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Executive Summary

The following “Project Management and Risk Management Plan (PRMP)” represents a text of reference for management and monitoring activities to be realized during the lifetime of the project SMILE. The PRMP complements other documents also relevant to this matter, like the Grant Agreement (GA), the Commission Rules and the Consortium Agreement (CA); should ambiguity of interpretation among these documents arise, the PRMP will take a subordinate role. Therefore, priority is given to the documents in the following order: GA, Commission Rules, CA, PRMP. After the PRMP, the “Dissemination and Communication Plan” follows in the prioritisation of documents. The overall objective of the PRMP is to facilitate the successful implementation of SMILE, the smooth realisation of project activities, proper coordination between partners, meeting project deliverables dates, monitor and control the technical and scientific quality of the project, and establish effective communication with the European Commission (EC). Also, it will help early the identification of conflicts and propose actions and mitigation to avoid risks during the whole project implementation. The last part of this document is the project risk assessment. At proposal stage, the consortium discussed potential risks and unforeseen obstacles that may arise during the implementation of the project. Therefore, the following risk assessment is an update of the precedent version.

This deliverable will be updated whenever necessary by FTK and RDIUP and any updates will be notified to the project beneficiaries.

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SMILE project introduction:

The SMILE project represents groundbreaking efforts to transform mental health support for young people by providing a gamified platform that will enhance the resilience of adolescents aged 10-24 years. SMILE started on 1st May 2023 and scheduled to conclude on October 31, 2026, SMILE aims to enhance the quality of mental healthcare by providing an integrated methodology that guides clinical decisions, promotes evidence-based interventions, and involves the social network of young people, who are parents, teachers and health care professionals.

During the course of the project, SMILE will implement and validate its digital tools and services through real-life case studies in seven European countries: the United Kingdom, Germany, Cyprus, Poland, Slovenia, Spain, and Italy. This extensive validation process, scheduled to reach Technology Readiness Level 7, will ensure the effectiveness and practicality of the innovations in various healthcare settings.

The SMILE project brings together a consortium of leading research centers, innovative SMEs, pilot centers, public universities, and policymakers from nine European countries. With their collective expertise and multidisciplinary approach, the project is poised to make a transformative impact in the field of resilience building for adolescents.

1 Project Management Plan of SMILE

The multinational and multi-sectoral characteristic of the consortium is one of its strengths as it nurtures new ideas and promotes replicability of results. Nevertheless, it implies a constant attention to the objectives and strong commitment to the project plan and meeting deadlines, in order to avoid undesirable trends that could become difficult to control. For this reason, the parts of the PRMP of SMILE that required a deeper analysis and that are therefore more interesting to show, are the following:

- The roles and responsibilities in directing and managing project execution;
- the work plan with the project time management;
- the internal communication and,
- the risk management.

1.1 Governance, Management Structure and Decision-Making Process

The management processes and structure of responsible bodies in SMILE follow the procedures laid out by the Consortium Agreement (CA). The consortium agreement itself follows the DESCA Model Consortium Agreement providing a well-tested framework for executing large scale and complex projects such as SMILE. SMILE

adopts the DESCAs model only with minor modifications not affecting the overall project management methodology.

The CA establishes the following Consortium Bodies:

- The Coordinator as the legal entity acting as the intermediary between the Parties and the Granting Authority. The Coordinator shall, in addition to its responsibilities as a Party, perform the tasks assigned to it as described in the Grant Agreement and this Consortium Agreement.
- The Executive Board as the supervisory body for the execution of the project, which shall report to and be accountable to the General Assembly (GeA)
- The General Assembly as the ultimate decision-making body of the consortium

1.1.1 Project Coordinator / Management Support Team (MST)

Composition: the Coordinator, Prof. Dr. Dominic Heutelbeck (FTK) and the Project Manager, Jana Mertens (FTK).

The Management Support Team (MST) is in charge of the day-to-day project management and provides support and assistance to the different project bodies. In accordance with the EC requirements, it plays a hands-on role in administrative actions as defined in the GA. Additionally, the MST prepares the needed logistical, legal and administrative documents and supervises the overall running of the project. It is responsible for ensuring that all the administrative steps required for effective progress of the project are fulfilled in good time. The Coordinator is responsible for taking all actions, in close collaboration with the consortium's partners, to enable proper decision making by the project bodies, thus ensuring smooth project operations: work plan maintenance, monitoring project progress, identification of potential problems and possible consequences for future research (GA Art. 19), submitting all required progress reports, deliverables and financial statements to the EC (GA Art. 20), communicating all information to the Commission and transferring payments to the partners (GA Art. 21).

FTK handles administrative, financial and contractual aspects of the project and is responsible for the dissemination of information inside the consortium, as well as for the communication with the EC officer. FTK is in charge of the implementation of appropriate management tools and their updating, including the present document, as well as of the organisation of the general meetings.

The MST is in constant communication with the Executive Board (Work package Leaders and key Stakeholders) on the status of the project (deliverables, new results, new risks, modifications, etc.), with all the partners, and will be the contact point between the Consortium and the European Commission. It is ultimately in charge of safeguarding the interests of the project, ensuring its smooth implementation, and representing it towards external stakeholders and networks (GA Art. 7). It is in regular contact with the Executive Board and participates to the strategic decisions.

1.1.2 The Executive Board (EB)

Composition: Dominic Heutelbeck (FTK), Habib Nasser (represented by Dah Diarra) (RDIUP), Gwendolyn Mayer (UKH), Jens Piesk (represented by Yash Shekhawat) (NURO), Vincenza Frisardi (IRCCS AOUBO), Izidor Mlakar (UoM), Zouhair Haddi (NVISION), Matthias Schwannauer (UoE), Alex Butean (WIZ), Mel McKendrick (HWU)

The Executive Board is a supervisory body that consists of representatives of all WP and proposes strategic orientations of the project to the General Assembly and implements it. Its tasks are:

- Supporting the general inter-workpackage processes in the project and ensuring communication between WP leaders as well as alignment with key stakeholders in the consortium.
- Preparing any scientific, political and strategic orientations of the project.
- Preparing the agenda and objectives of technical and consortium meetings, as well as EC reviews.
- Identifying needed contractual changes, including technical work plan changes and consortium agreement changes.
- Supervising the production of all reports and deliverables required in the frame of the Grant Agreement
- Arbitrating on deadlock situations occurring within the WPs and Tasks.

