ONCOSCREEN

D1.1 REPORT ON PROJECT MANAGEMENT AND CROSS ACTIVITIES (FIRST VERSION)

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DOCUMENT SUMMARY INFORMATION

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PROJECT PARTNERS

Partner	Acronym
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UNIVERSITAETSMEDIZIN DER JOHANNES GUTENBERG-UNIVERSITAET MAINZ	UMC-Mainz
INSTITUTE OF COMMUNICATION AND COMPUTER SYSTEMS	ICCS
FIRALIS	Firalis
UNIVERSITATSKLINIKUM SCHLESWIG-HOLSTEIN	UKSH
UNIVERSITAET zu LUEBECK	UzL
LIETUVOS SVEIKATOS MOKSLU UNIVERSITETAS	LSMU
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ETHNIKO KENTRO EREVNAS KAI TECHNOLOGIKIS ANAPTYXIS	CERTH
INNOVATION SPRINT	iSPRINT
SCIENTIFIC ACADEMY FOR SERVICE TECHNOLOGY EV	SERVTECH
AINIGMA TECHNOLOGIES	AINIGMA
CATALINK LIMITED	CATALINK
KONNEKT ABLE TECHNOLOGIES LIMITED	KT
BEIA CONSULT INTERNATIONAL SRL	BEIA
UNIVERSIDAD DE LA RIOJA	URIOJA
TIME.LEX	time.lex
CARR COMMUNICATIONS LIMITED	CARR
MINISTRY OF HEALTH	MoHGR
PAGALBOS ONKOLOGINIAMS LIGONIAMS ASOCIACIJA	POLA LT
EUROPACOLON PORTUGAL- ASSOCIACAO DE LUTA CONTRA O CANCRO DO INTESTINO	ECPT
ELLINIKI ETAIREIA OGKOLOGIAS PEPTIKOU	HSGO
EUROPEAN SOCIETY OF DIGESTIVE ONCOLOGY	ESDO
FUNDATIA YOUTH CANCER EUROPE	YCE
MEDIZINISCHE UNIVERSITAT INNSBRUCK	MUI
LIETUVOS RESPUBLIKOS SVEIKATOS APSAUGOS MINISTERIJA	MoH-LT
EY ADVISORY SPA	EY
AGENCIA ESTATAL CONSEJO SUPERIOR DE INVESTIGACIONES CIENTIFICAS	CSIC
UNIVERSITE DE FRANCHE-COMTE	UFC
ROZENBAUM KONSULTING	ROSENBAUM
GIE AXA	GIE AXA
ASSOCIATION GERCOR	GERCOR
LOUWEN ROGIER	CC RL
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LIST OF ABBREVIATIONS

Abbreviation	Description
CA	Consortium Agreement
CRC	Colorectal cancer
D	Deliverable
DoA	Description of Action
EC	European Commission
EU	European Union
GA	Grant Agreement
GDPR	General Data Protection Regulation
IPR	Intellectual Property Rights
WP	Work Package

Executive Summary

This deliverable presents the project management structure, methodologies, quality control, risk management and legal management being developed under the tasks T1.1 – T1.5. This document also mentions the monitoring procedures of the project and the relevant monitoring registries.

This document serves as the project handbook defining the structures used for managing the project throughout its lifecycle, while it reports a glance of the relevant activities as reported from the 1st plenary meeting. This deliverable is an essential point of reference for all project members and stakeholders of ONCOSCREEN.

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1 Introduction

ONCOSCREEN project is part of the Cancer Mission cluster of projects on 'Prevention, including Screening' aiming in particular at addressing the challenges associated with Colorectal Cancer (CRC) which is accountable for 12.4% of all deaths due to cancer. In particular, it plans to address the needs for accurate, non-invasive, cost-effective screening tests based on novel technologies and an increased awareness on the disease and its detection, while providing personalized approaches for screening. It plans to achieve those goals by developing a risk-based, population-level stratification methodology for CRC, to account for genetic prevalence, socio-economic status, and other factors. Such a methodology is complemented by a) developing a set of novel, practical, and low-cost screening technologies with high sensitivity and specificity, b) leveraging AI to improve existing methodologies for CRC screening, allowing for the early detection of polyps and provision of a personalized risk status stratification, and c) providing a mobile app for self-monitoring and CRC awareness raising. Furthermore, ONCOSCREEN develops an Intelligent Analytics dashboard for policy makers facilitating effective policy making at regional and national levels. The above-mentioned solutions are planned to be tested and validated through a multi-level campaign, while organizing a systematic clinical validation study.

The project is implemented by a multidisciplinary consortium, including technical, solutions providers, hospitals, Ministries of Health as policy makers, legal and ethics experts, insurance companies while involving actively end-users/citizens in all phases of implementation. ONCOSCREEN develops its value proposition in 7 WPs.

The successful implementation of the project requires the adoption of proper project and technical management methodologies which are executed as part of the tasks T1.1-T1.5 of the WP1. In particular, WP1 aims at a) monitoring the administrative, technical, scientific and financial aspects, while providing technical, medical and clinical steering; b) guaranteeing the adherence of work to the project plans, resources, timing; c) communicating with EU services and external actors; d) assuring the high quality of the project outcomes and compliance with existing standards; e) continuously identifying and assess risks applying risk management and mitigation processes; and f) establishing and applying the Ethics, Legal & Regulatory Framework.

This deliverable focuses on presenting the applied methodologies for project management, quality control, risk management, ethics and legal requirements. It also describes the monitoring procedures of the project including the overall KPIs and the relevant monitoring registries.

1.1 Document outline

The document initially describes in Section 2 and 3 the applied project management methodology, including the applied risk, requirements, quality and communication management approaches. Section 4 discusses the project progress measurement approach, while Section 5 presents the project roles and responsibilities. Section 6 discusses the risk management plan and associated monitoring approaches. Finally, Section 7 describes the Monitoring of Ethical, legal and societal aspects.

1.2 Deliverable objectives

Table 1 presents the connection of the contents of the present deliverable with the ONCOSCREEN Grant Agreement requirements in Work Package 1:

Table 1 Description of Action: WP1

ONCOSCREEN DoA requirements	Deliverable addressing the requirements	Brief description
Task 1.1 Administrative & Financial Planning and Coordination	D1.1 Report on Project Management and Cross Activities (First Version)	The deliverable presents the activities within tasks T1.1-T1.5, describing the project management methodologies, quality control and risk management, ethics and legal requirements and monitoring procedures of the project and the overall KPIs.
Task 1.2 Technology Steering		
T1.3 Clinical and Medical Steering		
T1.4 Quality Control, Risk Management and Contingency Planning		
T1.5 Continuous Monitoring of Ethical, legal and societal aspects		
T1.6 Data Management	D1.3 Data Management Plan (First Version)	This deliverable reported on the project's data management plan, policies and procedures to be followed during the project.

1.3 Relationship with other deliverables and tasks

Table 2 Linkages between D1.1 and other ONCOSCREEN deliverables

Deliverable	Description of the deliverable	Link to D1.1
D1.2	Report on Project Management and Cross activities (Final version)	This deliverable is the final version of D1.1, that will report any updates on the project management methodologies and the activities pursued in tasks T1.1-T1.5.

2 ONCOSCREEN Organization

2.1 Management Structure

The project management in ONCOSCREEN is based on the following three main principles:

- **Integrated Project Structure:** Develop an integrated project structure that incorporates technical, scientific and partner coordination as well as issues of commonplace business operation.
- **Adopt effective Project Management Instruments:** Apply internationally operated and state of the art management instruments and establish a strong commitment of the entire team. The applied project methodology will be based on the *PM*^{2} methodology [1].
- **Binding decision provisions and agreements:** Organize proper decision-making approaches close to responsible level of execution, elevate if necessary. Provide reliable and trusted agreements to protect intellectual properties of all partners.

Based on these three major principles the project management approach guarantees transparency and commitment to all engaged partners and thus facilitates an unobstructed and successful project execution. It is essential for ensuring that ONCOSCREEN meets its entire objectives on time, on budget, and with best quality results.

2.2 PROJECT ROLES & RESPONSIBILITIES

In the following section, the roles of major roles in the project are described alongside with their responsibilities, rights and duties.

