D7.1

Quality assurance guidelines

DW

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Abstract

The present deliverable constitutes a reference document at consortium partners' disposal for ensuring the highest quality in the execution of the project, by providing a framework of procedures, guidelines, standards and rules to guarantee the quality of project outcomes (e.g., deliverables, periodic reports, software, infrastructure). The deliverable first provides an overview of the project legal framework (Grant Agreement, Consortium Agreement). Then, it illustrates the management structure and bodies (Coordination Team, Governing Board, Steering Committee, Data Protection Manager, Ethics Manager, Ethics Advisory Board), including their different roles, tasks and procedures. After that, it provides the project risk monitoring and mitigation strategy, including a preliminary risk management plan. The deliverable also includes format and structure guidelines for the preparation of project deliverables, reports, presentations and other research or dissemination material, as well as guidelines for the preparation, review and submission of deliverables, reports (periodic reports, final report) and dissemination documents (publications, abstracts, poster and presentations). Finally, the deliverable provides a self-assessment plan where, for each WP and task, the consortium has defined appropriate qualitative and quantitative indicators to monitor and assess the implementation of task-specific goals at the end of each project reporting period (M18, M36, M48).

Keywords

Quality assurance, guidelines, structure, procedures, roles, tasks, standards, rules, legal framework, management, governance, bodies, risk monitoring and mitigation, risk management plan, format, structure, deliverables, reports, publications, abstracts, presentations, self-assessment plan, key performance indicators.

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Document information

Nature of the deliverable		**R**
Dissemination level		
PU	Public, fully open. e.g., website	✓
CL	Classified information as referred to in Commission Decision 2001/844/EC	
SEN	Confidential to SYNTHEMA project and Commission Services	

*** Deliverable types:**
R: document, report (excluding periodic and final reports).
DEM: demonstrator, pilot, prototype, plan designs.
DEC: websites, patent filings, press and media actions, videos, etc.
OTHER: software, technical diagrams, etc.

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Acronyms and definitions

AI	Artificial intelligence
CT	Coordination team
DC	Deputy Coordinator
DoA	Description of Action
DPM	Data Protection Manager
EAB	Ethics and Legal Advisory Board
EM	Ethics Manager
GB	Governing Board
IPR	Intellectual property right
IR	Internal reviewers
KPI	Key performance indicator
PC	Project Coordinator
PE	Publication editor
PM	Project Manager
PO	Project Officer
QM	Quality and Risk Manager
PDF	Portable Document Format
SC	Steering Committee
WP	Work package

1 Executive summary

The present deliverable constitutes a reference document at consortium partners' disposal for ensuring the highest quality in the execution of the project, by providing **a framework of procedures, guidelines, standards and rules to guarantee the quality of project outcomes** (e.g., deliverables, periodic reports, software, infrastructure). These include (1) project legal framework, (2) management structures and procedures, (3) Risk monitoring and mitigation strategies, (4) Format and structure rules for project technical and dissemination documents, (5) reporting guidelines, (6) dissemination document preparation guidelines, and (7) self-assessment of project implementation.

(1) Project legal framework. The legal framework of the project is defined by the ***Grant Agreement*** **(GA) and the** ***Consortium Agreement***. *The GA* forms the legal basis for the implementation of the project, including ***Description of the Action*** **(DoA)**, the estimated budget for the action, additional information on unit costs and contributions, accession forms, the duration on joint and several liabilities of affiliated entities, model for the financial statements, and other specific rules. It is signed by the EU and the Coordinator, and indirectly by all partners by signing the accession forms as individual contract partners. The CA organises in detail the provisions of the GA in terms of financial issues, payments, management, decision-making, conflict resolution, *intellectual property rights* (IPRs) and liability, and is signed between the partners of the consortium.

(2) Management structures and procedures. The SYNTHEMA governance structure is articulated into a series of governing bodies in relation to appropriate functions and tasks.

- The **coordination** function is performed by the ***Coordination team*** **(CT)**, which includes the ***Project Coordinator*** **(PC),** ***Deputy Coordinator*** **(DC),** ***Project Manager*** **(PM) and** ***Quality and Risk Manager*** **(QM)**.
- The **decision-making** function (i.e., address high-level strategic issues) is implemented by the ***Governing Board*** **(GB)**, composed of one representative per partner, usually the ***Principal Investigator*** **(PI)**, and is chaired by the PC.
- The **operational management** function (i.e., day-to-day coordination of specific WP-related activities) is performed by the ***Steering Committee*** **(SC)**, composed of the **CT and** ***Work Package Leaders*** **(WPL)**.
- The **advisory** function, with specific regard to **data protection and ethical aspects**, is carried out through the ***Data Protection Manager*** **(DPM), the** ***Ethics Manager*** **(EM) and the** ***Ethics and Legal Advisory Board*** **(EAB)**, composed of data-protection, ethics and patient-associations experts external to the consortium, to be identified during the action and summoned at specific intervals in the project.

(3) Risk monitoring and mitigation strategies. The SYNTHEMA risk monitoring, assessment and mitigation function is conducted using the **'risk charting approach'**, which focuses on resources, threats, modifying factors and adverse consequences, using a classic **risk assessment matrix (probability vs severity of consequences)**, and following the consolidated ***tolerate, treat, terminate, transfer*** **(4T) model**. The risk management process consists of **(1) risk identification** (WPLs, to report to the CT), **(2) risk estimation and (3) risk mitigation and follow-up**, on a monthly basis. A preliminary **risk management plan** is available and will be updated in the course of the action.

(4) Format and structure rules. A set of **formal guidelines** have been defined for the preparation of **any project-related document**, including deliverables, reports, presentations, also included in the **Deliverable template document**. It concerns text and titles, acronyms, lists, figures and tables, references, language and software.

(5) Reporting guidelines. A set of guidelines has been defined for the preparation, review and submission of **(1) deliverables**, **(2) periodic reports**, describing scientific progress and financial aspects relevant to the first (M1-M18), the second (M19-M36) and the third (M37-M48) reporting periods, and **(3) the final report**, a final, high-level summary of project activity and achievements in lay terms, to be used after the end of the project for dissemination purposes. The guide includes additional **formal aspects** (i.e., naming conventions, document history), and the **preparation, peer review and submission process** for each kind of document, including 2 assigned **internal reviewers (IRs)** for each of the project deliverables.

(6) Dissemination documents. Another set of guidelines has been arranged for the **preparation, peer review and submission** of dissemination documents, including **(1) publications**, such as peer-review publications and generalist publications, and **(2) abstracts, posters and ppts**. These rules concern quality control for acknowledgment of EU funding, open access, IP and confidentiality.

(7) Self-assessment. The **self-assessment plan**, collectively defined by all **WPLs and *task leaders*** **(TLs)** of the consortium, includes **qualitative and quantitative indicators** to monitor and assess the implementation of task-specific goals at the end of each project reporting period (M18, M36, M48).

1 Introduction

The present deliverable is meant as **a reference document at consortium partners' disposal for ensuring the highest quality in the execution of the project**, and specifically to serve as **a framework of procedures, guidelines, standards and rules to guarantee the quality of project outcomes (e.g., deliverables, periodic reports, software, infrastructure)**. These guidelines are not intended to overrule the current practices adopted internally by each partner, but to provide a common minimum framework of quality assurance for the project, to be adopted by the whole consortium.

This framework will facilitate the consortium in making sure that:

- The project is running smoothly, and risks are considered and timely mitigated with proper strategies.
- Reports and deliverables are complete, self-containing, clear, and properly presented.
- The outcomes of the project, as described in relevant deliverables, are coherent with the project scope, overall implementation approach, plan and expectations, as set forth in the *Description of Action* (DoA).
- The consortium can adequately assess its progress in the implementation of the workplan against a series of self-defined criteria.

In the first section, *'Legal framework'*, briefly recapitulates the project legal documents of reference, while the second, *'Management structure and procedures',* outlines the project management procedures adopted by the consortium for coordinating project activities and maximising the efficiency of cooperation among partners. The third section, '*Risk management and mitigation'*, describes the approach and procedures to anticipate and cope with any potential risk identified during the project implementation. The '*Format and structure'* section details all formal guidelines and standards for the preparation of project related documents, while in the '*Reporting'* and *'Dissemination'* sections, the document specifically addresses the procedures to be followed for the preparation and quality control of projects deliverables and reports, and the ones for dissemination, respectively. Lastly, the document includes a '*Self-assessment plan'* with includes, for each WP, a series of qualitative and quantitative KPIs to be assessed in the course of the project and serve as an internal, self-assessment tool to evaluate the progress of the research activities.