The Board will meet at least quarterly, by conference call or by physical meetings if required. Additional conference call meetings or Internet-based conferences will be organized at any time upon request of a member or of a partner of the Consortium. The Coordinator shall chair all meetings of the EB, unless decided otherwise by a majority of two-thirds (2/3) of the EB. Based on the interdisciplinary nature of SMILE an increased need for EB meetings has been identified and EB meetings are scheduled monthly until the EB decides otherwise.

1.1.3 The General Assembly (GeA)

Composition: Partners' representatives. One voice per partner.

The General Assembly (GeA) is the ultimate decision-making body of the consortium, endorsing decisions concerning the project implementation, as prepared and presented by the Strategic Board. The GeA meetings will take place once a year and will bring together the entire project participants and their working teams. The Coordinator shall chair all meetings of the GeA, unless decided otherwise in a meeting of the GeA.

During these meetings, special sessions will be organised, following any partner's or EB's request, to discuss legal, financial, organisational, or any other important issues relating to the project. Decisions will be made using the principle of consensus voting or,

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in exceptional circumstances, qualified votes (2/3 e.g.: 4 out of 6 votes). This requires the presence of more than 50% of the partner representatives.

The GeA will be held annually. The next meetings are planned to be hosted by jointly HWU and UoE (April 2024), NVISION (2025), and then IRCCS AOUBO (2026).

1.1.4 External Advisory Board (EAB)

To ensure the coherence and consistency of the work to be carried out under the various work packages, the decisional bodies will benefit from the support of the Project Officer of the European Commission an External Advisory Board will be created. Which will cover general advice and contain a sub-group of advisors specifically tasked to support ethics questions in SMILE.

The EAB is expected to be called into session biannually with additional meetings as required by the pilots to support decision making and development regarding ethical questions.

The EAB shall contain representatives of the following stakeholder groups:

- Policy Makers
- Schools
- Social Workers
- Youth centers
- AI Experts
- Data Protection Experts

Additionally, the ethics sub-group of the EAB shall contain:

- One member to represent each pilot site. These representatives can be from the funded institutions, but without direct funding. Representatives from third parties are welcome.
- At least one clinical expert
- At least one Statistician
- A Person for handling adverse events

At the time of writing this deliverable, the partners are finalizing the candidates for the EAB to be reached out to. And a number of persons already have agreed to join the EAB.

2 Work Plan

The overall work plan, deliverables, KPIs and milestones are documented in the DoA. In this deliverable, we primarily describe the process of handling updates to the work plan.

During the lifetime of the project it can happen that new opportunities arise or, on the contrary, that obstacles have to be faced and new solutions are proposed. In such cases, a change in the work plan would occur. It is the responsibility of the task leader to notify a deviation from the work plan, at first to the WP leader and to the Coordinator. In both cases of a positive or negative deviation, a change may occur, and the Coordinator will make a first evaluation of the types of changes, with the collaboration of the involved partners. If it is a minor change that can be managed internally to the consortium, the information will be communicated to the EB and GeA, and no action will need to be taken with the EC. If instead the change is substantial, or in case of doubt, the Coordinator will communicate to the EC about the change, in order to verify if it is necessary to start an amendment procedure. Of course, in case of changes that modify the nature of the project, the amendment would be rejected and an alternative to the proposed change would have to be found. If an amendment is needed, the Coordinator will be in charge of the procedure and will follow the EC guidelines.

3 Work packages, deliverables and milestones

SMILE's deliverables and milestones are fundamental at maintaining the highest standards in the outcomes of our project activities. In the subsequent sections, we will present the allocation of responsibilities among partners across work packages, tasks, deliverables, and milestones. Ensuring quality goes beyond roles' definitions, as the following sections will embrace various components such as the review process for project deliverables to attain quality approval, and the verification means employed for project milestones.

With the recent integration of Azienda Ospedaliero-Universitaria di Bologna (IRCCS AOUBO) and the University of Bologna (UniBo) into our consortium, it is important to note that the information presented below may require updates. We commit to include the necessary updates in a revised version of this deliverable, if necessary.