1.1 Project Coordination Team (PCT)

The Project Coordination Team (PCT) is responsible for the planning, execution and controlling of the project. More specifically the PCT operates under the supervision of the Project Coordinator and encompasses the following activities:

- Administration and scientific coordination activities,
- Implementation of all action plans,
- Establishing a budget and schedule-controlling system,
- Implementation of a 360^o quality assurance system,

[1] https://www.pm2alliance.eu/what-is-pm2/

- Providing clear guidance on Intellectual Property issues,
- Developing and maintaining a communication and reporting attitude,
- Creation of efficient team structures to minimize the number of meetings while being flexible.

The PCT consists of the following roles:

- **Project Coordinator (PC):** The Project Coordinator is responsible for the overall management, communication, and coordination of the project and will chair the two main project bodies, the Project Coordination Team and the Plenary Board. The Project Coordinator is the only official channel that interacts with the European Commission, especially with regards to the submission of deliverables, aspects related to third parties and the consortium.
- **Quality Manager (QM):** The Quality Manager is responsible for the implementation of the quality procedures determined in the Quality Plan and the verification of the project results.
- **Innovation Manager (IM):** The Innovation Manager is responsible for managing the knowledge produced during the project lifecycle. He manages the execution of the overall exploitation plan of the project and supports the partners in setting up their individual business plans, in order to exploit ONCOSCREEN results.
- **Project Administration (PA):** The management of the ONCOSCREEN Consortium and their corresponding administrative issues, require the support of full time and experienced personnel, integrated at the Project Administration. The project Administration will provide the Financial Control, External relations and Help Desk.

1.2 Management Roles

The project also assigns the following roles for overlooking and directing the different activities. These roles monitor the respective activities, report issues and suggest solutions to the project coordinator.

- **Technical Manager (TM):** This role ensures that the scientific and technological objectives of the project are met. The Technical Manager chairs the Technical Steering Committee and coordinates and assists WP Leaders on scientific and technical issues undertaking initiatives to propose technical solutions and fine-tune technical and scientific orientations.
- **Scientific Manager (SM):** This role leads the clinical committee and coordinates all medical and clinical aspects of the project. He acts as an intermediate layer between the Project Management Board and the relevant WP leaders, and will communicate any problems or conflicts that may occur

- **Communication Manager (COM):** This role suggests, plans and monitors the execution of the communication activities of the project. He manages the website and social media of the project and coordinates the communication activities of all partners.

- **Legal Advisor (LEA):** This role is responsible for the management of any legal issues relevant to the project, especially focusing on supporting approvals for the clinical trials execution.

- **Data Manager (DM):** This role defines a trustworthy and ethical data management policy of the project and monitors that the data collection, access, sharing, processing, storage etc. are applied consistently throughout the project.

- **End User Coordinator (EUC):** This role defines the management of handling horizontally requests referring to end users, liaising with the TM for the definition of End User and Technical Requirements.

- **Clinical Trial Manager (CTM):** This role defines the coordination of tasks and monitoring of the ONCOSCREEN Clinical Trial Procedure liaising with the Clinical Steering Committee.

1.3 Steering Committees

The project forms the following committees, which are responsible for the execution of the relevant activities.

- **Project Management Board (PMB):** This board consists of the WP leaders, specialist management roles like the TM, SM, LEA, DM, COM, EUC, CTM and is chaired by the PC. This board monitors frequently the execution of each project WP, discusses any issues and tries to resolve them. It ensures that the project activities are executed according to the project work plan and schedule.

- **Technology Steering Committee (TSC):** This committee coordinates the scientific/technical work including the technical progress monitoring, assessment and exchange of technical information among partners and the supervision of the technical deliverables.

- **Clinical Steering Committee (CSC):** This committee manages and coordinates all medical and clinical aspects of the project. It ensures that research activities and the elicitation of user requirements during the first phase, as well as the clinical validation and assessment of ONCOSCREEN during the latter stages of the project will be properly aligned with the project objectives. CSC is responsible to establish and maintain the Medical/Clinical Steering Committee that will be responsible to take decisions and solve conflicts regarding all medical/clinical aspects during the project.

- **Ethics and Review Committee (ERC):** This committee identifies and documents the: (i) legal restrictions on the use of different data types for the clinical studies including data ownership and controllership responsibilities and general data protection obligations; (ii)

legal requirements linked to the qualification of medical devices, the implementation of the FAIR rules, and the particularities of regulation of AI in the broader sense; (iii) the ethical considerations during designing/implementing the clinical studies, including the applications for ethical approvals and the appropriate involvement of research participants/patients in the clinical study (iv) operational or patient restrictions and requirements, based on patient needs and management processes of the participating clinics. The ERC shall be met on an Ad Hoc basis on the occasion of any critical issues of ethic nature.

1.4 Plenary Board

The Plenary Board consists of the representatives of all Partners, each having one vote. It is led by the Coordinator, who has the decisive vote in case of equal votes. This Board will meet once per year (during the plenary meetings) to review and plan project work. Any partner may raise issues. Minor issues may be discussed and decided within this Board. Major issues will be transferred to the Technical Committee or Clinical Committee level.

1.5 Assigned Project Roles

During the initiation period the consortium has decided on the assignment of the project roles to each partner. The partners who undertake the main project roles are presented in the following table:

Table 3: Main Project Roles

Role	Responsible Partner
Project Coordination Team	
Project Coordinator	EXUS
Quality Manager	EXUS
Innovation Manager	EXUS
Project Secretariat	EXUS
Assigned Management Roles	
Technical Manager	ICCS
Scientific Manager	UMC-MAINZ
Communication Manager	CARR
Legal Advisor	TIMELEX
Data Manager	TIMELEX
End User Coordinator	POLA

Clinical Trial Manager	FIRALIS
Steering Committees Members	
Project Management Board	EXUS, UMC-MAINZ MUG, CERTH, FIRALIS, URIOJA, CARR, ICCS, TIMELEX
Technology Steering Committee	ICCS, TECHNION, CERTH, EXUS,
Clinical Steering Committee	UzL, LSMU, IPO, IOB, UMINHO
Ethics and Review Committee	TIMELEX, EXUS, UMC-Mainz, UMINHO, ROSENBAUM
WP Leaders	
WP1	EXUS
WP2	UMC-MAINZ
WP3	MUG
WP4	CERTH
WP5	FIRALIS
WP6	URIOJA
WP7	CARR

1.6 End-Users

End-users (EU) involve the clinicians, policy makers, and citizens/patients, who participate in the project. They help to define the scientific and technical needs needs and requirements. They ensure that the project specifications and deliverables meet the needs of potential end users and approve on behalf of the users the project specification and acceptance criteria. They pparticipate in technical demonstrations and pilot phases and sign off documents related to the users (documentation, requirements, etc.).

3 Project Approach and Quality Management

3.1 Project Lifecycle

The project adopts the *PM²* methodology [2], which splits the lifecycle of a project into 4 phases, each one having different types of activities dominating:

1. Initiating phase
2. Planning phase
3. Executing phase
4. Closing phase

Since ONCOSCREEN is a RIA Horizon Europe project, the Initiating and Planning phases have already been performed and concluded during the proposal preparation and submission phase. As such, the project is in its Executing phase since 01/01/2023 and will enter in the Closing phase at 31/12/2026.

3.1.1 Executing phase

Within the Executing phase, the ONCOSCREEN project includes a number of sub-phases with planned Dates for moving forward from one sub-phase to the next one. These sub-phases are:

1. Sub-phase 1: Extraction of requirements, System-Architecture and Clinical Study Definition

During this phase, the consortium defines the use cases of ONCOSCREEN, and then elicit the user and technical requirements and specifications. The deliverable D1.3, which was submitted on M6 defined the data management plan of the project. The deliverable D2.1 what was submitted on M12 provides a comprehensive clinical knowledge base that drives the relevant activities. D4.1, submitted on M13 sets the basis for the overall system architecture of all technical solutions of the project, while a set of technical deliverables including D3.1 delivered on M13, and D4.3 delivered on M13 report on the progress achieved towards the design of diagnostics solutions. The 1st sub-phase concludes with the submission of D5.3 on M18 discussing bout the clinical study. During this phase the consortium worked passionately also on the implementation of the exploitation which is detailed in D7.4 delivered on M18.

