DigiCore

DIGICORE Excellence Pathway

Improvement plan

Istituti Fisioterapici Ospitalieri - Regina Elena National Cancer Institute

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Introduction to the DIGICORE Excellence Pathway assessment

Context: the DIGICORE network

DIGICORE (DIGital Institute for Cancer Outcomes Research) as a European cancer research community is aiming to transform cancer care through high-quality, digital, federated real-world outcomes research. DIGICORE brings together cancer centres, academic institutions, clinicians, data scientists, and industry partners with the shared objective of enabling robust, scalable, and reproducible oncology research using routinely collected healthcare data.

Central to DIGICORE's mission is the belief that improving cancer outcomes at scale requires more than access to data alone. It also depends on the organisational, technical, and analytical capabilities of participating institutions to curate data, apply common standards, operate within appropriate governance frameworks, and translate data into meaningful clinical and research insights. As a result, DIGICORE actively assists partner organisations not only through collaborative research initiatives, such as DigiONE, but also by supporting them in strengthening long-term digital research capability.

Definition and goals of the DIGICORE Excellence Pathway

The DIGICORE Excellence Pathway (DEP) is a programme designed to support DIGICORE members in strengthening their digital research capabilities in a consistent, credible, and development-focused manner. DEP is a key component of DIGICORE's broader strategy and aims to help members better understand their current capabilities, identify priority areas for improvement, and build a roadmap to enhance their participation in digital oncology research.

Rather than serving as a static accreditation or ranking exercise, the DEP has been intentionally designed as a developmental pathway. The focus is on supporting continuous improvement and organisational learning, recognising that DIGICORE partner institutions operate in diverse national, regulatory, and operational contexts and may be at different stages of digital maturity.

More specifically, the DEP aims to:

- Provide DIGICORE members with a structured assessment of their digital oncology research capabilities.
- Enable consistent and transparent evaluation of digital research readiness across the DIGICORE network.
- Offer practical, tailored improvement guidance that supports sites in strengthening their capabilities over time.
- Increase the overall credibility, attractiveness, and scalability of DIGICORE as a network for high-quality digital oncology research.

Overview of the DIGICORE Excellence Pathway assessment process

The DEP follows a structured and standardised process designed to minimise burden on participating sites while ensuring robustness and consistency of assessment.

The first step of the pathway is a self-assessment questionnaire, completed by the participating hospital or cancer centre. The questionnaire captures information across a defined set of assessment domains and focuses on current ("as-is") capabilities, practices, and track record related to digital oncology research. Responses are provided by the site based on its internal knowledge, systems, and governance arrangements.

Following submission of the questionnaire, the DIGICORE assessment team may issue targeted clarification questions to ensure accurate interpretation of responses, resolve ambiguities, and better reflect the site's actual operating context. This step helps improve consistency and fairness of assessment across participating organisations.

Based on the synthesised responses, each site is assigned a DEP maturity level (or badge) that reflects its overall digital research maturity at the time of assessment. In parallel, and as a core output of the programme, DIGICORE produces a bespoke improvement plan for the site. Both the assigned level and the improvement plan are included in this report. In particular, the improvement plan is the central output of the DEP and is designed to support each centre in translating assessment results into concrete and prioritised actions.

Executive summary

Overview of current level and next steps

IFO demonstrates a credible **Silver level** of digital oncology research maturity. The assessment is supported by well-developed organisational and governance enablers, a credible structured data foundation, and selected digital and real-world evidence (RWE) activity across tumour areas.

The overall profile is strongest in Organisation, where consent, ethics, software, and infrastructure foundations are well established. Data capability is credible but still requires further standardisation and operational formalisation for repeatable study use. Performance is the main constraint on progression, reflecting a developing rather than fully repeatable multicentre RWE delivery track record.

The suggested next step is to convert existing foundations into a more systematic, scalable, and repeatable model for digital oncology research, with emphasis on data operations, organisational embedding, and delivery performance. This would strengthen the current Silver profile and support progression towards future Gold-level maturity.

