INDICATE
CONNECTING DATA IN EUROPEAN HEALTHCARE

Project Management Handbook

WP1 Project Management and Coordination

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Part A: Project Management

1. Introduction

1.1. Purpose of this document

This Project Handbook outlines the organization and internal procedures of the INDICATE project, aiming to assist the consortium members with their daily project activities. It standardizes various aspects of the project, such as reports and deliverables, through the use of agreed procedures and templates where applicable. This ensures effective communication and helps achieve timely deliverables within budget. The Handbook will be updated as needed throughout the project to reflect the consortium's experiences and evolving needs.

1.2. Precedence

The fundamental principles for project execution are established in the EU Grant Agreement (GA), the Description of the Action (DoA), and the Consortium Agreement (CA). This Project Handbook does not supersede these agreements or the EU guidelines for project implementation and documentation. In case of any inconsistencies, the following order of precedence should be observed:

A. EU Grant Agreement, including the Description of the Action (EU GA Annex 1);

B. Consortium Agreement (CA);

C. Project Handbook (this document).

2. Legal Aspects

2.1. Grant Agreement

The Grant Agreement provides the legal framework for the project's implementation and includes the following components:

- Preamble
- Terms and Conditions (including Data Sheet);
- Annex 1 Description of the action (DoA);
- Annex 2 Estimated budget for the action;
- Annex 2a Additional information on unit costs and contributions (if applicable);
- Annex 3 Accession Forms;
- Annex 3a Declaration on joint and several liability of affiliated entities (if applicable);
- Annex 4 Model for the financial statements;
- Annex 5 Specific rules (if applicable)

Although the core contract is signed between the EU and the Coordinator of the project, all partners have become individual contract partners with the commission by signing the Accession Forms.

The Grant Agreement must be kept by all partners and should be provided to the auditor in case of an audit. It is downloadable in the participant portal; in document library of the INDICATE project.

2.2. Consortium Agreement

While the Grant Agreement is signed between the EU and the project partners, the Consortium Agreement is established among the partners themselves. It provides more detailed arrangements on various aspects of the project, including but not limited to: financial matters, payments, management, decision-making, conflict resolution, intellectual property rights, and liability.

2.3. Amendments

The main aim of the beneficiaries is to carry out the planned tasks and activities within the time scheduled and the foreseen resources as described in the Grant Agreement.

Any deviation (e.g. delays, change in the status of a beneficiary, etc.) must be communicated immediately to the Coordinator. The Coordinator shall resolve queries and advice to the beneficiaries. If further action is needed, the Coordinator will contact the EU Project Officer (PO) to request clarifications and procedures to be followed.

Significant deviations from the work plan described in the DoA may require an amendment. These deviations include:

- Change of partner(s);
- Change of legal entity;
- Changes in the Budget *(EU GA: Annex 2);*
- Changes in the DoA *(EU GA: Annex 1).*

Before requesting an amendment, the beneficiary/ies concerned must inform the Coordinator in writing. If an amendment is deemed necessary, the Coordinator will submit the request following a decision by the General Assembly, which requires a two-thirds (2/3) majority of the votes cast. For modifications related to the accession of a new party or any adjustment to a Party's Share, the Coordinator may make this decision in consultation with the Scientific Coordinator. Once confirmed, the Coordinator will circulate a written notification to the consortium, detailing the reasons for the changes and outlining any direct impacts on budget, activities, and the work plan.

If the amendment need is confirmed, the Coordinator will follow the rules detailed in the annotated Grant Agreement to comply with the requirements and procedures indicated by the EC, by requesting the amendment process to the EU PO on behalf of the consortium. After approval by the EC, the Coordinator shall distribute the revised Grant Agreement to the partners, replacing previous versions.

Budget changes that do not impact the content of the Description of the Action can be managed within the consortium. Such decisions should be made by the General Assembly, and the Project Officer should be informed.

Any project partner may request amendments.

3. Governance Structure

The INDICATE Governance Structure consists of various roles and bodies that assist the project Coordinator in carrying out management activities. This ensures the efficient execution of tasks, optimal use of resources, adherence to deadlines, and compliance with EC regulations.

3.1. Management Bodies

3.1.3. General Assembly

General Assembly is the consortium's ultimate decision-making body, who operates as agreed in CA 6.1-6.5.

Members

The General Assembly shall consist of one Member of each Party. The Member shall be authorised to deliberate, negotiate, and decide on all matters and to commit their organisation to the decisions made by the General Assembly.

Meetings

The General Assembly will meet at least once a year, or more frequently at any time upon written request of the Executive Board or 1/3 of the General Assembly Members. The Coordinator shall chair all meetings of the General Assembly. Day-to-day management of INDICATE is delegated by the General Assembly to the Executive Board.

Decisions

The General Assembly may act on its own initiative to develop proposals and make decisions. Further details are set out in paragraph 6.3.1.2 of the CA. Any decision of the General Assembly requires a two-thirds (2/3) majority of the votes cast.

3.1.4. Executive Board

The Executive Board (EB) ensures efficient daily management of INDICATE, timely delivery of the project's deliverables (see Table 1) and realisation of the overall project objectives and milestones (Table 2). It will also ensure the operation of the overall communication lines inside and outside the Project's remit.

Members

The EB consists of the project Coordinator, the project Scientific Coordinator, Technical Lead, Project Manager, and the Work Package Leaders (WPLs). The coordinating partner (Erasmus MC) will appoint the Project Manager to handle all consortium management issues professionally. The Executive Board is responsible for quality assurance of all deliverables from the project, and will implement all required procedures.

Meetings

The Executive Board (EB) will meet monthly during the first year of INDICATE, and thereafter once every one to two months, as deemed appropriate, or at any time upon the written request of any Executive Board Member. All EB meetings shall be chaired by the Scientific Coordinator.

Tasks

The tasks assigned to the Executive Board are described in Section 6.3.2.3.6 of the Consortium Agreement. They may all perform these tasks, with all actions carried out in accordance with the terms set by the Grant Agreement.

3.1.5. Coordinator (COO)

The project **Coordinator** (Dr. Michel van Genderen, Erasmus MC, the coordinating partner) will ensure that the project plan is executed in fulfilment of the contract with the European Commission. The Coordinator will coordinate all activities, monitor progress, coordinate reporting to the European Commission, and act as a link between the INDICATE project, the External Expert Advisory Board, the Ethical Advisory Board and other related projects, initiatives and commercial bodies. All decisions that are made by the Executive Board will be executed by the project Coordinator, who can in turn delegate this to the appropriate project manager or work package leader.

3.1.6. Scientific Coordinator (SCO)

The project **Scientific Coordinator** (Prof.dr. Christian Jung, UDUS) acts as the intermediary between the Parties and between the bodies and the consortium. The Scientific Coordinator shall, in addition to its responsibilities as a Party, perform the tasks assigned to it as described in 6.5.2 of the CA. Additionally, the Scientific Coordinator shall approve all Disseminations to ensure both the quality of the consortium's output and alignment with its objectives. Disseminations may only be published on behalf of the INDICATE consortium after receiving this approval.