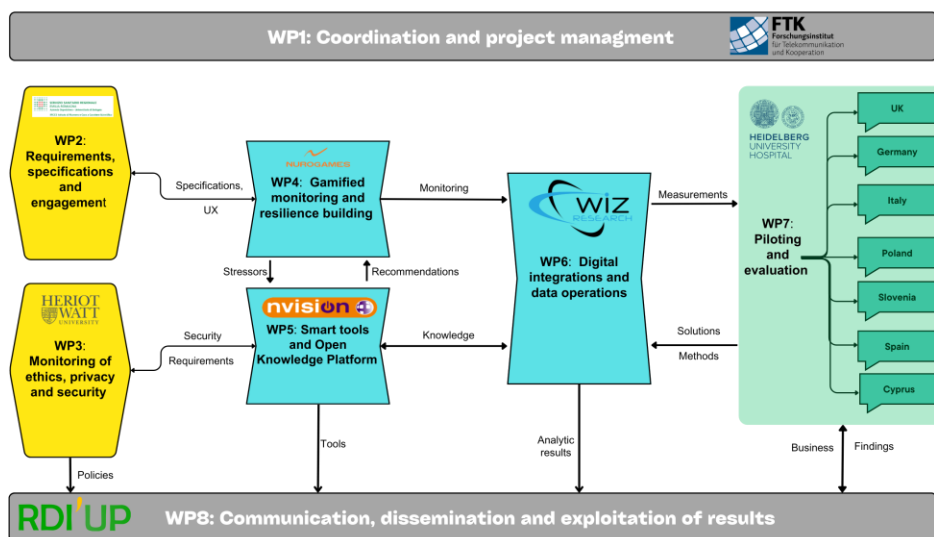
3.1 Work packages and tasks

The work plan is composed of 8 work packages (see figure below) implementing the SMILE objectives and concepts. WP1 is devoted to proper coordination and management and also defines the KPIs to ensure the quality assurance and monitor the scientific output. WP2 gathers the needs assessment and requirements to be implemented for SMILE functionalities and suite of tools. WP3 links regulatory requirements for ethics, privacy and data management with a clear process for establishing compliance and cybersecurity. WP4 defines the gamification scenarios and builds the self-assessment and monitoring framework and its integration. WP5 intends to develop smart tools (e.g. DSS), integrate all the developed modules and tools in the SMILE platform and elaborate the KM-EP. The WP6 will focus on the selection,

browsing, collection and in-depth analysis of data related to different exposures, treatment, and depression status. SMILE aims to propose tools to integrate, analyse and understand the experimental data and the shared information and experiences.

WP7 will be dedicated to the definition of appropriate case studies, allowing the collection of data useful for the purpose of the SMILE project. It will also work on the protocol of the trial phase. Then, it will coordinate the implementation and assessment of the developed gamification-based scenarios and digital tools in the selected cohorts from the involved clinical centres. Finally, WP8 is reserved for the dissemination, communication activities and exploitation of the project results. Market analysis, business models and SMILE services will be defined and set-up in this WP8.

SMILE Workpackage Structure



In line with our commitment to upholding the highest quality standards throughout the SMILE project, we follow a structured approach to the partners' responsibilities. Each WP is orchestrated by a dedicated partner, referred to as a WP Leader. Additionally, WPs are divided into specific tasks, each overseen by a Task Leader. These tasks may involve the participation of one, several, or all partners. This approach ensures transparent lines of responsibility and expertise in task implementation. Outlined below is a table detailing the key responsibilities of partners in the WPs and their respective tasks. This serves as a dynamic reference to promote transparency and streamline the collaborative efforts dedicated to achieving our high-quality outcomes.

Work Packages and Tasks	Leader	Participants
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WP1. Coordination and project management		FTK	
T1.1.	General operational and financial management	FTK	All partners
T1.2.	Technology and scientific management	RDIUP	All partners
T1.3.	Open Science and Data Management	UoM	WIZ, All partners
T1.4.	Quality and Risk Management	RDIUP	All partners
WP2. Requirements, Specifications and Engagement of Stakeholders		IRCCS-AOUBOU	
T2.1.	Identification of Barriers, Drivers and Requirement	IRCCS-AOUBOU	All partners
T2.1.1.	Literature review		
T2.1.2.	Content analyses		
T2.1.3.	Requirements checklist		
T2.2.	Stakeholders Analysis and Mapping	IRCCS-AOUBOU	All partners
T2.2.1.	Monitoring expectations and involvement		
T2.2.2.	Involving and networking with stakeholder		
T2.2.3.	Analysis of users' needs		
T2.3.	SMILE specifications and conceptual architect	NURO	UoM, HWU, RDIUP, WIZ, NION, FTK
T2.4.	Case studies and Scenarios requirement	INTRAS	All pilots, WIZ, CIP, UoM, NURO, RDIUP
T2.5.	User Experience (UX	NURO	WIZ, FTK, RDIUP, HWU, UoM, IRCCS-

			AOUBOU, UKH
WP3. Monitoring of Ethics, Security and Privacy		HWU	
T3.1.	Legislation	SWPS	FTK and all pilot sites
T3.2.	Privacy and Ethics monitoring framework	WIZ	FTK, all pilot sites
T3.3.	Medical device assessment	IRCCS-AOUBOU	RDIUP, UoM, WIZ
T3.4.	Societal and environmental wellbeing	UoE	All pilot sites
T3.5.	Project ethics board	HWU	All partners
WP4. Gamified monitoring and resilience building		NURO	
T4.1.	Definition of Serious Games for (self-)monitoring and resilience building	HWU	NURO, RDIUP, UoM, all pilots
T4.2.	Framework for Gamification and Asset Development	NURO	HWU, RDIUP
T4.3.	SMILE Gamification Engine Development	NURO	HWU, RDIUP, UoM
T4.4.	Middleware Component	WIZ	NURO, RDIUP, NION
T4.5.	Rewarding system	RDIUP	WIZ, FTK, UoM
T4.6.	Self-assessment and monitoring Framework - SAMF (digital biomarkers)	UoM	WIZ, FTK, RDIUP, UKH
WP5. Advanced tools and open knowledge platform		NION	
T5.1.	Design and architecture of the	NION	WIZ, FTK, RDIUP,

	platform		UoM, NURO
T5.2.	Development of XDSS assistance tool	NION	RDIUP, WIZ, UoM
T5.3.	Design and Development of the user interface	RDIUP	WIZ, NURO, HWU, UKH
T5.4.	Testing and deployment of open knowledge platform	NION	All technical partners involved in WP5, MoM
T5.5.	Deployment, customization and content of the KM-EP and the shared Knowledge base	FTK	All partners
WP6. Digital Integrations and Data Operations		WIZ	
T6.1.	Common Data Models and Semantic Interoperability	UoM	WIZ, RDIUP, FTK, MoM, HWU, all pilots, NURO
T6.2.	Data Ontology and Visualization	WIZ	RDIUP, UoM, FTK, MoM, HWU
T6.3.	Infrastructure for Compliance, Privacy, API, and UI Security	FTK	WIZ, NURO, RDIUP, MoM
T6.4.	Data operations, analytics and knowledge elaboration	RDIUP	WIZ, FTK, NURO
T6.5.	Development of Mobile awareness APP (Peer Review)	RDIUP	WIZ
T6.6.	Deployment support for pilots	WIZ	RDIUP, UoM, FTK
T6.7.	Orchestration and Digital Coordination	WIZ	RDIUP, FTK
WP7. Piloting and evaluation		UKH	
T7.1.	Pilot specification and preparation	SWPS	CIP, HWU, INTRAS, IRCCS-AOUBOU,