2. Sub-phase 2: Refinement of ONCOSCREEN solutions

This sub-phase starts on M18 of the project and performs the refinement of the ONCOSCREEN solutions, while executing the clinical study. This phase includes the submission of D3.2, D4.2 and D4.3, which are going to report on the final version of the system architecture and ONCOSCREEN technical solutions. It concludes on M36 with the submission of D5.4 concerning the clinical study progress.

3. Sub-phase 3: Evaluation of ONCOSCREEN solutions

[2] https://www.pm2alliance.eu/what-is-pm2/

This sub-phase focuses on the evaluation of ONCOSCREEN and validation in a series of use cases. This phase concludes on M48 with the submission of D5.7 reporting on the post clinical study results.

During the whole Executing phase, management activities and impact creation activities are performed, ensuring the proper execution of the project coordination and support tasks, along the completion of the project dissemination, communication, and exploitation activities.

3.1.2 Closing phase

Within this phase, which formally concludes the project, all activities related to the use of resources and the documentation for the EU will be prepared and finalised.

3.2 PM² Tailoring – Required Project Documentation

Artefact	Yes/No	Location	If No, briefly explain the reason
Project Initiation Request	✓	Submitted Proposal (internal repository document)	-
Business Case	X	-	Not applicable in RIA projects
Project Charter	✓	Grant Agreement-101097036_ONCOSCREEN (internal repository)	-
Project Handbook (this document)	✓	D1.1 (this document)	-
Stakeholder Matrix	✓	D1.1 (this document)	-
Project Work Plan	✓	WBS and GANTT of the Grant Agreement-101097036_ONCOSCREEN (internal repository)	-
Transition Plan	X	-	Not applicable in RIA projects

3.3 Decision Process

Decisions will normally be taken by the responsible team members, and organization bodies based on the Consortium Agreement (CA), the Description of Action (DoA) and the Quality Management Plan, as communicated regularly, and the individual Work Package or Task plans. In

case of a dispute between two or more team members, an escalation procedure must be followed, as discussed next.

3.4 Conflict Resolution and Escalations

Conflicts are situations in which one or both parties perceive a threat. They are considered to be critical issues and can be raised by any of the project stakeholders. The ONCOSCREEN Project Management team will proactively identify, log and raise such issues for resolution. When required, conflicts will be discussed on the bi-weekly management, technical and clinical sterring meetings and if needed, escalated to the Project Corrdinator and if needed to the Plenary Board.

Usually, agreement will be reached first by informal contact, followed by official confirmation via electronic mail, letter or agreed written minutes. For important issues, the agreement may take the form of a short report that needs to be signed by those responsible for decision-making. Non-technical factors such as resource allocation and contractual terms will also need to be agreed and documented in writing. Technical issues/conflicts within given contractual commitments that do not involve a change of contract, a change of budget and/ or a change of resources/ overall focus will be discussed/solved on the WP level first. If the decision being taken is unacceptable to partners found in the minority positions, the resolution of the conflict will be escalated according to the path as specified in the following figure.

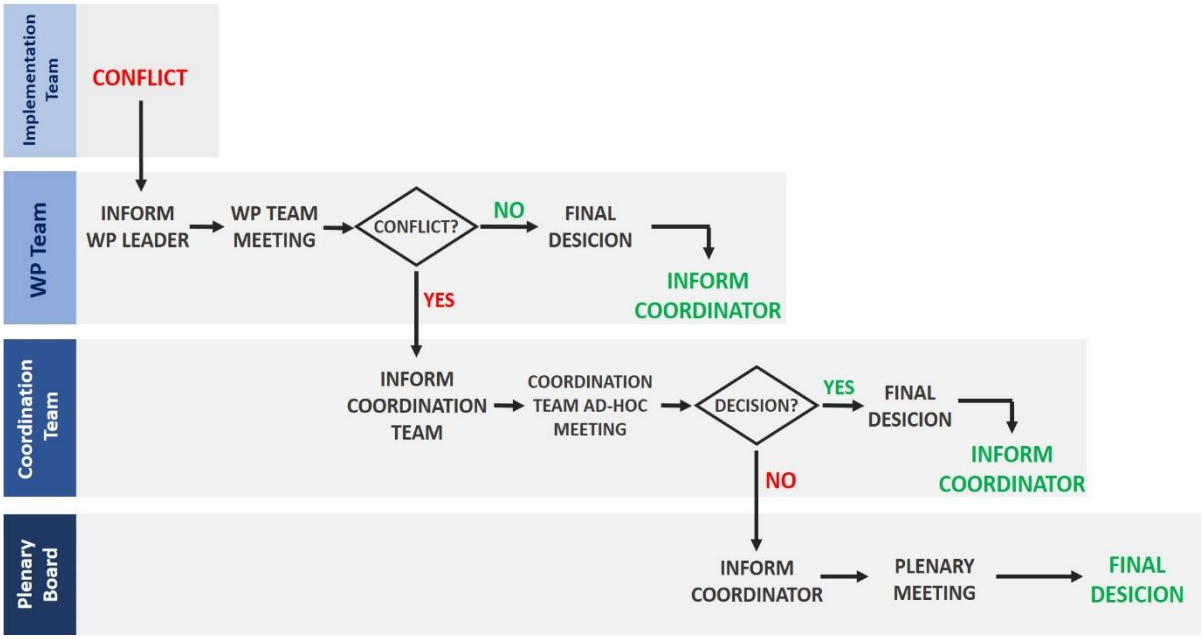


Figure 1: Conflict Resolution Process

The escalation procedure is summarized in the following steps:

- First, the implementation team will inform the WP leader about the conflict.
- The WP leader will organize a WP team meeting and the issue will be discussed. In case of agreement, the team will inform the coordination team and the Coordinator.

- The coordination team will meet with the relevant parties in order to discuss the conflict. If no agreement can be found, the issue will go to the Plenary Board who will have the authority for the final decision.

In all cases the project coordinator will inform the Project Management Board (PMB), to hear the opinions of the member, enhance transparency, and also trying to take collective decision to solve issues in a smooth manner while maximising acceptance and reducing human error or creation of new conflicts.

The final decision must be accepted by all parties.

3.5 Communications Management

The communications management process determines how to communicate most efficiently and effectively to the various stakeholders. It defines and documents the communication items content, format, frequency, the audience and expected results. It also defines how to communicate project status and the assignment of activities to the various stakeholders, and the communication strategy for each stakeholder, based on their interests, expectations and influence in the project.

3.5.1 Information Flow

Information flow within the Project will be ensured by:

- The exchange of internal technical and business documents.
- Notification of relevant new publications in the literature, or by the standard bodies.
- Reports from external meetings.

All technical documentation generated by the project shall be exchangeable in electronic format, according to an agreed set of guidelines defined in the various templates like the deliverable, presentation and minute template shown in Appendix C. The Quality Manager will enforce adherence to these guidelines.

Exchange of information will mainly occur via e-mail and through the project's collaboration site (Microsoft SharePoint) where all partners will have secure and author rights to create/edit/review documents/news etc. This collaborative space includes:

- A project library with all baseline documents and logos (DoA, Legal documents, CA, contract with EC, etc.), deliverables, WP documents, meeting minutes and presentations, telco minutes, reports, dissemination material, etc.
- Contacts: partner information.

The information is organized in 5 different root folders which include, Administration, Work Packages, Meetings, Templates and Final Deliverables. The Work Packages folders contain documents and/or tools about each WP, while in the Meetings folder partners can easily seek information discussed in each meeting. The Templates folder contain all the relevant templates

of the project and provide a quick reference of each partner as part of the quality management processes. The Deliverable folder contain all the final submitted deliverables as a quick reference.

The Project Coordinator team is responsible for the structure and maintenance of the collaboration site. Furthermore, selected information such as public deliverables, published papers, events and news will be disseminated through the project's public website: https://oncoscreen.health/

Urgent correspondence over e-mail will be sent with a request for explicit acknowledge. Ordinary mail will be used for strictly formal correspondence, i.e. when executive signatures are required. Adherence to the agreed communications standards will be enforced by the Project Coordinator and the Quality Manager.