3.1.7. Work Package Leads (WPL(s))

The Work Package Leads are responsible for ensuring the smooth management of their respective work packages. This includes facilitating regular WP meetings, keeping meeting notes, participating in the Executive Board, and coordinating with other WPs. They resolve any internal disagreements and, if necessary, escalate issues to the Executive Board. Additionally, they must request a draft of each deliverable four weeks before its submission deadline, with the final version due one week before the deadline. Together with the Project Manager, they assign and manage reviewers, ensuring reviews are completed three weeks before submission.

3.1.8. External Expert Advisory Board (EEAB) and Ethical Advisory Board (EAB)

Both the External Expert Advisory Board (EEAB) and the Ethical Advisory Board (EAB) support and advise the General Assembly, the Coordinator, and the Scientific Coordinator. Each member of these boards must sign a non-disclosure agreement (NDA), based on a standard template and no less stringent than the Consortium Agreement, within 30 days of their nomination or before they receive any Sensitive Information, whichever is earlier. Any substantive changes to the NDA template require written approval from all Parties.

The Coordinator is responsible for taking meeting minutes of both advisory boards and for implementing their suggestions. Members of the EEAB and EAB may attend General Assembly meetings when invited, but they do not have voting rights. The existence of these NDAs does not waive any Party's obligation to maintain confidentiality of Sensitive Information received from another Party, nor permit sharing such information with third parties (including advisory board members) without prior written consent from the disclosing Party.

3.2. Decision-making procedures

The INDICATE consortium bodies operate through a structured voting and decision-making process where two-thirds of members must be present (quorum) for valid decisions. Each member gets one vote, and decisions require a two-thirds majority. Decisions can be made either in meetings or through written procedure. Members have 15 days to veto decisions that could adversely affect their interests, IP rights, or confidential information. The coordinator records meeting minutes and distributes them within 15 days, giving members the right to correct factual inaccuracies.

4. Reporting

4.1 Continuous reporting in the EU portal

The project partners will continuously report on the action's progress (e.g., deliverables, milestones, outputs/outcomes, critical risks, indicators, etc.) through the Portal Continuous Reporting tool, adhering to the schedule and conditions defined therein (as agreed with the granting authority).

4.2. Reporting to the European Commission

4.2.1. Reporting Periods

The project has three formal reporting periods:

- Period 1: From M1 to M12: 01.12.2024 - 30.11.2025
- Period 2: From M13 to M30 : 01.12.2025 - 31.05.2027
- Period 3: From M31 to M42 : 01.06.2027 - 31.06.2028

The Periodic Report is divided into a technical and financial report.

4.2.2. Technical Report

The Technical Report consists of 2 parts:

- Part A contains structured tables with project information
- Part B is a narrative description of the work carried out during the reporting period.

Part A is generated by the IT system. It is based on the information which you enter into the Portal Continuous and Periodic Reporting modules.

Part B (+ annexes) must be uploaded on the Technical Report (Part B) screen. The templates to use are available there. This includes:

- summary of the work performed and achievements, results and impact,
- changes to the implementation plan,
- changes to the overall project management concept, quality assurance and monitoring and evaluation strategy,
- information about significant budget overruns or important changes in the financial management,
- state of play concerning the risks and risk mitigation measures,
- changes in the way participants work together, deviations from Annex 1 of the Grant Agreement regarding the organisation of staff or project teams,
- important changes in the management or decision-making mechanisms,
- changes in the impact analysis/strategy (if any) and the effects on the project/need for adaptations
- the communication and dissemination activities undertaken (to whom, which format, how many, etc.) as foreseen in your Dissemination and communication plan
- changes in the sustainability analysis/strategy (if any),
- corrective actions taken as a result of EU monitoring activities (including follow-up to EU project reviews, if any)
- implementation status of the activities that were to be implemented during the reporting period and explain deviations from Annex 1 of the Grant Agreement.

- changes to ethics issues identified in Annex 1 of the Grant Agreement.
- changes to security issues identified in Annex 1 of the Grant Agreement (if any).

4.2.3. Financial Report

The Financial Report consists of:

- The individual financial statements (Annex 4 to the GA) for each Beneficiary
- A summary financial statement
- A certificate on the financial statements (CFS) (if threshold reached).

The Financial Report is generated by the IT system on the basis of the financial information entered into the Periodic Reporting module (and any other documents uploaded, e.g. CFS).

Beneficiaries will have to submit also the financial statements of their affiliated entities (if any).

4.2.4. How to prepare and submit the Periodic Report?

The Periodic Report must be prepared by the consortium in the Continuous and Periodic Reporting modules and then be submitted by the Coordinator. The Continuous Reporting module is always open and can be updated at any moment during the project (submit deliverables, report on milestones, etc.). It automatically feeds Part A of the Periodic Report.

The Periodic Reporting module is opened after the end of the reporting period. It allows you to:

- Download and upload the Part B of the Technical Report (upload only by the Coordinator)
- Complete their financial statements on-line (each Beneficiary for themselves and their Affiliated Entities)
- Consolidate the individual financial statements into a summary statement (Coordinator)
- Submit the Periodic Report (Coordinator)

The Coordinator submits these reports with the Commission via the Participant Portal within 60 days following the end of each reporting period. Therefore, the before mentioned information for the technical and financial reports has to be sent to the Coordinator and to the participant portal by the project partners 14 days before submission deadline.

4.3. Internal progress report(s)

In addition to the official Periodic Reports, an internal interim progress report will be prepared to support the first official Periodic Reporting and to monitor the financial progress of the INDICATE project. At month 6 (M6), the Coordinator will collect information from all beneficiaries to draft this interim report. Its purpose is to track both technical progress and financial spending, and to facilitate preparations for the 12-month milestone. The same format as the official Periodic Reports will be used. If necessary, the Coordinator will conduct a second internal interim survey at month 21 (M21).

5. Payments

The following payments are foreseen in the project:

1. **Pre-financing:** At the start of the project, 80% of the total grant amount will be provided to the beneficiaries as a float. This sum remains the property of the EU until the final payment.
2. **Interim payment**: After approval of the periodic reports, an interim payment will be made within 90 days of receiving the periodic reports, up to a maximum of 90% of the total grant.
3. **Final payment**: Following approval of the final report, the remaining amount will be paid. This is the difference between the calculated EU contribution (based on eligible costs) and the amounts already disbursed.

