

CLARA

Center for Artificial Intelligence and Quantum Computing in System Brain Research

Deliverable 1.5

Title: Risk Assessment and Quality Plan

Project Number: 101136607

Project Acronym: CLARA

Call: HORIZON-WIDERA-2023-ACCESS-01



Funded by
the European Union





Project title	Center for Artificial Intelligence and Quantum Computing in System Brain Research (CLARA)	
Grant Agreement Nr.	101136607	
Funding scheme	HORIZON Coordination and Support Actions (CSA) Call: HORIZON-WIDERA-2023-ACCESS-01 Topic: HORIZON-WIDERA-2023-ACCESS-01-01-two-stage - Teaming for Excellence	
Project duration	1 November 2024 - 31 October 2030 (72 months)	
Project Coordinator	INDRC – International Neurodegenerative Disorders Research Center	
Deliverable number	D1.5	
Title of the deliverable	Risk Assessment and Quality Plan	
WP contributing to the deliverable	Workpackage 1	
Deliverable type	R R: document, report; DEM: Demonstrator, pilot, prototype, plan designs; DEC: Websites, patents filings, press & media actions, videos, etc.; OTHER: Software, technical diagram, etc.	
Dissemination level	PU PU = Public, fully open, e.g. web; CONFIDENTIAL-C; RESTRICTED-R; SEN – Sensitive	
Due submission date	31 January 2025 (M03)	
Actual submission date	31 January 2025 (M03)	
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Document Status – History of Changes

Version	Date	Contributor(s)	Description of Changes
v01	10/01/2025	Vít Vondrák	First draft
v02	20/01/2025	all contributors	Compliance with the kick of meeting minutes - approval process of the project outputs
v03	23/01/2025	all contributors	spell check, proofreading
v04	24/01/2025	Anna Němcová, Stephan Hachinger	New Template, internal review
v10	31/01/2025	Vít Vondrák	Final amendments and revisions
v20	31/01/2025	Vít Vondrák	Final version approved at the WP level
v30	31/01/2025	Vít Dočkal	Final version approved by the CLARA Interim Director
FINAL	31/01/2025	Vít Dočkal	Submitted

Document Keywords

Confidentiality

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Abbreviations

Abbreviation	Description
WP	Work package
DoA	Grant agreement Annex 1 Description of Action
PCA	Project Consortium Agreement
GPM	General Project Manager
EC	European Commission
KPIs	Key Performance Indicators
ToC	Table of Contents

Executive Summary

The purpose of this document is to define how risk assessment and quality management will be carried out during the CLARA project, in order to ensure high quality of project outputs and eliminate detected risks.

This is a CLARA project document; it is primarily intended for WP Leaders and those who are leading activities within the project.

1 Introduction

To ensure efficient risk assessment and high level of quality management within the project, we propose following key measures:

- to establish a quality assurance procedure, including peer review of outputs, i.e. deliverables and milestones;
- to organise ongoing monitoring of the project progress, methodology and supervision of project tasks, milestones, budget, etc.;
- to assess the expected impact of issues that could affect the project implementation in terms of delays, quality of work, derived impacts on other activities, etc.;
- to identify risks and propose backup or mitigation solutions (crisis planning).

The WP and Task Leaders will be responsible for the actual technical tasks and progress of the WP and will report to the Director of CLARA.

The Project Coordinator (INDRC) will take responsibility for the technical, administrative and financial aspects, results and overall performance of the consortium. The INDRC (supported by the WP Leaders and the respective Work Group) will also be responsible for coordinating the procedures for quality and safety assurance. Quality and risk assessments will be carried out continuously throughout the project. The results of risk management will be part of the Internal Progress Report and official Periodic Reporting.



2 Project Governance Structure

CLARA was established as an independent accounting unit of INDRC, representing an interdisciplinary and distributed center of excellence primarily focused on the application of advanced methods and technologies of artificial intelligence, machine learning, and quantum and supercomputing tools to address the etiology of neurodegenerative diseases.

The following bodies defined in the DoA and PCA were established by the CLARA Statute, approved on November 13, 2024 by the CLARA Supervisory Board: Supervisory Board, (Interim) Director, Collegium of Experts, Research Programmes, CLARA Scientific Advisory Board, General Project Manager, CLARA Testbed, CLARA Collaboratorium. Other optional bodies of CLARA may be established and governed by a separate CLARA Statute, which the CLARA Supervisory Board is authorised to issue. Details are described in the reported Deliverable 2.1 – Center Core Documents.