2 Legal framework

2.1 Grant Agreement

The ***Grant Agreement*** **(GA) forms the legal basis for the implementation of the project**. It consists of:

- Preamble
- Terms and Conditions (this is the core contract).
- Annex 1 *Description of the Action* (DoA).
- Annex 2 Estimated budget for the action.
- Annex 2a Additional information on unit costs and contributions.
- Annex 3 Accession forms.
- Annex 3a Declaration on joint and several liabilities of affiliated entities.
- Annex 4 Model for the financial statements.
- Annex 5 Specific rules.

The contract is signed between the EU and the Coordinator, however, by signing the accession forms all partners have become individual contract partners with the Commission. The GA must be kept by all partners and should be provided to the auditor in case of an audit. The GA is downloadable from the participant portal and the SYNTHEMA repository in Microsoft Teams.

2.1.1 Amendments

Circumstances may arise during the project to require an amendment of the GA, in relation to a series of issues including change of partner, legal entity, budget, DoA.
In case an amendment is needed, the PC shall submit such a request after an autonomous decision by all partners in the Governing Board. After approval of the amendment, the PC shall distribute the revised GA, replacing former versions, and inform the *Project Officer* (PO). Amendments may be requested by any of the project partners. Budget changes that do not affect the content of DoA can be taken care of by the consortium itself.

2.2 Consortium Agreement

The *Consortium Agreement* (CA) is signed between the partners of the consortium and organises in detail the provisions of the GA in terms of financial issues, payments, management, decision-making, conflict resolution, *intellectual property rights* (IPRs) and liability. The CA must also be kept by the partners and must be shown in case of audits.

3 Management structure and procedures

3.1 Governance structure

The SYNTHEMA governance structure, as depicted in **Figure 1**, was set up to guarantee smooth cooperation and optimal management of all operational, scientific and technical aspects of the project, can be described as follows, in relation to the main project-related functions:

1. **Coordination**, performed by the ***Coordination Team*** **(CT)** including the *Project Coordinator* (PC), *Deputy Coordinator* (DC), *Project Manager* (PM) and *Quality and Risk Manager* (QM).
2. **Decision making**, implemented by the ***Governing Board*** **(GB).**
3. **Operational management**, performed by the ***Steering Committee*** **(SC)**, composed of the CT and *work package leaders* (WPL).
4. **Advisory**, carried out through the ***Data Protection Manager*** **(DPM), the *Ethics Manager* (EM) and the *Ethics and Legal Advisory Board* (EAB)**.

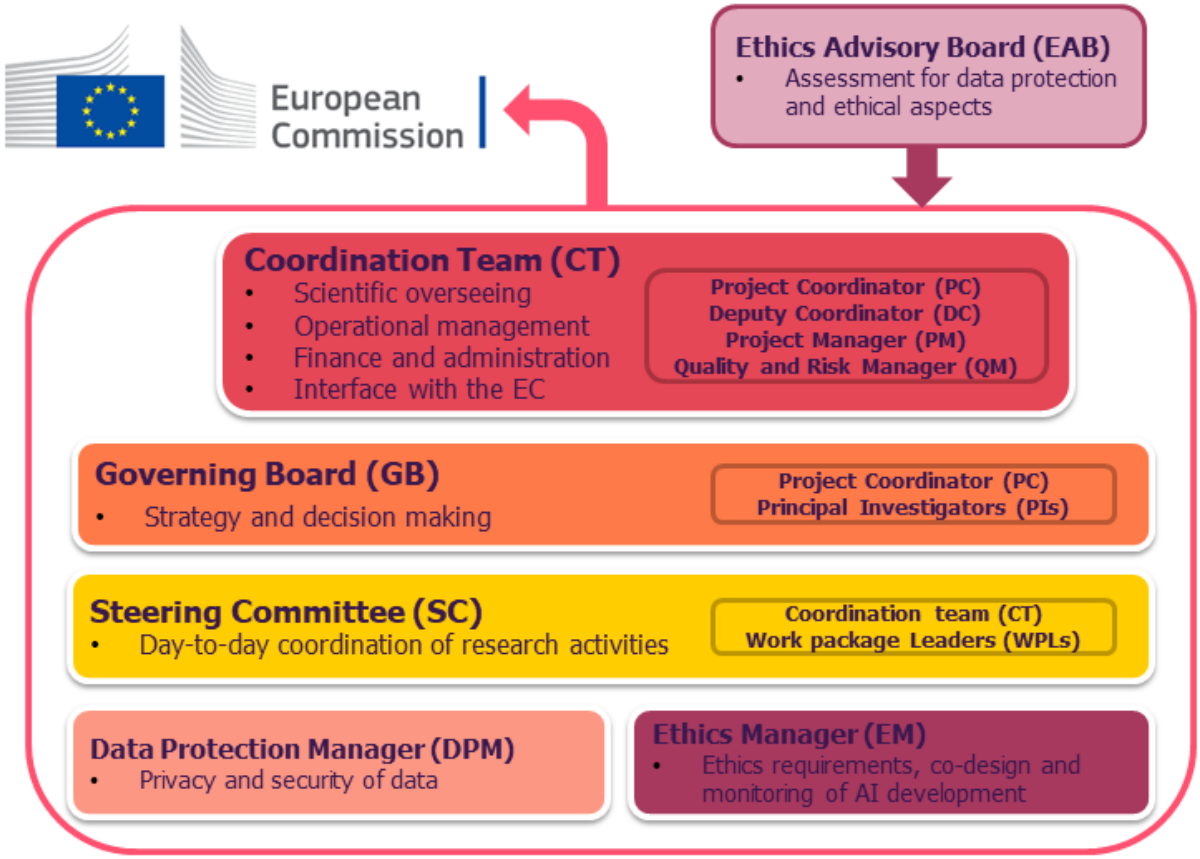

Figure 1. SYNTHEMA management structure.

3.1.1 Coordination

To optimise the overall management of the research action, coordination functions have been distributed as described below, and summarised in **Figure 2**.

- The **PC** coordinates project implementation from a scientific standpoint, ensuring a smooth progress of research activities according to the research plan, the quality of project results and their compliance with project objectives, and acts as intermediary between the consortium and the EC.
- The **DC** supports the PC in the scientific coordination of the project and, in absence of the former, acts on its behalf. It is the main point of reference for administrative and financial issues, and is also involved in operational management, risk monitoring and mitigation.
- The **PM** is the main responsible for the day-to-day management of project activities, quality assurance and risk monitoring, ensuring timely completion of milestones, deliverables and reports, oversight of meetings, interactions between WPs, dissemination activities.
- The **QM** supports the DC and the PM in risk management and mitigation, monitoring project activities and relevant risks and proposing solutions in accordance with the rest of the CT, and is also responsible for assessing the quality of deliverables and reports.

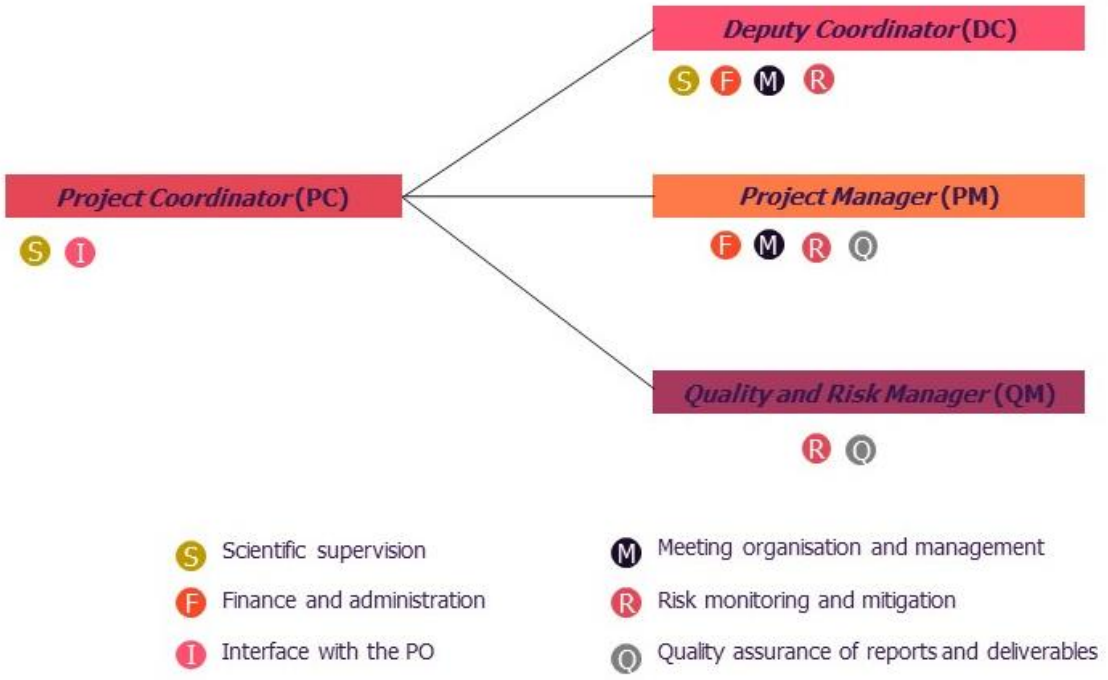

Figure 2. SYNTHEMA coordination team and relevant functions.