Strengths

- **Credible structured data foundation** across several core oncology concepts, supported by standardised reference data and demonstrated Observational Medical Outcomes Partnership (OMOP) capability in lung.
- **Well-developed governance and infrastructure enablers**, including consent, legal basis, ethics review, software, and secure hardware foundations.
- **Favourable operating context** for study preparation, including internal follow-up, structured treatment data, imaging access, and tumour-specific disease management teams.
- **Visible but still developing digital and RWE activity** across selected tumour domains and feasibility examples.

Improvement areas

- **Data operations require further standardisation**, particularly quality control, research dataset refresh, line of therapy derivation, and reusable handling of selected complex variables.
- **Organisational capability needs deeper embedding** through more systematic training, clearer collaborative research pathways, targeted international network participation, and stronger digital pathway integration.
- **Study delivery evidence needs to become more repeatable**, especially for commercial electronic medical record (EMR) - driven multicentre RWE participation, feasibility responsiveness, and commercial study initiation timelines.

Expected impact

- **Study readiness would become easier to evidence** through scheduled refresh, clearer quality checks, and more reusable derivation logic for priority oncology variables.
- **Delivery would become more scalable** as training, hand-offs, and governance pathways make current capability less dependent on individual teams or project-specific preparation.
- **Multicentre participation would become more predictable**, supporting a clearer pathway from the current Silver level towards future Gold-level maturity.

Introduction to the methodology and results reporting

Methodology – maturity level assessment

The DEP assessment framework evaluates digital oncology research readiness across three core domains, reflecting the key enablers required to deliver high-quality digital research at scale:

1. **Digital data** maturity, including availability, structure, quality, and standardisation of oncology data. The focus of this domain is on:
   - Improving data standardisation, completeness and quality to enable research readiness
   - Prioritising structured capture of Minimal Essential Description of Cancer (MEDOC) concepts and accelerating OMOP adoption, supported by robust and repeatable quality control processes, including automated validation and conformance checks
   - Strengthening data governance through clear standards for update frequency, metadata and traceability, while progressively integrating additional and unstructured data using natural language processing (NLP) and artificial intelligence (AI) to enhance depth and usability
2. **Organisation and governance**, covering governance structures, processes, resources, and skills supporting digital research. The focus on this domain is on:
   - Strengthening organisational enablers to ensure data can be accessed for digital research, also referred to as "secondary use of data" in the terminology used by the European Health Data Space (EHDS).
   - Implementing streamlined, RWE-appropriate governance with routine consent models and fit-for-purpose ethics review processes, alongside investment in scalable infrastructure
   - Establishing dedicated teams with clear accountability across data, analytics and delivery, supported by structured training and partnerships to build advanced capabilities in OMOP, data science and real-world evidence
3. **Research performance and track record**, reflecting the site's demonstrated experience in conducting and delivering digital oncology research. The focus on this domain is on:
   - Enhancing performance by linking data capabilities in order to measure research outputs and operational efficiency
   - Implementing performance management frameworks to track study throughput, approval timelines and research impact
   - Embedding continuous improvement through regular key performance indicator (KPI) review, systematic identification of bottlenecks and targeted optimisation of processes to increase the speed, scale and quality of digital and real-world studies

Please note that the self-assessment questionnaire also contains questions on a fourth domain, i.e., the centre's operating context. These are used to inform the assessment, but do not directly count towards the definition of the hospital level, as they probe aspects that are generally beyond the centres' control.

Responses to the self-assessment questionnaire, supplemented by clarification discussions where applicable, are synthesised across these three domains to provide the overall DEP level assigned to the site. The assessment emphasises a balanced view of technical, organisational, and performance-based capabilities rather than focusing on any single dimension in isolation.