Besides those CLARA center bodies, each project work package is led by a WP Leader and tasks within each WP are led by a Task Leader. The WP and Task Leaders will be responsible for the actual technical tasks and the WP's progress and will report to the CLARA Director. The project coordinator (INDRC) takes responsibility for the technical, administrative, and financial, results and overall performance of the consortium. INDRC (supported by the WP Leaders) will also be responsible for coordinating the quality and safety assurance procedures. Quality checks will be performed by a Work Group for Risk and Quality Assessment – This Work Group is established by the CLARA Director. This group is chaired by VSB as a Task 1.2 leader. The Work Group consists of members representing all project partners (1 member nominated per partner), CLARA Director and CLARA GPM. The first meeting of the Work Group shall be organized by the Work Group Chairperson no later than March 31, 2025.

According to the CLARA Statutes Article 4.5 and to the PCA, Article 6.4.5:

The CLARA Director in particular manages and coordinates the activities of the CLARA (Project), the Director of CLARA shall provide the CLARA Supervisory Board with an interim progress report at regular 6-month intervals, which shall include the information set out in the CLARA Statute, GA, PCA, or other relevant documents, submits to the CLARA Supervisory Board the plan of activities and the budget for the following period, submits to the CLARA Supervisory Board financial statements certified by an independent auditor selected by the CLARA Supervisory Board (PCA Art. 7.2.4), ensures that all members of CLARA bodies (or other persons where relevant) participating on the CLARA Project are contractually bound to confidentiality at least at the level set under the terms of this Consortium Agreement, the contractual confidentiality obligation shall remain in effect during the term of membership in the CLARA body and also after the termination of such membership, or as otherwise required by law, the confidentiality obligation shall apply to all confidential or proprietary information related to the CLARA Project. The CLARA Director issues binding internal acts for the CLARA organisational unit in the form of a Director's Regulation, which must be in accordance with the Statute.

According to the CLARA Statutes Article 9 and to the PCA Article 6.8:

The General Project Manager (GPM) shall be the intermediary between the Founding partners and the Granting Authority and shall perform all tasks assigned to them as described in the Grant Agreement and in the Consortium Agreement. GPM supported by project managers



from Parties, will take care of the administrative/financial management of the Project and will continuously assess the project progress and possible changes to be treated as acceptable for both the consortium and the European Commission (EC).

GPM is appointed by the CLARA Director and shall be subordinated to the CLARA Director. In particular, the GPM shall be responsible for monitoring compliance by the Parties with their obligations under the Consortium Agreement and the Grant Agreement, keeping the address list of Members and other contact persons updated and available, collecting, reviewing to verify consistency and submitting reports, other deliverables (including financial statements and related certification) and specific requested documents to the Granting Authority, promptly transmitting documents and information connected with the Project to the CLARA Director, administering the financial contribution of the Granting Authority and fulfilling the financial tasks described in Section 7.2 of PCA.

If one or more of the Parties is late in submission of any Project deliverable, the GPM may nevertheless submit the other Founding partners' Project deliverables, and all other documents required by the Grant Agreement to the Granting Authority in time.

3 Workplan

3.1 Workplan Structure

The detailed workplan file with all responsible WP and Task leaders is available internally in the Shared data Workspace (see Chapter 4). A detailed and regularly updated Gantt chart displays Phases, Workpackages, Tasks, Deliverables and Milestones in the timeline and is available at the same place as well as the status of the project KPIs.

The project progress is being tracked with the Only Office Projects tool. Each Deliverable and Milestone is defined as a "project" with responsible person, tracking function, group management, Gantt chart and deadline management.

3.2 Performance Monitoring

Achievement of the KPIs will be regularly checked by the General Project Manager on regular calls (see the PCA Article 6.8.3).

The performance of each partner will be checked every 6 months via the Internal progress report that will cover both the technical and financial part. It should describe the progress in separate tasks, fulfillment of deliverables and milestones, check the KPIs achievement, dissemination effort and risk occurrence and mitigation and finally the plan for the future implementation. CLARA partners will provide all inputs to the CLARA Director, who shall prepare and issue the Internal progress report for the CLARA Supervisory Board.

3.3 Change Management and Conflict Resolution

The progress of the project and compliance with Annex I of the Grant Agreement is regularly checked by the General Project Manager and the Workpackage Leaders.

In case of any potential deviation from the Annex I., the CLARA Director and project partners must collaborate to propose an amendment and subsequently inform the CLARA Supervisory Board. Then the GPM shall consult the EU Project Officer on possible solutions. Either



explanations inside the next Periodic Report is allowed or an Amendment of the Grant Agreement is requested.

In case of any conflict within the WP team, the WP leader covering the specific team shall be consulted. The WP leader then consults further steps with the GPM.