3.1.2 Decision making

The **GB** is composed of one representative per partner, usually the *principal investigator (*PI) and is chaired by the PC. It represents **the primary executive, decision making and arbitration body and addresses high-level strategic issues**, such as discussing and approving reallocation of the project budget, major modifications of the work plan and relevant amendments, request of contractual changes to the EC, resolution of conflicts within the consortium. Given its nature of a high decision-making body, the GB can be summoned upon need. A relative majority system is employed, with one vote for each partner.

3.1.3 Operational management

The **SC** is composed of all WPLs and coordinated by the PC, DC and PM and ensures day-to-day management of project activities. It represents the operational body of the project and has responsibility for **day-to-day coordination of specific WP-related activities** as defined in the implementation plan, in close collaboration with respective task leaders.
In each WP, the WPL is responsible for organising WP-related meetings and working groups (WGs), monitoring the timely completion of tasks and deliverables, reporting the achieved progresses, identifying risks and proposing technical solutions. WPLs will refer to the PC and DC for scientific and technical issues and the PM for management matters. The SC takes operational decisions regarding WP management based on the monitoring of milestones and expected results of each WP. It is also in charge of addressing and documenting internal risks which may impair progress toward WP objectives, suggesting strategies to anticipate and minimise potential risks. The SC is also responsible for implementing the decisions agreed by the GB, controlling the execution of the project in line with its agreed work plan, and monitoring corrective actions.

3.1.4 Advisory

The advisory function is operated by the DPM, the EM and the EAB. More specifically:

- The **DPM** is responsible for **overseeing the overall project data flows, including data collection, processing, storage and use**, ensuring compliance with the *General Data Protection Regulation* (GDPR) and relevant national legislation, in compliance with privacy of data subjects and security of data and project infrastructure.
- The **EM** oversees the **ethical aspects related to AI solution development**, as coordinates the collection of requirements for value-sensitive design and ethics-by-design in the development of AI technologies, and the ethical monitoring and assessment of developed technologies.
- The **EAB**, composed of **1 data protection expert, 1 expert in ethics, 1 representative of patient associations**, all external to the consortium, to be identified during the action, will be summoned at specific intervals in the project, ideally at least 3

times, to **assess project implementation and results with regard to data protection and ethical aspects**.

4 Risk monitoring and mitigation

Risk identification is conducted using the **'risk charting approach'**, which focuses on resources, threats, modifying factors and adverse consequences. The assessment uses a classic risk assessment matrix (probability vs severity of consequences) and will be revised and updated throughout the project implementation. Risk management will follow the consolidated ***tolerate, treat, terminate, transfer*** **(4T) model** and treatments that require actions will generate new milestones in the work plan.

As far as the risk management process is adopted, SYNTHEMA adopted a risk management approach aimed at continuously monitoring the risks that may potentially affect project outcomes and to allow a prompt reaction by the relevant project bodies, devising appropriate mitigation strategies and alternative plans.

The risk management process consists of three phases:

1. **Risk identification**: all project partners are concerned with risk detection. When a risk is detected, it is reported to the CT. This activity is performed by each WPL and reported by email or within relevant meetings.
2. **Risk estimation**: once a specific risk is identified, it is assessed and discussed with the relevant partners of the consortium, focusing on risk likelihood and risk impact.
3. **Risk mitigation and follow-up**: once the risk is identified, a specific partner is appointed for its management, monitoring, and reporting, while all the concerned partners are involved in conceiving appropriate mitigation strategies.

An overview of risks and relevant mitigation strategies will be provided in the periodic reports to the EC, while the **risk assessment methodology** is summarised in **Figure 3** below.

Figure 3. Risk management strategy in SYNTHEMA.

The **risk management plan** considers the envisaged risks, severity, WPs involved and mitigation actions as depicted in **Figure 4**. Risk evolution will be assessed monthly, during coordination meetings held by the SC, and during the monthly meetings of each WP, under the supervision of each WPL and the QM, the PM and the DC.

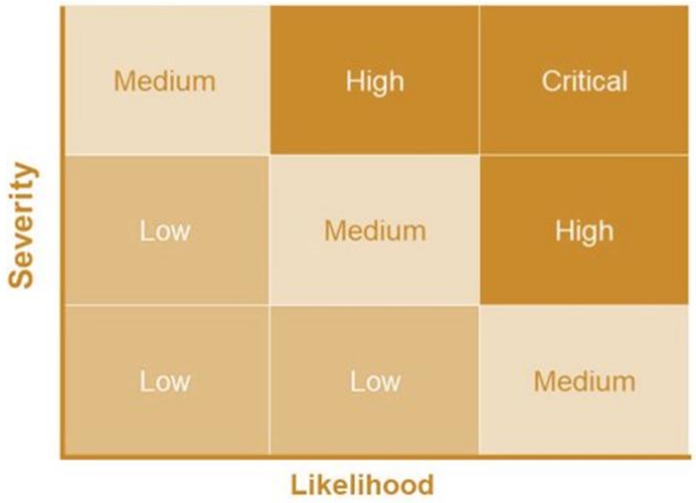

Figure 4. Risk assessment matrix.

Each person contributing to the project will be allowed to report, anonymously if appropriate (e.g., in cases where retaliation is feared), any risks that are not listed in the plan. A preliminary assessment of potential risks carried out by members of the consortium, is documented in **Table 1** below, together with envisaged mitigation steps. Such table, included in the GA and the EC's Participant Portal platform, will be periodically updated in the course of the action, at the latest before periodic reviews.

	Likelihood	Severity	WPs	Proposed mitigation measures
Ethical approval takes longer than planned	Low	High	1,4	Each clinical centre has already prepared similar protocols, so content and local processes are familiar. Time estimates are therefore realistic. Preparation of protocols will actually begin on award of funding, before the planned start date.
Conflict between infrastructure constraints and model requirements	Medium	Medium	2	Early and comprehensive planning to avoid such conflicts. Alternative infrastructure technologies present within the team existing capabilities.
Inadequate retrospective data to inform seed patient population	Low	Medium	1,4	Initial assessment indicates consortium resources are adequate. Clinical partners will engage with collaborating institutions to extend sources, if needed, following appropriate ethical approval.

Data preparation erroneous	Low	Medium	1	Proven methods and concepts of data preparation and analysis will be conducted in parallel to novel approaches. The consortium has a strong track record in EHR processing, proprietary protocols, and algorithms for data preparation.
The disparity between clinical data sources makes it difficult to harmonise them	Medium	High	1	Harmonisation will be tackled from early on in the project, considering the use / extension of partner available data preparation tools with analysis and semantics to facilitate such tasks
Shareable data assets pipeline strategy not flexible enough to integrate all WP3 outcomes	Low	Medium	3	Different flexible pipeline execution pipelines (e.g., Airflow or Prefect) are identified as candidate, but alternatives will be considered and tested from early on in the project.
Poor utility & privacy of generated data assets	Low	High	3	Partners with experience track in anonymisation and SDG. Early evaluation of models, tight collaboration, and contrast with community is planned.
Low visibility/ impact of promotional channels	Medium	Medium	6	The project will analyse the marketing campaigns developed and its performance metrics, identifying the causes and exploring new networks/contact points. This will include participation in relevant events throughout the project lifetime.

Table 1. Critical risks for implementation for SYNTHEMA, as reported in the GA and Participant Portal.

5 Format and structure

The guidelines below represent **a guide for the preparation of any project-related document, including deliverables, reports, presentations**.
Other than in the present deliverable, they are included in the *Deliverable template* document, available in the SYNTHEMA repository in Microsoft Teams.

5.1 Text and titles

All **heading styles** are part of a multi-level list for automatic section numbering.

Normal text is in Tahoma 11pt. This is **emphasized text**.

> This is a quote

Use **capital letters** for **SYNTHEMA.**
Use **sentence case** for **headlines and titles** (e.g., 'Reporting guidelines').

5.2 Acronyms

Acronyms shall be mentioned in *extenso and italic* the very first time in any document, followed by the acronym in capital letters, e.g., *intellectual property right* (IPR).
Then, it can be used only as an acronym for the rest of the document.