3.5.2 Meetings

To facilitate the monitoring, quality management and conflict and risk resolution approaches, the following project meetings are organised:

Table 4 List of ONCOSCREEN Meetings

Meeting	Chair	Frequency
Kick-off Meeting	Project Coordinator	Once
Management Board Meeting	Project Coordinator	Bi-Weekly
Technical Steering Meeting	Technical Manager	Bi-Weekly
Clinical Steering Meeting	Clinical Manager (SM)	Bi-Weekly
WP Meetings (WP2, - WP7)	WP2-WP7 Leader	Bi-Weekly, or when needed
Project Plenary Meeting	Project Coordinator	Annually
Project Review Meeting	EC	M18, M36, M48
Plenary Board	Project Coordinator	Annually, or when/if needed
Project-End Review Meeting	EC	Once

During the first period (M1-M18) the kick-off meeting took place in Athens on 12-13 January, during which representatives from all partners have the chance to discuss and plan the project work and agree on the project management and implementation processes.

Furthermore, the first annual plenary meeting took place on 1-2 February in Paris, bringing together 59 representatives from all partners. The 2 day meeting included presentations about the progress updates, the challenges and next steps in all WPs along with 5 workshops focusing on system architecture, clinical trials, end-user requirements, exploitation and citizen engagement. The detailed minutes of the meeting are provided in Annex D.

Note that at the end of each meeting type, the chair/lead partner is responsible to prepare and circulate Minutes, according to a Meeting Minutes template, which is shown in Annex C, as part

of the quality management. This ensures coherent communication of the information across all meeting and partners.

During this period several number of meetings with the appropriate representatives from the relevant partners were organized within each WP. The scope was the close collaboration and timely communication among partners to discuss the progress and resolve any issues and deviations, while planning the work that need to be carried out as the project progresses.

Some of the meetings that took place during this period M1-M18, are shown indicatively below.

Meeting	Place and Dates	Participants/Description
Management Board Meeting	MS Teams, on bi-weekly basis, starting from 1/2/2023 – 30/06/2024	Project monitoring and discussion among Management Board Partners
Technical Steering Meeting	MS Teams, on bi-weekly basis, starting from 1/2/2023 – 30/06/2024	Discussion between Technical Partners concerning technical updates and issues
Clinical Steering Meeting	MS Teams, on bi-weekly basis, starting from 30/1/2023 – 30/06/2024	Meeting with Clinical and Technical partners to implement the Clinical Study Phase A
WP2 Meeting	Bi-weekly meetings starting from 14/02/23 - 30/06/24	Partners involved in WP2 discussing the updates and issue resolution
WP3 Meeting	Throughout the first period via Webex.	Meetings among WP3 partners to discuss progress and current challenges
WP4 Meeting	Bi-weekly every Tuesday	Meeting among WP4 partners to discuss progress
WP6 Meeting	Monthly MS Teams telco, starting on 27/10/23 – 30-06-24	Review of tasks progress and planning the work of T6.1
WP7 Meeting	MS Teams telco on 1.06/23, 30/11/23	Discussion about the Living Lab and updates about the launched platform

4 Project Progress Monitoring

4.1 Internal Periodic Reports

The progress of the project will be evaluated annually, through the Internal Progress Report. The report will describe the progress achieved in each active task and WP, the role of partners, the use of resources, the issues identified and resolved during the period covered by the report, as well as the risks identified and the steps needed for the next reporting period. The information in the Project Progress Report will help in monitoring the progress and identifying early any issues, while being essential for preparing the Periodic Project Report at the end of each reporting period that will submitted to EU.

Such reports follow the structure of the periodic reports template provided by the European Commission (EC) and are based on consolidated reports provided by the WP Leaders including:

- Technical progress of the project per WP
- Problems encountered during the project
- Risk management
- Resource/financial statements including explanation about any deviations
- Key Performance Indicators (KPIs), discussed in Section 5.
- IPR Registry
- Dissemination and Communication Registry
- Gender and Balance Registry
- Requirements Registry

Such reports will be developed annually on M12, M30 covering the following periods M1-M12, and M19-M30 in between the periodic reporting periods.

4.2 Periodic Project Progress Report

The Project Progress Report are extended reports that form the basis for the editing of periodic progress report to be forwarded to the EC for reporting the progress of the project on M18, M36 and M48. The information will be presented in task-level, WP-level, and will also include deliverables submitted and milestones achieved. The use of resources will be justified. Finally, issues resolved, and risks identified will be presented. The whole project management activity and information flow will also be supported by reports provided to the WP leaders and each project partners. These are extended reports including:

- Official Cost statements including all expenses in the period
- Detailed technical progress of the project per WP

- Reports on the problems encountered during the project
- Risk management results
- Key Performance Indicators (KPIs), discussed in Section 5.

The periodic progress report will be based on the template provided by the EC.

4.3 Risk Management

The project risk management process defines the activities to identify, assess, prioritise, manage and control risks that may affect the execution of the project and the achievement of its outputs. This is a four step process:

- Risk Identification: risks are continuously identified throughout the project lifecycle by any project stakeholder and documented in the Risk Registry (by any project team member).
- Risk Assessment: risks are assessed based on their likelihood of occurrence and the impact in project scope and constraints. The product of their likelihood and impact (in 5 point scales) defines the Risk Level which is then used as a reference for their prioritisation and risk response development.
- Risk Response Development: there are four strategies to be considered as risk responses to threats: Avoid, Transfer, Reduce or Accept a risk. After the strategy for each risk has been selected, specific actions to implement the strategy will be defined, described, scheduled and assigned, while a Risk Owner assumes the responsibility for its implementation. These actions will be incorporated into the Project Work Plan.
- Risk Control: the Project Status Meetings are used to revise the status of risks, probabilities and impacts, and related actions, and to identify new risks. Risks will be revised weekly, but also after the occurrence of any significant event. If any of the identified risks occur, then the Project Coordinator will implement the contingency plans and communicate the issue to the Plenary Board.

This four-step process is further elaborated in the Risk Management Plan, provided in Section 6.

4.4 Internal Registries

The overall progress of the project will be monitored via the internal and official periodic reports but also through a set of registries, that are live documents that will be updated periodically on a 3-6 months basis. These registries include:

- Key Performance Indicators (KPIs) registry that will be discussed in Section 5.
- Risk Registry
- IPR Registry that is introduced in D7.4
- Dissemination and Communication Registry that is included in D7.3
- Gender and Balance Registry that will be used during periodic reports
- Requirements Registry

- Integration Registry

4.5 Internal Quality Control Procedures

To ensure that all submitted deliverables are of high quality, the Quality Manager will enforce a strict quality control procedure. According to this, each project deliverable is assigned to one leading responsible partner. This partner takes the responsibility that the deliverable is of high quality and timely delivered. The responsible partner assures that the content of a deliverable is consistent with the team-workings of the deliverable and that the overall goals of the project are met. Any issues endangering the success of the work package or the project has to be reported immediately to the project management and discussed with the Coordination team.

Project documentation is reviewed against the following criteria:

- **Main objective of the deliverable**: Check if the objectives are clearly stated and are in line with the DoA. Check if it is clear how these objectives are relevant to the overall targeted results of the project as a whole.
- **References to previous work**: Have the authors overlooked any state of the art, previous work, related projects, regulations or best practices? Does the report include relevant references?
- **Methodology:** Was the work, development, trial, experiment conducted in a sensible way? Are the methods/procedures appropriate and correct?
- **Conformance of results**: Did the deliverable do what was promised? Do the findings and results of the work match the objectives as described in the DoA and are these results clearly described in the deliverable?
- **Format Template**: Is the format template applied properly and according to Appendix 3.
- **Usefulness of results**: Is the deliverable useful to downstream tasks or end-users? Is it clear that the results are useful and relevant? Is it clear how results can be accessed?
- **Conclusion**: Is there a conclusion chapter and does it make sense?
- **Readability**: Is the document understandable?
- **Consistency with previous documentation:** Is the deliverable consistent with previous documentation, e.g. DoA, technical specifications combined with the definition of requirements, etc.
- **Language**: Are there any obvious spelling or grammar mistakes?
- **Structure**: Is the structure of the deliverable logical and easy to follow?
- **Graphics**: Are figures and tables legible and referred to in the text?

- **Length**: Is the deliverable less than 100 pages in total?
- **Referencing**: Are papers and other sources correctly cited and referenced?
- **Terms**: Are terms defined in the glossary?
- **Nomenclature**: Are mathematical symbols defined?
- **Technical aspects** of the documentation will be reviewed from the corresponding WP and Task leaders in order to ensure that the document meets the technical goals of the project, and that all technical information is advancing the current state-of-the-art and the recent technological research level.