The DEP framework defines four distinct levels of digital research maturity, each representing a progressive stage in the development of digital oncology research capabilities:

- **Level 1 - Digital beginner**. The site has basic digital infrastructure and governance for oncology research, but processes are largely manual, data is fragmented, and there is limited evidence of structured research activity. The focus is on building foundational systems and clarifying roles.
- **Level 2 - Bronze**. The site demonstrates emerging digital capabilities, with some standardised data and processes, and a governance model beginning to support digital research. There is evidence of participation in digital research projects, though integration and consistency require improvement.

- **Level 3 - Silver**. The site has robust digital research infrastructure and governance, with well-developed oncology data assets and credible participation in digital research. Capabilities are sufficiently established to support collaborative research, while further standardisation, scalability, and repeatability may be required before the site progresses to the next level.
- **Level 4 - Gold**. The site acts as a reference centre for digital oncology research, with advanced, fully integrated systems and governance. It demonstrates leadership in innovation, regularly initiates multicentre studies, and supports network-wide improvements.

These levels provide a clear pathway for sites to understand their current position and identify targeted areas for growth, without implying any negative judgement about the hospital's current status.

The score for each centre is based on a Likert scale and is derived from a synthesis of questionnaire responses, clarification discussions, and insights gathered through interactions with the centre. Scores are therefore not calculated mechanically from individual answers alone but reflect an expert review of the evidence across the relevant domains, including the consistency of reported capabilities, supporting examples, and the extent to which practices appear embedded, repeatable, and grounded in the organisation.

Methodology - Improvement plan

The improvement plan builds directly on the maturity assessment described above. It provides:

- Domain-specific recommendations focusing individually on digital data maturity, organisation and governance, and research performance
- Cross-cutting recommendations addressing overarching enablers and dependencies across domains
- Clear, practical actions designed to be achievable and prioritised, taking into account the site's current maturity level and operating context

The proposed actions are intended to support progressive improvement over time and to help the assessed organisation strengthen its ability to participate in, lead, and scale high-quality digital oncology research within the DIGICORE network.

Results reporting

The achieved level for each centre is clearly outlined within the relevant section of this report, ensuring transparency and ease of reference. In addition to highlighting the overall status, the report presents insights into each assessment domain, offering a nuanced understanding of the centre's current strengths and opportunities for growth. Following this, a comprehensive improvement plan is set out, beginning with an overarching summary to provide context, and then delving into tailored recommendations for each domain. These targeted actions are designed to be practical and prioritised, supporting the centre's ongoing journey towards digital oncology research excellence. As mentioned above, the approach is intended to foster constructive progress and does not imply any negative judgement about the hospital's present standing.

Maturity level assessment outcome



Assigned DEP maturity level

The Istituti Fisioterapici Ospitalieri - Regina Elena National Cancer Institute centre achieved a **Silver DEP maturity level**, supported by domain scores of **Data 3.75, Organisation 4, and Performance 2.75**. This reflects a credible Silver profile across the three DEP assessment domains, with the strongest evidence in Organisation and a well-developed but less fully operationalised Data profile. The designation is supported by structured cancer data across several core concepts, consented sample availability, systematic ethics processes, ATLAS software capability, secure infrastructure, and selected digital and RWE research activity across multiple tumour areas.

The assessment profile is uneven. The Organisation score of 4 indicates established governance and infrastructure enablers, while the Data score of **3.75** reflects credible structured data capability with remaining gaps in quality control, refresh frequency, line of therapy derivation, morphology / histology, adverse event capture, diagnosis-date consistency, and patient-reported outcome (PRO) readiness. The Performance score of **2.75** is the main constraint on the overall profile, reflecting limited commercial EMR-driven multicentre RWE experience, modest academic multicentre activity, and feasibility and initiation processes that are not yet consistently repeatable at scale.

The assigned Silver level is therefore appropriate. IFO has the organisational, data, and operating enablers required for credible participation in digital oncology and real-world evidence research, but these capabilities are not yet sufficiently systematic, scalable, and repeatable to support progression to the next maturity level.