			UoM, MoM, UKH
T7.2.	Living Lab testing	INTRAS	CIP, HWU, IRCCS-AOUBOU, UoM, MoM, SWPS, UKH
T7.3.	Implementation of the case studies and data collection	UKH	CIP, HWU, INTRAS, IRCCS-AOUBOU, UoM, MoM, SWPS
T7.4.	Case studies analysis, evaluations and KPIs	HWU	CIP, INTRAS, IRCCS-AOUBOU, UoM, MoM, SWPS, UKH
WP8. Dissemination, communication and exploitation		RDIUP	
T8.1.	Project communication and dissemination activities	RDIUP	All partners
T8.1.2.	Dissemination and Communication activities		
T8.2.	Stakeholders' dialogue, joint actions and clustering	CIP	All partners
T8.3.	Tailored business models	RDIUP	All partners
T8.4.	IPR and exploitation strategies	FTK	All partners

3.2 Deliverables' Reviewing Process

SMILE deliverables follow an appropriate reviewing process essential for upholding and elevating the quality of our work in alignment with the European Commission standards. Responsibilities are clearly delineated within the Consortium. The deliverable leader oversees tasks related to the deliverable, collaborating closely with the deliverable contributors. Simultaneously, the work package leader monitors activities, ensuring adherence to deadlines and the assurance of quality. All reviewer assignments are documented in a shared spreadsheet accessible through FTK's cloud platform. The detailed reviewing process for each deliverable is summarised in the table below.

Deliverable N°	Leader	Reviewer 1	Reviewer 2	Sending to review	Back for final revision	Due date
D1.1	FTK / RDIUP	UM	UKH	11/13/2023	11/23/2023	11/30/2023
D1.2	FTK	RDIUP	CIP	10/12/2023	10/24/2023	10/31/2023
D1.3	FTK	RDIUP	CIP	12/11/2024	12/20/2024	12/31/2024
D1.4	WIZ	HWU	SWPS	10/13/2023	10/24/2023	10/31/2023
D1.5	WIZ	HWU	SWPS	10/13/2025	10/24/2025	10/31/2025
D2.1	IRCCS	INT	UoE	10/12/2023	10/24/2023	10/31/2023
D2.2	NURO / INTRAS	FTK	MoM	4/12/2024	4/23/2024	4/30/2024
D2.3	NURO	NION	INT	10/14/2024	10/24/2024	10/31/2024
D3.1	UKH / WIZ	IRCCS	RDIUP	4/12/2024	4/23/2024	4/30/2024
D3.2	UoE	NURO	NION	4/11/2025	4/23/2025	4/30/2025
D3.3	HWU	MoM	UKH	10/13/2026	10/23/2026	10/30/2026
D4.1	HWU	UM	FTK	1/12/2024	1/24/2024	1/31/2024
D4.2	NURO	UoE	WIZ	10/14/2024	10/24/2024	10/31/2024
D4.3	UM	IRCCS	CIP	4/13/2026	4/23/2026	4/30/2026
D5.1	FTK	HWU	IRCCS	4/12/2024	4/23/2024	4/30/2024
D5.2	NION	NURO	UoE	4/11/2025	4/23/2025	4/30/2025
D5.3	FTK	UM	RDIUP	8/12/2025	8/22/2025	8/29/2025
D5.4	NION	MoM	UKH	8/12/2025	8/22/2025	8/29/2025
D6.1	UM	FTK	UoE	12/11/2024	12/20/2024	12/31/2024

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D6.2	WIZ	UM	NION	10/14/2024	10/24/2024	10/31/2024
D6.3	WIZ	UM	NION	4/11/2025	4/23/2025	4/30/2025
D6.4	RDIUP	NION	NURO	6/11/2025	6/23/2025	6/30/2025
D6.5	WIZ	SWPS	CIP	8/12/2025	8/22/2025	8/29/2025
D7.1	UKH	FTK	-	11/12/2024	11/22/2024	11/29/2024
D7.2	UKH	FTK	-	10/13/2025	10/24/2025	10/31/2025
D7.3	UKH	FTK	-	8/12/2026	8/24/2026	8/31/2026
D7.4	HWU	MoM	-	11/12/2024	11/22/2024	11/29/2024
D7.5	HWU	MoM	-	10/13/2025	10/24/2025	10/31/2025
D7.6	HWU	MoM	-	8/12/2026	8/24/2026	8/31/2026
D7.7	IRCCS	NION	-	11/12/2024	11/22/2024	11/29/2024
D7.8	IRCCS	NION	-	10/13/2025	10/24/2025	10/31/2025
D7.9	IRCCS	NION	-	8/12/2026	8/24/2026	8/31/2026
D7.10	UM	WIZ	-	11/12/2024	11/22/2024	11/29/2024
D7.11	UM	WIZ	-	10/13/2025	10/24/2025	10/31/2025
D7.12	UM	WIZ	-	8/12/2026	8/24/2026	8/31/2026
D7.13	CIP	RDIUP	-	11/12/2024	11/22/2024	11/29/2024
D7.14	CIP	RDIUP	-	10/13/2025	10/24/2025	10/31/2025
D7.15	CIP	RDIUP	-	8/12/2026	8/24/2026	8/31/2026
D7.16	SWPS	NURO	-	11/12/2024	11/22/2024	11/29/2024
D7.17	SWPS	NURO	-	10/13/2025	10/24/2025	10/31/2025
D7.18	SWPS	NURO	-	8/12/2026	8/24/2026	8/31/2026