Apart from checking the deliverable against the aforementioned criteria, ethics, legal and security concerns regarding the content of the deliverable are to be considered. Sensitivity of presentation should be considered. If relevant contributors will need to seek for support from the relevant role-managers. The content should be presented in a way that does not unintentionally discriminate, infringe upon, an individual's or community's dignity or otherwise negatively increase vulnerability. Transparency and accountability issues should be also considered. The aim is to be publicly transparent about what the author is doing and be open about the tools, data and algorithms used and their intentions. This is essential in order to ensure that authors are accepting liability and responsibility for the quality and representativeness of the data and the results

The procedure for the review project documentation is illustrated in the following figure and is described in the following paragraphs.

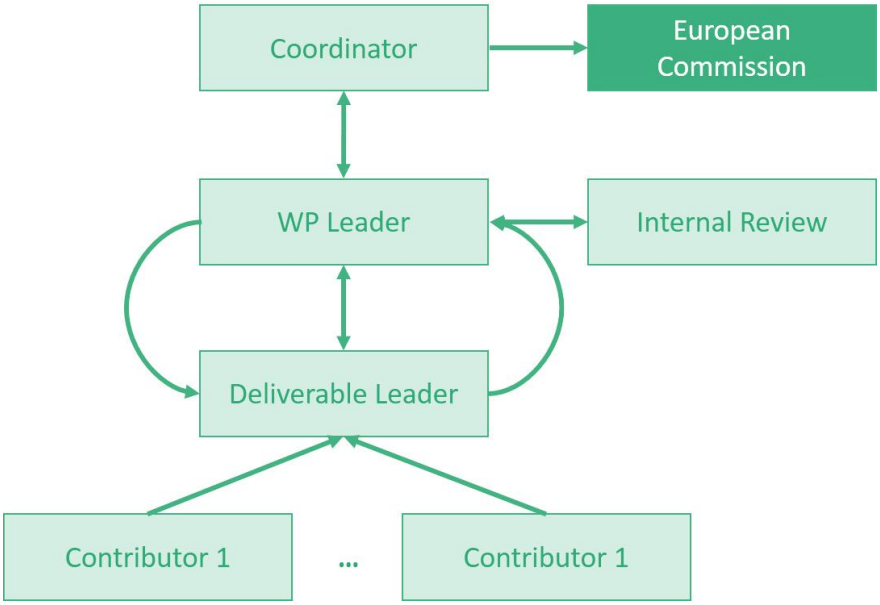


Figure 2: Preparation and Review Procedures of each Deliverable

The partner, who is responsible for preparing the deliverable, drafts a "table of contents" one month to three months before the due date, assigns tasks to all involved partners and sets the

respective deadlines. Involved partners provide their feedback/content within the deadlines and the responsible partner prepares the first draft of the document. This draft (Review Level 1) is sent to two peer reviewers and in Project Coordination Team members (Technical Manager, Ethics Advisor, Quality Manager and Project Coordinator). The Project coordinator is responsible for assigning the corresponding project coordination team members to review the deliverables in ad hoc basis depending on the nature of each deliverable. Comments and improvements/additions will be collected from responsible partners one week before the due date. The feedback period for project partners lasts four days. Feedback is sent directly to the responsible partner who revises the document and prepares the pre-final version (Review Level 2). The final version of the document is ready two days before due date. After a final check from the coordinator the document is submitted on the EC portal.

The Quality Control Process begins based on the pre-final version of the deliverable. At least two Internal Reviewers, who are not members of the authoring team but have expertise in relation to the deliverable, have been assigned in advance. In case that the deliverable is produced with the collaboration of all the partners then more than two Internal Reviewers will be assigned to cross read and peer review the complete version of the deliverable. The Internal reviewers send their comments to the responsible partner based on the DoA. This partner then improves the document based on their comments. In case the comments and suggestions cannot be realized, the reasons for this must be documented. If necessary (i.e. if there are too many comments in the first round), another round of comments from the Internal Reviewers takes place. Finally, the coordinator submits the document to the EC.

4.5.1 Peer Reviewers

The Peer Reviewers are assigned to review a deliverable based on the criteria described above. The peer-review process is considered as a means of “criticising” internal work towards ensuring the highest quality of results, hence PRs undertake a role of high responsibility. The PRs are responsible to follow the reviewing process deadlines and accurately report on the reviewing criteria established, holding responsibility of following that the corrective actions are performed from the leading beneficiary towards the submission and subsequent acceptance of the deliverable by the EC.

The partner accountable for a certain deliverable holds the highest responsibility to the Review Methodology and Process, to submit deliverables of high cognitive value addressing all appropriate objectives as defined by the DoA and to undertake all appropriate corrective actions to ensure the deliverable’s EC acceptance.

4.5.1 Review Process

The ONCOSCREEN Review process consists of:

1. A **Review Level 1**, which occurs 1 to 3 months before the final deliverable submission. In this level the Table of Contents (ToC) is produced. The ToC accurately captures the expected content of the deliverable as well as defines the content and scheduling of contributions expected by each involved partner. The Review Level 1 describes a

preliminary and speedy progress review focusing on document structure and content consolidated so far following – where appropriate - the above mentioned criteria as for the accountable partner to result at an intermediate deliverable.

2. A **Review Level 2**, which describes a complete and thorough document review conducted by the appointed peer-reviewers following the above-mentioned criteria; this will result in a final deliverable version to be submitted to the European Commission (EC).

All documentation generated during the above-described Review Process is maintained on the internal online workspace.

The internal peer reviewers for all deliverables until the end of the project have been assigned as depicted in Annex E. In this manner partners that draft the deliverables will know their reviewers along with the expected month for the review. This internal document will be monitored by the coordinator and will be available to all partners through the internal workspace. Three options (Low, Medium & High) will be available regarding the adoption of suggestions of the internal peer reviewers from the partners at first (table of contents, etc.) and second level (pre-final version of the deliverable). The coordinator will ask each partner on a self-assessment basis how much they adopted the suggestions. Two options (Done, Not Done) are also available for the cases that the deliverable is checked by Project Coordination Team (Technical Manager, Ethics Advisor, Quality Manager and Project Coordinator) and WP Leaders.

4.6 Evaluation of Project Coordination

In order to evaluate and improve the quality and efficiency of the project coordination an internal review process will take place every reporting period (interim and periodic). This involves the delivery of an electronic questionnaire to the members of the consortium to get their feedback on the project coordination. The questionnaire will contain multiple choice and free-text questions and will be anonymized. The methodology of the evaluation survey is shown in Annex G. The results of this process will be presented in the progress reports combined with a roadmap addressing partners' comments (if any) and a short-term time plan for achieving these goals.

5 Key Performance Indicators

5.1 Quality Attributes

To assess the quality of the project results several qualitative attributes will be used based on the nature of the ONCOSCREEN project and the characteristics of its end-users as well as the "context of use" of project results. the quality is also addressed by ensuring the compliance of all project activities to the "development process". The main attributes that address this need are:

- Planning accuracy;
- Rework occurrence;
- Conformity to methodologies;
- Redundancy;

All these attributes play an important role in the evaluation of the project key performance indicators (KPIs) described in the following section.

5.2 Key Performance Indicators

Monitoring of the progress of the project objectives is done through Key Performance Indicators (KPIs), which are monitored bi-annually and are part of the internal progress reports and official periodic reports. The List of KPIs, within each WP, their category and assessment metric are shown in the next table.