6. Deliverables and Milestones

6.1. List of Deliverables

Number	Deliverable name	Work package	Lead	Type	Dissemination level	Due date (month)
D1.1	Project handbook, including risk management plan and quality management plan	1	Erasmus MC	R Document, report	SE	2
D5.1	Comprehensive knowledge utilisation and strategic dissemination, exploitation and communication plan	5	Erasmus MC	R Report DEC —Website	PU	3
D7.1	OEI Requirement No. 1	1	Erasmus MC	ETHICS	SEN	3
D3.1	Publication of the ELSI-framework for data access, Data Management Plan, and Data Protection Impact Assessment.	3	Erasmus MC	R report, DEC Website, DMP Data Management Plan	PU	6
D2.1	Minimal dataset descriptions for all clinical use cases	2	UNIVREN	DMP Data Management Plan	PU	8
D4.1	Minimal Viable Product (MVP) versions of Core services and data federation network	4	KPMG	DEM Demonstrator: prototype in operational environment DEC —Website	PU	9
D6.1	MIMIC-EU MVP	6	UDUS	DATA federated data sets DEM Demonstrator	PU	9
D6.4	MVP Grand Round Workspace	6	TCD	DEC Website DEM Demonstrator	PU	12
D6.5	Guidance for Health Technology Assessment (HTA) of the six use cases	6	Erasmus MC	R Document, report	PU	12
D3.2	Roadmap for the sustained operations and governance of the ICU data infrastructure, including on-boarding and off-boarding plan and business model	3	KPMG	R report, DEC Website	PU	18
D4.2	Closed beta of the core services and data federation network, metadata catalogue, and centralised marketplace for services	4	KPMG	DEM Demonstrator: prototype in operational environment DEC —Website	PU	18
D5.2	MVP of the collaborative knowledge transfer platform	5	Cradeq	DEC Website	PU	18
D6.3	MVP Quality Benchmarking	6	Charité	DEC Website DEM Demonstrator	PU	18
D2.2	INDICATE Data Provider Handbook	2	SAS	DEC Website / R Document	PU	30
D2.3	Proposal for the extension of the OMOP CDM for time-series ICU data	2	PEN	R Document	PU	36
D2.4	Propose an interoperability framework for the deployment of (AI-based) decision support tools	2	Erasmus MC	R Document	PU	42
D6.2	Clinical demonstrations of Machine Learning models and AI, including a 'virtual human twin'	6	AP-HP	DEM Demonstrator	PU	42

Table 1: INDICATE Deliverables in chronological order

*PU: public, fully open; sensitive, limited under the conditions of the Grant Agreement; EU classified, RESTREINT-UE/EU-RESTRICTED, CONFIDENTIEL-UE/EU-CONFIDENTIAL, SECRET-UE/EU-SECRET under Decision 2015/444

6.2. List of Milestones

Number	Work package	Name	Lead	Due Date (month number)	Means of verification
MS1	1	Project governance established	Erasmus MC	2	D1.1
MS2	1	Expert Advisory Board established	Erasmus MC	3	Website describing the composition, responsibilities and tasks of the Expert Advisory Group
MS3	2	Data Provider Support Workgroup established	SAS	3	Website with a description of the composition, responsibilities, and tasks of the Data Provider Support Workgroup
MS7	3	Data Protection Workgroup established	Erasmus MC	3	Website describing the composition, responsibilities and tasks of the Data Protection Workgroup
MS8	3	Ethics Advisory Board established	Erasmus MC	3	Website describing the composition, responsibilities and tasks of the Ethics Advisory Board
MS14	5	Network of communication leaders established	Erasmus MC	3	D5.1
MS15	5	Training and Education Workgroup established	HSICM	8	Website detailing the members, responsibilities and tasks of the Training and Education Workgroup
MS4	2	First data provided by the innovator hospitals for Use Case 1 MIMIC-EU	SAS	9	D6.1
MS5	2	First test of interoperability between data providers	SAS	9	D6.1
MS10	4	Release of Minimal Viable Product (MVP) versions of Core services and data federation network	KPMG	9	Software templates that can be used to provision a secure processing environment (a virtual machine in the cloud) to upload or received data.
MS13	4	Cybersecurity and Incidence Response Team (CIRT) established	CHU Rennes	9	Website, English, CIRT can be reached via email on the consortium website, via a ticketing system, or via telephone.
MS16	6	Public release of the Grand Round Workspace	TCD	12	D6.4 Publication in a scientific journal in the ICU field.
MS11	4	Release of closed beta version of the core services.	KPMG	18	D4.2
MS17	6	Public release of the Quality Benchmark portal for ICUs across Europe	UMG	18	D6.3 Publication in a scientific journal in the ICU field.
MS6	2	All data elements for the use cases (WP6) are defined	SAS	24	D2.1
MS18	6	Public release of the MIMIC-EU federated database	UDUS	24	D6.1 Publication in a scientific journal in the ICU field.

Table 2: INDICATE Milestones in chronological order

6.3. Approval Process of Deliverables

The project partner assigned to each deliverable in the grant agreement (the lead beneficiary) holds final responsibility for its quality. Each deliverable must be reviewed by at least one Quality Reviewer, who cannot be an author or co-author of that deliverable. Quality Reviewers provide detailed, constructive feedback, including references when applicable, to enhance the deliverable. They are encouraged to engage with the Task lead early in the process of defining and creating the deliverable to ensure timely quality checks.

The formal deliverable review process follows the following timeline:

- 4 weeks before the submission deadline, a finalized draft is submitted for quality review.

- The reviewers will then have 1 week to complete the review process and deliver their recommendations to the Work Package Lead and Task Lead at least 3 weeks prior to the submission deadline.
- The Task Lead will then have 2 weeks to address suggestions and comments before delivering the submission version to the Project Management office and Executive Board at least 1 week before final submission.

Role of the WP Leader

- Timely preparation: Ensure deliverables within the Work Package (WP) are completed on schedule. A draft version must be made available for quality review in the project workspace at least four (4) weeks before the official EC submission deadline. The quality review must be completed at the least three (3) weeks prior to the submission deadline. The final version of the deliverable must be submitted to the Project Manager one (1) week prior to the official EC submission deadline for final approval.
- Quality review coordination: Designate Quality Reviewers in advance (the relevant information is available in the project workspace) and oversee the review process. Quality review may proceed as soon as requested by the Task coordinator, but no start later than four (4) weeks prior to the EC submission deadline.
- Meetings & collaboration: Organize meetings and involve any additional contributing partners as needed.
- Project coordination: Attend coordination group meetings and maintain regular communication with the Project Coordinator to ensure transparency.
- Risk management: Identify potential risks and communicate them to the Project Coordinator and Project Manager.
- Support quality review: Assist in ensuring that the quality review process is carried out properly for all deliverables in the WP.

Responsibilities of the lead beneficiary (deliverable owner)

- Document structure & information gathering: Define the document's structure and collect necessary input from contributing partners.
- Project guidelines: Use the project's document templates and graphical guidelines.
- Progress visibility: Provide updates on activity progress and keep the WP Leader informed of the deliverable's status.
- Information organization: Manage how information is compiled and oversee document versioning.
- Quality assurance: Engage with the designated Quality Reviewers at an early stage to ensure that the draft deliverable meets expectations, and to ensure that there is ample time to process feedback.
- Submission preparation:

- Deliver the final draft to the Work Package leader and Quality Reviewers four (4) weeks prior to the EC submission deadline.
- Process comments and suggestions for improvements.
- Deliver the final version to the Work Package leader, Quality Reviewers and Project Manager , at least one week before the EC submission deadline.

Responsibilities of the Quality Reviewer

Quality reviewers will be appointed by the Executive Board based on the recommendations from the Project Management Office and Work Package Leaders.

- Quality assurance: Engage with the lead beneficary (deliverable owner) at an early stage to ensure that the draft deliverable meets expectations, and to ensure that there is ample time to process feedback.
- Provide feedback on the final draft of the deliverable to the Work Package Leaders and the lead beneficiary at least three (3) weeks before the EC submission deadline.
- Review modifications to the deliverable.
- Give advice to the Work Package leader to approve or reject the deliverable for final submission.