5.3 Lists

Lists are defined by bullet points at different levels, as indicated below.

- **First** level bullet list
  - **Second** level bullet list
    - **Third** level bullet list
      - **Fourth** level bullet list

5.4 Figures

About figures, please remember to:

- Always align them in the centre of the page.
- Insert the figure caption below.
- Caption font size should be 10 pt.
- Captions should also be centred on the page.
- Don't forget to include the source if you insert external images.

Figure 5. This is a placeholder image caption.

5.5 Tables

About tables, please remember to:

- Always align them in the centre of the page and autofit to window.
- Insert table caption below.
- Caption font size should be 10 pt.
- Captions should also be centred on the page.
- Don't forget to include the source if you insert external tables.

5.5.1 Basic table

Below is an example of a basic table:

Column 1	Column 2	Column 3	Column 4
Text	Text	Text	Text

Table 2. This is a placeholder basic table caption.

5.5.2 Banded table

Below is an example of a banded table:

Column 1	Column 2	Column 3	Column 4
Text	Text	Text	Text

Table 3. This is a placeholder banded table caption.

5.5.3 Grid table

Below is an example of a grid table:

	Column 1	Column 2	Column 3	Column 4
Row 1	Text	Text	Text	Text
Row 2				
Row 3				

Table 4. This is a placeholder grid table caption.

5.6 References

This is a **standard footnote**[1]. For all references, please use the **Harvard citation style**.

Example:

(Torkzadehmahani et al., 2020)

Torkzadehmahani, R. et al. (2020) 'Privacy-preserving Artificial Intelligence Techniques in Biomedicine', arXiv [cs.CR]. Available at: http://arxiv.org/abs/2007.11621.

5.7 Language

The language reference for all project related documents is **UK English**.

5.8 Software

Microsoft Word, Excel and PowerPoint (2010 or later) are selected as standard tools in order to ensure easy access to the project documents and to reduce potential editorial burdens. All the project documentation to be published or with an external visibility when in their final version, must be released in ***Portable Document Format*** **(PDF)**.

[1] Example footnote

6 Reporting guidelines

The project reporting includes 3 main types of reports:
• **Deliverables**, reporting to the EC work done and results achieved on specific project relevant topics or tasks by a partner/group of partners.
• **Periodic reports**, describing scientific progress and financial aspects relevant to the first (M1-M18), the second (M19-M36) and the third (M37-M48) reporting periods, and are used to monitor project progress and compliance with all contractual obligations.
• **Final report**, that represents a final, high-level summary of project activity and achievements in lay terms, to be used after the end of the project for dissemination purposes.

6.1 Deliverables

Project deliverables as shown below in **Table 5**, defined for each WP in the GA, describe **the work done and achieved results in a defined area, mostly as the result of a specific task**. The following table illustrates all project deliverables (number, name, WP, lead partner, type, dissemination level, due month, due date), in chronological order.

N*	Name	WP	Lead*	Type	Diss level	Due month	Due date*
D6.4	Project website	WP6	AUS	DEC	PU	M3	28/02/2023
D7.1	Quality assurance guidelines	WP7	DW	R	PU	M4	31/03/2023
D5.1	Data management plan	WP5	I-HD	DMP	PU	M6	31/05/2023
D6.1	Impact master plan	WP6	AUS	R	PU	M6	31/05/2023
D1.1	Clinical use cases, eCRF and data quality	WP1	UNIPD	R	PU	M12	30/11/2023
D2.1	System requirements, components and specifications	WP2	UPM	R	SEN	M12	30/11/2023
D7.2	Ethical design requirements	WP7	DW	R	PU	M12	30/11/2023
D1.2	Data and metadata model	WP1	DW	R	PU	M18	31/05/2024
D1.3	Data collection and processing report	WP2	VHIR	R	PU	M24	30/11/2024
D2.2	Federated learning data platform	WP2	UPM	DEM	SEN	M24	30/11/2024
D4.1	Synthetic validation framework	WP4	UNIBO	R	PU	M24	30/11/2024
D5.2	GDPR interim compliance	WP5	I-HD	R	SEN	M24	30/11/2024
D5.4	Data management plan updated version	WP5	I-HD	DMP	PU	M24	30/11/2024
D4.2	Synthetic validation report	WP4	ICH	R	PU	M42	31/05/2026
D5.3	Privacy risk assessment report	WP5	UoS	R	SEN	M42	31/05/2026

D6.3	Exploitation and sustainability plan	WP6	DW	R	SEN	M48	30/11/2026
D3.1	Anonymisation pipeline	WP3	INTRA	R	PU	M48	30/11/2026
D3.2	Synthetic data generation pipeline	WP3	VICOM	R	PU	M48	30/11/2026
D6.2	Dissemination and communication report	WP6	AUS	R	PU	M48	30/11/2026
D7.3	Ethics handbook	WP7	DW	R	PU	M48	30/11/2026

Table 5. List of SYNTHEMA deliverables.

*Please note that, due to some errors occurred during the GA preparation, some deliverable numbers, names, lead partners and due month/date have been reported incorrectly in the GA. While deliverable due dates and months have been corrected in the EC platform, an Amendment is planned to amend for the remaining errors. Any discrepancy you may find with respect to the GA is due to this occurrence. The present table reports the deliverables as they will be corrected in the Amendment.

Most deliverables are written jointly with a range of partners. To optimise the effort for handling such documents, it is important for all participants to follow agreed standards to be used in deliverable editing and exchange.

6.1.1 Naming

It is important to follow a specific format of file naming in order to avoid losing track of their circulation. This is especially important for documents that require numerous contributions from different partners and may circulate frequently within the consortium.

All deliverables shall be named as follows:
SYNTHEMA_Dx.y_Title of deliverable_vk.h

To explain the place holders:

- **Dx.y = deliverable number**
  - x = number of the Work Package associated
  - y = sequential number as in the DoA

- **vk.h = version number + subversion (e.g., 1.0, 1.1, 3.0)**
  - 0 for draft versions before submission to the EC (e.g., v0.1, v0.2, etc.)
  - ≥1 for document submissions to the EC (e.g., v1.0, v2.0, etc.)

6.1.2 Document history

- The **partner responsible for a deliverable (lead partner)** is also responsible for the control of the versions produced and manages and updates the main document.

- All deliverables shall include a **document revision history,** as shown in **Table 6** , including the various versions and the contributions collected from the partners. The table below shall figure on the first pages of each deliverable.

Versio	Date	Description of change	Contributor(s)
v0.1	23-01-2023	1st version of deliverable template	Arantxa Echarte (AUS), Diana López (AUS)

Table 6. Document history table for deliverables.

6.1.3 Preparation, peer review and submission process

Deliverables follow a **2-month preparation, review and refinement process** before being submitted to the EC portal, as described below.

6.1.3.1 Preparation

Each deliverable shall be prepared by a ***deliverable author*** **(DA)** that is **responsible for its drafting, revision and completion** and who will coordinate relevant interactions with contributor and review partners involved.

Before starting its drafting, the DA should define **the structure (i.e., the table of contents) with the expected contributions from each partner** and will propose, discuss and agree the schedule for the development of the deliverable with all partners involved.

The drafting of the deliverable shall be started at the latest **8 weeks before the deliverable due date**, and a first, complete draft shall be ready for review at least **4 weeks before the due date.**

Deliverables shall be prepared following the **SYNTHEMA deliverable template**, available in the SYNTHEMA repository on Microsoft teams and the relevant **format and structure standards**, included in the template as well as in the **Format and structure** section of this document.

Deliverables shall be circulated to the consortium by uploading them in the **SYNTHEMA repository on Microsoft Teams and circulating the relevant link** for collaborative preparation and review.

6.1.3.3 Peer-review process

To achieve the highest possible quality of project outcomes, a**ll deliverables must undergo a peer review process** before they are submitted to the EC or shared with any other external party (e.g., Advisory Board, research community).

The peer review process has been set up in order to **obtain and guarantee the quality of the deliverables** (i.e., documentation, reports, software modules, prototypes, etc.) that will be produced during the course of the project and delivered to the EC, and more globally to the potential research community and industry.

The review will consider the following criteria:

1. **Technical and scientific approach and content.**
2. **Consistency with (a) the overall scope and strategic objectives of the project, (b) previous documentation, and (c) formal requirements** established in the GA and CA.
3. **Internal logical coherence**, e.g., clear link between the methodology, results and conclusion.
4. **Format and quality of the document(s)**, including layout, format, language and grammatically correct English.

