

DIGITAL-2023-CLOUD-AI-04-ICU-DATA

INDICATE

Deliverable D3.2

Roadmap for the sustained operations and governance of the ICU data infrastructure



1. Cover Page

PROJECT INFORMATION	
Project number:	101167778
Project acronym:	INDICATE
Project name:	A federated Infrastructure for Data of Intensive Care units in Europe
Project starting date:	01-12-2024
Project duration:	42 months

DOCUMENT INFORMATION	
Deliverable:	D3.2 – Roadmap for the sustained operations and governance of the ICU data infrastructure, including on-boarding and off-boarding plan and business model
Work Package:	WP3 – Governance, Business Models and Legal Framework
Lead Contributor	KPMG
Primary Author(s)	Jan van den Brand (Erasmus MC), Aliza Bos (Erasmus MC), Julia Palma (CeaDAR), Mark Driessen (KPMG), Anouk Kruiswijk (KPMG), Sarah de Maaker (KPMG)
Dissemination Level ¹	PU
Deliverable Type ²	R
Contractual delivery date	31-05-2026
Actual delivery date	29-05-2026
Document status	Final

TEAM	
Authors:	Mark Driessen (KPMG), Anouk Kruiswijk (KPMG), Sarah de Maaker (KPMG), Hylke Kingma (KPMG), Aliza Bos (Erasmus MC), Julia Palma (NUID UCD), Ricardo Simón Carbajo (NUID UCD)
Contributors:	-
Acknowledgements:	-
Reviewers:	Jan van den Brand (Erasmus MC) Anitha Bhat Talagini Ashoka (Fraunhofer IKS)

HISTORY OF CHANGES			
Version	Date (DD-MM-YYYY)	Author/reviewer	Description
0.1	19-02-2026	Anouk Kruiswijk	First draft
0.2	03-04-2026	Mark Driessen/Sarah de Maaker	Second draft
0.8	01-05-2026	Anouk Kruiswijk	For review
0.85	07-05-2026	Anitha Bhat Talagini Ashoka	Review
0.9	08-05-2026	Jan van den Brand	Review
0.95	12-05-2026	Anouk Kruiswijk / Mark Driessen	Addressing feedback from reviewers
0.98	18-05-2026	Hylke Kingma	Review
1.0	22-05-2026	Anouk Kruiswijk / Sarah de Maaker/ Mark Driessen	Final

¹PU = Public; SEN = Sensitive, limited under the conditions of the Grant Agreement; CO = Confidential, only for members of the Consortium.

²R= Document/Report; DEC = Website; DEM = demonstrator; DATA = federated datasets



2.Executive Summary

Purpose and policy context

INDICATE (A federated INfrastructure for Data of Intensive CAre uniTs in Europe) aims to establish a pan-European, federated infrastructure that enables secure and trusted access to intensive care unit (ICU) data, while preserving data sovereignty at the level of individual healthcare providers. During the project phase, development and coordination have been organised through a temporary consortium-based structure defined by the Grant Agreement and Consortium Agreement. While appropriate for implementation and piloting, this arrangement does not provide a sustainable basis for long-term operation beyond the project's funding period. This challenge is closely aligned with the broader European policy context. The European Data Strategy¹ and the European Health Data Space² explicitly call for durable organisational, governance, and operational structures to support trusted cross-border data sharing at scale. In this context, sustained operation of INDICATE requires a transition from a time-limited project to a permanent organisational set-up capable of ensuring continuity, accountability, regulatory compliance, and long-term value creation.

Objective and scope of Deliverable D3.2

The objective of Deliverable D3.2 is to define how the INDICATE infrastructure can be governed and operated sustainably beyond the project phase. Rather than introducing new technical components, the deliverable focuses on the organisational, legal, governance, and operational conditions required for long-term continuity and scalability.

Deliverable D3.2 is advisory and preparatory in nature. It supports informed decision-making by the consortium by outlining governance and organisational options, defining a target operating model and core capabilities, and describing a phased implementation roadmap towards sustained operations. The deliverable does not constitute a formal decision on legal or institutional arrangements, which remain subject to future agreement by the consortium and relevant authorities.

Organisational and governance foundations

The deliverable establishes the organisational and governance foundations required for the sustained operation of INDICATE beyond the project phase. It positions INDICATE within the context of the EHDS and other European data space initiatives and highlights the structural limitations of project-based governance for long-term operation.

Based on an analysis of European law, four suitable organisational options were identified. A subsequent comparative assessment of these options against INDICATE's design constraints

¹https://ec.europa.eu/commission/presscorner/api/files/attachment/862109/European_data_strategy_en.pdf

² https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space-regulation-ehds_en

and governance requirements identified the European Cooperative Society (ECS) as the preferred option, given its alignment with INDICATE's federated architecture, public interest orientation, and member-driven governance model, while providing sufficient flexibility for long-term sustainability. The ECS was subsequently presented to and endorsed by the General Assembly through a formal voting process. In the coming period, further steps will be taken to design and operationalize the ECS structure.

Building on the proposed organizational set-up, the deliverable defines a governance framework to support the long-term, transparent and accountable operation of the INDICATE data space. A coherent governance framework is defined to ensure transparency, accountability, and effective decision-making. The framework clearly distinguishes between strategic governance, operational governance, and day-to-day execution, and outlines the roles and mandates of the main governance bodies, including representative, executive, operational, advisory, and working-level structures.

Strategic portfolio, value delivery and sustainability

Central to the long-term sustainability of INDICATE is the establishment of a clearly governed strategic portfolio, thereby placing INDICATE's role within the broader European health data landscape. In this landscape, INDICATE complements other European initiatives by providing a domain-specific, ICU-focused data space with integrated governance, interoperability, and service delivery capabilities tailored to intensive care use cases.

The portfolio translates the federated ICU-data infrastructure into a coherent and evolving set of data products and services that deliver concrete value under the EHDS, supporting secondary use for research, innovation and policy, thereby contributing to improved clinical care.

The strategic portfolio provides a structured mechanism to prioritise, govern, and evolve INDICATE's offerings over time. It ensures that investments in data harmonisation, interoperability, and federated infrastructure result in reusable, scalable services aligned with EHDS obligations and stakeholder needs. Portfolio governance mechanisms support strategic alignment, lifecycle management, and informed decisions on onboarding, scaling, and sunseting of services.

The portfolio operates on a hybrid sustainability model, balancing public value with long-term financial viability. The model distinguishes between non-profit, research-oriented services and commercial, value-added offerings, and defines corresponding revenue mechanisms, cost structures, and incentives. Structural and predictable income streams are identified as essential to support the continuous operation, governance, and evolution of the INDICATE infrastructure beyond project funding.

Operating model and procedures

To translate governance and strategic choices into practice, the deliverable defines a target operating model for INDICATE. Core operational capabilities are identified across areas such as governance and compliance, participation management, infrastructure management, supporting services, and business operations. The model is designed to be lean in early stages

while remaining scalable as participation, service maturity, and operational complexity increase.

These capabilities are complemented by clear and proportionate operating procedures for onboarding and offboarding participants, knowledge management, and conflict resolution processes. Together, the operating model and procedures ensure that INDICATE can function in a consistent, transparent, and repeatable manner beyond the project phase.

Implementation roadmap and forward outlook

Finally, the deliverable presents a scenario-based implementation roadmap to support INDICATE's transition beyond the project phase. Recognising uncertainty regarding post-project maturity, possible collaboration with ICUdata4EU, and other external dependencies that may influence INDICATE's future organisational and operational setup, three development scenarios are defined across governance readiness, technical maturity, financial viability, and participant commitment.

A fully autonomous operating entity is identified as the preferred end state, in which INDICATE operates as an independent legal entity with established governance structures, a mature and scalable technical infrastructure, and sustainable revenue mechanisms supported by committed participants. Alternative scenarios provide transitional pathways that allow INDICATE to continue operating and progressively mature should full readiness not yet be achievable by the end of the project. This approach enables flexibility while maintaining strategic direction and supports informed, risk-aware decision-making for the post-project phase.

3. Table of Content

1.	Cover Page.....	1
2.	Executive Summary.....	3
3.	Table of Content.....	6
4.	Glossary of terms.....	8
5.	Context and architecture principles.....	10
5.1.	Background.....	10
5.2.	Architecture principles.....	11
6.	Organisational form.....	14
6.1.	Establishment of the new entity.....	14
6.2.	Preliminary decision: European Cooperative Society (ECS).....	16
7.	Governance.....	18
7.1.	Governance approach.....	18
7.2.	Data space governance authority.....	19
7.3.	Governance structure.....	20
7.4.	Governance bodies.....	21
7.4.1	General Assembly.....	21
7.4.2	Executive board.....	22
7.4.3	Management board.....	22
7.4.4	Advisory Boards.....	23
7.4.5	Working groups.....	24
7.5.	Role of participants in governance.....	24
7.6.	Decision-making procedures.....	25
7.7.	Transition from project governance to a permanent legal entity.....	26
8.	Strategic portfolio.....	27
8.1.	Strategic portfolio definition.....	27
8.2.	Service/Product Types.....	28
8.3.	Strategic alignment.....	28
8.3.1	Foundational use cases.....	29
8.3.2	Portfolio Expansion.....	29
8.4.	Portfolio management.....	30
8.5.	Portfolio KPIs (Evaluation Metrics).....	31
9.	Operating models and capabilities.....	33
9.1.	Capability model.....	33

9.2.	Description of capabilities.....	34
9.2.1	Organization	34
9.2.2	Participation management	35
9.2.3	Infrastructure management.....	36
9.2.4	Supporting services.....	36
9.2.5	Business operations.....	38
9.3.	Roles and responsibilities allocation across capabilities	39
10.	Operating procedures	42
10.1.	Onboarding -and offboarding.....	42
10.1.1	Onboarding.....	42
10.1.2	Offboarding.....	46
10.2.	Knowledge management.....	48
10.3.	Conflict resolution processes.....	50
10.3.1	<i>Phase 1– Project Phase (Scope of Consortium Agreement)</i>	50
10.3.2	<i>Phase 2 – Future Entity Phase</i>	52
11.	Business model.....	56
11.1.	Strategic foundation.....	57
11.2.	Value proposition and customer segments	59
11.2.1	Non-profit model.....	59
11.2.2	Commercial model	60
11.3.	Revenue streams	60
11.4.	Cost structure and sustainability.....	62
12.	Implementation roadmap	63
13.	Supplements/references	67
13.1.	Business models	67
13.2.	Implementation Roadmap.....	69

1. Glossary of terms

Preferred Term	Definition
Business model	A description of the operations of a business including the components of the business, the functions of the business, and the revenues and expenses that the business generates.
Capability model	A business capability is a particular ability or capacity that a business may possess or exchange to achieve a specific purpose or outcome.
Data holder	‘Data holder’ means a legal person, including public sector bodies and international organisations, or a natural person who is not a data subject with respect to the specific data in question, which, in accordance with applicable Union or national law, has the right to grant access to or to share certain personal data or non-personal data.
Data provider	Organisations that offer data for exchange responsible for providing data with appropriate metadata and usage policies.
Data space	A virtual environment enabling secure sovereign data sharing between organizations while maintaining data sovereignty and trust
Data space participant	Any organization that participates in the data space as either data providers, data consumers or service providers.
Data Space Governance Authority (DSGA)	The body of a particular data space, consisting of participants that is committed to the governance framework for the data space, and is responsible for developing, maintaining, operating and enforcing the governance framework.
Data Space Governance Framework	The structured set of principles, processes, standards, protocols, rules and practices that guide and regulate the governance, management and operations within a data space to ensure effective and responsible leadership, control, and oversight. It defines the functionalities the data space provides and the associated data space roles, including the DSGA and participants.
Data user	Organizations or entities that access retrieve and utilize data products and services within a data space. ‘Data user’ means a natural or legal person who has lawful access to certain personal or non-personal data and has the right, including under Regulation (EU) 2016/679 in the case of personal data, to use that data for commercial or non-commercial purposes.
European Health Data Space (EHDS)	EU initiative for secure health data sharing across member states providing legal framework for cross-border health data exchange.
Health Data Access Body (HDAB)	National entity responsible for granting access to electronic health data for secondary use.

INDICATE	Federated infrastructure for intensive care data in Europe.
OMOP Common Data Model (OMOP CDM)	Observational Medical Outcomes Partnership standard used for structuring and standardizing observational healthcare data
Onboarding	The structured process through which organizations join the data space ecosystem and become participants in accordance with governance, legal and technical requirements.
Offboarding	The structured process through which participants leave the data space while ensuring continuity of operations and protection of shared knowledge and governance artefacts.
Service provider	A participant that offers technical, analytical or operational services that support the functioning of the data space, such as interoperability services, analytics tools or infrastructure services.
Study Package	Standardized research protocols and analysis plans for collaborative ICU research including cohort definitions and data requirements

**The INDICATE Glossary of Terms was used as reference.*

2. Context and architecture principles

2.1. Background

Building the foundation for long-term INDICATE operations

INDICATE (A federated INfrastructure for Data of Intensive CAre uniTs in Europe) delivers a pan-European, federated data infrastructure that enables secure cross-border access to Intensive Care Unit (ICU) data, while preserving data sovereignty at the level of individual hospitals. During the project phase, the development, coordination and decision-making around this infrastructure are governed through a temporary, project-based structure defined by the Grant Agreement and Consortium Agreement.

While this governance arrangement is appropriate for implementation and piloting, it is inherently temporary as it is tied to project-based funding. As this funding ends, it does not provide a sustainable basis for long-term operation, accountability, or structured participation. This creates the need to define how INDICATE will be sustainably organised and governed to ensure its results can be maintained, scaled, and reused over time.

This challenge is further reinforced³ by the European Union Data Strategy³, which aims to establish a single market for data through the development of sector-specific European data spaces, alongside the European Commission's expectation that such initiatives evolve into sustainable organisational entities. The strategy emphasises federated data sharing based on trust, interoperability, clear governance arrangements, and strong protection of data sovereignty—particularly in sensitive domains such as health. Rather than relying on *ad hoc* or time-limited project coordination, the European Data Strategy explicitly calls for durable organisational structures that can support data sharing and collaboration at scale over time. INDICATE's role is positioned within the broader European health data landscape (See Section 11.1 for a comparative analysis of related initiatives).

As a concrete implementation in the health domain, INDICATE will align technically, organisationally, and operationally with these European ambitions. Deliverable 3.2 addresses this requirement by focusing on how INDICATE can transition from a time-limited consortium to a sustained European governance and operating model, capable of supporting long-term cross-border collaboration in intensive care research and innovation.

Deliverable 3.2: governance, operating models and the implementation roadmap

The objective of Deliverable 3.2 is to define how the INDICATE ICU data infrastructure can be governed and operated in a sustainable manner after the project phase. Rather than introducing new technical components, the deliverable establishes the organisational, legal, and operational conditions required to support long-term continuity, scalability, and trust. The deliverable is intended to support concrete decision-making by the consortium by clarifying governance options, sequencing transition steps and identifying organisational responsibilities for the post-project phase.

³ <https://digital-strategy.ec.europa.eu/en/policies/data-union>

Specifically, Deliverable 3.2 defines the key building blocks required for sustained operations, including:

- the envisaged long-term organisational and legal set-up for INDICATE at European level;
- the governance model, including decision-making structures, roles, responsibilities and accountability mechanisms;
- the target operating model and core capabilities required for day-to-day coordination, service management and regulatory compliance;
- a phased transition roadmap from the current consortium-based governance to a permanent European entity, including principles for onboarding and offboarding participants, and a high-level approach to financial and organisational sustainability. The roadmap is intended to support concrete decision-making by the consortium regarding institutionalization, sequencing of actions, and allocation of responsibilities after the project phase.

The scope of Deliverable 3.2 is intentionally focused on governance and sustained operations. Deliverable 3.2 is advisory and preparatory in nature and does not constitute a formal decision on legal or institutional arrangements, which remain subject to future agreement by the consortium and relevant authorities. It does not duplicate technical development activities, dissemination, and training efforts, or clinical use case work addressed in other work packages. Instead, it provides the overarching governance and operating framework within which these activities can be embedded, coordinated and maintained over time.

Overall, Deliverable 3.2 provides the organisational, legal, procedural, and operational foundations necessary to ensure that INDICATE matures from a successful project into a stable, scalable and collaborative EHDS.

2.2. Architecture principles

Architecture principles are essential to guide decisions regarding ownership, governance and operational models

Architecture principles provide high-level guidelines that guide the design, implementation and operation of the INDICATE data space. They support consistent decision-making regarding ownership structures, governance arrangements and operational models.

The principles applied in INDICATE are derived from established European data space frameworks, including the Data Space Support Centre (DSSC), OpenDEI, the Sitra Rulebook, the International Data Spaces Association (IDSA) and the Gaia-X framework. Based on these frameworks, a set of architecture principles has been identified across several dimensions of the data space, including business sustainability, governance, legal compliance, data interoperability, trust and sovereignty, and value creation enablers.

These principles serve three purposes. First, they provide strategic guidance for the design of the INDICATE ecosystem. Second, they offer evaluation criteria for assessing whether architectural

and governance choices support the intended goals of the data space. Third, they facilitate communication among stakeholders by providing a shared reference for discussing governance, ownership and operational responsibilities.