Summary by domain

DEP Domain	Median score (1 = lowest; 5 = highest)	Evidence supporting current maturity level	Key gap preventing higher score
Data	**3.75**	Supported by structured treatment and outcomes data, MEDOC coverage across at least four indications, disease stage and diagnosis coding, response evaluation criteria in solid tumours (RECIST) availability, regional death registry linkage, and demonstrated OMOP capability in lung.	Higher scoring is limited by quality control that remains relatively manual, formally ad hoc research dataset refresh, manual line of therapy resolution in over half of cancers, and selected complex variables requiring further standardisation.
Organisation	**4**	Reflects well-developed enablers: consented sample availability, clear legal basis for secondary data use, systematic ethics review, ATLAS software capability, scalable secure infrastructure, and established study governance processes.	Remaining constraints relate to training, international research network participation, patient-level collaborative research pathways, and digital health integration, which are less consistently embedded than the governance and infrastructure foundations.
Performance	**2.75**	Indicates a developing delivery profile, with activity across four to five tumour domains, low feasibility attrition, selected feasibility responses including Dinasty 02, Dinasty 03, and DigiACT, and academic EMR-driven multicentre experience through Dinasty Breast.	The main barriers to a higher score are limited commercial EMR-driven multicentre RWE experience, modest academic multicentre volume, feasibility responsiveness that is not yet consistently systematic, and commercial study initiation timelines of approximately two to three months.

Evidence supporting current maturity level

- **RWD availability and standardisation**. Structured cancer data are available in several core areas, including treatment and outcomes data, MEDOC coverage across at least four indications, structured stage, diagnosis coding, metastasis information, RECIST availability, direct regional death registry linkage, and adoption of reference standards including demonstrated OMOP capability in lung.
- **Advanced data and complex variables**. The assessment shows credible availability of several high-value variables, while line of therapy, morphology / histology, adverse events, diagnosis-date consistency, date of progression, and PRO readiness require further standardisation before they can be reused consistently across tumour areas.
- **Governance and infrastructure**. The centre reports routine consented sample availability, routine secondary data use consent covering academic and commercial research, systematic ethics review, robust software capability including ATLAS, and strong secure hardware infrastructure.
- **RWE delivery experience**. Performance evidence includes low feasibility attrition, academic EMR-driven multicentre experience through Dinasty Breast, selected feasibility responses for Dinasty 02, Dinasty 03, and DigiACT, and sustained digital / RWE activity across four to five tumour domains.
- **Strategic development basis**. The centre's operating context supports further development, including internal patient follow-up, structured systemic anti-cancer therapy data, batch imaging

retrieval for research, an emergency department, fortnightly ethics committee meetings, and disease management teams across indications.

Priority gaps

- **Data limitation**. Data capability is not higher because quality control is not yet fully systematic, research dataset refresh remains formally ad hoc, and selected complex variables still require manual or project-specific preparation.
- **Complex variable readiness**. Adverse event capture, morphology / histology, quality of life / patient-reported outcomes, date of diagnosis, and date of progression require more scalable approaches before they can be treated as consistently research-ready across tumour areas.
- **Organisation limitation**. Organisation capability is not higher because training, international network participation, patient-level collaborative research pathways, and digital integration across the patient pathway are less consistently embedded than the centre's infrastructure and ethics foundations.
- **Performance limitation**. Performance remains the main constraint, reflecting limited commercial EMR-driven multicentre RWE participation, modest academic multicentre volume, feasibility responsiveness that is not yet consistently systematic, and commercial study initiation timelines of approximately two to three months.

Improvement plan

Overall summary

The centre already demonstrates a credible level of digital oncology research maturity, with important strengths in structured cancer data, consented sample availability, ethics processes, software and hardware infrastructure, and an operating context that is favourable to digital and real-world evidence research. The suggested priority now is not to build capability *ex novo*, but to convert existing strengths into a more systematic, repeatable, and externally visible model for study delivery.

Three priorities could guide the next phase of improvement.

