the scientific/informative activities of HPV UNIT is developing strategies for information addressed to the citizens and for permanent professional training. In particular, HPV-UNIT is organizing in partnership with International papillomavirus Society (IPVS) the International HPV awareness day to get information about HPV, as screening and prevention. HPV-Unit is actively involved in translational researches on: Molecular carcinogenesis. It was showed that beta HPV15 can interfere with NF-κB activity and apoptosis in human keratinocytes favoring transformation. Molecular epidemiology. For the first time, it was shown that detection of HPV16 E5 oncoprotein in clinical sample is of pivotal importance, since E5 mediates resistance to PD-L1 blockade and can be targeted with rimantadine in head and neck cancer. New immunotherapies of HPV-associated cancers. A genetic vaccines is patented in Italy and will be extended to Europe. A similar vaccine was also produced in plant roots showing new manufacturing possibility. Finally, the activities of plant-derived natural compounds in adjuvating HPV genetic therapeutic vaccines were described and highlighted.

Department of Clinical and Experimental Oncology

Director: Prof. Roberto Biagini



Medical Oncology 1 Unit

Head: Prof. Francesco Cognetti, MD

Staff

Paolo Carlini, MD
Elvira Colella, MD
Fabiana Cecere, MD
Consuelo D'Ambrosio, MD
Alessandra Fabi, MD
Virginia Ferraresi, MD
Gianluigi Ferretti, MD
Cecilia Nisticò, MD
Michelangelo Russillo, MD
Antonella Savarese, MD
Massimo Zeuli, MD
Simona Gasparro, MD
Paola Malaguti, MD
Vanja Vaccaro, MD
Sabrina Vari, MD
Domenica Pellegrini, MD
Davide Renna, MD junior Fellows
Barbieri Vittoria, Resident
Silvia Bastucci, Data Manager
Marianna Introna, Data Manager
Agnese Provenziani, Data Manager
Marianna Ferrara, Data Manager
Alessandra Zambardi, Data Manager
Barbara Conforti, Data Manager
Katia Messana, Data Manager
Viviana Cangiano, Data Manager
Maria Di Santo, Nurse Coordinator
Massimo Zaratti, Nurse Coordinator
Pietro Calabretta, Nurse
Immacolata D'Orsi, Nurse
Giovanni Cortese, Nurse
Roberto Ferro, Nurse
Alessia Mariotti, Nurse
Gigliola Mammana, Nurse
Giuseppe Giambalvo, Nurse
Eleonora Cerasari, Nurse
Emanuela Ciofri, Nurse
Patrizia Minonne, Nurse
Wioletta Faltyn, Nurse
Maria Grazia Cioffi, Nurse
Arianna Cicerone, Nurse
Lorena Scarton, Nurse
Taraborelli Emanuela, Nurse
Anna Maria Biscu, Nurse
Antonella Gagliardo, Nurse
Emanuele Esposito, Nurse
Alessandro Mattia, Nurse
Anna Maria Barberini, Nurse
Ornella Barlone, Nurse
Massimo Colantoni, Nurse
Alessandra Pasqua, Nurse
Giorgia Righetti , Secretariat
Francesca Sabbatini, Secretariat
Valeria Rubino, Secretariat
Massimo Andaloro, Administrative Collaborator

Mission

The Division of Medical Oncology 1 has a long standing commitment in improving the diagnosis detection and treatment of solid cancers. The Division's clinical activity guarantees evidence-based treatments and clinical assistance for cancer patients requiring therapy disease monitoring and follow up. Moreover, the Division has been developing clinical research and new treatment strategies on solid tumors using both new immunotherapeutic agents such as checkpoint inhibitors or targeted agents for different tumors in addition to the classic antineoplastic drugs. The work's strategy is based on a multidisciplinary approach to the clinical aspects so assuring a personalized and integrated approach to the disease in the respect of the patient centrality and quality of life. The medical team is strongly oriented in creating collaborative pathways with national and international working groups and scientific societies and in participation to the strategic aims of the IRE.

Clinical Activity

The Division of Medical Oncology 1 consists in 4 separate units: a) in-patient unit which includes 22 beds dedicated to highly complex diagnostic procedures, oncological treatments and management of severe toxicities; b) out-patient unit dedicated to the first visit of new patients and clinical follow up and oncologic genetic counseling; c) Day Hospital and Ambulatory Chemotherapy Services for

administration of oral and intravenous antineoplastic drugs and supportive cares. d) Phase 1 Unit for early clinical trials.

Clinical activity is supported by weekly divisional meeting in order to share decisions on patients at first observation or critical clinical cases and ameliorate the internal procedures. Physicians of the Medical Oncology 1 are the most actively involved in all the interdisciplinary Disease Management Team (DMT). In each DMT, a group of physicians is dedicated to the treatment and follow up of patients according to national and international guidelines. Team members provide state of the art diagnosis and treatment of patients with solid cancers, and are able to follow the patient by continually updating the database that tracks the patient.

Research Activity

The main research topics of the Division is the study of new drugs (targeted therapies, immunological checkpoint inhibitors, etc) their combinations and/or sequence and new strategies of integrated treatments in almost all solid tumors of the adult population. Some studies are also addressed to the treatment of pediatric bone sarcomas. The Division is committed to conducting national and international clinical trials in collaboration with industries or no-profit cooperative groups. During 2020, 63 clinical studies were ongoing in different tumors, with the enrolment of 526 patients. Field of interest of the Division is also the involvement in projects that investigate and promote patient's quality of life (such as integrated medicine and narrative medicine) in collaboration with patient associations. The clinical research activity of the Division is sustained by five fully trained data manager with expertise in conducting clinical trials in good clinical practice. Special emphasis is moreover given to the collaboration with basic researchers to identify molecular prognostic or predictive biomarkers. This latter activity is shared with the internal laboratories department and with the research branch of other national cancer institutes. The medical division is also involved in the basic research that is carried out within its own laboratory, equipped with research personnel and instruments suitable for cell cultures and molecular diagnostics. The main field of activity is aimed at understanding the mechanisms of signal transduction and phosphorylation of tumor cells. This activity is supported with founds provided by national research organization (AIRC). Most physicians of the Division are involved in scientific boards, guidelines editing groups and in national and international networks.

Medical Oncology 2 Unit

Head: Prof. Federico Cappuzzo, MD

Staff

Antonella Amodio, MD
Maddalena Barba, MD, PhD,
Silvia Carpano, MD
Elisabetta Capomolla, MD
Francesca Conti, MD
Eriseld Krasniqi, MD
Lorenza Landi MD
Marcello Maugeri-Saccà, MD, PhD
Gabriele Minuti MD
Giancarlo Paoletti, MD
Laura Pizzuti, MD
Domenico Sergi, MD
Livia Tosetto, MD
Patrizia Vici, MD,
Stefania Di Paolantonio, Chief nurse
Valeria Colamartino, Chief nurse
Geolina Julita Amora, Nurse
Arianna Bassotti, Nurse
Paolo Bellucci, Nurse
Federica Bertini, Nurse
Viviana Boncristiano, Nurse
Emanuela Di Certo, Nurse
Francesca Gallina, Nurse
Marisia Soares, Nurse
Stefano Bucci, Nurse
Ana Cristina Cadaru, Nurse
Eleonora Peverini, Nurse
Sabrina Pieretti, Nurse
Massimiliano De Vecchis, Nurse
Alessandro Zennaro, Data manager
Anna Maria Edlisca, executive assistant

Mission

While encompassing the overall mission of National Cancer Institute Regina Elena the particular goals of the Medical Oncology 2 Unit (OM2) are to provide the highest quality of care to our patients and to advance the treatment of solid tumors, with special interest on thoracis malignancies, gastrointestinal cancers, head and neck cancers, gynecology and urogenital tract cancers.

Our investigations involve many of the most promising molecularly targeted agents, immunotherapy and combinations of agents currently known. We emphasize rigorous study conduct and impeccable study design, and many of our studies have been developed through cooperative group mechanisms.

The OM2 staff directly responsible for patient care is comprised of 14 physicians, 15 nurses, 4 data managers. Among our physician team, 5 of them are dedicated to thoracic medical oncology patients, with the others who treat other diseases in those respective outpatient clinic areas

Clinical Activity

The clinical activities of OM2 include an inpatient hospital service and outpatient clinics. All patients are evaluated by a specialized team of physicians according to their specific disease. All patients are screened for clinical trials and not eligible cases are candidate for standard medical oncology interventions including chemotherapy, hormone-therapies, target therapies, immunotherapy and/or supportive therapies. All cases are discussed with a multidisciplinary team, according to the specific site of disease.

Clinics: Oncology cases are followed and/or treated in a dedicated Day Hospital or in a specific unit. Outpatient visits are performed in dedicated rooms, according to the type of the disease (thoracic cancers, breast cancer, gastrointestinal cancer, Head&Neck or gynecology cancers, genito-urinary cancer or melanoma. Two additional rooms are dedicated for visits of patients receiving active therapy in our day hospital. This service includes 13 chairs and 4 beds. The inpatient unit includes 22 beds dedicated to toxicity management, staging and therapy of complex cases, clinical trials.

Research Activity

In 2020, our research pipeline focused mainly on genomic and clinical biomarkers of effectiveness and toxicity of anticancer treatments, with the aim of integrating clinical decisions for patients with solid tumors. All scientific activities are based on the active collaboration with other units (clinical, preclinical, diagnostic) and with other national and international cancer centers.

Although our unit for years was involved almost exclusively in breast cancer research, since September 2020 the interest is focused on thoracic malignancies and in phase I trials.

In lung cancer the Unit is now coordinating several national and international studies with immunotherapy or target therapies, in patients with non-small-cell lung cancer (NSCLC) or in small-cell lung cancer (SCLC). In all studies there is a relevant translational activity aiming at identifying molecular mechanisms involved in drug sensitivity or resistance. In December 2020 we started an international phase II trial comparing the best Epidermal Growth Factor Receptor (EGFR) Tyrosine Kinase Inhibitor sequencing in EGFR mutant NSCLC (CAPLAND trial). Several other trials will start in 2021 both industry sponsored or Investigator Initiated Trials. In breast cancer our Unit continued its research activity by coordinating the following multicentric studies:

1. In the neo/adjuvant setting: Hippo SAB, TRISKELE, NeoTAZ, NeoCarbo, PHOBOS and a study of prognostic relevance of DNA Damage biomarkers in elderly patients undergoing neoadjuvant hormone therapy.

2. In the advanced setting: the STEPP trial, focused on the therapeutic algorithm of HER2+ Bca, was awarded by the Ministry of Health; moreover, INDACO, PALBOSS , REPER, the TETRIS trial (under review), a retrospective study on the prognostic role of hormone receptor expression in HER2+ Bca and the SePher study, coordinated together with a preclinical department (under review); we also set up the PANHER, a multicenter retrospective study to investigate the performance of available treatments for metastatic HER2+ Bca patients in recent years.

Furthermore, we actively adhered with a non-coordinating role to the following trials: NATALEE, HERMIONE 8, HERMIONE 9, DEDiCa, Neogene, VIP, a retrospective study on Trastuzumab-related cardiotoxicity, SEQUERPLUS, VasMUoss, MARIO, POSITIVE, BioItaLEE, VICTOR3, VICTOR6 COMPLEEMENT-1, IMPASSION 131, EVA, ECHO, BRIDE, TiLT, GIM16-FEVEX, HERBA, ESEMPiO, eve-exe study.

Concerning solid tumors other than Bca, we also adhered to a phase I dose escalation and cohort expansion trial of an anti-PD-1 agent in advanced solid tumors. We also focused on the HIPPO pathway within the HIERARCHY study, a spontaneous multicentric multi-tumor study coordinated by the OM2.

For gynecological tumors, we join several MITO projects, the in-ACTO study and participate to multicenter TRAMANT-01 trial; furthermore, our researches on gynecologic cancer yielded further publications. The study of miR signature in relapsed, high-grade serous ovarian cancer is nearing completion and the final manuscript will be produced shortly.

Our trial on DNA damage and HIPPO biomarkers in locally advanced/metastatic gastric cancer, awarded by the Ministry of Health, is ongoing.

In 2020 a total of 37 paper have been published. A full list is included in the present report.

Anesthesia, Intensive Care and Reanimation Unit

Head: Dr. Ester Forastiere, MD

Staff

Maria Sofra MD,
Piera Di Angelo MD,
Francesca Principi MD,
Paolo Moricca MD,
Luana Fabrizi MD,
Luca Colantonio MD,
Maria Elena Marcelli MD,
Cecilia Coccia MD,
Federico Pierconti MD,
Alessandra Costantino MD,
Ilaria Monteferrante MD,
Claudia Frigieri MD,
Francesca Romana Giordano MD,
Giulia Torregiani MD,
Emanuela Venti MD,
Lorella Pelagalli MD,
Felice Centulio MD,
Antonio Calamaro MD,
Francesco Rendina MD,
Carmela Stigliano MD,
Claudia Claroni MD,
Gabriele Tola MD,
Carmela Bonarrigo MD,
Lamberto Laurenzi MD,
Giorgia Fedele MD,
Monique Alonzi MD,
Giulia Maria Vitelli MD,
Marco Prologo MD,
Valeria Giorgerini MD,
Federica Sardellitti MD

Mission

Perioperative evaluation of surgical patients. Management of intraoperative anesthesiology. Perioperative assistance to patients undergoing surgery. Intensive care of medical and surgical oncologic patients. Non operating room anesthesia (NORA). Pain management of oncologic patients. Management of in-hospital emergency.

Clinical Activity

Perioperative Medicine: management of perioperative patients for the following surgeries: thoracic surgery, urology, gynecology, plastic and reconstructive surgery, breast surgery, dermatology, neurosurgery, major orthopedic surgery, ORL surgery, digestive surgery, hepatobiliopancreatic surgery. Anesthesiologists participate in the Disease management teams of the various surgical teams.

Intensive care of surgical, oncologic and hematological patients.

NORA: sedation of patients in invasive procedures: interventional radiology, bronchoscopy, gastrocolonoscopy, CPRE, EBUS.

Pain therapy clinic: positioning of vascular accesses, PICC and PORT, treatment of oncologic pain with invasive and non invasive procedures.

Research Activity

Translational clinical research protocols, approved by the Ethics Committee with a retrospective, prospective, observational, randomized prospective structure. Collaboration with multi center studies.

Current Studies

Prospective multicentre international observational study of postoperative vasopressor use (SQUEEZE)

A multicentre international cohort study - Epidemiology and determinants of outcomes of hospital acquired blood stream infections in the intensive care – (Eurobact 2)

Decurarization After Thoracic Anesthesia – Reversal neuromuscolar block double blind prospective randomized multicenter study in thoracic surgery.

Intraoperative esophageal pressure monitoring in laparoscopic surgery.

International observational study to understand the impact and best practices of airway management in critically ill patients (INTUBE)

Preoperative Anaemia Prevalence in Surgical Patients – A prospective, international, multicentre observational study (ALICE)

ACCessi venosi centrali in pazienti cronici E fragili: managemeNT e Ottimizzazione dei percorsi (ACCENTO)

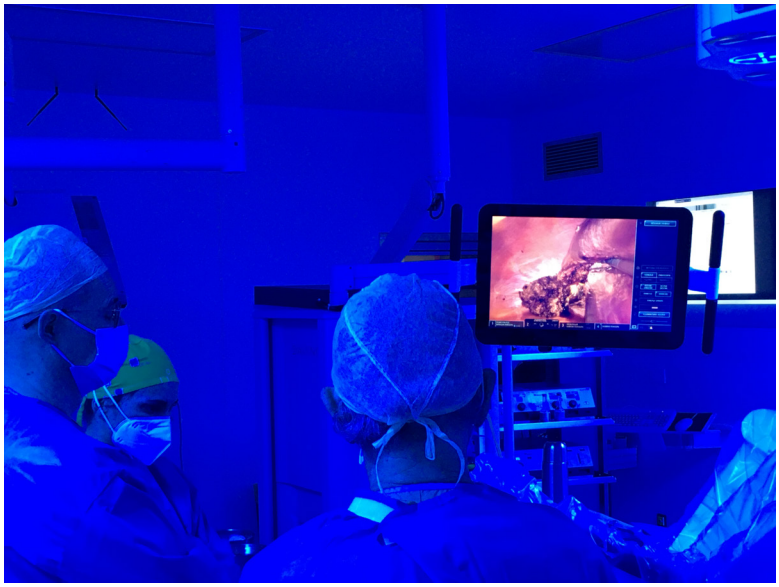
Intraoperative Electrical Impedance Tomography in Obese Patients Undergoing Robotic Assisted Radical Prostatectomy.

Hepato Biliary Pancreatic Surgery Unit

Head: Prof. Gian Luca Grazi, MD, PhD

Staff

Marco D'Annibale, MD
Giovanna Grazioli, Nurse Coordinator
Andrea Oddi,MD
Andrea Scarinci, MD
Pasquale Perri, MD
Maria Vittoria Carati, MD
Renato Oliva, MD



Mission

To increase the knowledge for hepato-biliary-pancreatic diseases surgically treatable. To treat, to propose innovation in the evaluation and in the cure and to study neoplastic diseases of the liver, pancreas and biliary tree. To evaluate the application of newly proposed surgical techniques, such as laparoscopy and robotics. To improve the postoperative approach of the patients with specific protocols of enhanced recovery after surgery

To offer surgical treatment for neoplastic colorectal diseases in a multidisciplinary setting. To define specific paths, from first suspected diagnosis to the appropriate treatment. To establish a stable network for referral and management of patients with hepatobiliary, pancreatic and colorectal tumors, in the view of the Regina Elena National Cancer Institute acting as a tertiary referring center for patients carrying such neoplasms

Clinical Activity

This is a General Surgery Unit with the main task of treating diseases of the liver, pancreas and o biliary tract. The vast majority of these surgical procedures are performed for malignant diseases, but also complex operations needed for benign diseases are carried out. Liver metastases from

colorectal cancer are the condition for which the larger portion of the surgical procedures are performed. The second most frequent disease is hepatocellular carcinoma, which can arise in cirrhotic and non-cirrhotic patients. The remaining portion of liver resection are performed for cholangiocarcinomas, both in intrahepatic and in perihilar locations. The Unit is among the four of the Lazio Region Health System which constantly perform more than 50 surgical procedures for primary liver tumor each year.

There are a consistent number of procedures performed for pancreatic cancers, either for pancreas head or tail. Furthermore, the unit provides treatment for patients with colorectal neoplastic diseases. A multimodal approach for rectal cancers is usually offered to the patients.

A mini-invasive surgical program based on the laparoscopic and on the robotic techniques is fully active for hepatobiliary, pancreatic and colorectal procedures.

The average value of the DRG's produced by the Unit is 2.60.

Research Activity

The Units collaborates with the following national or international registries:

LiverGroup.org

a collaborative of international liver surgeons to study the outcomes of liver surgery

Euro-Cholangio-Net

The European Cholangiocarcinoma Network

I Go MILS

prospective national database of mini-invasive liver resections

IGOMIPS

Italian registry of mini-invasive pancreatic surgery

HeRCOLEStudy Group

Hepatocarcinoma Recurrence on the Liver Study Group

A specific protocol that applied radiomics to surgery of liver metastases has started within the IRCCS.

Gynecologic Oncology and Oncofertility Center Unit

Head: Dr. Enrico Vizza, MD, PhD

Staff

Ermelinda Baiocco, MD
Valentina Bruno, MD
Benito Chiofalo, MD
Giuseppe Cutillo, MD
Rosanna Mancari, MD
Emanuela Mancini, MD
Cristina Vincenzoni, MD
Giuseppe Vocaturo, MD
Marcello Iacobelli
Anna Maria Lobascio
Livia Ronchetti
Rossella Leonardi
Giancarlo Brugnoletti
Fabiana Cipriani
Emilia Gentili
Laura Filip
Valeria Fiumara
Francesca Orlando
Francesca Parrini
Sabrina Santini
Flavia Gallo
Cinzia Cicerone
Eros Floridi
Aurora De Leo
Claudia Di Frischia
Sonia Girasole
Marianna La Vaccara
Emiliana Marinucci
Giuliana Panico
Enrica Ruffo
Stefania Guadagnini
Francesco Malci

Mission

To improve even more the standard of care for women with confirmed or suspected tumors and pre-cancerous lesions of the genital tract and for young women with cancer that desire to preserve their fertility. To prevent the incidence of gynecologic tumors in high and low risk patients. To preserve fertility in young women with cancer. To reduce even more the surgical invasiveness in gynecologic oncology. To provide high-quality standard of research in the field of gynecological oncology and fertility preservation strategies for young oncologic patients.

Clinical Activity

The Division has 18 in-patient beds, ten of which dedicated to the week-surgery activities, four to the day-surgery and four for the long-stay. We have available 3 full-day surgical rooms every week and one morning for day-surgery procedures. During 2020 more than 880 surgical operations were performed: 300 in day-surgery setting and 581 (66%) for suspect or histological confirmed tumor of the female reproductive tract. More than 90% of procedures were performed with a minimally invasive technique (laparoscopic or robotic). Some laparoscopic procedures were performed with percutaneous instruments, especially for adnexectomy and for ovarian tissue explant. All oncological cases and all adjuvants treatments were discussed in a weekly multidisciplinary meeting that include surgeons, medical oncologists, radiotherapists, pathologists and radiologists to identify the correct tailored treatment program. State-of-the-art surgery, including ICG (indocyanine green) guided surgery, minimally invasive approaches (robotic and laparoscopic surgery) and fertility-preserving surgery is offered to our patients. The Division also includes an outpatient clinic dedicated to the diagnosis and staging of cancer (hysteroscopy, 2D & 3D ultrasound and colposcopy are performed), to the care of young patients with cancer for fertility preservation purposes and to the treatment of genital cancer precursor with a multidisciplinary HPV unit.

Research Activity

The main fields of research include: 1) minimally invasive surgery (MIS) for the treatment of gynecological tumors, 2) impact of COVID-19 in gynecologic surgery, 3) immunologic pathway of endometrial tumors, 4) ovarian tissue cryopreservation (bank of ovarian tissue), 5) diagnosis and treatment of endometrial diseases with hysteroscopy. We gave our contribution to an European study (SUCCOR) comparing MIS and laparotomy for the treatment of cervical cancer, with the aim of clarifying a debated field in gynecologic oncoloy. The first international reccomendation for gynecologic surgery during the COVID-19 pandemic were produced by our group. Sentinel-node biopsy is commonly used in our division for endometrial and cervical cancer, regarding ovarian cancer a big multicenter trial is ongoing. Several studies have been published in the field of hysteroscopy during 2020. A study aimed to understand immune escape mechanisms in endometrial adenocarcinomas has been published and another in the same field is ready for pubblication. Thanks to the award of a ministerial grant, a big project on immunology in endometrial cancer will start soon. Research of the bank of ovarian tissue is mainly focused on: 1) in vitro maturation of immature antral oocytes retrieved from the ovarian cortex, 2) validation of the procedures of freezing and thawing of the ovarian tissue, 3) extraction of genomic DNA from cancer patients for mutational analysis.

Orthopaedics Unit

Head: Prof. Roberto Biagini, MD

Staff

Leonardo Favale
Nicola Salducca
Carmine Zoccali (PhD)
Barbara Rossi
Jacopo Baldi
Dario Attala
Alessandro Grò
Beatrice Calabrese
Wioletta Faltyn
Elisa Checcucci
Giovanni Meogrossi
Grazia Amato
Paolo Asquini
Daniele Cacciarelli
Fabio Conti
Antonella Cutini
Carolina Destito
Monica Barrucci
Sabrina Ganzenua
Stefano Landi
Alessia Milotti
Casula Alex
De Martino Stefania

Mission

The aim of the Unit is to diagnose, management and care of primary and secondary tumors of bone and soft tissues in pediatric and adult patients and to perform translational and clinical research in this field. The Unit performs every kind of orthopedic oncological operation for primitive and metastatic muscular-skeletal tumors in adults and pediatric patients.

During 2020, the Unit has perfected computer assisted navigated techniques and reconstruction with titanium 3D-printing prostheses after bone tumor removal.

Clinical Activity

The Oncological Orthopedics Unit of the Regina Elena Institute offers cutting-edge solutions for all primary or secondary neoplasms of bone and soft tissues, involving the Musculoskeletal System in pediatric and adult age. As intended as Sarcoma Unit in collaboration with the newborn Oncological IRE UOSD Sarcomas and Rare Tumors Unit, we brag about the membership of National Network of Rare Cancers and European Rare Cancer Network EURACAN; moreover, the Orthopaedic Unit is a Center of Excellence for Osteoncology and adheres to national and international guidelines from AIOM, ISG (Italian Sarcoma Group), ESMO and SIOT (National Society of Orthopeadic and Traumatology). Young pediatric patients with primary malignant neoplasms are treated at the Oncology Unit of the Bambino Gesù Children's Hospital in Rome. In selected cases, we collaborate with UOS of Hand Surgery of Ospedale Israelitico of Rome for reconstructive surgery hand surgery and microsurgery. Patients with bone metastases are managed in collaboration with IRE Medical Oncology 2 Unit. Besides the medical and nursing staff above-described, 2 Residents from Umberto I Hospital "La Sapienza" University take turns every 4 months to inward and surgical activities. Patients who need surgery for primary or secondary tumors of the bone and soft tissue are hosted in the ward (13 regular beds). The ward has a fully furnished (and painted) pediatric room with telematic-teaching service (available for long-term patients), videogames, books and comics. Five rooms out of seven are decorated with the intent of improving the patient's hospitalization experience. Surgical activity is performed on 12h-long operating theatre / week, every month, in one of the eight operating room of the operating block. The orthopedic staff is always available on call in order to assure emergency room h24. The number of surgical interventions during 2020 accounts overall 231 procedures and the Unit counted a total of 247 inward patients.

Personalized reconstruction and osteosynthesis are performed as needed: megaprosthesis, allograft prosthesis composite for massive skeletal defects; carbon fiber-reinforced nails and

plates; bone and tendineous allograft directly from IRE Tissue Bank. Functional results and nature of complications are reported and monitored for all types of cancer surgery on personalized digital medical records.

Biopsies for bony or soft tissue lesions are performed, once a week, in a dedicated small operating room.

In 2020 a total of 174 surgical biopsies have been performed.

There are a total of three specialistic orthopedic outpatient clinics par week: on Monday for benign and low-grade malignant tumors; on Wednesday for high grade sarcomas (multidisciplinary clinic in collaboration with Oncologist and Psychologist); on Friday for metastatic disease involving muskuloskeletal system. On the first Friday of every month there is a dedicated ultraspecialistic outpatient clinic for exostoses and cartilaginous tumors (benign to low-grade malignant) and other rare osteometabolic disorders. In 2020 a total number of 894 visits were performed for high grade sarcomas (124 first visits); 631 for metastatic disease (127 first visits).

Once a week, on Wednesday, there is dedicated clinic for post-surgical wound care and withdrawal of biopsy reports. Every Monday the regenerative medicine outpatient clinic is run by the Musculoskeletal Tissue Bank medical staff, performing periodic infiltration therapy for a total of 159 procedures for overall 38 patients.

Twice a week takes place the Disease Management Team (DMT) meeting for the multidisciplinar discussion of clinical cases. A Biobank collects biological samples from patients with musculoskeletal tumors, visceral sarcomas and muscular-skeletal metastasis.

In 2020 in particular two major issues have characterized our clinical activity: first, COVID-19 pandemic has obviously conditioned our work organization, so all the medical and nursing staff soon acted a pre- planned dedicated pathway for inward patients and outpatient, which was very successful and object of a scientific publication; second during this year a special attention has been dedicated as pilot- surgical unit to intranet digitization of health records and it is ongoing a trial for clinical use inward of Tabula Clinica Web App.

Research Activity

SARCOMA TROBS Trabectedin in Soft Tissue Sarcomas a retrospective analysis.

Observational study: ISG-STS 10.01 Localized high-risk soft tissue sarcomas of the extremities and trunk wall in adults: an integrating approach comprising standard vs histotype-tailored neoadjuvant Chemotherapy.

Phase III: closed at the moment jun-2016 2 19 ISG-OS-02 Multicentric, prospective, randomized clinical trial in patients with recurrence of osteosarcoma.

Phase III: open 5 -15 ISG/AIEOP EW1 Phase III trial on the efficacy of dose intensification in patients with non-metastatic Ewing Sarcoma.

Phase III : open 2 -8 RECURR International Randomised controlled trial of Chemotherapy for the treatment of recurrent and primary refractory Ewing Sarcoma Phase II/III.

Sacral Chordoma – IT – IREStudio randomizzato e osservazionale sulla CHIRURGIA in confronto alla RADIOTERAPIA nella malattia primitiva localizzata (SACRO).

Naobiotix n. 301: Studio multicentrico, randomizzato, in aperto, di fase II/III per confrontare l'efficacia di NBTXR3, impiantato con iniezione intratumorale e ttivo mediante radioterapia, risposto alla sola radioterapia, in pazienti affetti da Sarcoma della parete dei tessuti molli degli arti e del tronco, localmente avanzato.

EORTC-1553-SPECTA: invitation to join SPECTA for rare cancers (in collaboration with EURACAN/ROCHE)

SPECTA: Screening Cancer Patients for Efficient Clinical Trial Access

Breast Surgery Unit

Head: Dr. Claudio Botti, MD

Staff

Franco Graziano, MD
Loredana Piarulli, MD
Sonia Cappelli, MD
Fabio Pelle, MD
Fortunata Bonfà, Head nurse
Francesco Caldarola, Nurse
Mariapaola Decrestina, Nurse
Andrea Esposito, Nurse
Alessio Garga, Nurse
Giampiero Giansanti, Nurse
Monica Iorio, Nurse
Zacharie Mushengezi, Nurse
Silvia Ronchi, Nurse
Massimo Colasante, Health care
Giuseppe Crescenzi, Health care

Mission

To take care of patients with tumors of the breast and melanomas providing high-quality, patient oriented treatments according to the multidisciplinary evaluations (disease management team, DMT) aimed to improve survival and quality of life.

Clinical Activity

The activity is divided into: multidisciplinary evaluation at the breast unit and other pathology oriented DMT, outpatient surgery, day surgery, hospitalization.

Type of surgery performed:

- Conservative and radical surgery of breast tumors with particular reference to oncoplastic surgery (volume displacement techniques, volume replacement and innovative propeller flaps), choice of personalized and innovative techniques of immediate reconstruction after nipple sparing mastectomy in the context of the multidisciplinary treatments (chemo, immunologic and radiation therapies).
- Complex demolitive surgery in locoregionally recurrent cases.
- In selected cases intraoperative radiotherapy (IORT) is performed.
- Locoregional treatment of primitive and recurrent melanoma (wide excision, sentinel lymph node biopsy, radical regional lymphadenectomy, hyperthermic-antiblastic perfusion in selected cases, electrochemotherapy).

Research Activity

Main research lines:

- Identification of signature responsiveness to innovative drugs

- Identification of new imaging techniques in senology (CESM)
- Indocyanine green as a unique method for sentinel lymph node biopsy after neoadjuvant chemotherapy.
- Innovative technical application of conservative volume replacement oncoplasty by fascio--adipose propeller flaps set up by microsurgical anatomical dissection
- Development of personalized algorithm of breast reconstruction after mastectomy (optimize do not compromise)
- Precision surgery approach to generate living biobank (organoid) from primary breast cancer, metastases, adjacent tissues and benign tumors in order to identify innovative molecular vulnerabilities of metastatic disease and markers of early tumor progression

Collaborative studies ongoing:

- Prospective validation of TAZ score as a pathological complete response biomarker in patients with luminal B / HER2 positive breast cancer treated with trastuzumab based neo adjuvant therapy TRISKELE Trial
- Impact of expression of Hippo pathway components in patients with breast cancer treated or candidate for neoadjuvant chemotherapy
- Efficacy and Tolerability of Cario Patient Neopardive Chemotherapy in Patients with Triple Negative Breast Cancer: Multicenter Observational Study. NeoCarbo study
- Predictidicve / Prognostic Biomarkers IdentificaMon in Triple Negative Breast Cancer. NeoTAZ study
- TAZ as a prognostic biomarker in patients with early breast cancer. PHOBOS Trial
- Atorvastatin vs Observation in Patients with Initial Breast Cancer with High Ki-67 and Positivity for TAZ: randomized, non-comparative Phase II pre-surgical study
- Neo-Adjuvant Chemotherapy in Patients with Breast Cancer: Retrospective Evaluation of Effectiveness and Tolerability
- Analysis of the predictive value of efficacy of anti-neoplastic therapies based on the evaluation of molecular pathways associated with tumor stem cells: multi-setting and multi-tumor study. HIERARCHY Study
- Accuracy Diagnostics of Dual-Energy Digital Mammography (CESM) and Magnetic Resonance Imaging 3 Tesla Compared to Digital Mammography (FFDM) plus Ecography (US) in Detection and Characterization of Mammary Lesions: Results from an OpenStudy Pilot, monocentric, prospective Molecular mechanism of quadruplex targeted drugs: towards clinical candidate selection
- MetORg: a living biobank of human breast cancer metastases

Otolaryngology Head and Neck Surgery Unit

Head: Dr. Raul Pellini, MD

Staff

Valentina Manciocco, MD, PhD
Barbara Pichi, MD
Paolo Marchesi, MD
Jacopo Zocchi, MD
Francesco Mazzola, MD Specialist LP
Gerardo Petruzzi, MD, Specialist LP
Silvia Moretto, MD, Researcher
Flaminia Campo MD, Researcher
Giuseppe Oliveto MD, Resident
Matteo Campa MD, Resident
Giulia Bianchi MD, Resident
Teodosio de Bonis MD, Resident
Valentina Rosati MD Resident
Antonio Martano, Audiometrist
Sonia Gambardella, Audiometrist
Alessandra Masiello, Speech Therapist
Antonio Valerio, Nurse Coordinator
Alba Ara Pina, Nurse
Bruna Boldrini, Nurse
Serena Cucchiella, Nurse
Anna Ferrante, Nurse
Fernando Golino, Nurse
Marina Macis, Nurse
Iolanda Mantuano, Nurse
Francesco Mautone, Nurse
Debora Cacciato, Nurse Case Manager

Mission

We are committed to maintaining our status as leader in the discovery, innovation and implementation of the best practices, research and clinical care in otolaryngology and head & neck surgery.

We contribute to improve the health of individuals and populations through innovation and excellence in otolaryngology and head & neck surgical practice and research. Our program has a strong multidisciplinary translational approach focused on different aspects of Head and Neck Oncology.

Clinical Activity

Ear, nose and throat and maxillofacial oncological surgery. Treating of fairly common head and neck cancers to more complicated and difficult cases. Highly specialized surgical protocols and/or procedures are performed by the staff and every decision regarding clinical cases is submitted to the Head and Neck Disease Management Team, which includes specialists in surgery, radiation oncology, medical oncology, endocrinology, radiology, pathology, speech therapy, plastic and reconstructive surgery, dental and maxillofacial prosthetics, nutrition, and pain management. The group meets weekly and works together to meet their patients' diverse needs. The Unit of Otolaryngology Head and Neck Surgery provides a complete spectrum of head and neck services including Endocrine, Microvascular surgery and minimally invasive approaches or transoral robotics surgery.

Research Activity

1. Human papillomavirus involvement in Head and Neck cancer.
2. Feasibility and efficacy of electrochemotherapy in Head Neck Cancer .
3. mRNA expression profiling in Head Neck Cancer.
4. Immunotherapy in Head and neck cancer.

Thoracic Surgery Unit

Head: Prof. Francesco Facciolo, MD

Staff

Sandro Carlini, MD
Edoardo Mercadante, MD
Gabriele Alessandrini, MD
Virna Cerasoli, MD
Felicita Corzani, MD
Daniele Forcella, MD
Enrico Melis, MD
Filippo Tommaso Gallina, MD
Luigi Mosillo, MD

Nicoletta De Bello, Nurse
Adriana Ciacci, Case Manager
Simona Molinaro, Nurse
Antonio Ricciuti, Nurse
Alessio Calabretta, Nurse
Valeria Simonetti, Nurse
Vincenzo Lodico, Nurse
Silvia Fiorillo, Nurse
Chiara Spadavecchia, Nurse
Rossella Amato, Nurse
Raffaele Tomasone, Nurse

Mission

Surgical management of primary and secondary malignancies of the thorax (lung, mediastinum, pleura, chest wall, thoracic inlet, esophagus, trachea) with radical/ palliative / diagnostic intent.

Clinical Activity

Mainly focused on Locally Advanced Lung Cancer, Malignant Pleural Mesothelioma, Thymic Malignancies, Primary Tumors of the Chest Wall. Routinary employment of minimally-invasive techniques for major operations - Robot-Assisted Thoracoscopic Surgery (RATS); Video-Assisted Thoracoscopic Surgery (VATS) - and minimally-invasive diagnostic techniques - Fiber Optic Bronchoscopy, EUS and EBUS. Implementation of protocols for early extubation after surgery, post-operative fast-track rehab, management of post-operative pain. Active cooperation with basic science departments for translational research.

Research Activity

Coordinator center of two multicentric studies of new prognostic factors of early stage NSCLC and sarcoma pulmonary metastases. Contributor center of a prospective multicentric study about the prognostic impact o the kind of lymphadenectomy and lymph node characteristics on node positive patients underwent anatomical lung resection. Contributor center of a prospective multicentric study about the robotic approach in the treatment of locally advanced NSCLC after induction therapy. Collection and banking of tumoral and healthy tissue from lung cancers, thymomas, mesotheliomas for study of tumor's microenvironment and growth factors, cancer stem cells isolation and colture, identification of genomic signatures (miRNAs) and molecular prognostic factors; collection and banking of blood / serum / plasma samples from patients with malignancies of lung, thymus, pleura as circulating counterparts of tissutal samples for identification of peripheral diagnostic I prognostic markers. Active collaboration with ITMIG

Plastic & Reconstructive Surgery Unit

Head: Prof. Roy De Vita, MD

Staff

Maurizio Costantini, MD Assistants
Stefano Feliciano, MD Assistants
Pierpaolo Gullo, MD Assistants
Massimo Panimolle, MD Assistants
Marcello Pozzi, MD Assistants
Antonio Varanese MD Assistants
Veronica Vietti Michelina MD Assistants
Fortunata Bonfà, Nurse, Head

Mission

Plastic and Reconstructive Surgery is very important in the general management of oncologic patients of the Regina Elena National Cancer Institute and plays a seminal role in the therapeutic course of patients affected with breast cancer.

Our Unit is actively involved in the definition and use of innovative therapeutic protocols. In particular, the expertise obtained our Unit is cooperating with most representative national structures.

Clinical Activity

Breast reconstruction

Biological Mesh in implant-based breast reconstruction surgery

Microsurgery Breast recontructions

Perforator flap recontructions

The Plastic Surgery Unit deals with all types of skin cancers (epitheliomas, melanomas, other skin cancers locations) that focus especially on craniofacial locations that require complex reconstructions and together with the Dermatology Unit are dedicated on preventing skin cancer diseases.

In collaboration with the General and Orthopedic Surgery Unit, the activities are aimed against sarcomas of the limbs through the morpho-functional microsurgical reconstruction of the structures involved.