Several principles are particularly relevant for the governance and operating model described in this deliverable. These include the need for **adaptable governance structures, transparent roles and responsibilities, equitable participation**, and the ability to accommodate **different levels of participant maturity** within the ecosystem.

The following table summarises the architecture principles guiding the INDICATE data space.

ID	Principle	Category
APR01	Participation must be mutually beneficial to ensure innovation, shared value creation and long-term sustainability.	Business
APR02	All components should be designed from the perspective of the end users to ensure that all services add value to the data space participants.	Business
APR03	All components and transactions could be energy optimized to promote environmental sustainability and reduce operational costs.	Business
APR04	Data Space Governance must be adaptable to changing needs and context to enable scalability of data, participants and capabilities	Governance
APR05	Roles, responsibilities and rules must be transparent to foster trust, accountability, fair competition, and informed decision-making.	Governance
APR06	Participation should be equitable through transparent and fair governance to provide equal opportunities for all participants.	Governance
APR07	All components must be designed with different levels of participant maturity in mind to ensure that components accommodate varying levels of organizational maturity in technical infrastructure, personnel expertise, governance processes, and resource availability while maintaining quality standards that preserve the data space's value proposition.	Governance
APR08	There must be a contractual framework for all transactions to ensure legal clarity, compliance and trust among participants.	Legal
APR09	All components and transactions must comply with EU law and norms to safeguard fundamental rights, promote fair competition, and legal compliance.	Legal
APR10	Data must be findable, accessible, interoperable and reusable for multiple users and purposes to maximize value, foster collaboration, and ensure transparency of data.	Data interoperability

APR11	Data quality should be ensured by design and from the start to ensure reliability, usability, and trustworthiness of the data.	Data interoperability
APR14	All components should be deployed as code using open standards to ensure community participation in the continued development of the data space and interoperability within and between data spaces.	Value creation enablers
APR15	Personal Data must remain at the Data Provider to ensure privacy-by-design-and-default, and data sovereignty.	Trust
APR16	All components and transactions must be secure by design and from the start to protect data and infrastructure from threats.	Trust
APR18	All components must be loosely coupled to ensure that they can be easily developed, maintained, replaced, and reused without impact on operations.	Value creation enablers
APR19	All components should be designed and implemented with cloud support to ensure that participants can select their preferred infrastructure and platforms	Value creation enablers
APR20	All components should be designed so that they can be adapted to evolving regulatory requirements to ensure compliance with new European regulations and national laws	Value creation enablers

Note that APR12, APR13, and APR17 are purposefully missing from the list. These were superseded by an extension of APR10.

3. Organisational form

3.1. Establishment of the new entity

To ensure the continuity of INDICATE, a new entity will be established for the governance and maintenance of the data space

Why a new legal entity is required

INDICATE currently operates under a project-based governance structure defined by the Grant Agreement and Consortium Agreement. While this framework is sufficient during the project lifetime, it is inherently temporary and cannot provide long-term accountability, enforcement, or operational continuity.

Sustained operation of the INDICATE data infrastructure requires a permanent governance and coordination entity that can enforce shared rules, manage liabilities, ensure regulatory compliance, and act as a stable trust anchor for participating hospitals, researchers, and service providers beyond the project duration.

Design constraints for the legal form

The choice of legal form for the INDICATE entity is constrained by several key design considerations. INDICATE operates as a pan-European, cross-border data space and therefore requires an organisational form established under European law to avoid fragmentation across national jurisdictions.

The entity must support participation by both public and private organisations, ensure a level playing field among participants, align with non-profit and public-interest objectives, and provide sufficient flexibility to support long-term sustainability and potential future evolution of services.

Shortlisted legal forms

Based on the design constraints and reference frameworks, four different organisational forms have been identified as potentially suitable for the INDICATE data space entity:

- European Digital Infrastructure Consortium (EDIC)
- European Company (SE)
- European Cooperative Society (ECS)
- European Economic Interest Grouping (EEIG)

These were analysed in detail on the following sections, assessing their alignment with INDICATE's governance objectives, operational needs, and legal requirements.

The establishment of a new legal entity requires a choice of organisational form. These forms have different requirements on ownership and governance

Key design choices that are considered:

- *Participation of member states*
Possible participants of INDICATE (i.e., hospitals or research institutes) can be either public or private entities. The EDIC legal form contains a requirement that public entities, which can be considered member state participants, have the majority of the voting power within the entity. That restricts a level playing-field.

- *National vs EU law*

INDICATE aims to facilitate cross-border data exchange within Europe, and is, by definition, active in multiple European member states. Any establishment within a specific member state could introduce legal and operational barriers. Hence, the new entity will be established under European Law to facilitate cross-border collaboration.

- *For profit vs non-profit*

It needs to be determined whether INDICATE aims to generate profits for its members, as well as the extent to which members are liable for profits or losses attributed to them. A non-profit structure may better align with the public interest objectives of the data space, but this must be weighed against long-term sustainability and funding needs.



Figure: Data Space Support Centre - Decision tree including some of the core design choices for organizational form⁴

⁴ <https://dssc.eu/space/BVE2/1071253671/Organisational+Form+and+Governance+Authority>

The ECS fits best with the design principles and provides flexibility for the future organisation



Figure: analysis of the legal forms

6.2 Preliminary decision: European Cooperative Society (ECS)

In a preliminary voting the ECS is selected as the best fit for Indicate

Based on the comparative assessment of legal forms, the ECS emerges as the most suitable option for INDICATE at this stage. The ECS provides a balanced framework that supports long-term coordination and service provision, while remaining compatible with the federated and public-interest nature of the INDICATE data space.

Table 1: Details of voting process regarding the ECS as preliminary preferred legal form (28 October 2025).

	Number of Beneficiaries
No	0
I abstain	3
Absent	7
Yes, I approve	20
Total	30

ECS aligns best with governance principles

The cooperative model enables democratic, member-based governance in which participating organisations collectively shape strategic direction and oversee operations. This is particularly relevant for INDICATE, where hospitals, research organisations and service providers must be

able to participate on equal terms, without disproportionate influence by any single category of actor. The ECS supports this through principles such as equal voting rights and shared ownership, which align with INDICATE's design principles of transparency, trust and accountability.

An ECS offers sufficient flexibility to support long-term sustainability

From an operational perspective, the ECS offers a legally robust structure under European law, with limited liability for its members. This is an important consideration for operating a sustained data space infrastructure, where coordination, rule enforcement, and service provision require a stable legal personality that can enter into contracts, employ staff, and manage operational risks. Compared to lighter collaboration structures, the ECS provides sufficient institutional weight to act as a long-term governance and coordination entity.

Financial arrangements and sustainability mechanisms

Although operating on a non-profit basis, the ECS allows for sustainable financial arrangements through membership contributions, service-based cost recovery, and project-based funding. Where appropriate, the ECS framework also allows for the establishment of controlled for-profit subsidiaries to deliver specific services, while ensuring that such activities remain clearly separated from the core governance and public-interest mission of the data space.

Preliminary nature and future adaptability

The selection of the ECS is explicitly considered a preliminary decision. It reflects the current legal and policy environment, including the governance constraints associated with EDICs at the time of writing. The ECS governance framework can be designed to remain compatible with future European policy developments, allowing for adaptation or transition should conditions change, for example in response to revised EDIC governance arrangements or new European initiatives.

In parallel hospitals and industry partners currently involved in the consortium are going to conduct an internal legal analysis to determine whether participation in INDICATE is permitted within their organisation and under which legal, regulatory, or organisational conditions this can take place.

4. Governance

4.1. Governance approach

The INDICATE data space requires a governance framework that ensures transparency, trust and coordinated decision-making among participating organisations. As a federated ecosystem involving healthcare providers, researchers, service providers and other stakeholders, INDICATE must balance distributed participation with clear governance structures and operational accountability.

During the project phase, governance is organised through the structures defined in the Grant Agreement, including the General Assembly and Executive Board. These bodies ensure coordination between consortium partners and enable effective management of project activities.

However, the project governance structure is temporary and limited to the duration of the project. To enable sustained operation of the INDICATE data space beyond the project phase, this deliverable proposes a governance model aligned with the establishment of a permanent legal entity, currently envisaged as an ECS.

The governance framework therefore builds upon the existing consortium governance while adapting it to the requirements of a sustainable European data space. The model follows principles derived from the European Data Strategy⁵, the Data Spaces Support Centre (DSSC)⁶, and the Sitra Rulebook⁷ for data spaces.

The governance framework is designed according to the following principles:

- **Member-driven governance:** participants collectively determine the strategic direction of the data space through the General Assembly.
- **Clear separation between governance and operations:** strategic oversight is exercised by governance bodies, while operational responsibilities are delegated to the INDICATE entity.
- **Transparency and accountability:** governance processes are clearly defined and documented.
- **Scalability:** governance structures can evolve as the data space expands.
- **Trust and compliance:** governance ensures that data sharing takes place in a secure and legally compliant manner.

Within this framework, governance authority is exercised by the members of the cooperative, while the operational implementation of governance decisions is delegated to the management board.

⁵ <https://digital-strategy.ec.europa.eu/en/policies/data-union>

⁶ <https://dssc.eu/>

⁷ <https://www.sitra.fi/en/publication/rulebook-for-a-fair-data-economy/>

4.2. Data space governance authority

The operation of a data space requires a governance authority responsible for establishing, maintaining and enforcing the rules that enable trusted data sharing among participants. In the context of INDICATE, governance refers to the organisational structures and processes that ensure the ecosystem operates in a transparent, secure and coordinated manner.

A governance authority typically consists of a set of specialised organisational bodies that perform distinct governance functions. These bodies may operate at different levels of decision-making and may focus on specific governance domains such as strategy, compliance, or technical oversight. Examples include representative decision-making bodies such as a general assembly, executive bodies responsible for operational management, and advisory bodies providing expert guidance.

Within INDICATE, these bodies jointly constitute the **INDICATE DSGA**.

The governance authority performs several key functions that are common to data spaces:

- defining internal rules and policies governing participation in the data space;
- ensuring compliance with internal governance rules and applicable external regulations;
- resolving conflicts that may arise between ecosystem participants;
- establishing mechanisms for continuous improvement of the data space;
- managing identity and access control mechanisms;
- monitoring risks and maintaining trust and quality within the ecosystem.

Through these functions, the governance authority ensures that the data space operates according to shared rules and that participants can engage in secure and trusted data transactions.

The governance authority is partly institutionalised within the new INDICATE entity responsible for operating the data space. Most governance bodies are embedded within this entity, while some advisory structures may operate independently but contribute to the overall governance of the ecosystem.

In addition to implementing governance decisions, the INDICATE entity provides operational services that support the ecosystem. These include coordination of participation processes, infrastructure management, and knowledge management services that enable participants to interact effectively within the data space.

Positioning of INDICATE roles under the EHDS framework

The EHDS Regulation defines specific legal roles for the secondary use of health data, including Health Data Holders, Health Data Access Bodies (HDABs), Authorised Participants, and Secure Processing Environment (SPE) providers.

INDICATE does not currently intend to assume the role of Health Data Holder under the EHDS. In line with the federated architecture principles of the data space, healthcare providers participating in INDICATE remain the Health Data Holders, as they retain control over personal health data and determine the conditions under which such data may be made available for secondary use.

Similarly, INDICATE is not positioned as an HDAB by default. HDAB designation is expected to remain a Member State competence and to be embedded within national public authorities or bodies formally appointed under national law. INDICATE is therefore positioned as a supporting and enabling infrastructure that facilitates compliant cross-border secondary use workflows between Data Holders and the relevant HDABs, and may act as a service provider on behalf of HDABs to support and operationalise data access processes.

Within the EHDS role taxonomy, the future INDICATE entity is best understood as a service provider and ecosystem coordinator, providing shared governance, interoperability, secure processing capabilities, and participation management services that enable Authorised Participants to access data through nationally designated HDAB procedures. Where applicable, INDICATE or third-party providers operating under its governance framework may act as providers of Secure Processing Environments (SPEs), subject to compliance with EHDS technical and security requirements.

This role positioning is intentionally designed to preserve regulatory flexibility. As the EHDS implementing acts, national transposition, and HealthData@EU operational practices mature, INDICATE's role(s) may evolve (e.g. through formal mandates, partnerships with HDABs, or delegated operational functions), subject to decisions by the General Assembly and compliance with applicable law.

4.3. Governance structure

The governance structure of INDICATE is organised around a set of decision-making bodies, advisory bodies and operational structures that together enable the management of the data space.

Participants join the ecosystem as members of the cooperative and collectively determine the strategic direction of the data space through the General Assembly. The Executive Board supervises the operational management of the ecosystem, while the management board performs day-to-day operational activities.

Advisory boards provide independent expert input to governance bodies, and working groups (Participation management, Infrastructure management and supporting services) support operational development of the ecosystem.

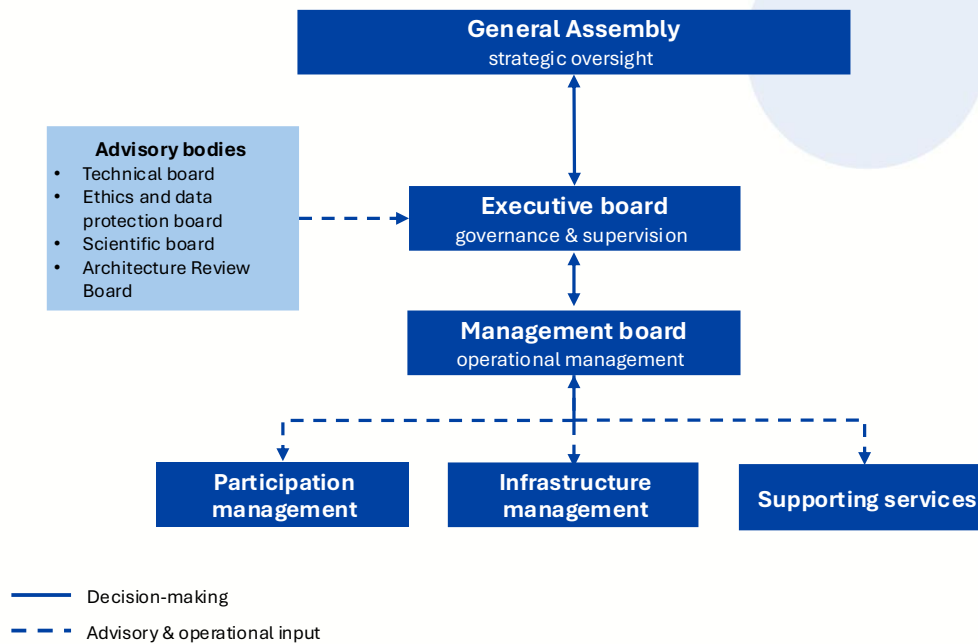


Figure: proposed governance bodies

Advisory Boards provide expert advice to the governance bodies, while Working Groups support the operational development of standards, procedures, and best practices. This governance model ensures that strategic authority remains with the members of the cooperative, while operational responsibilities are delegated to a dedicated organisational structure.

4.4. Governance bodies

4.4.1 General Assembly

Element	Description
Mandate	The General Assembly represents the members of the INDICATE and serves as the highest decision-making body of the data space.
Responsibilities	Approve the strategic roadmap and priorities of the data space. Approve governance policies and rulebook updates. Admit or remove members. Approve financial and sustainability plans. Appoint and supervise the Executive Board. Oversee ecosystem performance.
Topics	Governance framework updates. Membership policies. Financial sustainability.

Input	Strategic proposals from the Executive Board. Recommendations from advisory boards. Operational reports from the management board. Ecosystem feedback from participants.
Output	Strategic decisions and resolutions. Approval of policies and governance changes. Appointment or dismissal of board members. Approval of long-term plans.
Meeting frequency	Once or twice per year.

4.4.2 Executive board

Element	Description
Mandate	The Executive Board operates under the mandate of the General Assembly and supervises the operational management of the INDICATE data space.
Responsibilities	Implement decisions of the General Assembly. Supervise the management board. Oversee operational governance of the ecosystem. Monitor compliance and risk management. Approve operational procedures and policies. Develop strategic plans Develop major ecosystem initiatives.
Topics	Infrastructure performance. Participation processes. Operational risks. Service portfolio management. Ecosystem performance.
Input	Operational reports from the management board. Recommendations from working groups. Advisory board input. Performance indicators.
Output	Operational decisions. Implementation directives. Proposals to the General Assembly. Performance monitoring reports.
Meeting frequency	Quarterly

4.4.3 Management board

Element	Description
---------	-------------

Mandate	The Management board performs the day-to-day operational management of the data space.
Responsibilities	Operate and maintain the data space infrastructure. Manage onboarding and offboarding of participants. Ensure compliance and security. Coordinate ecosystem services. Implement governance policies and procedures.
Topics	Infrastructure operations. Participation management. Service coordination. Compliance monitoring. Knowledge management.
Input	Governance decisions from the Executive Board. Operational needs from participants. Recommendations from working groups.
Output	Operational reports. Service delivery. Implementation of governance policies. Ecosystem coordination.
Meeting frequency	Continuous operational management with regular reporting to the Executive Board.

4.4.4 Advisory Boards

Element	Description
Mandate	Advisory Boards provide independent expert advice to support governance decision-making. Advisory recommendations are non-binding and support governance decision-making.
Responsibilities	Provide guidance on scientific priorities. Review ethical and data protection considerations. Advise on technical architecture and interoperability developments.
Topics	Ethical governance. Scientific priorities. Technical developments. Ecosystem risks and opportunities.
Input	Requests for advice from governance bodies. Developments within the ecosystem. External developments in science and regulation.
Output	Advisory reports and recommendations.