- **Industrialise the data environment for repeatable study delivery**. The strongest immediate opportunity is to strengthen systematic quality control, move from *ad hoc* to routine research dataset refreshes, and make derivation of line of therapy, diagnosis dates, and other complex variables more reusable across studies.
- **Strengthen organisational depth behind strong infrastructure**. Existing ethics, consent, software, and hardware capability could be matched by more systematic training, clearer international network participation, and more scalable pathways for patient-level collaborative research.
- **Expand performance from promising activity to repeatable track record**. The centre already reports low feasibility attrition, activity across multiple tumour areas, and selected academic and feasibility examples. The next step is to create a more deliberate performance model that increases commercial study participation, improves feasibility responsiveness, and reduces initiation timelines.

Taken together, these actions would help IFO progress from strong capability in selected areas toward a more repeatable institutional model for digital research excellence. In practical terms, this could increase readiness for multicentre academic and commercial RWE studies, reduce dependence on manual curation, improve confidence in feasibility outputs, and support stronger evidence generation across a broader oncology portfolio.

Data

Current state

The Data profile is credible but still maturing. The centre has a strong data foundation for digital oncology research: structured and research-shareable cancer data are available for many core variables, with most EMR cancer data reported in structured format, including treatment and outcomes data. Molecular data are structured, although automated linkage remains difficult due to data silos. MEDOC concepts are present in at least four indications, while date of death is highly mature through routine updates via a direct digital link to the regional death registry, making vital status information available within approximately one month of the event. The centre also reports structured disease stage, primary cancer diagnosis coding, metastasis information, automated RECIST availability for some cancer indications, low feasibility attrition, and adoption of reference standards, including a lung OMOP cohort.

The score is not higher because data readiness is not yet fully industrialised across all high-value variables. Quality control processes are currently limited and mostly manual, despite the centre's ISO 9001:2015 certification. Research dataset refresh frequency is formally ad hoc, although the information collected indicates this is evolving, with automated more frequent refreshes implementable in a matter of days and biweekly refresh currently considered the preferred direction. Line of therapy can be resolved manually in over half of cancers, morphology / histology is available in structured form for some tumour types, adverse event capture is mainly limited to severe events with clear diagnoses, and quality of life / patient-reported outcome capture is still at pilot stage in selected cancers.

Key gaps

- Quality control remains an area for development. The score for QC processes is low relative to the stronger Data items, indicating that current processes are not yet sufficiently systematic or tool-supported for repeatable study preparation.
- Research dataset refresh frequency is not yet operationalised as a routine process, despite the centre indicating that more frequent automated refreshes are feasible in the near term.
- Line of therapy, morphology / histology, adverse events, date of diagnosis, and quality of life / patient-reported outcomes remain less mature than the centre's strongest data assets and require more manual or project-specific effort.
- Structured molecular data exist, but linkage across data silos remains a constraint for automated research use and could limit efficient cohort construction in selected precision oncology studies.

Short-term priorities (0-12 months)

- **Formalise a practical quality control pathway**. Define a minimum set of routine quality checks for study-ready datasets, starting with duplicate detection, completeness checks, conformance checks, and plausibility checks for key MEDOC concepts.
- **Move refresh frequency from *ad hoc* to scheduled**. Convert the currently evolving refresh approach into a documented scheduled process, prioritising the biweekly or monthly cadence already described as within reach.
- **Prioritise line of therapy derivation using the structured medication workflow**. Build on the fact that systemic anti-cancer therapies are structured and queryable with dates to define reusable derivation rules for at least the highest-demand tumour areas.
- **Target the most consequential variable gaps**. Focus near-term improvement on histology standardisation, date of diagnosis reconciliation, adverse event capture, and quality of life / patient-reported outcome availability where these variables are likely to constrain upcoming studies.