Table 5 List of the ONCOSCREEN Key Performance Indicators (KPIs)

WP	KPI Category	KPI	KPI Metric	KPI identifier
WP1 – Project Management & Innovation Development Coordination	Qualitative Deliverables submitted on time	1.1 On time submission of deliverables	1.1.1 In time project progress: Number of deliverables submitted on time	KPI-1.1.1
		1.2 Quality of deliverables	1.2.1 Percentage of re-work requests (over total number of deliverables)	KPI-1.2.1
WP2 – End User requirements and Evidence Based Studies	User Requirements	2.2 Risk Group Identification	2.2.1 High Risk groups identified <50 years old	KPI-2.2.1
		2.3 CRC Biomarker Identification	2.3.1 New CRC Biomarkers identified and clinically validated	KPI-2.3.1

		2.4 Reveal Inequalities retrospectively	2.4.1 Statistically Significant inequalities revealed retro and prospectively	KPI-2.4.1
WP3 - Advancements on CRC Diagnostics	New CRC Screening Technologies	3.1 Develop Accurate VOC based CRC Diagnostics	3.1.1 Sensitivity of VOC based CRC Diagnostics	KPI-3.1.1
			3.1.2 Specificity of VOC based CRC Diagnostics	KPI-3.1.2
		3.2 Develop Accurate Metabolomics based CRC Diagnostics	3.2.1 Sensitivity of Metabolomics based CRC Diagnostics	KPI-3.2.1
			3.2.2 Specificity of Metabolomics based CRC Diagnostics	KPI-3.2.2
		3.3 Develop Accurate CRISPR-Cas Dipstic based CRC Diagnostics	3.3.1 Sensitivity of CRISPR-Cas Dipstic based CRC Diagnostics	KPI-3.3.1
			3.3.2 Specificity of CRISPR-Cas Dipstic based CRC Diagnostics	KPI-3.3.2
		3.4 Develop Accurate CRC Diagnostics based on Microfluidic Assay for CTCs with Antibody decoration	3.4.1 Sensitivity of Microfluidic Assay based CRC Diagnostics	KPI-3.4.1
			3.4.2 Specificity of Microfluidic Assay based CRC Diagnostics	KPI-3.4.2
	AI-based Polyp Detection & Classification	3.5 AI-assisted Tissue Image Analysis Polyp Detection	3.5.1 Sensitivity of AI-assisted Tissue Image Analysis Polyp Detection	KPI-3.5.1
			3.5.2 Specificity of AI-assisted Tissue Image Analysis Polyp Detection	KPI-3.5.2
	Bio-bank and FAIR access	3.6 Open Data Bio-bank	3.6.1 Number of Prospective Entries of combined diagnostics results	KPI-3.6.1

			3.6.2 Number of Retrospective Entries of Algorithm Results	KPI-3.6.2
WP4 - Intelligent Platform & Tools for Citizens, Clinicians & Policy Makers	Risk Stratification	4.1 Develop Trustoworthy and Correct Personalised Risk Stratification	4.1 Percentage of Clinicians (from the clinical sites) who evaluate risk stratification as trustworthy and correct	KPI-4.1.1
	Mobile App	4.2 Develop a Useful Personalised Mobile App	4.2 Percentageof Citizens/Patients enrolled for the studies positively evaluate the mobile app usage	KPI-4.2.1
	Clinical Decision Support System (cDSS)	4.3 Clinical Decision Support System (cDSS) for issuing real time recommendations to Clinicians	4.3.1 Percentage of Clinicians rate recommendations as trustworthy and valuable	KPI-4.3.1
			4.3.2 Percentage of Human Error reduction in polyp detection	KPI-4.3.2
			4.3.3 Number of Junior histopathologists trained with the AI assisted polyp detection algorithms	KPI-4.3.3
	Integrated Diagnostics Methodology	4.4 Develop an Integrated Diagnostics Methodology for CRC Detection	4.4.1 Sensitivity of Integrated Dignostics for CRC Screening	KPI-4.4.1
			4.4.2 Specificty of Integrated Dignostics for CRC Screening	KPI-4.4.2
	Analytics Dashboard for Policy Makers	4.5 Intelligent Analytics Dashboard for Policy Makers	4.5.1 Percentage of Policy Makers rate provided evidence analytics trustworthy and valuable	KPI-4.5.1
WP5 - Clinical trials design implementation and validation	Upskill non-experts and junior colonoscopists	5.1 Train Upskilled non-experts and junior colonoscopists for AI-assisted polyp detection	5.1.1 Adenoma Detection Rate from Non-experts (e.g. Nurse Endoscopists; from ~25-35% current level)	KPI-5.1.1

		from colonoscopy sessions	5.1.2 Improvement in Adenoma Detection Rate for Junior Colonoscopists	KPI-5.1.2
		5.2 Train Upskilled personnel from Regional & National Authorities on Evidence-based Analysis	5.2.1 Number of People from National/Regional Authorities upskilled on Evidence-based Analysis	KPI-5.2.1
		5.3 Train Upskilled Histopathologists from AI-assisted Tissue Image Analysis	5.3.1 Number of Junior Histopathologists upskilled on AI-Assisted Tissue Image Analysis	KPI-5.3.1
	ONCOSCREEN Solutions validation	5.4 ONCOSCREEN solutions validated at Lab	5.4.1 Percentage of solutions validated at lab	KPI-5.4.1
			5.4.2 Percentage of ONCOSCREEN solutions' results being integrated	KPI-5.4.2
		5.5 ONCOSCREEN solutions validated in short scale Clinical Trial	5.5.1 Number of CRC Patients participating in the small-scale clinical trial providing prospective data	KPI-5.5.1
			5.5.2 Percentage of Primary objective achieved	KPI-5.5.2
			5.5.3 Percentage of ONCOSCREEN solutions validated in the small-scale clinical trial	KPI-5.5.3
		5.6 ONCOSCREEN solutions validated in large scale Clinical Trial	5.6.1 Number of different countries participating in the multi-centre clinical trial	KPI-5.6.1
			5.6.2 Number of Different Clinical Settings participating in the trial	KPI-5.6.2

			5.6.3 Number of countries involve patients from ≥ 2 different regions within the country	KPI-5.6.3
			5.6.4 Number of CRC Patients participating in the large-scale clinical trial	KPI-5.6.4
			5.6.5 Percentage of Primary objective achieved	KPI-5.6.5
			5.6.6 Percentage of Secondary objectives achieved of	KPI-5.6.6
			5.6.7 Percentage of ONCOSCREEN solutions validated in the large-scale clinical trial	KPI-5.6.7
WP6 -Evaluation and Living Guidelines for Solutions Uptake	Pathways for Solutions Updake	6.1 Living Guidelines for CRC Screening	6.1.1 Number of New High-Risk groups <50 years old recommended to be monitored periodically	KPI-6.1.1
			6.1.2 Number of Recommendation Conclusions for CRC screening commonly agreed from at least 50 CRC Clinical Experts across Europe	KPI-6.1.2
		6.2 Low-Cost Breath Biopsy CRC Screening Solution	6.2.1 Cost/Examination	KPI-6.2.1
		6.3 Low-Cost CRISPR-based Liquid Biopsy Screening Solution	6.3.1 Cost/Examination	KPI-6.3.1
		6.4 Low-Cost CTC based Liquid Biopsy CRC Screening Solution	6.4.1 Cost/Examination	KPI-6.4.1

		6.5 Low-Cost NMR based liquid Biopsy CRC Screening Solution	6.5.1 Cost/Examination	KPI-6.5.1
		6.6 Reduced Cost AI-assisted Colonoscopy Sessions	6.6.1 % Cost reduction in colonoscopy sessions being conducted from non-experts	KPI-6.6.1
		6.7 Reduced Cost AI-assisted Tissue Image Interpretations	6.7.1 % Cost reduction in tissue image analysis achieved through human error reduction and time-gained in Tissue Image analysis examination	KPI-6.7.1
		6.8 Blended Financial Schemes Proposed for covering CRC screening cost	6.8.1 Number of financial schemes proposed for public private partnership and citizens for covering screening cost	KPI-6.8.1
		6.9 Adoption of ONCOSCREEN CRC Screening Methodology from EU countries	6.9.1 Number of countries that adopt or partially adopt proposed methodology altering national guidelines and initiatives on CRC screening	KPI-6.9.1
			6.9.2 Number of MoUs signed between CRC diagnostics methods partners	KPI-6.9.2
		6.10 Financial & Life expectancy Evaluation of ONCOSCREEN CRC Screening Methodology as a whole	6.10.1 Expected Life Years (LYs) gained by citizens underwent ONCOSCREEN screening solutions	KPI-6.10.1
			6.10.2 Expected Quality-Adjusted Life-Years (QALYs) gained	KPI-6.10.2