D7.19	INT	UoE	-	11/12/2024	11/22/2024	11/29/2024
D7.20	INT	UoE	-	10/13/2025	10/24/2025	10/31/2025
D7.21	INT	UoE	-	8/12/2026	8/24/2026	8/31/2026
D7.22	HWU	FTK	-	10/13/2026	10/23/2026	10/30/2026
D7.23	UKH	UM	-	7/14/2026	7/24/2026	7/31/2026
D8.1	RDIUP	IRCCS	INT	10/12/2023	10/24/2023	10/31/2023
D8.2	FTK	UKH	CIP	10/12/2023	10/24/2023	10/31/2023
D8.3	CPI	HWU	UKH	8/12/2025	8/22/2025	8/29/2025
D8.4	CPI	HWU	UKH	8/12/2026	8/24/2026	8/31/2026
D8.5	RDIUP	SWPS	INT	8/12/2025	8/22/2025	8/29/2025
D8.6	RDIUP	SWPS	INT	10/13/2026	10/23/2026	10/30/2026

3.3 Milestones and means of verification

In the SMILE's regular meetings, the WP leaders showcase an overview of the progress of the activities, and associated milestones. Also, they highlight any deviations unforeseen and provide justifications.

N°	Title	WPs	Partner	Mean of verification	Date
1	Communication, Engagement and Dissemination (CED) plan	WP8	RDIUP	D8.1 and roadmap of upcoming events	31 Oct 2023
2	Identification of requirements and needs	WP2	IRCCS	D2.1	31 Oct 2023
3	Data management plan	WP1	FTK	D1.2	31 Oct 2023
4	Legal and ethical	WP3	HWU	D3.1	30 Apr 2024

	framework				
5	Scenarios and technical specifications	WP2	IRCCS	D2.2	30 Apr 2024
6	Development of gamification engine	WP4	NURO	D4.2	31 Oct 2024
7	SAMF development	WP4	NURO	D4.3, preliminary results	30 Apr 2025
8	Explainable DSSs	WP5	NION	D5.2	30 Apr 2025
9	Mobile awareness APP	WP6	WIZ	D6.4	30 Jun 2025
10	KM-EP development (including OKP)	WP5	NION	D5.3, preliminary results from LLs testings	31 Aug 2025
11	Data integration and operations	WP6	WIZ	D6.5, results from integration workshop	31 Aug 2025
12	Pilots assessed and evaluated	WP7	UKH	D7.1-D7.21 (pilot initiation and execution) + D7.23 (pilot implementation) - preliminary results from D7.22 (pilot evaluation)	31 Aug 2026
13	Exploitation and business strategies	WP8	RDIUP	D8.6 and first market feedback	31 Oct 2026

The verification of project progress and the monitor of the milestones will strengthen the quality of the project.

4 Quality Assurance

This section aims to describe the guidelines that shall be applied during the lifetime of the project to assure the high quality of all outputs, both in terms of their technical contents, clarity of writing and appropriateness for the target audience. Each beneficiary shall perform the work in accordance to these quality regulations concerning mainly deliverable control and approval, but also rules for document naming and referencing. Quality Assurance procedures internal to a partner organisation will complement this

quality assurance policy and will not be in contrast with it. Planning and executing quality assurance and control activities can be a significant investment of time and effort and are to be considered part of WP1.

In particular, task 1.4 “**Quality and Risk Management**” (leader: RDIUP) aims to monitor and control the technical and scientific quality of the project through periodically reviewing of the project objectives, progress, and quantifying impacts. A review procedure will be setup to guarantee the quality of the project methodologies and outputs. This will cover technical and scientific methodologies used, project progress, outputs, deliverables and compliance with objectives, as well as the monitoring and updating of the possible identified risks and mitigation measures. To ensure the high quality of the project for capacity building results and compliance with the contract commitments, all project deliverables and key events will be monitored and reviewed internally. Moreover, an International External Advisory Board will be set up to provide external expert advice and steering to the technical and scientific development and output of the project. The technical and scientific impact of project outputs will be collected, quantified, and analysed in this task in order to deliver a sustained impact on resilience of young people. Furthermore, Task 1.4 aims to identify early risk management, ensure the mediation of any potential conflict, propose corrective actions to avoid conflicts, and define rules to ensure quality of reporting and progress.

The activities carried out in task 1.4 will help the successful Task 1.1 “**General operational and financial management**” (leader: FTK). Beyond the operational financial tasks, here specific KPIs are defined to allow the Coordinator to monitor and follow the progress of the project. Also, all partners will participate in providing contributions to the interim and final reports and other administrative issues as required by the EC and the Coordinator.

For these reasons, the following processes and procedures for data management will be established: data governance, architecture including data modelling, General Data Protection Regulation (GDPR), the instructions for data erasure, and database management. A detailed Data Management Plan (DMP) has been developed and was submitted as a public deliverable at M6.

Concerning document management, in order to prevent unauthorised changes and traceability of modifications, some internal communication guidelines have been set. A specific section will be dedicated to this aspect, that is fundamental also to facilitate good working relationships between project partners, encouraging and stimulating open communication and full sharing of information.

This chapter will initiate with an important section describing the communication and reporting to the relevant Commission services.

4.1 Quality of the Outputs, Document Reviewing and Approval Process

To monitor the progress related to the Key Performance Indicators (KPI), and to monitor and control the technical and scientific quality of the project, internal reporting procedures have been set.