Extravasation of anticancer drugs m Oncology: Prevention, treatment and outcomes. The incidence of extravasation of antineoplastic drugs reported in the literature, ranges from3'X, to 6%. This percentage, however, is increasing for introducing new chemotherapeutic drugs such as Vinorelvina and Taxanes. While these drugs certainly represent an important therapeutic alternative in the treatment of solid tumors, particularly breast cancer, local toxicity levels are higher in these drugs than those that preceded them.

Urology Unit

Head: Dr. Simone Giuseppe, MD, PhD

Staff

Luciano Lamanna MD
Vincenzo Pompeo MD
Maria Consiglia Ferriero MD, PhD
Umberto Anceschi MD
Gabriele Tuderti MD
Aldo Brassetti MD
Leonardo Misuraca MD
Manuela Costantini MD, PhD
Alfredo Bove, MD
Riccardo Mastroianni, MD
Salvatore Guaglianone MD
Ashanti Zampa, Data Manager

Mission

Providing the highest quality of medical and surgical care to uro-oncology patients. Developing and standardizing complex surgical procedures in uro-oncology; expanding indications of minimally invasive and robotic procedures; developing of clinical and translational research in the field of prostate cancer, kidney cancer and bladder cancer.

Clinical Activity

The urological clinical activity mainly concerns minimally invasive surgery, especially robot-assisted and laparoscopic procedures. We have particularly expanded our expertise and gained experience in robotic radical cystectomy with totally intracorporeal reconstruction of orthotopic and etherotopic diversions, robot assisted radical nephrectomy with inferior vena cava tumor thrombectomy and in minimally invasive off clamp partial nephrectomy. All these complex surgical procedures are today a standard of care in our Institution.

Research Activity

Clinical research on new minimally invasive surgical techniques, imaging advances in early cancer detection or imaging-guided surgery and oncologic outcomes after surgical treatments are our main research objectives. Translational research on molecular biomarkers, genetic and microenvironment tumor profiling, stem cells investigation, together with new precision medicine diagnostic and prognostic not invasive tools in urological malignancies as liquid biopsy or E-nose volatilome profiling are additional research activities that our Unit carries out in cooperation with dedicated departments of the Regina Elena National Cancer Institute and other prestigious national and international Institutions. The Urology Unit has been national site coordinator of observational studies and it is involved in multiple clinical trials on prostate cancer treatments, renal cancer and urothelial cancer.

Haematology and Stem Cell Transplantation Unit

Head: Dr. Andrea Mengarelli, MD

Staff

Svitlana Gumenyuk MD,
Francesco Marchesi MD,
Francesca Palombi MD,
Francesco Pisani MD,
Daniela Renzi MD,
Atelda Romano MD,
Antonio Spadea MD
Caterina Viggiani Nurse,
Ambra Albertini Nurse,
Anna Attico Nurse,
Giuseppina Cafarella Nurse,
Roberta Capobianco Nurse,
Silvia Di Fraia Nurse,
Katia Di Prospero Nurse,
Graziella De Luca Nurse,
Gianluca Falzone Nurse,
Federica Izzo Nurse,
Andrea Longo Nurse,
Marco Prete Nurse,
Anna Petrucci Nurse,
Fabrizio Pochettino Nurse,
Romina Riccio Nurse,
Simona Sgromo Nurse,
Raffaele Speranza Nurse,
Elena Papa Clinical Research Coordinator and Quality Manager
Chiara Falcicchio Psychologist

Mission

Hematology and Transplant Unit identifies its own reason for existence with the provision of care services and assistance of patients with hematologic malignancies, according to the policy and mission of Regina Elena National Cancer Institute of Rome. In this framework, through scientific research, the development of medical knowledge and collaboration with other organizations at national and international level, Unit resolved to be a center of excellence for the diagnosis and treatment of such pathologies.

Clinical Activity

Hematology and Transplant Unit is specialized in the evaluation, treatment and care of patients with lymphoma, leukemia, multiple myeloma, myelodysplastic syndrome and myeloproliferative disorder. Although chemotherapy remains an integral component of the treatment for most hematologic malignancies, the development of disease-specific or targeted therapeutics or biomarkers represents the research goal of our Unit investigators.

Treatments are delivered according to National and International clinical trials coordinated by cooperative groups (like GIMEMA, FIL, EORTC, IELSG) involved in the treatment of several onco-hematological diseases. For patients outside clinical trials, treatments are delivered according to Guide-Lines proposed by the most important Italian (SIE-SIES-GITMO) and International (ESMO-ELN-NCCN) hematologic clinical societies. Moreover, in order to better standardize the diagnostic and therapeutic algorithms for patients outside clinical trials, in 2019 five PDTA (Percorsi Diagnostici Terapeutici Assistenziali Aziendali) were updated by the Institute for the following malignancies: acute myeloid leukemia, chronic myeloid leukemia, follicular lymphoma, multiple myeloma and diffuse large B cell lymphoma.

Stem cell transplantation often is indicated for the treatment of hematologic malignancies. U.O.S.D. Ematologia e Trapianti is one of the 6 Institutions located in Rome who belongs to Rome Transplant Network (RTN), a Metropolitan Hematopoietic Stem Cell Transplant Program for adult patients established as a cooperative network. RTN is an innovative entity, which follows rules and standards established by The Joint Accreditation Committee ISCT-EBMT (JACIE) accreditation

program. In June 2013, Policlinico "Tor Vergata" University Hospital, Regina Elena National Cancer Institute and Campus Biomedico University Hospital have been found to meet the standards of the JACIE for Autologous & Allogeneic Transplantation in Adult Patients, as certificated on 21.01.2014; the renewal of certification took place on 18.01.2021.

In 2020 RTN registered 181 Transplants (56 allogeneic and 125 autologous), 31 of them performed in our Unit.

The objectives of the RTN are: 1) to standardize transplants procedures; 2) to improve quality of transplant care; 3) to extend the potential of transplant activity over the metropolitan area; 4) to share expertise and professional education among healthcare providers; 5) to promote excellence of single transplant Centres; 6) to rationalize cost-management of public health.

Research Activities

The effort of Hematology and Transplant Unit was aimed at carrying out clinical trials of primary relevance in different hematological malignancies working in cooperation with other hematological institutions. In particular, our Unit is a member of the following cooperative group:

- Gruppo Italiano Malattie EMatologiche dell'Adulto (GIMEMA)
- European Organisation for Research and Treatment of Cancer (EORTC)
- Fondazione Italiana Linfomi (FIL)
- International Extranodal Lymphoma Study Group (IELSG)
- Gruppo Romano Mielodisplasie (GROM)
- Gruppo Laziale Sindromi Mieloproliferative Croniche Ph1 neg.
- Sorveglianza Epidemiologica Infezioni Fungine in Emopatie Maligne (SEIFEM)
- Dutch-Belgian Cooperative Trial Group for Hematology Oncology (HOVON)
- Gruppo Italiano Trapianto Midollo Osseo (GITMO).

Circulating and tissue microRNAs in Diffuse Large B-Cell Lymphoma (DLBCL): preliminary data suggest that high expression level of serum miR-22 in DLBCL at diagnosis is independently associated with a worse clinical outcome (Journal of Experimental & Clinical Cancer Research 2018). These data have been recently confirmed in a validation patient cohort. Moreover, miR-22 plays a role as predictor of response to R-CHOP in these patients. To better understand the molecular basis of this clinical observation, we are studying miR22 in DLBCL cell lines. Our data show that a high extracellular/intracellular miR-22 ratio is significantly correlated to R-CHOP resistance in six different DLBCL cell lines (manuscript in preparation). In addition, the transfection of miR-22 mimic into these cell lines significantly affects their proliferation. To ensure a more reliable mirror of the complexity of the disease, we have performed a global expression profiling of circulating miRNAs in serum samples collected at diagnosis from a training cohort of responsive to R-CHOP versus primary refractory DLBCL patients. Our analysis shows 9 serum miRNAs differentially expressed ($p<0.05$) according to treatment response. Moreover, ROC curve analysis, shows an area under the curve >0.7 ($p<0.05$) demonstrating a predictive accuracy of the identified miRNA signature. These data suggest the possibility to early identify the chemo-resistant patients using this miRNA signature, with immediate consequence in therapeutic approach and pathogenesis understanding to these high-risk patients.

Transcriptional and epigenetic landscape in Multiple Myeloma (MM): the aim of this project is to identify the transcriptional and epigenetic mechanisms responsible for the resistance of MM patients treated with first-line chemotherapy schemes by characterizing the transcriptome in order to quantify neoplastic cells that have the same gene/epigenetic profile as the treatment-resistant cell population. A prospective multicenter clinical study is underway, recently approved by the Ethics Committee of our Institute, in collaboration with the Hematology Unit of the Tor Vergata University and Campus Bio-Medico University of Rome. The ultimate goal of this project is to be able to understand the epigenetic mechanisms underlying resistance to treatments for multiple myeloma and to be able to personalize the therapy based on the genomic background of the disease.

Biofilm in hematologic malignancies patients with bloodstream infection (BSI): Preliminary data on biofilm-producing K. pneumoniae strains showed a significant correlation between strong biofilm production and mortality rate in oncological patients (Front Cell infect Microbiol 2020). Based on these data, we aimed to analyze host and microbial risk factors and assesses their impact on BSI development and mortality. A total of 96 patients with hematologic malignancies developing a BSI during chemotherapeutic program have been so far analyzed. Our data show that the presence of strong biofilm-producing bacteria (P=0.013) and multidrug-resistant strains (P=0.006) were independent risk factors associated with 30-day mortality (manuscript in preparation). Biofilm production could represent an important factor significantly affecting survival in hematologic maligiancies patients.

Multiomics characterization of acute myeloid leukemia (AML): we are planning a collaborative study on behalf of Onco-Hematology Working Group of Alliance Against Cancer aimed to perform a multiomics analysis of hematologic malignancies. In particular, we aim to study through Whole-Exome Sequencing (WES) bone marrow samples of secondary and therapy-related AML patients treated with CPX-351, in order to better understand the genomic basis of treatment resistance in this high-risk group of patients.

Autologous stem cell transplantation (ASCT): the most widely used high-dose chemotherapy (HDC) before ASCT in lymphoma patients is BEAM regimen (carmustine, etoposide, cytarabine and melphalan), which is considered the gold standard both in United states and Europe. In Italy alternative regimens are FEAM or TEAM in which carmustine is replaced by fotemustine or thiotepa due to difficult suppling. We aimed to investigate in a retrospective fashion the comparison between BEAM, FEAM and TEAM regimen in terms of efficacy and safety in lymphoma patients undergoing ASCT. 414 consecutive lymphoma patients transplanted in three Italian Institutions (Sapienza University-Rome n=218, Regina Elena National Cancer Institute-Rome n=144, Cardarelli Hospital-Naples n=52) were analyzed: the 2 years PFS of BEAM and FEAM groups was significantly better than that of TEAM group, whereas no significant differences in terms of 2 years OS were reported. TEAM regimen seems to be better tolerated because of significantly lower rates of grade 3-4 oral mucositis, whereas infectious complications, other non-hematologic toxicities and TRM were similar among the three groups of patients. These data were presented at the 45th Annual Meeting of the European Group for Blood and Marrow Transplantation (EBMT) and published on Leukemia and Lymphoma in 2020.

Epidemiology of COVID-19 infection in patients with hematological malignancies (HM): currently very few data on COVID-19 infection in the specific subset of HM patients are available. To gain knowledge about this life-threatening disease in HM patients two observational studies have been launched in 2020: the first one coordinated by the Italian Hematology Alliance on behalf of the Società Italiana di Ematologia (SIE), the Gruppo Italiano Trapianto Midollo Osseo (GITMO), the Società Italiana di Ematologia Sperimentale (SIES), the Sorveglianza Epidemiologica Infezioni Fungine in Emopatie Maligne (SEIFEM) and the Fondazione Italiana Linfomi (FIL) and the second one by the European Haematology Association (EHA). Our Unit is involved in both studies that are multicenter retrospective/prospective, cohort, non-interventional observational studies with the primary objective to assess the epidemiology and outcomes of patients with HM infected of COVID-19 disease. Preliminary data have been published on Lancet Haematology in 2020: when comparing mortality in the study cohort with the Italian population with COVID-19, the standardised mortality ratio in the whole study population was 2.04; when comparing mortality in the study cohort with the non-COVID-19 cohort with HM the standardised mortality ratio was 41.3.

In 2015 the Unit created a web-based intra-net system of data collection: Progettoemat.it. This software system features diversified disease-specific data-bases designed to meet the most important control requirements of the clinical endpoints such as survival, relapse, effectiveness of treatment protocols and more. This system provides for the transfer of clinical data of about a thousand of patients from paper to electronic format. In recent months the database has been continuously updated and modified according to the needs which arise during data entry. The work that has preceded the actual data entry aimed at recovering all the records of patients who

died, were lost or left the follow-up. A computer file was then created in which 1500 patients are included. The Unit chose to start with two diseases: Follicular Lymphoma (FL) and Diffuse Large Cell Lymphoma (DLBCL). To date 187 patients were included with FL and 336 patients with DLBCL. In September 2016 data-entry started about patients with multiple myeloma (so far 100 records were filed). The activity of the Secretariat and Data Manager also provides the database update of DMT and satisfaction questionnaires.

The patient's enrollment in the project "Psychological Functioning and quality of life after autologous stem cell transplantation in patients with onco-hematological disease" continued in 2019. The objective of this prospective longitudinal study is to assess the impact of graft on the quality of life and psychological functioning of adult patients undergoing ASCT, and to identify potential demographic, clinical, and psychological predictors of variables under study. The hypothesis is that patients with high scores of physical well-being, more education, lower levels of anxiety and depression, more resilient, more adaptive coping strategies, higher self-efficacy and increased social support before transplantation are those with better quality of life and psychological functioning immediately after transplantation and in a one year follow-up. In 2019 we completed the enrollment in the study for an overall population of 80 patients; in 2020 we continued follow-up evaluation of all patients enrolled in the study and administered a total of 286 questionnaires for measuring the quality of life, the perceived social support, the psychological distress, the resilience and self-efficacy before and after transplant procedure. Data analysis and manuscript preparation is ongoing.

As for clinical trials, during the 2020, 48 clinical research protocols proposed by Hematology and Transplant Unit and approved by Regina Elena I.F.O. Ethics Committee have been open to recruitment and 468 patients have been enrolled.

Sarcomas and Rare Tumors Unit

Head: Dr. Virginia Ferraresi, MD

Staff

Sabrina Vari, MD Assistant
Concetta Elisa Onesti, MD Assistant
Wioletta Faltyn, Case Manager of Sarcomas Disease Management Team
Silvia Bastucci, Data Manager
Elisa Checcucci, Data Manager

Mission

Rare solid tumours of the adult, accounting altogether for approximately 18% of all tumors, are generally associated to a worse prognosis due to frequent misdiagnosis, fewer dedicated clinical trials and poor economic investment by companies that ultimately hesitate in lack of evidence-based treatment guidelines and limited specific expertise.

The Regina Elena Institute (IRE) boasts a ten-year commitment in Rare Tumors, a commitment initially born with the participation in the Rete Nazionale Tumori Rari and, more recently, in the European network EURACAN of which Dr. Ferraresi is the representative for IFO. IFO is one of the european centre of EURACAN and accreditated for 8 out of 10 rare cancers domains. In the wake of this growing interest, the UOSD Sarcomas and Rare Tumors was activated in 2020 with the mission of dealing with the diagnosis and treatment of soft tissue and bone sarcomas and coordinating the clinical and scientific activities of the Units dedicated to other rare tumors. Another important goal of the UOSD is to ensure patients with Rare Tumors a facilitated path of access to the facility for the rapid start of diagnosis and staging procedures or second opinion activities for taking charge and to evaluate inclusion in national and international clinical trials (from phase I to phase IV studies) active in IRE. The achievement of this last goal was facilitated by the opening of the Rare Cancer and Rare Diseases Desk in December 2020.

Clinical Activity

The UOSD guarantees the diagnosis, treatment (chemotherapy, target therapy, and immunotherapy) and assistance for patients wirh sarcomas requiring drug administration and clinical follow up.

Clinical activity is supported by an interdisciplinary Disease Management Team (DMT) that meets on a biweekly bases. The new patients needing a first clinical evaluation and the patients in the post surgical setting and in clinical follow up are visited in the multidisciplinar Sarcoma Clinic two times a week. In 2020 about 250 new patients with sarcomas have been observed from the sarcoma DMT. Short intravenous or oral therapies and outpatient supportive cares are delivered in Day Hospital while complex chemotherapy regimens or severe toxicities requiring hospitalization are managed with 6 dedicated beds. The activities of the DMT sarcomas and of the Sarcoma Clinic are facilitated by the presence of a case manager fully involved in patients management. A psycological support is also offered to all patients with sarcomas starting from the diagnostic phase and throughout the oncological therapies and the follow up. A project of Narrative Medicine is also active for patients on active treatments.

Research Activity

The UOSD is actively involved in national and international clinical trials (phase 1,2, and 3 trials) exploring new drugs and approaches in sarcomas (soft tissue sarcomas, GIST, high-grade bone sarcomas, osteosarcoma, and Ewing sarcomas) and muscle-skeletal benign aggressive tumors (like Tenosynovial Giant Cell Tumours). It is also one of the centre of the Italian Sarcoma Group (ISG)

and Dr. Ferraresi is a member of the Executive Committee of the Group. Dr. Ferraresi is moreover a component of the board for clinical guidelines for soft tissue sarcomas and GIST of AIOM (Associazione Italiana di Oncologia Medica), She is also in the board of EURACAN guidelines for soft tissue and bone sarcomas. Research activity is conducted with the involvement of 2 fully trained data manager specifically addressed to follow clinical trials in good clinical practice.

Pain Therapy Unit

Head: Dr. Lorella Pelagalli

The Pain Management Italian Network brings together consumers and clinicians to promote equity of access to pain management services for patients with chronic pain and determine priorities for action. It also develops and supports implementation of new evidence-based models of care to improve integration and coordination of care between hospital-based specialist multidisciplinary pain clinics and community and primary health services (Law 38/2010)

The Pain Management Unit at Regina Elena National Cancer Institute is Centre of Referral for Cancer Pain Management in Latium Region.

Mission

Clinical and research activity of Pain Therapy Unit is dedicated to the diagnosis, therapeutical approaches of pain symptoms in cancer patients. The unit conducts assessment and treatment for persistent, chronic pain and provides patients with a comprehensive management plan involving an integrated team of specialists.

Clinical activities

The unit is a vital part of the oncologic clinical and research department and deals with approx 1500 patients episodes per years.

The Pain Management Unit offers an interdisciplinary approach to cancer pain management.

Different health professionals of multiple disciplines, all specializing cancer pain management, are part of the team.

- The core team includes:
- Physicians, trained in anesthesia with additional training in pain management.
- Intervex\ntional pain physician.
- Nurse clinician specialist in oncology and pain therapy .
- Psychologist.

The multidisciplinary team is functioning in accordance with the International Pain Society's recommendations.

The Pain Management Unit provides a consultation and liaison service across the hospital, assessing and treating patients within 24 hours. Pain assessment is conducted in all patients admitted in the oncological wards, by pain score charts as a part of the medical records.

Recently, we have created the itinerant pain clinic, such a rapid response team, to manage acute pain syndromes inside the hospital.

The inpatient pain service guarantees:

- Pain assessments.
- Drugs titration.
- Anesthetic blocks for procedural pain.
- Interventional pain management
- Pain educational corners in the oncological/hematological day hospital and in the radiotherapy clinic.

The outpatient activity is dedicated to cancer patients who belong to the take in charge, to

Dayhospital, Day-Surgery at the two Institutes and to all people in need of evaluation and ongoing monitoring of pain during chemo-radiotherapy

Peritoneal Tumor Unit

Head: Dr. Mario Valle, MD, FACS

Staff

Fabio Carboni, MD, PhD, MMeD
Francesco Corona,MD
Orietta Federici, MD
Settimio Zazza, MD
Giovanna Grazioli, Coordinator

Clinical Activity

A multicentric research protocol study of treatment is in progress evaluating pressurized intraperitoneal aerosol chemotherapy (PIPAC) in patients with peritoneal carcinomatosis of colorectal, ovarian, gastric and primary peritoneal origin, not suitable for peritonectomy with HIPEC. The technique is a new approach of chemotherapy delivery in the abdominal cavity first described at the Rhur University of Bochum, Germany.

It allows a more homogeneous and concentrated diffusion of the chemotherapic agent in the closed space of the abdominal cavity. Drug doses are ten times lower than those used ijn HIPEC, since the increased intraperitoneal pressure seems to improve the intratumoral spreading of the drug.

PIPAC does not replaces HIPEC, which is a curative treatment, but it may limit the progression of carcinoisis and improve patient prognosis and quality of life. PI: Dr. O. Federici

Peritoneal Carcinomatosis: The Unit has been recognized as SICO referral center for the treatment of primary and secondary peritoneal malignancies. A pilot study is ongoing evaluating the association between expression and heterogeneity of DNA damage markers and clinical outcomes in patients who underwent peritonectomy and hipec for peritoneal carcinosis from ovarian cancer. PI: Dr M. Valle; Dr O. Federici

AMAD - Multidisciplinary Outpatient Clinic for the Digestive System. AMAD was activated the 1st October 2016. It is a multisciplinary outpatient clinic coordinated by Dott. S. Zazza (surgeon) and Dott. G. Paoletti (oncologist), with the availability of real time consulting of radiotherapist and gastroenterologist, in case of neoadjuvant treatments and radiologists for diagnostic imaging. Both initial and follow up visits for patients affected by Colo-Rectal cancers are provided, applying the paths described in the relevant PDTA and reporting to DMT, with the support of a Case Manager, through the utilization of dedicated spaces in all the other UOC, UOSD and Services.

Research Activity

Peritoneal Disease: Translational research of micro-RNA modifications induced by HIPEC.

Minimally Invasive Techniques in Surgical Oncology: The experts are well aware of the work published by our group on laparoscopic diagnosis of peritoneal carcinosis and hyper-thermic antiblastic perfusion of the abdomen in refractory neoplastic ascites with mini-invasive. The group's experience in advanced minimally invasive surgery in over 30 years of activity also includes colon and rectum resection, wedge resections of the stomach and small intestine, distal pancreaetctomy, splenectomy for haematological diseases, adrenalectomy. PI: Dr. M. Valle, Dr. O. Federici, Dr. F. Carboni

ULTRAPLACAD (ULTRAsensitve PLAsmonic devices for early Cancer Diagnosis) within the framework of the European project (funds 15/07/R/33) headed by Dr Giacomini (Oncogenomics

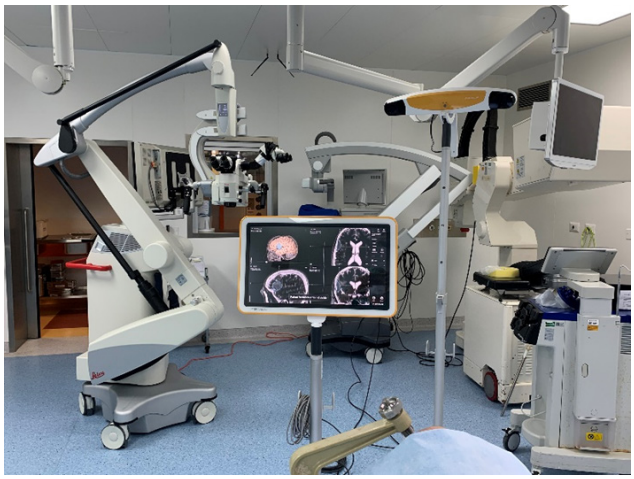
Laboratory). From the preliminary results, the possibility of identfying circulating neoplastic DNA, which could be of great useful in the early diagnosis of primary tumors and relapses after treatment. The indications for front line chemotherapy, appears very promising. PI: Dr F. Carboni; Dr. S. Zazza.

Gastric Cancer: a research study is about to begin evaluating the association of biologic drugs to standard neoadjuvant chemotherapy in locally advanced gastric cancer. These new protocols of therapies have been used in the adjuvant setting only until now, but they could allow retrieval of patients for radical surgery. PI: Dr M. Valle, Dr. F. Carboni

Sarcomi: A selected group of tumours is included, requiring a multidisciplinary approach with ortophedic, oncologist, radioterapist, radiologist, nuclear physician, pathologist and psicologist. The main role of surgeon is the treatment of primary and recurrent retroperitonal tumours, as well as diffuse sarcomatosis. The coordination with the other specialties is managed by Dr. F. Corona

Neurosurgery Unit

Head: Dr. Stafano Telera, MD



Staff

Laura Raus, MD
Piero Oppido, MD
Francesco Crispo, MD
Catia Pompea Delfinis, MD
Mario Lecce, MD
Fabrizio Rasile, MD
Antonio Valerio- Nurse Coordinator and Case Manager
Angelocola Anna, Nurse
Balzano Silvana, Nurse
Lauro Gerarda, Nurse
Rinaldi Sabrina, Nurse
Francesca Mastropietro, Nurse
Marzia Piccoli- Amministrative Assistant

Mission

The activity of Neurosurgical Unit is devoted to research, diagnosis and treatment of nervous system tumors, with a prevalent interest in malignant primary and secondary lesions. Our activity is deeply embedded in the multidisciplinary group of Neuro-Oncology, with the principal aim of defining more specific diagnostic and therapeutic strategies for the most relevant brain and spine tumors.

The research activity of the Unit of Neurosurgery is focused on several relevant topics, regarding translational and clinical studies on new bio-molecular characterization and therapeutic approaches in the integrated diagnosis and treatment of primitive and secondary tumors of the nervous system. As such, we take active part either to national and international cooperative groups or to relevant academic and sponsored clinical trials.

In the field of secondary CNS lesions, we cooperate with the Hematologic, Oncologic and Radiotherapy Units, offering important support into diagnostic and therapeutic processes of systemic and hematologic tumor diseases.

Clinical Activity

In 2020, despite the severe limitations provoked by the coronavirus Covid-19 pandemic, the Unit of Neurosurgery performed 104 surgical procedures, for intracranial pathologies, spine lesions and tumors of the peripheral nervous system.

Our activity is devoted to increase the efficacy of therapeutic strategies for primitive brain tumors: fluorescence guided microsurgical resection, neurophysiologic monitoring, intra-operative ecography, conformal RT, adjuvant chemotherapy.

The latest upgraded Neuronavigation system has been introduced in service, allowing in combination with intraoperative Ecography, to further refine the precise and tailored removal of primitive and metastatic brain tumors.

The Italian Society of Neurosurgery (SINCH) have created a Task Force (ST is a member of this

group), to draw consensus review of evidence and recommendation for diagnosis, staging, and treatment options of cerebral metastases.

The endoscopic activity, both intraventricular and transphenoidal, has been maintained and developed.

The recent acquisition of the new Exoscopic 3D system for implemented visualization in microsurgical and open surgical procedures, is able to combine the benefits of microsurgery and endoscopy, improving ergonomic work and workflow of the entire neurosurgical team in difficult accessible brain and spine area.

Patients affected by metastatic spinal tumors are treated with separation surgery consisting of vertebro/kyphoplasty, open decompression and percutaneous stabilization, followed by Radiosurgery. The introduction of silicon products allowed to perform complex cases with an increased margin of safety and efficacy.

For intradural-extramedullary tumors the unilateral mini-invasive approach has become the standard of care, reducing surgical aggressiveness and time of hospitalization. Neurophysiologic monitoring of the motor and sensory function is commonly employed during surgery of all intradural tumors.

A large experience on treatment of peripheral nerve sheath tumors like schwannomas, has been also developed in the last twenty years

Research Activity

Research activity has been oriented either toward translational neuro-oncological projects as well as toward new, innovative, more effective surgical techniques.

The aim of our multi-specialist translational group was to identify new molecular glioma biomarkers useful for better determine the diagnosis, prognosis and/or therapeutic response. To accomplish this goal, we take advantage of an extensive database including retrospective as well prospective case series collected at IRE.

We currently participate to the "Glioma Project" which has been developed by the Neuro-Oncology Unit, to combine the results of Radiomics and molecular analysis of primitive brain tumors and we will contribute to the "CLINGLIO" randomized, double blind, placebo-controlled adjuvant trial in newly diagnosed primary glioblastoma, to assess the efficacy and safety of 2-hydroxyleic acid (2-OHOA) in combination with Radiotherapy and Temozolamide standard of care treatment.

A relevant issue is related to research and identification of circulating biomarkers for detection and prognosis of primary brain tumors. We are evaluating eleven circulating serum microRNAs, previously associated with brain tumors, as potential non-invasive diagnostic biomarkers for glioma patients.

The role of microRNA has been also investigated in brain metastases. In particular, it has been assessed whether aberrant expression of specific microRNAs could contribute to brain metastases. Comparison of primary lung tumors and their matched metastatic brain disseminations identified shared patterns of several microRNAs, including common down-regulation of miR-145-5p, which appeared to play a pivotal role in malignancy progression and in metastasis.

The Neurosurgical Unit has been actively involved in the METAMECH (Master Protocol Mechanobiology Translational Research in Breast Cancer) a multicenter study funded by AIRC, with the primary aim to build a resource of clinical annotated biological samples feeding the consortium laboratories and allowing a mechano-focused "precision research" in breast cancer.

The potential contributes of CSF cytometry analysis for early detection and characterization

of tumor cells in the presence of leptomeningeal carcinomatosis and lymphomas, is also under investigation.

Fluorescence-guided resection with 5-ALA, can reliably increase the extent of surgery in primitive brain tumors. Our experience regarding more than 130 patients has been presented in several scientific meetings.

With regard to spinal tumors, vertebral pathological fractures represent one of the most challenging issues. The emerging role and integration of minimally invasive surgery with Radiosurgery, the so called "separation surgery" has been investigated by the Neurosurgical and Radiotherapy Units with the purpose to present a combined protocol of treatment. The results of our innovative mini-invasive approaches have been published in 2018 in Clinical Neurosurgery and 2019 in World Neurosurgery.

Cardiology Unit

Head: Prof. Francesco Rulli, MD, FACC

Staff

Armando Carpino, MD
Maria Paoloa Cicini, MD
Fabio Maramao, MD
Nicola Antonio Morace, MD
Fabio De Luca, Nurse Coordinator
Laura Cervellione, Nurse
Gianni Chiarabini, Nurse
Gianni Pompei, Nurse
Antonella Perenzin, Nurse

Mission

The Cardiology Task Force performs all non invasive cardiac diagnostic current required by the surgical facilities, medical oncology and dermatology Institutes. The patients are studied by consulting cardiac ECG, echo, stress ECG, 24 hours ECG and 24 hours monitoring blood pressure. Patients who belong to our Unit, with a path shared by colleague practitioners, have a predetermined follow-up and facilitated in terms of access benefits with waiting times of 48 hours.

Clinical Activity

The Cardiology Unit carries out assistance activities and clinical-instrumental advice to all cancer patients Institute Regina Elena and S. Gallicano Institute.

The outpatient activity is dedicated to cancer patients who belong to the take in charge, to Day-hospital, Day-Surgery at the two Institutes and to all people in need of evaluation and ongoing monitoring of chemo-radiotherapy or remote treatment within the follow set up programmed by shared treatment protocols.

Research Activity

The Cardiology operating Unit substantially has three aspects:

- Support to surgery in terms of preoperative cardiovascular function evaluation in the intra-operative emergency and in any patient's appreciation as a results of complications.
- The state of cardiac evaluation of the patient to be subjected to chemotherapy or radiotherapy, pre or post-surgery, given the already documented cardiotoxicity of some therapeutic lines and in particular of some specific groups of drugs. To this is added the periodic monitoring, clinical and instrumental, the treated patient, and in accordance with research protocols defined and shared with colleague oncologists conforming with the guidelines defined by available.
- The UO Cardiology is part of the most solid and accreditated reality associational cardiology and cardio-oncology, in the evaluation of cardiotoxic effects of some anticancer drugs, in research and in the development of myocardial damage markers in outcome and patient who underwent cardiac surgery for cancer.

Oncological Endocrinology Unit

Head: Dr. Marialuisa Appetecchia, MD

Staff

Lauretta Rosa, MD
Alfonsina Chiefari, MD
Marta Bianchini, MD
Marilda Mormando, MD
Eros Floridi, Area Nursing Coordinator
Aurora De Leo, nurse
Claudia Di Frischia, nurse
Giulia Puliani, PhD student

Mission

The Oncological Endocrinology Unit of IFO deals with diagnostics and therapy for oncological pathologies of endocrine tumors (thyroid, pituitary, adrenal, parathyroid) and neuroendocrine tumors. It also deals with the management of osteoporosis and endocrine-metabolic sequelae in cancer patients. The Unit includes the graduate students of the School of Specialization in Endocrinology and Metabolic Diseases, and a research doctorate in Endocrinology within the framework agreement with the "Sapienza" University of Rome. The Unit has collaborative relationships and participates in multicenter clinical trials with the main national and international universities and research institutes (Sapienza University of Rome, Biomedical Campus of Rome, Catholic University of the Sacred Heart of Rome, University of Pisa, University of Florence, University of Siena, University of Milan, EOC Swiss Cantonal Hospital Body) and with many Scientific Societies (eg SIE, SIOMMS, AIOM, ESMO, ITANET, ENETS). The mission is to achieve excellence in the prevention, diagnosis, and treatment of endocrine and neuroendocrine tumors, in the management of osteoporosis and endocrine-metabolic sequelae in cancer patients.

The Unit is part of the Regione Lazio endocrine and metabolic network. It has also been identified as a "Hub" center for thyroid diseases; this implies that the center is able to independently manage all aspects of the diagnostic and therapeutic process of these pathologies, also providing a multidisciplinary team with proven experience in the sector. As a Hub center, it also deals with the dissemination of information and knowledge on the territory, is in contact with scientific societies and patient associations. The Unit was also identified as a "Spoke" center for pituitary, parathyroid, adrenal, neuroendocrine tumors and for the management of osteoporosis.

The Unit pays particular attention to gender medicine both in the care and research fields. It is part of the table for Gender Medicine at the Ministry of Health as a referent of the IFOs

Clinical Activity

To date, the Unit is characterized by taking care of patients suffering from endocrine and neuroendocrine tumors in the context of rare solid adult tumors. The Unit is part of the EURACAN Network, The European Reference Network on Rare Adult Cancers (solid tumors), in the domain G4 (neuroendocrine tumors) and G6 (endocrine cancers). In 2020 the new cases of Neuroendocrine and Endocrine tumors represented about 20% of all cases included in the IFO Rare tumors platform. The patients affected by the oncological pathologies described above as well as being followed during the diagnosis and therapy processes, with dedicated pathways (PDTA), are assessed collectively in active multidisciplinary groups (Disease Management Team-DMT thyroid and DMT neuroendocrine tumors, both coordinated by the writer). Over the years, the consolidated history of care and research in the field of endocrine and neuroendocrine tumors

of the aforementioned structure can be demonstrated with the type of patients taken care of (about 3000 patients in follow-up for thyroid cancer, about 100 families with hereditary tumors, about 250 patients affected by Neuroendocrine Gastroenteropancreatic tumors-NET GEP), with the numerous national and international clinical trials in which it participates (data available from the IRE Scientific Direction) and with scientific publications printed in journals with IF (PUBMED). The structure has also activated, with authorization from the Strategic Department, from 2018 a reference outpatient clinic for multiple endocrine neoplasms-MEN.

Other areas of interest

Osteoporosis and bone metabolism disorders in cancer patients

Most patients with cancer disease have long-term survival and may suffer from related bone metabolic diseases. In these patients, the treatment of metabolic bone disease becomes more necessary than in non-cancerous patients, not only for the overall improvement of its compliance, but also for the psychological implications. It has also been reported that some metabolic bone diseases tend to emulate neoplastic diseases while others are true paraneoplastic pathologies. The Oncological Endocrinology Unit often visits cancer patients to set specific therapies for osteoporosis. Treatment of these patients should be based on indicators other than those normally used in non-cancer patients with osteoporosis. The Unit has been part of the IFO Center of Excellence in Osteoncology, certified by the Italian Society of Osteoncology (SIO) (renewal of the accreditation in progress) and of the Onco-Bone Network, a network of clinical and scientific collaboration between endocrinologists, oncologists and expert bone metabolism specialists.

Thyroid cancer and Familial adenomatous polyposis (FAP)

Familial polyposis (FAP) patients have a higher risk of developing thyroid cancer than the general population.

The IRE Digestive Endoscopy UOSD is a Reference Center of the Regione Lazio for FAP, a rare disease for which affected patients should be insured to receive complete clinical management, with dedicated pathways, providing diagnostic evaluations and organ follow-up target, including the thyroid gland. Therefore, it is necessary for these people to also carry out visits and diagnostic evaluation of the thyroid. For this reason, a dedicated multidisciplinary IRE PDTA was created, of which the UOSD of Oncological Endocrinology is a part. To date, about 100 patients with FAP and endocrine diseases have been followed at the UOSD of Oncological Endocrinology.

Management of endocrine sequelae of neoplasms or antineoplastic, chemotherapy, radiotherapy, biological and immunotherapy treatments.

Due to antineoplastic therapies, patients with carcinoma often have a condition of early menopause or hypogonadism which leads to problems related to sexual, reproductive and bone metabolism. In these patients, therefore, the treatment of metabolic disorders (dysthyroidism, alterations of mineral and lipid metabolism) induced by drugs is of particular importance. With the advent of the new target and immune therapies, alone or in association with traditional radio / chemotherapy, the life expectancy of patients has undergone significant improvements both in terms of increasing survival and improving quality of life. Anticancer treatments have led to a radical change in "setting" and users are increasingly independent in their care path, less and less tied to traditional hospitalization. The good therapeutic response obtained with the use of these drugs requires monitoring and controlling the numerous and often very disabling side effects, in order to improve the quality of life and reduce the number of therapeutic interruptions. Several endocrine toxicities induced by targeted therapies are reported. Endocrine toxicities can lead to a reduction in the dosage of antineoplastic therapies, to alter the kinetics and clearance of drugs, with undesirable effects and a negative impact on the patient's quality of life and on the prognosis of the disease. Thyroid dysfunction, in particular hypothyroidism occurs in 20-50% of patients treated with tyrosine kinase inhibitors (sunitinib, sorafenib, axitinib, pazopanib, regorafenib) and immunotherapy.

Hereditary endocrine tumors syndromes

Hereditary Genetic mutation are increasingly recognized in the development of endocrine neoplasms. Depending on the endocrine tumor type, 10% to 40% of cases are associated with genetic disorders, including the classic multiple endocrine neoplasia syndromes (MEN1 and MEN2), hyperparathyroidism–jaw tumor syndrome, SDH-related paraganglioma-pheochromocytoma, von Hippel-Lindau syndrome, neurofibromatosis type 1, Carney complex, McCune-Albright syndrome, and familial non-medullary thyroid cancer syndromes, as well as newer entities (MEN4, DICER1 syndrome, glucagon cell hyperplasia and neoplasia syndrome). Although some features commonly seen in familial disease (early onset, family history, multifocal neoplasia, multi-organ involvement) may alert one to the possibility of an underlying genetic predisposition, endocrine neoplasia syndromes tend to be phenotypically complex and heterogeneous and present variably with de novo mutations, making it difficult to recognize and classify on clinical grounds alone. In an era of precision medicine, pathologists play a central role in the diagnosis of familial cancer syndromes, by leading the way toward screening and molecular histopathology prediction models. In particular, the identification of "pathognomonic" morphologic and immunohistochemical "clues" is crucial to raise the possibility of an inherited genetic disorder and to guide further management, including gene testing, counseling, and targeted therapy. Seventeen patients with MEN and 30 patients with pheochromocytoma / paraganglioma syndrome are followed today at the Oncological Endocrinology Unit. The Unit is part of the IFO Reference Center for rare endocrine diseases in the Regione Lazio Rare Diseases Information system (SiMaRaL).