The **quality and acceptance criteria** for deliverables shall also include:

- **Coherence** (e.g., uniform and standardised templates and terminology applied)
- **Conciseness** (e.g., concise information)
- **Completeness** (e.g., complete document with all the necessary information included)
- **Traceability** (e.g., investigating the origin and connections of information)

The reviewers must provide **detailed comments on the specific parts of the deliverables**, particularly if changes are suggested.

All deliverables will be evaluated by

- At least **2 internal reviewers (IRs)**, particularly the **WP leader or another task leader of the WP**, and a **second partner with a different expertise**. Other reviewers may be asked to further review the deliverable, if necessary. IRs for each deliverable have been assigned to ensure an even distribution of efforts and are reported in **Table 7** below.
- At least **2 members of the CT**, and more specifically the DC, and the PM and/or the QM.

Deliverable	1st IR	2nd IR
D1.1 - Clinical use cases, eCRF and data quality (UNIPD, R, PU, M12)	CHA	VICOM
D1.2 - Data and metadata model (DW, R, PU, M18)	VHIR	UPM
D1.3 - Data collection and processing report (VHIR, R, PU, M24)	ICH	AUS
D2.1 - System requirements, components and specifications (UPM, R, SEN, M12)	UNIBO	APHP
D2.2 - Federated learning data platform (UPM, DEM, SEN, M24)	SBA	GLSMED
D3.1 - Anonymisation pipeline (INTRA, R, PU, M48)	UPM	CHA
D3.2 - Synthetic data generation pipeline (VICOM, R, PU, M48)	SBA	UMCU
D4.1 - Synthetic validation framework (UNIBO, R, SEN, M24)	ICH	UNIPD
D4.2 - Synthetic validation report (ICH, R, SEN, M42)	INTRA	APHP
D5.1 - Data management plan (i~HD, R, PU, M6)	UoS	GLSMED
D5.2 - GDPR interim compliance assessment report (i~HD, R, SEN, M24)	UoS	UPM
D5.3 - Privacy risk assessment report (UoS, R, SEN, M42)	i-HD	UMCU
D6.1 - Impact master plan (AUS, R, PU, M6)	DW	UNIPD
D6.2 - Dissemination and communication report (AUS, R, PU, M48)	DW	VHIR
D6.3 - Exploitation and sustainability plan (DW, R, SEN, M48).	AUS	INTRA
D6.4 – Project website (AUS, R, PU, M3)	DW	UPM
D7.1 – Quality assurance guidelines (DW, R, PU, M4)	ALL	
D7.2 - Ethical design requirements (DW, R, PU, M12)	i-HD	UNIBO
D7.3 - Ethics handbook (DW, R, PU, M48)	VICOM	VHIR

Table 7. Deliverable assigned internal reviewers' (IR) scheme. The 1st IR is the WP leader or – if the WP leader is already the deliverable author (DA) - another partner contributing to the WP. The 2nd IR is another partner in the consortium.

Peer reviewers are **notified at least 8 weeks ahead the deadline by the DA** and, once received the deliverable draft, required to **review the document within 7 days after receiving the deliverable from the DA**. In case of any expected delay, peer reviewers should notify the DA immediately. During the peer review process, peer reviewers are encouraged to discuss the problems identified in the deliverable with the DA.

If minor of substantial revision is necessary, the **DA should make changes and produce the final version of the deliverable** before due submission date.

The **final responsibility for the content of the deliverable remains with the DA** and it is thus its final decision about how to address and integrate the feedback from the peer reviewers.

The final version of the deliverable must be released **at least 2 weeks prior to be delivered to EC** for internal review for all interested consortium partners.

6.1.3.4 Submission

Each deliverable needs to be submitted to the EC, at the latest on the due date, and get preliminary approval from the *Project Officer* (PO). Final acceptance of documents is obtained at the subsequent periodic review by EC's appointed reviewers as shown in **Figure 6.** Preparation, peer review and submission process for deliverables involving the deliverable author (DA), internal reviewers (IRs), coordination team (CT) including Deputy Coordinator (DC), Project Manager (PM) and Quality and Risk Manager (QM)..

If project deliverables are not accepted, the payment can be delayed. **It is thus in the interest of all concerned partners that documents are produced according to the quality standards and on time.**

Figure 6. Preparation, peer review and submission process for deliverables involving the deliverable author (DA), internal reviewers (IRs), coordination team (CT) including Deputy Coordinator (DC), Project Manager (PM) and Quality and Risk Manager (QM).

6.2 Periodic reports

Periodic reports **official reports to be submitted within 60 days following the end of each reporting period (i.e., M18, M36, M48) via the EC Grant Management Portal**, using forms and templates provided in the electronic exchange system. They describe **in detail the scientific activity carried out during a given reporting period with respect to the objectives of the action and the workplan, as well as the use of PMs and financial resources** spent to conduct such activity.

In SYNTHEMA, periodic reports will be prepared at **M18, M36 and M48**, in correspondence with **the first (M1-M18), the second (M19-M36) and the third (M37-M48) reporting period**.

Periodic reports are composed of **(1) a technical report (TR)**, to report scientific progress of the project in each WP, including issues and risks, and prepared through a dedicated Microsoft Word template provided by the EC and then submitted via PDF on the Grant Management Portal, and **(2) a financial report (FR),** including requests for payment, that is arranged for each partner in a dedicated section of the Portal, that shall be compiled online, submitted by each partner and validated by the Coordinator before the submission of periodic report. All financial statements must be drafted in euro (required conversions must be done previously). The instructions to complete the forms and templates will be sent by the CT in due time.

6.2.1 The periodic technical report

This part can be further divided into two parts, **Part A and Part B**.

- **Part A** is automatically generated by the IT system based on the information entered by the participants in the electronic exchange system in the Participant Portal, and includes the cover page, a summary for publication, and answers to the questionnaire related to the project implementation and the economic and social impact.
- **Part B** is the narrative part that includes the description of the work carried out by partners, including progress overview towards the objectives of the action, including milestones and deliverables, justification and explanation of differences between expected and carried out work, compared with objectives, deliverables and milestones defined in the DoW. This part also includes a report of dissemination exploitation, dissemination and communication activities (i.e., summary for publication by the EC, answers to the action implementation and economic and social impact questionnaire, and key performance indicators).

To achieve that, the PM sends a WP form to be compiled by WPLs with the support of TLs and sent to the CT, that integrate and consolidate the provided information and sends the complete

periodic technical report to the consortium for review. The final approved version is uploaded as a PDF document into the Participant Portal by the PC.

6.2.2 The periodic financial report

The financial report is a **financial statement compiled by each partner covering the entire reporting period**, where eligible costs are detailed for each budget category, including justification for the use of resources and information on subcontracting (if any) and in-kind contributions provided by third parties. Amounts not declared in financial statements will not be considered by the EC.

A periodic summary financial statement is automatically created by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and includes the request for interim payment.

The CT will have a final check on the statements and accept or revoke them and ask for clarifications and resubmission by the concerned partner(s), if needed. If any of the partners fails to respect the deadlines, the CT will submit the PR on time.

Missing data from one or more partners will not be considered. This procedure ensures to avoid delays in the payment of other partners. If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

Once the complete PR has been verified and deemed correct and complete, the CT submits it to the EC participant portal.

6.2.3 Preparation, review and submission

The preparation, review and submission process will be structured as follows.

1. At the end of each reporting period (8 weeks before deadline), **the CT (DC and PM)** circulates an initial **template of the technical report**, asking **WPLs** for contributions on the respective WPs, and requesting all **PIs** to prepare the financial report on the EC portal.
    - The **CT** is responsible for preparing the **general sections of the report** (e.g., introduction, compliance with the objectives of the action, deviations from the workplan, etc.).
    - **WPLs** coordinate the reporting of the relevant WPs, in strict collaboration with **task leaders**, that will be asked to describe the activity of relevant tasks.
    - **PIs**, in cooperation with their **financial officers**, are responsible for compiling the financial report for each partner in the EC portal.
2. After 4 weeks, the **CT finalises the 1st draft of the technical report** and asks **WPLs** to review the draft, and starts reviewing the financial part, asking **PIs and financial officers** to adjust their reports in case some errors or inconsistencies occur.

3. After the needed rounds of revision, 2 weeks ahead deadline **the technical report is shared with ALL partners** for final review, refinement and consolidation, and further integrations and revisions are asked to **PIs** if necessary.
4. At the latest 1 day before deadline, the **CT finalises the report** and submits it through the EC Portal.