4.1.1 Internal Reporting Procedures

In order to ensure a proper reporting to the EC in duly time and manner, a specific procedure has been designed for monitoring project evolution from a technological and scientific side (results, impacts, etc.) as well as a procedure to monitor costs and consumed resources. With this purpose, apart from formal reporting periods, additional interim follow-up procedures have been established in order to better monitor the project implementation along the whole project duration.

4.1.2 Technical reporting

The Work Package leaders have autonomy in organising the monitoring of activities related to their respective WPs. Technical information regarding the project implementation should be prepared by WP Leaders and submitted to the Project Coordinator by means of minutes of meeting and/or technical documentation of the software shared via the internal document management system hosted by FTK.

The WP leaders are responsible to transmit in due time their WP deliverables to the Coordinator for the EC review. The results of the WPs will be discussed within the EB and corrective measures will be proposed if needed.

4.1.3 Financial reporting

All information concerning expenses and resources utilisation will be reported directly by each partner to the Coordinator. FTK will revise the information provided and prepare a summary to be submitted for approval to the EB; corrective actions will be proposed when necessary. In formal reporting periods, the finance offices of partners will be also required to complete Periodic Financial Report (for the Financial Statement) using the electronic tool provided by the EC.

4.1.4 Interim and Final Reporting to EC

The European Commission monitors progresses and controls correctness in project implementation through the interim reporting (M18, M30, M42) and the project reviews (expected M20, M32, M42), in addition to the evaluation of project deliverables submitted in the continuous reporting.

These forms of assessment present the evidence that the project is progressing, it should continue, that the Consortium has completed its duty as set out in the Grant Agreement, and that it is eligible for the EC payment.

FTK collects all the technical, scientific and financial documents and information in support of the reporting and of project reviews. Starting from the Internal reporting (technical and financial), the EB will verify if additional information is needed and, if so, request partners to integrate missing data at least one month before the due date of the reporting or the review. The draft version of the reports to be submitted to the EC will be circulated for comments to designated internal reviewers at least two weeks before the delivery date.

4.2 Internal Communication

The project is carried out by a large transnational consortium with partners coming from Europe. In order to assure the smooth communication among partners, some tools and channels have been chosen in respect of the expected output.

First, all the persons participating in the project are included in a contact list with their respective email address that is shared among all the partners.

It is responsibility of each partner to update the list directly in the shared file and/or ask to the PM for inclusion in the list.

For day-to-day communication, the professional emails are the more immediate channel. Considering the large participation from personnel with different expertise, the definition of the relevant target of the communication is recommended and some thematic mailing lists have been created at this effect, for example for relevant people in Work Packages.

The primary channels are the project mailing list and Slack channels. Partners notify the Coordinator when new employees join or leave the team so that access can be adjusted accordingly.

For the sharing of files relevant to the project, there is a dedicated cloud directory in the FTK server. The documents are uploaded in their final version by FTK. The modification of a document will imply a new version and the substitution of the previous one (that will be moved to the “old version” folder).

Moreover, consortium partners convene regularly through online meetings, further enhancing our internal communication framework. Bi-weekly technical meetings occur every Wednesday mainly for the technical partners, while Thursdays are dedicated to weekly games specifications meetings involving all partners. Additionally, the clinical team engages in CBT Scripting meetings every Friday. Moreover, monthly meetings on clinical requirements derived from the literature review are organised. Beyond these scheduled meetings, Work packages leaders have the flexibility to organise meetings

with Work packages' contributors as needed. These meetings serve to inform the concerned consortium partners about the Work packages progress, discuss tasks, and ensure alignment on deliverables and milestones.

All meeting are documented in a shared calendar so that every member of the project is informed of the meetings.

4.3 Deliverables Approval and Submission to EC

The different actors involved in the deliverable production are:

- Lead Beneficiary: it is the organisation responsible for the deliverable, as indicated in the deliverable list in the DoA,
- Contributor(s): person(s) responsible of activities related to the deliverable,
- Reviewer(s) : person(s) or the organisation(s) involved in the activities related to the deliverable, different from the organisation of the lead beneficiary,
- Document approval: Work Package leader

The main contributor is the person in charge of the production of a document. When the document is ready in its first draft status, he/she may share it among other project partners that are concerned, in order to gather the different parts/inputs and make a version for the final review. Before submitting formal deliverables of each WP to the EC, the deliverables will be reviewed internally by project partners, as indicated in the table SMILE Deliverables & Milestones in the FTK cloud. This process requires the deliverable reports to be ready for internal review before the official deadlines to allow a sufficient time window for reviewing them and addressing any comments from reviewers. Feedback from reviewers and responses from lead beneficiary and contributors will be recorded through proper version control of the documents. In addition to providing comments in the document, the reviewer is requested to fill-in the peer-review evaluation form, available in the FTK Cloud. After the integration and document update, the document has to be delivered to the Work Package leader for approval and quality check. After the approval, the deliverable can be uploaded by the main contributor to the EC platform for project monitoring or can be sent to FTK (Jana Mertens) for submission to the EC. The figure below details the deliverables production process to be considered and adjusted in case of delays.

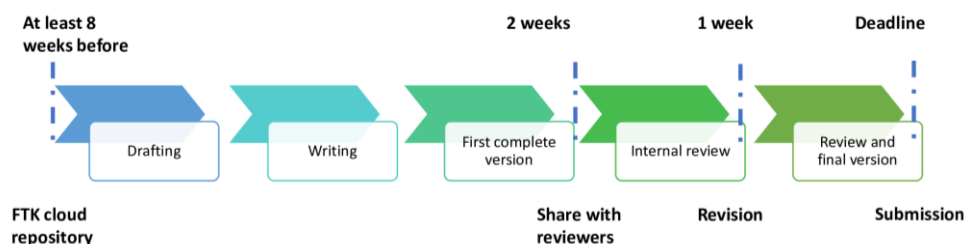


Figure 1: Deliverables' production process

4.3.1 Guidelines for Documents

The deliverables are realised in general in form of reports; even if the deliverable itself is another kind of artefact, such for example a physical equipment, a piece of software, a database or a demo, a report to be uploaded to the EC Tender & Funding Portal will be produced, which demonstrates the work carried out.