In case of any conflict between the WP teams, WP leaders covering those teams shall consult the conflict with the GPM with possible mitigation/escalation procedure towards CLARA Director and CLARA Supervisory Board.

In case of any conflict between the project partners, they consult with the CLARA Director who can in severe cases consult the Supervisory Board (in case of need, an Amendment can be launched).

4 Online Cooperation: Shared Data Workspace

4.1 Document Repository and Online Cooperation

All the project documents will be stored in the project repository. An OnlyOffice instance (CLARA OnlyOffice) has been created as a collaborative workspace and storage at <https://clara.it4i.cz> and <https://onlyoffice.clara-center.eu/> for this purpose.

The storage is located on the partner's servers (it is not hosted in a third-party cloud). The rights to individual files and folders are set by the CLARA Director and/or GPM. Primary login is possible via institutional user authentication, in the backup case user accounts are created locally. The system is regularly updated and backed up ensuring all relevant privacy and security functions.

4.2 Online Cooperation

Collaborative workspace and storage is preferred for proper sharing of information. Collaborative writing is hosted on the partner's servers; no parts of the text are sent anywhere to the cloud of third parties. The software enables editing of documents by several users at once, where the standard functions that the user uses when editing documents and spreadsheets are included.

4.3 Document Templates

In advance, templates for reporting will be provided to consortium members in the collaborative workspace and storage (CLARA GENERAL). Other templates for dissemination and communication of the project will be created within the "WP6 repository" and shared with partners in the collaborative workspace and storage.

4.4 Contact Lists

All work packages will communicate through separate mailing lists to ensure targeted communication. Also, mailing lists for management bodies will be created. They shall use the clara-center.eu domain.

Registered people will be assigned to groups. The grouping will be used not only for mailing but also for other communication channels (for example chat, notification from CLARA office) and Project & responsibility tracking.

4.5 Shared Calendar

CLARA OnlyOffice allows to create and share calendars between users.



4.6 Shared Code Repository

A shared code repository for code management will be made available by VSB IT4I (<https://opencode.it4i.eu/>).

4.7 Research Related Data

Management, sharing, and storage of research related data and project results will be described in deliverable D2.4 Data Management Plan (M6) and updated continuously during the project lifetime.

5 Project Outputs Quality Management

5.1 Deliverable Template

CLARA will employ a standardised template for deliverables, see Annex 1 of this deliverable.

5.2 Deliverable Approval Process

5.2.1 Deliverable Drafting (8 to 3 weeks to delivery date)

WP leaders are responsible for the review of all deliverables produced by their WPs. The deliverables are being checked by internal reviewers (see section 5.2.2) and the GPM, then the CLARA Director gives the consent with its publication to the EC Portal. The final version of the deliverable/milestone is submitted to the EC Portal by the GPM.

Deliverable preparation is a responsibility of the respective deliverable leader. The preparation itself consists of the designing of the document structure in the Table of Content (ToC), distributing of the writing duties among the participating partners (after/in parallel to the organization of the work to be done within the task), and harmonising the produced contents by a consistent overall editing.

Contributing partners provide their contributions to the deliverable leader via the online collaborative space in the shared repository (under responsibility of the deliverable leader according to the dissemination level – PU/SEN). The deliverable leader then compiles all information and prepares the first deliverable version for the internal revision to task participants and WP leader.

5.2.2 Deliverable Peer Review (3 weeks to delivery date)

During the kick off meeting, the following process was approved:

The first preliminary version is supposed to be provided for review 3 weeks before the deadline. At least 1 reviewer will revise the quality of the deliverable (will be proposed by the respective WP leader). The reviewers should be members of the project team.

5.2.3 Deliverable Approval (1 week to delivery date)

The final version for review shall be provided to the CLARA Director 10 days before the deadline. The Director has 5 working days to give feedback. After that, the deliverable leader has 3 days to incorporate comments and send the final version to the GPM.

The GPM oversees the preparation process and is responsible for submitting the final version to the European Commission or the Czech Ministry. In case the output is not accepted by the



granting authority, GPM ensures that the output is corrected, approved by the CLARA Director again and resubmitted.

5.3 Deliverable Versioning

A version history will be kept in each deliverable in a dedicated table. Versioning follows stages:

- First Draft v0.x; Responsible person: Task Leader.
- Draft approved at the Task level v1.x; Responsible person: Task Leader.
- Draft approved at the WP level v2.x; Responsible person: WP Leader.
- Final version approved by the Director v3.x; Responsible person: CLARA Director.
- Submitted version, i.e. EC level: vFinal.x; Responsible person: GPM.

5.4 Approval of milestones

The provisions on the process for producing and approving deliverables shall apply mutatis mutandis to Milestones.