			6.10.3 % Expected Mean Cost reduction of ONCOSCREEN diagnostics & Colonoscopy per LYs compared to Stool Test & Colonoscopy	KPI-6.10.3
			6.10.4 % Expected Mean Cost Reduction of ONCOSCREEN diagnostics & Colonoscopy per QALYs compared to Stool Test & Colonoscopy	KPI-6.10.4
	Enhance citizen awareness, and acceptance of CRC screening programs	6.11 User Accepted Technologies	6.11.1 of patients participating in the trial are satisfied with proposed CRC screening solutions	KPI-6.11.1
		6.12 Make Citizens Aware for New CRC Screening Technologies	6.12.1 People outreached (upon a robust and effective communication strategy, see S2.2.2) during the 48-month project period regarding the new CRC technologies proposed by the project	KPI-6.12.1
		6.13 Citizen derived Ideas/prototypes for CRC Screening	6.13.1 Ideas/Prototypes proposed in virtual hackathons conducted by the Living Lab	KPI-6.13.1
		6.14 Targeted Prevention Campaign for High-Risk Target Groups	6.14.1 CRC prevention strategies developed in at least 2 countries for High Risk population groups with emphasis in vulnerable ones	KPI-6.14.1
WP7 - Dissemination, Communication, Exploitation and Impact Creation	Dissemination	7.1 Scientific Publications in scientific, technological and medical Journals	7.1.1 Number of publications on novel diagnostics	KPI-7.1.1
			7.1.2 Number of articles submitted for publication on AI assisted Colonoscopy and Tissue Image Polyp detection	KPI-7.1.2

			7.1.3 Number of articles submitted for publication on relating environmental stressors with CRC	KPI-7.1.3
			7.1.4 Total Number of publications in scientific, technological and medical Journals of high impact	KPI-7.1.4
		7.2 Attend Events/Conferences	7.2.1 Number of conferences covering all ONCOSCREEN technologies (Nanotechnology, Materials, Health Informatics, ICT, (Bio)Medical, Cancer Diagnostics)	KPI-7.2.1
		7.3 Organize Workshops (Virtual/Physical)	7.3.1 Number of workshops from Diagnostics and Software tools Developers (including Design thinking)	KPI-7.3.1
		7.4 Publicize Data	7.4.1 Number of datasets from tech partners	KPI-7.4.1
			7.4.2 Number of Entries in Horizon Results Platform	KPI-7.4.2
			7.4.1 Number of Dataset Entries in OpenAIRE	KPI-7.4.3
		7.5 Clustering with other projects	7.5.1 Joint Clustering Meetings	KPI-7.5.1
			7.5.2 Joint White paper	KPI-7.5.2
			7.5.3 Joint Virtual Public Events	KPI-7.5.3
		7.6 Organize ONCOSCREEN Final Conference with emphasis in exploitation of results	7.6.1 Final Conference (physical or virtual) targeting ≥ 250 participants with Key Representatives from Ministries, Experts and DGs (DG SANTE, DG REGIO, DG	KPI-7.6.1

			ENV) and other EU bodies like JRC, CINEA and ECHA	
	Dissemination Outreach	7.7 Increase Outreach to scientific communities and relevant Stakeholders	7.7.1 Citations 5 years after the end of the project	KPI-7.7.1
			7.7.2 expected participants in events/conferences	KPI-7.7.2
			7.7.3 Distribution of leaflets at events, fairs and conferences	KPI-7.7.3
			7.7.4 Total Number of expected participants in organized workshops	KPI-7.7.4
			7.7.5 MoUs signed between CRC diagnostics methods partners	KPI-7.7.5
			7.7.6 Downloads of pubic datasets after 5 years	KPI-7.7.6
	Communication	7.8 Meetings with National / Regional Health Authorities	7.8.1 Number of High level meetings	KPI-7.8.1
			7.8.2 Number of EU (regional, national) Health policy makers reached	KPI-7.8.2
		7.9 Meetings with Cancer Patient Associations	7.9.1 Number of Meetings	KPI-7.9.1
			7.9.2 Number of Patient associations reached	KPI-7.9.2
		7.10 Meetings with CRC HCPs Associations/Societies	7.10.1 Number of Meetings	KPI-7.10.1
			7.10.2 Number of CRC HCPs associations reached	KPI-7.10.2

		7.11 Newsletters, Videos, Website	7.11.1 Number of websites	KPI-7.11.1
			7.11.2 Number of visits per day after Y3	KPI-7.11.2
			7.11.3 Number of people hits from 60 countries	KPI-7.11.3
			7.11.4 Number of Press releases	KPI-7.11.4
			7.11.5 Number of emails via website per week received	KPI-7.11.5
			7.11.6 Number of media outlets at national and EU level	KPI-7.11.6
			7.11.7 Number of videos	KPI-7.11.7
			7.11.8 Number of views in videos	KPI-7.11.8
		7.12 Social media, Blog, Stakeholders Database	7.12.1 Number of blog entries	KPI-7.12.1
			7.12.2 Number of posts per month in social media accounts	KPI-7.12.2
			7.12.3 Number of Twitter followers	KPI-7.12.3
			7.12.4 Number of followers on F/B	KPI-7.12.4
			7.12.5 Number of members onLinkedIn	KPI-7.12.5
			7.12.6 Number of stakeholders reached	KPI-7.12.6
			7.12.7 Number of people outreach	KPI-7.12.7
			7.13.1 Number of logos	KPI-7.13.1

		7.13 Project logo & Visual material, White Papers	7.13.2 Number of PPT templates	KPI-7.13.2
			7.13.3 Number of Short Presentations on Diagnostics and software tools	KPI-7.13.3
			7.13.4 Number of White Papers	KPI-7.13.4
			7.13.5 Number of banners	KPI-7.13.5
			7.13.6 Number of posters	KPI-7.13.6
			7.13.7 Number of brochures	KPI-7.13.7
			7.13.8 Number of infographics	KPI-7.13.8

5.3 Monitoring of Key Performance Indicators

In order to monitor the KPIs described in section 5.2, a KPI registry has been created (See Annex A) by the coordinator that will monitor each internal and periodic reporting period the level of achievement of the KPI values until the overall status is achieved. The overall status is dropdown with two options Achieved and Not Achieved. Values will have to be numeric as the targets.

Each KPI has a unique identifier as can also be observed in the above table. The KPI Registry will also ask for means of verification to ensure the transparency of the achieved targets. The coordinator is responsible for circulating the KPI registry near the reporting period (every six months) to all partners, aggregating all inputs from the partners in a single file and uploading it to the internal workspace. As stated also in section 4, KPI monitoring results shall be reported in both interim (M12, M30, M42) and periodic reports (M18, M36 and M48). Requests from the partners for revision of originally defined KPIs from this document, should be well justified in the KPI Registry – Tracking of KPI revisions and presented in the interim or periodic report. The summary of results of the KPIs and potential changes, should be discussed in the project plenary meetings, ensuring that all partners are in alignment with the project targets.

6 Risk Management Plan

6.1 Introduction

The *Risk Management Plan* defines and documents the Risk Management Process followed in ONCOSCREEN. It describes how risks will be identified and assessed, what tools and techniques can be used, what are the evaluation scales and tolerances, the relevant roles and responsibilities, how often risks need to be revisited, etc. The Risk Management Plan also defines the risk monitoring and escalation process as well as the structure of the *Risk registry* which is used to document and communicate the risks and their response actions.

The purpose of this section is:

- To outline the risk approach and process to be used for the ONCOSCREEN project;
- To identify the roles and responsibilities related to risk management;
- To specify the methodology, standards, tools and techniques used in ONCOSCREEN to support risk management.

6.2 Risk Management Objectives

Risk management brings visibility to risks and accountability as to how they are handled, and ensures that project risks are proactively dealt with and regularly monitored and controlled.

The main objectives of project risk management are:

- Project risks are identified, assessed, approved and reported throughout the project;
- All major risks are reported to the ONCOSCREEN Plenary Board;
- Risk response strategies are in line with stakeholders' risk appetite and approved risk level thresholds;
- All risks are monitored and under control;
- Risk response actions are implemented effectively.

6.3 Risk Management Process Description

The project risk management process defines the activities to identify, assess, prioritise, manage and control risks that may affect the execution of the project and the achievement of its objectives. This process is divided into four steps:

Step 1: Risk Identification

The purpose of this step is to facilitate the identification and documentation of risks that can impact the project objectives.

Various techniques will be used for risk identification which typically focus on past trends or future exposure, on a bottom-up or a top down analysis.

The techniques that will be used for risk identification within the ONCOSCREEN project are documented below, in section 6.5.