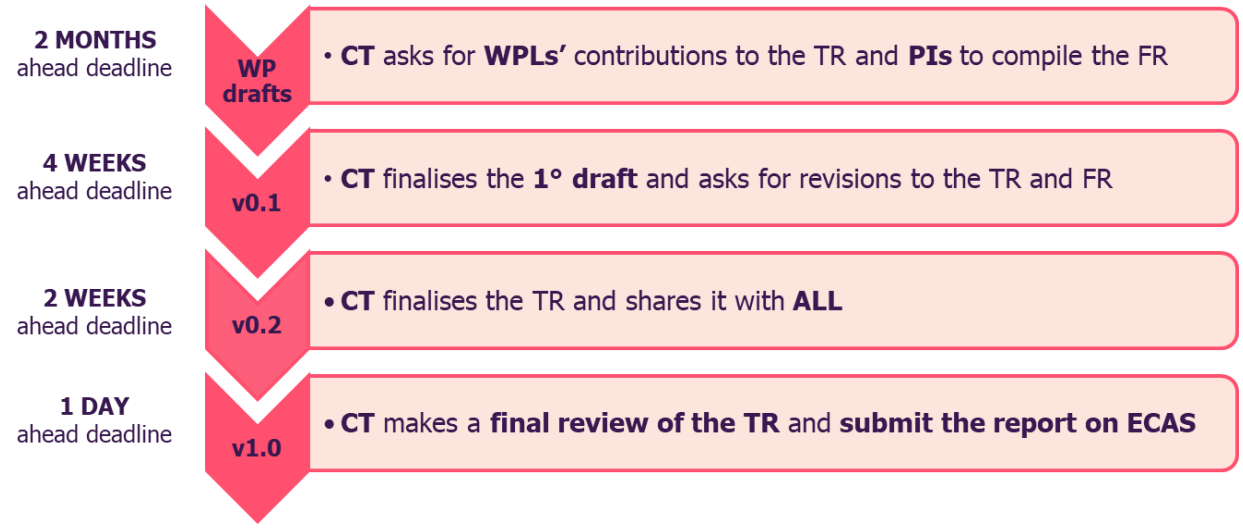

Figure 7. Preparation, peer review and submission process for periodic reports, involving CT, WPLs, PIs.

6.3 Final report

In addition to the periodic reports, the **final report is delivered at the latest 60 days after the end of the 3rd reporting period (M48)** and includes:

1. **a technical report** in the form of a **summary for publication**, including overview of the work carried out, results overview, foreseen socio-economic impacts, exploitation and dissemination potential.
2. **a financial report**, including **a final summary financial statement**, automatically created by the electronic exchange system, consolidating the individual financial statements for all reporting periods and including the request for payment of the balance; a financial statement certificate for each beneficiary as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices.

6.3.1 Preparation, review and submission

The preparation, review and submission process will be structured similarly to the periodic reports, with some minor differences as described in **Figure 8.** Preparation, peer review and submission process for the final report, involving CT, WP6L, PIs..

1. At the end of the project, the **CT (DC and PM)** prepares a first draft of the **technical report**, in close collaboration with **WP6L**, and requests all **PIs** to revise the financial reports in cooperation with their **financial officers**, are responsible for compiling the financial report for each partner in the EC portal.
2. After 4 weeks at the latest, the **CT finalises the technical report** and asks **PIs** to review the draft, and starts reviewing the financial part, asking **PIs and financial officers** to adjust their reports in case some errors or inconsistencies occur.
3. After the needed rounds of revision, 2 weeks ahead of the deadline **the technical report is shared with ALL partners**, and further integrations and revisions are asked to **PIs** if necessary.
4. At the latest 1 day before the deadline, the **CT finalises the report** and submits it through the EC Portal.

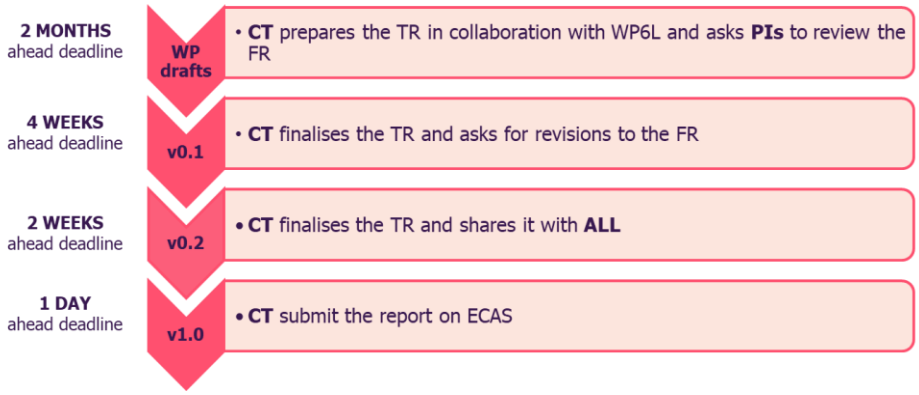

Figure 8. Preparation, peer review and submission process for the final report, involving CT, WP6L, PIs.

7 Dissemination documents

Dissemination documents include **(1) publications**, such as **peer-review publications** (e.g., research articles and reviews in peer-reviewed journals, conference papers) as well as **generalist publications** (e.g., press releases, newspaper articles, magazine articles, white papers, newsletters, blog posts, etc.). Also, dissemination documents include shorter documents such as **(2) abstracts, posters and ppts**.

7.1 Publications

For longer publications, including peer-review (journal articles, conference papers) and generalist publications (e.g., press releases, white papers, newsletters, blog posts) the preparation, review and submission process can be described as per **Figure 9**, and below.

- **Preparation**: each publication tackles a specific subject and must have a *publication editor* (PE) who coordinates the production of the specific interaction as necessary with the other partners involved.
- **Review**: before they are shared with any other external party, at least 30 calendar days before the expected submission, the publication is shared with ALL consortium partners to be assessed against the following criteria:
  1. **IP and confidentiality issues**, by the CT as well as individual partners for what concerns their joint IP.
  2. **Acknowledgment of EU funding**: the CT shall check the presence of acknowledgment of EU funding through the statement *"SYNTHEMA is an initiative funded by the European Union's Horizon Europe Research and Innovation programme under grant agreement N° 101095530"*.
  3. **Open access**: the CT shall also check whether open access of the publication is foreseen, either via gold route (i.e., submission to an open access/hybrid journal in open access) or green route (i.e., via Zenodo or other submission archive).

- **Submission:** If no objection is made by **1 week before expected submission,** the publication is permitted.

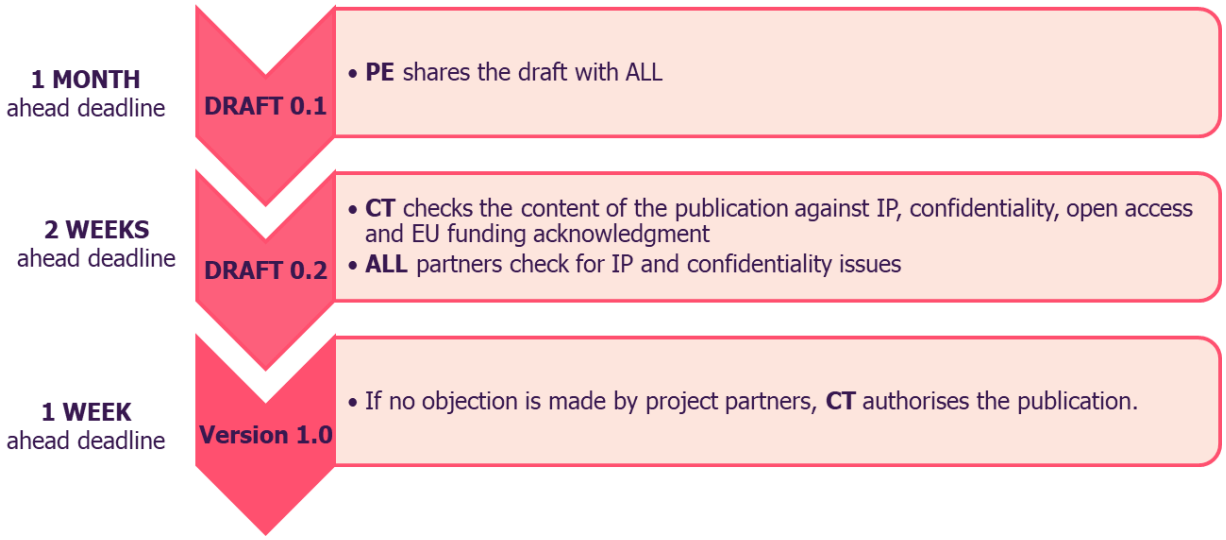

Figure 9. Preparation, peer review and submission process for publications, involving ALL partners.

7.2 Abstracts, poster and presentations

For shorter publications, such as **abstracts, posters and presentations**, the procedure is similar to beforementioned and shown in **Figure 10**.