Meeting frequency	Once or twice per year.
-------------------	-------------------------

Examples of advisory boards include the Scientific Advisory Board and the Ethics and Data Protection Advisory Board, which includes independent experts and representation of the patient and/or lay public perspective. Technical governance is further supported by a dedicated Architecture Review Board, acting as a specialised technical advisory body providing guidance on architecture, interoperability and security.

4.4.5 Working groups

Element	Description
Mandate	Working groups (Participation management, infrastructure management, supporting services) support the operational development of the data space by focusing on specific thematic areas.
Responsibilities	Develop operational guidelines and technical standards. Support onboarding processes. Maintain technical documentation. Identify operational improvement opportunities.
Topics	Data interoperability standards. Technical architecture. Provider support processes. Operational best practices.
Input	Operational challenges from participants. Requests from governance bodies or the INDICATE entity.
Output	Technical guidelines. Documentation. Recommendations for improvement.
Meeting frequency	As required.

4.5. Role of participants in governance

Participants play a dual role within the INDICATE ecosystem. On the one hand, they act as users and contributors to the data space by providing data, services or expertise. On the other hand, as members of the cooperative they participate in governance through representation in the General Assembly. This structure ensures that governance remains participant-driven, while operational responsibilities are delegated to the INDICATE entity.

Service providers may interact with the ecosystem in different ways. In some cases, they provide services directly to participants, for example supporting data providers in implementing interoperability standards. In other cases, service providers may operate as subcontractors to

the INDICATE entity. The governance framework distinguishes between these roles to avoid ambiguity regarding responsibilities and reporting lines.

7.6 Decision-making procedures

Decision-making authority is distributed across the governance bodies according to their respective mandates, ensuring that strategic decisions remain under the control of the members while operational decisions can be taken efficiently.

In line with the cooperative governance model, decision-making authority is structured across three levels: strategic decision-making, operational governance, and operational execution.

Decision level	Body	Example decisions
Strategic	General Assembly	Strategy, membership, financial plan
Operational governance	Executive Board	Policies, operational priorities
Operational execution	Management Board	Service delivery, onboarding

Advisory input and consultation

Advisory Boards provide independent expert guidance to inform governance decisions. While their recommendations are non-binding, they play an important role in ensuring that governance decisions are informed by scientific, ethical and technical expertise.

Working Groups may also provide recommendations on operational matters such as technical standards, interoperability guidelines or operational procedures.

These recommendations are submitted to the Executive Board, which may decide to adopt them directly or escalate them to the General Assembly where strategic decisions are required.

Transparency and documentation

All governance decisions are documented and communicated through the governance structures of the INDICATE ecosystem. Meeting minutes, policy decisions and operational directives are recorded to ensure transparency and traceability of governance processes. Where appropriate, governance decisions may also be communicated to ecosystem participants through the knowledge and communication channels maintained by the INDICATE entity.

Escalation of decisions

In cases where decisions cannot be resolved at the operational level, issues may be escalated to the appropriate governance body. This will be further defined in Chapter 10.3, operational procedures, conflict resolution processes.

7.7 Transition from project governance to a permanent legal entity

The governance model described in this deliverable assumes a deliberate transition from the project-based consortium governance to a permanent legal entity, currently targeted as a European Cooperative Society (ECS). This transition is not automatic and requires explicit legal, organisational and operational steps to be completed by participating organisations.

Participation in the future ECS is therefore not granted by default to current consortium partners. Organisations wishing to become members must formally apply and complete the onboarding process, including accession to the statutes, acceptance of governance and financial obligations, and demonstration of the required technical and organisational readiness to operate within the INDICATE data space.

In the coming period, steps will be initiated to establish the new legal entity, with the ambition to align the transition as closely as possible with the end of the project phase and minimise any gap between the consortium structure and the future organisation. However, even in a scenario where INDICATE activities continue directly under the newly established entity, a transitional (bridging) period is expected in practice. During this period, governance arrangements, operational processes, and supporting procedures will continue to mature and be formalised in practice before reaching full institutional stability.

To support this transition, an interim governance set-up will be established to ensure continuity of coordination, decision-making, and operational execution. This interim governance may build on the existing consortium structures (such as the General Assembly and Executive Board), operating under a clearly defined mandate and with a defined sunset clause until the governance of the new entity is fully operational. This approach ensures that governance responsibilities remain clear and enforceable, while allowing for a controlled transition towards the permanent organisational structure.

The interim phase is not merely a transitional necessity but an essential step in the maturation of the INDICATE ecosystem. It enables the validation and refinement of governance procedures, the operationalisation of roles and responsibilities, and the alignment of participants with the future operating model. It also provides the flexibility to adapt governance and operational arrangements based on initial experience, regulatory developments, and evolving ecosystem needs.

As outlined in Chapter 12 (Implementation roadmap), INDICATE recognises that the timeline for establishing the ECS and achieving full operational maturity may vary depending on legal, organisational, and external factors. In the event that the establishment of the ECS takes longer than anticipated, interim governance arrangements will be extended or adapted to ensure that INDICATE continues to operate in a controlled, accountable, and legally sound manner, without relying on the formal existence of the future entity.

This phased and adaptive approach to governance ensures alignment with the scenario-based implementation roadmap described in Chapter 12. It supports different maturity pathways, ranging from immediate transition to a fully operational entity to more gradual progression through intermediate stages. Across all scenarios, the objective remains consistent: to ensure continuity of operations while progressively establishing a stable, legally anchored and scalable governance structure for INDICATE.

5. Strategic portfolio

The INDICATE Strategic Portfolio manages the collection of services, data products, and research initiatives that fulfil the new entity's mandate under the EHDS framework. It ensures that investments in infrastructure and data harmonization translate into clinical insights and operational efficiency across European Health Data Holders' ICUs and member states' HDABs in meeting their mandatory obligations under the EHDS Regulation⁸ for data quality, interoperability, and secure secondary use.

5.1. Strategic portfolio definition

The strategic portfolio operationalises the value proposition, as mentioned in chapter 11.2 of the INDICATE project. It translates the technical capabilities of the Federated ICU Data Space into a structured set of data products and service offerings. This portfolio is designed to be dynamic, evolving as the EHDS regulations and the needs of the Health Data Holders within the intensive care community mature. The INDICATE strategic portfolio is intended to align with the European Electronic Health Record Exchange Format (EEHRxF) and secondary use of health data and embraces an open-by-default approach for its non-proprietary technical layers. While EEHRxF primarily focuses on primary use, its conceptual principles are considered relevant for INDICATE's data architecture; further analysis and formal alignment will be assessed in a subsequent phase. This strategy ensures that the federated infrastructure remains a public good, capable of being audited, improved, and adopted by Member States' HDABs beyond the project's initial lifecycle.

The project prioritises the use and development of open-source tools for the core federated infrastructure. By contributing to and maintaining open repositories for Common Data Model (CDM⁹) mappings and privacy-preserving technologies, and by aligning with EEHRxF, INDICATE lowers the barrier to entry for new ICU nodes. This open-source software allows the broader developer community to patch vulnerabilities or optimise performance, possibly crowdsourcing the maintenance of the portfolio's technical foundation. A cornerstone of the strategic pipeline is the creation of open data assets, such as an atlas of acute care cases (working title MIMIC-EU). Unlike restricted clinical datasets, these open initiatives provide de-identified or synthetic ICU cohorts to the global research community. These assets act as a marketing tier for the portfolio. By providing high-quality open data for testing and education, the project builds a

⁸ European Commission. (2024). *Regulation (EU) 2024/2852 of the European Parliament and of the Council of 23 October 2024 on the European Health Data Space*. Official Journal of the European Union.

⁷ Rashan A, Püttmann DP, de Keizer NF, Dongelmans DA, Cornet R, Ranzani O, Waweru-Siika W, Smith M, Harris S, Beane A, Bakhshi-Raiez F; Collaboration for Research, Implementation and Training in Critical Care —Asia and Africa Investigators, and the Dutch National Intensive Care Registry. Using the Observational Medical Outcomes Partnership Common Data Model for a multi-registry intensive care unit benchmarking federated analysis: lessons learned. *JAMIA Open*. 2025 Jul 22;8(4):ooaf052. doi:10.1093/jamiaopen/ooaf052. PMID: 40698026; PMCID: PMC12282983.

pipeline of users who will eventually transition to a restricted federated environment for sensitive, high-impact research.

5.2. Service/Product Types

The INDICATE portfolio is organised into four categories. Each category is subject to distinct access requirements and sustainability expectations, as further defined in Chapter 11 (Business Model).

Disclaimer: The value propositions outlined in this chapter are indicative and subject to further development.

Portfolio Category	Value Propositions	Strategic Objective
Governance Framework / Core Infrastructure	Identity management.	Ensure seamless, secure and trusted cross-border connectivity between ICU nodes.
Data Products	Harmonized ICU Datasets (OMOP/FHIR), synthetic data cohorts, benchmarking tables, federated analytics outputs, federated learning artefacts, model validation datasets/environments, off-the-shelf studies, metadata catalogue.	Provide high-quality, harmonised data for secondary-use through research, analytics, and machine learning and dissemination, shortening time-to-access and reducing legal complexity for users. Clinical decision support through AI enabled systems.
Clinical Services and Value-Added Applications	Regulatory compliance, consulting, onboarding support, study support and validation services	Support innovators and users in meeting ethical, regulatory and technical requirements
Preparedness and Resilience	Business continuity and disaster recovery, capacity planning	Disaster preparedness, strategic resilience

5.3. Strategic alignment

The portfolio is prioritised based on its ability to support EU citizens and healthcare providers through the secondary use of health data, in line with the EHDS, while addressing the needs of

Member States responsible for its implementation. Where relevant, the outputs of secondary use may indirectly support primary use applications (e.g. clinical care), without INDICATE itself operating as a primary use infrastructure.

Every asset in the portfolio must provide a clear value link to the upcoming business plan:

- **Secondary use supporting clinical applications:** development and validation of models, as well as insights that can be translated into bedside decision support tools and operational dashboards, funded through membership fees and/or operational subscriptions where applicable.
- **Secondary use - Public Interest Research:** federated access for academic and public stakeholders, primarily supported by the non-profit model.
- **Secondary use - Policy Making:** rapid-response dashboards and benchmarking services supporting Member State responsibilities, potentially financed via EU & Member State funding.
- **Secondary use - Regulatory/Industry:** Validation environments for MedTech and AI developers, including premium onboarding and study support services, financed through memberships fees and pay-per use arrangements as part of the commercial model.

5.3.1 Foundational use cases

Initially, the portfolio is strictly adapted to the six core INDICATE use cases to ensure technical and legal robustness within the EHDS framework. Each use case represents a specific data product or service within the strategic portfolio:

- **MIMIC-EU (Atlas of Anonymized Acute Care Cases):** A pan-European backbone of anonymized ICU datasets for AI training.
- **Early Detection of Organ Failure:** Machine learning models utilizing time-series data for faster clinical intervention.
- **Virtual Digital Twin of Mechanical Ventilation:** Simulation tools for personalized respiratory care.
- **Prediction of Neonatal and Pediatric Sepsis:** Specialized federated infrastructure for pediatric bloodstream infection identification.
- **Quality Benchmarking Dashboards:** Comparative performance tools for cross-border quality improvement.
- **Grand Rounds Workspace:** A collaborative platform for real-time knowledge exchange.

While these use cases currently drive the technical development, their long-term position in the portfolio depends on the sustainability models defined in Chapter 11.

5.3.2 Portfolio Expansion

Upon successful validation of the initial portfolio, INDICATE will gradually expand to support broader and more advanced applications, including selected commercial and validation-oriented use cases. This expansion will be closely aligned with the maturation of the INDICATE business model, as outlined in Chapter 11 (Business Model).

Portfolio growth will be phased and conditional, considering the evolving sustainability of the ecosystem, the uptake of value-added services, and the robustness of governance and compliance mechanisms. As the hybrid business model develops over time – transitioning from project-based funding towards more structural revenue streams – additional portfolio

components may be introduced in a controlled and responsible manner (such as introducing commercial AI validation).

This approach ensures that portfolio expansion supports long-term financial sustainability, preserves INDICATE's public-interest mission, and remains aligned with the access, trust and compliance principles underpinning the pan-European federated data space.

5.4. Portfolio management

To ensure the portfolio remains lean and high-impact, assets are managed through a value gate process:

- **Onboarding:** New ICU nodes or datasets are assessed for data quality and interoperability, according to the procedures set in Chapter 10.1.
- **Maintenance:** Continuous alignment with the Operating Model (Chapter 9) to ensure technical uptime.
- **Review:** Annual assessment of usage metrics. Assets with low utility may be "unsettled" to reduce the operational costs identified in the business model (Chapter 11).

The value gate process acts as the primary filter for the alignment with the business model (Chapter 11), ensuring that the project does not accumulate technical debt or operational overhead for assets that do not have a clear path to sustainability. Every asset that passes through the onboarding gate must be mapped to a specific revenue or funding stream identified in the business model, whether through (structural) public funding, tiered membership fees, pay-per use mechanisms, or off the shelf study packages. This prevents a structural mismatch between the technical and governance costs of maintaining complex, harmonised ICU datasets and the financial resources available within the federation.

Furthermore, the review and sunseting gates are critical for maintaining the cost-benefit analysis that underpins the INDICATE sustainability strategy. By systematically using usage and adoption metrics to retire underperforming assets, the portfolio management approach actively limits the accumulation of standardisation debt, for example, the recurring cost of updating datasets to new EHDS, OMOP or interoperability standards. This lean management approach supports the financial projections presented in Chapter 11 by improving cost predictability and aligning operational expenditure with actual portfolio usage. It ensures that the strategic portfolio remains an engine for value creation and sustainability, where the most utilised or monetizable data products can cross-subsidise essential but lower-revenue governance and infrastructure components.

Finally, the portfolio's expansion strategy reflects the hybrid business model underpinning INDICATE. Early use cases are primarily realized within the non-profit stream, supported by public and research funding, while future applications—such as MedTech sandboxes or commercial APIs—are expected to enter the portfolio through the commercial model defined in Chapter 11. By tying portfolio expansion to differentiated pricing tiers, memberships and service packages, INDICATE ensures that technical innovation is directly linked to validated market demand and sustainable revenue mechanisms, supporting the long-term viability of the federated data space.

5.5. Portfolio KPIs (Evaluation Metrics)

The ultimate success of INDICATE's strategic portfolio is measured by the concept of "Data Liquidity", the efficiency, velocity, and reliability with which raw ICU data is transformed into actionable clinical insight. High data liquidity signifies that the technical and legal barriers to cross-border research have been minimised, allowing high-quality data to flow securely to the researchers and clinicians who need it most. To track this, the project focuses on three primary targets that bridge technical completeness with operational agility and financial viability, following the findings from the HealthData@EU Pilot project¹⁰.

- **Target 1: Comprehensive Data Standardization and Coverage**

The aim is to achieve at least 80% coverage of core ICU variables, including biomarkers, laboratory results, medications, and diagnoses, across all federated nodes. This level of depth is critical for the secondary use of health data, as predictive AI models required readily available data to produce actionable results suitable for clinical decision support. By standardising these variables into a common format (such as OMOP CDM), the portfolio ensures that research conducted in one Member State can be validated across the entire federation without manual data cleaning, thereby increasing the intrinsic value of the data assets.

- **Target 2: Optimization of Access Latency (Time to Access)**

From an operational perspective, the portfolio aims to reduce the time-to-access for approved researchers to under 30 days, contingent upon the regulatory timelines of the relevant HDABs. This KPI targets the "bureaucratic friction" that historically plagues multi-centre ICU research. By providing pre-vetted datasets and automated compliance workflows, INDICATE minimises the administrative burden on researchers. Achieving this target demonstrates that the portfolio's governance framework is not only compliant with EHDS mandates but is also optimised for the speed required by modern medical innovation and emergency health response.

- **Target 3: Long-term Sustainability and Service Tiering**

Target 3 focuses on ensuring the long-term financial and operational sustainability of the INDICATE strategic portfolio by aligning differentiated service tiers with demonstrated user value and utilisation. While foundational data readiness (Target 1) and efficient governance processes (Target 2) are non-negotiable prerequisites for portfolio participation, long-term sustainability requires that higher-value services generate predictable revenue streams sufficient to maintain and evolve the federated infrastructure over time. The portfolio therefore adopts a value-based service tiering approach, in which pricing and revenue mechanisms are linked to the incremental value delivered to distinct user segments, rather than to basic participation or data contribution alone. Premium services, such as advanced federated analytics, validation environments, regulatory-aligned study support, and tailored onboarding, are positioned

¹⁰ Christiansen CF, Doupi P, Schutte N, Ivanković D. Piloting an infrastructure for the secondary use of health data: learnings from the HealthData@EU Pilot. *Eur J Public Health*. 2025 Sep 1;35(Supplement_3):iii3-iii4. doi: 10.1093/eurpub/ckaf073. PMID: 40926476; PMCID: PMC12420900.

within higher service tiers and may be subject to differentiated access conditions and pricing models, as further elaborated in Chapter 11 (Business Model).