Medium-term priorities (1-3 years)

- **Industrialise quality control and reporting**. Progress from manual or ad hoc quality checks toward systematic, tool-supported quality control reporting for research datasets, including where appropriate OMOP-aligned checks such as Achilles or Data Quality Dashboard outputs.
- **Expand reusable derivation logic for complex endpoints**. Document and reuse rules for line of therapy, date of diagnosis, date of progression, and RECIST-related variables across tumour areas, reducing dependence on study-specific manual curation.
- **Reduce linkage constraints across data silos**. Prioritise data architecture improvements that make structured molecular data, treatment data, outcomes data, and sample-linked data easier to connect for research use.
- **Broaden patient-reported and adverse event data readiness**. Move from pilots and selected severe-event capture toward more systematic digital capture in the tumour areas where these endpoints are most important for RWE studies.

Expected benefits

A more industrialised data environment would reduce manual effort, improve repeatability of feasibility and study delivery, and increase confidence that key variables can be reused across studies. Over time, this would help IFO strengthen its current Silver profile by combining its existing structured data and demonstrated OMOP capability in lung with more routine refreshes, stronger quality checks, and more reproducible derivation of complex oncology endpoints, supporting progression towards the consistency and repeatability expected at Gold level.

Organisation

Current state

The Organisation profile is well developed. The information collected indicates routine consented sample availability, with broad consent foundations supporting academic and commercial research. The legal basis for secondary data use is strong and linked to the centre's status as an *Istituto di Ricovero e Cura a Carattere Scientifico* (IRCCS). Ethics processes are systematically applied to research involving human subjects or patient data, including real-world and digital research. The centre also reports robust software capability, including structured data environments, ATLAS, REDCap, routine maintenance, and validation; hardware capability is strong, with scalable secure infrastructure and documented quality, risk, and safety management processes, although some documentation is in Italian and may require approximately one month of advance access permissions.

The score is not higher because several organisational practices are less consistently embedded than the centre's governance and infrastructure foundations. Training for digital and real-world research is still relatively informal and not systematic. Formal international research network participation is limited. Patient-level data sharing for collaborative research remains constrained, with only aggregated data release beyond the institution without study-specific consent. Digital health data collection is integrated across key stages of the pathway but is not yet fully embedded across long-term follow-up, patient-facing tools, and research recruitment. These gaps matter because IFO's strong governance and infrastructure foundations need a more repeatable operating model to support broader and more consistent collaborative delivery.

Key gaps

- Training for digital and real-world research appears less mature than the centre's infrastructure, consent, and ethics capabilities. This may limit the ability to scale strong practices consistently across teams.
- Patient-level collaborative research pathways remain constrained, with routine sharing outside the institution limited compared with centres that can enable broader pseudonymised data collaboration under defined safeguards.
- Formal enrolment into international research networks is limited, reducing the visibility and strategic influence that stronger-performing centres often use to generate multicentre research opportunities.
- Digital health integration into the patient pathway is not yet at the level of seamless patient-facing research enablement, digital consent, and registry-linked recruitment seen in the most mature centres.

Short-term priorities (0-12 months)

- **Introduce a structured training plan for digital / RWE research**. Define role-based training priorities for clinicians, data teams, research governance, and study delivery staff, including OMOP, secondary data use, data quality, federation principles, and reproducible analytics.
- **Clarify patient-level collaboration pathways**. Map the legal, consent, and operational steps needed to support collaborative research beyond aggregated outputs, distinguishing federated analysis from any situations where pseudonymised data sharing may be required.
- **Prioritise targeted international network engagement**. Select one or two networks or consortia where IFO's strongest assets, such as biobanking, OMOP potential in lung, imaging research, or tumour-specific expertise, could be used to increase visibility and structured collaboration.
- **Use infrastructure strengths to define a clearer delivery model**. Translate existing software, hardware, ethics, and consent foundations into a simple internal operating model that defines ownership, timelines, and handoffs for digital RWE studies.