- **Preparation**: the 1° draft shall be shared by the PE with the TC within 1 week ahead deadline at the latest.
- **Review**: within 3 days ahead deadline, the CT revises the draft against the following criteria:
  1. **IP and confidentiality issues**.
  2. **Acknowledgment of EU funding**: the CT shall check the presence of acknowledgment of EU funding through:
     - The banner with the EU flag and the phrase "*Funded by the European Union", and*
     - The statement *"SYNTHEMA is an initiative funded by the European Union's Horizon Europe Research and Innovation programme under grant agreement N° 101095530".*
- **Submission:** If no objection is made by **1 day before deadline**, the publication is permitted, and the document is shared with **ALL** partners.

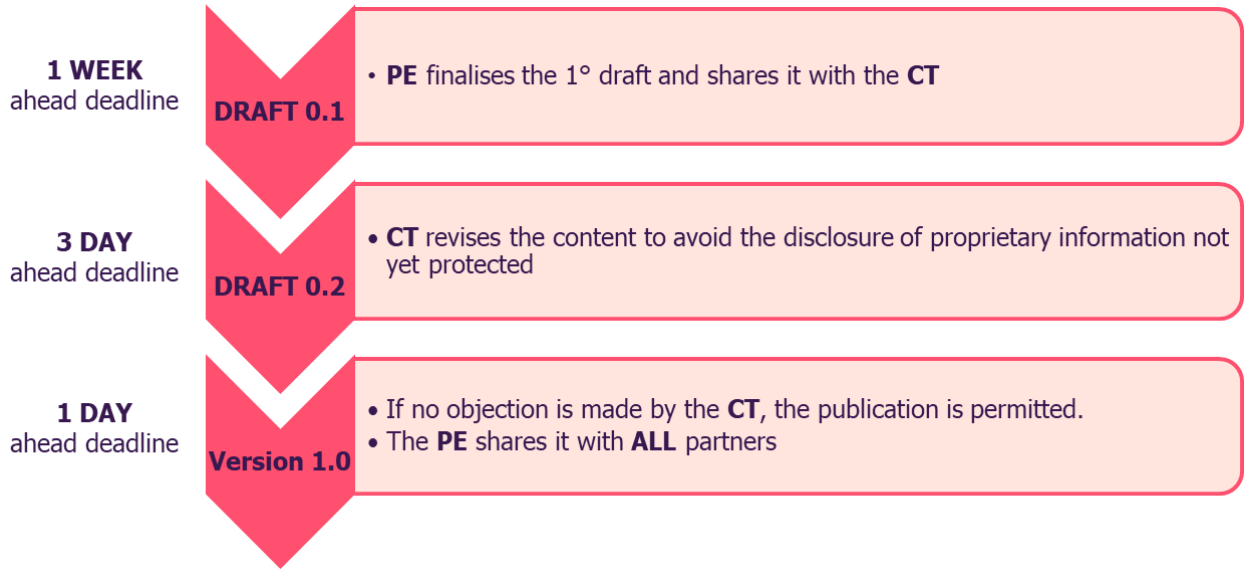

Figure 10. Preparation, peer review and submission process for abstracts, posters and presentations, involving ALL partners.

8 Self-assessment plan

The aim of the self-assessment plan is to **identify a clear set of criteria to evaluate the progress of the project activities and relevant outcomes**, allowing us to compare the actual results with the expected results at significant project time points (M18, M36, M48).
To achieve that, each **WPL has been asked to define, for each task, quantitative and qualitative KPIs and relevant target values, for acceptable and optimal results, together with relevant means of verification at the foreseen self-assessment check points**. Following this approach, the consortium has a clear tool for understanding the current implementation level of the project, making it possible to acknowledge the existence of delays or issues and timely design and put in place appropriate mitigation strategies. At the same time, the self-assessment plan constitutes an objective tool for evaluation and understanding of the project status for external reviewers.

The procedure can be described as follows:

1. Each WPL, in coordination with TLs, has defined for each task **relevant measurable units, processes or outcomes**. Both qualitative and quantitative indicators have been used, depending on the nature of the specific task.
2. A subsequent series of **correlated quantitative indicators (KPIs)** have been defined as the expected outcome in **specific time-points of the project (M18, M36, M48)**, one for the minimum acceptable result, and one for the optimal result.
3. For each KPI, relevant **means of assessment** were indicated to clearly define the assessment procedure specific for each indicator at the scheduled time points.

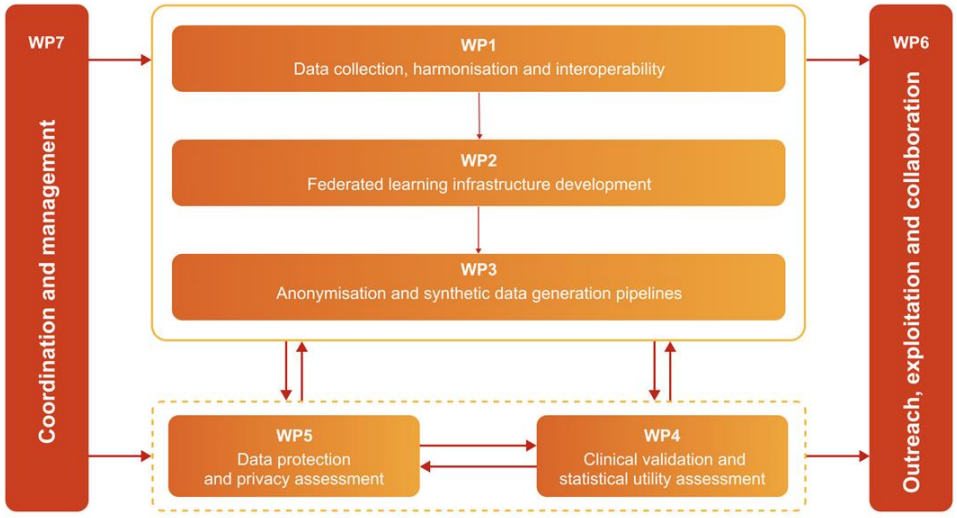

Figure 11. SYNTHEMA pert.

As a result, it will be possible to **compare the actual results at a certain time-point of the project with the forecast results defined in the self-assessment**, thus having a clear and immediate understanding of the progress of the project compared with the initial plan. The list of KPIs for each WP and means of verifications is reported in **Table 8**.

WP (Lead)	Task (Lead)	Measurable units	KPIs (acceptable – optimum)		
			M18	M36	M48
WP1 Data collection, harmonisation and interoperability (VHIR, M1-M24)	T1.1: Clinical use case design and outcome definition (UNIPD, M1-M12)	• Definition of clinical aims for AI application for each use case (SCD, AML) • Definition of user requirements for clinicians (clinical research and care) • Definition of user requirements for AI developers (AI development, training and validation)	3 – 5 clinical aims 5 – 10 user requirements 5 – 10 user requirements	-	-
	T1.2: Electronic clinical report form and data quality plan (VHIR M1-M12)	• Definition of data variables (clinical records, omics and imaging) and n° of patients/samples for each use case (SCD, AML) and clinical centre (VHIR, ICH, UMCU, APHP, CHA, UNIPD, GLSMED LH)	4 – 7 clinical centres characterised	-	-
	T1.3: Data model and transformation plan (DW, M13-M18)	• Definition of 1 OMOP data model per use case (SCD, AML)	2 OMOP data models	-	-
	T1.4: Ethical clearance, data collection and processing (VHIR, M1-M24)	• Ethical clearance documentation submitted by each clinical centre (VHIR, ICH, UMCU, APHP, CHA, UNIPD, GLSMED LH) • Ethical clearance obtained at each clinical centre research ethics committee (VHIR, ICH, UMCU, APHP, CHA, UNIPD, GLSMED LH)	5 - 7 clinical centres 4-5 clinical centres	7 clinical centres 7 clinical centres	-

WP2 Federated learning infrastructure Development (UPM, M1-M24)	T2.1: System requirements, components and specifications (UPM, M1-M12)	• Percentage (%) of system requirements envisioned w.r.t. final amount • Percentage (%) of architectural design coverage	95 - 100 % requirements gathered 65 – 80 % design **fully** covers all modules except for SMPC and DP	100 % requirements gathered 100 % full design specifications	-
	T2.2: FL framework organisation and deployment (UPM, M7-M18)	• N of milestones (agile periods) • N of nodes integrated into the federation	2 - 4 milestones fully accomplished in GitLab 3 – 4 nodes integrated	6 – 8 milestones fully accomplished in GitLab 6 nodes integrated	-
	T2.3: SMPC module development (INTRA, M13-M18)	• Level of integration of SMPC with FL	SMPC experimental testbed	Partial – full integration of SMPC with FL	-
	T2.4: DP process development (SBA, M13-M18)	• Level of integration of DP with FL	DP experimental testbed	Partial – full integration of DP with FL	-
	T2.5: Integration of platform components and interactions (INTRA, M19-M24)	• Percentage (%) of modules integrated into CI/CD	50 – 60 % modules integrated	80 – 100 % modules integrated	-