The portfolio KPIs operationalise the strategic objectives by translating them into measurable governance signals that inform onboarding, scaling and sunseting decisions within the portfolio. These KPIs are indicative and will evolve as the portfolio matures, regulatory requirements under EHDS are finalised, and the business model is validated in operation.

Table. Conceptual portfolio mapping of strategic objectives to KPIs

Strategic objective	KPI	Measurement
Trusted cross-border data sharing	Target 1: Coverage	Technical and semantic readiness of ICU nodes
Efficient secondary use under the EHDS	Target 2: Time-to-access	Effectiveness of governance and access processes
Long-term sustainability	Target 3: Sustainability	Ability of portfolio to fund and maintain itself

In summary, the INDICATE strategic portfolio is a specialized value-delivery engine designed to navigate the complexities of the emerging European health data landscape, including both technical and non-technical components. By bridging the gap between clinical necessity and regulatory requirements the portfolio ensures that the federated infrastructure generates high-quality data and insights that can ultimately inform clinical applications, while building a robust foundation for secondary use research.

Through its commitment to open-source principles, rigorous value gate governance, and a hybrid business model set out in chapter 11, INDICATE creates a scalable blueprint for the future of digital intensive care. Ultimately, these managed assets transform the ICU from an isolated data silo into a vital node within the EHDS Regulation, fostering a resilient ecosystem where data liquidity translates directly into improved patient outcomes across the Union.

6. Operating models and capabilities

6.1. Capability model

A first concept capability model for the DSGA – the central entity for managing INDICATE - is developed

The business capability model is used to design which capabilities will be organized within the new entity responsible for managing the INDICATE data space.

These are based on several references of different data spaces and academic articles. Mainly those collected and edited in data spaces: design deployment and future directions (Curry et al., 2022). However, it should be noted that the references from other data spaces are limited in number and detail. To develop this concept, also references for platform organisations and regional collaborations (comparable to data spaces) have been used.

“ A business capability is a particular ability or capacity that a business may possess or exchange to achieve a specific purpose or outcome” – TOGAF¹¹

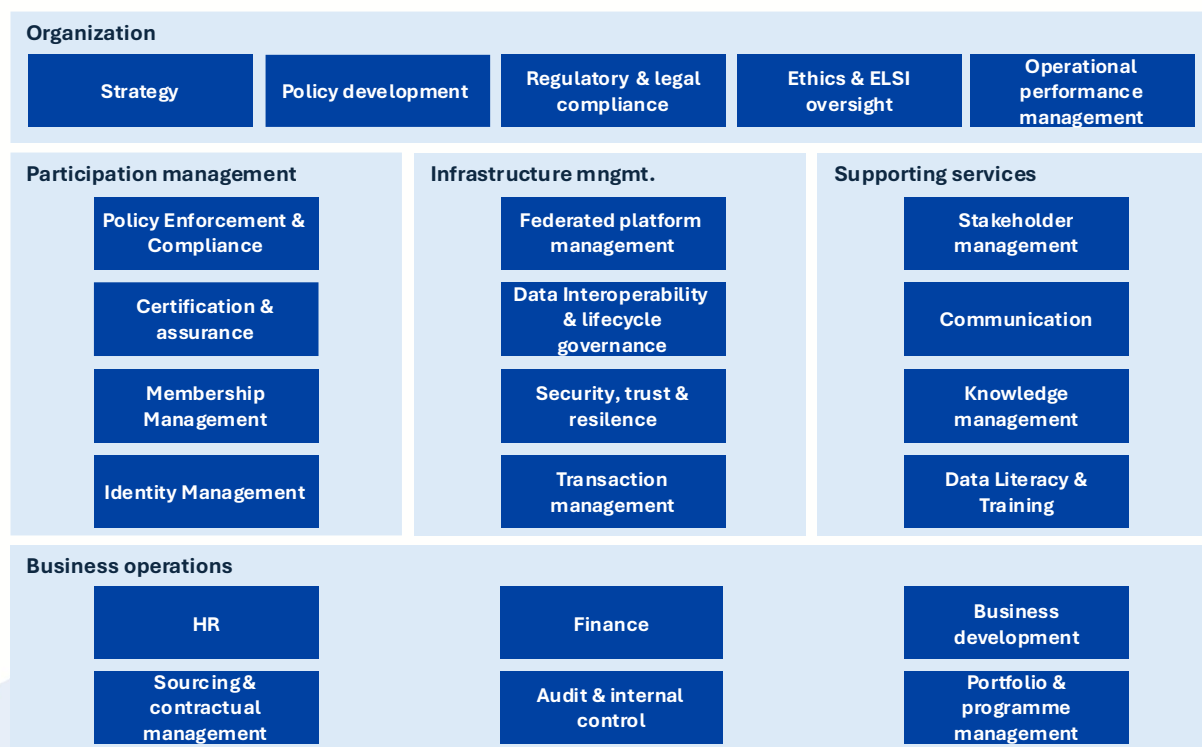


Figure: first concept capability model INDICATE

¹¹ The Open Group (2022). TOGAF Services Guide: Business Capabilities (version 2) <https://pubs.opengroup.org/togaf-standard/business-capabilities/chap02.html>

6.2. Description of capabilities

6.2.1 Organization

Strategy

The Strategy capability defines and periodically updates the long-term direction of INDICATE as a sustainable European federated ICU data space. It translates European policy developments (such as the EHDS and Data Act), technological trends and ecosystem needs into concrete strategic priorities, investment decisions and growth pathways. This capability includes multi-year planning, risk identification, prioritization of capability development, and alignment between governance, infrastructure and business objectives. It ensures that INDICATE evolves from a project-based initiative into a stable institutional actor with a clear mandate and defined value proposition. Strategic oversight lies with the Board, which ensures that operational and financial decisions remain aligned with the mission and long-term sustainability objectives.

Policy Development

Policy Development covers the structured design, documentation, implementation and lifecycle management of INDICATE's governance framework. This includes participation conditions, onboarding and offboarding procedures, access control rules, contractual templates, data use policies, service agreements and internal operating procedures. Beyond drafting policies, this capability ensures version control, stakeholder consultation, formal approval processes and periodic review cycles. It also guarantees that all collaborations, agreements and contractual relationships are transparently documented and traceable. Policy Development thus provides the normative backbone of the data space, ensuring clarity, predictability and enforceability across the ecosystem.

Regulatory Compliance

Regulatory Compliance ensures that INDICATE operates in conformity with applicable European and national legislation, including data protection, health data regulations, cybersecurity requirements and emerging data governance frameworks. This capability defines participant responsibilities and allocates legal roles (e.g. data controller, processor), monitors compliance adherence, and provides guidance to participants on their obligations and rights. It includes regulatory monitoring, impact assessments, internal compliance reviews and preparation for external audits. The function operates centrally to ensure consistent interpretation and application of legal requirements across all participating organisations.

Ethics oversight

Ethics Oversight safeguards responsible and proportionate use of health data within INDICATE. It ensures that cross-border data collaboration respects fundamental rights, transparency principles and societal expectations.

This capability includes ethical review of governance mechanisms, responsible AI considerations, proportionality assessments and guidance on secondary data use. The Ethics Committee provides independent advisory input to the Governance Authority and supports the integration of ethical considerations into operational decision-making. It also ensures that the implementation of FAIR principles is aligned with ethical safeguards and public trust requirements.

Operational Performance Management

Operational Performance & KPI Management provides a structured approach to measuring and improving the functioning of INDICATE as a data space. It defines quantitative and qualitative performance indicators related to participation growth, data quality, interoperability compliance, transaction volumes, service availability and ecosystem engagement. This capability includes continuous monitoring, reporting cycles, performance dashboards and corrective action mechanisms. It supports evidence-based decision-making at Board level and enables early identification of operational bottlenecks. By linking governance objectives to measurable outcomes, this function drives maturity progression and long-term scalability.

6.2.2 Participation management

Policy Enforcement & compliance

This capability ensures that all participants adhere to INDICATE's rulebook, contractual obligations and operational standards. It includes monitoring of access rights, verification of compliance with data sharing conditions and management of non-compliance situations.

Where deviations occur, corrective measures, remediation plans or escalation procedures are activated in line with governance rules. Policy Enforcement protects the integrity of the ecosystem and maintains trust among participants by ensuring that agreed principles are consistently applied.

Certification & assurance

Certification & Assurance establishes formal validation mechanisms before and during participation. For data providers, this includes digital maturity assessments, interoperability validation (e.g. conformity to CDMs), and data quality checks. For service providers, it includes evaluation of security standards, technical compatibility and contractual alignment. The capability may include structured reassessment cycles, quality monitoring and documentation requirements. Certification strengthens technical reliability and reduces operational risk within the data space.

Membership management

Membership Management governs the lifecycle of participants within INDICATE. It includes admission procedures, role assignment, contractual accession, membership tracking and structured offboarding. The function ensures transparent participation rules and balanced representation within the governance structure.

Identity Management

Identity Management provides secure, federated authentication and authorisation mechanisms across the ecosystem. It supports role-based access control, federated institutional login and identity verification procedures. The capability ensures that users only access services and information consistent with their role and contractual rights. It underpins trust, traceability and enforceability within INDICATE's federated architecture.

6.2.3 Infrastructure management

The Infrastructure Management building block defines how INDICATE's shared technical environment is organized, maintained, and governed. It ensures that all participants can interact, exchange data, and run services on a stable and secure foundation. Infrastructure Management is essential to ensure that the data space remains scalable, interoperable, and aligned with overarching governance requirements. This building block also covers day-to-day technical operations, including DevOps activities required to ensure platform reliability and continuity.

Federated Platform Management

This capability oversees the coordination and operation of the federated technical infrastructure. It includes management of core services such as the metadata catalogue, broker functions, secure processing environments and API interfaces. Rather than centralising data, this function ensures harmonised operation of decentralised nodes under common governance standards. Operational responsibilities include deployment, configuration, monitoring and continuous improvement of these services through DevOps practices (e.g. CI/CD, release management).

Data Interoperability & lifecycle governance

This capability governs the adoption, maintenance and evolution of CMDs (e.g. OMOP, FHIR), semantic vocabularies and interoperability standards. It includes data quality monitoring, model updates, issue management and lifecycle governance of datasets and schemas. The objective is to ensure consistent, reusable and interoperable data across participating institutions.

Security & Resilience

Security & Resilience ensures the protection and continuity of INDICATE's federated infrastructure. It includes cybersecurity controls, secure processing environments, access controls, incident response procedures and resilience planning. This capability safeguards data integrity and operational stability. DevOps teams contribute to this capability through operational security measures such as patching, monitoring, incident handling and recovery processes.

Transaction Management

Transaction & Provenance Management governs the secure execution and traceability of data queries and exchanges within the federated environment. It ensures logging, contract enforcement, monitoring of data usage and auditable tracking of transactions, without transferring identifiable patient data.

6.2.4 Supporting services

Supporting Services enable the effective functioning, adoption and long-term sustainability of INDICATE as a federated EHDS. While not directly part of core governance or technical infrastructure, these capabilities are essential for ecosystem coherence, knowledge continuity and operational consistency.

Stakeholder management

Stakeholder Management ensures structured and continuous engagement with all relevant actors in the INDICATE ecosystem, including hospitals, research institutions, service providers, policymakers, regulatory bodies and European data space initiatives.

This capability includes mapping and segmentation of stakeholder groups, structured consultation mechanisms, representation management, feedback collection and relationship management. It ensures that stakeholder expectations are aligned with INDICATE's governance framework and operational capabilities.

Stakeholder Management also supports ecosystem expansion by identifying potential new participants and fostering cross-border collaboration. It contributes to policy alignment and ensures that INDICATE remains positioned within broader European health data developments.

Communication

Communication ensures transparent, consistent and structured dissemination of INDICATE's objectives, governance updates, operational developments and performance outcomes. This capability includes external communication (e.g. website, publications, reporting to the European Commission, participation in conferences) and internal communication (e.g. updates to participants, governance decisions, operational changes). Communication plays a critical role in maintaining trust and legitimacy, ensuring that participants clearly understand governance expectations, operational procedures and strategic direction. It also supports visibility and credibility of INDICATE within the European data space landscape.

Knowledge management

Knowledge management ensures that all governance documentation, operational procedures, technical guidelines, training materials and lessons learned are systematically captured, maintained and made accessible across the ecosystem. This capability includes:

- structured documentation repositories;
- version control and update procedures;
- defined ownership of knowledge domains;
- validation and review mechanisms;
- access management aligned with participant roles.

Knowledge management reduces dependency on individual contributors and safeguards institutional memory. It ensures that onboarding processes are consistent, governance decisions are traceable and operational know-how is retained even when participants enter or exit the ecosystem. In a federated data space, Knowledge Management functions as the connective tissue between governance, operations and ecosystem growth.

Data Literacy & Training

Data Literacy & Training strengthens the capacity of participants to operate effectively within the federated data space. It encompasses onboarding courses, governance briefings, technical training, documentation walkthroughs and structured learning pathways for different participant

roles (e.g. data providers, data users, service providers). This capability ensures that participants understand:

- their governance obligations;
- technical interoperability standards;
- secure data handling practices;
- procedural steps for study execution.

By building digital and governance literacy, this function reduces operational risk, increases adoption of standards and accelerates ecosystem maturity. It also supports scaling by enabling new participants to integrate efficiently and consistently.

6.2.5 Business operations

Human Resources (HR)

The HR capability manages staffing, organisational roles and capacity planning within the INDICATE entity. It ensures that the organisation maintains sufficient expertise across governance, compliance, technical coordination, stakeholder management and financial administration.

HR includes recruitment processes, role definition, performance evaluation and professional development planning. It also supports succession planning to reduce dependency on individual actors and ensure continuity of critical functions. A robust HR capability is essential for transitioning from a project-based structure to a stable institutional organisation.

Finance

Finance & Financial Governance ensures transparent and accountable management of financial resources. This capability includes budgeting, financial planning, cost allocation mechanisms, membership contributions, invoicing procedures and financial reporting.

It also supports the development and monitoring of sustainable funding models, ensuring that INDICATE's operational costs are covered beyond initial grant funding. Financial Governance includes internal controls, segregation of duties and oversight mechanisms to ensure compliance with legal and accounting standards.

Sourcing & contract management

Sourcing & Contract Management governs procurement activities and contractual relationships with external suppliers and service providers. It includes vendor selection, contract negotiation, service level agreement (SLA) management and oversight of intellectual property and licensing arrangements.

This capability ensures that external services—such as technical components, certification services or knowledge platforms—are aligned with INDICATE's governance and security requirements. It also manages contractual risks and ensures legal clarity in relationships with third parties. statutory/tax compliance.

Audit

Audit provides independent oversight over governance processes, financial management and compliance mechanisms. It includes periodic internal reviews, risk assessments, documentation checks and audit preparedness.

This capability ensures that INDICATE can demonstrate accountability to members, regulators and funding bodies. It strengthens transparency and mitigates governance and operational risks.

Business Development & Ecosystem Growth

Business Development & Ecosystem Growth focuses on expanding participation, strengthening strategic partnerships and increasing adoption of INDICATE services.

This capability includes market analysis, value proposition refinement, partnership development and alignment with European data space initiatives. It supports identification of new use cases, collaboration opportunities, and funding pathways. By actively managing growth, this function ensures that INDICATE evolves from a pilot network into a scalable European infrastructure.

Portfolio & programme management

Portfolio / Service Management coordinates the lifecycle of INDICATE's services, infrastructure components and governance initiatives. It ensures prioritisation of activities, structured resource allocation and alignment with strategic objectives. This capability replaces traditional project management with a more mature service-oriented approach. It supports structured evolution of the data space by managing updates, new services, decommissioning of outdated components and continuous optimisation. Portfolio Management ensures that INDICATE operates as a stable service provider rather than as a time-limited project consortium.

6.3. Roles and responsibilities allocation across capabilities

From capabilities to institutional roles

The future INDICATE entity is designed as a lean but scalable institutional structure capable of operating a federated European ICU data space beyond the project phase.

The organisational design is guided by the following principles:

- Clear separation between governance oversight and operational execution
- Consolidation of roles in early maturity stages
- Progressive functional specialisation as ecosystem scale increases
- Embedded compliance, trust and performance monitoring
- Financial sustainability and accountability

The entity transitions from a centrally coordinated project structure to a federated operational organisation with distributed responsibilities under harmonised governance rules.

The table below translates the INDICATE capabilities into concrete institutional roles for the future legal entity. During the project phase, required competences are distributed across work packages and beneficiaries under the Consortium Agreement. In the sustained phase, these competences must be structurally embedded within a permanent organisational set-up. Rather than replicating the project’s work package structure, the new entity consolidates related competences into a limited number of core roles.

In the initial maturity stage (“Understand” – centralised coordination), several competences are intentionally combined within single roles. As INDICATE scales (“Streamline → Automate → Scale”), selected functions progressively specialise.