Research Activity

The research activities of the IFO Oncological Endocrinology Unit are focused on the evaluation and development of new tools useful in the diagnosis, treatment and monitoring of human endocrine and neuroendocrine tumors with particular attention to precision medicine and the management of the endocrine-metabolic sequelae in cancer patients.

Research lines

Below are listed the IRE research lines of which the UOSD of Oncological Endocrinology is part.

Identification of prognostic and predictive factors in endocrine and neuroendocrine tumors.
Responsible: Marialuisa Appetecchia

Endocrine and neuroendocrine neoplasms (NEN) are rare tumors since the number of new cases per year is less than 5 per 100,000 people. Endocrine tumors are rare (thyroid, NEN) or very rare (adrenal / paraganglioma and parathyroid tumors) with well-established diagnostic and therapeutic tools, for which the new frontiers of molecular target therapies and immunotherapy pose new challenges for the evaluation of efficacy and toxicity. They include diseases that are clinically and biologically different, the complex management of which requires the expertise of different specialist figures (pathologist, medical oncologist, surgeon, nuclear doctor, endocrinologist, gastroenterologist, interventional radiologist, nutritionist, radiotherapist). It is crucial that these figures cooperate within a multidisciplinary group that establishes a global therapeutic strategy suitable for the individual patient. The research line has as main scientific interest the identification of new diagnostic biomarkers and the development of new innovative therapeutic approaches for endocrine and neuroendocrine tumors. Particular emphasis is placed on the identification and development of molecular and biochemical diagnostic tools, as the identification of indicators that allow a personalized approach to the diagnosis and treatment of patients, through the development of preclinical models and clinical validation to be applied to clinical practice.

Drug induced endocrine toxicity.
Responsible: Marialuisa Appetecchia.

The related projects are essentially part of a research area aimed at studying the manifestations of endocrine toxicity induced by traditional systemic and loco-regional antineoplastic

treatments (cytotoxic chemotherapy, radiotherapy) and innovative (molecular targeted therapies, immunotherapy) on the endocrine system and on bone metabolism. The progressive use in clinical practice of new molecularly targeted drugs (eg tyrosine kinase inhibitors, TKI) and immunotherapy (eg monoclonal antibodies known as immune checkpoint inhibitors, ICI) typically are burdened by varying degrees of endocrine toxicity, making necessary the current diagnostic diagnosis, in-depth activities, the improvement of therapeutic approaches and stimulated the search for specific predictors of endocrine toxicity. Attached to this document is the list of 2020 publications.

Regarding Gender Medicine in 2020 the Unit contributed to the drafting of two national documents on this topic on behalf of the Ministry of Health: the "National Plan for Gender Medicine" as Coordinating Center and "COVID-19 and Gender Medicine".

Since May 2020 the Chief of the Unit is a member of the EGOI (Experts Group on Inositol in Basic and Clinic research) international network.

List of Protocols approved in 2020

1. Risk factors in gastro-entero-pancreatic neuroendocrine neoplasms: a case control study.

2. Itanet Registry: multicentric registry of Gastro-Entero-Pancreatic neoplasms.

3. Retrospective-prosective observational study on the impact of gender on efficacy and safety of Lenvatinib in patients with radioiodine-refractory differentiated thyroid cancer. Gisel Study.

4. A Study of Selpercatinib (LY3527723) in Participants With RET-Mutant Medullary Thyroid Cancer (LIBRETTO-531)

5. Impact of gender in oncological endocrinology.

Gastroenterology and Digestive Endoscopy Unit

Head: Dr. Vittoria Stigliano, MD

Staff

Paola Capra , Lead Nurse
Laura Argento, Nurse
Daniela Cannone, Nurse
Alessandra Cinti, Nurse
Danilo Festa (From October To December)
Susanna Pampinella, Nurse
Marina Santamaria, Nurse
Stefano Podestà, Nurse
Cinzia Toresi, Health Worker
Mario Di Stefano , Health Worker
Maicol Sisca, Health Worker
Daniela Assisi, MD
Rocco Lapenta, MD
Cinzia Quondamcarlo, MD (By March)
Lupe Sanchez Mete, MD
Francesco Covotta, MD (From October)

Mission

To offer the diagnosis and the clinical management for Hereditary Colorectal Cancer Syndromes and rare gastrointestinal tumors. Moreover, this unit is Reference Centre of Lazio Region for Familial Adenomatous Polyposis (FAP), Lynch and Peutz-Jeghers syndrome.

To improve the use of new advanced endoscopic technologies for detection and treatment of gastrointestinal tract precancerous and cancerous diseases

To support nutritional status in cancer patients and to improve cancer-related malnutrition management

To develop clinical and translational research in the field of colorectal and pancreatic cancer, particularly in Hereditary Colorectal Cancer Syndromes and rare gastrointestinal tumors

Clinical Activity

- Diagnosis and treatment of precancerous and cancerous lesions of the gastrointestinal tract, through the use of high definition endoscopes, digital chromoendoscopy and the Confocal laser endomicroscopy technology.
- Diagnosis and staging of gastrointestinal submucosal lesions, pancreatic, mediastinic and lung neoplasia through the use of endoscopic ultrasound.
- Diagnosis and treatment of precancerous and cancerous lesions of the small bowel through the use of capsule endoscopy and device assisted enteroscopy.
- Diagnosis and palliative treatment of gastrointestinal, pancreatic and biliary tree cancer.
- Emergency endoscopy for acute gastrointestinal bleeding.
- Nutritional counselling and support for cancer patients and Endoscopic placement of enteral feeding tubes.
- Physicians of this Unit are actively involved in the interdisciplinary Disease Management Teams dedicated to the treatment and follow-up of patients, according to national and international guidelines.

Research Activity

The major research interest of our Unit is in the field of colorectal cancer, in particular of familial and hereditary colorectal cancer.

Further fields of interest are EUS and biliary stenting

During 2020 we pursued the following Research Projects

- RC Project: Identification of new susceptibility genes for Hereditary colorectal cancer Principal Investigator: Dr Lupe Sanchez Mete
- Funded Project: Randomised, double-blind, placebo-controlled study of the, efficacy, safety and tolerability of EPA-FFA gastro-resistant capsules, in patients with Familial Adenomatous Polyposis (FAP); funded by SLA Pharma. Principal Investigator: Dr Vittoria Stigliano
- IRFARPC Italian Registry of Families At Risk of Pancreatic Cancer (Registro Italiano Multicentrico di sorveglianza prospettica dei soggetti a rischio genetico di cancro del pancreas) Principal Investigator: Dr Vittoria Stigliano
- Valutazione dell'accuratezza dell'ecoendoscopia con agoaspirato nella diagnosi delle linfoadenopatie mediastiniche Principal Investigator: Dr Daniela Assisi

Pulmunary Physiopathology Unit

Head: Dr. Maria Papale, MD

Staff

Eliuccia Mastropasqua, MD
Giorgio Piperno, MD

Mission

Physiopathology Respiratory Unit has forwarded its traditional mission addressing and programming in research activity through useful objectives aimed at the prevention, diagnosis, cure and rehabilitation of pulmonary diseases, in particular oncology and smoke related diseases. The directives have been:

- primary and secondary prevention in the field of pneumology through education clinical-functional diagnostics
- respiratory therapy and rehabilitation for both inpatients and outpatients
- participation in research program
- participation and organization of courses, conferences and congresses both for reports as well as professional updating.

Regarding the activities and objectives the Unit confirm his commitment to respiratory rehabilitation activities with the aim to improve the quality of life and the respiratory functionality at the same time to reduce the days of stay. The Unit is also dedicate to patients suffering from Interstitial lung disease and IPF (Idiopathic pulmonary fibrosis) rare diseases but frequently verified in our Institute as outcomes of administered therapies. In addition to early diagnosis and therapy of the IPF, it contributes to prevention of related lung cancer.

The smoking cessation clinic (referral Centre for the Observation of Smoke, Alcohol and Addiction, I.S.S.), has continued its own activity helping patients quit smoking even with pharmacologic treatment. In regards to the effort to prevent smoking, the focus has been on educational and counseling for the staff of our Institute.

Clinical Activity

During 2020 about 17.400 services (visits, consultations, instrumental tests and respiratory rehabilitation activity) have been conducted on patients coming from different Units of the Institute. Cooperation, above all, with Thoracic Surgery, for a more accurate identification of surgical risks, has been particularly intense.

There has been a total of 8400 services conducted for outpatients who came either for pulmonary oncology and other diseases or for to quit smoking or to run respiratory rehabilitation.

Respiratory rehabilitation activity is offered mainly to external patients who either have to undergo major thoracic or abdominal surgery, or have already undergone pulmonary resection for cancer and suffer from COPD. In 2020, about 8.400 services of respiratory rehabilitation have been performed on internal patients and 2.600 services on external patients.

In 2020 the COVID-19 pandemic , circulating in the community, posed a potential risk to all patients attending lung function services and the staff working there. Consequently, in according

to ERS statement, we restricted the range of tests allowable and also limit the availability of testing to those who require it the most. For this reason the services conducted for outpatients has undergone a reduction, while the activity concerning internal patients remained the same.

Research Activity

The Unit has taken part along with "Mario Negri Institute for Pharmacological Research" coordinated by the Italian Association of Hospital Pneumologists (AIPO) in: "Studio multicentrico osservazionale sull'utilizzo della sigaretta elettronica in Italia" and in 2020 has been published in Tumori Journal: "Electronic cigarette use among Italian smokers: patterns, settings, and adverse events".

The Unit continued to participate in the study BR31 "A phase III prospective double blind placebo controlled randomized study of adjuvant medi4736 in completely resected non-small cell lung cancer".

The Unit has participated, about the research line 1 "Prevention and early diagnosis of Cancer", in study "Role of the estradiol axis in the carcinogenesis and prevention of mesothelioma".

The Unit has taken part in "Registro asma grave- Studio osservazionale e/o retrospettivo non interventistico, multicentrico, nazionale" coordinated by the Italian Association of Hospital Pneumologists (AIPO).

The Unit is taking part in a national, multicentre observational study:

"The impact on the health status and adherence in a real life setting of italian patients with chronic obstructive pulmonary disease in treatment with a fixed triple association pmdi b.i.d.: a 12-month prospective observational study triple therapy in real life: impact on adherence and health status (TRITRIAL)"

Neuroncology Unit

Head: Dr. Andrea Pace, MD

Staff

Edvina Galiè, MD
Marta Maschio, MD
Tatiana Koudriavtseva, MD
Veronica Villani, MD, PhD
Dario Benincasa, MD,PhD
Annamaria Biscu, Nurse
Roberta Rafaelli, Nurse
Giuliana Graziano, Technician
Gianluca Petreri, Technician
Marzia Piccoli, Data manager
Alessia Zizzari, Physioterapist
Stefano Di Felice, Physiotherapist
Luciano Urbani, Physiotherapist
Cristiano Parisi, Physiotherapist
Maria Andreina Rotondi, Social worker
Margaux Lamaro, Physioterapist
Silvia Focarelli, Data Manager
Antonio Tanzilli, Neuro-psychologist
Andrea Maialetti, Neuro-psychologist

Mission

Clinical and research activity of Neuroncology Unit is dedicated to the diagnosis, therapeutical approaches and supportive and palliative care of primary brain tumors. Moreover, the Unit is involved in clinical and research activity related to Central and Peripheral Nervous System neurological complications of cancer and neurotoxicity of anticancer treatments.

Clinical Activity

The clinical activities of Neuroncology Unit include:

- Neurology clinic
- Neuro-oncology clinic
- Center for Tumor-related Epilepsy
- Neuropathic Pain Clinic
- Neuropsychology and cognitive rehabilitation
- Neuro-oncologic Day Service for chemotherapy and supportive treatment of brain tumor patients
- Neurophysiology lab (Electromyography, Electroencephalography, Evoked Potentials)
- Rehabilitation service specialized in cancer rehabilitation for in- and out-patients
- Palliative and supportive home care for brain tumor patients

Research Activity

The research activity of Neurology Unit is focused on several topics. These include:

- Clinical neuro-oncology - The role of chemotherapy in recurrent malignant brain tumor has been evaluated in phase II trials exploring the activity and toxicity of several anticancer agents: temozolomide, fotemustine, bevacizumab, carboplatin, regorafenib. Recent trials have been launched including: weekly carboplatin AUC2 in recurrent malignant glioma; cloropromazine associated to temozolomide in newly diagnosed GBM.

- Traslational research - Next generation sequencing in glioma patients for identification of potential target therapy: NGS panels assessment allowing the simultaneous analysis of both DNA and RNA in order to identify either the presence of point variants and fusion genes or variations in the number of gene copies with a panel of 50 genes that are recognized to have a key role in tumour development, with the aim to identify potential therapeutic target

- Cognitive impairment assessment and rehabilitation - The role of cognitive rehabilitation

programs has been investigated in different setting of care (in patients, outpatients, home care setting). Preliminary data showed beneficial effects of a computer-based cognitive rehabilitation programme and positive impact on Quality of Life in neuro-oncological patients. Preliminary results have been presented in national and international scientific meetings.

- Home-care for brain tumor patients - The efficacy of a program of comprehensive palliative care for brain tumour patients supported by the Lazio Regional Health System was evaluated analyzing place of death, caregiver satisfaction, re-hospitalization rate and the impact on Health System costs. The results of this project have been presented in national and international scientific meeting.

- Palliative neuro oncology and telemedicine. We developed a health WEB site portal applied to Neuro-Oncology supportive and palliative care issues (www.portaleneuroncologia.it). Neuroncology Unit of IRE is involved in an international project aimed to define guidelines and treatment recommendations on supportive and palliative care in brain tumor patients. The guidelines produced by the palliative care task force have been recently published on Lancet Oncology.
- Peripheral neurotoxicity of anticancer drugs - We are involved in an international study: The Chemotherapy-Induced Peripheral Neuropathy Outcome Measures Standardization (CIPerinoms) including 20 European and US oncology and neurology centres specifically designed to compare the validity and reliability of different methods proposed for the assessment of chemotherapy-induced peripheral neuropathy in a formal way. The results have been published on Annals of Oncology, European Journal of Cancer and Journal of Peripheral Nervous System.

- Rehabilitation in Oncology - Neuroncology Unit research activity includes the clinical research and methodological assessment of rehabilitation strategies in oncology. The definition of the role of rehabilitation in different setting of care (early rehabilitation of anticancer treatment sequelae; long term survivors rehabiltation needs, palliative rehabilitation) is the main object of several research projects.

- Role of comorbidities in the elderly glioblastoma - A prospective study: This study evaluated the impact of comorbidities on outcomes in elderly GBM patients. Comorbid conditions were indentified with the modified version of the Cumulative Illness Rating Scale (CIRS). The results showed that comorbidities play an important prognostic role in elderly with GBM. Preliminary results have been presented in national and international scientific meetings. The final results have been published in 2019.

- The prognostic value of pyrosequencing-detected MGMT-promoter hypermethylation in newly diagnosed patients with glioblastoma - We collected tumour samples of GBM patients who underwent surgery or biopsy and were/are followed at the Neuro-oncology Unit of National Cancer Institute Regina Elena. Preliminary data showed that patients with a cut-off <35% of methylation had a shorter PFS but not significant difference we observed in terms of overall survival. A multicentric study, with the participation of Italian neuroncology centers, on the methylation status of glioblastoma determined with pyrosequencing is ongoing.

- Headache as a presenting symptom of glioma: a cross-sectional study. Five hundred and twenty-seven patients were interviewed; 66 (12.5%) of them had headache as a presenting symptom of brain tumour. In our sample, headache resembled a tension-type headache in 31 patients (6% of all glioma cases) and the classic benign thunderclap headache (BTH) was found in 28 cases (5% of all glioma cases). The paper has been submitted for publication.

- Tumor related Epilepsy - The Center of Tumor-related Epilepsy is Coordinator of Italian League Against Epilepsy (LICE) Study Group on "Brain tumor-related Epilepsy". This group includes 35 Italian epilepsy centers.

The CET is one of the only 4 European Centers, and the only Italian member, included in the world

network on Tumor Epilepsy, the International Brain Tumor-Related Epilepsy Research Consortium:

http://tumorepilepsy.com/index.html

Ongoing Clinical Trials

1. Glioma Project: Glioma, aspetti biomolecolari dal tessuto alla Radiomica. Traslational study. Ongoing

2. Definizione dei temi rilevanti per le cure palliative nei pazienti affetti da neoplasia cerebrale e loro caregivers. (studio ancillare per la produzione di Linee Guida Nazionali Italiane sulle cure palliative in neuroncologia). Ongoing

3. Rational drug repositioning for an efficient and safe combined therapeutic approach to glioblastoma multiforme. Antipsicotic chlorpromazine in combination with temozolomide in first line treatment of un-methylated Glioblastoma patients. A multicentric phase II trial. Ongoing

4. Coagulation/complement activation and cerebral hypoperfusion in relapsing-remitting multiple sclerosis. MoH project. In collaboration with Università di Roma La Sapienza and with Icahn School of Medicine at Mount Sinai, New York, NY, United States. Ongoing

5. Valutazione del valore predittivo dei biomarkers ematochimici trombofilici metabolici ed infiammatori pre-operatori per complicanze post-operatori e per sopravvivenza in pazienti affetti da glioma e da metastasi cerebrali - studio osservazionale retrospettivo. Ongoing

6. A model of comprehensive care and tele-health in brain tumor related epilepsy patients. Ongoing

7. Studio clinico-neuropatologico-molecolare di pazienti affetti da glioblastoma lungo-sopravviventi. Multicentric study (ACC). Ongoing

8. Revision of the module 'EORTC QLQ-BN20': Phase I-III. EORTC QoL group. Ongoing

9. Neurotoxicity prevention with nutracetics in myeloma patients treated with Bortezomib. A Pilot Study. Ongoing

10. Efficacy and tolerability of low dose vs standard doses of AEDs in newly diagnosed epileptic patients (STANDLOW). Multicentric, randomized trial.

11. Studio prospettico osservazionale multicentrico sulle complicanze neurologiche indotte da checkpoint inhibitors.

Psicology Unit

Head: Dr. Patrizia Pugliese, Psychologist

Staff

Alessandro Bonucci, Psychologist
Anita Caruso, Psychologist
Maria Franca Condoleo, Psychologist
Giovanna D'antonio, Psychologist
Chiara Falcicchio, Psychologist
Massimo Giuliani, Psychologist
Lara Guariglia, Psychologist
Sonia Ieraci, Psychologist
Gabriella Maggi, Psychologist
Maria Perrone, Psychologist
Stefania Torelli, Psychologist

Mission

Unit of Psychology is focused on prevention, treatment and rehabilitation of psychological suffering and on quality of life in clinical and research activity.

Clinical Activity

The main clinical approach for achieving these objectives is the integration of psychological care within the medical care in DMT and in the departments of oncology and dermatology, aimed to decrease both the psychological suffering and to improve quality of life. The psychologists use individual, group, couple and family psychotherapies, phone and online support. The clinical activity includes also the mediation of the psychologist in the doctor-patient relationship and in the therapeutic pathway. Other activities are the integration of psychologists with the other professionals involved in the setting of care (nurses and volunteers) and the creation of a network of Lazio psychologists, working in various hospitals and local structures, for a patients correct sending.

The productivity of the Service is in line with the budget negotiation 2020. In accordance with project of humanization, the Psychology Unit has achieved levels of satisfaction in 94% of patients.

Research Activity

Quality of life study

The study "Facilitatori e/o barriere all'accesso al supporto psicologico in pazienti oncologici: uno studio multicentrico" aims to identify the clinical, demographic, psychosocial factors and the pathway of patients sending associated with adherence to psychological support in cancer patients. The study coordinator is IRE, in collaboration with the psycho-oncology structures of the Lazio region.

The multicenter study "Bisogni riabilitativi nelle pazienti affette da carcinoma mammario in fase precoce: l'utilizzo di un approccio basato sul patient reported outcome (PRO), coordinated by IRE and in collaboration with the other italian oncological IRCCS, is based on validation of a PRO questionnaire for the detection in the survival phase of rehabilitation needs in women with early breast cancer.

Translational study

The studies "Epigenetic control of breast cancer progression: animal and clinical studies" (Ministero della Salute) and "Stile di vita come fattore di rischio nella progressione del tumore al seno: indagine sui biomarcatori neuroendocrini e molecolari dello stress" (Fondazione Umberto Veronesi) in collaboration with IRE Medical Oncology and ISS were aimed to elucidate the molecular mechanisms involved in the effects of stress on breast cancer progression both in

animal models and in high risk breast cancer patients.

Since July 2012 to date the clinical study enrolled 80 women (mean age = 50.5). At a median follow up of 20 months 40 women were evaluable for the first analysis.

The results showed that after six months of chemotherapy, patients showed increased levels of depression as well as cortisol and serum chemokine MIP-1b LFA-IV-, which has not only a tumor-promoting role but also is directly related with a poor prognosis. As concern psychological tests no difference emerged after six months after chemotherapy. However, the average score detected using the Beck depression inventory (BDI) indicated mild depression. Interestingly, we found increased levels of BDNF associated to decreased anxiety and depression levels at 12 months' follow-up. Overall, data indicate that psychological factors can affect physiological responses in breast cancer patients. This is especially relevant since stressful events and negative affective states can amplify the consequences of the pathology precipitating disease progression and promoting recurrence. Further analyses are in progress in order to detect disease recurrence and increase the strength of the data.

Phase 1 Clinical Trial Center

Head: Dr. Alessandra Fabi, MD; since December 2020 Dr. Lorenza Landi, MD

Staff

Isabella Bertazzi, Chief nurse
Sonia Di Berardino, Nurse
Elisabetta Canofari, Nurse
Gabriella Lecce, Nurse
Maria Carmela Giordano, Nurse
Marianna Introna, Data management

Mission

According to the overall mission of National Cancer Institute Regina Elena, the goal of the Phase 1 trials Unit is to seamlessly integrate preclinical drug discovery, proof-of-principle phase I trials and tumour-specific evaluation of novel agents. Moreover, because our Institution is formed by Regina Elena and San Gallicano Dermatological Institute, our Center serves as hub for conduction of phase I trials of both Entities.

Ongoing and upcoming studies are involving many of the most promising molecularly targeted agents, immunotherapy and combinations of agents in early phase of development. We assure rigorous study conduction and design. The staff of Phase 1 Unit is directly responsible for patient care and adherence to study protocol.

Clinical and Research Activity

The clinical activities include an inpatient hospital service and outpatient clinics (pre-screening activities and follow-up). All patients are evaluated by a specialized team according to their specific disease condition.

Patients are treated in a dedicated Day Hospital (DH) or in a specific unit. Outpatient visits are performed in a dedicated room and treatment are delivered in a DH service, including 3 chairs and 2 beds. The inpatient service includes 2 beds dedicated to trials procedures and/or adverse events management.

In addition, according to Phase 1 procedures, we guarantee

- Technologies for monitoring and surveillance of patients as a sub-intensive therapy.
- A network of support Clinical Units and Professionals for each type of study prepared according to the AIFA Resolution n. 809/2015
- AIFA conformity certifications for phase 1 studies
- "Temperature controlled" transport systems
- Operating procedures for activities related to the investigation paths and relations with other internal or external structures of the IFO.

In 2020, a total of five studies were active and/or active/recruiting

A. Phase 1 Dose Escalation and Cohort Expansion Study of TSR-042, an anti-PD-1 Monoclonal Antibody, in Patients with Advanced Solid Tumors

B. A phase Ib, open-label, multicenter study (BO40933) evaluating the safety and efficacy of

ipatasertib in combination with rucaparib in patients with advanced breast, ovarian, or prostate cancer

C. BLU-667-1101: A Phase 1/2 Study of the Highly-selective RET Inhibitor, BLU-667, in Patients with Thyroid Cancer, Non-Small Cell Lung Cancer (NSCLC) and Other Advanced Solid Tumors

D. MK-1308-001 Study of Quavonlimab (MK-1308) in Combination with Pembrolizumab (MK-3475) in Advanced Solid Tumors

E. DCC-3014-001: A Multicenter Phase 1/2, Open-Label Study of DCC-3014 to Assess the Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics in Patients with Advanced Tumors and Tenosynovial Giant Cell Tumor.

Future Perspectives

The activity of the Phase 1 Clinical Trials Center is growing with a constant increased number of clinical trials including no-profit Phase 1 studies, First-in-human studies and collaboration with other institutions. Moreover, the medical staff will be increased, with the arrival of additional dedicated oncologists. Participation in multicentric studies and international meetings, will increase Center visibility and patient recruitment. The Center will also undertake general, non-trial specific advertising and screening procedures to recruit potential trial participants, prior to inviting them to participate in a specific trial. Finally, intensive educational activities involving physicians and nurses will be supported by our Center.

Department of Research Advance Diagnostic and Technological Innovation

Director: Prof. Giuseppe Sanguineti

Pathology Unit

Head: Prof. Edoardo Pescarmona, MD

Staff

Mariantonia Carosi, M.D. Pathologist
Renato Covello, M.D. Pathologist
Maria Diodoro, M.D. Pathologist
Ferdinando Marandino, M.D. Pathologist
Mirella Marino, M.D. Pathologist
Letizia Perracchio, M.D. Pathologist
Andrea Russo, M.D. Pathologist
Paolo Visca, M.D. Pathologist
Maria Benevolo, Biologist
Simonetta Buglioni, Biologist
Beatrice Casini, Biologist
Anna Di Benedetto, Biologist
Elisa Melucci, Biologist
Stefania Filippi, Technician
Angela Lattanzi, Technician
Barbara Frollano, Technician
Sabrina Lori, Technician
Patrizia Palmarelli, Technician
Arianna Papadantonakis, Technician
Annarita Pennetti, Technician
Patrizia Scordati, Technician
Barbara Antoniani, Technician
Francesca Romagnoli, Technician
Matteo Bergamaschi, Technician
Cristiana Ercolani, Biologist
Enzo Gallo, Biologist
Francesca Rollo, Biologist
Simona di Martino, Biologist (Biobank IRE)
Valentina Laquintana, Biologist (Biobank IRE)
Claudia Bonomo, Technician
Aldo Palange, Technician

Mission

The Pathology Unit, which represents a pivotal hub for innovative diagnostic services and research programs, has the following missions :

1. To provide the 'state of the art' in pathology, that is crucial for patients' care, allowing disease prevention and treatment in a comprehensive, coordinated and cost-effective manner.

2. To implement the diagnostic expertise setting up novel molecular assays to be applied to diagnosis and care of tumours in the era of precision medicine, facilitating collaborations with the other clinical units.

3. To promote innovative scientific programs, spanning the spectrum from basic to translational disease-oriented research. The participation to multidisciplinary and multicentric research is an essential component of the overall clinical and research mission. Furthermore, as custodians of tumour tissue Biobank, an important role of the Pathology Unit research mission is the proper and authorized use of tumour tissue samples.

Clinical Activity

In 2020 the clinical activities have included as a rule macroscopy and conventional histopathology on biopsy and surgical samples (surgical pathology), cytology on cytological samples (diagnostic cytology), and clinical necroscopy (autopsy). Furthermore, immunohistochemistry, FISH/SISH analysis, HPV detection a/o genotyping, and gene mutational status analysis (by NGS a/o real time PCR analysis) were also routinely performed. In 2020 surgical or biopsy samples from about 10.000 patients have been studied, encompassing the whole spectrum of the main human tumours (in particular urological, lung, breast, head & neck, and colorectal cancers). All cases of malignant tumours have been histologically typed and graded according to the most recent WHO classifications, and pathologically staged (pTNM) according to the latest TNM/UICC edition. Whenever required, ancillary (histochemistry, immunohistochemistry and molecular) studies were performed. In 2020 cytological samples from about 7.500 patients have been studied, including FNAC, effusions, urine and cervico-vaginal cytology. In 2020 about 18.000 tests of diagnostic immunohistochemistry have been performed, including mainly tumour immunohistological typing,

and assessment of tumour prognostic and/or predictive factors. In 2020 about 400 FISH/SISH tests have been performed, mainly in cases of breast and gastric carcinoma (HER2 gene), in cases of lung adenocarcinoma (ALK and ROS1 genes), and in selected cases of 'aggressive' B-cell lymphomas (Bcl2, Bcl6, and c-MYC genes), sarcomas, and primary CNS tumours. In 2020 the mutational status of about 1000 patients with non small cell lung carcinomas (NSCLC), colorectal adenocarcinomas, metastatic melanoma, soft tissues sarcomas and GastroIntestinal Stromal Tumours (GIST) has been studied mainly by Next Generation Sequencing (NGS) procedures, based on different panels of 'target' genes. Furthermore, in 2020 about 650 molecular tests for MGMT promoter gene metilation status, and IDH1-IDH2 genes mutational status in primary CNS tumours, BRCA1-BRCA2 somatic mutational status mainly in ovarian cancer, and MSI evaluation mainly in colorectal cancer (but also in other tumour types) , have been performed.

Research Activity

Breast cancer. We have shown that paracrine signaling from breast cancer cells causes activation of ID4 expression in tumor-associated macrophages. We have studied the prognostic relevance of coagulation activation in risk assessment and stratification in locally advanced breast cancer. We have demonstrated that pyrvinium pamoate induces death of triple-negative breast cancer stem-like cells and reduces metastases; and that aberrant transcriptional and post-transcriptional regulation of SPAG5, a YAP-TAZ-TEAD downstream effector fuels breast cancer cell proliferation. Finally, we have published an observational study on p53 and Bcl2 immunohistochemical expression across molecular subtypes in a large series of early breast cancer patients with long-term follow-up, and we have observed the loss of HER2 and the decreased T-DM1 efficacy in HER2 positive advanced breast cancer treated with dual HER2 blockade.

Colorectal cancer. We have performed by liquid biopsy a cross-sectional analysis of circulating tumor DNA in primary colorectal cancer at surgery and during the post-surgery follow-up, and also showed the presence of a distinctive microRNA (miRNA) signature in the blood of colorectal cancer patients. Further, we have investigated the relationships between TRF2 and VEGF-A and prognosis/survival in colorectal cancer patients, and shown that BRAF status modulates interleukin 8 expression through a CHOP-dependent mechanism in colorectal cancer. In addition, we have demonstrated a direct plasmonic detection of circulating RAS mutated DNA in colorectal cancer patients, and we have performed a multicohort and cross-platform validation of a prognostic Wnt signature in colorectal cancer.

Gynecological & Urological tumours. In cervical carcinoma we have performed a study on the interlaboratory concordance of p16/Ki67 dual-staining interpretation in HPV-positive women in a screening population, we have evaluated the p16/Ki67 and E6/E7 mRNA accuracy and prognostic value in triaging HPV DNA positive patients, and we have assessed the p16/Ki67 adequacy and positivity in HPV-positive women from a screening population. Further, we have investigated the urinary expression of let-7c cluster as non-invasive tool to assess the risk of disease progression in patients with high grade non muscle invasive bladder cancer.

Head & Neck tumours. We have evaluated the Anyplex II HPV28 assay in the detection of human papillomavirus in archival samples of oropharyngeal carcinomas, and we have demonstrated that abnormal cytology in oropharyngeal brushings and in oral rinses is not associated with HPV infection. Further, we have shown that PI3K inhibitors curtail MYC-dependent mutant p53 gain-of-function in head & neck squamous cell carcinoma, and that HPV sensitizes oropharyngeal squamous carcinoma cells to cisplatin-induced apoptosis by inhibiting autophagy through E7-mediated degradation of AMBRA1.

Lung cancer. We have shown that CytoMatrix is a simple and reliable tool for the characterization of lung cancer stem cells from malignant pleural effusions. Further, we have demonstrated the presence of KEAP1-driven co-mutations in lung adenocarcinoma unresponsive to immunotherapy despite high tumor mutational burden.

Soft tissues & bone sarcomas. We have proposed Next Generation Sequencing approaches

for the identification of pathognomonic fusion transcripts in sarcomas, and we have evaluated the diagnostic and clinical impact of 18F-FDG PET/CT in staging and restaging soft-tissues sarcomas of the extremities and trunk. Further, we have published a retrospective analysis on the real-life journey of elderly patients in soft tissues and bone sarcomas.

Radiology Unit

Head: Dr. Antonello Vidiri, MD

Staff

Anelli Vincenzo MD
Bertini Luca MD
Cappelli Federico MD
Caterino Mauro MD
Ciolina Maria MD
Ferranti Francesca Romana MD
Greco Marcello MD
Greco Laura MD
Kayal Ramy MD
Marsella Annelisa MD
Piacentini Francesca MD
Piludu Francesca MD
Pizzi Giuseppe MD
Saracca Elena MD
Vallati Giulio MD
D'Auria Lorenzo, Radiology Techinician C.
Fodde Francesca, Radiology Techinician C.
De Leo Rodolfo, Radiology Technician
Dominici Fabrizio, Radiology Technician
Farella Michele, Radiology Technician
Fetonti Gaetano, Radiology Technician
Fringuelli Stefania, Radiology Technician
Gessani Martina, Radiology Technician
Lattanzi Gianluca, Radiology Technician
Longo Anna, Radiology Technician
Morelli Graziella, Radiology Technician
Pandini Roberto, Radiology Technician
Pasqualucci Rita, Radiology Technician
Portieri Fabio, Radiology Technician
Rea Franco, Radiology Technician
Rinaldi Francesco, Radiology Technician
Tomassini Elisa, Radiology Technician
Trotta Simone, Radiology Technician
Sglavo Anna Rita, Radiology Technician
Strino Giulio, Radiology Technician
Rosi Fabio, Coordinator ff Nurse
Annibali Cristina, Nurse
Cicconardi Alba, Nurse
Del Vecchio Serena, Nurse
Fantozzi Roberto, Nurse
Ferraro Matteo, Nurse
Guido Franco, Nurse
Schiavone Raffaella, Nurse
Tolu Sebastiano, Nurse
Boi Cristina, Administrative Coll.
Settembrini Cristina, Administrative Coll.
Farella Flavia, Administrative Coll.

Mission

The mission of the Radiology Unit is diagnosis and staging of the tumor, target for surgical and radiotherapy treatments, guide patient stratification, predict and monitor therapeutic efficacy. In the Unit there are two MR at 1.5 T and 3T, two multidetector CT at 128 and 68 Layers, Ultrasound with color-doppler and with use of contrast-medium and Elastosonography, Digital Mammography, Contrast Enhanced Mammography (CESM), Digital Breast Tomosynthesis (DBT) and Mammotome. There is an Interventional Service image-guided for diagnosis and treatment of neoplasms. Topics are: evaluation of head-neck and prostate cancer, lung cancer and pleural mesothelioma, integrated breast diagnostic, neuro-oncology, soft and osseous tumors.. The department is also involved in all diagnostic therapeutic ways (PDTA) and participates in all Disease Management Team (DMT) meetings.

Clinical Activity

The clinical diagnostic activity includes detection, characterization and monitoring of the tumors, utilizing Traditional X-ray, Ultrasound, CT, MR, and Mammography that are performed every day (morning and afternoon) except Saturday afternoon. The Interventional service is open from Monday to Friday. MR unit offers service as functional imaging, diffusion and perfusion, in brain, head-neck, breast, soft tissue neoplasms and prostate tumors; in the Breast unit is possible to obtaine biopsy image-guided with mammotome, Digital Mammography, and Digital Breast Tomosynthesis (DBT). In US is possible to perform exam with contrast medium infusion in particular in the evaluation of liver lesions. In the Interventional unit are performed biopsy and treatment with thermoablation, radiofrequences and with the use of radionuclide (Sirtex).

Is possible to obtaine prostate biopsy with fusion imaging between MR and US.

Research Activity

- Radiomic: involves the analysis and translation of medical images into quantitative data with

the underlying hypothesis that imaging reflects not only macroscopic but also the cellular and molecular properties of tissues. The objective of radiomics is to generate image-driven biomarkers that serve as instruments that provide a deeper understanding of cancer biology to better aid clinical decisions. We are using this techinique in lung, in patients underwent surgery, in head and neck in the differentation of parotid tumor and in liver tumors, in patients with metastases from colon carcinoma underwent surgery after chemotherapy.

- Radiogenomic : field of research aimed at developing tools for non-invasive genotyping by identifying imaging biomarkers for genomic subtypes. Radiogenomic analysis refers to the integration of radiophenothypes and genomic data in order to find radiogenomic association. A correlation study is underway between CT radiomic features and specific drivers mutational status of NSCLC.

- In Head and Neck tumors underwent surgery we investigate the correlation between the parameters identified by perfusion imaging (neo-vascularization) and diffusion (cellularity and stroma) with those of the immunohistochemistry and digital pathology, RNASEQ, and with the immunoprofiling of the cells of the immune system in the periphery.

- Investigate the possibility to obtaine before treatment diagnostic elements predictive of the response to treatment.

- Multiparametric-MR prostate studies before and after therapy, in particular in the evaluation of the alterations after radiotherapy compared with those PET-CT scan.

- Neo-adjuvant treatments using 3T MR with functional sequences (diffusion and perfusion) in the sarcomas, osteosarcoma and Ewing sarcoma.

- In the Interventional service we use targeted therapy dosimetry - guided that may significantly impact on patient's specific therapy selection and treatment.

- In the brain tumors we are investigating correlation between MR imaging with those pathological date and molecular profile (Glioma Project).

Radiotherapy Unit

Head: Prof. Giuseppe Sanguineti, MD

Staff

Pinnarò Paola, MD
Saracino Bianca Maria, MD
Marucci Laura, MD
Petrongari Maria Grazia, MD
Farneti Alessia, MD
Faiella Adriana, MD
Francesco Dionisi, MD
Serena Nucciarelli MD
Silvia Takanen MD
Di Ridolfi Paolo, Nurse coordinator
Avram Camelia, Nurse
Bigiarini Luciano, Nurse
Mondati Mara, Nurse
Pacella Rossella, Nurse
Petitti Patrizia, Nurse
Giardina Giuseppa Barbara, Nurse
Angelica Borges da Silva, Nurse
Lunghi Vincenzo, Therapist coordinator
Bedini Fabio, Therapist
Canciani Laura, Therapist
De Luca Francesco, Therapist
Di Giammaria Flavio, Therapist
Gabriele Teresa, Therapist
Labonia Alessandro, Therapist
Mafrica Carmelo, Therapist
Marcelli Francesca, Therapist
Marini Roberto, Therapist
Mei Stefano, Therapist
Musella Giuseppe, Therapist
Pepe Stefano, Therapist
Rispoli Antonio, Therapist
Vorzillo Maria, Therapist
Marco Zucca, Therapist
Riccardo Petrotta, Therapist
Iacopo Costantini, Therapist
Ilaria Valenti, Therapist
Francesca Checquolox, Therapist
Monica Montano, Therapist
Francesca Corti, Therapist
Francesca Cascino, Therapist
Parodi Laura, Administrative assistant
Moretti Luisa, Administrative assistant
Franzoso Paola, Data manager
Ilaria Farina, Study Nurse

Mission

The Department of Radiotherapy is characterized by experienced professionals and technology that allow the realization of high-precision irradiation techniques such as Intensity Modulated Radiotherapy (IMRT), Rapid Arc (RA)/Volumetric Modulated Arc Therapy (VMAT), Stereotactic Radiotherapy Surgery (SRS) and Stereotactic Body Radiotherapy (SBRT). Image guidance is achieved with cone beam CTs or DRRs. The latter ones are implemented within the Cyberknife system to track the position of the target in real time. Moreover, respiratory movement control techniques are available to reduce the confounding effect of the position of the target to be irradiated. A constant collaboration with the Radiology and Nuclear Medicine allows us to have access to advanced imaging solutions to correctly identify the location of the disease prior to treatment planning, such as multiparametric MRI and novel tracer PET-CT.