Responsibilities of the Project Manager

- Monitoring & escalation: Track the completion of deliverables to ensure on-time submission, and alert the Project Coordinator if there is any risk of delay.
- EC submission: Submit deliverables to the EC portal on behalf of the project partners.
- Archiving: Ensure that final versions of all deliverables are correctly archived in the Project Workspace.

7. Rules and Guidelines for document preparation

7.1. Documentation publication rules

- The Project Manager will ensure the adherence to the requirements of the Grant Agreement and acknowledge the financial contribution of the European Commission.
- All publications and any other dissemination material relating to results of INDICATE should include a statement to indicate that this result was generated with the assistance of financial support from the European Union.
- Any dissemination of results (in any form, including electronic) must:
    - Display the EU emblem
    - Include the following acknowledgement: “Co-funded by the European Union”.
    - Include the disclaimer: “Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or [name of the granting authority]. Neither the European Union nor the granting authority can be held responsible for them.”
- Pre-prints of articles shall be placed in the Teams for the whole consortium.
- The document’s owner shall invite and solicit contributions from the whole consortium when applicable.
- All dissemination and communication outputs must be approved by the Scientific Coordinator to ensure quality and consistency.
- The contributors and authors of the publication shall abide by clause 9 of the Consortium Agreement allowing the Consortium to be notified of the planned publication at least 45 days before the intended submission date.
- Any objections on the publication of specific results (i.e. in case such result is susceptible to breach Intellectual Property Rights of another party within the consortium) shall be made to the Coordinator by the party raising the objection.
- The coordinator shall notify the consortium.
- Any objections and resolutions shall be dealt with in accordance with the INDICATE consortium agreement.

Document lay-out

All partners will use standard document templates provided by the Project Manager in order to apply a consistent look for all project documents. One generic document template will be provided and several specific templates for particular documents such as deliverables, Periodic Report etc. The templates are available from the INDICATE Teams.

The generic document template will follow guidelines given by the EU and contains the following:

1. Layout of the title page
2. Layout of headers and footers
3. Styles that are to be used in the documents

Templates available:

1. Template for the Interim and Periodic Reports
2. Template for the deliverables

3. Template for presentations

Document Management

All partners will note the date, version, author, and a brief description of changes to the document upon committing the document, in order to establish a changelog.[1] In addition, all partners will note the date, version, reviewer, and approval of any reviews of the document.

7.2. File name conventions

Each document shall be uniquely identifiable together with its version. See the table below for the way to name files. Other document types should also follow this logic. Final versions are saved as v1.0 in pdf.

File naming conventions:

Document type	IDer	Convention	File name example
Deliverables	D	INDICATE_D[WP#].[D#]_[Short Title]_[lead partner]_v[version#]_[YYYYMMDD].[extension]	INDICATE_D1.1_ProjectHandbook_ErasmusMC_v1.0_20250112.doc
Meeting minutes	MM	INDICATE_MM_[type of meeting]_[YYYYMMDD].[extension]	INDICATE_MM_EB_20250112.pdf
Periodic Reports	PR	INDICATE_PR[period#]-v[version#].[extension]	INDICATE_PR1_v0.1.doc
Interim Reports	IR	INDICATE_IR[period#]-v[version#].[extension]	INDICATE_IR1_v0.1.doc

[1] https://keepachangelog.com/en/1.1.0/

8. Communication

8.1. Communication with the Commission

The Project Coordinator serves as the main liaison between the consortium and the European Commission (EC). Project partners should not contact EC officers directly; instead, the Project Coordinator will communicate with the EC on their behalf. If necessary, the Coordinator will invite partners to contribute to communications or join meetings with the EC.

8.2. Internal Communication

Project Workspace

All project partners must register for the shared Project Workspace (Microsoft Teams) that has been provided. All project-related files will be stored and exchanged within this platform.

Phone & Video Calls/Conferences

When necessary, project partners will communicate via phone or online video conferencing.

Face-to-Face Meetings

In-person meetings will be scheduled as required.

8.3. Administrative data for formal communication

All project partners will ensure that they provide the Project Manager with up-to-date information regarding administrative data, for example:

- The address to which to send paper documentation if required.
- Details of contact persons.
- Banking information form (to be confirmed before any wire transfer from the Coordinator towards the project partners).
- Any changes in legal structure (change of ownership, change of name, etc.).

8.4. Meetings/call conferences

The INDICATE project partners will meet whenever necessary, considering budgetary limitations allocated for travel and other conditions. Online Video/Call Conferences are considered an effective way to be in contact and provide updates about progress.

- At least one face-to-face meeting is planned during the duration of the project. This Kick-off Meeting, will take place on January 27-28, 2025, in Sevilla. Dates for other face-to-face meetings and locations will be scheduled once the project has commenced.
- The General Assembly will meet **at least twice per year**. Extraordinary meetings of the General Assembly will be held at any time upon written request of any Member.
- The Executive Board will meet monthly during the first year of the project and, as needed, every one to two months throughout project years 2 to 3.5.
- Project Coordinator and Project Manager will meet weekly.
- Coordinating Team (Project Coordinator, Scientific Coordinator, Technical Lead and Project Manager) will meet bi-weekly.

Other project meetings will be held as necessary:

- WP meetings/call/web conferences: whenever the Task Leader or the Work Package Leader requests.
- Tasks meetings/call/web conferences: whenever the Task Leader or the Work Package Leader requests.
- Review meetings with the participation of the EC PO + external reviewers are organized if needed, as indicated in the Grant Agreement.

As far as possible, Consortium meeting dates and times shall be defined and shared with the project partners at least two months in advance.

8.5. External Communication

All communication from the INDICATE project must contain the following:

- Project logo
- The EU flag and an EU acknowledgement
- As per article 17 of the Grant Agreement, any communication or dissemination activity related to the action must use factually accurate information. Moreover, it must indicate the following disclaimer (translated into local languages where appropriate): “Co-funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the European Health and Digital Executive Agency (HADEA). Neither the European Union nor the granting authority can be held responsible for them.”

8.5.1. Project Website

The project website, launched in December 2024, will encompass general information about the project. This information will cover aspects such as a project description, objectives, results, impacts, consortium information, and contact details. Dynamic information such as brochures, news, public deliverables, publications, and complementary content, providing visitors with more detailed insights into the project progress will be included in the project website.

8.5.2. Social Media

Social media will also be used to raise awareness of news, public deliverables, publications, and related content. Any content intended for social media must be sent to the Project Manager, who—after consultation and approval from the Coordinator and Scientific Coordinator—may publish it directly or delegate publication to the WP5 leads and contributing parties.

8.5.3. Dissemination Materials and Rules

The dissemination, exploitation and communication activities of the project, along with strategies for mapping and engaging stakeholders, will be described in the Deliverable 5.1, the Dissemination, Exploitation and Communication Plan, due by M3.

Dissemination materials e.g., brochures, posters, white papers, videos, scientific publications, press material, newsletters, press releases, presentations, etc., will be prepared to promote the INDICATE results. These materials will follow the project’s visual identity and quality standards and be distributed in the regular dissemination activities scheduled in the project and performed by WP5 project partners.

All materials will be produced in English. When required, they will be translated into other languages with the support of local partners. Dissemination material will be available to download from the project's internal Project Workspace.