Medium-term priorities (1-3 years)

- **Embed training into institutional research development**. Move from *ad hoc* exposure to a documented, monitored training programme linked to digital research roles and institutional research priorities.
- **Strengthen governance for collaborative research**. Build a more repeatable model for federated and collaborative studies, ensuring that privacy, ethics, contracting, and technical requirements are addressed through standard pathways rather than project-specific negotiation.
- **Expand digital pathway integration**. Progress from key-stage integration toward more systematic patient-facing digital tools, patient-reported outcome collection, and linkage between research registries and routine care workflows.
- **Increase strategic participation in external networks**. Use selected high-performing areas to move from project-based participation toward more sustained institutional participation and, over time, leadership roles in European or international research initiatives.

Expected benefits

A stronger organisational operating model would help IFO convert its robust infrastructure, consent, and ethics foundations into more scalable delivery capability. This would support better internal consistency, stronger external collaboration, improved readiness for federated and commercial studies, and clearer progression from its current Silver profile towards future Gold-level maturity.

Performance

Current state

The Performance profile is developing in digital and real-world oncology research. The information collected indicates low feasibility attrition, with feasibility attrition tracked per study and reported as low. The centre has participated in at least one academic EMR-driven multicentre RWE study, specifically Dinasty Breast, and has responded to selected feasibility requests including Dinasty 02, Dinasty 03, and DigiACT. It also reports sustained digital and RWE research performance across four to five tumour domains, supported by disease management teams across indications and strong imaging research capability, including participation in federated radiology image studies such as D34Health.

The score is below 3 because delivery is not yet sufficiently visible, systematic, and repeatable across multicentre RWE activity. Commercial EMR-driven multicentre RWE participation is currently limited, academic EMR-driven multicentre participation remains modest, and feasibility responsiveness is below the level expected for a stronger performance profile. Typical commercial study initiation takes approximately two to three months. Performance review is structured but still mainly operational, with an opportunity to use metrics more actively for prioritisation, benchmarking, and continuous improvement.

Key gaps

- Commercial EMR-driven multicentre RWE track record is still limited, which may reduce external visibility despite strong underlying infrastructure and data capabilities.
- Academic EMR-driven multicentre experience exists but remains modest, suggesting that current capability is not yet translating into a high-volume multicentre portfolio.
- Feasibility response rates are below stronger-performing centres, even though selected feasibility requests have been addressed and attrition from feasibility to study execution is low.
- Commercial study initiation timelines of approximately two to three months suggest that approval, contracting, privacy, and operational preparation could become more streamlined.

Short-term priorities (0-12 months)

- **Create a performance dashboard for digital / RWE studies**. Track feasibility requests, response times, conversion to execution, initiation timelines, tumour areas covered, study type, and reasons for delay or non-participation.
- **Build a repeatable feasibility response process**. Use recent feasibility examples such as Dinasty 02, Dinasty 03, and DigiACT to define standard inputs, roles, timelines, and data checks required for future requests.
- **Select priority tumour areas for portfolio expansion**. Focus initially on tumour areas where structured data, disease management team engagement, imaging capability, or sample availability already make scale-up realistic.
- **Identify bottlenecks in commercial study initiation**. Review the steps from protocol availability to ethics, contracting, privacy approval, data extraction, and analysis readiness, and identify where templates or pre-agreed pathways could reduce timelines.

Medium-term priorities (1-3 years)

- **Increase multicentre RWE study participation**. Convert existing infrastructure and tumour-area strengths into a more deliberate pipeline of academic and commercial EMR-driven multicentre studies.
- **Use performance metrics for active improvement**. Move beyond descriptive monitoring toward regular review of bottlenecks, conversion rates, timelines, and tumour-area performance, with clear improvement actions assigned.
- **Reduce commercial initiation timelines**. Use standard templates, clearer ownership, and pre-defined governance pathways to move closer to the faster initiation timelines seen in stronger-performing centres.
- **Position the centre as a reference site in selected strengths**. Build visibility around areas where IFO already has differentiating assets, such as biobanking, imaging research, demonstrated OMOP capability in lung, and selected tumour-domain expertise, using these as anchors for broader portfolio growth.