Clinical Activity: Clinical activity covers all options of photon-based external beam radiotherapy including IMRT, VMAT, SRS, SBRT, IORT. Moreover, the recent introduction of Cyberknife (CK) allows SRS/SBRT of both intracranial and extracranial lesions (both malignant and benign) with high precision and live motion tracking.

Research and Clinical Activity

1. Induction Durvalumab (MEDI4736) & Radiotherapy (RT) for Locally Advanced but Resectable Head and Neck Squamous Cell Carcinomas: A Pilot Study. The study will evaluate the feasibility/activity of upfront Durvalumab-RT before standard of care treatment in patients with locally advanced but resectable HNSCC. RT consists of low dose multifractionated RT (10 Gy in 4 fractions) to the primary tumor site only; Durvalumab at the dose of 1500 mg will be delivered on day 0 of preoperative radiotherapy

a. Four weeks after preoperative radio-immunotherapy (day 28) patients will undergo surgery
b. Patients will be evaluated during both the induction phase and perioperative period for side effects and tolerance. Moreover both clinical and pathological response rates will be investigated.

2. A prospective randomized phase II trial of DCE-MRI hypoxia-targeted boost chemoradiotherapy for head and neck cancer. This is a randomized, prospective, single-institution, phase II trial, planning to enroll 91 patients affected by HNSCC. Patients will undergo a DCE-MRI before treatment (baseline, MR1). Only patients with at least 5cc or more hypoxic volume at the primary site will be considered eligible and randomized between stIMRT and deIMRT. A second DCE-MRI will be performed at 2 weeks into CRT (MR2), and the hypoxic volume will reassessed; in case of a larger than initial hypoxic sub-volume, the IMRT plan in the deIMRT arm will be adapted accordingly. Patients will then be followed for primary tumor response and recurrence. Actuarial Kaplan Meier) local control rates in the two arms will be compared with the log rank test at 2 yrs after treatment completion.

3. Phase I-II study to evaluated feasibility and the effectiveness of SBRT with Linear Accelerator in 3 fractions for low/intermediate risk Prostate cancer: evaluate the feasibility and locoregional toxicity of SBRT in 3 fractions using LINAC; evaluate the effectiveness hypofractionated "extreme" (3 fractions) delivered using SBRT for low /intermediate risk localized prostate cancer.

4. Evaluation of neurotoxicity in cancer patients with multiple (4-10) brain metastases treated with stereotaxic radiation therapy : This is a prospective observational study that aims to evaluate neuro-cognitive toxicity, quality of life and incidence of radionecrosis in patients treated with stereotactic radiation therapy for multiple lesions (from 4 to 10).

5. Radio-induced modifications of lymphoid subpopulations involved in resistance and escape mechanisms to the treatment of localized prostate cancer: This prospective study aims to evaluate the effect of radiotherapy on immuno-regulatory B, plasma cells, NK, T, and T lymphocyte populations in order to evaluate any toxicity effects and selective decrease / increase of the various populations and to correlate these effects with the clinical course of the disease. We hypothesize that the radio-induced effects are extremely early, to justify an investigation already after the first treatment session. Furthermore, we hypothesize that different RT dose fractionation schemes may induce different modifications on cell populations, allowing to identify scheduling that minimizes the risk of induction of immunosuppressive cells.

6. Toxicity and its possible association with the immune response during Radio-Cetuximab therapy in Patients with Squamous Carcinoma of the Head and Neck District, stage III or IV disease. This is a prospective cohort study aimed at assessing the impact of systemic therapy with cetuximab associated with radiation therapy on the burden of acute symptoms of the treatments proposed in locally advanced squamous carcinomas of the cervicocephalic district. It also investigates the possible correlation between activation of the ADCC and skin toxicity. For the objectives, see the statistical considerations.

7. Pilot study evaluating the use of 64Cu-PET / CT total body in patients with recurrence in the prostate lodge visible in mpMR. The study in question has the following objectives:

    a. Primary objective: To evaluate the detection rate of 64Cu-PET / CT of relapses in patients undergoing radical prostatectomy and subsequent biochemical recurrence;
    b. Secondary objectives: To evaluate any change in radiotherapy strategy in terms of lesion delineation and dose distribution planning. Evaluate the performance of both methods (mpMR and 64Cu-PET / TC) in evaluating the response to radiation treatment with or without hormone therapy

8. Single vocal cord stereotactic Radiotherapy for early stage glottis cancer (cTis-1): Prospective phase I-II study to evaluated feasibility and the effectiveness of SBRT for early stage (cTis-1N0M0) glottic cancer.

9. Accelerated Hypofractionated radiotherapy inclusive of nodal radiation after conservative surgery for women whit node-positive breast cancer. Feasibility study. To evaluated acute toxicity of radiotherapy schedule in which therapy was completed in 11 fractions over 3 weeks inclusive of a sequential boos.

10. Longitudinal Evaluation of Intestinal, Haematological and Urinary Toxicity From Pelvic Irradiation for Prostate Cancer (IHU-WPRT-TOX): The aim of this study is to develop predictive models of IMRT-WPRT induced patient-reported intestinal, hematologic and urinary toxicity in PCa treatment.

11. The rationale of the prophylactic irradiation of pelvic lymph-nodes by means of Whole-Pelvis Radiotherapy (WPRT) in prostate cancer (PCa) is to eradicate subclinical lymph-nodal involvement. Even though delivered by means of modern Intensity-Modulated Radiotherapy techniques, WPRT may result in intestinal, hematologic and urinary toxicity severely affecting patients' daily health- related quality-of-life (HRQoL) within the so-called and inadequately investigated Pelvic Radiation Disease.

12. A Randomized, Double-blind, Placebo-controlled Phase 3 Study of JNJ-56021927 in Subjects with High-risk, Localized or Locally Advanced Prostate Cancer Receiving Treatment with Primary Radiation Therapy: To determine if JNJ-56021927 plus gonadotropin releasing hormone (GnRH) agonist in subjects with high-risk, localized or locally advanced prostate cancer receiving primary radiation therapy (RT) results in an improvement of metastasis-free survival (MFS) evaluated by blinded independent central review (BICR)

13. DUE02 - Urinary and Erectile Dysfunction – 02. Validation of predictive toxicity models after radiotherapy treatment for prostate cancer: The prospective observational study (DUE02) proposes to enroll patients with prostate cancer treated with high-dose external radiotherapy and to follow them during follow-up, in order to be able to validate the models developed in the previous study DUE01 on an independent population.

14. Acral Chordoma: a Randomized & Observational study on surgery versus definitive radiation therapy in primary localized disease (SACRO): This study is aimed at estimating the effectiveness of definitive radiotherapy as compared to standard surgical treatment for patients with primary sacral chordoma who are candidates to a complete en-bloc resection, in term of relapse-free- survival (RFS).

15. A Randomized, Phase 3, Double-Blind Study of Chemoradiotherapy With or Without Pembrolizumab for the Treatment of High-risk, Locally Advanced Cervical Cancer (KEYNOTE-A18 / ENGOT-cx11): the primary objective is to compare concurrent chemoradiotherapy plus pembrolizumab with concurrent chemoradiotherapy plus placebo with respect to progression-free survival per RECIST 1.1 as assessed by blinded independent central review or by histopathologic confirmation of suspected local disease progression (in the absence of radiographic disease progression per RECIST 1.1).

16. 1Sbrt±Tad for Unfavorable iNtermediate risk/high risk prostate cancer (STUNNIN): a Randomized Phase II Study: The primary objective of the study is 3-yr bNED survival. If bNED survival is not significantly different between the two experimental arms, the one without AD will be chosen in a future comparison with the standard of care.

17. Granisetron transdermal system (GTDS) in preventing nausea and vomiting induced by cisplatin-based chemotherapy and concurrent radiotherapy for head and neck cancer: the primary objective is to evaluate the activity of Snacuso patch in controlling nausea and vomiting in patients with HNC undergoing chemo-radiotherapy treatment.

18. Radio-Hyperthermia in soft tissue sarcomas: MRI and PET functional imaging response criteria related to anatomo-pathological and clinical data: Primary endpoint is to evaluate the diagnostic accuracy of the various PET and post-therapy MRI parameters (alone or in combination) in predicting histological response to radiotherapy/hyperthermia.

Nuclear Medicine Unit

Head: Dr. Rosa Sciuto, MD

Staff

Alessio Annovazzi, MD
Serenella Bergomi, MD
Lutathera Pasquale Iannantuono, MD
Costanza Mazzone, MD
Rosella Pasqualoni, MD
Sandra Rea, MD
Luisa Romano, MD
Silvia Di Traglia, Fellow
Salvatore Annunziata, MD
Aura D'Arcangeli, Head Nurse
Gaetano Salviati, Chief Technician

Mission

The mission of the Nuclear Medicine Unit is to perform clinical and research activities in nuclear oncology aiming to the following main objectives:

- Achieve professional exellence both in nuclear diagnostics and in nuclear therapy according national and international standards
- Develope and validate innovative technologies and new radiopharmaceuticals for molecular imaging and molecular target therapy in the context of theranostic models
- Transfer research results into clinical practice and national health system program
- Monitor process influence on final outcome according to a vision of a process-oriented culture and patient's centered care

Clinical Activity

The activities of the Nuclear Medicine Unit focus on clinical research directed towards therapy and diagnostics in main oncology fields. In 2018 over 16.000 therapeutic and diagnostic procedures were performed with approximately 300 cancer radionuclide treatments. Standard of all diagnostic and therapy activities are assured by ISO 9000 and professional quality certification is assured by AIMN-Bureau Veritas.

1. Therapy, as the main field of clinical activities, includes the radionuclide treatment of thyroid carcinoma, liver tumors, bone metastases using both beta emitters and alfa-emitters and Neuroendocrine Tumors using 177 -Lu Oxodotreotide. The Centre is leader in Italy and Europe in the field of selective internal radiation therapy of liver tumors with more than 1000 treatment performed and followed. Biological optimization of radiation dose studies have been performed using new algorithms and integrated imaging to evaluate heterogeneous dose distribution in tumor lesions and to develop personalized therapy plans. Training on innovative treatments with new alfa-emitters radiopharmaceuticals were performed and clinical protocols validated

2. Diagnostics includes: - PET / CT imaging with FDG and non FDG tracer and in particular the Centre is leader in F-Choline PET imaging of prostate cancer and FDG PET imaging of musculoskeletal tumors ; - all traditional planar and SPET oncological scan (mainly sentinel node mapping, cardiac gated-SPET and 131I whole –body scan) and state of art SPET/CT

imaging

Research Activity

Research activities of the Nuclear Medicine Unit focus on radionuclide therapy and molecular imaging SPET/CT and PET/CT in different tumors (thyroid, head and neck, sarcoma, gynecological and urological tumors, lymphoma, breast and lung cancer, liver tumors) aiming to improve early diagnosis, biological characterization and response monitoring, biological volume contouring to guide radiotherapy.

Main currently specific topic of research includes:

- new PET radiopharmaceuticals (64-Cu and 64 Cu-PSMA) performance and safety evaluation in prostate cancer
- F-choline diagnostic performance in early prostate cancer recurrence detection at low PSA values
- clinical impact of SPET/CT vs. to standard planar or SPET protocols in oncology
- comparison of clinical impact and cost-effectiveness of different available diagnostic technologies of bone imaging (bone scintigraphy vs. F-choline PET)
- role of FDG PET in clinical management of musculoskeletal tumors
- biodistribution, radiobiological effects and long –term safety studies after treatment with alfa –emitter (223-radium) in metastatic prostate cancer patients and adapted protocols
- role of integrated imaging with 131I SPET/CT and 18F-FDG PET/CT in advanced thyroid carcinoma both for diagnosis than for biological and dosimetric optimization
- identification of specific selective internal radiation therapy with 90Y- and 166 Ho -microspheres indications in the context of the standard HCC guidelines
- quantitative 3D dosimetry based on hybrid imaging and biomarkers correlation to optimize therapy in HCC patients treated with 90Y and 166-HO microspheres and in NET tumors treated with 177- Lu - Oxodotreotide.

Clinical Pathology and Cancer BioBank Unit

Head: Dr: Laura Conti, MD, PhD

Staff

Antenucci A. Biologist
Cigliana G. Biologist
Cochi S. Biologist
Cordone I. MD, PhD
D'Alessandro M.G. Biologist
Digiesi G. MD
Mandoj C. Biologist
Martayan A. Biologist
Masi S, BS. PhD
Merola R. Biologist
Orlandi G. Biologist
Vercillo G. MD
Spinosa Patrizia. Technician
Ascani R. Technician
Attanasio M. Technician
Autullo L. Technician
De Bellis F. Technician
Del Carlo C. Technician
Giommi S. Technician
Lattanzio C. Technician
Pasquale A. Technician
Pisani S. Technician
Haoui M. Technician
Preziosi E. Administrative Collaborator

Mission

Clinical Pathology performs laboratory biological tests using the most modern techniques of investigation, that contribute to the clinical management of oncologic patients submitted to conventional and experimental therapies.

The Unit participates as a Reference Laboratory in the activities of the "Centro Studi Early Phase" (CSEP) for Phase 1 studies and supports "Clinical Trial Center" (CTC) activities for the subsequent Phase studies. Since 2014 Laboratory has been involved in the development of an Institutional Biobank as a strategic link between clinical and research activities. The research program is focused on the identification and validation of cancer-related molecular targets, the utilization of new technical approaches for tumor diagnosis, prognosis and monitoring in the context of innovative cancer therapies, for the best bench-to-bedside clinical research application.

The Clinical Pathology has already been certified with a UNI EN ISO 9001:2015

Clinical Activity

In 2020, about 1,000,000 examinations were carried out return of 4.000.000 Euro.

Onco-haematology

Innovative activities include the Primary Central Nervous System Lymphoma diagnosis by flow cytometry (FC) through disaggregation of a single brain stereotactic core biopsy for a better classification and management of brain lesions; leptomeningeal metastasis diagnosis and monitoring by cerebrospinal fluid FC and Minimal Residual Disease assessment in Multiple Myeloma by an original FC strategy of analysis based on intra-cytoplasmic immunoglobulin (cy-Ig) light chains ratio evaluated on patient-specific plasma cells immune profile. More recently the FC studies include an innovative antibodies combination for MM MRD assessment in patients undergoing anti-CD38 (daratumumab) treatment.

Molecular Diagnostics

Liquid biopsy

In Non Small Cell Lung Carcinoma (NSCLC) patients liquid biopsy allows to identify patients whose tumors have specific EGFR mutations, thus making them eligible for EGFR-targeted therapies (e.g. erlotinib). Liquid biopsy in these patients is also a valuable tool for the monitoring of disease progression and for the detection of mechanisms of resistance to EGFR-targeted therapies, e.g. EGFR T790M mutation. The early detection of T790M mutation is of great clinical value for switching to 3rd generation therapies (e.g. osimertinib - Tagrisso). The latter has been also approved by FDA as first-line treatment for EGFR+ NSCLC patients. Almost 400 plasma samples have been analyzed so far.

Hereditary Cancer syndromes (HCS)

Genetic testing with NGS technology on the genes associated with the most frequent HCS such as: Lynch syndrome (LS), Hereditary Breast and Ovary Cancer syndrome (HBOC), APC-associated polyposis and MUTYH-associated polyposis (AAP and MAP) and Multiple Endocrine Neoplasia syndrome type 1 and type 2 (MEN1 and MEN2). Moreover, in selected cases, a pan-hereditary cancer panel (HCS - Sophia Genetics) with 27 cancer-associated genes is used. As to Hereditary Colorectal Cancer (HCC), a custom gene panel has been developed including POLE, POLD1, NTHL1, MSH3, BMPR1A, GREM1 and SMAD4 genes and been will be used for patients with diagnosis suspicion of HCC and no mutations in the genes included in the above-mentioned HCS panel. Pheochromocytoma and Paraganglioma

Pheochromocytoma and paraganglioma are rare tumors that arise from neural crest tissue: pheochromocytoma forms in the adrenal medulla whereas paragangliomas form outside the adrenal gland. Certain inherited disorders increase the risk of both tumors: MEN2, von Hippel-Lindau (VHL), Neurofibromatosis type 1 (NF1) and Hereditary Paraganglioma Syndrome. According to the diagnosis suspicion of either of the above-mentioned syndromes genetics testing of the specific disease-related genes will be performed.

Hereditary Hemochromatosis and Porphyria

Hereditary hemochromatosis (HH) is a clinically and genetically heterogeneous disorder of iron metabolism. To date, five different forms of the disease and corresponding genes (HFE, HAMP, HJV, TFR2 and SLC40A1) have been reported. According to the diagnosis suspicion of either of the different forms of the disease genetic testing of the specific gene is performed.

Porphyria is a rare hereditary disease characterized by an abnormal metabolism of the hemoglobin. There are two general categories of porphyria: acute, which mainly affects the nervous system, and cutaneous, which mainly affects the skin. According to the clinical manifestations of the disease genetic testing of the associated genes (UROD, ALAS2, HMBS, PPOX, FECH) is performed.

Pharmacogenetics

Pharmacogenetics in oncology is of a great significance because of the narrow therapeutic index of chemotherapeutic drugs and the risk for life-threatening adverse effects.

5-Fluorouracil (5FU) is a fluorinated pyrimidine analogue commonly used in combination chemotherapy regimens for patients with breast, colorectal, lung, and other malignancies. Dihydropyrimidine dehydrogenase (DPD), an enzyme encoded by the DPYD gene, is the rate-limiting step in pyrimidine catabolism and deactivates more than 80% of standard doses of 5FU and the oral 5FU prodrug capecitabine. Therefore, according to EMA (European medicine Agency), AIFA(Agenzia Italiana del Farmaco) and AIOM (Associazione Italiana Oncologi Medici) recommendations, testing the presence of severe toxicity-associated polymorphisms in DPYD gene is performed before treatment upon request by clinicians. Irinotecan is a commonly applied anticancer drug whose activity is regulated by the enzyme UDP-glucuronosyltransferase 1A1 (UGT1A1). Several genetic variants within the UGT1A1 gene are known to be associated with reduced UGT1A1 enzyme activity with an increased risk for irinotecan-related severe toxicity. Therfeore, as of AIOM recommendations, pre-therapeutic UGT1A1 genotyping to reduce the risk

severe toxicity is also performed.

Cytogenetics

Cytogenetics play a role in pathogenesis of hematolymphoid malignancies and precursor lesions, including acute myelogenous and lymphoid leukemias, myelodysplasias, myeloproliferative disorders, and lymphomas. Chromosomal alterations in these genes are known to have clinical significance in diagnosis, prognosis, response to therapy, disease monitoring. Cytogenetic Lab is actively involved in clinical activity of Haematology Unit (PDTA Leucemia Acuta, PDTA Mieloma Multiplo, PDTA Leucemia Mieloide Cronica).

Research Activity

Diagnostic harmonization initiative on Multiple Myeloma for Gruppo Laziale Mieloma Multiplo (GLMM).

The project aims to reach a consensus among regional laboratories specialized on onco-haematology diagnosis regarding the flow cytometry antibodies panel, data analysis and clinical report for Multiple Myeloma (MM) diagnosis and monitoring.

The network is also focusing on the positive selection of the plasma cell population by immune-magnetic beads separation, for a better assessment of the cytogenetic profile in plasma cell disorders.

New forms have been designed, approved and introduced on RedCap, the clinical and laboratory data base shared among all the GLMM Centers. The new collection forms focus on cytogenetic and immunophenotype data of MM patients at diagnosis and on follow up.

A National project is ongoing to create an "Italian MM MRD network" that will share the same method for MRD analysis in MM patients across hub-Haematology centers in Italy. The most common employed methods for MRD evaluation (both flow cytometry and molecular biology-based) will be harmonized among the involved "start-up" centers.

Role of Che-1 in transgenic mouse model of Multiple Myeloma

In collaboration with the SAFU laboratory, we investigated the role of Che-1, a RNA binding protein witch is involved in the control of transcription and cellular proliferation by regulating the state of the chromatin and by increasing its accessibility in Multiple Myeloma (MM). In particular we performed Serum Protein Electrophoresis (SPEP) to detect the levels of monoclonal immunoglobulins in serum of the Vk*Myc transgenic mouse model, which, through activating c-Myc oncogene in maturing B cells, recapitulates the pathogenesis and clinical manifestations of human MM, including progression from MGUS to plasma cell expansions (Chesi et al.; Cancer Cell 2008). At this purpose CD138+ neoplastic cells were isolated from the bone marrow (BM) of these mice and manipulated for knockdown of Che1 by siRna and transplanted into 5 recipient wild-type mice for each group. The delay in disease progression in Che-1 depleted MM cells, it was been recognize by analyzing the levels of monoclonal immunoglobulins in murine serum, as a distinct band (M-spike).

Urine monoclonal Free Light Chains

In collaboration with the Protein Study Group of Italian Society of Clinical Biochemistry and Molecular Biology (SIBioC) in the last year we participated in the revision and update of the "Consent document for the research and quantification of the BENCE JONES protein". The document is now being published. . With same national Group we started in 2020 a collaboration on new project for the harmonization of serum Electrophoresys and Immunofixation reporting aimed at drafting a national consensus document

Upper extremity venous thrombosis in cancer patients with peripherally inserted central inserted catheters

Symptomatic PICC related deep venous Thrombosis (DVT) are frequent in cancer patients receiving chemotherapy. In collaboration with the Vascular Access Management Team we conducted a retrospective cohort study in cancer patients who underwent PICC placement for the administration of chemotherapy to evaluate the incidence of upper extremity venous thrombosis (UEVT) and establish the most predictive risk factors for the development of PICC-related thrombosis in cancer patients during chemotherapic treatment, for the future design of an integrated care pathway (ICT) that could be used to prevent thrombotic events. All patients were followed for a minimum of 6 months after PICC insertion, unless they died during this period. Factors previously associated with catheter-related thrombosis, including side of catheter placement, tip location, tumor type, inherited and acquired thrombophilia and environmental factors have been evaluated. The data collection study allowed to highlight a decrease in the incidence of the number of DVT events from 6.8% to 2.9%.

Accurate dosimetry and biomarkers improve survival in HCC patients treated with resin 90Y-μspheres: a randomized trial

Hepatocellular Carcinoma (HCC) is the most frequent liver primary tumor worldwide. An increasing amount of evidence supports the effectiveness of Yttrium-90 (90Y) labeled microspheres to treat intermediate and advanced disease in these patients. The trial (in collaboration with Medical Physics Laboratory, Nuclear Medicine and Radiology Departments) aims at demonstrating that a robust patient-specific dosimetry associated with PIVKA-II analysis improves the patients' survival compared with standard BSA (Body Surface Area) method.

Radio-induced modifications of lymphoid subpopulations involved in resistance and escape mechanisms to the treatment of localized prostate cancer.

Aim of the study is to evaluate the effect of radiotherapy (RT) on immuno-regulatory B and T lymphocyte subpopulations (Breg and Treg) and plasma cells and possible correlations with the clinical course of the disease and acute and late toxicity.

The flow cytometry characterization developed in our laboratory allowed the identification of Treg and Breg peripheral blood subpopulations through the acquisition of a high number (> 5000) of regulatory cells using innovative acquisition and analysis strategies. Twenty-one patients were analyzed before treatment (T0), 3 hours after the first RT session (T1), after an average dose of 24 Gy (T2), after the last RT session (T3), at + 6 months (T4) and at + 12 months (T5) after RT. Six patients entered the study and were analyzed also before hormono-therapy (T-1) for a total of 135 characterization. Analysis of the regulatory sub-populations modulation and modifications are ongoing.

Cerebrospinal fluid (CSF) flow cytometry in the diagnosis of leptomeningeal disease in onco-haematology.

Cerebrospinal fluid (CSF) flow cytometry has a crucial role in the diagnosis of leptomeningeal disease in onco-haematology. We are evaluating the cytometry characterization of 138 CSF samples from patients affected by non-Hodgkin lymphoma, negative for disease infiltration. The aim is to focus on the CSF non-neoplastic population, to compare the cellular composition of the CSF with paired peripheral blood samples and to document the feasibility of flow cytometry in hypocellular samples.

Preliminary results have documented that T lymphocytes aree the most abundant subset in CSF with a predominance of CD4-positive over CD8-positive T cells (CD4/CD8 ratio = 2) together with a minority of monocytes. No B cells are present. The differences between CSF and paired peripheral blood lymphoid phenotype is under evaluation to investigate the existence of an active mechanism of lymphoid migration through the meninges.

Coagulation/complement activation and cerebral hypoperfusion in relapsing-remitting multiple sclerosis

Multiple sclerosis (MS) is a demyelinating disease of the central nervous system with an underlying immune-mediated and inflammatory pathogenesis. Innate immunity, in addition to the adaptive immune system, plays a relevant role in MS pathogenesis. It represents the immediate non-specific defense against infections through the intrinsic effector mechanism "immunothrombosis" linking inflammation and coagulation. Moreover, decreased cerebral blood volume (CBV), cerebral blood flow (CBF), and prolonged mean transit time (MTT) have been widely demonstrated by MRI in MS patients. We hypothesized that coagulation/complement and platelet activation during MS relapse, likely during viral infections, could be related to CBF decrease. Our specific aims are to evaluate whether there are differences in serum/plasma levels of coagulation/complement factors between relapsing-remitting (RR) MS patients (RRMS) in relapse and those in remission and healthy controls as well as to assess whether brain hemodynamic changes detected by MRI occur in relapse compared with remission. This will allow us to correlate coagulation status with perfusion and demographic/clinical features in MS patients. This is a multi-center, prospective, controlled study. RRMS patients (1° group: 30 patients in relapse; 2° group: 30 patients in remission) and age/sex-matched controls (3° group: 30 subjects) will be enrolled in the study. Patients and controls will be tested for either coagulation/complement (C3, C4, C4a, C9, PT, aPTT, fibrinogen, factor II, VIII, and X, D-dimer, antithrombin, protein C, protein S, von-Willebrand factor), soluble markers of endothelial damage (thrombomodulin, Endothelial Protein C Receptor), antiphospholipid antibodies, lupus anticoagulant, complete blood count, viral serological assays, or microRNA microarray. Patients will undergo dynamic susceptibility contrast-enhanced MRI using a 3.0-T scanner to evaluate CBF, CBV, MTT, lesion number, and volume. Our work aims to identify a link between activation of the coagulation / complement system and cerebral hypoperfusion that could improve the search for new biomarkers and molecular and / or imaging targets, leading to the development of new effective therapeutic strategies in MS.

Coagulation/complement activation and cerebral hypoperfusion in relapsing-remitting multiple sclerosis

Multiple sclerosis (MS) is a chronic immune-mediated inflammatory demyelinating and degenerative disease of the central nervous system. It has been demonstrated that not only adaptive immunity but also innate immune system plays a relevant role in MS pathogenesis. There are several studies supporting coagulation/complement and platelet involvement in the innate immune response in MS by linking inflammation and coagulation. Beyond, decreased MRI cerebral blood volume and flow (CBV, CBF), and its prolonged mean transit time (MTT) have been demonstrated in all forms of MS.

This is a multicenter, prospective, controlled study. Informed and consenting MS patients [1st group: 30 relapsing patients; 2nd group: 30 patients in remission] and 30 age and gender controls (3rd group) will be enrolled in the study.

Our study is based on hypothesis that coagulation/complement activation due to inflammatory-thrombotic processes in the course of MS relapse could determine cerebral blood flow deceleration.

The specific aims of the study are to evaluate both in patients and controls:

- The serum/plasma concentrations of coagulation/complement factors
- Absolute cerebral blood flow (CBF), blood volume (CBV) and mean transit time (MTT), by dynamic susceptibility contrast-enhanced 3.0-T MRI
- The correlation between the serum/plasma levels of coagulation/complement factors with both MRI perfusion data and demographic/clinical (age, gender, disease duration, disability) features of MS patients

The relationships between the laboratory and clinical data and the MRI perfusion findings could lead to the development of new effective therapeutic strategies in MS.

Use of antibody tests for screening and prevention of the transmission of the infection from Pilot Observational Study

The aim of this study, according to the WHO guidelines, is the implementation ofa validation study of serological tests for the search for antibodies to SARS-Cov-2 and the

possible relationship with an asymptomatic carrier status, ongoing infection or complete recovery with protective immunity.

The first phase for validation will be the evaluation of the prevalence of the positive examination in some populations of subjects belonging to the IFO and the comparison of the results between the different types of test.

The data collected will allow to evaluate the effectiveness of the immunological diagnostics of the infection and contribute to validate the immunological profiles correlated with the status of asymptomatic infection or with pictures of complete recovery with acquisition of protective immunity and they will also be able to provide key elements for defining the procedures necessary to ensure COVID-FREE nosocomial realities.

At first 300 informed and consenting health workers will be enrolled and only in a later time we will examine 150 serum of cancer patients stored in our Biobank and enrolled previously.

Medical Physics and Expert Systems Unit

Head: Interim head Dr. Valeria Landoni, Medical Physicist, head from 1st October 2020: Dr. Antonella Soriani, Medical Physicist

Staff

Vicente Bruzzaniti, Medical Physicist
Bartolomeo Cassano, Medical Physicist
Marco D'Andrea, Medical Physicist
Giuseppe Iaccarino, Medical Physicist
Anna Ianiro, Medical Physicist
Erminia Infusino, Medical Physicist
Valeria landoni, Medical Physicist
Simona Marzi, Medical Physicist
Pedro Luis Ordonez, Medical Physicist
Antonella Soriani, Medical Physicist
Sara Ungania, Medical Physicist,
Giampiero Carlino, Technician
Sandro Carpino, Technician
Stefano Luppino, Technician
Sandro Nocentini, Technician
Francesco Quagliani, Technician
Mariola Downar, Technician
Emiliano Loi, Fellow, Physicist in training
Marica Masi, Fellow, Physicist in training
Elena Solfaroli Camillocci, Fellow, Kapis Otieno, Physicist in training
Giuseppe Anastasio, Fellow

Mission

The Medical Physics Department (MP Dpt) collaborates with different departments of the hospital to ensure patient safety and to lower clinical risk. Its activities are addressed to reduce the undue dose to patients, workers and environment according to national and international indications and to optimize the technical aspects in all the activities that are based also on the use of other physical agents, such as magnetic resonance, ultrasounds and lasers. The MP Dpt takes part to the installation, commissioning and acceptance testing of high technology equipment and acts to improve diagnostic accuracy and treatment precision through the implementation of quality assurance protocols, the carrying out of checks and measurements, the continuous optimization and revision of procedures. The MP Dpt conducts research activities in the field of diagnosis and treatment of cancer giving its perspective to the clinical team by means of its knowledge in imaging, radiological physics and radiobiological sciences

Clinical Activity

The MP Dpt staff daily develops personalized radiotherapy treatment plans for patients including conventional and high dose and high precision radiotherapy and intra-operative radiotherapy, while in nuclear medicine treatments the MP Dpt staff performs patient-specific dosimetry, with the aim of improving tumor control while sparing normal tissues. Dosimetry checks are performed on a daily basis and quality assurance programs are routinely carried out for the activities of Radiotherapy Dpt, Nuclear Medicine Dpt and Diagnostic Dpt. Support is given daily within many aspects of technical managing of clinical procedures. The MP Dpt staff also takes part into the conceiving and drawing up of many of clinical protocols giving its contribution from the physicist perspective to novel treatment strategies and techniques. Physicists of the MP dept often participate at HT (high technology) tenders collaborating to evaluate proposals. MP Dpt ensures radioprotection of patients and workers, thirdly part (familiars, care givers and population in general) and environment from physical agents. The MP Dpt provides educational programs. Since 2009, the MP Dpt is ISO 9001 certified.

Research Activity

The MP Dpt is involved in research activities related to

- Participating to radiotherapy clinical trials and performing data analysis of clinical and dosimetric results.
- Personalized dosimetry in selective radiation therapy with Y-90 for treatment of hepatic lesions. Personalized dosimetry in neuroendocrine tumors by Lu-177 dotatate. Implementation of a home-made software for personalized dosimetry in nuclear medicine.
- Novel CT dosimetry.
- Study and development of methods for evaluating the observer's performance in radiology.
- Optimization PROcesses in RAdiotherapy: clinical and dosimetric audits (OPRORA) Project Code: RF-2016 02362662 (Ministero Salute), Cod. IFO 20.01.R.13 RF. Co-investigator: A. Soriani
- Early Diffusion Weighted Magnetic Resonance Imaging Changes to Predict Tumor Response to Chemoradiotherapy in HN Cancer. AIRC project (n° 17028). Co-investigator: S.Marzi
- Development and optimization of a novel system to deliver hyperthermia for the treatment of sarcoma. Lazioinnova cod. IFO 18/14/R/29 PI: A. Soriani
- Development of a real time system for the reporting and collection of data to be used to reconstruct the dose to the operator in unexpected exposure events in nuclear medicine. Progetto BRiC, INAIL, SIREN: Co-investigator V. Landoni
- Techniques for the evaluation of the dose to lenses in workers exposed to ionization radiation in the medical field, modeling of biological effects and strategies for risk reduction. Progetto BRiC, INAIL: PI V. Bruzzaniti
- A radiogenomic approach to assess treatment response to anti-PD-1 immune checkpoint inhibitor in metastatic melanoma patients using CT texture analysis combined with tumor molecular profile as potential predictive biomarker: a pilot study GR-2019-12369697 S. Ungania
- Proton dosimetry : In the framework of the ItalianTOP-IMPLART project (Regione Lazio), ENEA-Frascati, ISS and IFO are developing and constructing the first proton linear accelerator based on an actively scanned beam for tumor radiotherapy with final energy of 150 MeV. COD IFO 13/41/R/30
- Study of an artificial intelligence algorithm for the classification of digital breast tomosynthesis images for the automated diagnosis of breast cancer (RS N. 1414/20) V. Landoni

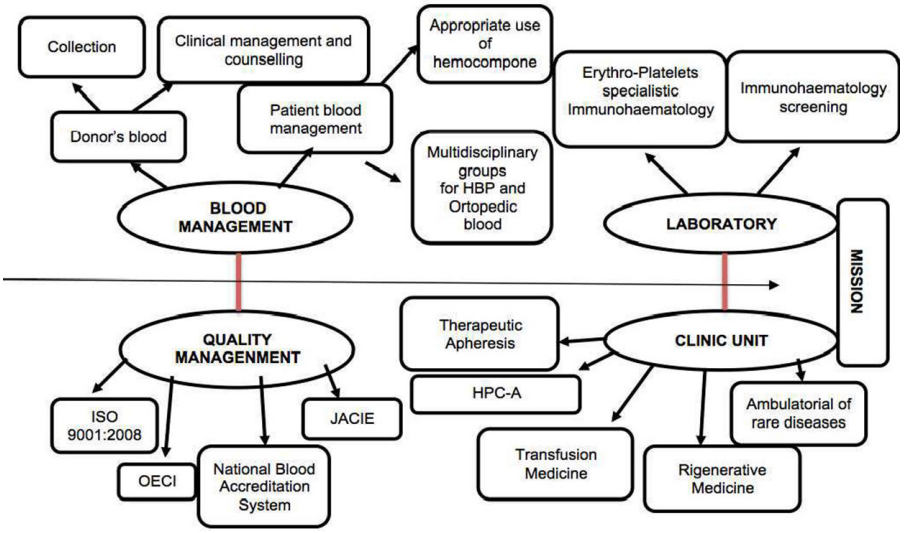
Dr Marzi is member of the WG "Quantificazione, interconfronti e assicurazione di qualità in RM", AIFM, Associazione Italiana Fisica Medica.

Dr Landoni is member of the Scientific Committee of the AIFM, Associazione Italiana Fisica Medica

Dr Landoni is member of the Editorial Board of Physica Medica, Europ Journ of MedPhy

Transfusion Medicine Unit

Head: Dr. Maria Laura Foddai, MD



Staff

Mafalda De Rienzo, MD
Stefano Iaboni, MD
Giuseppina Natale, MD
Marco Zucchiatti, Technician Coordinator
Nadia Coculo, Technician
Maria Piedimonte, Technician
Daniela Mozzetti, Technician
Daniela Di Mambro, Technician
Chiara Cherri, Technician
Claudia Caruso, Technician
Giuseppina Chichierchia, Biologist
Ilenia Saladini, Nurse
Fabio Schiumarini, Nurse
Adriana Merola, Nurse
Angela Marceddu, Nurse
Domenico Sorrentino, Nurse

Clinical Activity

The Immunohaematology and Trasfusion Medicine Service is an articulated structure that complies with specific tasks provided by the Italian Legislation in the field of transfusion and supports with diagnostics and therapeutic activities the clinical departments for the treatment of haematological, dermatological, oncological, internal and surgical diseases. The activities are mainly directed to:

- Ensure the constant availability of blood and hemocomponents for the departments' needs;
- Verify the appropriateness of blood and hemocomponents clinical use;
- Manage cryopreserved pheripheral blood stem cells
- Control the quality and safety requirements of the hemocomponents.

In the Unit, there are the following areas of excellence: Therapeutic Apheresis, Regenerative Medicine, outpatient management of rare deseases and Erytro-Platelets Immunohaematology.

We are also implementing the patient blood management with the intent to inform health-care practitioners and health service managers about the pre, intra and postoperative care of patients undergoing surgery or invasive procedures, particularly those in which blood loss is anticipated such as orthopedic, urological and digestive surgery.

The unit of Therapeutic Apheresis makes use of the latest generation cell separators that allow to perform plasma exchange and photopheresis procedures in autoimmune, dysimmune and neoplastic diseases, particularly in dermatological patients affected by Pemphigus Vulgaris, Atopic Dermatitis, cutaneous T-cell lymphomas like Mycosis Fungoid and Sezary syndrome, Psoriasis,

etc.

The unit of Therapeutic Apheresis gives its contribution to plasma hyperimmune collection from COVID-19 convalescent donors to improve COVID-19 patients treatment.

The Regenerative Medicine is a new therapeutic approach aimed at the biological regeneration of tissues instead of replacing them, and finds its most relevant applications in orthopedics (tendinopathies), dermatology, plastic and reconstructive surgery (lichen sclerosus genitalis) and corrective medicine.

The clinical unit for rare diseases deals with care and treatment of patients affected by hereditary hemochromatosis, porphyria, cutaneous T-cell lymphomas.