Relevant external events will be attended throughout the duration of the project.

9. Project Workspaces

The Project Workspace is an efficient tool to internally manage, and share documents and information related to the project. It is a repository of all the useful documents (templates, GA, CA, guidelines, list of contacts, WP documents, etc.) and a management tool to plan meetings, maintain a calendar of internal events/meeting dates, etc. The files stored in the workspace can be edited online and thus, this is also an effective tool for partners to use to work on files in a collaborative manner.

9.1. INDICATE MS Teams

Erasmus MC as the project coordinator provides access to workspace for INDICATE project in its Microsoft Teams environment. The project manager maintains an updated list of persons involved with the project who have access to the workspace.

Each project partner is responsible for informing the coordinator who from their organization needs an access to the project workspace and if the access should be revoked due to personnel / role changes.

9.1.1. Main Sections and Tools

The Microsoft Teams workspace consists of following main sections:

- Channels: general channel + individual channel / WP
- Files: folder structure for each task of the WP where documents and deliverables are stored
- Task planner tool: available for each WP channel to set scheduled tasks assigned to a person.

General channel includes folders for INDICATE joint management structures (General assembly, coordination groups etc.) and the project fundamental documents (agreements, templates etc).

9.1.2. Parallel

Parallel is an additional project management tool developed and maintained by Cradeq B.V. As a central resource for project-related inquiries and information, it also functions as a repository for files and documents. All completed deliverables are uploaded there for reference.

10. Conclusions

This Project Handbook is designed to offer the consortium clear guidelines for executing project activities and to support monitoring of INDICATE's progress. All INDICATE project partners should apply these guidelines to develop and share an operational methodology that minimizes overhead and boosts efficiency. Additionally, all partners are expected to be familiar with the general points covered in this document to help ensure the project's success.

11. References

The following sources have been referred to in this document.

- INDICATE Description of Action (DoA)
- INDICATE Grant Agreement
- INDICATE Consortium Agreement (CA)

Part B: Quality Management Plan

1. Introduction

1.1. Purpose of this document

The Quality Management Plan (QMP) is a key component of the Project Management Handbook, designed to ensure and maintain the quality of the INDICATE project's deliverables and outcomes. Together with the Project Handbook (Part A) and the Risk Management Plan (Part C) (RMP), it provides a comprehensive framework for the entire Consortium. These elements work together to monitor and control project processes, prevent deviations from the Work Plan, and guarantee the delivery of high-quality results. The QMP should be read alongside the Project Handbook and Risk Management Plan for a complete understanding of the quality assurance processes and responsibilities within the INDICATE project.

2. Quality assurance process for deliverables

The quality assurance process for **INDICATE** deliverables is designed to ensure that all project outputs meet the highest standards of quality and are delivered on time. This process includes multiple stages, from initial drafting to final submission, with clearly defined responsibilities and timelines. Each stage incorporates specific tasks and quality checks to guarantee thorough review and refinement before submission.

2.1 New Deliverable Document

The process begins with the creation of a new deliverable document. The standard **INDICATE** deliverable template shall be used, and it can be found on the shared **INDICATE** workspace (Teams and Parallel). The Work Package WP Leader and the Deliverable Leader are responsible for initiating this step by defining the scope and objectives of the deliverable. This foundational step sets the direction and goals for the deliverable.

2.2 Initial Draft

The WP Leader and Deliverable Leader develop the initial draft, outlining the main ideas, assigning contributions, and setting deadlines. This stage ensures all team members understand their roles and the deliverable's timeline.

2.3 Consolidation

In the consolidation stage, inputs from various contributors are integrated into a cohesive document. The WP Leader and Deliverable Leader oversee this step, ensuring diverse perspectives are incorporated and all relevant information from partners is included.

2.4 Final draft

After consolidating inputs, the WP Leader and Deliverable Leader finalize the draft, ensuring it addresses all topics and objectives defined in the Description of Action (DoA). The final draft should be ready **four weeks** before the official delivery date, providing sufficient time for the review process.

2.5 Quality review

The quality review involves a peer evaluation of the deliverable by an **internal reviewer** assigned specifically for each deliverable. A table specifying deliverables, their authors, and assigned reviewers can be found on the **INDICATE** Teams environment.

Peer reviewers thoroughly examine both the content and presentation of the document, providing detailed comments, suggestions, and feedback. This review must be completed **three weeks** before the official delivery date, allowing adequate time for necessary revisions.

2.6 Final editing

Using feedback from the internal reviewers, the WP Leader and Deliverable Leader revise and refine the deliverable. This includes:

- Addressing all reviewer comments.
- Ensuring consistency in formatting and style.
- Verifying completeness and accuracy.

Once revisions are complete, the author notifies the reviewer so they can verify the changes. The updated document is then submitted to the Project Coordinator **one week** before the delivery date.

2.7 Formatting check

The INDICATE Project Manager conducts a technical quality check, confirming that:

- Formatting requirements are met.
- Naming conventions are followed.
- Versioning is correctly applied.

Versioning should appear at the beginning of each deliverable and follow this convention:

- First draft: **0.1**
- Second draft: **0.2**, etc.
- Final version submitted to the EC: **1.0**

All changes must be recorded in the Document History and Document Internal Review History sections, noting version, author, date, and any brief change descriptions.

2.8 Submission

Finally, the Project Coordinator is responsible for submitting the finalized deliverable to the European Commission (EC) on or before the official delivery date.

2.9 Considerations for finalizing the deliverables for peer review

To maintain high-quality deliverables in the INDICATE project, it is crucial to follow a structured review process. Table 1 (not included here but referred to in the text) would outline the key considerations for authors and reviewers. This typically includes:

- Subject Matter Coverage: Ensuring the deliverable comprehensively addresses the objectives.
- Accurate Document Versioning: Maintaining an up-to-date record of changes.
- Consistency in Terminology and Citations: Uniform use of acronyms, references, and style.
- Detailed Feedback: Reviewers providing thorough comments; authors incorporating partner input.

By adhering to these guidelines, authors and reviewers help produce coherent, well-documented, and high-quality deliverables aligned with the project's standards and objectives.

3. Conclusions

This Quality Management Plan (QMP) for the INDICATE project ensures that all project deliverables are produced to the highest standards of quality. Supported by the INDICATE Project Handbook and the INDICATE Risk Management Plan, it provides a structured framework for managing the quality of project activities and outputs.

From initial drafting to final submission, each stage in the deliverable process is governed by clear guidelines and responsibilities. The involvement of WP Leaders, Deliverable Leaders, Internal Reviewers, and the Project Coordinator fosters a collaborative effort toward consistently high-quality outcomes.

Biannual reviews by the Quality Manager, along with regular evaluations and updates to the QMP, allow the consortium to address emerging challenges and apply best practices. This commitment to continuous improvement keeps INDICATE on track to achieve its objectives effectively and efficiently.

By following the procedures in this plan—alongside the INDICATE Project Handbook and INDICATE Risk Management Plan—the consortium demonstrates its dedication to excellence. Thorough peer reviews, attention to comprehensive subject matter coverage, and meticulous document preparation underpin our ability to deliver top-tier project results.