6 Risk Management

6.1 Continuous Risk Management Approach

An internal instrument of the progress and risk management was established, which is the internal progress report. Based on the PCA requirements, it will be prepared every 6 months. The first internal progress report is due end of May 2025. See also PCA Attachment 3. In line with article 4.5.1 the Parties commit to provide every six months information on the progress of the implementation of the work packages, Tasks and KPIs within the Consortium Plan (Internal Progress Reports). Parties will provide all inputs to the CLARA Director, who shall prepare and issue an Internal Progress Report for the CLARA Supervisory Board. The Internal Progress Report provided should allow for an assessment of the status or completion of obligations to enable monitoring, e.g. through certain performance indicators as defined in the Consortium Plan, including a 6-months accounting report capturing financial flow of the account center related to CLARA (Project). The internal progress report shall particularly include (on the level of each party): report on fulfillment of milestones and deliverables with supportive documentation, report on KPIs progress, report on financial costs and person-month consumption per WP and tasks, report on specific successes and achievements, report on risks, incl. mitigation actions, report on delays, incl. mitigation actions, plan for the next 6-month period.

Risks shall be regularly (every 6 months) assessed by the Work Group for Risks and Quality Management (on the call of the Chair and/or GPM) and the risk monitoring table will be updated accordingly. Risks must be identified before the start of each WP and entered into the list of identified risks and mitigating measures must be proposed according to their severity.

Template for Risk assessment is provided as Annex 2 of this deliverable: **Risk assessment of WP template.xlsx**

6.2 Risk Monitoring Responsibility

The General Project Manager and the CLARA Director are primarily responsible for risk management and communication between partners. WP leaders, co-workers, and partners



collaborate on identification of risks within their areas of responsibility and implementation of measures.

6.3 Risk Assessment

Each risk is assessed based on three levels of severity, enabling more effective planning of prevention and mitigation measures. Risk assessment is based on a combination of two main parameters: the likelihood of the risk occurring and the severity of its impact on the project.

Impact

Impact	Severity of Impact
Minimal or no significant consequences to other partners or other WPs	1
Moderate consequences that can affect some other partners or some other WPs	2
Severe consequences with substantial effects to other WPs or partners	3

Likelihood of Risk Occurrence

Likelihood of Risk Occurrence	Scale	Occurrence
Unlikely	1	The event is unlikely, and its occurrence is rare. The risk is almost negligible but not entirely excluded.
Possible	2	The event might happen and cannot be entirely excluded. The risk is moderately probable.
Probable	3	The event is highly likely, occurring frequently or regularly. The risk is practically certain unless preventive measures are taken.

Risk Level

$$\text{Risk Level} = \text{Impact} * \text{Likelihood}$$

Risk level		Likelihood		
		1	2	3
Impact	1	Low	Low	Medium
	2	Low	Medium	High
	3	Medium	High	High

Proposed Mitigations by Risk Level



Risk Level	Proposed mitigations
Low	Requires basic monitoring but no immediate action is typically needed.
Medium	Requires proactive measures to reduce risk and a response plan in case the risk materializes.
High	Demands immediate attention, robust mitigation strategies, and contingency plans to minimize impact.

See Risk assessment of WP template.xlsx there are two worksheets: CLARA-RA and Parameters. The Risk Assessment will be done at least each 6 months, with regards to the Internal Progress Reporting.

7 Conclusion

The Deliverable defines basic rules and guidelines for risk and quality management of the CLARA project. It also provides information about collaborative workspace as a key tool for document and information sharing and distribution among project partners. General Deliverable template and Risk assessment template are provided as Annex 1 and Annex 2 of this deliverable.

The quality and risk management represents a critical function of the CLARA Center of Excellence. This function is carried out by the Work Group for Risk and Quality Assessment each 6 months at the latest (Internal Progress Report). The Work Group consists of members representing all project partners (1 member nominated per partner), CLARA Director and GPM. This group will be chaired by VSB as a Task leader.

The Deliverable sets the rules for the development and approval of the Project outputs (Deliverable, Milestone) as well as versioning and revisions tracking:

Versioning follows stages:

- First Draft v0.x; Responsible person: Task Leader.
- Draft approved at the Task level v1.x; Responsible person: Task Leader.
- Draft approved at the WP level v2.x; Responsible person: WP Leader.
- Final version approved by the Director v3.x; Responsible person: CLARA Director.
- Submitted version, i.e. EC level: vFinal.x; Responsible person: GPM.

8 List of Annexes

Annex 1: CLARA deliverable template.docx

Annex 2: Risk assessment of WP template.xlsx