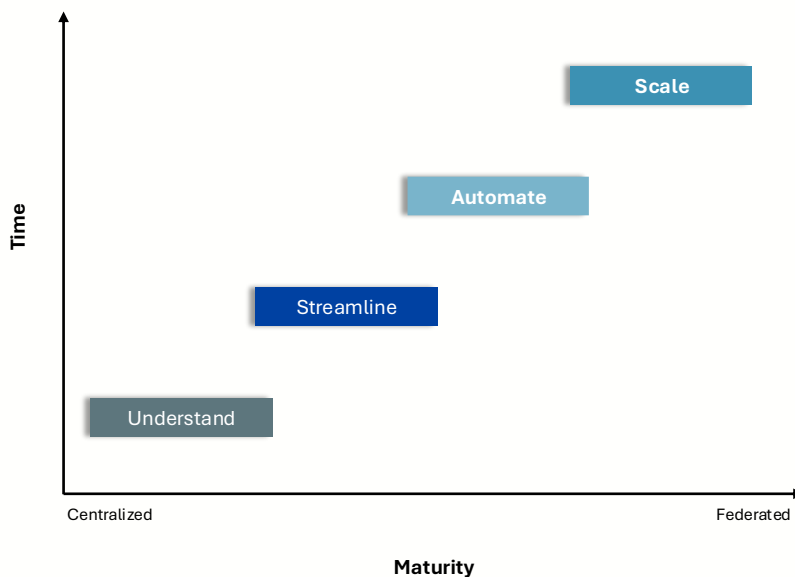


Figure: capability growth model

Disclaimer: The presented growth model is conceptual and illustrative and should not be interpreted as a scientifically validated model.

Core roles of the INDICATE Entity (Phase 1)

In its initial operational phase, the INDICATE entity can function with an estimated 4.5 to 6 FTE distributed across the following core roles (see table).¹²

Scalability Consideration

The competence-to-role mapping is designed to evolve alongside the capability maturity trajectory of INDICATE. As transaction volume, participation and service complexity increase, selected functions (e.g. security, certification, compliance monitoring, business development) may be further specialised into dedicated roles.

This staged approach ensures that the organisational structure remains proportionate in the early phase while being capable of scaling into a mature European federated data space.

¹² This is an estimation and needs to be further validated.

Role	Estimated FTE
Executive director	1.0
Technical operations lead (including e.g., DevOps team)	1.0-1,5
Data interoperability lead	0.8-1.0
Compliance officer	0.8-1.0
Ecosystem & knowledge manager	0.8-1.0
Finance & administration	0.5
Total	~4.5-6 FTE

Capabilities*	Project Fase		Phase 1: New entity		Growth	
	Roles	FTE	Roles	FTE	Roles	FTE
Organizational - Strategic direction - Policy development & compliance - Ethics oversight - Performance management	Coordinator / WP Leads		Executive director	1.0	Needs to be determined at a later stage	
	WP3 Governance / ELSI		Compliance officer	0.8		
	Ethics Board		Ethics committee	0.2		
	WP3		Executive director	-		
Participation management - Membership management - Certification & assurance - Policy enforcement - Identity management	WP5		Ecosystem manager	0.8		
	WP2+WP5		Data Interoperability lead	-		
	WP3		Compliance officer	-		
	WP4		Technical operation lead	-		
Infrastructure management - Federated platform - Security & resilience - Data interoperability - Transaction	WP4		Technical operation lead	1.0		
	WP4		Technical operation lead	-		
	WP2		Data interoperability lead	0.8		
	WP4		Technical operation lead	-		
Supporting services - Communication - Knowledge management - Training & literacy - Stakeholder engagement	WP5		Ecosystem manager	-		
	WP3+WP5		Ecosystem manager	-		
	WP5		Ecosystem manager	-		
	WP5		Executive director	-		
Business operations - Finance - Contract management - Audit - Business development - HR	Coordinator		Finance officer	0.5		
	Coordinator		Compliance officer	-		
	Coordinator		Compliance officer	-		
	N/A		Executive director	-		
	Beneficiaries		Executive director	-		

Figure: capability growth and maturity trajectory

7. Operating procedures

This chapter describes the core operating procedures required to support the consistent, transparent and compliant functioning of the INDICATE infrastructure beyond the project phase. It outlines role-based procedures for onboarding and offboarding, knowledge management and conflict resolution, translating the governance and operating model described earlier into practical, repeatable processes. The procedures are designed to be proportionate and scalable, supporting a phased transition towards sustained operations while allowing flexibility as the INDICATE ecosystem evolves.

7.1. Onboarding -and offboarding

7.1.1 Onboarding

The onboarding approach described in this section is aligned with and further elaborates on the principles and processes defined in deliverable D2.1 (ELSI framework), the Data Provider Handbook (v0.2), and the Plateau 1 onboarding architecture. These documents provide the detailed legal, governance and technical foundations underpinning the INDICATE onboarding process.

Data provider

The onboarding process for data providers begins when an organisation expresses interest and submits an application through the INDICATE portal. Following eligibility verification and preliminary role classification, the organisation enters an initial onboarding phase that combines governance, legal and technical preparations.

At an early stage, the organisation is invited to the INDICATE platform environment, where federated identity and initial user configuration are enabled. This technical onboarding step ensures that designated representatives can access the portal and proceed with the role nomination and accession process.

Once the data provider role is confirmed, the organisation nominates the required internal roles, such as Legal Representative, Data Steward and other operational contacts, through the INDICATE platform. The applicable Accession Agreement for the data provider role is then concluded, formally defining rights and obligations within the data space.

In parallel, INDICATE assesses the organisation's operational and technical readiness. For data providers, this includes validation of interoperability and data quality requirements, such as verification of OMOP CDM conformity and related quality checks. This assessment supports alignment with INDICATE's technical and governance standards, without prescribing a fixed implementation pathway.

Following successful validation, the organisation completes remaining procedural and training components, including internal workflow alignment and role-based access configuration. Upon confirmation that governance, legal and technical conditions are met, the organisation is

activated as a data provider within the INDICATE ecosystem. Study-specific agreements are managed separately within the study governance framework.

Data user

Data users initiate onboarding by submitting an application and indicating their intended role. After eligibility verification, the organisation enters an initial onboarding phase that includes technical access preparation and governance alignment.

Similar to other participant types, initial technical onboarding ensures that nominated representatives are invited to the INDICATE platform and can authenticate using federated identity mechanisms. This enables subsequent role nomination and formal accession steps.

Once the data user role is validated, the organisation concludes the applicable Accession Agreement and nominates authorised representatives through the INDICATE platform. Role-based permissions are configured in accordance with INDICATE's identity and access management framework.

Training and governance familiarisation are then provided to ensure that users understand participation conditions, access rules and the study proposal and approval process. After completion of these steps, the organisation is activated as a data user.

Individual studies remain subject to separate governance review and approval procedures. Study-specific Data Sharing Agreements are established between participating parties in accordance with INDICATE's study governance model.

Service provider

Service providers join INDICATE as technical or infrastructural contributors that support the functioning of the federated data space. Following application and eligibility verification, they enter the common initial onboarding phase, which includes technical access preparation and governance alignment. As with other participant types, designated representatives are invited to the INDICATE platform environment and federated identity mechanisms are enabled to allow secure authentication and role nomination. Once the service provider role is validated, the applicable Accession Agreement is concluded, defining rights, obligations and boundaries of responsibility within the ecosystem.

Service providers are assessed based on the relevance, suitability and compliance of the services they intend to provide. This may include support for data transformation, quality assessment, federated analytics, privacy-enhancing technologies or infrastructure management. Rather than prescribing fixed implementation approaches, INDICATE verifies alignment with interoperability standards, security principles and architectural guidelines. Although service providers typically do not access patient-level data, their tools and services must operate in a privacy-preserving and security-compliant manner, typically supporting execution within secure local environments and adhering to least-privilege access principles. Technical integration and validation are completed in coordination with relevant stakeholders to ensure reliable deployment within the federated architecture. Service providers may also contribute documentation, technical guidance and knowledge assets to support adoption and consistent implementation across the ecosystem. Once governance, legal and technical alignment are confirmed, the organisation is activated as a service provider within INDICATE.

Others (Observers, Advisors, Partners)

Organisations that participate in INDICATE in an advisory, observational or otherwise non-operational capacity follow a proportionate onboarding pathway. After application and eligibility validation, they enter the common onboarding phase, including initial technical access preparation where relevant.

Observers and advisory partners conclude an Accession Agreement tailored to their non-data-handling role. This agreement defines the scope of participation, access limitations and governance rights appropriate to their function within the ecosystem.

These participants do not engage in technical data processing, do not participate in study execution and do not access secure processing environments. Their involvement focuses on contributing expertise, participating in governance discussions where appropriate, supporting dissemination and training activities, and enriching the shared knowledge base.

Should an organisation later wish to transition into a data provider, data user or service provider role, it may enter the corresponding onboarding pathway, including any additional legal, governance and technical requirements applicable to that role.

This differentiated onboarding approach enables INDICATE to benefit from broader ecosystem engagement while preserving data protection, security and operational integrity within the federated architecture.

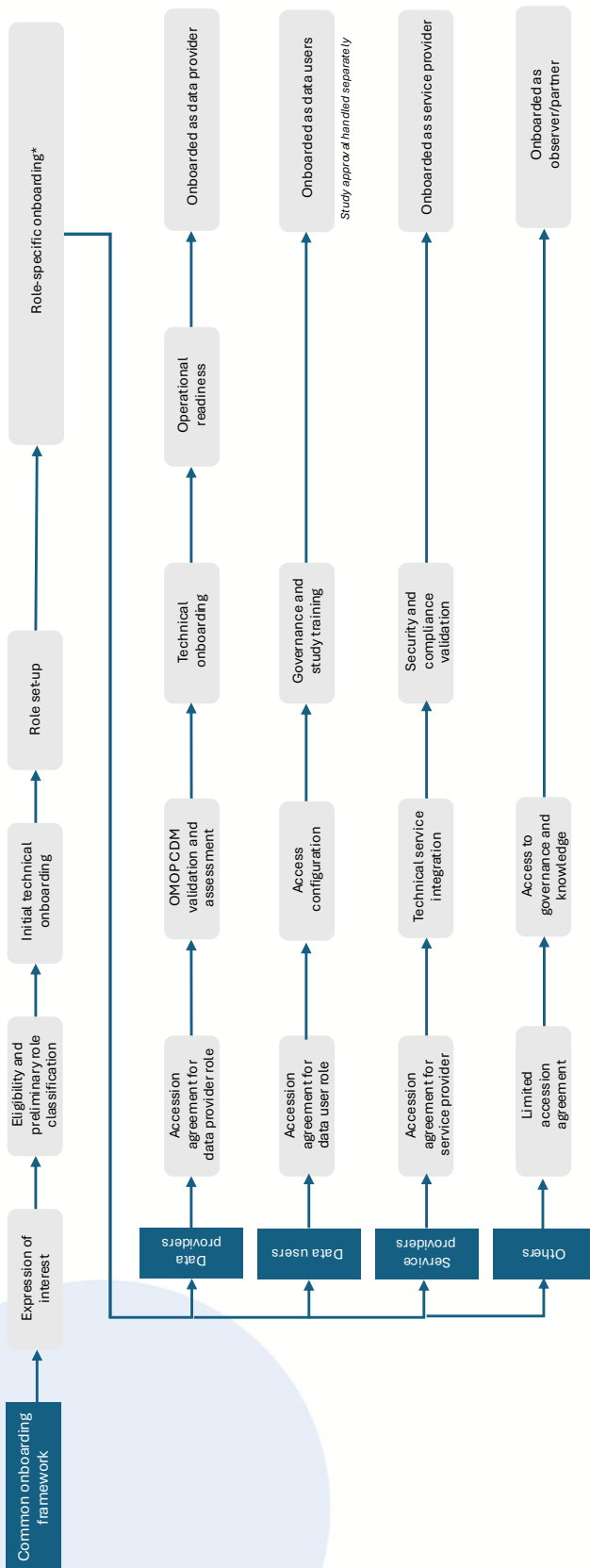


Figure: Structured, role-based onboarding within the INDICATE participation lifecycle. *All participants undergo initial technical onboarding and federated identity configuration prior to role-specific accession and activation

7.1.2 Offboarding

Offboarding forms an integral component of the INDICATE participation lifecycle and is governed with the same level of oversight and proportionality as onboarding. Participants may exit the ecosystem voluntarily, upon completion of collaboration activities, or as a result of governance decisions, changes in eligibility, or non-compliance with agreed rules.

Offboarding is managed through a structured and proportionate process that safeguards legal certainty, data protection, operational continuity and ecosystem stability. While the specific steps may vary depending on the participant's role and the circumstances of exit, all offboarding pathways operate within a common governance framework.

Specific attention is given to scenarios where participants exit during active collaboration (e.g. ongoing studies), as these may introduce risks related to patient data governance and research continuity.

To mitigate such risks, the offboarding framework defines a set of minimum requirements applicable across participant roles. These include:

- a predefined minimum notice period, differentiated by participant role and type of engagement;
- clearly defined obligations during a wind-down period, including the responsible completion, transfer, or orderly termination of active studies and collaboration;
- explicit provisions governing the treatment of data sharing agreements at the point of exit, including continuation, transfer, or termination conditions in line with legal and contractual requirements;
- and a structured financial settlement process addressing outstanding membership obligations.

At a general level, the offboarding process includes formal notification and acknowledgement of exit, review of applicable contractual and governance obligations, and alignment on any outstanding responsibilities. Access rights and platform credentials are adjusted or revoked in accordance with INDICATE's identity and access management framework. Where relevant, disengagement from operational services and technical components is coordinated in a controlled manner to prevent disruption within the federated architecture.

For data providers and data users, particular attention is given to the handling of ongoing studies, applicable data sharing arrangements, and legally required retention or documentation obligations. For service providers, technical integration points are reviewed and adjusted to maintain architectural stability. For observers or advisory partners, access rights are proportionately modified in line with their limited participation scope.

In parallel, ecosystem continuity is safeguarded. Governance artefacts, shared documentation and validated knowledge assets remain part of the INDICATE knowledge base, independent of individual participant membership. Participant-specific information and role-bound access are adjusted accordingly, ensuring that exit does not compromise institutional memory or the integrity of the data space.

The detailed procedural steps are further elaborated in the subsequent section. Together, these measures ensure that participant exit is managed in a transparent, auditable and proportionate manner, preserving trust and long-term sustainability within the INDICATE ecosystem.

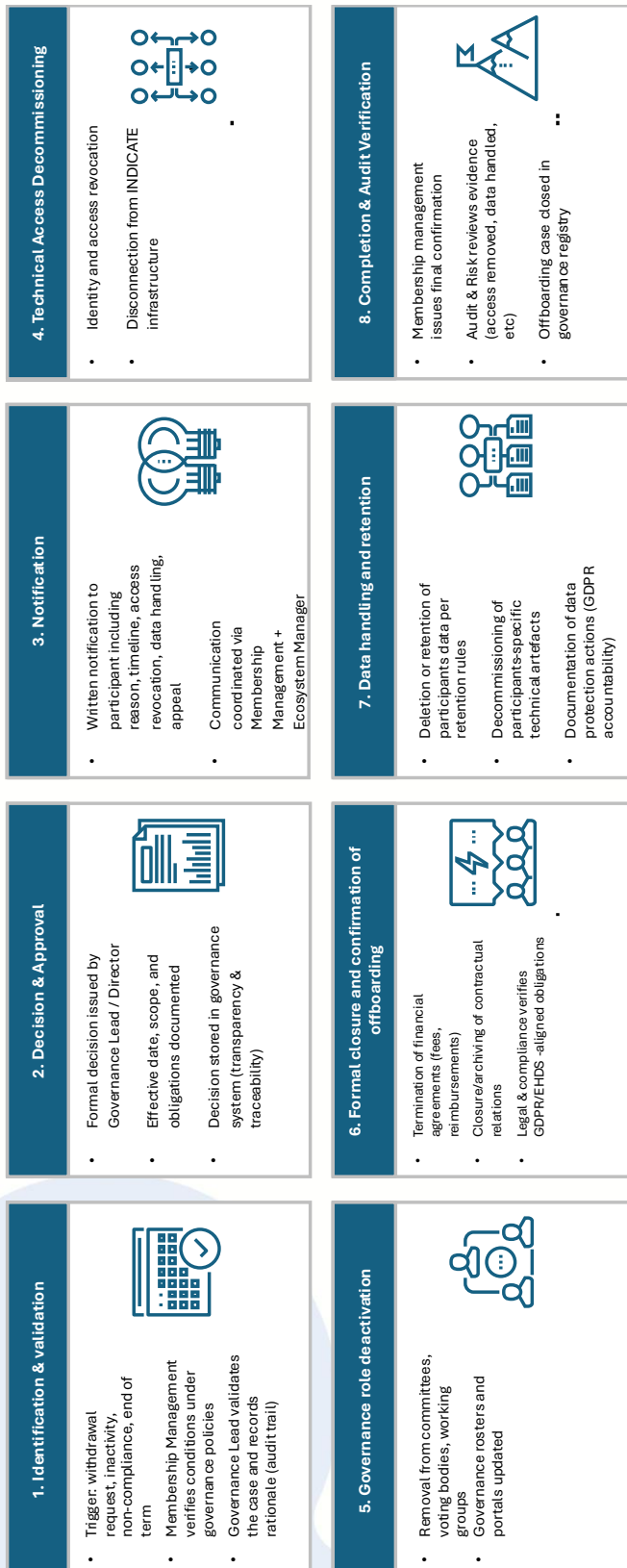


Figure: offboarding process (proposed steps)

7.2. Knowledge management

Knowledge as core enabling function

Knowledge management is a core enabling function for the sustained operation of the INDICATE data infrastructure. Beyond the project phase, the ability to capture, maintain and reuse knowledge is essential to ensure continuity, trust and scalability of the data space.