WP3 Data anonymisation and synthetic data generation pipelines (VICOM, M7-M48)	T3.1: Shareable data assets pipeline (VICOM, M7-M48)	• N of anonymisation pipeline for SCD	1-2 x Market-based anonymisation pipelines for SCD	1-2 x Innovative anonymisation pipeline for SCD	
		• N of anonymisation pipeline for AML	1-2 x Market-based anonymisation pipelines for AML	1-2 x Innovative anonymisation pipeline for AML	
		• N of SDG pipeline for SCD	1-2 x non-FL trained SDG for clinical (tabular data) for SCD	1-2 non-FL trained SDG for image data 1-2 x non-FL trained SDG for omics data (tabular data) for SCD	1-2 x FL trained SDG (tabular data) for SCD
		• N of SDG pipeline for AML	1-2 x non-FL trained SDG for clinical (tabular data) for AML	1-2 x non-FL trained SDG for omics (tabular data) for AML	1-2 x FL trained SDG (tabular data) for AML
	T3.2: Anonymisation engine for target data modalities (INTRA, M13-M24).	• N of anonymisation pipeline for SCD	1-2 market-based minimization techniques for SCD	1-2 market-based anonymisation techniques for SCD 0-1 innovative anonymisation technique for SCD	-
		• N of anonymisation pipeline for AML	1-2 market-based minimization techniques for AML	1-2 market-based anonymisation techniques for AML 0-1 innovative anonymisation	

				technique for AML	
	T3.3: SDG engine for target data modalities (VICOM, M13-M24)	• N of clinical SDG algorithms in engine for SCD • N of clinical SDG algorithms in engine for AML • N of tabular genomic SDG algorithms in engine for SCD • N of tabular metabolomic SDG algorithms in engine for SCD • N of tabular genomic SDG algorithms in engine for AML	1-3 clinical SCD 1-3 clinical AML	1-3 SCD MRI-ED-T1, FLAIR and DWI AML HPI 1-3 tabular based on omics SCD 1-3 tabular based on omics AML	-
	T3.4: Federated training of SDG models (SBA, M25-M36)	• N of federated SDG models trained	1-2 federated SDG algorithms for tabular data	1-2 federated SDG algorithms for Genomic and metabolomics data 1-2 federated SDG algorithms for image feature data 0-1 federated SDG algorithms for image data	-
	T3.5: In-silico modelling of optimal treatments (UPM, M13-M42)	• N of clinical in-silico modelling of optimal treatments for AML • N of clinical in-silico modelling of optimal treatments for SCD	-	1-2 AML preliminary distributed implementations 1-2 SCD preliminary distributed implementations	1-2 AML federated implementations 1-2 SCD federated implementations

WP4 – Clinical validation and utility assessment (ICH, M7-M42)	T4.1: Identification of specific data domains of interest for clinical validation (ICH, M7-M12)	• Common and disease-specific data domains for clinical validation • Validation measures for synthetic data	3-5 common 2-5 per use case 2-4 common 3-6 per use case	-	-
	T4.2: Definition of research questions of clinical relevance (ICH, M13-M18)	• Validation methos defined for each use case (SCD, AML) • Outcomes to test the reliability of synthetic data in clinical research defined	5-10 per use case 6-10 per use case	-	-
	T4.3: Definition and implementation of the synthetic validation framework (UNIBO, M19-M42)	• Metrics for the validation of different synthetic data types applied	-	5-10 per use case	
	T4.4: Clinical meaningfulness of synthetic data (ICH, M25-M42)	• Methodologies applied for the comparative assessment of the performance of synthetic data vs real data for patient stratification-based outcome prediction	-	1-3 applies per use case	4-6 applied per use case

WP5 – Privacy and security assessment (UoS, 1-48)	T5.1: Data flow assessment for data protection and governance (i~HD, M1-M6)	• Data flows described • Data management plan • Data protection impact assessment	As required 1 Draft	-	-
	T5.2: Legal and regulatory privacy and security compliance (i~HD, M7-M48)	• Data protection impact assessment • Additional legal agreements • Codes of practice and policies	Initial As required As required	As required As required As required	As required As required As required
	T5.3: Privacy risk classification (UoS, M7-M12)	• Privacy risk factors identified • Qualitative risk assessment framework • Developed/extended (impact & likelihood) • Taxonomy of risk factors created	As required As required As required As required	-	-
	T5.4: Privacy metrics for the evaluation of FL, anonymised and synthetic data (SBA, M7-M12)	• Techniques to assess privacy of FL, anonymised and synthetic data evaluated and developed	As required	-	-
	T5.5: Privacy risk modelling, simulation and assessment implementation (UoS, M13-M42)	• Updated knowledgebase including privacy risks • Models of information system(s) • Risk assessments of information system(s)	As required As required As required	As required As required As required	As required As required As required

WP6 Outreach, exploitation and collaboration (AUS, M1-M48)	T6.1: Stakeholder collaboration framework (AUS, M1-M48)	• Stakeholder collaboration framework defined • Agile marketing lab framework defined and applied	As required Defined and iterated	As required (further expanded) Further iterated	As required (further expanded) Further iterated
	T6.2: Dissemination and communication (AUS, M1-M48)	• Website and social media ○ Unique visitors to the website ○ N of social media followers (Twitter, LinkedIn, YouTube) • Publications ○ Peer-reviewed scientific publications in journals and conferences ○ Awareness publications • Events ○ N of scientific events, webinars and workshops participated ○ N of webinars/workshops (co-)organised • Newsletters ○ N of newsletters (produced+referrals) • Communication materials ○ Logo ○ Banner for acknowledgment EU funding ○ PPT template ○ Infographics • Videos ○ n of videos produced • Open access: n of assets uploaded	150-200 800-1000 1-2 2-3 15-25 1-3 2-4 1-2 1-1 1-1 1-5 1-4 1-4	180-250 900-2000 2-3 3-4 20-35 2-5 3-8 1-2 1-1 1-1 4-8 3-5 3-7	250-300 2000-2500 3-5 4-7 35-50 5-7 8-12 2-2 1-1 1-1 8-10 5-6 6-11

	T6.3: Innovation management, exploitation and sustainability (DW, M13-M48)	• Project *key exploitable results* (KERs) defined • Exploitation and business plan for the platform • Value proposition defined	-	Initial set of potential KERs defined Initial concept Initial concept	Completed set of KERs defined Final exploitation and business plan defined Final value proposition for (1) clinical centres for research and care (2) research institutions, industries and SMEs
	T6.4: Training programmes (VHIR, M13-M48)	• Training programmes defined for healthcare professionals defined • Training programmes defined for patients	-	First concept defined First concept defined	Finalised and implemented Finalised and implemented

WP7 Coordination and management (UPM, M1-M48)	T7.1: Scientific and technical coordination (UPM, M1-M48)	• Definition of the research strategy	Initial definition	Updated as required	Updated as required
	T7.2: Financial, administrative and contractual coordination (UPM, M1-M48)	• GA finalised • CA finalised • Financial allocations	Finalised Finalised 1st instalment distributed	NA NA 2nd instalment distributed	NA NA Final instalment distributed
	T7.3: Operational management (DW, M1-M48)	• Project archive • Definition of *working groups* (WGs) and mailing lists • Consortium meetings • Project reports and deliverables (in due time)	Implemented Implemented 3-4 onsite/online As required	Updated as required Updated as required 5-7 onsite/online As required	Updated as required Updated as required 7-9 onsite/online As required
	T7.4: Quality assurance, risk management and mitigation (DW, M1-M48)	• Quality assurance guidelines delivered • Self-assessment KPIs defined • Risk assessment plan update iterations	Finalised Finalised 1-3 iterations	NA NA 2-6 iterations	NA NA 3-8 iterations
	T7.5: Ethical assessment framework development and implementation (DW, M1-M48)	• Identification of different stakeholder values to be embedded in the design of technologies • Identification of the risk category under the AI act • Tailor-made measure for social acceptance identified	At least 7 different stakeholders group mapped and respective values identified	Risk category under the AI Act identified At least 3 workshops with technical partners carried out, to embed values in the design of technologies	1 Policy recommendations framework for risk management processes to comply with the AI Act delivered to consortium and policy makers

Table 8. Self-assessment KPIs for each WP and task.