The list of deliverables, the level of dissemination (e.g. public, confidential), and the due date of all deliverable are listed in GA.

The deliverable will be structured with a cover page (as the one in the present deliverable), and a list of parts or chapters including at least: the acknowledgement and the disclaimer, the EC and SMILE project logos, the revision and history table, the summary, the list of acronyms, the executive summary. A template for deliverables is uploaded in the shared directory to allow for uniform and recognisable style, whenever possible. The Coordinator will report about the progress to the EB and to the GeA.

5 Risk management, project implementation risks

The project set up a project-internal Risk Management in order to:

- Identify and proactively manage risks related to the project (both internal and external)
- Track and continuously review all project risks in a risk register
- Implement and, if required, initiate suitable risk mitigation strategies

Checklist analysis (KPIs) will help to identify pending or problematic tasks that pose risks to the project. While a root cause analysis will make it easier to assign follow-up activities and proactive changes to solve tasks, most of the identified risks will be managed by referring directly to the WP leaders and the SMILE coordinator.

Risk analysis will cover both, the potential impact (or consequence) of the identified risks, and their likelihood (probability). In the case of likelihood, an intrinsic likelihood will be first considered, considering the nature of the risk and its probability in the absence of controls or other mitigation, and then adjusted for mitigating controls that will be confirmed as being in place.

Once a risk is identified, it will be analysed for further decision processing. The following definitions will be used to indicate the individual risk status:

- Low: not expected to have a serious impact
- Medium: significant impact on tasks and/or work packages, but not expected to impact project milestones
- High: major impact on the project and possible serious consequences to tasks, work packages and/or the entire project; likely to affect a milestone

- Unacceptable: priority attention; no affected work package or task will be allowed to proceed unless the WP leader or Project Coordinator (PC) manages to erase it or at least mitigate its potential impact or find a contingency plan

As to the risk management, SMILE will use a bottom-up approach:

- WP leaders collect risks for their activities after kick-off and a significant time prior to each GA meeting usually done yearly.
- RDIUP collects the individual risk reports and presents them to the Executive Board (EB).
- RDIUP schedules a virtual conference (or uses the existing ones) with the EB where the risk report is being discussed and remedial actions are being decided. The conclusions are collected and added to the risk report. RDIUP presents the risk report at the GA and at the annual Project Board meetings, where actions might be decided.

In case of failure to manage the consortium risks, resources will be reallocated to strengthen certain efforts, and a change of consortium partners will be considered. In case a partner resigns from the consortium for his own reasons, the coordinator will in advance prepare a list of potential qualified partners and respond promptly to recruit another partner together with the respective Coordinator of the resigning partner. The PC will monitor the performance of the partners. In collaboration with the work package leaders, he will look for early signs of non-performance of any of the partners (i.e. he will check if partners fail to comply with their obligations to the consortium).

Finally, strategies to mitigate the risks will be identified and described in the following principal areas: personnel, facility and equipment, procedure/methodology.

Additionally, we will detail the project's conflict resolution approach in the subsequent section.

5.1 Identified risks and mitigation measures

The SMILE consortium is aware of the external and internal risks that may affect the project's performance. Anticipating a Risk Management Plan, a preliminary analysis allowed the identification of an initial set of early-phase risks, for which possible contingency solutions have been already formulated in the list below.

Critical risks for implementation (L: Likelihood, I: Impact)

- 1) Description of risk: Withdrawal of partners. For several unexpected reasons, even unrelated to the project, a partner could decide to discontinue the collaboration and formally leave the consortium.

Likelihood: Low, Impact: Medium

Affected: All WPs

Proposed risk-mitigation measures: This risk is averted by the definition of adequate contracts to regulate possible conflicts or default cases (Consortium Agreement). The coordinator will prepare a proposal for replacement/swap of activities, including possible effort relocation. We will agree on a collaborative knowledge management system with sharing and continuous storage of partners' knowledge.

This risk has actually manifested with the departure of AUSL-IRCCS. SMILE is currently onboarding replacement partners and is reassigning some minor tasks and efforts to fully cover the required work for executing the proposed research as defined in the DoA. We do not expect this event to increase the risk of recurrence and will therefore not readjust the mitigation measures.

- 2) Description of risk: Project internal disagreements or lack of consensus.

Likelihood: *High*, Impact: *Medium*

Affected: *All WPs*

Proposed risk-mitigation measures: The spirit of SMILE is to achieve consensus. The experience and skills of all partners in working on such multi-disciplinary projects will ensure we avoid and defuse conflicts via negotiation. Some disagreements can be healthy to align goals and strategies. However, especially with regard to the topic of adolescents' mental health it is important to reach a common understanding between technical and clinical partners, considering their respective language and working culture. Misunderstanding would otherwise lead to features and elements in the SMILE game that might have negative impact on the projects' outcome.

- 3) Description of risk(s): Project deliverables or milestones delayed

Likelihood: *Medium*, Impact: *Medium*

Affected: *All WPs*

Proposed risk-mitigation measures: This risk is mitigated by balancing partner's participation in several WPs, ensuring that the overall picture is clear to all partners and scheduling regular project meetings and project management and follow ups

- 4) Description of risk: SMILE results fail to attract researchers and/or practitioners' interest and mobilization

Likelihood: *Low*, Impact: *Low*

Affected: *All WPs*

Proposed risk-mitigation measures: To avoid this risk, strong monitoring is detecting mismatching between communities expectations and early project results. If required, outcomes and impacts are readjusted while improving alignment to targeted audiences.

5) Description of risk: Difficulties to train adolescents.