INDICATE generates a wide range of knowledge assets, including governance documentation, operational procedures, technical specifications and clinical best practices. Knowledge assets are maintained at ecosystem level rather than by individual participants, ensuring continuity independent of partner turnover or individual contributors.

Within the sustained INDICATE set-up, knowledge is treated as a shared asset that directly supports governance and day-to-day operations. Authoritative governance, operational and technical guidance forms the basis for consistent onboarding of new participants, informed decision-making, regulatory compliance and the long-term reuse of project results. Knowledge management is therefore explicitly distinguished from dissemination and communication activities, which are primarily aimed at awareness raising and training.

During the project phase, INDICATE knowledge assets are supported by project-specific platforms such as Azure DevOps (e.g. code repositories, issue tracking and technical documentation), SharePoint workspaces and project wikis. These environments operate under the contractual arrangements of the European Commission-funded project and are therefore time-limited in nature.

For the sustained phase, no automatic transfer of these project-phase platforms to the future INDICATE entity (e.g., ECS) is assumed. In line with INDICATE's open-by-default and federated principles, the preferred direction is a platform-neutral knowledge environment governed by the future entity, to which selected and validated knowledge assets may be migrated. Project-specific environments (such as the current Azure DevOps organisation) may subsequently be archived or wound down in a controlled manner, in alignment with the implementation roadmap.

Knowledge domains and key artefacts

The knowledge generated within INDICATE spans multiple domains, including governance, operations, technology and clinical use cases, specified to specific member states. Together, these domains constitute a coherent and evolving knowledge base that enables INDICATE to function as a durable EHDS beyond the lifetime of the project.

Governance-related knowledge includes the INDICATE rulebook, policies, decision logs and documentation of governance processes. These artefacts ensure transparency, accountability and traceability of decisions within the data space. Changes to governance-related knowledge artefacts (e.g. rulebook, policies, procedures) are reviewed through designated governance bodies and formally endorsed before publication, ensuring accountability.

Operational knowledge covers standard operating procedures, onboarding and offboarding playbooks, incident handling procedures and service documentation. This knowledge enables consistent execution of services and reduces dependency on individual organisations or experts.

Technical knowledge consists of architecture documentation, interoperability guidelines, code repositories, data models and technical standards required for federated operation. Clinical and use-case knowledge includes best practices, benchmarks, lessons learned and methodological guidance derived from real-world implementations.

Together, these knowledge domains form a shared asset of the INDICATE ecosystem.

Governance of knowledge assets

The sustained INDICATE entity is responsible for the stewardship and coordination of shared knowledge assets, ensuring their quality, accessibility and alignment with agreed governance principles. Knowledge governance focuses on continuity, quality assurance and coordination, rather than ownership of underlying data.

Strategic oversight of knowledge management is embedded within the overall governance structure of the ECS. Operational responsibility lies with the management of the entity, which ensures that knowledge artefacts are maintained, updated and made available to participants. Domain-specific working groups act as content owners for their respective knowledge areas. These groups are responsible for the substantive accuracy and relevance of knowledge artefacts, while the central INDICATE entity provides coordination, quality assurance and continuity across domains.

Domain-specific working groups and expert bodies contribute to the creation, review and updating of knowledge within their respective areas of expertise. Participants contribute knowledge through project activities and operational use, while adhering to agreed standards and validation processes. Overarching coordination roles ensure consistency, structure and alignment across the full knowledge base.

The sustained INDICATE entity formally determines which knowledge artefacts are considered official INDICATE guidance, while community contributions are supported but clearly distinguished. This governance approach ensures that knowledge remains authoritative, up to date and trusted, while allowing for community-driven contributions.

Knowledge lifecycle and reuse

Knowledge within INDICATE follows a defined lifecycle to support sustained reuse and continuous improvement. Knowledge is created through project activities, operational experience and use-case implementation, and is subsequently reviewed and validated by designated domain experts using pragmatic, light-weight validation processes. This lifecycle is explicitly iterative, with periodic reviews to ensure that knowledge assets and documentation remain accurate, relevant, and aligned with evolving practices and insights. INDICATE actively maintains and updates its knowledge base to ensure that all stakeholders have access to up-to-date information, enabling smooth collaboration, reducing ambiguity, and proactively addressing emerging questions. This approach balances quality assurance with operational efficiency and avoids overly rigid approval chains that could hinder timely updates.

Validated knowledge is published through agreed knowledge platforms and actively reused in governance processes, onboarding activities and daily operations. User feedback, particularly during onboarding and operational use, is an integral part of the validation cycle and supports the continuous improvement of knowledge assets. Core governance and operational knowledge remains accessible at ecosystem level after participant offboarding, while access to role- or data-specific materials is adjusted accordingly.

An identified area for further development concerns the proactive monitoring of regulatory and policy changes at European and national level. While the knowledge governance framework supports timely updates, additional mechanisms may be required over time to systematically detect and assess regulatory developments relevant to INDICATE.

Together, this governance and lifecycle approach ensures that INDICATE knowledge remains authoritative, up-to-date and resilient to organisational change, while preserving institutional memory and supporting long-term sustainability.

7.3. Conflict resolution processes

The INDICATE conflict resolution framework will operate across two distinct phases. The current phase of the project is governed by the Consortium Agreement between the founding partners of the project. The future entity phase, will become relevant and apply at the end of the project when INDICATE makes the transition of a permanent ECS. While these phases do not run in parallel, they are grounded in the same fundamental principles of transparency, subsidiarity, and proportionality, but can differ in scope, applicable components, and the involvement of governance bodies.

7.3.1 Phase 1– Project Phase (Scope of Consortium Agreement)

Overview

Within the current INDICATE consortium, conflicts may arise regarding participation in the action, decision-making and governance, access right and intellectual property, allocation of resources and division of tasks, and other matters that can affect a Member's rights or obligations under the Consortium Agreement. Because of potential for arising conflicts, the Consortium Agreement establishes a structured framework for addressing such conflicts through governance, decision-making, and enforcement mechanisms and practices. While the Consortium agreement does not encompass a standalone article regarding dispute resolution, it embeds a comprehensive framework surrounding conflict resolutions through its governance, veto, breach, responsibility, and liability provisions, which together enforce a transparent and structured approach to managing disputes within the consortium.

Governance and Decision Making

The INDICATE consortium has two governance bodies, the Executive Board and the General Assembly, which are responsible for resolving issues that are requiring of formal decision-

making, in accordance with the consortium requirements and a 2/3 majority voting rule, which has been defined in the Consortium Agreement. Decisions that materially affect a Member's work, costs, intellectual property, liabilities, access rights, sensitive information, or legitimate interests are all subject to veto rights. Such rights may be exercised within 15 calendar days following the distribution of the minutes of meeting, helping to ensure that Parties have a well-defined and transparent opportunity to raise objections.

Breach and Enforcement

Within the INDICATE consortium, cases that arise relating to potential breach of obligations, the Consortium Agreement outlines the formal escalation procedure, in which, a written notice of breach must be issued to the concerned Member from the Coordinator, followed by a 30 day period to provide a notice of remedy to the identified breach. This helps to ensure that procedural fairness by allowing the concerned Member sufficient time to respond and take corrective measures. However, in cases where breach is not remedied within this period, the Member may be declared a Defaulting Member, in which, enforcement measures are to be applied, including but not limited to potential termination of participation, as outlined in the Consortium Agreement.

Liability and Governing Law

Liability relating to conflicts and enforcement is governed under Belgian law, with financial liability capped at the Member's share, except in cases of fraud, gross negligence, or wilful misconduct. Belgian law applies because Erasmus MC, as coordinating institution, is based in the Netherlands but the Consortium Agreement designates Belgian law and the courts of Brussels as the governing jurisdiction, a common choice for multi-member EU research consortia given Belgium's neutral position and proximity to EU institutions.

Alignment with [Sitra Rulebook](#)

This approach is aligned with the principles and foundations set out in the Rulebook for a Fair Data Economy by Sitra, in which an emphasis is placed on fairness, transparency, and clearly defined governance structures as the primary mechanisms for addressing and ultimately managing conflicts within data spaces. As opposed to a reliance on a standalone dispute resolution procedure, the rulebook promotes the use of agreed rules, roles, and decision-making processes to prevent and address conflicts. In the context of the INDICATE project, this framework operationalises these principles through the provisions of the Consortium Agreement, which define decision-making, veto rights, breach procedures, and enforcement mechanisms.

7.3.2 Phase 2 – Future Entity Phase

The following framework describes conflict resolution practices for the future INDICATE entity, foreseen to be as a ECS. It is advisory and preparatory in nature and subject to future agreement by the consortium and future relevant authorities.

Purpose and Scope

The transition from the project-based consortium to a permanent ECS bring changes to the nature of relationships among participants and the governing body. The Consortium Agreement will govern during the duration of the project, meaning it is time-limited and only applicable to the founding partners. Once a future entity is established, a broader and more diverse set of participants, including but not limited to, data providers, data users, and service providers outside the original consortium, will interact within the INDICATE platform under their respective Accession Agreements.

The conflict resolution framework for the future entity is accounted therefore in a wider scope than the project-phase framework. It not only addresses disputes between participants but also disputes between a participant and the INDICATE entity itself. The purpose of this is to help ensure that all participants can engage in the data space with confidence that disagreements will be addressed in a structured, transparent, and proportionate manner, and that the integrity of the platform is maintained.

Types of Conflicts

The conflict resolution process for the future entity covers the following categories of dispute:

- **Participant-to-participant disputes:** disputes between participants regarding data access rights, study execution, or the terms of Data Sharing Agreements.
- **Certification and onboarding disputes:** disputes arising from the assessment of interoperability, data quality, or security standards as part of the certification and assurance process.
- **Offboarding and exclusion disputes:** disputes where a participant challenges a decision by the INDICATE entity to restrict, suspend, or terminate their participation.
- **Compliance and rulebook disputes:** disputes regarding adherence to the INDICATE rulebook, Accession Agreement obligations, or applicable operating procedures.
- **Service delivery disputes:** disputes involving service providers regarding the delivery, scope, or quality of services provided within or to the ecosystem.
- **Data use and intellectual property disputes:** disputes involving data use obligations, intellectual property arrangements, or licensing conditions applicable under the INDICATE framework.
- **Cross-jurisdictional disputes:** disputes with a cross-border dimension, where applicable national law may interact with the ECS governance framework.

Disputes that fall under the scope of data protection or ethical dimension are subject to referral to the Ethics and Data Protection Advisory Board for expert input before a formal determination is made.

Conflict Resolution Process

The conflict resolution process is structured around three tiers, following the subsidiary principle that has been applied throughout the governance model of INDICATE: conflicts are resolved at the lowest appropriate level and escalation only takes place when an informal resolution has failed.

Level	Body responsible	Types of conflict	Timeframe
Informal	Management board	Operational disputes, access issues, study execution disagreements, service delivery concerns	Up to 20 working days
Escalation	Executive board	Unresolved operational disputes, certification/onboarding decisions, findings of non-compliance, offboarding disputes	Up to 30 working days from initial referral
Final decision	General Assembly	Unresolved escalations, disputes involving the Executive Board, member exclusion, strategic governance conflicts	Next scheduled or special circumstance General Assembly meeting

Tier 1 – Informal Resolution

When conflict arises, the affected member or parties are expected to bring the matter promptly and in good faith at the operational level, where the Management Board serves as an initial contact point. The Management Board therefore is responsible for facilitating the communication between the parties, elaborating and clarifying rules and procedures applicable to the situation, and providing support for a mutually agreed upon resolution within a period of 20 working days. Informal resolution can include a parallel discussion among the parties, with communication being facilitated by the Management Board, or clarification of applicable rules and procedures. The main objective at this stage is to promptly resolve the matter without formal escalation, aiming to preserve working relationships and minimize procedural burden. Where the conflict involves a data protection or ethical dimension, the Management Board may seek advisory input from the Ethics and Data Protection Advisory Board before proposing a resolution path.

Tier 2 – Escalation to the Executive Board

If informal resolution does not result in an agreed upon outcome within the appropriate timeframe, either member can formally escalate the matter to the Executive Board. Such escalation must be initiated in writing, setting out the nature of the dispute, the steps that were taken at the informal level, and the outcome in which the member is seeking. The Executive Board will then review the provided documentation from the parties, and may request additional information or hear representations. A formal determination will be made within 30 working days of receiving the formal referral. This determination is formally binding on the parties, subject to the right of referral to the General Assembly. Furthermore, the Executive Board is also the primary decision-making body for disputes that arise directly from governance decisions of the INDICATE entity, such as but not limited to certification outcomes, onboarding assessments, or findings of non-compliance.

Tier 3 – Final Decision by the General Assembly

The General Assembly holds the ultimate decision-making authority within the governance structure of INDICATE. Where a dispute remains unresolved following the determination of the Executive Board, or where the dispute involves the Executive Board itself, either member may refer the matter to the General Assembly for a final decision. The General Assembly will address referred disputes at its next scheduled meeting or, where urgency requires, through a specially convened meeting.

Matters requiring a General Assembly decision include unresolved escalations, disputes involving potential exclusion of a member from the cooperative, and conflicts involving strategic governance decisions that exceed the scope of the Executive Board's operational mandate.

If a dispute cannot be resolved through the internal governance process, the parties may seek external resolution through mediation or, as a last resort, through the competent courts as defined in the ECS statutes. The applicable jurisdiction and governing law will be specified in the statutes of the future entity.

To ensure procedural fairness, the framework includes the possibility for escalation and review within the governance structure. Participants may seek reconsideration of decisions through referral to a higher governance body as described above. All conflict resolution processes operate within the bounds of applicable law. The detailed legal framework for dispute resolution, including governing law and jurisdiction, will be defined in the statutes and accession agreements of the future INDICATE entity, without being pre-defined in this deliverable.

Roles and governance bodies involved in conflict-resolution processes

- **Management Board:** serves as the first operational point of contact, facilitates informal resolution, documents the conflict and the steps taken, and refers unresolved matters to the Executive Board. It maintains the conflict register and ensures that all conflict-related communications are traceable.
- **Executive Board:** reviews formally escalated disputes, issues of binding determinations, and ensure that the conflict resolution process is applied consistently and in accordance with the INDICATE rulebook. It may seek advisory input from relevant advisory boards where specialist expertise is required.

- **General Assembly:** as the ultimate governance authority of the cooperative, issues final decisions on unresolved disputes and on matters with strategic governance implications. Its decisions are documented in meeting minutes and communicated to all relevant parties.
- **Ethics and Data Protection Advisory Board:** where a conflict has a data protection or ethical dimension, provides non-binding expert input to the Management Board or Executive Board before a formal determination is made. Its recommendations are documented and form part of the conflict record.
- **Participants:** are expected to engage in good faith at each stage of the process, provide relevant documentation in a timely manner, and comply with determinations issued by the competent governance body.

Documentation

Transparent and auditable documentation is a core requirement of the conflict-resolution process, consistent with the broader governance and transparency requirements of the INDICATE entity:

- All conflict notifications must be submitted in writing through the designated INDICATE communication channel. Verbal notifications must be followed up in writing within five working days.
- The Management Board maintains a conflict register recording the date of notification, the parties involved, the nature of the dispute, the steps taken at each tier, and the outcome reached.
- Determinations issued by the Executive Board and decisions issued by the General Assembly are recorded in formal meeting minutes and communicated in writing to all parties concerned.
- Where the Ethics and Data Protection Advisory Board has provided input, its recommendations are appended to the conflict record.
- Anonymised and aggregated conflict data may be reported to the General Assembly on an annual basis as part of governance performance reporting, to support continuous improvement of the framework.
- All conflict documentation is retained in accordance with the data retention policy of the future entity and applicable legal requirements.

Alignment with the Sitra Rulebook

The framework for conflict resolution practices for the future entity continues to operationalize the core principals outlined in the Sitra Rulebook for Fair Data Economy. The rulebook places an emphasis that conflicts within data spaces should be prevented and ultimately addressed through well-defined governance structures, agreed upon rules, and transparent decision-making processes as opposed to reactive or standalone dispute procedures. The aforementioned three-tier process helps to embed these principles in a direct manner: informal resolution reflects the subsidiarity principle, the clear escalation pathway provides a predictable and enforceable governance model, and the General Assembly's final authority helps to ensure democratic accountability within the cooperative structure.

8. Business model

The long-term sustainability of INDICATE depends on a business model that simultaneously supports its public-interest mission and ensures the financial operational sustainability of INDICATE after the project phase. INDICATE is designed as a pan European, federated infrastructure for ICU data, enabling secure, cross-border access to harmonised datasets while preserving data sovereignty at the level of each hospital. This strategic orientation places INDICATE among Europe's flagship data space initiatives, such as Catena13 and the Mobility Data Space14, which pioneer sustainable multi-actor architectures based on trusted data sharing and sector-wide governance models.

Experience from these initiatives shows that sustainable business models depend on actively orchestrating multi-sided network effects, particularly in early phases where both data supply and demand must be developed simultaneously. Public funding, flagship participants, and low-barrier onboarding are critical to overcome the initial cold-start problem and reduce participant hesitation. Strong governance and transparent rules are essential to build trust, while early investment in interoperability and standardisation enables scalability despite significant upfront costs. Over time, revenue models typically evolve from public funding towards hybrid models combining membership, service-based, and value-added revenues. In the healthcare context of INDICATE, these lessons are reinforced by stricter regulatory requirements, the need for public trust, and the dual objective of delivering both societal and economic value.