As a living document, this QMP evolves with INDICATE, adapting to new developments and consistently improving processes. Through these efforts, the INDICATE project aims to exemplify quality in project management and deliverables, ultimately contributing to the success and impact of its mission.

Part C: Risk Management Plan

1. Introduction

1.1 Purpose and Scope

This Risk Management Plan establishes the framework for identifying, assessing, mitigating and monitoring risks throughout the lifecycle of the INDICATE project. The purpose is to proactively manage uncertainties and potential issues that could impact the successful delivery of the federated ICU data infrastructure in line with project objectives.

The plan covers all aspects of the project, including technical development, organizational alignment, stakeholder engagement, legal compliance, and long-term sustainability. It applies to all project team members, work packages, and partner organizations involved in INDICATE.

The key objectives of the risk management plan are:

- To establish a systematic and consistent process for risk management
- To identify and prioritize risks early in the project lifecycle
- To develop and implement effective risk mitigation strategies
- To monitor risk exposure and track the effectiveness of risk responses
- To provide visibility of risks to support informed decision-making
- To foster a risk-aware culture that proactively addresses uncertainties

1.2 Relationship to Project Management

Risk management is an integral part of the overall project management approach in INDICATE. Risks are identified and managed at the work package level and escalated to the project level as necessary. The risk management process is aligned with key project management activities:

- Risks inform project planning and resource allocation decisions
- Risk status is regularly reported as part of project status reporting
- Risk mitigation actions are tracked in the project schedule
- Risk management effectiveness is considered in project reviews and lessons learned

The Executive Board has overall responsibility for risk management and makes strategic decisions on risk appetite, tolerance levels, and treatment strategies. The Project Management Office facilitates the risk management process, maintains the risk register, and provides risk reports and analytics to support decision-making.

1.3 Risk Management Approach

INDICATE adopts a proactive and iterative approach to risk management, based on industry standards such as ISO 31000 and PMI's PMBOK. The key elements of the approach are:

- Continuous risk identification throughout the project lifecycle, involving all stakeholders
- Structured risk assessment using qualitative and quantitative techniques
- Prioritization of risks based on probability, impact, and urgency
- Development and implementation of targeted risk mitigation strategies

- Regular monitoring and review of risks and the effectiveness of risk responses
- Integration of risk information into project governance and decision-making processes
- Communication and reporting of risks to relevant stakeholders in a timely and transparent manner
- Continuous improvement of the risk management framework based on lessons learned

The details of the risk management process, roles and responsibilities, and governance mechanisms are elaborated in the subsequent sections of this plan.

In summary, this Risk Management Plan provides the structure and guidance for effectively managing risks in the complex, multi-stakeholder environment of the INDICATE project. By proactively identifying and addressing potential issues, the project aims to minimize negative impacts, capitalize on opportunities, and ultimately deliver a successful, sustainable federated data infrastructure for ICU research and innovation in Europe.

2. Risk Management Framework

2.1 Risk Assessment Process

The INDICATE risk assessment process follows a systematic approach to identify, analyze, and evaluate risks to the federated data infrastructure. This process occurs continuously throughout the project lifecycle and consists of four key phases:

Risk Identification Phase

Risk identification draws on multiple sources including stakeholder interviews, brainstorming sessions, risk checklists, and risk breakdown structures. The process examines both internal factors (such as technical capabilities and resource constraints) and external factors (such as regulatory changes and market conditions) that could affect project success.

Risk Analysis Phase

Each identified risk undergoes detailed analysis, using both qualitative and quantitative techniques, to understand its potential causes, triggers, and impacts. Qualitative analysis assesses risk probability and impact based on expert judgment and historical data. Quantitative analysis uses numerical data, statistical models, and simulations to estimate risk exposure in terms of financial impact, schedule delays, or performance metrics.

Risk Evaluation Phase

Risks are evaluated against the established risk appetite and tolerance levels defined in the project's governance framework. The target residual risk level for INDICATE is medium, with a focus on reducing high risks to an acceptable level through appropriate mitigation strategies. Risk prioritization is based on the risk score derived from the probability and impact matrix.

Risk Treatment Phase

Based on the evaluation, appropriate risk treatment strategies are selected and implemented. High risks require immediate action, such as implementing stringent control measures, adjusting project scope or timelines, or allocating additional resources. Medium risks are managed through enhanced monitoring and targeted mitigation actions. Low risks are accepted and monitored as part of regular project management activities.

2.2 Risk Categories

INDICATE organizes risks into four primary categories, each with distinct characteristics and management approaches:

Technical Risks

- Infrastructure and system performance
- Data quality and interoperability
- Cybersecurity and data protection
- Technical integration challenges

Organizational Risks

- Stakeholder engagement and adoption

- Resource availability and allocation
- Communication and coordination
- Change management

Legal and Compliance Risks

- Regulatory compliance (GDPR, AI Act)
- Cross-border data sharing
- Ethics and privacy requirements
- Contractual obligations

Business Risks

- Financial sustainability
- Market adoption
- Service delivery
- Competition and innovation

2.3 Risk Scoring Matrix

INDICATE employs a 5x5 risk scoring matrix that combines probability and impact ratings:

Probability\Impact	Minimal	Minor	Moderate	Major	Severe
Very Low	1	2	3	4	5
Low	2	4	6	8	10
Medium	3	6	9	12	15
High	4	8	12	16	20
Very High	5	10	15	20	25

Probability Levels:

- **Very Low** 1-10% likelihood; expected to occur once every 5 years
- **Low** 11-30% likelihood; expected to occur once every 2-3 years
- **Medium** 31-60% likelihood; expected to occur once per year
- **High** 61-80% likelihood; expected to occur once per quarter
- **Very** High 81-100% likelihood; expected to occur monthly or more often

Impact Levels:

- **Minimal** Less than 5% deviation in project scope, schedule, or budget
- **Minor** 5-10% deviation in project metrics, manageable with minimal intervention
- **Moderate**10-20% deviation, requiring replanning and management attention
- **Major** 20-40% deviation, threatening key project milestones and objectives
- **Severe** Over 40% deviation, endangering overall project viability

The resulting risk score (Probability x Impact) ranges from 1 to 25, categorized into three risk levels:

- Low Risk (1-8): Standard monitoring
- Medium Risk (9-15): Enhanced monitoring and control
- High Risk (16-25): Immediate attention required

2.4 Roles and Responsibilities

General Assembly

- Approves risk management framework
- Reviews high-risk items
- Makes strategic decisions on risk tolerance

Executive Board

- Oversees risk management implementation
- Approves risk mitigation strategies
- Allocates resources for risk management

Project Management Office

- Maintains risk register
- Coordinates risk assessment activities
- Produces risk reports and analytics
- Monitors mitigation effectiveness

Project Coordinator

- Ultimately accountable for risk management
- Ensures alignment of risk management with overall project governance
- Communicates critical risks to steering committee and external stakeholders

Work Package Leaders

- Identify and assess risks within their scope
- Implement mitigation measures
- Report on risk status and effectiveness

Technical Teams

- Monitor technical risks
- Implement technical controls
- Provide expertise for risk assessment

2.5 Review and Update Procedures

The risk management framework undergoes regular review and updates to ensure its continued effectiveness:

Continuous Updates

- New risk identification, including emerging risks and early warning signals
- Risk status updates based on mitigation progress and changing circumstances
- Mitigation effectiveness tracking through defined KPIs and metrics
- Escalation of risks that exceed defined thresholds

Monthly Reviews

- Risk register updates
- Mitigation progress assessment
- Resource allocation review
- Performance metrics evaluation

Quarterly Reviews

- Framework effectiveness assessment based on risk trends and audit findings
- Process improvement identification through lessons learned and best practices
- Update of risk criteria and thresholds based on project stage and external factors
- Stakeholder feedback integration, including risk perceptions and risk reporting needs

Annual Reviews

- Comprehensive framework evaluation
- Update of risk categories and scoring
- Review of roles and responsibilities
- Strategic alignment assessment

All updates to the framework are documented and communicated to relevant stakeholders, with formal version control of framework documents. The framework will continue to evolve based on organizational learning and external good practices to remain fit-for-purpose throughout the project lifecycle.