Expected benefits

This performance pathway would help IFO convert strong readiness into a more visible and repeatable study track record. It would support faster feasibility responses, stronger conversion into study execution, broader tumour-type coverage, and greater attractiveness for external partners by demonstrating not only strong capability, but also consistent delivery performance.

Cross-domain enablers

- **Data readiness and feasibility performance are directly linked**. More systematic quality control, refresh frequency, and derivation logic would improve confidence in feasibility outputs and reduce preparation time.
- **Training and scale are directly linked**. Structured training would help translate strong software, hardware, ethics, and consent foundations into consistent delivery practices across tumour teams.
- **Collaboration pathways and external attractiveness are directly linked**. Clearer models for federated and patient-level collaborative research would make the centre easier to engage in multicentre studies while maintaining appropriate privacy and governance safeguards.
- **Performance metrics and portfolio growth are mutually reinforcing**. Better tracking of feasibility, initiation timelines, and study outputs would help prioritise tumour areas, allocate effort, and demonstrate progress toward a more repeatable institutional model over time.

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Appendix – Operating context

Replies to the questions in the operating context domain of the information collected are reported here for context, although, as mentioned, they do not directly count towards the definition of the hospital level, as they probe aspects that are generally beyond the centres' control.

Question topic	Question	Response
Patient follow-up inside vs outside centre	Are oncology patients routinely followed up inside or outside your institution after treatment?	Most patients followed-up inside
EHR medication workflow enabling derivation of treatment regimens and line of therapy	In your EHR medication workflow (*e.g.*, CPOE + eMAR / pharmacy dispensing system), are systemic anti-cancer therapies captured in a structured, queryable format with start/stop dates (and regimen components) that enables derivation of treatment regimens and line of therapy (e.g., 1L/2L/3L) for each patient?	Yes: routinely structured & queryable
Presence of emergency department to capture data on AEs	To capture data on adverse events, is an emergency department present at your centre, that can promptly take care of patients experiencing adverse events from cancer treatment?	Yes
Imaging services integration	Does your PACS enable you to retrieve images in batches for research, or is it limited to clinical use?	Yes, it enables us to retrieve images in batches for research
Scope of ethics approvals at centre	In the RWE context, what is the scope of ethics approval in your centre?	Comparable to randomised controlled trial / study-specific approval, including where relevant a RWE-tailored pathway
Years since joining DIGICORE	DIGICORE / IQVIA have asked for feasibility request to selected centres but are always open to expand the network. If you have received any requests, when did your centre join DIGICORE / start receiving DIGICORE/IQVIA feasibility requests?	More than 2 years ago
Frequency of ethics committee meetings	If an ethic committee is present at your centre, how often are meetings held?	Fortnightly; 2026 has 23 scheduled sessions
Scope of oncology RWE research	Across the tumour types treated at your centre, do you have tumour-specific MDTs to support participation in observational / RWE studies?	Yes, for all or most tumour types treated at the centre

Appendix – Glossary of abbreviations

This appendix provides definitions of the abbreviations and acronyms used throughout the report.

Abbreviation	Definition
AE	Adverse event
AI	Artificial intelligence
ATLAS	OHDSI tool used to support observational research using the OMOP Common Data Model
DEP	DIGICORE Excellence Pathway
EMR	Electronic medical record
IRCCS	Istituto di Ricovero e Cura a Carattere Scientifico
ISO	International Organization for Standardization
KPI	Key performance indicator
MEDOC	Minimal Essential Description of Cancer
NLP	Natural language processing
OHDSI	Observational Health Data Sciences and Informatics
OMOP	Observational Medical Outcomes Partnership
PACS	Picture Archiving and Communication System
PRO	Patient-reported outcome
RECIST	Response Evaluation Criteria in Solid Tumours
REDCap	Research Electronic Data Capture
RWE	Real-world evidence