The Immunohaematological diagnostic is important in oncologic and polytransfused patients to prevent alloimmunization and consist in typing of rare erythrocyte groups, research of anti-erythrocyte and anti-platelets antibodies and identification of auto and allo-antibodies, immunohaematological management of neoplastic patients under monoclonal antibodies therapy (i.e anti-CD38 antibodies –daratumumab- in multiple myeloma patients)

Research Activity

Blood derivatives ameliorate myogenic progenitor cells proliferation and differentiation:

In collaboration with Department of Biology of Rome University Tor Vergata, we are developing a project regarding the effect of human blood derived serum and/or growth factor on human derived perivascular myogenic progenitor/stem cell, namely pericytes. So, the project purpose is to test human blood derivatives in order to supersede problems related to animal medium supplement and cell therapy for clinical application; moreover, working with human derived stem cdls, we are analyzing the effect of human serum and growth factors on the myogenic capabilities of human skeletal muscle derived pericytes.

Bcl-2 promotes recruitment and differentiation of macrophages towards a M2-like phenotype:

Evaluation of platelets-rich plasma effectiveness m vulvar lichen sclerosus in collaboration with plastic surgery unit.

Epidemiology and Cancer Registry Unit

Head: Dr. Valerio Ramazzotti, MD

Staff

Maria Cecilia Cercato, MD
Oreste Aronadio, MD
Teresa Borruso, nurse cancer registrar (part-time in project EURACAN)
Elisabetta Fragalà, nurse cancer registrar (part-time in project EURACAN)
Emma Santoro, nurse cancer registrar
Giuseppina Caolo, research assistant (IRE Scientific Directorate, part-time in Hospital Cancer Registry)
Annunziata Di Turi, research assistant (IRE Scientific Directorate, part-time in Hospital Cancer Registry)

Mission

The 'Epidemiology and Cancer Registry' Unit¬ operates in the framework of the public health branch, aiming at the monitoring, control and prevention of cancer. The unit is mainly involved in descriptive epidemiology based on cancer registration; evaluative epidemiology based on data from the regional and national programs for the evaluation of health care interventions; medical humanities and personalization of care. The unit actively takes part in the ongoing projects included in the 'improvement action plan' and contributes to the implementation of the Institute's Information and Communication Technology system, aiming at facilitating access and analysis of clinical and research data.

Research Activity

Descriptive Epidemiology

Population and hospital cancer registers are the core of the activities. Population cancer registration is a crucial tool in assessing the frequency and distribution of tumors in order to understand their causes and adopt appropriate prevention and treatment measures. Hospital cancer registers, instead, support clinical research and management of hospitals.

1.Since 2015, in accordance to a regional law establishing the Population Based Cancer Registry of the Lazio region (RTL), the Unit has assumed – under the coordinating action of the Department of Epidemiology for the Lazio Regional Health Service – the role of "functional unit" for the 'Città metropolitana di Roma' area, covering a population of over 4,330,000 inhabitants and more than 24,000 estimated incident cases per year of malignant neoplasms per year. The Functional Unit has been involved in the validation, coding and registration of the cases collected from a dedicated regional platform. In addition, the unit has started combining the data from the regional platform with clinical data detected at IFO, in order to improve the quality of the registration. In 2020 the database of reference for the selection and registration of incident cases exceeded the threshold of 100,000 records, relative to all available years.

2.The hospital-based cancer registry (RTO) of the National Cancer Institute 'Regina Elena' was designed to define the occurrence, the topography and the morphology of the treated cases per year, to provide statistical reports according to the OECI standards, and - as collaborative unit of the Clinical Trial Centre IFO - to estimate the number of eligible patients for the clinical trials by specific neoplastic features. The registration activity continued with reference to the neoplastic sites of the breast, lung and colorectal for the years 2016-2019, reaching over 5,500 registrations in 2020. Periodic data analysis was performed for internal reports and for a planned scientific article.

EURACAN (EUropean network for Rare Adult solid CANcer)

EURACAN will enable a major improvement in the access to excellence diagnosis and treatment for European patients. IFO has been recognized as an ERN (European Reference Network) member with expertise in eight groups of rare tumors. The Unit was actively involved in the related activities, particularly in designing and implementing an institutional database capable of collecting data from the rare solid cancer patients who are diagnosed and/or treated at the Institute.

In 2020, the Unit has focused on the implementation of the IT platform in regard to the cases of patients with rare cancer referring to IFO since 2018; at the end of 2020 over 2.500 cases were registered. The Unit has also conducted training of the personnel involved in the process of identification and registration of cases. Other activities included periodic data analysis and reporting, and the publication of a scientific article on the clinical series relating to elderly patients with sarcoma.

Rarity Project

The Unit has participated in the national ACC RARITY project (Register rAre adult solid canceRs In iTalY). The goal of the project is to create an Italian clinical register, shared among the Italian centers accredited in EURACAN, which will collaborate within the European STARTER project for the definition of the European clinical register on rare cancers. The activity carried out concerned the definition of the methodology for data collection (core variables) and analysis.

Evaluative Epidemiology.

The evaluation of the outcomes of health interventions is of particular relevance in an "Istituto di Ricovero e Cura a Carattere Scientifico" (IRCCS) such as the Regina Elena Institute. The evaluation, based on multiple indicators - both quantitative and qualitative - allows comparisons with other IRCCSs and hospitals, both at the regional and national level. The data obtained allow to monitor specific indicators for several neoplastic sites and to evaluate the quality of the coding diagnosis and treatments, taking into account concurrent risks in patients.

The Unit was involved in the internal audit for: 1) the Regional Outcome Evaluation Program (P.Re. Val.E.); 2) the National Outcome Evaluation Program (PNE). The main objectives are: observational assessment of the efficacy and the effectiveness of health-care interventions; identification of factors within the health-care delivery process that affect outcomes; monitoring levels of care. In this framework, technical reports for the National Cancer Institute "Regina Elena" (Report on P.Re. Val.E. 2020; Report on PNE 2019) were submitted to the Medical Directorate.

The Unit has also coordinated audits prescribed by the Department of Epidemiology of Regional Health Service of the Lazio Region on "Mortality within 30 days after surgery for malignant tumors of lung" and "Mortality within 30 days after surgery for malignant tumors of colon" in the context of the findings of the P.Re.Val.E.

Related Activities

Narrative Medicine

Since 2009 the Unit has been involved in initiatives related to Narrative Medicine, promoting training courses, conferences and research projects. Trials aiming to validate clinical-care methodologies for the application of narrations and the arts in oncological clinical practice, targeting different population and setting, have been carried out.

In 2020 "Creativity as a resource. A pilot study on the Integrated Drama Therapy in the supportive care of cancer patients (DIPSO)" started. The objective of the study concerns the validation of a method based on experiential workshops involving breast cancer patients, aiming to improve their empowerment through the use of the arts.

A further clinical trial (EPIMENAT) was approved by the Ethics Committee. The study enrolls patients at the Center for the treatment of Tumor Epilepsy IFO with the aim of evaluating the feasibility and validity of a digital diary set to integrate narration of patients with their clinical data during treatment.

The Unit has continued monitoring, collecting and evaluating data concerning the studies started in previous years: IMPERO (application of narrative medicine in oncological clinical practice: impact on health care professional); AMENAS (application of narrative medicine in patients with sarcoma); TARPEA (a multicentric pilot study involving a three-dimensional evaluation of aromatase inhibitor toxicity in early breast cancer patients: expected, detected and perceived).

Telemedicine

The activity was launched during the first COVID-19 emergency as an urgent and immediately applicable procedure. During the year, following the Lazio Region's directives on the subject, a multidisciplinary working group on "Specialization and Telemedicine" was set up at the Institute. The Unit is involved in the IFO Task Force of the group, together with the UOC Clinical Engineering and Technologies and Information Systems, in collaboration with DNM Srl, the social start-up supplier of the DNMLAB platform. Activities carried out included: definition and drafting of an operational protocol; creation of virtual outpatients paths based on the existing organization; training of health care professionals and monitoring of activities; adaptation of the paths and tools to regional directives on telemedicine.

Gender medicine

Participation to the IRCCS working table, which contributed to the preparation of the document of the Ministry of Health on the relationship between COVID 19 and gender health.

Participations To Commissions, Committees, Working Groups

- HB-HTA. IFO (Health Technology Assessment) commission.
- CC-CICA. Control Committee of Infections Related to the CC-CICA – IFO.
- OECI: elaboration of data for the self-assessment in the OECI certification process.
- LIMeNar Steering Committee. ISS research project ("Use and application contexts of the guidelines for the use of NARRATIVE MEDICINE in clinical care and associations area)
- SIMeN Membership (Italian Society of Narrative Medicine)
- JCM Guest Editors for a Special Issue: Bone and Soft Tissue Sarcoma.

Oncogenomics and Epigenetics Unit

Head: Dr. Giovanni Blandino, MD, PhD

Staff

Giulia Fontemaggi, Senior Scientist
Silvia Di Agostino, Senior Scientist
Gianluca Bossi, Senior Scientist
Federica Ganci, Junior Scientist
Sara Donzelli, Senior Scientist
Federica Lo Sardo, Junior Scientist
Valeria Canu, PhD, Junior Scientist
Fabio Valenti, PhD, Junior Scientist
Marco Varmi, Technician
Roberto Bernardi, Administrative collaborator
Claudio Pulito, PhD, Junior Scientist
Etleva Korita, PhD
Chiara Turco, PhD Student
Alina Palcau, Student
Claudia Catulli, Student
Giulia Orlandi, Student
Anna Maria Biroccio, PhD
Pasquale Zizza, PhD, Junior Scientist
Angela Rizzo, PhD, Junior Scientist
Sara Iachettini, PhD, Junior Scientist
Eleonora Petti, PhD, Junior Scientist
Roberto Dinami, PhD, Junior Scientist
Carmen D'Angelo, Technician
Angela Dello Stritto, Master Student
Carmen Maresca, Technician
Luca Pompili, PhD, Junior Scientist
Patrizio Giacomini, MD, Senior Scientist
Matteo Allegretti, PhD, Junior Scientist
Katia Messana, PhD, Junior Scientist
Elisa Tremante, PhD, Junior Scientist
Elena Giordani, Technician
Rocco Fraioli, Technician
Paolo Romania, PhD, Junior Scientist
Maria Simitakos, Erasmus Graduate Student
Oreste Segatto, MD, Senior Scientist
Sergio Anastasi, Senior Scientis
Dante Lamberti, PhD, Junior Scientist
Giulia Cristinziano, PhD student
Maria Giulia Rizzo, PhD, Senior Scientist
Giulia Regazzo, PhD, Junior Scientist
Manuela Spagnuolo, PhD, Junior Scientist
Federica Rinaldi, Master Student
Elham Rahimzadeh, Master Student
Ana Belen Diaz Mendez, PhD student

Mission

Developing more precise diagnostic approaches to predict cancer progression and prognosis is the key to precision medicine. The mission of the Oncogenomic and Epigenetic Unit mirrors at specific genomic and epigenetic alterations in both solid and hematopoietic malignancies that hold the potential to represent novel cancer biomarkers or druggable targets. This is pursued through genome wide approaches applied to cell systems, animal models, tissues and biological fluids ctDNA and non-coding RNAs of cancer patients.

Clinical Activity

The Oncogenomic and Epigenetic Unit actively contributes to the clinical research activity of Regina Elena National Cancer Institute through:

The generation of molecularly and clinically annotated databases of specific types of tumors. This also includes the collection and the storage of DNA, RNA and proteins from both tissues and biological fluids from cancer patients.

The establishment of datasets of raw data from genome wide analysis coding and con-coding RNA profiles, RNA-Seq and DNA mutational analysis of matched cancer lesions.

The establishment of early passage culture from melanoma, breast, lung, ovary, endometrial, brain, head and neck cancer lesions.

Research Activity

The research objectives of the Oncogenomic and Epigenetic Unit are pursed through the integrated experimental work of the following groups:

Blandino's group is actively pursuing the identification of molecular biomarkers non-coding RNAs whose association with the TP53 status may predict recurrence of head and neck cancers.

Biroccio's group is actively investigating the extra-telomeric role of TRF2 in oncogenesis with the aim to identify novel therapeutic targets for antitumoral therapies in colon cancer.

Giacomini's group is actively developing and optimizing nanoparticles for cancer therapeutics, and assays to detect circulating tumor DNA ctDNA in real-life Liquid Biopsy LBstudies.

Rizzo's group is actively investigating the role of extracellular circulating miRNAs in hematopoietic malignancies and brain tumors as promising biomarkers for disease classification and outcome prediction.

The Segatto's group has generated genetically defined mouse models of intrahepatic cholangiocarcinoma iCCA driven by FGFR2 fusion proteins FFP.These models are being used to identify iCCA vulnerabilities associated to oncogenic dependence from FFPs.

Immunology and Immunotherapy Unit

Head: Dr. Paola Nisticò, MD

Staff

Francesca Di Modugno, Senior Scientist, PhD
Anna Maria Mileo, Senior Scientist, PhD
Aldo Venuti, Senior Scientist, MD
Luca Cardone, Senior Scientist, PhD
Antonella Sistigu, Senior Scientist, PhD
Gabriele Toietta, Senior Scientist, PhD
Silvia Baldari, Senior Scientist, PhD
Anna Di Carlo, Senior Scientist, PhD
Roberta Melchionna, Senior Scientist, PhD
Belinda Palermo, Senior Scientist, PhD
Francesca Paolini, Senior Scientist, PhD
Paola Trono, Senior Scientist, PhD
Lorenzo D'Ambrosio, Junior Scientist, PhD Student
Annalisa Tocci, Junior Scientist, PhD Student
Carla Mottini, Junior Scientist, PdD
Susanna Falcucci, Junior Scientist, PdD
Eleonora Sperandio, Junior Scientist, PdD
Annalisa Antonini, Technician
Giuliana Falasca, Technician
Vittoria Balzano, Technician, Fellow
Giulia Campo, Technician, Fellow
Mariangela Panetta, Technician, Fellow
Maria Vincenza Sarcone, Administrative collaborator
Flavio Di Michele, Student
Diana Vanessa Duarte Gomes, Student
Melo Alanne Rayssa Da Silva, Student
Beatrice Pinci, Student

Mission

This Unit is focused on understanding the immune response against tumor by studying the biological processes and signaling pathways involved in the complex interaction between tumor cells, extracellular matrix ECM, cancer associated fibroblasts CAFs and immune cells in the tumor microenvironment (TME). Our aim is to provide the rationale for designing novel immunotherapeutic treatment to be used also in combination to overcome therapy resistance. The mission is: to develop and standardize methodologies of immune-monitoring; to establish preclinical models of patient-derived organotypic cultures of tumors; identify surrogate biological markers of clinical response, focusing on immune checkpoint inhibitor treatment; to identify novel targets related to the tumor microenvironment, suitable for developing CAR T cells able to infiltrate solid tumors also exploring oncolytic virus activity. In cooperation with the HPV Unit we participate in programs of cancer prevention on HPV vaccination for males and we are defining new formulations of DNA vaccines against HPV oncoproteins. Close cooperation with the clinical departments is a cornerstone of our Unit to define immune landscape in particular during radiotherapy and to design combined immunotherapeutic clinical trials.

Research and Clinical Activity

PI Nisticò: The group activity obtained results on the role that the isoforms of the actin regulator hMENA may have in shaping NSCLC microenvironment by regulating the dialogue among tumor, fibroblasts and immune cells. We have demonstrated that hMENA and its isoforms contributes to cancer progression by regulating tumor cell-autonomous signalling, including: 1) AXL; TGFβ/SMAD and IFN type I pathways with PD-L1 up-regulation related to the absence of hMENA11a isoform. In parallel, hMENA/hMENADv6 isoforms identify a subtype of pro-invasive immunosuppressive CAFs. hMENA isoforms from both tumor cells and CAFs impact ECM composition and quality and localization of immune cell in the tumor site. Studies are ongoing to evaluate hMENA derived signatures as theranostic biomarker in NSCLC patients treated with immune checkpoint inhibitors. We have identified significant modulation of immune cell subsets in periphery with respect to distal and tumoral tissue in NSCLC patients by multicolour flow cytometry. An in depth immune-monitoring in prostate cancer patients undergoing curative

radiotherapy RT revealed important modification of immune cell frequency and quality, indicating the role of novel targets to be used in combined radio/immunotherapeutic clinical trials.

Paola Nisticò as National coordinator of the WG Immunotherapy of Alleanza Contro il Cancro contributes through an integrated experimental and clinical work in different network projects.

PI Di Modugno: To explore the mechanisms that underline the role of hMENA isoforms in the dialogue among tumor cells CAFs and immune cells we found that the pattern of hMENA isoforms expression in NSCLC tumor cells and CAFs affects the expression level and the activation of the downstream NF-kB pathways of the lymphotoxin beta receptor, crucial in tertiary lymphoid structures organization and maintenance. In CAFs hMENA affects the FN1 expression and fibrillogenesis, a relevant process in extracellular matrix assembly that could act as a barrier to the lymphocyte infiltration in the tumor. Multiplex staining of NSCLC tissue with confocal microscopy evidenced the TLS peritumoral localization in the presence of an hMENA enriched stroma.

To evaluate the role of irradiation (IR) on CAF secretoma we treated lymphocytes with the CAF conditioned medium, demonstrating that IR potentiates the immunosuppressive properties of CAFs and inhibits the lymphocyte proliferation.

PI Cardone: We have identified key metabolic vulnerabilities supporting metastases in a model of metastatic Triple-negative breast cancer and highlighted the importance of lipid metabolism in metastatic cancer stem-like cells survival. To identify novel potential therapeutic to treat a specific subpopulation of patients with pancreatic cancer we have demonstrated that Decitabine may represent an anticancer drug repurposing opportunity.

PI Mileo: To delve into the molecular mechanisms elicited by the remodelling of actin cytoskeleton and involved in cancer progression we identified a pivotal role of HPV16E7-GSN physical interaction on Epithelial-Mesenchymal Transition via Hippo-YAP axis.

As part of the integrated analysis of bidirectional crosstalk between tumor cell and stromal compartment and, specifically, of the role of cytoskeletal dynamics on lung cancer progression, we evaluated also the CAF pro-tumor activity related to cytoskeletal features actin-dependent, driven also by hMena isoforms activity. By exploring the signaling pathways involved in the "cooperative dialogue" between tumor cells and their supporting microenvironment components, we focused our studies on the paracrine activity of CAFs on cellular mechanotransduction processes and on YAP-dependent gene induction related to NSCLC cancer progression. We attempted to characterize the hMena-related CAF functionality via the identification of CAF pro-tumorigenic soluble factors able to affect on lung cancer cells the Hippo/YAP axis, a pivotal signaling pathway involved on tumor progression, stemness, metastasis and immune evasion.

PI Sistigu: We showed that Type I IFNs (IFNs-I), during immunogenic chemotherapy, may act as molecular hubs of resistance as they trigger the epigenetic regulator KDM1B, which account for an adaptive, yet reversible, transcriptional rewiring on cancer cells towards stemness and immune escape. Indeed, pharmacological inhibition of KDM1B, antagonizes CSC appearance. IFN-I-adapted CSCs show phenotypical/functional heterogeneity in terms of multidrug resistance, plasticity, invasiveness and immunogenicity. Importantly, in breast cancer patients receiving anthracycline-based chemotherapy, IFN-I and KDM1B signatures positively correlate with CSC and immune evasion markers. By elucidating the downside of IFNs-I, our findings may ultimately help the development of more informed, combined therapies to increase the chances of cure.

PIToietta: We aim to develop innovative therapeutic strategies for targeting TME components. To this end, we have identified TME-related genes as putative targets for chimeric antigen receptor-modified T cells (CAR-T) and bispecific T-cell engagers (BiTE). Moreover, we are assessing whether treatment with oncolytic viruses can promote T cell trafficking into "cold" solid tumors. Moreover, we characterized a clinical grade product obtained by emulsification of adipose tissue-derived stromal vascular fraction, used in regenerative medicine clinical studies in virtue of its immunosuppressive, immunomodulatory, and pro-angiogenic potentials.

PI VENUTI: . In cooperation with the HPV Unit we participate in programs of cancer prevention on HPV vaccination for males and, recently, we started an International clinical trial on this issue as Italian Coordinator Centre. Patients were enrolled and three years follow-up taking place. We achieved new insight the therapy of HPV-associated cancer. The study in collaboration with University of California, identified a novel mechanism of resistance to anti-PD-1/PD-L1 immunotherapy mediated by HPV16 E5 oncoprotein, which can be exploited using the HPV E5 inhibitor rimantadine to improve outcomes for head and neck cancer patients. Exploring the role of HPV in non-genital cancers, we evidenced that presence of persistent infection by beta papillomavirus type 15 might influence the biological fate of patient with a rare hereditary disease, Inontinentia Pigmenti (IP) by altering NF-κB activation and apoptosis in IKKγ mutated cells, favouring their survival and possibly the development of tumors in the late stage of disease. The platform for the production of DNA therapeutic vaccines has been improved by exploring adjuvating activity of natural compounds. Finally, our mouse model of oral cancer AT-84 was challenged with oncolytic viruses to improve CAR –T cell therapy in solid tumours.

Preclinical Models and New Therapeutic Agents Unit

Head: Dr. Anna Bagnato

Staff

Valeriana Di Castro, Senior Scientist, PhD
Donatella Del Bufalo, Senior Scientist, PhD
Rossella Galati, Senior Scientist, PhD
Laura Rosanò, Senior Scientist, PhD
Daniela Trisciuoglio, Senior Scientist, PhD
Rosanna Sestito, Senior Scientist, PhD
Piera Tocci, Senior Scientist, PhD
Simona D'Aguanno, Senior Scientist, PhD
Marta Di Martile, Senior Scientist, PhD
Elisabetta Valentini, Senior Scientist, PhD
Valeria Pecci, Junior Scientist, PhD
Ilenia Masi, Junior Scientist, PhD
Anna Maria Luciano', Junior Scientist, PhD Student
Alessia Ricci, Junior Scientist, PhD Student
Aldo Lupo, Technician
Valentina Caprara, Technician
Barbara Nuvoli, Technician
Andrea Cerri, Technician
Adele Petricca, Administrative collaborator
Alessandro Renna, Student
Federica Timoteo, Student
Federica Badoni, Student
Valentina Pau, Student
Matteo Brignone, Student

Mission

The aim of this Unit is to define mechanistic rules for combinatorial treatments to overcome resistance and maximize response in pertinent pre-clinical models, including patient-derived xenografts, and organoid/tumoroid technology derived from ovarian, lung, colon cancer, melanoma, mesothelioma. In these models we investigate the mechanisms activated by critical pathways i.e. endothelin-1, estrogen, or bcl2 signaling that regulate metastasis and drug response. Recent studies have provided valuable biological insights into the mechanisms of drug resistance, which include the crosstalk between signalling pathways that compensate for therapeutic inhibition, and activation of feedback loops that overcome drug function. These insights could be used to rationally and effectively design combined regimens based on the biology of resistance and potentially the evolutionary projection of the treated tumour. The novel patient-derived preclinical models can be exploited to screen treatment modality optimization that would enable clinicians to predict how tumours respond to treatment.

Research and Clinical Activity

The ultimate goal of this Unit is to develop meaningful combinatorial strategies leading to rationally-designed (and potentially personalised) novel treatment regimens for specific cancers, exploring in pertinent preclinical models how cancer cells respond to perturbations of specific pathways and how resistance to therapies arises, being transformed into a set of mechanistic rules. The activity of the Unit concerns patient-centred research, learning from every patient the complexity of disease biology.

PI A. Bagnato

We focused beyond cell intrinsic factors alone and explored the role of the surrounding cells or stroma, including the extracellular matrix. We discovered the alliance between endothelin-1 and YAP pathway, regulating mutant p53-mediated transcriptional networks acting as a therapeutic escape route of drug-resistant ovarian cancer (OC) cells. In our study, we provided valuable insights into mechanisms of response to platinum and PARP inhibitor (PARPi) therapy supporting the premise that both molecular and spatial features in the tumor microenvironment (TME) are potentially linked to response to therapy. Our study highlights that targeting endothelin-1 receptor (ET-1R) activities in tumor and TME elements may disclose unexplored opportunities for OC

therapy. To design and identify more effective integrated treatments, we combined drugs (platinum or PARPi), with the dual ET-1R antagonists that work on targets expressed in tumoral and stromal compartment in complementary pathways so that they can be given at a lower and less toxic doses whilst maintaining efficacy and reducing side effects. In this context, we designed sequential drug treatment protocols in which new vulnerabilities (such as the transcriptional complex YAP/mutant p53/HIF-1α) can be targeted. It is expected that the validation of proposed mechanistic rules for potential combinatorial treatments in realistic preclinical models will be an essential aspect for the successful translation to early-phase clinical trials. The future scientific strategies to address our mission will be implemented through the integration of single-cell spatially resolved data and pertinent patient-derived models that might provide valuable information on the determinants of response to therapy, and reveal new treatment modalities, fulfilling the gap between basic researches and clinical practice.

PI L. Rosanò

To unravel the complex mechanisms governing the early steps of OC metastatic dissemination we characterized tumor-stroma interactions guiding tumor cells to attach in the metastatic sites, as the peritoneum and omentum. Specifically, we uncovered the interactions of OC cells with the normal cells surrounding them to understand how matrix and TME cells affect the growth and plasticity of cancer cells, elucidating how mesothelial cells and cancer cell interactions promote OC invasion in the metastatic niche. This study led us to identify the crosstalk between ET-1R and integrin pathways as a bridge of adhesive and proteolytic signals directing invadopodia-mediated invasion, and metastatic spread. These findings are expected to provide the scientific rational for the design of novel opportunities for defeating metastatic OC.

PI D. Del Bufalo

By using melanoma preclinical models, we provided new insights into the roles of bcl-2 family members in melanoma progression and therapy. In particular, we explored the crosstalk between melanoma cells overexpressing bcl-2 protein and TME. We demonstrated that bcl-2 in melanoma cells i) regulates interleukin-1β (IL-1β) expression, ii) induces M2 polarization/recruitment of macrophages through a NF-kB-dependent mechanism, iii) correlates with increased infiltration of M2-polarized macrophages in tumor specimens from metastatic melanoma patients. A melanoma syngeneic mouse model evidenced the ability of bcl-2 to impair T cell response, through reduced production of interferon γ and the effector T cells population, thus indicating bcl-2 ability to impair specific antitumor immunity. Taken together, our results show that melanoma-specific bcl-2 controls an IL-1β-driven axis of macrophage diversion that establishes TME conditions favouring melanoma progression indicating that interfering with this pathway might provide novel therapeutic strategies. In a search for new therapeutic agents, we discovered the antitumoral activity of i) a lysine acetyltransferase inhibitor, CPTH6, acting as antiangiogenic agent; ii) novel quinoline compounds acting at the same time as DNA methyltransferase inhibitors and degraders, iii) dual enhancer of zeste homolog 2/histone deacetylases inhibitor, iv) M2 muscarinic receptor agonist.

PI Galati

The aim of the study is to investigate new combination therapies to improve their effectiveness in the treatment of different tumors, including malignant mesothelioma. Based on previous studies highlighting that the induction of cyclooxygenase-2 (COX-2) and high prostaglandin E2 (PGE2) levels contribute to the pathogenesis of mesothelioma, as well as that PGE2 upregulates aromatase (CYP19A1) expression in other cancers, we investigated the interplay between COX-2 and CYP19A1 in the pathogenesis of mesothelioma. The insights obtained on a panel of 2D and 3D mesothelioma cell cultures and in mesothelioma specimens highlighted a novel COX2/CYP19A1 axis in the pathogenesis of mesothelioma that can be pharmacologically targeted, opening new therapeutic options.

Cellular Network and Molecular Therapeutic Targets Agent Unit

Head: Dr. Silvia Soddu, MD, PhD

Staff

Rita Falcioni, PhD, Senior Scientist
Marco Giorgio Paggi, MD, Senior Scientist
Alessandra Verdina, PhD, Senior Scientist
Gabriella D'Orazi, MD, PhD, Senior Scientist
Maria Pia Gentileschi, technician
Claudia Abbruzzese, PhD, Junior Scientist
Giulia Bon, PhD, Junior Scientist
Giuliana Di Rocco, PhD, Senior Scientist
Giulia Federici, PhD, Junior Scientist
Alessia Garufi, PhD, Junior Scientist
Rossella Loria, PhD, Junior Scientist
Silvia Matteoni, PhD, Junior Scientist
Laura Monteonofrio, PhD, Junior Scientist
Ilaria Virdia, PhD, Junior Scientist
Davide Valente, PhD, Junior Scientist
Micol Di Segni, PhD student
Michele Persico, MD student
Marta Mollari, undergraduate student
Oumaima Mhamdi, undergraduate student

Mission

Cellular networks and new therapeutic targets are key areas of innovation in the field of cancer therapy. The potential targeted pathways for personalized cancer therapies consist in oncogenic signals and in the events generated by biochemical and/or genetic alterations that characterize cancer cells. Our mission is to develop and to sustain sound expertise in these areas to understand the hierarchy of therapeutic targets and the molecular mechanisms underpinning the pharmacological action of innovative therapies. This Unit has a dual function. On one hand, it aids researchers and clinicians to plan preclinical and clinical research activities, as well as to conduct, stimulate and support research programs integrated into innovative investigator-driven clinical trials. On the other hand, it assists other researchers who aim to discover and plan the development of novel biomarkers and therapeutic agents.

Clinical Activity

The Unit Cellular Networks and Molecular Therapeutic Targets contributes to the clinical research activity of the Regina Elena National Cancer Institute on the following projects:

Working Groups of "Alleanza Contro il Cancro" ACC. Dr Falcioni and Dr. Paggi are the Institutional Representatives for IRE of the Sarcoma and Glioblastoma Working Groups, respectively. Dr. Falcioni contributes to set up a shared NGS platform among different laboratories for the identification of sarcoma fusion transcripts, confirming the sensitivity of anchored-based NGS profiling approaches.

Drug resistance in solid tumors. In collaboration with the Oncology 2 Unit, Dr. Falcioni contributes to the characterization of drug resistance to second line therapy with T-DM1 after trastuzumab/pertuzumab adjuvant therapy in Advanced Breast Cancer HER-positive. In collaboration with the Oncology 1 Unit, the same group contributes to the characterization of drug resistance to Dabrafeb/Pertuzumab in BRAF human melanoma.

Repurposing of chlorpromazine (CPZ) in the treatment of glioblastoma (GB): CPZ is an antipsychotic drug, which has been employed for over six decades. Recent reports and our own studies ascribe to CPZ the ability to strongly hinder GB cell growth in preclinical settings. Dr. Paggi is the PI of a Phase II clinical trial condicted in collaboration with the Neuroncology Unit. The clinical trial involves the combination of CPZ with temozolomide during the adjuvant phase of the first line GB protocol.

Classification of variants of unknown significance VUS of the ATM gene. NGS has generated detailed catalogues of genetic variation in driver and actionable genes but our ability to predict the phenotypic consequences of each genetic variant remains poor, limiting the medical impact of sequence information. This problem is highlighted by the large numbers of variants of uncertain significance VUS identified. We combine the use of genome editing with an ATM-specific functional test i.e., the p53-MCL test developed for ATM pathogenic variants to exploit the functional consequences of ATM VUS in hereditary breast cancer.

Research Activity

The research objectives of the Unit "Cellular Networks and Molecular Therapeutic Targets" are pursued through the integrated experimental work of the following groups:

Falcioni's group actively contributes to the identification of the molecular mechanisms responsible for the resistance to therapy with T-DM1 in Breast Cancer and Dabrafenib in BRAF-mutant melanoma and to the identification of novel therapeutic targets in both tumors. In the first case, this group discovered that adjuvant therapy with combo trastumab/pertuzumab induces translocation of HER2 to the nucleus, making this receptor no longer available for T-DM1 administrated in second line treatment. In the second case, the group found that Semaphorine6A, strongly expressed in BRAF-mutated melanoma, is a crucial mediator of tumor/stroma interactions involved in the resistance to MAPK inhibition.

Paggi's group actively contributes to drug repurposing in the treatment of GB. Intelligent and rational drug repurposing or repositioning are possible strategies to develop new therapies implicating lower risks, shorter timelines to bedside and lower costs. To this end, we employ cell biology and proteomic platforms, as reverse-phase protein arrays (RPPA), activity-based protein profiling (ABPP), SeaHorse and confocal microscopy, to delve into pharmacodynamic characteristics of old drugs amenable of repositioning in the therapy of GB. In addition, this group was proficient in attributing to the kinase inhibitor SI113 the correct mechanism of action in inhibiting the PI3K/mTOR pathway and epithelial-to-mesenchymal transition, as well as in stimulating autophagy.

D'Orazi's group is actively investigating the mechanisms of induced chemoresistance, in particular in solid cancers such as GB, breast, colon, and pancreatic cancers and with respect of the HIPK2-p53 pathway and of mutant p53 modulation. Particular attention has been dedicated to 1 the contribution of overexpressed NRF2 (in hyperglycemia or following treatments with novel curcumin complexes) in tuning down the drug-induced cancer cell death by reducing p53 apoptotic activity and 2 the potential role of NRF2 as inhibitor of HIPK2 apoptotic activity; 2 the interplay between endoplasmic reticulum (ER) stress and autophagy in inducing mutant p53 degradation, as potential druggable molecular targets; 3 the use of phenylbutyrate (PBA), already approved by FDA for the treatment of urea cycle disorders, as strong cytotoxic anticancer agent preferentially in mutant p53-carrying cancer cells, leading to mutant p53 degradation and downregulation of mutant p53-regulated pathways such as the mevalonate pathway. These findings highlight the role of NRF2 as potential biomarker of tumor response to therapies and underscore the key outcome of mutant p53 degradation to restore cancer cell sensitivity to anticancer drugs.

Soddu's group is actively pursuing the molecular characterization of mitosis and cytokinesis functions of proteins usually involved in the DNA damage response, such as p53, HIPK2, and histone H2B. Particular attention has been dedicated to the contribution of centrosomal p53 in the mitotic surveillance pathway; the role of extrachromosomal histone H2B in abscission; the identification and characterization of a new HIPK2 isoform with a cytokinesis-specific function.

SAFU Unit

Head: Dr. Maurizio Fanciulli, MD, PhD

Staff

Federico De Marco MD, Senior Scientist
Carlo Leonetti PhD, Senior Scientist
Giulia Piaggio, Senior Scientist
Giancarlo Cortese, Staff Technician
Tiziana Bruno, Staff Technician
Enrico Spugnini, MD, Veterinary
Sabrina Strano, MD, Senior Scientist
Aymone Gurtner, PhD, Senior Scientist
Francesca De Nicola, PhD, Senior Scientist
Frauke Goeman, PhD, Senior Scientist
Ludovica Ciuffreda, PhD, Senior Scientist
Simona Iezzi, PhD, Senior Scientist
Isabella Manni, PhD, Senior Scientist
Valeria Catena, PhD, Senior Scientist
Celia Cortile, PhD Junior Scientist
Lorenzo D'Ambrosio, PhD Junior Scientist
Stefano Scalera, PhD Junior Scientist
Giacomo Corleone, PhD Junior Scientist
Cristina Sorino, PhD Junior Scientist
Serena De Vito, PhD Junior Scientist
Bruno Amadio, Technician
Stefano Giovenale, PhD Student

Mission

The mission of the SAFU UOSD focuses on the establishment of innovative mouse models of human cancer including implantation of tumor specimens into immunocompromised mice at the heterotopic and orthotopic sites and genetically engineered mouse models. All mouse models are devoted to study cancer initiation, immune system roles, tumor angiogenesis, environmental carcinogenesis, invasion as well as response to novel anticancer strategy. Currently, several models are being designed to allow in vivo imaging of tumor development from earlier stages and to follow tumor response to therapeutics. Besides to the research activities, this UOSD has the responsibility for day-to-day management of the Institute animal house. In agreement, this structure coordinates the activity of Animal Welfare Body (D.Lgs. n.26/2014), evaluating scientific projects in which are involved animal experimentations.

Alongside these activities, SAFU unit carries out an intense development and validation of NGS technologies in exploratory research, also contributing to the generation of specific software for analyzing the data produced. In fact, in the light of the scientific knowledge acquired, it is clear that molecular analysis of the genome is not sufficient to improve diagnosis and therapy, as the response of a neoplasm to therapeutic treatment does not depend only on the characteristics of its genome, but also on the transcriptome and the epigenome. RNA analysis provides important information on transcriptional variations related to the tumor phenotype, identifying aberrations in the regulation of gene expression and also pathogenic gene fusions. Of absolute importance, by associating these analyses with exome sequencing, it is possible to identify specific neoantigens present in tumor cells, as well as fusion proteins generated in the tumor. In addition, RNA-seq analyses are carried out to analyze the composition of the immune infiltrate within the tumors, while exomic analysis is often used to evaluate the mutational load of a single tumor. More recently, the NGS methodology has also been used to analyze the expression variations of miRNAs and long non coding RNA in various tumor forms. Unlike the genome, the epigenome is not a static entity: an epigenetic variation can precede or be a consequence of the onset of a disease, environmental exposure, or reflect specific factors and lifestyles. This makes the epigenome attractive as a field of investigation for the identification and transfer to the clinic of biomarkers of very different pathologies and of specific predisposing conditions such as tumors. Through these analyzes it is possible to determine how chromatin conformation changes affect neoplastic transformation, altering the access to specific DNA regions by transcription factors or RNA polymerase.

Research Activity

Metastatic melanomas harboring BRAF-V600 mutations are currently treated with combinations

of BRAF and MEK inhibitors (MAPKi) increasing the objective responses, disease free survival and overall survival over monotherapy with BRAF inhibitors. Unfortunately, several patients suffer from ab initio or acquired resistance to these agents. Several efforts have been directed in recent years to understand mechanisms of resistance to MAPK inhibitors. These studies have shown a prominent involvement of non-mutational adaptive events, among which also deregulation of a class of small non-coding RNAs, namely microRNAs.

Dr. Fattore's research activities are focused on the study of the role of miRNAs in this phenomenon. His work stems from a comprehensive analysis of the entire miRNome using an in vitro model of acquired drug resistance to BRAF inhibitors represented by several melanoma cell lines mutated in the BRAF oncogene. In this way, it was highlighted a general dysregulation of a large network of miRNAs, both oncosuppressors and oncomiRs involved in several signaling pathways responsible for the modification of cell intrinsic and cell extrinsic features characteristic of drug resistant tumors. In particular, the focus has been directed to four miRNAs, two known oncosuppressor miRNAs, miR-199b-5p and miR-204-5p, and two novel oncomiRs, namely miR-4443 and miR-4488. Their characterization as therapeutic and diagnostic tools has been the focus of the work of Dr. Fattore in the last year. The first activity has taken advantage of Lipid Nanoparticles (LNPs) carrying oncosuppressive miRNAs (i.e. miR-199b-5p and miR-204-5p), which have been tested in vitro in different melanoma cell lines alone or in combination with target therapy. Results have demonstrated the capability of LNPs to reduce melanoma cell growth; these effects are strongly improved when they have been combined with BRAFi+MEKi. These findings have paved the way to perform in vivo validation using melanoma cell lines xenografted in nude mice. The goal will be to determine the capability of LNPs+BRAFi+MEKi to reduce tumor growth and delay tumor recurrence in vivo. As to the diagnostic applications, they have been measured the circulating levels of miR-204-5p, miR-199b-5p, miR-4443 and miR-4488 in the serum of 51 BRAF-mutated melanoma patients before the beginning of therapy with MAPKi. Results demonstrated that miR-204-5p circulating levels before starting therapy have a strong predictive value for OS and PFS. Concerning OS, patients with a ΔCt value under the ROC cut-off show a shorter median time to death in comparison to patients with a ΔCt value over the ROC cut-off (10 months 95% confidence interval (95%CI): (3.9-16.1) vs 34 months 95%CI: (25.7-42.3); p-value=0.013). Concerning PFS analysis, patients with a ΔCt value under the ROC cut-off have a shorter median time to progression in comparison to patients with a ΔCt value over the ROC cut-off (5 months 95%CI: (4.1-5.9) vs 18 months 95%CI: (7.9-28.1); p-value=0.006). Furthermore, this miRNA is also able to predict both OS and PFS in combination with miR-199b-5p and miR-4488. These promising findings justify further efforts to: 1) increase the predictive value of the circulating miRNAs and 2) confirm their relevance on a larger cohort of patients. The goal is to develop this signature as a companion diagnostic in the clinic.