In line with the IDSA Position Paper on Data Space Business Models15, no single business model can sustain a data space alone. Instead, a data space typically requires a combination of interdependent models for data providers, data users, data space authority and service providers. Reflecting this, INDICATE adopts a hybrid business model that distinguishes between (1) a non-profit research-oriented stream and (2) a commercial value-added service stream. Within these two streams, differentiated value propositions and revenue logics exist for data providers, data users and service providers. This hybrid approach supports both academic collaboration and commercial use cases, enabling long-term financial sustainability while honoring INDICATE's public mandate under the EHDS. Both models are described in detail in supplementary file 13.1.

A key prerequisite for the successful implementation of the INDICATE business model is the establishment of a minimum viable network of participants. As with other data space initiatives, initial adoption is constrained by the interdependency between supply and demand.

To address this challenge, INDICATE adopts a structured network activation approach aimed at accelerating early participation and creating initial value within the ecosystem. This approach is based on three mutually reinforcing elements.

First, the engagement of founding members is critical to establish credibility and initial scale. Early participants are expected to contribute data, define initial use cases and validate

¹³ <https://catena-x.net/overview-use-case-cluster/>

¹⁴ <https://mobility-dataspace.eu/>

¹⁵ https://internationaldataspaces.org/wp-content/uploads/dlm_uploads/IDSA-Position-Paper-Data-Spaces-Business-Models.pdf

governance and operational processes. Tailored incentives, such as preferential access to services or reduced participation costs, may be applied to support early adoption.

Second, INDICATE prioritises the deployment of anchor use cases that demonstrate tangible value for participants. These use cases are aligned with the initial project portfolio and focus on both clinical and research applications, such as benchmarking, early detection models and federated analytics. By delivering measurable outcomes, these use cases act as catalysts for broader participation.

Third, the establishment of a minimum viable network ensures that sufficient data coverage, technical readiness and governance maturity are in place to enable meaningful data exchange. This includes a critical mass of participating hospitals, baseline interoperability and initial operational capabilities.

In parallel, the project phase provides an opportunity to validate the underlying business assumptions through pilot activities. These pilots serve to test value propositions, assess willingness to participate and contribute financially, and refine governance, pricing and service configurations.

By combining staged network activation with iterative validation, INDICATE aims to transition from a project-based collaboration into a self-sustaining European data space capable of delivering continuous value to its participants.

This chapter sets out the strategic direction for the INDICATE business model. The detailed operational design, financial deep dive and implementation of these mechanisms will be progressively elaborated and validated during the following years, in line with the maturation of the ecosystem and the implementation roadmap.

8.1. Strategic foundation

INDICATE operates within a broader European health data ecosystem that includes, among others, initiatives such as EHDEN, the OHDSI network, national Health Data Access Bodies (HDABs), and the emerging HealthData@EU infrastructure. These initiatives address partially overlapping stakeholder needs across data holders and data users. Within this landscape, INDICATE is positioned as a complementary, domain-specific data space with a distinct focus on intensive care.

INDICATE differentiates itself along three key dimensions:

- **Domain specialisation:** Unlike general-purpose health data networks, INDICATE is specifically focused on intensive care data. This enables tailored data models (e.g. OMOP and FHIR), ICU-specific use cases, and community-driven AI applications directly aligned with critical care practice. This specialisation provides targeted value for both hospitals and researchers operating in the ICU domain.
- **Sustainable and collaborative governance:** INDICATE is designed to transition into a permanent, member-driven entity, providing participants with a formal role in governance and strategic direction. In contrast, initiatives such as EHDEN have primarily focused on technical standardisation within time-limited project structures, while OHDSI operates as an

open scientific community without a formal governance or service delivery framework. INDICATE's cooperative governance model combines structured decision-making with operational service provision.

- **Alignment with the EHDS and HDAB ecosystem:** INDICATE is designed to complement, rather than replace, regulatory structures under the EHDS. Participating hospitals remain Health Data Holders, while INDICATE supports the harmonisation, interoperability, and preparation of ICU data for secondary use. In doing so, INDICATE facilitates more efficient interaction with national HDABs and future infrastructures such as HealthData@EU, adding a domain-specific operational layer to the broader ecosystem.

Together, these characteristics position INDICATE as a specialised, implementation-oriented data space that enables participants to access and generate value from ICU data in a structured, scalable, and EHDS-aligned manner. For both data holders and data users, participation in INDICATE offers a combination of domain-specific services, shared infrastructure, and governance participation that is not provided by existing horizontal initiatives alone.

This positioning directly informs the design of the INDICATE business model. In line with IDSA principles, the business model is shaped by four core characteristics:

- **Collaborative and multi-sided:** Value increases as more data providers and data users participate, creating positive network effects across the ecosystem.
- **Strong compliance and trust framework:** INDICATE operates through enforceable governance mechanisms, certification procedures, and alignment with EHDS, GDPR, and the AI Act.
- **Tiered services and value-added offerings:** The model differentiates between foundational research-oriented access and advanced, value-added services.
- **Evolution over time:** The model transitions from initial reliance on public funding and Member State support towards a more self-sustaining structure as services mature and adoption increases.

Structural and recurring revenue streams are essential to support long-term sustainability. One-off project funding or purely transaction-based fees are insufficient to cover the continuous costs of platform operations, governance, compliance, and service delivery. Mechanisms such as membership contributions, subscriptions, and service-based fees provide predictable revenue streams that enable long-term planning, operational stability, and risk management.

At the same time, these mechanisms reinforce participant commitment by linking financial contributions to sustained access to services, shared infrastructure, and governance participation. In this way, the business model aligns economic incentives with the long-term development and use of the INDICATE ecosystem.

8.2. Value proposition and customer segments

The value proposition of INDICATE is shaped by the need to serve multiple customer segments within a single federated ecosystem, while maintaining a sustainable balance between public value creation and financial viability. Hospitals and other health data providers form the core of this ecosystem by contributing ICU data, models and clinical expertise to the INDICATE infrastructure, which in turn enables different forms of value creation for distinct user groups.

As illustrated in the figure below, INDICATE is designed to support multiple value pathways that are enabled by the same pan European federated infrastructure. Data, insights and best practices circulate between hospitals, researchers and industry actors, allowing INDICATE to simultaneously support scientific collaboration, health system learning and innovation driven use cases, thereby contributing to improved health outcomes. This structure underpins the hybrid business model described below and provides the basis for differentiating value propositions and customer segments in the subsequent sections.

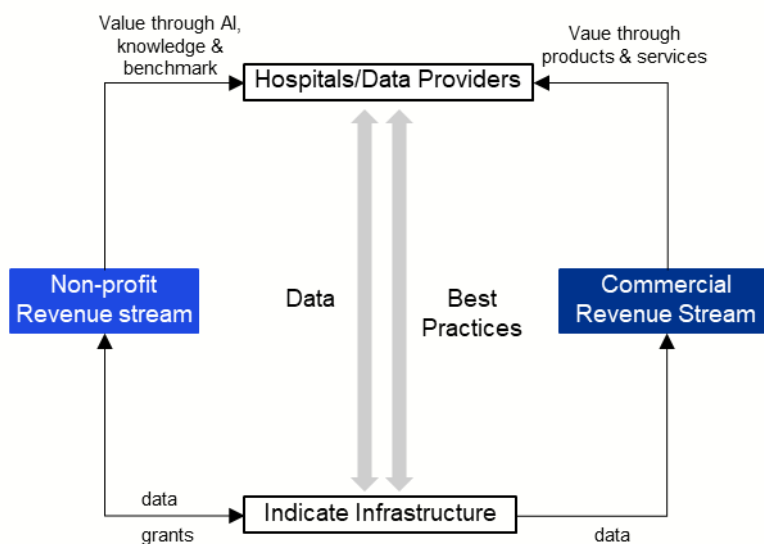


Figure: Visual representation of the hybrid business model for the INDICATE ecosystem

8.2.1 Non-profit model

The non-profit model (Supplementary file 13.1) focuses on enabling scientific research, clinical improvement and public value creation. It supports a broad range of stakeholders, including healthcare providers, researchers and public authorities.

The initial value proposition includes the following and is expected to expand over time as the INDICATE ecosystem matures:

- high-quality, harmonised ICU datasets mapped to OMOP/FHIR and clinical vocabularies;
- privacy-preserving analytics and federated learning tools;

- reduced time-to-access through standardised governance gateways;
- benchmarking dashboards for quality improvement;
- reusable infrastructure aligned with EHDS requirements.

While essential for achieving the societal objectives of INDICATE, the assumption is that this model alone does not ensure long-term financial sustainability, as it requires a careful balance between proportional and affordable access for non-commercial stakeholders and the structural coverage of operational, maintenance and innovation cost

8.2.2 Commercial model

The commercial model (Supplementary file 13.1) targets industry actors that require scalable, high-quality, regulatory-aligned environments for product development, validation and deployment. Custer segments include parties such as; Medical Technology and AI developers, Pharmaceutical companies, CROs and start-ups.

Its value proposition includes the following and is expected to expand over time as the INDICATE ecosystem matures:

- validation and testing of AI and digital health solutions;
- federated model training and deployment;
- clinical trial recruitment support via AI supported patient screening;
- commercial API access and technical integration services;
- tailored onboarding and study support.

These users recognise direct economic value, enabling value-based pricing aligned with IDSA recommendations. In addition, commercial parties may assume a dual role within the INDICATE ecosystem, acting both as data provider and data user.

8.3. Revenue streams

A core design principle (see Chapter 1) of the INDICATE business model is to maintain a balanced and sustainable ecosystem between data providers and data users. Long-term growth depends on attracting and retaining participants on both sides, while ensuring that each group experiences clear and tangible value. To achieve this, INDICATE applies differentiated pricing, incentives for data contribution, and targeted support to lower barriers to participation.

INDICATE adopts a hybrid sustainability model that combines several complementary revenue mechanisms, with the explicit aim of ensuring long-term financial stability through durable revenue streams. This includes fostering long-term partnerships, memberships and recurring service uptake to create predictable and stable income flows.

While the EHDS introduces the possibility of regulatory access fees via HDABs, INDICATE is not envisaged to act as an HDAB in the baseline operating model. HDAB designation is expected to remain a Member State competence. Consequently, HDAB access fees are not assumed as a core revenue stream in the baseline business model. Potential future revenue linked to delegated HDAB or SPE-related functions is considered a longer-term option, subject to regulatory designation.

At this stage, the revenue model remains subject to further refinement; the mechanisms below therefore reflect the current baseline assumptions. The following revenue mechanisms are not exhaustive and may be further specified and adapted in the next development phase:

- **tiered membership** fees based on functionality and data usage:
 - Gold: access to full data platform features, high volume of data usage;
 - Silver: access to broad set of core platform features, moderate volume of data usage;
 - Bronze: access to limited data platform features, low volume of data usage;
- **off the shelf study packages** (bundled with a minimum bronze membership);
- **pay-per-use** mechanisms;
- **(structural) public funding** (e.g., EU and Member State contributions).

Examples of possible discount mechanism:

- **More data, lower fees:** reduced membership fees for hospitals that contribute high quality, complete datasets and/or act as both data providers and data users.
- **Multi-year participation:** discounted membership or subscription rates in exchange for multi-year commitments, supporting predictable demand and long-term financial stability.
- **Volume based usage discounts:** lower unit prices linked to committed or predictable consumption of infrastructure intensive- services (e.g. compute, storage, analytics).
- **Bundled access:** preferential pricing for bundled access to core INDICATE services combined with selected value added- capabilities.
- **Start-up incentives:** reduced rates to encourage early innovation and lower access barriers for SMEs and emerging companies.

By leveraging economies of scale and predictable demand, particularly for infrastructure-heavy components, INDICATE can reduce unit costs while offering participants financial advantages for stable engagement. This approach supports both affordability for non-commercial stakeholders and financial robustness for the data space as a whole, without compromising its public interest mission.

Potential future revenue streams:

- marketplace services for third-party tools, models or analytics;
- consultancy and expert services;
- leasing of the INDICATE platform.

Together, these mechanisms reinforce positive cross-side network effects, reward active contribution and support effective scaling of the pan-European INDICATE infrastructure.

8.4. Cost structure and sustainability

The cost structure across both models includes:

Platform Operations (run)	Platform Development & Evolutions (change)
<ul style="list-style-type: none"> • Cloud compute, storage & networking • Secure computing environments • Federated services & trust layer • DevOps & platform engineering (salaries) • Monitoring, incident & performance management 	<ul style="list-style-type: none"> • Future development of the federated ICU data space • New use-cases and portfolio tiers • Metadata, standards and interoperability • Subcontractors (development/innovation) • Feature development
Ecosystem & Service Operations	Governance, Compliance & Oversight
<ul style="list-style-type: none"> • Onboarding support (hospitals, data users) • Data quality checks & support • Community & stakeholder management • Training & knowledge management • Study support (light vs commercial in intensity) 	<ul style="list-style-type: none"> • Policy development (GDPR, AI Act, EHDS) • Governance bodies & meetings • Compliance oversight & audits • Ethics boards & certification alignment

As participation grows, economies of scale reduce per-user costs. The objective is for INDICATE to operate as a self-sustaining, pan European ICU data infrastructure beyond the project phase, while the coming period will be used to further detail the revenue mechanisms and cost structures required to support this transition.

INDICATE's business model combines public-interest accessibility with commercial viability, supporting long-term sustainability while preserving its core mission under the EHDS. By adopting a hybrid structure, embedding incentives for data contribution and aligning with proven design patterns from initiatives like Catena-X, INDICATE positions itself as a durable, scalable and trustworthy pan-European infrastructure for ICU data. This ensures that INDICATE not only supports immediate research and innovation needs, but becomes an enduring pillar of Europe's health data ecosystem.

9. Implementation roadmap

INDICATE aims to continue beyond the European Commission-funded project phase as a sustainable organisation. The strategic ambition is to evolve into a fully autonomous and financially viable operating entity capable of ensuring long-term continuity through structural revenue streams, appropriate governance arrangements, and sustained participant engagement. At the same time, it is recognised that the organisational, financial, and technical conditions at the end of the project period cannot yet be predicted with full certainty, as future developments will depend on evolving maturity levels, stakeholder commitment, and broader contextual dependencies.

In this regard, it is also relevant to consider the European Commission's request, made after the official start of the INDICATE project, for INDICATE to explore potential collaboration with the ICUdata4EU consortium, including the possible establishment of a joint or aligned entity structure. Although initial contact between the two consortia was already established during the first project year, the current discussions remain exploratory in nature. At present, the primary focus is on assessing and aligning the different technical approaches and interoperability options required to enable potential technical integration or collaboration between the two initiatives.

The current intention is to first continue discussions aimed at reaching a common understanding and shared direction regarding the technical alignment between both initiatives before addressing broader strategic, organisational, governance, or legal aspects of a potential collaboration or aligned entity structure. Furthermore, several key aspects of the ICUdata4EU initiative, including its governance model, sustainability approach, legal entity considerations, division of responsibilities, and overall organisational maturity, have not yet been sufficiently clarified to allow for a comprehensive assessment of the feasibility, scope, and long-term implications of such a collaboration.

As a result, it is currently not yet possible to reliably determine the extent to which a future collaboration, structural partnership, or potential merger scenario could affect INDICATE's preferred implementation pathway, legal entity creation strategy, governance structure, but also deliverables, resource allocation, and associated timelines. Depending on the outcome and maturity of the ongoing discussions, certain assumptions underlying the current ECS, governance timelines, deliverable planning, and post-project implementation scenarios may therefore require reassessment and further adaptation.

More specifically, revisiting the ECS may become necessary if:

- a joint governance or operational structure between the initiatives becomes desirable or required;
- shared infrastructure ownership or federated service management models are proposed;
- sustainability models, funding streams, or participant structures become interdependent;
- or if the European Commission provides further strategic direction regarding consolidation or alignment between both initiatives.

At present, however, the discussions are not yet at a stage where concrete conclusions regarding entity form, merger feasibility, or long-term governance integration can be drawn. The current post-project scenarios therefore remain valid as planning instruments, while retaining sufficient flexibility to accommodate future collaboration outcomes should these materialise in later project phases.

To remain adaptive and future-oriented, INDICATE therefore adopts a scenario-based approach to implementation planning. Three post-consortium scenarios are elaborated, each representing a distinct development pathway and maturity level across four key dimensions: governance readiness, technical maturity, financial viability, and participant commitment. While all scenarios allow for continuation beyond the project phase, Scenario Route 1 – a new operating entity – represents the preferred and targeted end state, with Scenarios 2 and 3 serving as transitional alternatives should full maturity not yet be achievable by 2028.

To support informed decision-making, further development of explicit scenario triggers and selection criteria remains required. While the scenarios provide a structured overview of potential development pathways, the General Assembly will require more clearly defined thresholds and decision criteria to determine which route is most appropriate at a given point in time. This will be further elaborated in the next development phase.