2.6 Risk Governance and Reporting

The risk management framework is an integral part of INDICATE's overall governance structure. The Project Director, supported by the Executive Board, sets the tone for risk management and defines the project's risk appetite. This is cascaded down to guide risk-based decision making at all levels.

Key risks are regularly reported to the Steering Committee as part of project status updates. High risks that threaten project objectives are escalated in a timely manner for strategic guidance and resource allocation decisions.

Critical risks with potential external impact are proactively communicated to relevant stakeholders, such as regulatory authorities, partner organizations, and user communities. Transparent risk communication builds trust and allows for collaborative risk management.

3. Key Risk Areas

3.1 Technical Risks

The technical implementation of INDICATE faces several critical challenges related to infrastructure, integration, and security. Data providers must maintain substantial computational resources to handle both routine clinical operations and federated analytics workloads, including sufficient processing power for real-time data harmonization and adequate storage capacity for historical data analysis. System integration presents difficulties when harmonizing data across different clinical information systems, especially regarding the standardization of high-frequency monitoring data and clinical annotations. Many healthcare organizations utilize legacy systems with proprietary data formats, making standardization to common data models technically complex and resource-intensive. Cybersecurity risks are amplified in a federated system, where each node represents a potential point of vulnerability. A security breach at any participating institution could compromise sensitive health data and damage trust in the entire infrastructure, making robust security measures and rapid incident response capabilities essential across all participating organizations.

3.2 Organizational Risks

Successful implementation of INDICATE depends heavily on sustained engagement from multiple stakeholder groups. Healthcare institutions may hesitate to participate due to concerns about data sovereignty and operational impacts on their clinical services. To build trust, the project must demonstrate transparent data governance practices and clear value propositions for each stakeholder group. Healthcare worker engagement presents another significant challenge, as clinical staff must integrate new systems and processes into their existing workflows while maintaining high standards of patient care. This necessitates comprehensive training programs and ongoing support systems, tailored to different roles and technical proficiency levels. Coordination across partners requires careful orchestration through regular steering committee meetings, standardized project management procedures, and clear communication channels. Resource availability must be carefully monitored to ensure consistent progress across all work packages, with particular attention to specialized technical expertise that may be in limited supply.

3.3 Legal and Compliance Risks

The regulatory landscape for health data sharing in Europe presents complex challenges that INDICATE must navigate carefully. Different national interpretations of GDPR requirements, particularly regarding the legal basis for health data processing and cross-border transfers, necessitate a flexible yet robust compliance framework. For example, some member states require explicit consent for health data processing, while others allow processing under different legal bases for research purposes. The handling of pediatric data requires exceptionally stringent controls, including enhanced consent mechanisms and additional safeguards for data protection. The project must also anticipate and prepare for upcoming regulatory changes, particularly the AI Act, which may introduce new requirements for AI system transparency and accountability in healthcare applications. This requires maintaining close relationships with regulatory bodies and legal experts to ensure continuous compliance while preserving the infrastructure's operational effectiveness.

3.4 Business Risks

The long-term sustainability of INDICATE depends on establishing a viable economic model that serves all participants in the data space. Revenue streams must be carefully structured to balance accessibility with sustainability, potentially including usage-based fees for commercial users, certification fees for service providers, and value-added services for advanced analytics capabilities. However, these revenue sources must be sufficient to offset both central infrastructure costs and support services for participants. Market adoption represents a critical risk factor, requiring clear demonstration of the infrastructure's value through carefully documented use cases and measurable outcomes in clinical practice. Early adopters must see tangible benefits to justify their investment and encourage broader participation. Cost-effectiveness demands careful attention to resource optimization, including cloud resource management, shared service models, and economies of scale in training and support services. The business model must also account for varying levels of technical maturity among participants, offering flexible engagement options while maintaining consistent service quality across the network.

Thank you for the detailed feedback. Let me enhance Section 4 with more specific examples and practical applications:

4. Risk Mitigation Strategies

The following section describes risk mitigation strategies for the INDICATE project. The table below provides a structured overview of the key risks and their corresponding mitigation measures. The "Type" column indicates whether each measure is primarily aimed at preventing risks before they occur, detecting issues early, responding to problems that arise, or providing contingency plans for worst-case scenarios. The rest of this section goes into more detail about the risk mitigation steps.

Risk Category	Specific Risk	Risk Mitigation Measure	Measure Type
Technical	Insufficient computational resources at data providers	Provide cloud-based deployment options with scalable resources	Prevention
Technical	Data quality inconsistencies across providers	Automated quality control checks during ETL process	Detection
Technical	Security breach in federated system	Multi-layer security architecture with encryption and access controls	Prevention
Technical	System integration failures	Standardized ETL tools and reference implementations	Prevention
Technical	Infrastructure performance issues	Monitoring system with automated alerts	Detection
Technical	Data harmonization errors	Validation framework with quality metrics	Detection
Organizational	Stakeholder hesitation to participate	Certification program recognizing technical capabilities	Prevention
Organizational	Poor healthcare worker adoption	Role-specific training programs and user support	Prevention
Organizational	Inconsistent resource availability	Project management tracking system	Detection
Organizational	Communication breakdowns between partners	Regular coordination meetings and clear escalation paths	Response
Organizational	Loss of key personnel	Cross-training and documented procedures	Contingency
Legal	GDPR compliance issues	Template agreements with standardized compliance clauses	Prevention
Legal	Regulatory changes affecting implementation	Active participation in regulatory forums	Detection
Legal	Cross-border data sharing challenges	Enhanced data protection frameworks	Prevention
Legal	Pediatric data protection requirements	Additional safeguards and approval processes	Prevention
Legal	Ethics violations	Ethics Advisory Board review process	Detection
Business	Insufficient revenue generation	Usage-based pricing model with tiered access	Prevention
Business	High operational costs	Consortium-wide cloud service agreements	Prevention

Business	Slow market adoption	Pilot implementations with documented outcomes	Response
Business	Service quality issues	Service level agreements with monitoring	Detection
Business	Competition from alternative solutions	Continuous innovation and feature development	Response
Business	Financial sustainability concerns	Regular cost-benefit analysis and optimization	Detection

4.1 Technical Risk Mitigation

The technical risk mitigation strategy employs a graduated adoption pathway that allows organizations to build capability over time. In the initial phase, data providers can begin with basic functionalities such as sharing standardized clinical observations and laboratory results. As their technical maturity increases, they can progress to more complex data types such as high-frequency monitoring data and advanced analytics capabilities.