By using advanced preclinical models, Leonetti's group investigated new therapeutic approaches for the treatment of human solid cancers. Preliminary in vitro experiments performed in breast cancer cells, demonstrated that G-quadruplex (G4) compounds, which are able to interact with G4 DNA structures present in cancer cells, synergizes with antineoplastic drugs in killing cancer cells. The in vivo results, obtained in an orthotopic model of breast cancer, which recapitulate clinical situation, confirmed that G4 ligands were able to increase the efficacy of Paclitaxel, thus suggesting a possible clinical application of this combination. The recent advances in organoids, in vitro 3D culture of human cancer, have opened new avenues for a more efficient translation of basic cancer research into novel treatment regimens. To this purpose, the same group have established orthotopic models of colon cancer by implanting organoids possessing KRAS mutations, which are generally associated with clinical aggressiveness of this cancer and reduced survival of the patients. This model, which closely mimic the clinical setting, will be used for investigating more efficacy therapies in the context of KRAS mutated colon cancer for which no effective therapies exist. Finally, analysis with the Open Array Real-Time PCR platform which include 624 cancer genes, permitted to identify genes regulated by G4 ligands. In particular, the analysis evidentiated 5 genes up-regulated and 19 genes down-regulated after the treatment with the G4 ligand. Interestingly, these genes have a relevant role in colon cancer progression and 3 out of 5 genes up-regulated and in 11 out of 19 down-regulated, possess G4 sequences, thus confirming the

transcriptional control of the G4 ligand. Future studies are planned to establish the functional relevance of these genes with the aim to identify new therapeutic targets.

Multiple myeloma (MM) is a neoplasm characterized by the accumulation of proliferating antibodies producing plasma cells in the bone marrow. Despite several therapeutical improvements, MM remains incurable with patients subject to relapses. This disease is characterized by a high frequency of structural variants (SVs) and copy-number abnormalities (CNAs). In addition, an increasing number of studies provides evidence of numerous regulatory shifts in the genomic organization during the development of MM. Importantly, several undifferentiated MMs show reorganization of the chromatin including euchromatic histone marks up-regulation. Consistent with these findings, in MM cells an increase in the accessibility of chromatin compared to normal plasma cells was observed, with a significant conversion of heterochromatic regions into accessible "active chromatin". Che-1/AATF (Che-1) is a protein identified by its ability to bind RNA polymerase II (Pol II)12. Several studies have demonstrated its involvement in the regulation of gene transcription and tumor cell proliferation. Che-1 is present in histone acetyltransferase complexes SAGA and ATAC through its interaction with the transcriptional co-activators ADA2, ADA3 and GCN5 and it acts as an endogenous HDAC1 inhibitor through its ability to disrupt the binding of pRb and Sp1 proteins to this enzyme. In addition, Che-1 plays an important role in the cellular response to the DNA damage (DDR) or to other cellular stressors, and sustains cell survival in MM cells by inhibiting mTORC1 activity and inducing autophagy. During this year, we demonstrated that Che-1 plays a crucial role in the transformation and proliferation of MM cells by increasing chromatin accessibility at both proximal and distal regulatory elements in in vitro and in vivo MM models. Using a comprehensive plethora of low- and high- throughput approaches coupled with ad hoc bioinformatic analysis, we observed a linear relationship between Che-1 and general histone acetylation in MM patients. Strikingly, Che-1 depletion induces a global transcription shut-off by systematically reducing histone acetylation. These results contribute to further elucidate the role of Che-1 as an essential component of the transcription machinery in MM, and in confirming Che-1 as a possible target for enhancing the efficacy of anti-tumor agents.

Cancer stem cells (CSCs) are tumor subpopulations driving disease development, progression, relapse and therapy resistance, and their targeting ensures tumor eradication. CSCs display heterogeneous replication stress (RS), but the functionality/relevance of the RS response (RSR) centered on the ATR-CHK1 axis is debated. In collaboration with Prof. Ilio Vitale, during this year we show that the RSR is efficient in primary CSCs from colorectal cancer (CRC-SCs), and describe unique roles for PARP1 and MRE11/RAD51. We demonstrated that PARP1 is upregulated in CRC-SCs resistant to several replication poisons and RSR inhibitors (RSRi). In these cells, PARP1 modulates replication fork speed resulting in low constitutive RS. Moreover, we showed that MRE11 and RAD51 cooperate in the genoprotection and mitosis execution of PARP1-upregulated CRC-SCs. These roles represent therapeutic vulnerabilities for CSCs. Indeed, PARP1i sensitized CRC-SCs to ATRi/CHK1i, inducing replication catastrophe, and prevented the development of resistance to CHK1i. Furthermore, MRE11i + RAD51i selectively killed PARP1-upregulated CRC-SCs via mitotic catastrophe. These results provide the rationale for biomarker-driven clinical trials in CRC using distinct RSRi combinations.

Strano's group is actively investigating the involvement of the HIPPO transducers, YAP and TAZ, in the chemoresistance of diverse types of human cancers. The targeting of the transcriptional axis YAP/TAZ/TEAD holds promising therapeutic value as novel approach for cancer treatment. Moreover, Drs. Strano is focusing her efforts on the identification of non-coding RNA circulating biomarkers predicting mucositis as major side effect of chemo-radiotherapeutic treatment of human cancers.

The solar ultraviolet (UV) radiation is a most powerful environmental carcinogen. Skin tumours are steadily increasing at any latitude and among any racial and social group and such a trend is expected worsen in the next decades. Through protein oxidation studies our group has demonstrated that UV radiation preferentially oxidizes a subset of cellular proteins involved in stress response; protein folding/refolding and quality control; proteasomal function; DNA damage repair; cell architecture; adhesion/migration; proliferation and oncosuppression; As a

consequence intercurrent genetic alteration are inefficiently removed and transformant clones are increasingly generated. Thus, environmental UV radiation is both a cancer initiating and a strong cancer promoting agent. Finally, UV act a selective agent to for those clones with increased fitness to Oxidative Stress thus increasing the cell genomic instability and promoting an accelerated rate of neoplastic evolution.

Papillomaviruses are a first-class single carcinogen whose relevance for human oncology is going to stay despite the vaccine availability. The recent identification of a mouse Papillomavirus paves the way to the setup of a convenient animal model for human HPV related neoplastic diseases. Our preliminary results indicate that in mouse newborn keratinocytes, following "in vitro" infection with MoPV The IFN type 1 response is poorly activated and takes place with a rather slow RNA kinetics. Conversely the IFN type 3 response occurs, as expected, within a few hours since the challenge. In both IFN type1 and type 3 response a rather poor TLR3 and TLR9 induction is seen. Such a lack of activation may be a crucial reason for establishment of persistent infection. These data deserve to be confirmed in more large and comprehensive experiments

The pandemic in 2020 has strongly influenced the Piaggio's group research activities. Indeed, from the beginning of the pandemic in March 2020, the group has been involved in the development of protocols to study the impact of the SARS-CoV-2 virus on the immunological response of cancer patients. In the last month of the year, the group was also involved in projects on vaccine efficacy, which are being continued in 2021. Alongside the activities related to COVID-19, the group also continued the projects already started in previous years, also in collaboration with other groups, aimed at the identification of novel features of the neoplasia micro and macroenvironments.

Dr. Aymone Gurtner studies aim at identifying mutp53-dependent miRNAs and their target genes as useful prognostic and/or predictive biomarkers of response to therapy in patients with CRC. Since for many genes putatively regulated by mutp53 identified in these studies there are drugs approved by the FDA or undergoing clinical trials, these results open the way to identify "vulnerabilities" of mutp53 with studies on organoids derived from patients. Furthermore, her research interests are based on understanding the molecular mechanisms of miRNA deregulation in cancer. In this regard she is obtaining data that demonstrate a new GOF of mutp53 that resides in its ability to inhibit the expression of miRNA at the level of biogenesis interfering with Dicer activity. Moreover, in collaboration with Giulia Piaggio's group, she is characterizing the functional role of NF-Y on transcriptional deregulation of miRNAs during epithelial mesenchymal transition of colon tumor cells.

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Scientific Directorate

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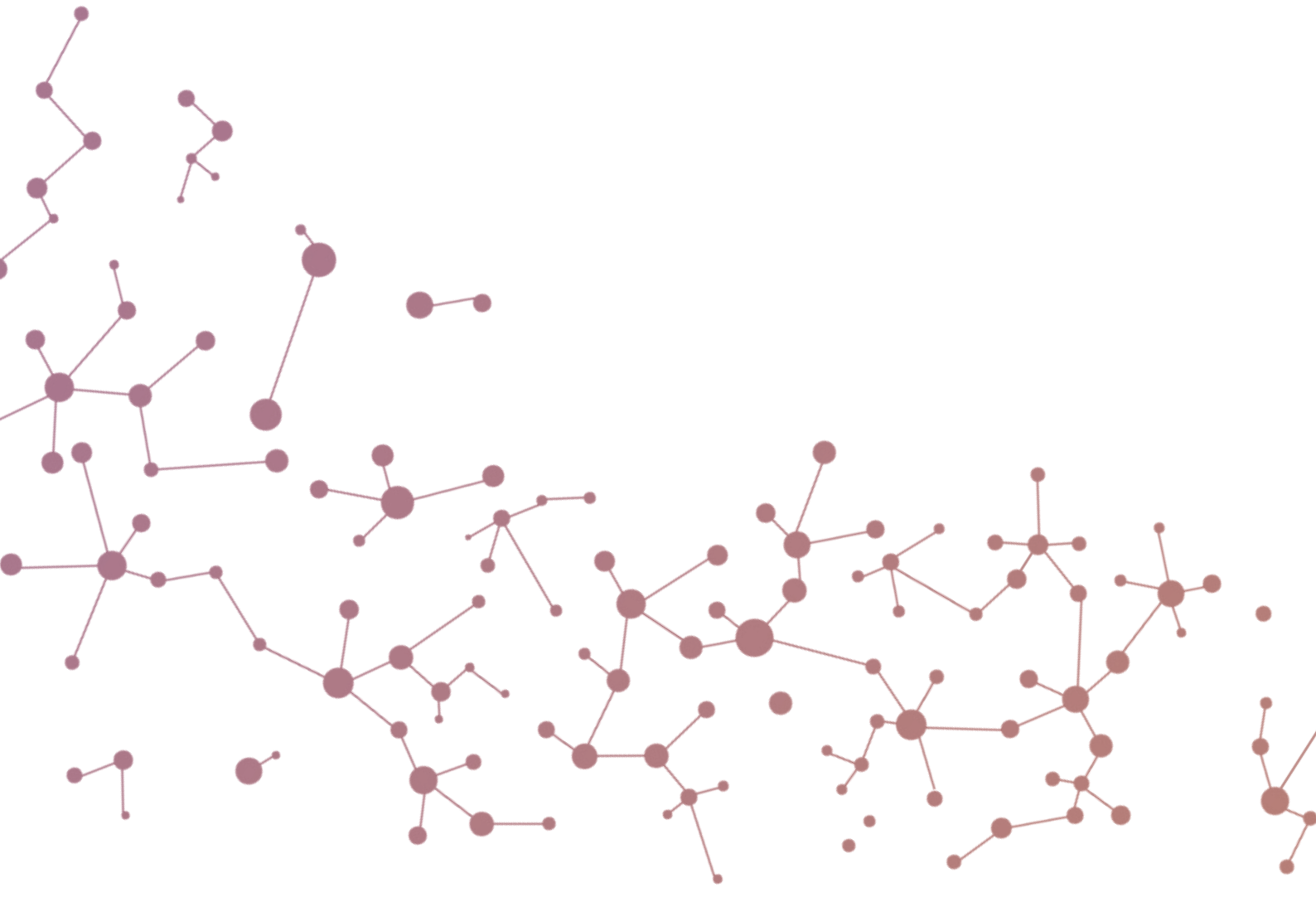
Clinical Trials 2020



Brain

Status*	Title	Division	Principal investigator	Patients IRE 2020
O	A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED ADJUVANT TRIAL IN NEWLY DIAGNOSED PRIMARY GLIOBLASTOMA SUBJECTS TO ASSESS THE EFFICACY AND SAFETY OF 2-HYDROXYOLEIC ACID (2-OHOA) IN COMBINATION WITH RADIOTHERAPY AND TEMOZOLOMIDE STANDARD OF CARE TREATMENT	Medical Oncology 1	Alessandra Fabi	0
C	Andamento delle cefalee primarie in pazienti con glioma ad alto grado, uno studio osservazionale multicentrico	Neuroncology	Andrea Pace	0
O	Definizione dei temi rilevanti per le cure palliative nei pazienti affetti da neoplasia cerebrale e loro caregivers attraverso un questionario semi-strutturato e focus group (Studio ancillare per la produzione di Linee Guida Italiane sulle cure palliative nei pazienti affetti da neoplasia cerebrale)	Neuroncology	Andrea Pace	4
O	DEVELOPMENT OF A QUESTIONNAIRE TO MEASURE INSTRUMENTAL ACTIVITIES OF DAILY LIVING (I-ADL) IN PATIENTS WITH PRIMARY BRAIN TUMORS AND BRAIN METASTASES: PHASE IV INTERNATIONAL FIELD TESTING	Neuroncology	Andrea Pace	8

O	EFFICACY AND TOLERABILITY OF LOW VS. STANDARD DAILY DOSES OF ANTIEPILEPTIC DRUGS IN NEWLY DIAGNOSED, PREVIOUSLY UNTREATED EPILEPSY (STANDLOW). A MULTICENTER, RANDOMIZED, SINGLE-BLIND, PARALLEL GROUP TRIAL	Neuroncology	Marta Maschio	0
O	Glioma: aspetti biomolecolari dal tessuto alla Radiomica	Neuroncology	Veronica Villani	47
C	Il processo decisionale relativo al trattamento nei pazienti neuronocologici	Neuroncology	Andrea Pace	0
C	Percorso di assistenza integrata e teleconsulenza al paziente con epilessia secondaria a neoplasia cerebrale	Neuroncology	Marta Maschio	20
O	REGORAFENIB IN RELAPSED GLIOBLASTOMA. A MULTICENTER, PROSPECTIVE AND OBSERVATIONAL STUDY	Neuroncology	Veronica Villani	0
O	REPURPOSING THE ANTIPSYCHOTIC DRUG CLORPROMAZINE AS A THERAPEUTIC AGENT IN THE COMBINED TREATMENT OF NEWLY DIAGNOSED GLIOBLASTOMA MULTIFORME	Cellular Network and Therapeutic Target	Marco Giorgio Paggi	4
O	REVISION OF THE EUROPEAN ORGANISATION FOR RESEARCH AND TREATMENT OF CANCER (EORTC) QUALITY OF LIFE QUESTIONNAIRE (QLQ)-BN20 BRAIN TUMOUR MODULE	Neuroncology	Andrea Pace	12
O	Studio di validazione di una serum-miRNA signature, associata allo stuatus di IDH1, come biomarcatori non-invasivi diagnostici e prognostici, in pazienti affetti da glioma	Oncogenomics and Epigenetics	Maria Giulia Rizzo	7

O	Valutazione del valore predittivo dei biomarkers ematochimici trombofilici,metabolici ed infiammatori pre-operatori per complicanze post-operatorie e per sopravvivenza in pazienti affetti da glioma e da metastasi cerebrali - studio osservazionale retrospettivo	Neuroncology	Tatiana Koudriavtseva	44
C	Valutazione dell'efficacia e della tollerabilià del brivaracetam in pazienti con epilessia tumorale: studio retrospettico multicentrico	Neuroncology	Marta Maschio	2

Breast

Status*	Title	Division	Principal investigator	Patients IRE 2020
11	PHASE 3 STUDY OF SACITUZUMAB GOVITECAN (IMMU-132) VERSUS TREATMENT OF PHYSICIAN'S CHOICE (TPC) IN SUBJECTS WITH HORMONAL RECEPTOR-POSITIVE (HR+) HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR 2 (HER2) NEGATIVE METASTATIC BREAST CANCER (MBC) WHO HAVE FAILED AT LEAST TWO PRIOR CHEMOTHERAPY REGIMENS	Medical Oncology 1	Francesco Cognetti	0
O	A MASTER PROTOCOL EMPOWERING MECHANOBIOLOGY TRANSLATIONAL RESEARCH IN BREAST CANCER -	Oncogenomics and Epigenetics	Giovanni Blandino	50
C	A MULTI-CENTRE, OPEN-LABEL, RANDOMIZED CLINICAL TRIAL COMPARING THE EFFICACY AND SAFETY OF THE ANTIBODY-DRUG CONJUGATE SYD985 TO PHYSICIAN'S CHOICE IN PATIENTS WITH HER2-POSITIVE UNRESECTABLE LOCALLY ADVANCED OR METASTATIC BREAST CANCER	Medical Oncology 1	Francesco Cognetti	5
O	A PHASE 2 STUDY OF TAS-120 IN METASTATIC BREAST CANCERS HARBORING FIBROBLAST GROWTH FACTOR RECEPTOR (FGFR) AMPLIFICATIONS	Medical Oncology 1	Francesco Cognetti	0

O	A PHASE 2, OPEN LABEL, MULTICENTER, SINGLE ARM TRIAL EVALUATING THE ACTIVITY AND SAFETY OF ABEMACICLIB + AROMATASE INHIBITORS (AIS) AFTER 1ST-LINE TREATMENT WITH HIGH-DOSE FULVESTRANT IN HORMONE-RECEPTOR-POSITIVE (HR+), HUMAN-EPIDERMAL-GROWTH-FACTOR-NEGATIVE (HER2-) ADVANCED BREAST CANCER PATIENTS. THE HERMIONE-7 TRIAL	Medical Oncology 1	Paola Malaguti	0
O	A PHASE 2, OPEN LABEL, MULTICENTER, SINGLE ARM TRIAL EVALUATING THE ACTIVITY AND SAFETY OF ABEMACICLIB + AROMATASE INHIBITORS (AIS) AFTER 1ST-LINE TREATMENT WITH HIGH-DOSE FULVESTRANT IN HORMONE-RECEPTOR-POSITIVE (HR+), HUMAN-EPIDERMAL-GROWTH-FACTOR-NEGATIVE (HER2-) ADVANCED BREAST CANCER PATIENTS. THE HERMIONE-7 TRIAL	Medical Oncology 2	Patrizia Vici	3
O	A PHASE II TRIAL OF ATEZOLIZUMAB PLUS CARBOPLATIN PLUS PACLITAXEL AS FIRST-LINE THERAPY IN METASTATIC TRIPLE-NEGATIVE PD-L1 POSITIVE BREAST CANCER PATIENTS	Medical Oncology 1	Paola Malaguti	1

O	A PHASE III RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTICENTER STUDY EVALUATING THE EFFICACY AND SAFETY OF GDC-9545 COMBINED WITH PALBOCICLIB COMPARED WITH LETROZOLE COMBINED WITH PALBOCICLIB IN PATIENTS WITH ESTROGEN RECEPTOR-POSITIVE, HER2-N	Medical Oncology 2	Patrizia Vici	0
C	A PHASE III, MULTICENTER, RANDOMIZED, OPEN-LABEL TRIAL TO EVALUATE EFFICACY AND SAFETY OF RIBOCICLIB WITH ENDOCRINE THERAPY AS AN ADJUVANT TREATMENT IN PATIENTS WITH HORMONE RECEPTOR-POSITIVE, HER2-NEGATIVE, EARLY BREAST CANCER (NEW ADJUVANT TRIAL WITH RIBOCICLIB [LEE011]: NATALEE)	Medical Oncology 1	Francesco Cognetti	2
C	A PHASE III, MULTICENTER, RANDOMIZED, OPEN-LABEL TRIAL TO EVALUATE EFFICACY AND SAFETY OF RIBOCICLIB WITH ENDOCRINE THERAPY AS AN ADJUVANT TREATMENT IN PATIENTS WITH HORMONE RECEPTOR-POSITIVE, HER2-NEGATIVE, EARLY BREAST CANCER (NEW ADJUVANT TRIAL WITH RIBOCICLIB [LEE011]: NATALEE)	Medical Oncology 2	Patrizia Vici	3

C	A RANDOMISED, MULTICENTRE, OPEN-LABEL PHASE II TRIAL INVESTIGATING ACTIVITY OF CHEMOTHERAPY AND LAPATINIB AND TRASTUZUMAB IN PATIENTS WITH HER2-POSITIVE METASTATIC BREAST CANCER (MBC) REFRACTORY TO ANTI HER2 THERAPIES	Medical Oncology 1	Francesco Cognetti	0
C	A STUDY EVALUATING THE PREGNANCY OUTCOMES AND SAFETY OF INTERRUPTING ENDOCRINE THERAPY FOR YOUNG WOMEN WITH ENDOCRINE RESPONSIVE BREAST CANCER WHO DESIRE PREGNANCY	Medical Oncology 2	Patrizia Vici	0
O	A THREE-DIMENSIONAL EVALUATION TOXICITY OF AROMATASE INHIBITOR IN WOMEN WITH BREAST CANCER AT AN EARLY STAGE: EXPECTED, DETECTED AND PERCEIVED TOXICITY. MULTICENTER PILOT STUDY. TARPEA STUDY.	Medical Oncology 1	Mariantonietta Simona Gasparro	3
C	ADJUVANT TREATMENT FOR HIGH-RISK TRIPLE NEGATIVE BREAST CANCER PATIENTS WITH THE ANTI-PD-L1 ANTIBODY AVELUMAB: A PHASE III RANDOMIZED TRIAL	Medical Oncology 1	Francesco Cognetti	1

O	ATEZOLIZUMAB, PERTUZUMAB AND TRASTUZUMAB WITH CHEMOTHERAPY AS NEOADJUVANT TREATMENT OF HER2 POSITIVE EARLY HIGH-RISK AND LOCALLY ADVANCED BREAST CANCER (APTNEO)	Medical Oncology 1	Francesco Cognetti	10
O	EPIK-B2: A TWO PART, PHASE III, MULTICENTER, RANDOMIZED (1:1), DOUBLE-BLIND, PLACEBOCONTROLLED STUDY TO ASSESS THE EFFICACY AND SAFETY OF ALPELISIB (BYL719) IN COMBINATION WITH TRASTUZUMAB AND PERTUZUMAB AS MAINTENANCE THERAPY IN PATIENTS WITH HER2-POSITIVE ADVANCED BREAST CANCER WITH A PIK3CA MUTATION	Medical Oncology 1	Francesco Cognetti	1
C	ERIBULIN CONCOMITATN TO RADIOTHERAPY IN HER-2 NEGATIVE ADVANCED BREAST CANCER DISEASE WITH BONE METASTASES: MULTICENTER NON INTERVENTISTIC OBSERVATIONAL STUDY	Medical Oncology 1	Alessandra Fabi	0
O	EVALUATION OF MEDICAL TREATMENTS (CHEMOTHERAPY, ORMONAL THERAPY AND BIOLOGICAL THERAPY) IN METASTATICA BREAST CANCER PATIENTS ACCORDING TO BIOLOGICA SUBTYPE AND LINE OF TREATMENT	Medical Oncology 1	Francesco Cognetti	72
O	EXPLORING OPTIMAL SEQUENCE TREATMENT IN HER2+ PERTUZUMAB PRETREATED	Medical Oncology 2	Laura Pizzuti	2

	ADVANCED BREAST CANCER PATIENTS. THE STEP TRIAL			
O	FULVESTRANT AND TRASTUZUMAB IN PATIENTS WITH HORMONE RECEPTOR POSITIVE HER2 POSITIVE METASTATIC BREAST CANCER	Medical Oncology 1	Alessandra Fabi	4
O	FULVESTRANT AND TRASTUZUMAB IN PATIENTS WITH HORMONE RECEPTOR POSITIVE HER2 POSITIVE METASTATIC BREAST CANCER : AN OBSERVATIONAL RETROSPECTIVE STUDY	Medical Oncology 2	Patrizia Vici	11
O	FULVESTRANT FOLLOWED BY EVEROLIMUS PLUS EXEMESTANE VS EXAMESTANE AND EVEROLIMUS FOLLOWED BY FULVESTRANT IN POSTMENOPAUSAL WOMEN WITH HR+ AND HER2- LOCALLY ADVANCED (LABC) OR METASTATIC BREAST CANCER (MBC) PREVIOUSLY TREATED WITH NSAI	Medical Oncology 1	Francesco Cognetti	0
C	FULVESTRANT FOLLOWED BY EVEROLIMUS PLUS EXEMESTANE VS EXAMESTANE AND EVEROLIMUS FOLLOWED BY FULVESTRANT IN POSTMENOPAUSAL WOMEN WITH HR+ AND HER2- LOCALLY ADVANCED (LABC) OR METASTATIC BREAST CANCER (MBC) PREVIOUSLY TREATED WITH NSAI	Medical Oncology 2	Patrizia Vici	0

O	GENOMIC TEST AIMING TO IDENTIFY ACTIONABLE MUTATIONS IN HORMONE RECEPTOR (HR) NEGATIVE/HER2 POSITIVE OR TRIPLE NEGATIVE (TN) BREAST CANCER RESISTANT TO NEOADJUVANT THERAPY: FEASIBILITY AND IMPROVEMENT	Medical Oncology 1	Francesco Cognetti	2
O	GENOMIC TEST AIMING TO IDENTIFY ACTIONABLE MUTATIONS IN HORMONE RECEPTOR (HR) NEGATIVE/HER2 POSITIVE OR TRIPLE NEGATIVE (TN) BREAST CANCER RESISTANT TO NEOADJUVANT THERAPY: FEASIBILITY AND IMPROVEMENT	Medical Oncology 2	Patrizia Vici	4
C	Il ruolo del TDM-1 nella real world evidence	Medical Oncology 1	Alessandra Fabi	0
O	Incidenza delle infezioni del sito chirurgico nella chirurgia oncologica della mammella durante la pandemia SARS-CoV 2: esperienza di un centro italiano ad alto flusso	Breast Surgery Unit	Claudio Botti	0
O	LIQUID BIOPSY: INTERCEPTING MUTATIONAL TRAJECTORIES OF HER2 BREAST CANCER IN PATIENTS UNDER T-DM1 TREATMENT	Medical Oncology 1	Francesco Cognetti	12
O	METASTATIC DISEASE: THE KEY UNMET NEED IN ONCOLOGY/ METORG: A LIVING BIOBANK OF HUMAN BC METASTASES (WP2 TASK 2.2 AIRC PROJECT: THE KEY UNMET NEED IN ONCOLOGY)	Oncogenomics and Epigenetics	Giovanni Blandino	75

C	MULTICENTER, RANDOMIZED, PHASE II STUDY OF NEOADJUVANT CHEMOTHERAPY ASSOCIATED OR NOT WITH ZOLEDRONATE AND ATORVASTATIN IN TRIPLE NEGATIVE BREAST CANCERS- YAPPETIZER STUDY	Medical Oncology 1	Paola Malaguti	3
O	NEW THERAPEUTIC APPROACHES IN HER2-DRIVEN BREAST CANCER: ROLE OF THE CHAPERONIN HSP90 IN RESPONSE TO PHARMACOLOGICAL TREATMENTS	Medical Oncology 1	Gianluigi Ferretti	0
O	PALBOCICLIB PLUS FULVESTRANT IN WOMEN WITH HORMONE RECEPTOR POSITIVE AND HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR TYPE 2 NEGATIVE LOCALLY ADVANCED OR METASTATIC BREAST CANCER PREVIOUSLY TREATED WITH A CDK4/6 INHIBITOR IN COMBINATION WITH HORMONAL THERAPY: A MULTICENTER, PHASE II TRIAL	Medical Oncology 1	Mariantonietta Simona Gasparro	3
O	PHASE II, MULTICENTER, SINGLE ARM TRIAL TO ASSESS THE FEASIBILITY OF FIRST LINE RIBOCICLIB IN COMBINATION WITH A NON STEROIDAL AROMATASE INHIBITOR IN ELDERLY PATIENTS WITH HORMONE RECEPTOR POSITIVE/ HER2 NEGATIVE ADVANCED BREAST CANCER	Medical Oncology 1	Paola Malaguti	0

O	SECOND LINE ERIBULIN FOLLOWED BY CAPECITABINE OR THE REVERSE SEQUENCE IN HER2-NEGATIVE METASTATIC BREAST CANCER (MBC) PATIENTS: A RANDOMIZED PHASE II STUDY - ERICA TRIAL	Medical Oncology 1	Mariantonietta Simona Gasparro	2
C	Studio BRIDE. Diagnosi e trattamento del carcinoma mammario in Italia: studio osservazionale prospettico nazionale della Fondazione AIOM	Medical Oncology 1	Alessandra Fabi	14
C	Studio BRIDE. Diagnosi e trattamento del carcinoma mammario in Italia: studio osservazionale prospettico nazionale della Fondazione AIOM	Medical Oncology 2	Patrizia Vici	11
C	Studio multicentrico su Palbociclib nel trattamento del carcinoma mammario: Real World Data e indicatori di farmacoutilizzazione	Pharmacovigilance	Felice Musicco	136
O	THE IDENTITY STUDY: A RETROSPECTIVE-PROSPECTIVE OBSERVATIONAL COHORT STUDY TO EVALUATE CANCER PREVENTION STRATEGIES IN WOMEN WITH A DELETERIOUS MUTATION IN BRCA1-2	Medical Oncology 1	Paola Malaguti	8
O	THE IDENTITY STUDY: A RETROSPECTIVE-PROSPECTIVE OBSERVATIONAL COHORT STUDY TO EVALUATE CANCER PREVENTION STRATEGIES IN WOMEN WITH A DELETERIOUS MUTATION IN BRCA1-2	Medical Oncology 2	Patrizia Vici	0

O	Studio osservazionale prospettico sul trattamento ormonale adiuvante delle pazienti in premenopausa con carcinoma mammario precoce positivo ai recettori degli estrogeni	Medical Oncology 1	Mariantonietta Simona Gasparro	5
O	Studio osservazionale prospettico di valutazione dell'attività clinica e della tollerabilità della combinazione Ribociclib+letrozolo in pazienti con carcinoma mammario avanzato HR+	Medical Oncology 1	Mariantonietta Simona Gasparro	10
C	GINSENG AMERICANO (PANAX QUINQUEFOLIUS) nella prevenzione della fatigue moderata-severa in pazienti con carcinoma della mammella operate e sottoposte a chemioterapia adiuvante. STUDIO NICSO (Network Italiano Cure di Supporto in Oncologia)	Medical Oncology 1	Alessandra Fabi	12
O	Studio multicentrico osservazionale sulla scelta terapeutica a progressione da trattamento di prima linea con CDK4/6 inhibitors e inibitori delle aromatasi in pazienti con diagnosi di carcinoma mammario HR+ HER2	Medical Oncology 1	Alessandra Fabi	11
O	Studio multicentrico osservazionale sulla scelta terapeutica a progressione da trattamento di prima linea con CDK4/6 inhibitors e inibitori delle aromatasi in pazienti con diagnosi di carcinoma mammario HR+ HER2	Medical Oncology 2	Patrizia Vici	0

O	Efficacia e tollerabilità della chemioterapia neoadiuvante contenente carboplatino nelle pazienti affette da carcinoma mammario triplo negativo: studio multicentrico osservazionale prospettico. NeoCarbo study	Medical Oncology 2	Patrizia Vici	2
O	Infiltrato linfocitario tumorale nel carcinoma della mammella triplo negativo pT1 pN0	Medical Oncology 2	Patrizia Vici	0
O	Valutazione di biomarcatori predittivi di efficacia e tossicità in pazienti affette da carcinoma mammario avanzato HR+HER2- in trattamento con inibitori delle chinasi ciclino-dipendenti CDK4/6. Lo studio INDACO.	Medical Oncology 2	Patrizia Vici	37
O	Studio osservazionale prospettico di valutazione dell'attività clinica e della tollerabilità della combinazione Ribociclib+letrozolo in pazienti con carcinoma mammario avanzato HR+	Medical Oncology 2	Patrizia Vici	0
C	Effetto della combinazione di dieta a basso indice glicemico, esercizio fisico e vitamina D sulla ricorrenza del carcinoma della mammella (studio DEDiCa)	Medical Oncology 2	Patrizia Vici	0
O	Studio multicentrico osservazionale prospettico di valutazione dell'impiego di chemioterapia metronomica con vinorelbina, capecitabina e ciclofosfamide in pazienti affette da carcinoma mammario metastatico HER2-negativo	Medical Oncology 2	Patrizia Vici	0

O	Efficacia e tollerabilita'di eribulina come chemioterapia di seconda linea in pazienti con tumore della mammella metastatico triplo negativo. Studio osservazionale retrospettivo multicentrico. TETRIS Trial	Medical Oncology 2	Patrizia Vici	44
O	Rilevanza prognostica dell'attivazione della coagulazione nella stratificazione del rischio e valutazione degli outcome di trattamento in pazienti affette da carcinoma mammario localmente avanzato: lo studio ARIAS	Medical Oncology 2	Patrizia Vici	25
O	Valutazione complessiva dei pattern terapeutici e outcomes clinici nelle pazienti affette da carcinoma mammario avanzato HER2 positivo trattato con agenti anti-HER2.Studio retrospettivo multicentrico. PANHER study	Medical Oncology 2	Patrizia Vici	0
O	La creatività come risorsa nel processo della malattia oncologica. Studio pilota sulla introduzione della Drammaterapia Integrata nel Percorso assistenziale di Sostegno al paziente Oncologico	Epidemiology & Tumor Registry	Maria Cecilia Cercato	9
O	Studio di un algoritmo di Intelligenza Artificiale per la classificazione di immagini di Tomosintesi Digitale del Seno per la diagnosi automatizzata del cancro alla mammella	Medical Physics	Valeria Landoni	0
O	Bisogni riabilitativi nelle pazienti affette da carcinoma mammario in fase precoce: validazione di un questionario patient reported outcome (PRO)	Psychology	Patrizia Pugliese	0

Endocrine

Status*	Title	Division	Principal investigator	Patients IRE 2020
O	A MULTICENTER, RANDOMIZED, OPEN-LABEL, PHASE 3 TRIAL COMPARING LOXO-292 TO PHYSICIANS CHOICE OF CABOZANTINIB OR VANDETANIB IN PATIENTS WITH PROGRESSIVE, ADVANCED, KINASE INHIBITOR NAÃ VE, RET-MUTANT MEDULLARY THYROID CANCER (LIBRETTO-531)	Endocrinology Oncology	Marialuisa Appetecchia	0
O	A PHASE 3, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY OF CABOZANTINIB (XL184) IN SUBJECTS WITH RADIOIODINE-REFRACTORY DIFFERENTIATED THYROID CANCER WHO HAVE PROGRESSED AFTER PRIOR VEGFR-TARGETED THERAPY	Endocrinology Oncology	Marialuisa Appetecchia	0
O	OBSERVATIONAL RETROSPECTIVE/ PROSPECTIVE STUDY ON GENDER BASED IMPACT ON SAFETY AND EFFICACY IN LENVATINIB TREATED PATIENTS WITH RADIO IODINE REFRACTORY DIFFERENTIATED THYROID CANCER –DTC. GISEL STUDY	Endocrinology Oncology	Marialuisa Appetecchia	8
O	I fattori di rischio delle neoplasie neuroendocrine gastro-entero-pancreatiche (GEP-NENs): studio caso controllo	Endocrinology Oncology	Marialuisa Appetecchia	50
O	Itanet Registry: raccolta multicentrica dei casi di Tumore Neuroendocrino Gastro-Entero-Pancreatico	Endocrinology Oncology	Marialuisa Appetecchia	4

O	L'impatto del genere nell'endocrinologia oncologica	Endocrinology Oncology	Marialuisa Appetecchia	1107
O	Progetto di prescrizione dell'Informazione INFO RP	Endocrinology Oncology	Marialuisa Appetecchia	10
O	Valutazione della funzione gonadica nei pazienti affetti da carcinoma differenziato della tiroide, sottoposti a terapia Radiometabolica con I 131	Endocrinology Oncology	Marialuisa Appetecchia	0

Gastrointestinal

Status*	Title	Division	Principal investigator	Patients IRE 2020
O	Impatto sulla sopravvivenza globale di piano terapeutico personalizzato con dosimetria quantitativa 3d versus piano terapeutico standard nella radioembolizzazione epatica con 90Y nell'epatocarcinoma: trial clinico randomizzato	Nuclear Medicine	Rosa Sciuto	9
O	A PHASE 3, OPEN-LABEL, RANDOMIZED, ACTIVE-CONTROLLED, MULTICENTER STUDY TO EVALUATE THE EFFICACY AND SAFETY OF PEMIGATINIB VERSUS GEMCITABINE PLUS CISPLATIN CHEMOTHERAPY IN FIRST-LINE TREATMENT OF PARTICIPANTS WITH UNRESECTABLE OR METASTATIC CHOLANGIOCARCINOMA WITH FGFR2 REARRANGEMENT (FIGHT-302)	Medical Oncology 1	Massimo Zeuli	0
O	A PHASE III, RANDOMISED, DOUBLE BLIND, PLACEBO CONTROLLED, MULTICENTRE STUDY OF MAINTENANCE OLAPARIB MONOTHERAPY IN PATIENTS WITH GBRCA MUTATED METASTATIC PANCREATIC CANCER WHOSE DISEASE HAS NOT PROGRESSED ON FIRST LINE PLATINUM BASED CHEMOTHERAPY	Medical Oncology 1	Vanja Vaccaro	0
O	DECIPHERING THE MOLECULAR TRAITS OF NON-CANONICAL RESPONDERS TO ADVANCE PERSONALIZED THERAPY IN GASTRIC CANCER	Medical Oncology 2	Marcello Maugeri Sacca'	0