	Scenario Route 1 New operating entity	Scenario Route 2 "Empty shell" entity processes yet to be defined	Scenario Route 3 Temporary extension of the consortium agreement
Entity	<ul style="list-style-type: none"> INDICATE is a legal entity 	<ul style="list-style-type: none"> INDICATE is a legal entity 	<ul style="list-style-type: none"> Legal entity not yet established
Governance readiness	<ul style="list-style-type: none"> Full operating governance in place Clear roles, mandates and decision rights 	<ul style="list-style-type: none"> Minimal governance in place: continuation of project governance 	<ul style="list-style-type: none"> Extension of the consortium agreement
Technical maturity	<ul style="list-style-type: none"> Stable, secure and scalable platform with active use cases Structural support for federated analytics, ML and model deployment Knowledge platform Processes in place [HR, billing] 	<ul style="list-style-type: none"> Operational platform, still maturing Pilot use cases, not fully operating Clear roadmap for stability and scaling 	<ul style="list-style-type: none"> Initial infrastructure available Use-cases developed but not operating
Financial viability	<ul style="list-style-type: none"> Operating business models in place Structural revenues / membership fees Financially sustainable beyond project funding 	<ul style="list-style-type: none"> Financing by participants (<i>not through operating business models, but via an alternative funding mechanism</i>) Business models defined but not yet operational 	<ul style="list-style-type: none"> Financing by participants (<i>not through operating business models, but via an alternative funding mechanism</i>) Business models defined but not yet operational
Participant commitment	<ul style="list-style-type: none"> Acceptance of the legal structure by participating parties Contractual and financial participation through a membership structure 	<ul style="list-style-type: none"> Acceptance of the legal structure and commitment to support the legal entity and transition Commitment to provide capacity and resources Willingness to professionalize over time 	<ul style="list-style-type: none"> Project- and use-case driven participation Commitment mainly in-kind and short-term

Figure: Post-consortium scenarios towards a sustainable entity

Scenario Route 1: New Operating Entity (Preferred Scenario)

In Scenario Route 1 (Supplementary file 13.2), INDICATE operates as a fully independent and autonomous legal entity with complete organisational, technical, and financial maturity. However, as outlined in Chapter 7.7, even in this scenario a translational period is expected in practice, during which governance arrangements, operational processes, and supporting procedures continue to mature before reaching full institutional stability.

Governance readiness is characterised by a clearly defined and enforced governance structure, with a formal separation between governance, management, and operations. Roles, mandates, accountability mechanisms, and decision rights are explicitly defined and supported by legal frameworks and operating governance models.

From a technical maturity perspective, the INDICATE platform is fully operational, stable, secure, and scalable, with multiple active use cases. Standardised operational processes, such as onboarding and offboarding, are in place, as well as clear ownership and responsibility for technical components. The infrastructure structurally supports federated analytics, federated machine learning, and model deployment, complemented by a knowledge platform and fully established supporting processes such as human resources and billing.

In terms of financial viability, the entity is financed through operating business models that generate sufficient revenue to cover operational costs and ensure long-term sustainability beyond project funding. Participants financially contribute via structured mechanisms, such as through membership fees.

Participant commitment in this scenario is long-term and formalised. Participating organisations accept INDICATE as an autonomous entity and commit contractually through formal participation agreements. Commitment includes both structural financial contributions and organisational engagement, providing a stable foundation for continued growth and professionalization.

Scenario Route 2: Legal entity with processes yet to be defined (“empty shell”)

In Scenario Route 2 (Supplementary file 13.2), INDICATE is established as a legal entity, but organisational, technical, and financial processes are still maturing. Governance readiness is limited, largely extending the consortium governance structures. While the legal entity exists, governance arrangements remain minimal, with initial steps taken towards role clarity, formal responsibility, and basic steering and escalation mechanisms.

Regarding technical maturity, the platform is operational but not yet fully mature. Pilot use cases are available, and functionality exists, but dependencies on participant infrastructure and technical expertise remain. Standardised support, maintenance, and operational processes are only partially organised, requiring further development to reach full scalability and robustness.

Financial viability in this scenario relies on temporary participant-based funding, as operating business models are not yet active. While these business models are defined, financial continuity is ensured through transparent cost structures and short- to medium-term financial planning, enabling continued operation and gradual progression towards full financial sustainability.

Participant commitment focuses on supporting the legal entity and enabling the transition towards more formal operations. Participants are willing to contribute resources, including human capacity and expertise, and to invest in organisational growth. However, long-term contractual commitments and structural financial arrangements are not yet fully established.

Scenario Route 3: Temporary extension of the consortium agreement

Scenario Route 3 (Supplementary file 13.2) describes a short-term continuation of INDICATE through an extension of the existing consortium agreement. It reflects the lowest level of post-project maturity and is not intended to provide a sustainable long-term operating model.

Governance readiness is limited to coordination and consensus-based decision-making within the consortium, with no clear separation between ownership, strategic steering, and operational responsibility. Governance therefore primarily facilitates collaboration rather than formal accountability.

From a technical maturity perspective, only initial infrastructure components are available. While core technical elements may exist, platform usage remains limited in scale and heavily dependent on individual participant environments. Use cases are developed but not yet operational, and technical integration across participants is still at an early stage.

As a result, financial viability relies on participant contributions rather than operating business models. Although potential business models are defined, they are not implemented.

Consequently, participant commitment is primarily use-case driven. While there is a shared interest in collaboration and continuation, participation depends on immediate interests and available capacity. Commitments are mainly in-kind and lack the formal, long-term structure required for sustainable operation as an independent entity.

10. Supplements/references

10.1. Business models

Key Partners	Key Activities	Value Proposition	Customer Relationships	Customer Segments
<ul style="list-style-type: none"> Hospitals & ICU Ecosystem Partners (Federated ICU Nodes/Health data holders and ICU Clinical Networks) Health data access bodies MedTech/ AI developers Academic & research institutes Technology providers Certification & compliance bodies EU governance bodies (DSSC, European Commission) Patient and professional associations (e.g. nursing federations) Patient 	<ul style="list-style-type: none"> Federated ICU Data Space (maintenance/operations & innovation) Manage data standards Manage governance, compliance and ethics guidelines Manage privacy-preserving analytics Maintain & update portfolio tiers Onboarding Foundational Use Cases Open Data Assets Monitoring quality of data Stakeholder engagement Knowledge management & training 	<ul style="list-style-type: none"> High-quality, harmonised ICU datasets Privacy-preserving analytics & federated learning tools Benchmarking tables and cross-border quality dashboards Reduced time-to-access (<30 day target) Reduced legal complexity Reusable European infrastructure 	<p>Self-service:</p> <ul style="list-style-type: none"> Federated analytics platform Documentation and knowledge base <p>Assisted services:</p> <ul style="list-style-type: none"> Onboarding support Interoperability support Study support <p>Ecosystem relationships:</p> <ul style="list-style-type: none"> Research collaboration Working groups Governance participation 	<p>Primary Segments*</p> <ul style="list-style-type: none"> Health data holders/ ICU nodes Health Data Access Bodies & Member State Authorities Public Interest Researchers Clinicians (Primary use) Policy makers
	Key Resources		Channels	
	<ul style="list-style-type: none"> Technical: Federated data infrastructure, Interoperability standards Organisational: Governance bodies, INDICATE entity Data: ICU datasets from participating hospitals Knowledge: Documentation, training, best practices 		<ul style="list-style-type: none"> Federated data Infrastructure Consortium communication network Knowledge platform/ academy ICU clinical networks Onboarding process EU-level dissemination and cross-border platforms 	<p>*Core users and beneficiaries of the data space who are essential for INDICATE's mission and long-term legitimacy</p>
Cost Structures		Revenue Streams		
<p>Platform Operations (Run)</p> <ul style="list-style-type: none"> Cloud compute, storage & networking Secure computing environments Federated services & trust layer DevOps & platform engineering (salaries) Monitoring incident & performance management <p>Platform Development & Evolution (Change)</p> <ul style="list-style-type: none"> Future development of the federated ICU data space Nieuw use-cases and portfolio tiers Metadata, standards and interoperability Subcontractors (development/innovation) Feature development <p>Ecosystem & Service Operations</p> <ul style="list-style-type: none"> Onboarding support Data quality checks & support Community & stakeholder management Training & knowledge management Study support (light vs commercial in intensity) <p>Governance, Compliance & Oversight</p> <ul style="list-style-type: none"> Policy development Governance bodies & meetings Compliance oversight & audits Ethics boards & certification alignment 		<p>Non-profit revenue stream</p> <ul style="list-style-type: none"> Cost-recovery fees for dataset access Gold/silver/bronze Membership fees Node onboarding support Off-the-shelf study packages EU & Member State funding Public Interest research support Publishing research papers <p>Additional possibilities</p> <ul style="list-style-type: none"> Training services Interoperability support Benchmarking services 		

Figure: non-profit business model canvas

Data providers	Possible content
Gold membership	Low tier - non-profit data participants who provide [X] data for the platform
Silver membership	Middel tier - non-profit data participants who provide [X] data for the platform
Brons membership	High tier - non-profit data participants who provide [X] data for the platform
Data users	
Gold membership	High tier – Access to full data platform features (later to be determined) / high volume of data usage (later to be determined) / off-the-shelf study packages
Silver membership	Middel tier – Access to [x] data platform features / [x] volume of data usage / off-the-shelf study packages
Brons membership	Low tier – Access to limited data platform features / [x] volume of data usage / off-the-shelf study packages (minimum brons membership fee)
Pay-per-use	Discount depending on the volume of data usage and duration of data usage (e.g. more data and longer data usage the larger the discount)
EU & Member State Funding	(Structural) funding (monthly, yearly) or a one time grant
Future revenue possibilities	
Consultancy	INDICATE professionals get hired by organisations who have a specific need. For example: data onboarding support (help with mapping ICU data to FHIR and quality checks), governance & compliance support (guidance on GDPR, EHDS alignment), study setup & custom analyses (tailoring a study beyond standard packages, e.g. additional variables or cohorts)
Leasing INDICATE platform	In the future the INDICATE platform could be either leased or sold to other pan-European data initiatives comparable to INDICATE
Reuse of INDICATE infrastructure	INDICATE can be offered as a shared platform where external data initiatives or organisations use the existing infrastructure as separated environments, without needing to build or operate their own platform. Costs are shared across users reducing operational costs.

Figure: non-profit revenue streams

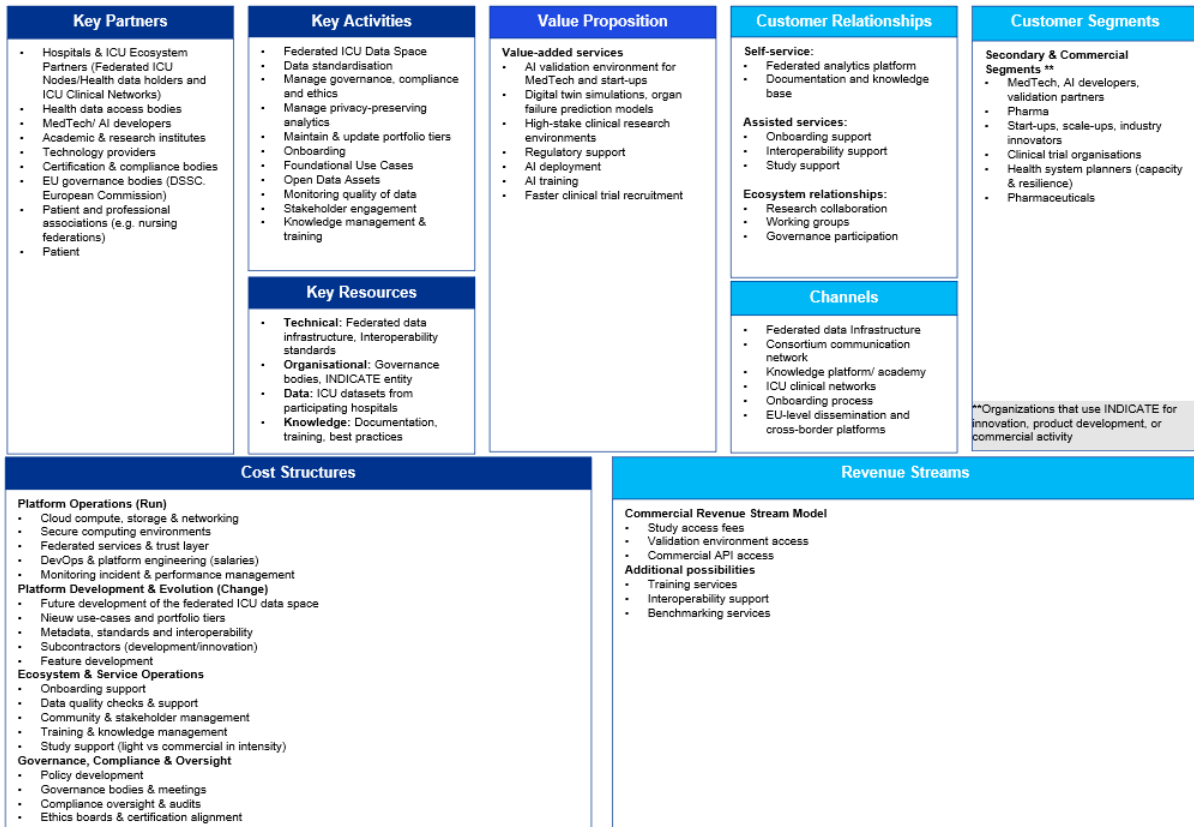


Figure: commercial business model canvas

Data providers	Possible content
Gold membership	Low tier - non-profit data participants who provide [X] data for the platform
Silver membership	Middel tier - non-profit data participants who provide [X] data for the platform
Brons membership	High tier - non-profit data participants who provide [X] data for the platform
Data users	
Gold membership	High tier – Access to full data platform features (later to be determined) / high volume of data usage (later to be determined) / off-the-shelf study packages
Silver membership	Middel tier – Access to [x] data platform features / [x] volume of data usage / off-the-shelf study packages
Brons membership	Low tier – Access to limited data platform features / [x] volume of data usage/ off-the-shelf study packages (minimum brons membership fee)
Pay-per-use	Discount depending on the volume of data usage and duration of data usage (e.g. more data and longer data usage the larger the discount)
Future revenue possibilities	
Consultancy	INDICATE professionals get hired by organisations who have a specific need. For example: study design advice, hospital onboarding coordination for specific studies conducted by commercial organisations, compliance support.
Leasing INDICATE platform	In the future the INDICATE platform could be leased or sold to other pan-European data initiatives comparable to INDICATE
Reuse of INDICATE infrastructure	INDICATE can be offered as a shared platform where external data initiatives or organisations use the existing infrastructure as separated environments, without needing to build or operate their own platform. Costs are shared across users reducing operational costs.
Commercial API access	Companies pay for technical access to INDICATE services via APIs enabling integration into their own products

Figure: commercial model revenue streams

10.2. Implementation Roadmap

Governance Readiness	Technical maturity	Financial viability	Participant commitment
<ul style="list-style-type: none"> INDICATE functions as a fully independent operating entity Governance structure is defined, accepted, enforced There is a clear distinction between governance, management and operations Defined roles, mandates and accountability Legal playbooks and decision rights There is an operating governance model 	<ul style="list-style-type: none"> Fully operational infrastructure Standardised operational processes [On- and offboarding] Defined ownership and technical responsibilities Platform is stable, secure and scalable with active use cases Supports structural services such as federated analytics, federated machine learning, model deployment Knowledge platform in place Processes in place [HR, billing] 	<ul style="list-style-type: none"> Financing through operating business models Ability to cover operational costs and plan long-term sustainability 	<ul style="list-style-type: none"> Participant commitment <ul style="list-style-type: none"> Commitment is long term and formalised Participants accept INDICATE as an autonomous entity Formal participation agreement Structural financial and organisational commitment

Figure: Scenario Route 1: New Operating entity

Governance Readiness	Technical maturity	Financial viability	Participant commitment
<ul style="list-style-type: none"> Legal entity is established Governance is minimal – largely an extension of project/ consortium governance First steps towards role clarity and formal responsibility Steering and escalation mechanisms are organised 	<ul style="list-style-type: none"> Platform is operational but maturing Pilot use cases Some dependency remains on: <ul style="list-style-type: none"> Participant infrastructure Participant technical expertise Standardised support and maintenance is partially organised 	<ul style="list-style-type: none"> Financing by participants (<i>not through operating business models, but via an alternative funding mechanism</i>) Business models defined but not yet operational Transitional funding mechanisms, cost visibility and financial planning for the short to medium term is organised 	<ul style="list-style-type: none"> Participants support the legal entity and the transition towards more formal operations Commitment includes resources (people, capacity) and willingness to invest in maturity growth There is no long-term contractual commitments fully in place

Figure: Scenario Route 2: Legal entity with processes yet to be defined (“empty shell”)

Governance Readiness	Technical maturity	Financial viability	Participant commitment
<ul style="list-style-type: none"> Coordination and decision-making via consortium agreement Decisions largely based on consensus There is no separation between ownership, strategic steering, operational responsibility Governance is focused on collaboration, not accountability 	<ul style="list-style-type: none"> Core technical components may exist Platform usage is limited in scale and dependent on individual participant environments Initial infrastructure is in place Use cases developed but not operating 	<ul style="list-style-type: none"> Financing by participants (<i>not through operating business models, but via an alternative funding mechanism</i>) Business models defined but not yet operational 	<ul style="list-style-type: none"> Participants are willing to collaborate There is a shared interest in continuation Commitment is use case specific Participation depends on immediate interests and available capacity

Figure: Scenario Route 3: Temporary extension of the consortium agreement