Likelihood: *Low*, Impact: *Low*

Affected: *WP2, WP7*

Proposed risk-mitigation measures: It will be mitigated by motivating adolescents through a rewarding mechanism, providing training dedicated and tailored for each age group, defining comprehensive learning with clear explanation, and using digital and animated tools to teach them. The SMILE elements themselves, finally, will use a simple and clear language targeted to the needs of different age groups.

6) Description of risk: Insufficient recruitment of participants for the case studies.

Likelihood: *Low*, Impact: *High*

Affected: *WP2, WP7*

Proposed risk-mitigation measures: Consortium partners have significant expertise in the fields of recruitment and ethics; moreover, formal and informal caregivers' skills are planned to be involved. A timely start of communication with potential participants is guaranteed. WP 8 materials support this step. The number of participants for each use case is defined closely by each partner considering the worst-case scenarios (capacity of each cohort) and after performing focus groups during this proposal preparation

7) Description of risk: Security breaches at different deployed systems and repositories.

Likelihood: *Medium*, Impact: *Medium*

Affected: *WP3*

Proposed risk-mitigation measures: WP3 will implement adequate security management and reporting processes (partners, data, systems). The security management will ensure responsibilities, reporting and response to cybersecurity challenges.

- 8) Description of risk: Patient uptake of the serious game. It is difficult for users to uptake a new game if they are not psychologically attuned to gaming.

Likelihood: *Medium*, Impact: *Medium*

Affected: *WP4*

Proposed risk-mitigation measures: Games genres and gamification scenarios will be defined in collaboration with clinicians and patients at an early stage. The implication of clinicians will continue even during the serious game development to ensure its acceptability by the patients.

- 9) Description of risk: Difficulties to integrate all developed modules and tools in SMILE platform

Likelihood: *Low*, Impact: *Medium*

Affected: *WP4, WP5, WP6*

Proposed risk-mitigation measures: SMILE platform will be developed in two versions. SMILE plans that each developed module/tool will be integrated, tested and validated separately. This step-by-step process ensures integration of the whole platform.

- 10) Description of risk: Fear of caregivers and adolescents potentially developing dependency on technology (gaming disorders or addiction) or to feel sceptical about game-intervention or tools.

Likelihood: *Medium*, Impact: *Low*

Affected: *WP2, WP6*

Proposed risk-mitigation measures: To address these concerns, preliminary teaching sessions will be performed to understand these fears and scepticisms and how to overcome them. A comprehensive information on the aims of SMILE before the start of the pilots will mitigate these fears.

- 11) Description of risk: Fear of health professionals (i.e. general practitioner), that SMILE platform will take over their jobs.

Likelihood: *Low*, Impact: *Low*

Affected: *WP7*

Proposed risk-mitigation measures: Health professionals are invited to focus groups and in-depth interviews that will inform them on the aims of SMILE. Information is

moreover provided via website and on conferences with the respective professional groups.

- 12) Description of risk: The difficulty to define a sustainable business model.

Likelihood: *Low*, Impact: *High*

Affected: *WP8*

Proposed risk-mitigation measures: The participation of target groups in workshops, webinars and virtual info-days promotes the involvement and implication of end-users through our services.

- 13) Description of risk: Low level of stakeholders' engagement and difficulties in achieving expected communication, engagement, dissemination KPIs.

Likelihood: *Low*, Impact: *High*

Affected: *WP8*

Proposed risk-mitigation measures: Thanks to the continuous monitoring of the Communication, Engagement and Dissemination (CED) activities (via outreach and engagement monitoring tools and feedbacks) and the scalable and flexible approach of the CED strategy it will be possible to adopt corrective measures to reach the expected impacts.

5.2 Conflict Resolution Approach

Maintain harmony within the SMILE consortium, especially as we navigate the realms of technical, scientific, and commercial collaboration, requires an effective conflict resolution strategy. SMILE approach involves a multi-tiered system design to address and resolve conflicts promptly and amicably.

As a foundational step, conflicts and disagreements will be addressed informally through open discussions among consortium partners and direct communication between the involved parties. Agreements or resolutions resulting from these discussions, will be documented through means, such as emails or agreed upon minutes.

If the informal resolution is elusive, the matter will be escalated to the Work package leader, who will organise a Work package team meeting to discuss and address the issue.

If the conflicts persist, the matter will be elevated to the project coordinator who will, in turn, engage with the involved parties to reach a resolution.

If consensus is still not reached, further escalation may involve the Project Officer to make effective decisions.

SMILE conflict resolution strategy ensures a systematic approach, starting with open dialogue and progressing through a structured escalation process. Rooted in open communication, collaboration, and adherence to project regulations, this approach aims to sustain the productivity and success of the SMILE consortium.

The risk management will be monitored and updated continuously as the project progresses and any conflicts are identified.

6 Conclusion

This deliverable comprises the project management, work, quality assurance and the risk management plans. Both the project and quality assurance plan outlines structures aiming at ensuring the ongoing maintenance of high quality throughout the project's implementation and outcomes. This plan specifically defines governance, management structures, and decision-making processes. It outlines the roles related to quality assurance, both within the consortium and externally, the reporting procedures, the internal communication strategies, and the deliverables' production processes.

Dedicated to proactive risk management, the risk management plan focuses on identifying and anticipating potential risks before they arise to ensure proper actions and mitigation measures are taken. It outlines processes for identifying and monitoring the risks, analysing their exposure ratings, detailing their monitoring procedures, and describing steps for preparing and implementing appropriate contingency actions. Additionally, the plan incorporates the SMILE approach to conflict resolution, outlining protocols and escalation procedures to maintain a harmonious project environment.

Currently, the consortium partners have agreed on the mentioned protocols, and where applicable, the protocols were being successfully put into practice.

As the project progresses, consortium partners will regularly evaluate which aspects of the Quality Assurance and Risk Management require refinement or adjustment, thereby strengthen the project's resilience and uphold its commitment to excellence.

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