O	EARLY DETECTION OF RELAPSES IN STAGE IV COLORECTAL CANCER PATIENTS - REDCLOUD (REsidual Disease, Colorectal cancer, Liquid biOpsy Detection)	Hepato-Biliary-Pancreatic Surgery	Gianluca Grazi	0
C	ERBITUX METASTATIC COLORECTAL CANCER STRATEGY STUDY: A PHASE III RANDOMIZED TWO ARM STUDY WITH FOLFIRI + CETUXIMAB UNTIL DISEASE PROGRESSION COMPARED TO FOLFIRI + CETUXIMAB FOR 8 CYCLES FOLLOWED BY CETUXIMAB ALONE UNTIL DISEASE PROGRESSION IN FIRST LINE TREATMENT OF PATIENTS WITH RAS AND BRAF WILD TYPE METASTATIC COLORECTAL CANCER	Medical Oncology 1	Massimo Zeuli	0
O	HE.RC.O.LE.S. PROJECT HEPATOCARCINOMA RECURRENCE ON THE LIVER STUDY GROUP - FASE 2 -	Hepato-Biliary-Pancreatic Surgery	Gianluca Grazi	0
C	HIPK2 AS A PROGNOSTIC BIOMARKER IN STAGE I AND STAGE II COLORECTAL CANCER: VALIDATION AND UNDERLYING MECHANISMS	Cellular Network and Therapeutic Target	Silvia Soddu	70
O	IN VIVO IMAGING OF MACRO-ENVIRONMENT BEFORE TUMOR APPEARANCE: NOVELAPPROACH TO IDENTIFY EARLY TUMOR BIOMARKERS IN PANCREATIC CANCER	SAFU	Luisa de Latouliere	0
O	INNOVATIVE TOOLS FOR EARLY DIAGNOSIS AND RISK ASSESSMENT OF PANCREATIC CANCER	Immunology and Immunotherapy	Paola Nistico'	13

O	INTERMITTENT OR CONTINUOUS PANITUMUMAB PLUS FOLFIRI FOR FIRST-LINE TREATMENT OF PATIENTS WITH RAS/B-RAF WILD-TYPE METASTATIC COLORECTAL CANCER: A RANDOMIZED PHASE 2 TRIAL	Medical Oncology 1	Massimo Zeuli	0
O	ISOLATION AND CHARACTERIZATION OF TUMOR STEM CELLS IN INTRA- AND EXTRA-HEPATIC CHOLANGIOCARCINOMA	Hepato-Biliary-Pancreatic Surgery	Gianluca Grazi	5
O	MANAGEMENT OF COMPLICATED INTRA-ABDOMINAL COLLECTIONS AFTER COLORECTAL SURGERY. PROT. COMPASS	Hepato-Biliary-Pancreatic Surgery	Gianluca Grazi	8
O	NEXT-GENERATION SEQUENTING ANALYSIS OF PRIMARY COLORECTAL CANCER LESIONS AND PAIRED DISTNT METASTASES	SAFU	Carlo Leonetti	0
O	PHASE II RANDOMIZED STUDY OF MAINTENANCE REGORAFENIB VS PLACEBO IN NO PROGRESSION PATIENTS AFTER FIRST-LINE PLATINUM AND FLUOROPYRIMIDINES BASED CHEMOTHERAPY IN HER2 NEGATIVE LOCALLY ADVANCED/ METASTATIC GASTRIC OR GASTROESOPHAGEL JUNCTION CANCER (A-MANTRA STUDY)	Medical Oncology 1	Francesco Cognetti	0
O	PROSPECTIVE VALIDATION OF A DNA DAMAGE REPAIR-HIPPO PATHWAY SIGNATURE IN PATIENTS WITH ADVANCED GASTRIC CANCER	Medical Oncology 2	Marcello Maugeri Sacca’	12

O	RANDOMIZED PHASE III STUDY OF TRIPLET mFOLFOXIRI PLUS PANITUMUMAB versus mFOLFOX6 PLUS PANITUMUMAB AS INITIAL THERAPY FOR UNRESECTABLE RAS AND BRAF WILDTYPE METASTATIC COLORECTAL CANCER PATIENTS	Medical Oncology 1	Francesco Cognetti	0
O	RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, STUDY OF THE EFFICACY, SAFETY AND TOLERABILITY OF EPA-FFA GASTRO-RESISTANT CAPSULES, IN PATIENTES WITH FAMILIAR ADENOMATOUS POLYPOSIS (FAP)	Digestive Endoscopy	Vittoria Anna Maria Stigliano	2
O	RETROSPECTIVE OBSERVATIONAL STUDY ON THE USE OF IMMUNOTHERAPY WITH ANTI-PD1 ANTIBODIES IN PATIENTS WITH MSI-H METASTATIC COLORECTAL CANCER	Medical Oncology 1	Francesco Cognetti	0
O	STUDY TO ASSESS THE SAFETY, TOLERABILITY, PHARMACOKINETICS, AND PHARMACODYNAMICS OF TRK-750 IN COLORECTAL CANCER PATIENTS WITH CHEMOTHERAPY-INDUCED PERIPHERAL NEUROPATHY FOLLOWING OXALIPLATIN-CONTAINING CHEMOTHERAPY IN THE ADJUVANT SETTING	Neuroncology	Andrea Pace	0
O	THERAPEUTIC TARGETING OF FGR2 FUSIONS IN MODELS OF INTRAHEPATIC CHOLANGIOCARCINOMA	Oncogenomics and Epigenetics	Oreste Segatto	0

O	TRF2 ONCOGENIC FUNCTIONS: FROM MECHANISTIC INSIGHTS TO THERAPEUTIC TARGETING	Oncogenomics and Epigenetics	Annamaria Biroccio	19
O	ULTRASENSITIVE PLASMONIC DEVICES FOR EARLY CANCER DIAGNOSIS	Oncogenomics and Epigenetics	Patrizio Giacomini	44
O	Identificazione di nuovi bersagli immunoterapeutici e di nuovi antigeni nel carcinoma del colon-retto	Hepato-Biliary-Pancreatic Surgery	Gianluca Grazi	13
O	Caratterizzazione clinico-epidemiologica, isto-morfologica e biologica del colangiocarcinoma e partecipazione a un progetto di ricerca internazionale denominato cholangiocarcinoma (CCA) registry of the european network for study of cholangiocarcinoma (ENS CCA): an international cohort study on cholangiocarcinoma at basic, translational and clinical level	Hepato-Biliary-Pancreatic Surgery	Gianluca Grazi	0
O	Registro italiano di resezioni epatiche mini-invasive	Hepato-Biliary-Pancreatic Surgery	Gianluca Grazi	25
O	Identificazione di nuovi bersagli immunoterapeutici nell'epatocarcinoma attraverso lo studio delle cellule T regolatorie e del secretoma	Hepato-Biliary-Pancreatic Surgery	Gianluca Grazi	13
O	Registro Italiano Chirurgia Mininvasiva Pancreatica (IGOMIPS)	Hepato-Biliary-Pancreatic Surgery	Gianluca Grazi	0
O	Studio interventistico senza medicinale multicentrico in pazienti affetti da adenocarcinoma localmente avanzato del pancreas: radioterapia stereotassica - IRENE-1	Radiotherapy	Giuseppe Sanguineti	0
C	MKK3 come target terapeutico in tumore al colon-retto	Medical Physics	Gianluca Bossi	13

O	Studio multicentrico pilota sull'utilizzo della Chemioterapia Intra- Peritoneale a flusso d'Aria Pressurizzata (PIPAC) in pazienti affetti da carcinosi peritoneale di origine intestinale, ovarica, gastrica e nei tumori primitivi del peritoneo non eleggibili a peritonectomia + HIPEC	Perithoneal Tumor Unit	Orietta Federici	2
O	Identificazione di una signature di microRNA regolata da TRF2 con valore progostico e terapeutico nel tumore del colon-retto	Oncogenomics and Epigenetics	Pasquale Zizza	17
O	Analisi differenziale dei profili di espressione dei microrRNA in colangiocarcinoma, epatocarcinoma e metastasi epatiche	Oncogenomics and Epigenetics	Giovanni Blandino	26
O	Sviluppo di un modello preclinico avanzato di tumore del colon-retto per identificare trattamenti efficaci in pazienti resistenti alla terapia ANTI-EGFR	SAFU	Manuela Porru	6
O	Studio dei microRNA regolati dalle proteine p53 mutate e dei loro geni target come biomarcatori prognostici e/o bersagli terapeutici nel tumore del colon-retto (CRC)	SAFU	Aymon Gurtner	10
C	A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTICENTER, TRIAL OF CRENOLANIB IN SUBJECTS WITH ADVANCED OR METASTATIC GASTROINTESTINAL STROMAL TUMORS WITH A D842V MUTATION IN THE PDGFRA GENE	Sarcoma and Rare Tumor Unit	Virginia Ferraresi	0

Gynecological

Status*	Title	Division	Principal investigator	Patients IRE 2020
O	A PHASE 3, RANDOMIZED, DOUBLE-BLIND, MULTICENTER STUDY OF DOSTARLIMAB (TSR-042) PLUS CARBOPLATIN-PACLITAXEL VERSUS PLACEBO PLUS CARBOPLATIN-PACLITAXEL IN PATIENTS WITH RECURRENT OR PRIMARY ADVANCED ENDOMETRIAL CANCER	Medical Oncology 1	Antonella Savarese	1
O	A PHASE II TRIAL OF OLAPARIB IN PATIENTS WITH RECURRENT OVARIAN CANCER WILD TYPE FOR GERMLINE AND SOMATIC BRCA 1 AND 2 GENES: THE MITO 31 TRANSALATIONAL STUDY	Medical Oncology 1	Antonella Savarese	0
O	A PHASE IIIB, RANDOMISED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTICENTRE STUDY OF OLAPARIB MAINTENANCE RETREATMENT IN PATIENTS WITH EPITHELIAL OVARIAN CANCER PREVIOUSLY TREATED WITH A PARPI AND RESPONDING TO REPEAT PLATINUM CHEMOTHERAPY(OREO)	Medical Oncology 1	Francesco Cognetti	0
C	A RANDOMIZED, DOUBLE-BLIND, PHASE 3 COMPARISON OF PLATINUM-BASED THERAPY WITH TSR-042 AND NIRAPARIB VERSUS STANDARD OF CARE PLATINUM-BASED THERAPY AS FIRST-LINE TREATMENT OF STAGE III OR IV NONMUCINOUS EPITHELIAL OVARIAN CANCER	Medical Oncology 1	Antonella Savarese	0

O	A RANDOMIZED, PHASE 3, DOUBLE-BLIND STUDY OF CHEMORADIOTHERAPY WITH OR WITHOUT PEMBROLIZUMAB FOR THE TREATMENT OF HIGH-RISK, LOCALLY ADVANCED CERVICAL CANCER (KEYNOTE-A18 ENGOT-CX11)	Medical Oncology 1	Antonella Savarese	0
C	AN OPEN-LABEL, RANDOMIZED, PHASE 3 CLINICAL TRIAL OF REGN2810 OF INVESTIGATOR'S CHOICE OF CHEMOTHERAPY IN RECURRENT OR METASTATIC CERVICAL CARCINOMA	Medical Oncology 1	Antonella Savarese	1
C	DYNAMIC SIGNALING RECIPROCITY SHAPES INVADOPODIA FUNCTION AND METASTATIC PROCESS OF OVARIAN CANCER: ROLE OF ENDOTHELIN-1	Preclinical Models and new Therapeutics	Laura Rosano'	0
O	MAINTENANCE THERAPY WITH TRABECTEDIN AFTER COMBINATION THERAPY LIPOSOMAL DOXORUBICIN PLUS TRABECTEDIN VS LIPOSOMAL DOXORUBICIN PLUS TRABECTEDIN IN PATIENTS AFFECTED BY RELAPSED OVARIAN CANCER RECURRING BETWEEN 6 AND 12 MONTHS AFTER PLATINUM BASED CHEMOTHERAPY	Medical Oncology 1	Antonella Savarese	1
O	MAINTENANCE THERAPY WITH TRABECTEDIN AFTER COMBINATION THERAPY LIPOSOMAL DOXORUBICIN PLUS TRABECTEDIN VS LIPOSOMAL DOXORUBICIN PLUS TRABECTEDIN IN PATIENTS AFFECTED BY RELAPSED OVARIAN CANCER RECURRING BETWEEN 6 AND 12 MONTHS AFTER PLATINUM BASED CHEMOTHERAPY	Medical Oncology 2	Patrizia Vici	0

O	MICROVESICLES' MICRORNA PROFILING IN BIOLOGICAL FLUID AND TISSUES OF OVARIAN CANCER PATIENTS	Pathology	Mariantonia Carosi	0
O	MITO CERV 3:PHASE II STUDY ON CARBOPLATIN-PACLITAXEL-PEMBROLIZUMAB IN NEOADJUVANT TREATMENT OF LOCALLY ADVANCED CERVICAL CANCER	Medical Oncology 1	Antonella Savarese	0
O	MITO CERV 3:PHASE II STUDY ON CARBOPLATIN-PACLITAXEL-PEMBROLIZUMAB IN NEOADJUVANT TREATMENT OF LOCALLY ADVANCED CERVICAL CANCER	Medical Oncology 2	Patrizia Vici	0
O	NIRAPARIB AS MAINTENANCE TREATMENT IN PLATINUM RESPONSIVE OVARIAN CANCER PATIENTS: A REAL LIFE STUDY BY MITO GROUP	Medical Oncology 1	Antonella Savarese	5
O	NIRAPARIB AS MAINTENANCE TREATMENT IN PLATINUM RESPONSIVE OVARIAN CANCER PATIENTS: A REAL LIFE STUDY BY MITO GROUP	Medical Oncology 2	Patrizia Vici	0
O	ONCOLOGICAL OUTCOME AFTER COMPLETING OR ABANDONING (RADICAL) HYSTERECTOMY IN PATIENTS WITH CERVICAL CANCER AND INTRAOPERATIVE DETECTION OF LN POSITIVITY	Medical Oncology 1	Antonella Savarese	0

O	POST-AUTHORIZATION SAFETY STUDY TO EVALUATE THE RISKS OF MYELODYSPLASTIC SYNDROME/ACUTE MYELOID LEUKEMIA AND SECOND PRIMARY MALIGNANCIES IN ADULT PATIENTS WITH PLATINUM-SENSITIVE, RELAPSED, HIGH-GRADE SEROUS EPITHELIAL OVARIAN, FALLOPIAN TUBE, OR PRIMARY PERITONEAL CANCER RECEIVING MAINTENANCE TREATMENT WITH ZEJULA® (NIRAPARIB)	Medical Oncology 1	Antonella Savarese	6
O	PREDICTIVE ROLE OF A MICRORNA SIGNATURE IN RELAPSED, HIGH-GRADE SEROUS, OVARIAN CANCER PATIENTS RECHALLENGED WITH PLATINUM-BASED REGIMENS	Medical Oncology 2	Patrizia Vici	0
O	SENTINEL LYMPH NODE IN EARLY OVARIAN CANCER: THE SELLY PROTOCOL	Ginecology	Enrico Vizza	0
O	TARGETING ENDOTHELIN-1/Î'-ARRESTIN1 NETWORK AT THE TUMOR-STOMA INTERFACE IN HIGH GRADE SEROUS OVARIAN CANCER	Preclinical Models and new Therapeutics	Anna Bagnato	0
C	Chirurgia mininvasiva vs chirurgia laparotomica nei carcinosarcomi uterini: un'esperienza multi-centrica	Ginecology	Enrico Vizza	35
C	Pattern di recidiva nel carcinoma della cervice uterina stadio FIGO IB1: confronto tra approccio chirurgico laparotomico vs chirurgia mini-invasiva	Ginecology	Emanuela Mancini	105
O	Il DNA libero circolante (cfDNA) come biomarcatore prognostico nel cancro dell'endometrio	Ginecology	Enrico Vizza	0

C	Dall'immunotolleranza materno-fetale all'immune-escape nella patologia ginecologica maligna: potenziali target di immuno-terapia nel carcinoma endometriale. Studio pilota	Ginecology	Enrico Vizza	41
O	Regolazione della sintesi di mediatori lipidici pro-infiammatori e pro-risolventi del processo infiammatorio nel tumore dell'ovaio	Ginecology	Enrico Vizza	0
O	MITO 9b: studio osservazionale prospettico sui tumori rari ginecologici	Medical Oncology 1	Antonella Savarese	0
C	Studio multicentrico, interventistico non farmacologico, no-profit su conoscenze, attitudine ed esperienza verso gli studi clinici randomizzati in donne con una diagnosi di tumore ovarico	Medical Oncology 2	Patrizia Vici	11

Head and Neck

Status*	Title	Division	Principal investigator	Patients IRE 2020
O	A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED ADJUVANT TRIAL IN NEWLY DIAGNOSED PRIMARY GLIOBLASTOMA SUBJECTS TO ASSESS THE EFFICACY AND SAFETY OF 2-HYDROXYOLEIC ACID (2-OHOA) IN COMBINATION WITH RADIOTHERAPY AND TEMOZOLOMIDE STANDARD OF CARE TREATMENT	Medical Oncology 1	Alessandra Fabi	0
C	Andamento delle cefalee primarie in pazienti con glioma ad alto grado, uno studio osservazionale multicentrico	Neuroncology	Andrea Pace	0
O	Definizione dei temi rilevanti per le cure palliative nei pazienti affetti da neoplasia cerebrale e loro caregivers attraverso un questionario semi-strutturato e focus group (Studio ancillare per la produzione di Linee Guida Italiane sulle cure palliative nei pazienti affetti da neoplasia cerebrale)	Neuroncology	Andrea Pace	4
O	DEVELOPMENT OF A QUESTIONNAIRE TO MEASURE INSTRUMENTAL ACTIVITIES OF DAILY LIVING (I-ADL) IN PATIENTS WITH PRIMARY BRAIN TUMORS AND BRAIN METASTASES: PHASE IV INTERNATIONAL FIELD TESTING	Neuroncology	Andrea Pace	8

O	EFFICACY AND TOLERABILITY OF LOW VS. STANDARD DAILY DOSES OF ANTIEPILEPTIC DRUGS IN NEWLY DIAGNOSED, PREVIOUSLY UNTREATED EPILEPSY (STANDLOW). A MULTICENTER, RANDOMIZED, SINGLE-BLIND, PARALLEL GROUP TRIAL	Neuroncology	Marta Maschio	0
O	Glioma: aspetti biomolecolari dal tessuto alla Radiomica	Neuroncology	Veronica Villani	47
C	Il processo decisionale relativo al trattamento nei pazienti neuronocologici	Neuroncology	Andrea Pace	0
C	Percorso di assistenza integrata e teleconsulenza al paziente con epilessia secondaria a neoplasia cerebrale	Neuroncology	Marta Maschio	20
O	REGORAFENIB IN RELAPSED GLIOBLASTOMA. A MULTICENTER, PROSPECTIVE AND OBSERVATIONAL STUDY	Neuroncology	Veronica Villani	0
O	REPURPOSING THE ANTIPSYCHOTIC DRUG CLORPROMAZINE AS A THERAPEUTIC AGENT IN THE COMBINED TREATMENT OF NEWLY DIAGNOSED GLIOBLASTOMA MULTIFORME	Cellular Network and Therapeutic Target	Marco Giorgio Paggi	4
O	REVISION OF THE EUROPEAN ORGANISATION FOR RESEARCH AND TREATMENT OF CANCER (EORTC) QUALITY OF LIFE QUESTIONNAIRE (QLQ)-BN20 BRAIN TUMOUR MODULE	Neuroncology	Andrea Pace	12
O	Studio di validazione di una serum-miRNA signature, associata allo stuatus di IDH1, come biomarcatori non-invasivi diagnostici e prognostici, in pazienti affetti da glioma	Oncogenomics and Epigenetics	Maria Giulia Rizzo	7

O	Valutazione del valore predittivo dei biomarkers ematochimici trombofilici,metabolici ed infiammatori pre-operatori per complicanze post-operatorie e per sopravvivenza in pazienti affetti da glioma e da metastasi cerebrali - studio osservazionale retrospettivo	Neuroncology	Tatiana Koudriavtseva	44
C	Valutazione dell'efficacia e della tollerabilià del brivaracetam in pazienti con epilessia tumorale: studio retrospettico multicentrico	Neuroncology	Marta Maschio	2

Hematological

Status*	Title	Division	Principal investigator	Patients IRE 2020
O	A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, TWO-ARM, PHASE 2 STUDY OF ME-401 IN SUBJECTS WITH FOLLICULAR LYMPHOMA AFTER FAILURE OF TWO OR MORE PRIOR SYSTEMIC THERAPIES	Haematology Oncology	Andrea Mengarelli	1
O	A PHASE 3, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY OF ACALABRUTINIB IN COMBINATION WITH RITUXIMAB, CYCLOPHOSPHAMIDE, DOXORUBICIN, VINCRISTINE, AND PREDNISONE (R-CHOP) IN SUBJECTS <= 65 YEARS WITH PREVIOUSLY UNTREATED NON-GERMINAL CENTER DIFFUSE LARGE B-CELL LYMPHOMA	Haematology Oncology	Francesca Palombi	0
O	A RANDOMISED PHASE III STUDY TO COMPARE ARSENIC TRIOXIDE (ATO) COMBINED TO ATRA VERSUS STANDARD ATRA AND ANTHRACYCLINE-BASED CHEMOTHERAPY (AIDA REGIMEN) FOR NEWLY DIAGNOSED, NON HIGH-RISK ACUTE PROMYELOCYTIC LEUKEMIA	Haematology Oncology	Andrea Mengarelli	0
C	ACCURACY OF ALTERNATIVE TP53 SOMATIC MUTATIONAL AND EXPRESSION ANALYSES FOR THE PROGNOSTICATION OF MYELODYSPLASTIC SYNDROME	Haematology Oncology	Atelda Romano	0

C	AN INTERNATIONAL PHASE II TRIAL ASSESSING TOLERABILITY AND EFFICACY OF SEQUENTIAL METHOTREXATE-ARACYTIN-BASED COMBINATION AND R-ICE COMBINATION, FOLLOWED BY HIGH-DOSE CHEMOTHERAPY SUPPORTED BY AUTOLOGOUS STEM CELL TRANSPLANT, IN PATIENTS WITH SYSTEMIC B-CELL LYMPHOMA WITH CENTRAL NERVOUS SYSTEM INVOLVEMENT AT DIAGNOSIS OR RELAPSE (MARIETTA REGIMEN)	Haematology Oncology	Francesca Palombi	0
C	AN OPEN-LABEL, MULTI-CENTER, PHASE IIIB STUDY TO ASSESS THE SAFETY AND EFFICACY OF MIDOSTAURIN (PKC412) IN PATIENTS 18 YEARS OF AGE OR OLDER WITH NEWLY-DIAGNOSED FLT3-MUTATED ACUTE MYELOID LEUKEMIA WHO ARE ELIGIBLE FOR 7+3 OR 5+2 CHEMOTHERAPY	Haematology Oncology	Andrea Mengarelli	0
O	CHANGES IN DISEASE APPROACH AND OUTCOME IN 2010 AND 2013 OF NEWLY DIAGNOSED AND 2ND LINE MULTIPLE MYELOMA PATIENTS TREATED IN HEMATOLOGY CENTERS IN LAZIO REGION (ITALY)	Haematology Oncology	Francesco Pisani	0
O	CHANGES IN DISEASE APPROACH AND OUTCOME IN 2015 AND 2018 OF NEWLY DIAGNOSED AND R/R MULTIPLE MYELOMA PATIENTS TREATED IN HEMATOLOGY CENTERS IN LAZIO REGION (ITALY)	Haematology Oncology	Svitlana Gumenyuk	0

O	DETECTION OF POOR MOBILIZER (PM) IN MULTIPLE MYELOMA (MM) PATIENTS: PROSPECTIVE PRODUCT REGISTRY	Haematology Oncology	Andrea Mengarelli	3
O	EFFICACY OF ELTROMBOPAG PLUS LENALIDOMIDE COMBINATION THERAPY IN PATIENTS WITH IPSS LOW AND INTERMEDIATE-RISK MYELODYSPLASTIC SYNDROME WITH ISOLATED DEL5Q: A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO CONTROLLED STUDY	Haematology Oncology	Atelda Romano	0
O	ELTROMBOPAG FOR THE TREATMENT OF THROMBOCYTOPENIA DUE TO LOW- AND INTERMEDIATE RISK MYELODYSPLASTIC SYNDROMES. (EQOL-MDS)	Haematology Oncology	Atelda Romano	0
O	EPIDEMIOLOGY OF COVID-19 INFECTION IN PATIENTS WITH HEMATOLOGICAL MALIGNANCIES: A EUROPEAN HEMATOLOGY ASSOCIATION SURVEY	Haematology Oncology	Francesco Marchesi	41
O	HEMATOLOGICAL MALIGNANCIES ASSOCIATED BLOODSTREAM INFECTIONS SURVEILLANCE	Haematology Oncology	Antonio Spadea	4
O	ITALIAN REGISTRY ON THE PREVALENCE OF IDH1/IDH2 MUTATIONS IN PATIENTS WITH ACUTE MYELOID LEUKEMIA	Haematology Oncology	Andrea Mengarelli	0
O	LIQUID BIOPSY: CIRCULATING MICRORNAS AND TUMOR DNA(CTDNA) AS NOVEL NON-INVASIVE BIOMARKERS IN DIFFUSE LARGE B-CELL LYMPHOMA	Oncogenomics and Epigenetics	Maria Giulia Rizzo	17

O	LONG TERM QUALITY OF LYFE SYMPTON BURDEN IN ACUTE PROMYELOCYTIC LEUKEMIA (APL) PATIENTS TREATED WITH ARSENIC TRIOXIDE (ATO) OR STANDAR CHEMIOTHERAPY	Haematology Oncology	Atelda Romano	0
O	LONG TERM SURVIVAL OF PATIENTS AFFECTED BY MULTIPLE MYELOMA.AN ITALIAN MULTICENTER RETROSPECTIVE, OBSERVATIONAL STUDY OF A REAL-LIFE EXPERIENCE (LTS-IN-MM)	Haematology Oncology	Francesco Pisani	20
C	NATIONAL TREATMENT PROGRAM WITH SEQUENTIAL CHEMOTHERAPY AND BLINATUMOMAB TO IMPROVE MINIMAL RESIDUAL DISEASE RESPONSE AND SURVIVAL IN PHILADELPHIA CHROMOSOME-NEGATIVE B-CELL PRECURSOR ADULT ACUTE LYMPHOBLASTIC LEUKEMIA	Haematology Oncology	Antonio Spadea	0
O	NEXT-GENERATION SEQUENCING FOR BCR-ABL KD MUTATION SCREENING IN PHILADELPHIA CHROMOSOME-POSITIVE LEUKEMIAS	Haematology Oncology	Andrea Mengarelli	0
O	NON-INTERVENTIONAL STUDY TO ASSESS THE SAFETY PROFILE OF IDELALISIB IN PATIENTS WITH REFRACTORY FOLLICULAR LYMPHOMA (FL)	Haematology Oncology	Francesca Palombi	2

O	PHASE III STUDY TO ASSESS THE IMPACT OF GEMTUZUMAB OZOGAMICIN, IN COMBINATION WITH STANDARD CHEMOTHERAPY, ON THE LEVELS OF MINIMAL RESIDUAL DISEASE, AND THE ROLE OF GLASDEGIB AS A POST-TRANSPLANT MAINTENANCE, IN ADULT PATIENTS, AGED 18-60 YEARS, WITH PREVIOUSLY UNTREATED, DE NOVO, FAVORABLE-INTERMEDIATE-RISK ACUTE MYELOID LEUKEMIA	Haematology Oncology	Andrea Mengarelli	0
O	PHASE-III RANDOMIZED STUDY TO OPTIMIZE TKIS MULTIPLE APPROACHES - (OPTKIMA) - AND QUALITY OF LIFE (QOL) IN ELDERLY PATIENTS (>=60 YEARS) WITH PH+ CHRONIC MYELOID LEUKEMIA (CML) AND MR3.0/MR4.0 STABLE MOLECULAR RESPONSE	Haematology Oncology	Atelda Romano	0
O	PROSPECTIVE RANDOMIZED STUDY ON THE FEASIBILITY OF ALLOGENEIC STEM CELL TRANSPLANTATION IN HIGHER-RISK-MYELODYSPLASTIC SYNDROMES, PERFORMED UPFRONT OR PRECEDED BY AZACITIDINE OR CONVENTIONAL CHEMOTHERAPY, ACCORDING TO THE BM-BLAST PROPORTION (ACROBAT STUDY)	Haematology Oncology	Svitlana Gumenyuk	0

O	PROSPECTIVE, OBSERVATIONAL, MULTICENTESTUDY OF THE ROLE OF PRIMARY ANTIFUNGAL PROPHYLAXIS TO PREVENT INVASIVE ASPERGILLOSIS IN ELDERLY PATIENTS WITH ACUTE MYELOID LEUKEMIA UNDERGOING CONSOLIDATION THERAPY	Haematology Oncology	Francesco Marchesi	5
O	REAL-LIFE USE OF CARFILZOMIB, LENALIDOMIDE AND DESAMETHASONE (KRd)	Haematology Oncology	Svitlana Gumenyuk	0
O	REVISION OF ANTIFUNGAL STATEGIES DEFINITIONS FOR INVASIVE FUNGAL INFECTIONS (PROVEN/ PROBABLE/POSSIBLE) IN PATIENTS WITH HEMATOLOGICAL MALIGNANCIES (REDEFI-SEIFEM)	Haematology Oncology	Francesco Marchesi	12
O	ROLE OF CHE-1 IN TRANSCRIPTIONAL ADDICTION OF MULTIPLE MYELOMA	SAFU	Maurizio Fanciulli	55
O	SARS-CoV-2 infection in patients with hematological malignancies: the Italian Hematology Alliance	Haematology Oncology	Andrea Mengarelli	39
O	THE ROLE OF A NEW NUTRACEUTICAL COMPOUND IN THE PREVENTION OF BORTEZOMIB-RELATED NEUROTOXICITY IN NEWLY DIAGNOSED MULTIPLE MYELOMA PATIENTS: A PILOT STUDY	Neuroncology	Marta Maschio	7
O	Valutazione dell'efficacia di un percorso di educazione terapeutica e sviluppo di competenze di self-care utilizzando conversation map nei pazienti con mieloma multiplo in esordio	DITRAR-Nursery Division	Nicolo Panattoni	0

C	Evidenza citofluorimetrica di un sistema linfatico cerebrale nel liquido cefalo-rachidiano di pazienti affetti da linfoma-non Hodgkin senza compromissione lepto-meningea da malattia	Biobank BBIRE	Iole Cordone	138
O	Registro epidemiologico della leucemia mieloide cronica (LMC)	Haematology Oncology	Atelda Romano	0
O	Studio osservazionale retrospettivo e prospettico per il monitoraggio della leucemia mieloide cronica nei pazienti adulti nella Regione Lazio	Haematology Oncology	Atelda Romano	0
O	Studio osservazionale sull'Incidenza di infezioni fungine in pazienti affetti da leucemia mieloide acuta FLT3+ trattati con chemioterapia+midostaurina	Haematology Oncology	Francesco Marchesi	7
O	Studio retrospettivo osservazionale multicentrico sulle infezioni batteriche/ fungine/virali nei pazienti con leucemia mieloide acuta secondarie trattati con daurorubicina-citarabina liposomiale (VYXEOs) nella real-life	Haematology Oncology	Francesco Marchesi	10
O	Studio prospettico osservazionale sulle complicanze infettive in pazienti con Leucemia Acuta Mieloide trattati in prima linea con agenti demetilanti nel periodo 2019-2020	Haematology Oncology	Antonio Spadea	3
C	Studio prospettico osservazionale sull'utilizzo e sul monitoraggio della cardiotossicità delle antracicline in pazienti con linfoma diffuso a grandi cellule B	Haematology Oncology	Francesca Palombi	0
C	Valutazione dei livelli plasmatici di isavuconazolo in pazienti ematologici con infezioni fungine invasive	Haematology Oncology	Francesco Marchesi	0

C	Identificazione e studio dell'impatto di varianti Genetiche di suscettibilità in Leucemia Mieloide Acuta (AML) adolescenziale	SAFU	Maurizio Fanciulli	2
O	Analisi trascrittomica ed epigenomica per l'identificazione di biomarcatori coinvolti nei meccanismi di farmacoresistenza del Mieloma Multiplo	SAFU	Maurizio Fanciulli	55

Lung

Status*	Title	Division	Principal investigator	Patients IRE 2020
O	A PHASE 2 STUDY OF POZIOTINIB IN PATIENTS WITH NON-SMALL CELL LUNG CANCER, LOCALLY ADVANCED OR METASTATIC, WITH EGFR OR HER2 EXON 20 INSERTION MUTATION (POZITIVE20-1)	Medical Oncology 1	Fabiana Cecere	2
O	A PHASE 3, MULTICENTER, RANDOMIZED, OPEN-LABEL TRIAL TO COMPARE THE EFFICACY AND SAFETY OF PEMBROLIZUMAB (MK-3475) IN COMBINATION WITH LENVATINIB (E7080/MK-7902) VERSUS DOCETAXEL IN PREVIOUSLY TREATED PARTICIPANTS WITH METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) AND PROGRESSIVE DISEASE (PD) AFTER PLATINUM DOUBLET CHEMOTHERAPY AND IMMUNOTHERAPY (LEAP-008)	Medical Oncology 1	Francesco Cognetti	3
O	A PHASE 3, RANDOMIZED, BLINDED, PLACEBO-CONTROLLED STUDY OF TISLELIZUMAB (BGB-A317) PLUS CHEMORADIOTHERAPY FOLLOWED BY TISLELIZUMAB MONOTHERAPY IN NEWLY DIAGNOSED, STAGE III SUBJECTS WITH LOCALLY ADVANCED UNRESECTABLE NON-SMALL CELL LUNG CANCER	Medical Oncology 1	Fabiana Cecere	0

C	A PHASE II RANDOMIZED STUDY OF PEMBROLIZUMAB IN PATIENTS WITH ADVANCED MALIGNANT PLEURAL MESOTHELIOMA	Medical Oncology 1	Fabiana Cecere	1
O	A RANDOMIZED PHASE 2 STUDY COMPARING IMMUNOTHERAPY WITH CHEMOTHERAPY IN THE TREATMENT OF ELDERLY PATIENTS WITH ADVANCED NSCLC	Medical Oncology 1	Fabiana Cecere	0
O	A RANDOMIZED, NON-COMPARATIVE, PHASE II STUDY INVESTIGATING THE BEST EPIDERMAL GROWTH FACTOR RECEPTOR TYROSINE KINASE INHIBITOR (EGFR-TKI) SEQUENCE IN ADVANCED OR METASTATIC NON-SMALL-CELL LUNG CANCER (NSCLC) HARBORING EGFR MUTATIONS	Medical Oncology 2	Federico Cappuzzo	3
O	A RANDOMIZED, OPEN-LABEL, PHASE 3 STUDY OF PRALSETINIB VERSUS STANDARD OF CARE FOR FIRST LINE TREATMENT OF RET FUSIONPOSITIVE, METASTATIC NON-SMALL CELL LUNG CANCER	Medical Oncology 1	Fabiana Cecere	0
C	A STANDARD REGIMEN OF DEXAMETHASONE IN COMPARISON TO TWO DEX-SPARING REGIMENS IN ADDITION TO NEPA IN PREVENTING CINV IN NAÃ VE NSCLC PATIENTS TO BE TREATED WITH CISPLATIN BASED CHEMOTHERAPY: A THREE-ARM, OPEN-LABEL, RANDOMIZED STUDY	Medical Oncology 1	Fabiana Cecere	0

C	BE-PACIFIC ITALIAN OBSERVATIONAL STUDY ON PATIENT MANAGEMENT STRATEGIES IN REAL-WORLD CLINICAL PRACTICE FOR PATIENTS WITH LOCALLY ADVANCED (STAGE III) NSCLC	Medical Oncology 1	Fabiana Cecere	2
O	DECURARIZATION AFTER THORACIC ANESTHESIA - A PROSPECTIVE MULTICENTER DOUBLE-BLIND RANDOMIZED TRIAL COMPARING SUGAMMADEX VS NEOSTIGMINE REVERSAL AFTER THORACIC ANESTHESIA	Anaesthesiology, Critical Area andIntensive Care	Cecilia Coccia	0
O	DEVELOPMENT OF AN IMMUNOSCORE TEST TO DEFINE IMMUNOLOGICAL PARAMETERS ASSOCIATED WITH THE RISK OF RECURRENCE IN N0 NSCLC PATIENTS, WITHIN THE NATIONAL ONCOLOGY NETWORK ALLEANZA CONTRO IL CANCRO OF THE ITALIAN MINISTRY OF HEALTH	Immunology and Immunotherapy	Paola Nistico'	36
O	EXPLORATORY STUDY FOR THE IDENTIFICATION OF THE COMPONENTS OF AN IMMUNOLOGICAL SCORE BASED ON BIOMOLECULAR ANALYSIS AND ITS ASSOCIATION WITH THE RESPONSE TO ICBS IN PATIENTS WITH ADVANCED LUNG CANCER, WITHIN THE NATIONAL ONCOLOGY NETWORK ALLEANZA CONTRO IL CANCRO OF THE ITALIAN MINISTRY OF HEALTH	Immunology and Immunotherapy	Paola Nistico'	7

O	HMENA SPLICING IN THE DIALOGUE BETWEEN TUMOR, ECM, CAFS AND IMMUNE CELLS: ROLE IN NSCLC PROGRESSION AND DRUG RESISTAN	Immunology and Immunotherapy	Paola Nistico'	132
O	IASLC INTERNATIONAL STAGING PROJECT 9th edition TNM	Pathology	Mirella Marino	0
O	ITALIAN OBSERVATIONAL STUDY ON POST-DURVALUMAB PROGRESSION TREATMENT STRATEGIES IN REAL WORLD CLINICAL PRACTICE FOR PATIENTS WITH UNRESECTABLE STAGE III NSCLC	Medical Oncology 1	Fabiana Cecere	0
O	ITALIAN OBSERVATIONAL STUDY ON POST-DURVALUMAB PROGRESSION TREATMENT STRATEGIES IN REAL WORLD CLINICAL PRACTICE FOR PATIENTS WITH UNRESECTABLE STAGE III NSCLC	Medical Oncology 2	Federico Cappuzzo	0
O	PHASE II SINGLE ARM STUDY WITH CABOZANTINIB IN NON-SMALL CELL LUNG CANCER PATIENTS WITH MET DEREGULATION	Medical Oncology 1	Fabiana Cecere	0
O	PHASE II STUDY TO EVALUATE THE ACTIVITY AND SAFEETY OF CABOZANTINIB IN TRETREATED, ADVANCED RET-RE ARRANGED NON-SMALL CELL LUNG CANCER PATIENTS	Medical Oncology 1	Sabrina Vari	0

O	PHASE II TRIAL EVALUATING THE EFFICACY OF DURVALUMAB (MEDI4736) AS SECOND-LINE THERAPY IN NON- SMALL-CELL LUNG CANCER PATIENTS RECEIVING CONCOMITANT STEROIDS	Medical Oncology 1	Consuelo D'Ambrosio	1
O	PHASE II, OPEN-LABEL STUDY, OF ATEZOLIZUMAB IN A COHORT OF PRETREATED, ADVANCED NON-SMALL CELL LUNG CANCER (NSCLC) PATIENTS WITH RARE HISTOLOGICAL SUBTYPES (CHANCE TRIAL)	Medical Oncology 1	Fabiana Cecere	0
C	ROBOTIC VS MANUAL VATS LOBECTOMY: PROSPECTIVE, RANDOMIZED, MULTICENTRIC STUDY ON VIDEOTHORACOSCOPIC (VATS) VS ROBOTIC APPROACH FOR LOBECTOMY OR ANATOMICAL SEGMENTECTOMY IN PATIENTS AFFECTED BY EARLY LUNG CANCER	Thoracic Surgery	Francesco Facciolo	0
C	THE IMPACT ON THE HEALTH STATUS AND ADHERENCE IN A REALLIFE SETTING OF ITALIAN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE IN TREATMENT WITH TRIMBOW pMDI b.i.d.:A 12-MONTH PROSPECTIVE OBSERVATIONAL STUDY	Pulmonary Phisiopathology	Maria Papale	0
O	VALIDATION OF THE ALLIANCE AGAINST CANCER LUNG PANEL IN PATIENTS WITH NON SMALL CELL LUNG CANCER	Medical Oncology 1	Fabiana Cecere	0