For infrastructure deployment, INDICATE offers both cloud-based and on-premises solutions. The cloud-based option, implemented through Microsoft Azure, provides rapid deployment and scalability with minimal upfront investment. Organizations can leverage existing cloud security certifications and compliance frameworks. The on-premises option gives organizations complete control over their data infrastructure but requires more substantial technical expertise and infrastructure investment. Both options use standardized landing zone templates to ensure consistent security and performance.

The automated quality control system implements multiple validation layers. At the data level, it verifies completeness, consistency, and adherence to standardized vocabularies. At the semantic level, it checks for logical relationships between clinical concepts. The system generates detailed quality reports that data providers can use to improve their data harmonization processes before promoting data to the federated infrastructure.

4.2 Organizational Risk Mitigation

The stakeholder engagement strategy builds on successful approaches from related European health data initiatives. For example, drawing from the EHDEN project's experience, INDICATE implements a certification program for data providers that recognizes their technical capabilities and data quality standards. This approach has proven effective in building trust and maintaining high-quality participation.

Training materials are customized for specific roles within the healthcare ecosystem. For clinicians, the focus is on integrating federated analytics into clinical decision-making workflows. For data engineers, training emphasizes technical implementation and maintenance of secure processing environments. IT security professionals receive specialized training on the infrastructure's security architecture and incident response procedures.

The feedback system operates through regular structured reviews with clinical users. Monthly user group meetings provide a forum for discussing operational challenges and suggesting improvements. The project maintains a transparent issue tracking system where users can monitor the status of their suggestions and see how their feedback influences platform development.

4.3 Legal and Compliance Risk Mitigation

Template agreements incorporate standardized clauses for data protection, intellectual property rights, and service level agreements. These templates, developed in consultation with legal experts and data protection authorities, reduce negotiation time while ensuring compliance. They include specific provisions for cross-border data sharing and clear definitions of roles and responsibilities under GDPR.

For pediatric data protection, additional safeguards include mandatory ethics committee review for all research projects, enhanced audit logging of data access, and specialized training requirements for users accessing pediatric data. The system implements age-specific consent management and maintains detailed documentation of parental authorization where required.

INDICATE maintains active participation in key regulatory forums, including the European Health Data Space initiative and AI Act working groups. This engagement allows the project to anticipate regulatory changes and adapt its infrastructure proactively. Regular briefings from these forums inform updates to the project's compliance framework and technical architecture.

4.4 Business Risk Mitigation

Pilot implementations are selected based on clear criteria including clinical impact, technical feasibility, and stakeholder readiness. Success metrics encompass both technical performance (such as data quality and system reliability) and business outcomes (such as time saved in research preparation and improved clinical decision support). The project documents these outcomes through detailed case studies that demonstrate concrete value to potential participants.

The digital marketplace facilitates the exchange of validated analytics tools, machine learning models, and specialized data services. Service providers can offer capabilities such as advanced visualization tools, automated quality assessment services, or specialized analytics for specific clinical domains. The marketplace implements standardized pricing models and clear terms of service to facilitate transactions.

Cost management leverages economies of scale through consortium-wide cloud service agreements that provide significant discounts compared to individual contracts. The usage-based pricing model allows smaller organizations to participate without large upfront investments while ensuring sustainable revenue from higher-volume users. Regular cost-benefit analysis helps identify opportunities for optimization, such as automatically scaling down compute resources during low-usage periods.

5. Risk Monitoring and Control

The next section describes the procedures and documentation to monitor risks and report the status of risk and mitigation measures through the project.

5.1 Monitoring Procedures

The INDICATE project maintains a comprehensive risk monitoring framework centered on a structured Central Risk Register. This register categorizes risks according to their nature (technical, organizational, legal, business) and tracks their current status, mitigation measures, and responsibility assignments. Each risk entry includes a unique identifier, risk category, description, current probability and impact ratings, implemented controls, and mitigation status.

Automated monitoring systems will be set-up to track specific Key Performance Indicators aligned with project objectives:

- Technical Performance:
  - System availability (target: 99.9%),
  - response times (<2 seconds), and
  - data quality conformance (>95% compliance with defined standards)
- Security Metrics:
  - Failed access attempts,
  - security patch status,
  - encryption verification
- Operational Metrics:
  - Resource utilization,
  - ETL process completion rates,
  - data harmonization success rates

The Cybersecurity Incident Response Team conducts monthly vulnerability assessments and quarterly penetration testing of critical infrastructure components. Additional security assessments occur whenever significant system changes are implemented or new data providers join the infrastructure.

5.2 Reporting Requirements

Work Package leaders submit standardized monthly risk assessment reports using the INDICATE Risk Report Template. This template ensures consistent reporting across all project areas and includes:

- Executive Summary: Overall risk status and key changes
- Risk Status Matrix: Current assessment of all identified risks
- New Risk Analysis: Details of newly identified risks including root cause analysis
- Mitigation Effectiveness: Quantitative and qualitative assessment of control measures
- Resource Status: Current vs. planned resource utilization
- Action Items: Specific recommendations with assigned responsibilities and deadlines

The Project Management Office consolidates these inputs into an interactive risk dashboard that provides:

- Risk heat maps showing severity and likelihood distributions
- Trend analysis of key risk indicators over time

- Mitigation strategy effectiveness metrics
- Resource allocation status
- Critical action items requiring Executive Board attention

5.3 Escalation Paths

Risk escalation follows clearly defined criteria at each level:

Level 1 Work Package Level:

- Risks within single work package scope
- Impact limited to specific deliverables
- Resolution possible within existing resources
- Response Time: 24-48 hours

Level 2 Project Management Office:

- Risks affecting multiple work packages
- Budget impact up to €50,000
- Schedule impact up to 1 month
- Response Time: 48-72 hours

Level 3 Executive Board:

- Significant impact on project objectives
- Budget impact exceeding €50,000
- Schedule impact exceeding 1 month
- Response Time: 1 week

Level 4 General Assembly:

- Strategic impact on consortium
- Major regulatory compliance issues
- Fundamental changes to project approach
- Response Time: 2 weeks

Emergency procedures for critical risks (such as security breaches or data protection incidents) enable immediate escalation to the Executive Board and relevant authorities, bypassing normal escalation paths.

5.4 Review Cycles

The risk management framework operates on multiple review cycles with specific objectives and outputs.

Monthly Reviews:

- Work Package risk assessments with documented findings
- Technical monitoring report including all KPI measurements
- Updated risk register with tracking of all changes
- Distribution of risk dashboard to all stakeholders

Quarterly Reviews:

- Executive Board evaluation of risk management effectiveness
- Formal assessment of mitigation strategy performance

- Resource allocation optimization recommendations
- Process improvement identification and implementation
- External expert consultation on specific risk areas

Annual Reviews:

- Independent third-party audit of risk management framework
- Comprehensive review of risk identification and assessment processes
- Stakeholder satisfaction survey regarding risk management effectiveness
- Update of risk management procedures based on lessons learned
- External advisory board evaluation of risk management approach

All review findings are documented and maintained in the project's quality management system, with clear tracking of resulting actions and improvements.