O	VALIDATION OF THE ALLIANCE AGAINST CANCER LUNG PANEL IN PATIENTS WITH NON SMALL CELL LUNG CANCER	Medical Oncology 2	Silvia Carpano	19
O	Valore prognostico della Ratio Neutrofili Linfociti e della Ratio Piastrine Linfociti in pazienti sottoposti a chirurgia radicale per NSCLC	Thoracic Surgery	Francesco Facciolo	1100
O	Profilo mutazionale mediante Next Generation Sequencing di oncogeni e oncosoppressori coinvolti nella patogenesi del carcinoma polmonare non a piccole cellule: implicazioni biologiche e impatto clinico	Pathology	Simonetta Buglioni	126
O	Sorveglianza attiva delle complicanze infettive polmonari postoperatorie dopo interventi di chirurgia toracica: instituzione di un database per la valutazione dell'appropriatezza della profilassi antibiotica	Anaesthesiology, Critical Area andIntensive Care	Cecilia Coccia	0
O	Studio dei meccanismi di immuno-evasione delle cellule staminali tumorali (CSC) di adenocarcinoma del polmone	Thoracic Surgery	Francesco Facciolo	11
C	Validazione della proposta di Classificazione Linfonodale del TNM per il tumore del polmone non a piccole cellule: ruolo dell'istologia, della linfoadenectomia e dei trattamenti integrati	Thoracic Surgery	Francesco Facciolo	80
O	Analisi Radiomiche di immagini TC in pazienti con non-small cancer del polmone in trattamento con immunoterapia	Radiology	Mauro Caterino	161
O	REGISTRO ASMA GRAVE - Studio osservazionale, trasversale e/o retrospettivo, non interventistico, multicentrico, nazionale	Pulmonary Phisiopathology	Maria Papale	0
O	Analisi del ruolo dell'estradiolo e dei suoi metaboliti nella progressione della patologia pleurica	Preclinical Models and new Therapeutics	Rossella Galati	0

Sarcoma / Bone Tumors

Status*	Title	Division	Principal investigator	Patients IRE 2020
O	A MULTICENTER PHASE 1, OPEN-LABEL STUDY OF DCC-3014 TO ASSESS THE SAFETY, TOLERABILITY, PHARMACOKINETICS, AND PHARMACODYNAMICS IN PATIENTS WITH ADVANCED TUMORS	Sarcoma and Rare Tumor Unit	Virginia Ferraresi	0
O	A MULTICENTER RETROSPECTIVE OBSERVATIONAL STUDY OF EFFECTIVENESS OF HIGH DOSE OF IFOSFAMITE THROUGH ELASTOMETRO (HD-IFOEL) IN PATIENTS AFFECTED BY RELAPSER/REFRECTORY OSTEOSARCOMA (R/R OS)	Sarcoma and Rare Tumor Unit	Virginia Ferraresi	0
O	EPITHELIOID SARCOMA. AN OBSERVATIONAL STUDY. EPISOBS	Sarcoma and Rare Tumor Unit	Virginia Ferraresi	0
O	GENOMIC CHARACTERIZATION STUDY FOR THE IMPROVEMENT OF SARCOMA DIAGNOSIS	Cellular Network and Therapeutic Target	Rita Falcioni	24
O	INTERNATIONAL RANDOMISED CONTROLLED TRIAL OF CHEMOTHERAPY FOR THE TREATMENT OF RECURRENT AND PRIMARY REFRACTORY EWING SARCOMA	Sarcoma and Rare Tumor Unit	Virginia Ferraresi	1
C	LOCALIZED HIGH-RISK SOFT TISSUE SARCOMAS OF THE EXTREMITIES AND TRUNK IN ADULTS: AN INTEGRATED APPROACH COMPRISING STANDARD VS HISTOTYPE-ORIENTED NEOADJUVANT CHEMOTHERAPY (ISG-STS 10-01)	Sarcoma and Rare Tumor Unit	Virginia Ferraresi	0

O	PHASE 2 RANDOMIZED TRIAL OF TRABECTEDIN + OLAPARIB VS. TRABECTEDIN IN ADVANCED, METASTATIC OR UNRESECTABLE SOFT TISSUE SARCOMA AFTER FAILURE OF STANDARD TREATMENTS	Sarcoma and Rare Tumor Unit	Virginia Ferraresi	1
O	PULMONARY METASTASECTOMY FOR SARCOMA	Thoracic Surgery	Francesco Facciolo	75
O	THE METROPHOLYS STUDY. METRONOMIC CYCLOPHOSPHAMIDE VS DOXORUBICIN IN ELDERLY PATIENTS WITH ADVANCED SOFT TISSUE SARCOMAS RANDOMIZED, CONTROLLED OPEN LABEL CLINICAL TRIAL	Sarcoma and Rare Tumor Unit	Virginia Ferraresi	0
O	Studio del significato clinico di cellule ed acidi nucleici tumorali circolanti nei sarcomi dei tessuti molli e dell'osso	Orthopaedics	Roberto Biagini	4
O	Intelligenza artificiale nella caratterizzazione dei tumori dell'osso a matrice cartilaginea e dei tessuti molli	Orthopaedics	Roberto Biagini	57
O	La protesi di gomito Mutars nella ricostruzione dopo resezioni di tumori ossei del gomito; indicazioni, risultati e complicanze	Orthopaedics	Carmine Zoccali	0
O	Rischio di osteopenia/ osteoporosi indotte da chemioterapia in pazienti con sarcomi ossei. Studio osservazionale prospettico	Endocrinology Oncology	Marialuisa Appetecchia	0
O	Applicazione della Medicina basata sulla Narrazione nel trattamento dei pazienti affetti da sarcoma	Epidemiology & Tumor Registry	Maria Cecilia Cercato	3

C	Valore dei parametri quantitativi della 18FDG-PET/CT nella previsione della risposta istologica alla chemioterapia neoadiuvante e delle recidive cliniche nei pazienti con sarcoma di Ewing dell'osso e dei tessuti molli	Nuclear Medicine	Rosa Sciuto	28
C	Impatto clinico-diagnostico della PET/TC con 18F-FDG nella stadiazione e ristadiazione dei sarcomi dei tessuti molli	Nuclear Medicine	Alessio Annovazzi	282
O	Nuove terapie a bersaglio molecolare nei sarcomi pediatrici e dell'adulto	Cellular Network and Therapeutic Target	Rossella Loria	0
O	Studio multicentrico prospettico per l'analisi del profilo genomico di sarcomi di pazienti pediatrici e giovani adulti alla diagnosi e/o alla ricaduta/refrattarietÃ di malattia	Sarcoma and Rare Tumor Unit	Virginia Ferraresi	0
O	Pattern di cura nei pazienti anziani con sarcomi dell'osso e dei tessuti molli; analisi retrospettiva	Sarcoma and Rare Tumor Unit	Virginia Ferraresi	0
O	Efficacia del trattamento con Gemcitabina - Docetaxel in pazienti con osteosarcoma andati incontro a recidiva dopo trattamento di prima linea con HD- IFO - studio osservazionale retrospettivo	Sarcoma and Rare Tumor Unit	Virginia Ferraresi	0

Skin

Status*	Title	Division	Principal investigator	Patients IRE 2020
O	A MICRORNA-BASED APPROACH TO ADVANCED DIAGNOSIS AND THERAPY OF METASTATIC MELANOMA	Scientific Directorate	Gennaro Ciliberto	22
C	A PHASE II TRIAL OF VEMURAFENIB PLUS COBIMETINIB IN PATIENTS TREATED WITH PRIOR FIRST-LINE SYSTEMIC IMMUNOTHERAPY FOR INOPERABLE LOCALLY ADVANCED OR METASTATIC MELANOMA	Medical Oncology 1	Francesco Cognetti	0
C	A RETROSPECTIVE CHART REVIEW OF ITALIAN PATIENTS WITH ADVANCED/METASTATIC MELANOMA WITH LIMITED OR NO TREATMENT OPTIONS AND TREATED WITH PEMBROLIZUMAB IN THE PEMBROLIZUMAB (MK-3475) EXPANDED ACCESS PROGRAM (EAP)	Medical Oncology 1	Virginia Ferraresi	0
O	COMBINATION OF TARGETED THERAPY (ENCORAFENIB AND BINIMETINIB) FOLLOWED BY COMBINATION OF IMMUNOTHERAPY (IPILIMUMAB AND NIVOLUMAB) VS IMMEDIATE COMBINATION OF IMMUNOTHERAPY IN PATIENTS WITH UNRESECTABLE OR METASTATIC MELANOMA WITH BRAF V600 MUTATION: AN EORTC RANDOMIZED PHASE II STUDY (EBIN)	Medical Oncology 1	Virginia Ferraresi	3

C	SPANNING BCL-2 FUNCTIONS IN MELANOMA MODELS: FROM MICROENVIRONMENT TO MICRORNA MODULATION	Preclinical Models and new Therapeutics	Donatella Del Bufalo	0
C	Validazione di un nuovo pannello di next generation sequencing per l'analisi mutazionale di campioni istopatologici di pazienti con melanoma metastatico trattati con inibitori di BRAF e MEK o con anticorpi anti-PD-1	Medical Oncology 1	Virginia Ferraresi	0
O	Melanoma 4p: biobanking e nuove metriche biomolecolari	Oncogenomics and Epigenetics	Patrizio Giacomini	97

Skin

Status*	Title	Division	Principal investigator	Patients IRE 2020
O	A MICRORNA-BASED APPROACH TO ADVANCED DIAGNOSIS AND THERAPY OF METASTATIC MELANOMA	Scientific Directorate	Gennaro Ciliberto	22
C	A PHASE II TRIAL OF VEMURAFENIB PLUS COBIMETINIB IN PATIENTS TREATED WITH PRIOR FIRST-LINE SYSTEMIC IMMUNOTHERAPY FOR INOPERABLE LOCALLY ADVANCED OR METASTATIC MELANOMA	Medical Oncology 1	Francesco Cognetti	0
C	A RETROSPECTIVE CHART REVIEW OF ITALIAN PATIENTS WITH ADVANCED/METASTATIC MELANOMA WITH LIMITED OR NO TREATMENT OPTIONS AND TREATED WITH PEMBROLIZUMAB IN THE PEMBROLIZUMAB (MK-3475) EXPANDED ACCESS PROGRAM (EAP)	Medical Oncology 1	Virginia Ferraresi	0
O	COMBINATION OF TARGETED THERAPY (ENCORAFENIB AND BINIMETINIB) FOLLOWED BY COMBINATION OF IMMUNOTHERAPY (IPILIMUMAB AND NIVOLUMAB) VS IMMEDIATE COMBINATION OF IMMUNOTHERAPY IN PATIENTS WITH UNRESECTABLE OR METASTATIC MELANOMA WITH BRAF V600 MUTATION: AN EORTC RANDOMIZED PHASE II STUDY (EBIN)	Medical Oncology 1	Virginia Ferraresi	3

C	SPANNING BCL-2 FUNCTIONS IN MELANOMA MODELS: FROM MICROENVIRONMENT TO MICRORNA MODULATION	Preclinical Models and new Therapeutics	Donatella Del Bufalo	0
C	Validazione di un nuovo pannello di next generation sequencing per l'analisi mutazionale di campioni istopatologici di pazienti con melanoma metastatico trattati con inibitori di BRAF e MEK o con anticorpi anti-PD-1	Medical Oncology 1	Virginia Ferraresi	0
O	Melanoma 4p: biobanking e nuove metriche biomolecolari	Oncogenomics and Epigenetics	Patrizio Giacomini	97

Thimic

Status*	Title	Division	Principal investigator	Patients IRE 2020
O	CLINICAL-PATHOLOGIC AND MOLECULAR STUDY OF THYMIC EPITHELIAL TUMORS (ON ITMIG DATABASES)	Pathology	Mirella Marino	0
O	IMPROVING TREATMENT STRATEGIES IN THYMIC EPITHELIAL TUMORS: A TYME COLLABORATIVE EFFORT	Medical Oncology 1	Fabiana Cecere	0

Urological

Status*	Title	Division	Principal investigator	Patients IRE 2020
O	A PHASE 3, RANDOMIZED, OPEN-LABEL, CONTROLLED STUDY OF CABOZANTINIB (XL184) IN COMBINATION WITH ATEZOLIZUMAB VS SECOND NOVEL HORMONAL THERAPY (NHT) IN SUBJECTS WITH METASTATIC CASTRATION-RESISTANT PROSTATE CANCER	Urology	Giuseppe Simone	0
O	A PHASE III, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED CLINICAL TRIAL OF PEMBROLIZUMAB (MK-3475) AS MONOTHERAPY IN THE ADJUVANT TREATMENT OF RENAL CELL CARCINOMA POST NEPHRECTOMY (KEYNOTE-564)	Medical Oncology 1	Gianluigi Ferretti	0
O	A RANDOMIZED PROSPECTIVE MULTICENTRE OPEN-LABEL PHASE II STUDY OF ANDROGEN DEPRIVATION THERAPY (ADT) PLUS RADIOTHERAPY WITH OR WITHOUT ABIRATERONE ACETATE AND PREDNISONE IN LOCALLY ADVANCED VERY HIGH-RISK PROSTATE CANCER	Medical Oncology 1	Paolo Carlini	0
O	A RANDOMIZED, DOUBLE-BLIND, PLACEBO CONTROLLED PHASE 3 STUDY OF JNJ-56021927 IN SUBJECTS WITH HIGH RISK, LOCALIZED OR LOCALLY ADVANCED PROSTATE CANCER RECIVED TREATMENT WIRH PRIMARY RADIATION THERAPY	Radiotherapy	Giuseppe Sanguineti	0

O	A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, PHASE 3 STUDY OF APALUTAMIDE IN SUBJECTS WITH HIGH-RISK, LOCALIZED OR LOCALLY ADVANCED PROSTATE CANCER WHO ARE CANDIDATES FOR RADICAL PROSTATECTOMY	Urology	Giuseppe Simone	26
C	ASSESSMENT OF HER2 PROTEIN EXPRESSION IN RENAL COLLECTING DUCT CARCINOMA: THERAPEUTIC IMPLICATION	Urology	Giuseppe Simone	14
O	BIOMARKER STUDY TO IDENTIFY SUBJECTS WITH ADVANCED UROTHELIAL CANCER AND FIBROBLAST GROWTH FACTOR RECEPTOR GENE ABERRATIONS	Urology	Giuseppe Simone	46
O	Correlazione tra dosimetria fisica, effetti biologici e tossicita' clinica nel paziente con carcinoma della prostata metastatico resistente alla castrazione (mCRPC) trattato con radium-223	Nuclear Medicine	Rosa Sciuto	3
O	HIGHER DIAGNOSTIC ACCURACY OF 64CU PET/CT COMPARED TO STANDARD 18F-CHOLINE PET/CT IN THE DETECTION RATE OF METASTASIS FROM PROSTATE CANCER	Nuclear Medicine	Rosa Sciuto	31
C	RADICAL CYSTECTOMY IN THE TIME OF COVID-19 PANDEMIC: REAL LIFE SNAPSHOT BY THE END OF THE STORM	Urology	Giuseppe Simone	32
O	Ruolo della PET con 64Cu-PSMA nel carcinoma della prostata (PC): diagnosi precoce di recidiva biochimica	Nuclear Medicine	Rosa Sciuto	40

O	USE OF 64CUCL2 PET/ CT IMAGING IN THE SELECTION OF PATIENTS WITH PROSTATE CANCER IN BIOCHEMICAL RELAPSE AFTER PROSTATECTOMY, TO BE SUCCESSFULLY TREATED WITHSALVAGE RADIOTHERAPY ON THE PROSTATIC BED	Nuclear Medicine	Rosa Sciuto	0
C	Valutare l'impatto dell'assenza della tonaca muscolare nel carcinoma uroteliale Ta di basso grado della vescica sulla sopravvivenza libera da recidiva	Urology	Giuseppe Simone	117
O	Variazioni di pressione transpolmonare in condizioni di pneumoperitoneo e steep Trendelenburg durante chirurgia videolaparoscopica robot-assistita. Studio pilota prospettico osservazionale	Anaesthesiology, Critical Area and Intensive Care	Ester Forastiere	7
O	Aderenza alla terapia ormonale nei pazienti con carcinoma prostatico resistente alla castrazione: validazione di un questionario	Medical Oncology 1	Paolo Carlini	0
O	Studio multicentrico randomizzato di fase III: docetaxel vs ormonoterapia come trattamento di seconda linea in pazienti asintomatici o oligosintomatici con tumore della prostata metastatico, resistente alla castrazione, in progressione dopo terapia con abiraterone o enzalutamide	Medical Oncology 1	Paolo Carlini	0
C	Studio Pilota di valutazione dell'utilizzo della 64Cu-PET/ TC total body in pazienti con recidiva in loggia prostatica visibile in RMmp	Radiotherapy	Giuseppe Sanguineti	1
O	Validazione di modelli predittivi di tossicta' dopo trattamento radioterapico per tumore della prostata. Disfunzione Urinaria ed Erettile - 02	Radiotherapy	Giuseppe Sanguineti	3

O	Studio di fase I-II sulla fattibilita' e attivita' della Radioterapia Stereotassica con Acceleratore Lineare in 3 frazioni per Carcinoma della Prostata a rischio basso/ intermedio	Radiotherapy	Giuseppe Sanguineti	13
O	Modificazioni radioindotte delle sottopopolazioni linfoidi coinvolte nei meccanismi di resistenza e di escape al trattamento del carcinoma localizzato della prostata	Radiotherapy	Giuseppe Sanguineti	1
O	Studio osservazionale prospettico multicentrico della tossicità intestinale, ematologica e urinaria da irradiazione dell'area linfonodale pelvica (IHU WPRT TOX) nel tumore della prostata	Radiotherapy	Giuseppe Sanguineti	0
O	Studio pilota di radioterapia stereotassica pre-operatoria per carcinoma renale operabile in stadio iniziale (Ct1)	Radiotherapy	Giuseppe Sanguineti	0
O	Validazione del Mitomic Test nello screening del tumore della prostata	Urology	Giuseppe Simone	38
C	Cistectomia radicale open versus robotica con derivazione urinaria totalmente intracorporea. Studio prospettico randomizzato mono-centrico	Urology	Giuseppe Simone	41

Miscellaneous

Status*	Title	Division	Principal investigator	Patients IRE 2020
11	A MULTICENTER, OPEN LABEL, PHASE III EXTENSION TRIAL TO STUDY THE LONG-TERM SAFETY AND EFFICACY IN PARTICIPANTS WITH ADVANCED TUMORS WHO ARE CURRENTLY ON TREATMENT OR IN FOLLOW-UP IN A PEMBROLIZUMAB TRIAL	Medical Oncology 1	Mariantonietta Simona Gasparro	0
O	A PHASE 1 DOSE ESCALATION AND COHORT EXPANSION STUDY OF TSR-042, AN ANTI-PD-1 MONOCLONAL ANTIBODY, IN PATIENTS WITH ADVANCED SOLID TUMORS	Medical Oncology 2	Patrizia Vici	0
O	A PHASE 1 OPEN LABEL, MULTI-ARM, MULTICENTER STUDY OF MK-1308 IN COMBINATION WITH PEMBROLIZUMAB IN SUBJECTS WITH ADVANCED SOLID TUMORS	Medical Oncology 1	Francesco Cognetti	0
C	A PHASE 2 STUDY OF INCMGA00012 (PD-1 INHIBITOR) IN PARTICIPANTS WITH SELECTED SOLID TUMORS (POD1UM-203)	Medical Oncology 1	Francesco Cognetti	0
O	A PHASE 2, OPEN-LABEL, SINGLE ARM, MULTICENTER STUDY TO EVALUATE THE EFFICACY AND SAFETY OF PEMIGATINIB IN PARTICIPANTS WITH PREVIOUSLY TREATED LOCALLY ADVANCED/METASTATIC OR SURGICALLY UNRESECTABLE SOLID TUMOR MALIGNANCIES HARBORING ACTIVATING FGFR	Medical Oncology 1	Francesco Cognetti	0

C	A PHASE Ib, OPEN-LABEL, MULTICENTER STUDY EVALUATING THE SAFETY AND EFFICACY OF IPATASERTIB IN COMBINATION WITH RUCAPARIB IN PATIENTS WITH ADVANCED BREAST, OVARIAN, OR PROSTATE CANCER	Medical Oncology 1	Francesco Cognetti	0
O	ACCURACY OF TRANSOESOPHAGEAL ENDOSCOPIC ULTRASOUND FINE NEEDLE ASPIRATION IN DIAGNOSIS OF THORACIC DISEASES	Digestive Endoscopy	Daniela Assisi	251
O	ANALYSIS OF THE TRANSCRIPTIONAL EXPRESSION PROFILE AND MICRORNAS IN BRAIN METASTASES FROM PRIMARY TUMORS OF VARIOUS ORIGIN	Oncogenomics and Epigenetics	Giovanni Blandino	2
O	COAGULATION/ COMPLEMENT ACTIVATION AND CEREBRAL HYPOPERFUSION IN RELAPSING-REMITTING MULTIPLE SCLEROSIS	Neuroncology	Tatiana Koudriavtseva	1
O	DEVELOPMENT AND VALIDATION OF A TOOL FOR PATIENT-REPORTED ASSESSMENT OF CANCERRELATED FINANCIAL TOXICITY	Biostatitic	Diana Giannarelli	0
C	Epidemiology and determinants of outcomes of Hospital Acquired Blood Stream Infections in the Intensive Care	Anaesthesiology, Critical Area andIntensive Care	Lorella Pelagalli	1
C	GLOBALSURG-COVIDSURG WEEK: DETERMINING THE OPTIMAL TIMING FOR SURGERY FOLLOWING SARS-COV-2 INFECTION	Otolaryngology Head & Neck	Raul Pellini	55

C	GLOBALSURG-COVIDSURG WEEK: DETERMINING THE OPTIMAL TIMING FOR SURGERY FOLLOWING SARS-COV-2 INFECTION	Urology	Giuseppe Simone	19
C	MOLECULAR MECHANISM OF QUADRUPLEX-TARGETED DRUGS: TOWARDS CLINICAL CANDIDATE SELECTION	SAFU	Carlo Leonetti	23
O	MULTICENTER, NON-INTERVENTIONAL STUDY ON PATIENTS WITH ATRIAL FIBRILLATION (AF) AND CANCER (DIAGNOSED WITHIN THE LAST 3 YEARS PRIOR TO ENROLMENT)	Cardiology	Francesco Rulli	3
O	NON CODING RNA IN SOLID TUMORS	Pathology	Mariantonia Carosi	20
O	Pan Tumor Study for Long Term Follow-up of Cancer Survivors Who Have Participated in Trials Investigating Nivolumab	Medical Oncology 1	Francesco Cognetti	2
O	POSTOPERATIVE VASOPRESSOR USAGE: A PROSPECTIVE INTERNATIONAL OBSERVATIONAL STUDY	Anaesthesiology, Critical Area Andintensive Care	Giulia Torregiani	55
C	PREOPERATIVE ANAEMIA PREVALENCE IN SURGICAL PATIENTS- A PROSPECTIVE, INTERNATIONAL, MULTICENTRE OBSERVATIONAL STUDY (ALICE)	Anaesthesiology, Critical Area Andintensive Care	Marco Covotta	24
C	PREVALENCE OF INTERSTITIAL PNEUMONIA AT 18F-FDG PET/CT IN ONCOLOGICAL ASYMPTOMATIC PATIENTS WITHOUT KNOWN INFLAMMATORY LUNG DISEASE. A MULTICENTRIC RETROSPECTIVE STUDY	Nuclear Medicine	Rosa Sciuto	15

O	SACRAL CHORDOMA: A RANDOMIZED & OBSERVATIONAL STUDY ON SURGERYVERSUS DEFINITIVE RADIATION THERAPY IN PRIMARY LOCALIZED DISEASE (SACRO)	Radiotherapy	Maria Grazia Petrongari	3
O	SPECTA: SCREENING CANCER PATIENTS FOR EFFICIENT CLINICAL TRIAL ACCESS	Pathology	Edoardo Pescarmona	0
	THE ROME TRIAL FROM HISTOLOGY TO TARGET: THE ROAD TO PERSONALIZE TARGET THERAPY AND IMMUNOTHERAPY			
	THE ROME TRIAL FROM HISTOLOGY TO TARGET: THE ROAD TO PERSONALIZE TARGET THERAPY AND IMMUNOTHERAPY			
O	TRANSFUSION OF CONVALESCENT PLASMA FOR THE EARLY TREATMENT OF PNEUMONIA DUE TO SARSCOV2 (TSUNAMI STUDY): A MULTICENTER OPEN LABEL RANDOMIZED CONTROL TRIAL	Transfusion Medicine Unit	Maria Laura Foddai	0
O	VIP: VALIDATION OF THE ITALIAN VERSION OF THE PATIENT- REPORTED OUTCOMES - COMMON TERMINOLOGY CRITERIA FOR ADVERSE EVENTS (PRO-CTCAE): A PROSPECTIVE MULTICENTER OBSERVATIONAL STUDY ON DIFFERENT CANCER TYPES	Medical Oncology 1	Antonella Savarese	13

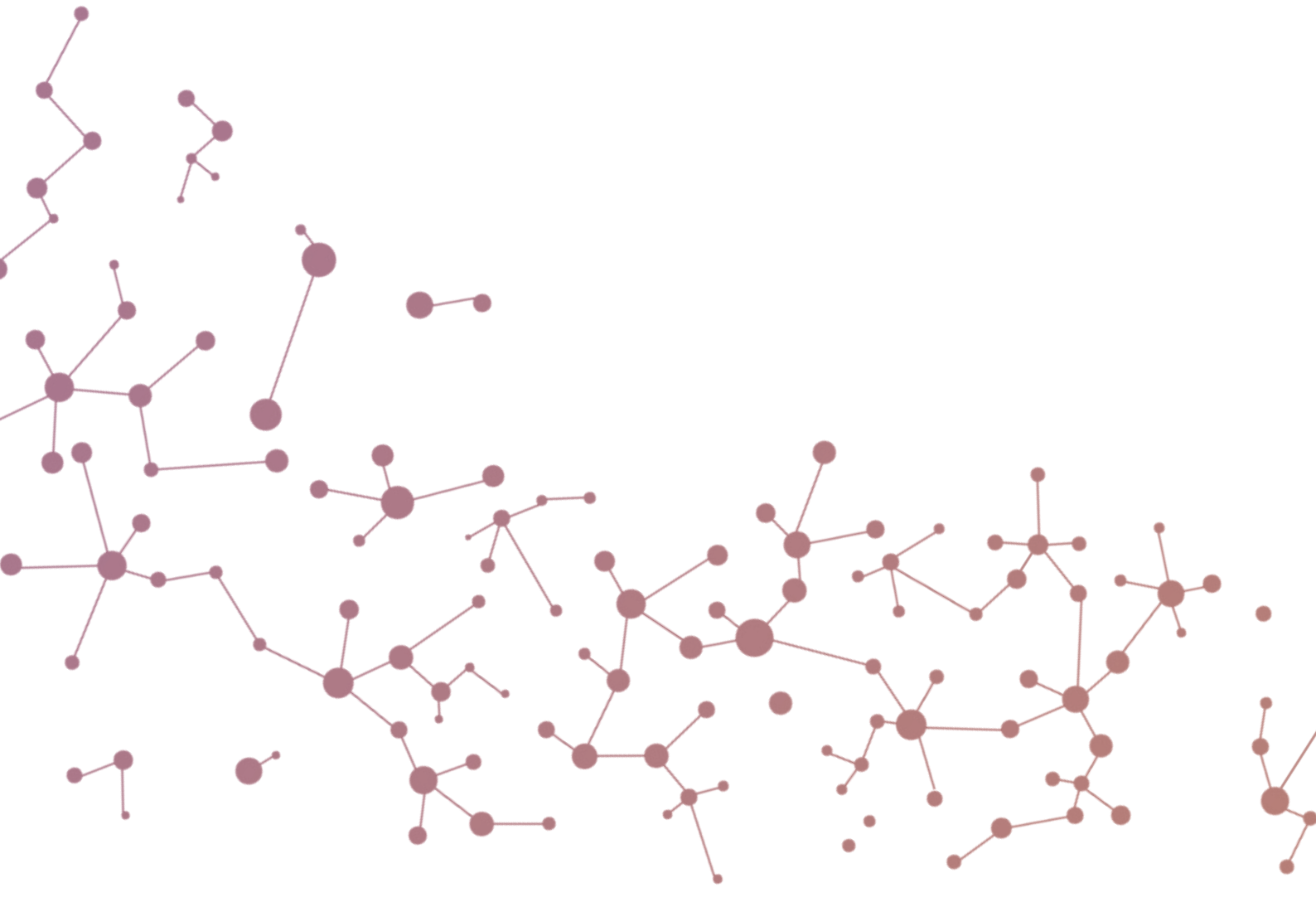
O	VIP: VALIDATION OF THE ITALIAN VERSION OF THE PATIENT- REPORTED OUTCOMES - COMMON TERMINOLOGY CRITERIA FOR ADVERSE EVENTS (PRO-CTCAE): A PROSPECTIVE MULTICENTER OBSERVATIONAL STUDY ON DIFFERENT CANCER TYPES	Medical Oncology 2	Patrizia Vici	4
O	VIP: VALIDATION OF THE ITALIAN VERSION OF THE PATIENT-REPORTED OUTCOMES - COMMON TERMINOLOGY CRITERIA FOR ADVERSE EVENTS (PRO-CTCAE): APROSPECTIVE MULTICENTER OBSERVATIONAL STUDY ON DIFFERENT CANCER TYPES	Neuroncology	Andrea Pace	9
O	Studio osservazionale prospettico multicentrico su efficacia e sicurezza di rituximab originatore o biosimilare nei pazienti che accedono ai Servizi di Ematologia del SSN	Pharmacovigilance	Felice Musicco	0
O	La malattia di Castleman multicentrica: una rivisitazione dello stato dell'arte	Pathology	Mirella Marino	0
O	Studio di fattibilità per la diagnosi genomica congiunta di rischio genetico e di sensibilità ai nuovi farmaci nelle neoplasie del seno, ovaio e colon	Pathology	Edoardo Pescarmona	0
O	Medicina di Precisione: l'importanza clinica di identificare le fusioni geniche di recettori chinasici della Tropomiosina - TRK	Pathology	Elisa Melucci	50
O	Valutazione dell'espressione dell'antigene GD2 in una casistica di sarcomi dell'osso e dei tessuti molli dell'adulto	Pathology	Edoardo Pescarmona	6

O	Studio osservazionale retrospettivo sulla prevalenza di alterazioni molecolari rare suscettibili di trattamenti agnostici (instabilità microsatellitare, riarrangiamenti dei geni NTRK, ALK1, ROS1, mutazioni del gene BRAF) in pazienti giovani affetti da tumori solidi maligni.	Pathology	Simonetta Buglioni	0
O	ACCessi venosi centrali in pazienti cronici E fragili: managemeNT e Ottimizzazione dei percorsi	Anaesthesiology, Critical Area andIntensive Care	Ester Forastiere	187
O	Studio osservazionale, multicentrico, per la valutazione dell'efficacia di un intervento multifattoriale per migliorare la comunicazione verso i familiari di pazienti ricoverati in Terapia Intensiva	Anaesthesiology, Critical Area andIntensive Care	Lorella Pelagalli	0
C	Studio Nazionale NICSO: Progetto Di Monitoraggio Medico- Infermieristico Degli Effetti Collaterali Da Terapie Oncologiche	Medical Oncology 1	Alessandra Fabi	0
C	Indicazione al vaccino anti-influenzale durante immunoterapia oncologica con inibitori dei checkpoint immunitari. studio prospettico osservazionale multicentrico	Medical Oncology 1	Vanja Vaccaro	2
C	L'esperienza immersiva della realtà virtuale in corso di trattamento chemioterapico adiuvante nelle donne con neoplasia della mammella e dell'ovaio in fase precoce	Medical Oncology 1	Alessandra Fabi	3
O	Registro nazionale delle mutazioni actionable	Medical Oncology 1	Francesco Cognetti	0
O	Analisi del valore predittivo di efficacia delle terapie anti-neoplastiche basata sulla valutazione di pathways molecolari connessi alle cellule staminali tumorali: studio multi-setting e multi-tumore. HIERARCHY Study	Medical Oncology 2	Patrizia Vici	0

C	Valutazione dei risultati a medio termine delle ricostruzione di emibacino con protesi custom-made stampate in titanio con tecnologia additiva: studio bicentrico	Orthopaedics	Carmine Zoccali	9
O	Studio clinico spontaneo, multicentrico, osservazionale, prospettico, in aperto non controllato, per la verifica dell'efficacia del kit DAC (Denfensive Antibacterial Coating) gel nella prevenzione delle complicanze settiche nella chirurgia megaprotesica in pazienti sottoposti a ricostruzione dopo grandi resezioni ossee	Orthopaedics	Carmine Zoccali	3
O	Valutazione della neurotossicita' in pazienti oncologici affetti da Multiple (4-10) metastasi cerebrali trattati con radioterapia stereotassica	Radiotherapy	Laura Marucci	15
C	Impiego di test anticorpali per lo screening e prevenzione della trasmissione dell'infezione da SARS-COV-2	Biobank BBIRE	Laura Conti	150
C	La valutazione psicologica in cardioncologia: il ruolo della alessitimia e del senso di coerenza nella costruzione di significato e nella crescita post-traumatica	Cardiology	Francesco Rulli	0
O	Effetto funzionale della radioterapia su cellule tumorali e fibroblasti associati al tumore e loro proprieta' immunomodulatrici: modelli di 3D bioprint per disegnare nuove terapie combinate	Immunology and Immunotherapy	Francesca Di Modugno	5
O	ACC-ImmunoPortal, un data-repository italiano per l'ottimizzazione dell'immunoterapia con ICI: uno studio osservazionale ambispettico	Immunology and Immunotherapy	Paola Nistico'	0

C	Plasma da donatori guariti dalla malattia da nuovo coronavirus 2019 (COVID-19) come terapia per i pazienti critici affetti da COVID-19	Transfusion Medicine Unit	Maria Laura Foddai	0
C	Chirurgia delle metastasi intradurali: risultati dell'intervento chirurgico. Studio multicentrico.	Neurosurgery	Roberto Gazzeri	12
O	Studio clinico sull'tilizzo di un polimero elastico a base di silicone (VK-100) per l'augmentation vertebrale (elastoplastica), in comparazione (2:1) con il PMMA (cemento), nelle fratture somatiche da insufficienza correlate con patologie metastatiche o localizzazioni di malattie emolinfoproliferative e vertebre osteoporotiche in malattie neoplastiche	Neurosurgery	Stefano Telera	0
C	Valutazione dei biomarkers ematochimici in pazienti affetti da glioma e sclerosi multipla e valore predittivo di essi per sopravvivenza nel glioma - studio osservazionale retrospettivo	Neuroncology	Tatiana Koudriavtseva	217
O	La Biopsia Liquida: studio di fattibilità e trasferibilità alla routine clinica	Oncogenomics and Epigenetics	Patrizio Giacomini	14
O	Facilitatori e/o barriere all'accesso al supporto psicologico in pazienti oncologici: uno studio multicentrico	Psychology	Patrizia Pugliese	0

Institutional Courses 2020



Responsabile Scientifico	Ed	Inizio	Fine	Nome Evento
Prof. Gennaro Ciliberto	1	9/17/2020	9/24/2020	Refworks:sistema di gestione delle citazioni bibliografiche
Prof. Aldo Morrone	1	10/1/2020	10/5/2020	I curricula digitali della ricerca biomedica: ORCID e Researcher ID
Dr.ssa Antonia La Malfa	2	5/9/2020	5/30/2020	Formazione del personale infermieristico sulle procedure per la preparazione delle terapie citotossiche
Dr.ssa Antonia La Malfa	3	10/3/2020	10/14/2020	Formazione del personale infermieristico sulle procedure per la preparazione delle terapie citotossiche
Dr.ssa Tiziana Lavalle	1	6/30/2020	6/30/2020	Professioni di aiuto: competenze e metodi di gestione delle situazioni complesse
Dr.ssa Tiziana Lavalle	1	7/13/2020	7/13/2020	E-learning d sviluppo delle competenze attraverso il digitale: progettazione e gestione dei corsi in formazione a distanza. Modulo 2 progettare e sviluppare e-learning
Dr.ssa Tiziana Lavalle	1	9/28/2020	9/28/2020	E-learning d sviluppo delle competenze attraverso il digitale: progettazione e gestione dei corsi in formazione a distanza.Progettazione moodle. Modulo 3
Dr.ssa Tiziana Lavalle	1	10/2/2020	10/2/2020	La gestione strategica della formazione in tempo di covid-19
Dr.ssa Tiziana Lavalle	1	10/8/2020	10/22/2020	La health literacy nei contesti sanitari. Come promuovere e comunicare salute.

DMT

Responsabile Scientifico	Ed	Inizio	Fine	Nome Evento
Laura Eibenschutz – Pasquale Frascione	1	2/20/2020	4/16/2020	DMT tumori della cute non melanoma- I modulo
Laura Eibenschutz – Pasquale Frascione	1	7/16/2020	10/15/2020	DMT tumori della cute non melanoma- II modulo
Virginia Ferraresi	1	2/17/2020	12/21/2020	DMT neoplasie muscolo-scheletriche - sarcomi viscerali e gist – I modulo
Andrea Mengarelli	1	2/17/2020	6/8/2020	DMT- incontri multidisciplinari in ematologia – I modulo
Andrea Mengarelli	1	10/26/2020	12/14/2020	DMT- incontri multidisciplinari in ematologia – III modulo
Pasquale Frascione – Emilia Migliano	1	9/15/2020	11/3/2020	Incontri multidisciplinari DMT melanoma – II modulo
Antonello Vidiri	1	2/20/2020	3/12/2020	Discussione di casi di pratica clinica settimanali
Antonello Vidiri	1	9/18/2020	10/9/2020	Diagnostica per immagini ed interventistica della mammella: rivalutazione multidisciplinare - I modulo
Dr. Raul Pellini	1	2/19/2020	7/29/2020	Incontri multidisciplinari dmt orl - I modulo
Dr. Raul Pellini	1	10/7/2020	12/16/2020	Incontri multidisciplinari dmt orl - II modulo

Psyconcology

Responsabile Scientifico	Ed	Inizio	Fine	Nome Evento
Anita Caruso	1	2/17/2020	2/19/2020	L'intervento clinico interdisciplinare
Anita Caruso	1	7/6/2020	7/8/2020	Il contesto familiare e le dinamiche emotive degli operatori