Risks are continuously identified throughout the project lifecycle; however, very early during the Initiating phase (i.e., the proposal writing phase), an initial risk list has been created which is thereafter frequently updated.

The *Risk registry* contains the risks identifier, risk name and short description, the risk category and owner, as well as strategies, actions and timing which will facilitate the monitor and control aspects of the project.

Step 2: Risk Assessment

The purpose of this step is to assess the likelihood and impact of the identified risks in terms of their influence to the project objectives. This assessment is necessary before any risk response planning can be done.

Risks are assessed based on their likelihood of occurrence and the impact in project objectives. The product of their likelihood and impact defines the Risk Level, which is then used as a reference for their prioritisation and risk response development.

Step 3: Risk Response Development

The purpose of this step is to select the best risk response strategy and identify and plan the actions to control the risks.

The selection of the risk response strategy will be based on the results of the risk assessment (risk level), the type of risk, on the effects on the overall project objectives (e.g. schedule and costs), as well as on the cost of the strategy and its benefits (cost/benefit analysis). The strategy (or strategies) selected for each risk are documented in the *Risk registry.*

There are four strategies to be considered as risk responses: Reduce, Avoid, Transfer, or Accept a risk. For the risks that have been accepted, contingency plans may be defined to help control their impact in case they occur.

After the strategy for each risk has been selected, specific actions to implement the strategy will be defined, described, scheduled and assigned, while a Risk Owner assumes the responsibility for its implementation.

Actions will detail concrete activities, milestones and deliverables and will be documented in the *Risk registry*. Moreover, they will clearly identify the target resolution date, as well as the estimation of resources involved and dependencies. These actions (at least the most effort/cost consuming ones) will be incorporated into the *Project Work Plan*, to have a consolidated view of all project related activities.

Step 4: Risk Control

The purpose of this step is to monitor and control the implementation of the risk response activities while continuously monitoring the project environment for new risks or changes (e.g. probability and/or impact) in the risks already identified.

The Project Follow-up Meetings are used to revise the status of risks and related actions, and to identify new risks that can impact project milestones, deliverables or objectives. Risks will be revised at regular predetermined intervals, but also after the occurrence of any event that might have a significant impact on the project environment and hence the project risks. The updating of the *Risk registry* can include adding new risks or actions, updating the status of response activities, changing risk levels based on mitigation actions, changing the assignment of actions, etc.

The Risk Owner will report periodically the status of the risk and any response activities to the Project Coordinator.

The Project Coordinator will report to the Plenary Board, the status of the major risks and to other project stakeholders. If any of the identified risks occur, then the Project Coordinator will ensure the implementation of the contingency plans and communicate the issue to the Plenary Board.

The activities described above are performed by the Project Coordinator throughout the project lifecycle in line with the *Risk Management Plan*.

6.4 Risk Registry

The *Risk Registry (See Annex B)* for the ONCOSCREEN project is using PM^2 *Risk* template with minor changes related to the Research and Innovation nature of the ONCOSCREEN project.

The Risk Registry is developed in excel and is composed of three different sheets: a) the actual Risk Registry field containing the risk description, risk assessment and risk impact evaluation information, b) the Risk Trend and c) the Risk Report, all of which contribute to the essential risk monitoring and management steps described in Section 6.2.

6.4.1 Risk Registry Sheet

The first field of the Risk Registry contains the following fields:

Table 6 The ONCOSCREEN Risk Registry sheet

Field Name	Field Explanation	Example
Risk ID	The id of each new risk	1
Risk Title	Short Title for each risk	Staff availability
Risk Category	Dropdown selection of the following categories: Overall, Project Co-ordination, Resource, Intellectual Property Rights (IPR), Legal, Political,	Resource

	Stakeholder Engagement, Security, Sustainability, Organizational, Other	
Risks Description	Description of the risk	There is a risk that appropriately skilled staff will not be available throughout the project with the consequence that delays will occur in parts of the project and the quality of deliverables will be adversely affected.
Related Task	Linkage with a specific task	T1.1
Responsible Partner Organization	Dropdown selection with partner names	EXUS
Risk Owner	Name of person who monitors the risk	Anaxagoras Fotopoulos
Risk Trigger	How you know the risk is becoming an issue or has reached a point that requires action.	We will need to extend the expected delivery date by 3 Months.
Probability	Estimate how likely is to occur. Dropdown selection with three options: Low, Medium & High.	Low
Impact	Estimate of how significant the impact of this risk will be if/when occurs. Dropdown selection with three options: Low, Medium & High.	Low
Severity Score	Automatic Calculation. It sums the Risk Probability and Impact. Low, Medium & High have score 1,2,3 respectively. Minimum score is 2 (Low Probability, Low Impact) and maximum score is 6 (High Probability, High Impact).	2
Severity Status	Automatic Calculation. Has three values based on severity score: Low Medium, High	Low
Period Identified	Which Q-period (3-month) was identified. Dropdown selection with the following options: Q1|2019, Q2|2019, Q3|2019, Q4|2019, Q1|2020, Q2|2020, Q3|2020, Q4|2020,	Q2|2019

	Q1|2021, Q2|2021, Q3|2020, Q4|2021, Q1|2022, Q2|2022.	
Risk Period	Which year is going to take place? Is it for the entire period of the project? Dropdown selection with options: Y1, Y2, Y3, Y4, Lifetime of Project.	Lifetime of Project
Risk Result	What will happen if the risk becomes an issue and no action is taken	We will not be able to extend the necessary activity to complete the task. Product may never get to market and be deemed a total failure.
Mitigation Plan	What is the mitigation measures in order to prevent the risk from happening?	Establish common documentation standards in project Quality Manual for all work to reduce delays when handing over work. Where appropriate recruit using fixed-term contracts which cover the periods where work is to be undertaken by the team member. Establish knowledge transfer arrangements for team members and colleagues within and between partners.
Status	Is this risk still Open or Closed? Dropdown selection with options Open & Close	Open
Risk Response Type	Decision made by coordinator. Options: No action, Mitigate Risk.	Mitigate Risk
Contingency	Write down the contingency measures that will be activated in case that the risk occurs.	Inform consortium about extension, inform Project Officer, initiate amendment process, update GANTT, reallocate resources.
Comments	Provide any further comments.	Given that our team has a mostly stable velocity, a proven ability to meet commitments and deliver

		value, we expect a positive answer for extension.

6.4.2 The Risk Trend Sheet

Although the first field of the risk registry that is described in Section 6.3.1 enables the in-depth documentation of risks, the risk trend sheet contains information regarding the evolvement of each risk (referred to as risk trends). The excel sheet for monitoring risks should be considered as a living document. The risk trends showcase the evolvement of the risks each yearly quarter. There are going to be 4 main trend categories from the dropdown: Rising, Steady, Falling & Closed. Risks shall be monitored from the coordinator throughout the year based on the response from the partners.

Risk ID	Risk Title	Risk Category	Risk Trend per Period								
			Q1|2023	Q2|2023	Q3|2023	Q4|2023	Q1|2024	Q2|2024	Q3|2024	Q4|2024	Q1|2025
1	Partner underperforms or leaves the consortium	Project Co-ordination	Steady	Rising	Falling	**Closed**	Rising	Falling	Steady	Steady	Steady

Figure 3: Example of Risk Trend monitoring per quarter

6.4.3 The Risk Report Sheet

The last sheet in the Risk Registry is the Risk Report, which generates automatically a series of graphs based on the provided input in the risk registry sheet. These useful insights provide a visualization of risks per different categories. They are essentially for effective quality management & coordination, since they provide an easy and fast overview to the Coordinator and partners. Results from these graphs, can be also used in the interim and periodic reports. In the following pictures, a series of results that can be provided are shown as examples. It is expected that the visualizations will also benefit the overall review process.

The following figures depict a snapshot overview of the risks per category, per WP and per partner during a phase of the project in the previous period. The latest version of the risk registry and the accompanied fields will be depicted in the periodic report to avoid data duplication.

RISKS Per Category	
Risk Category	Number of Risks
Overall	7
Technical	18
Project Co-ordination	6
Resource	0
Intellectual Property Rights (IPR)	1
Legal/Ethical/Societal/Cultural	2
Political	0
Stakeholder Engagement	14
Security	0
Finanancial	0
Organizational	2
Environmental	0
Other	0

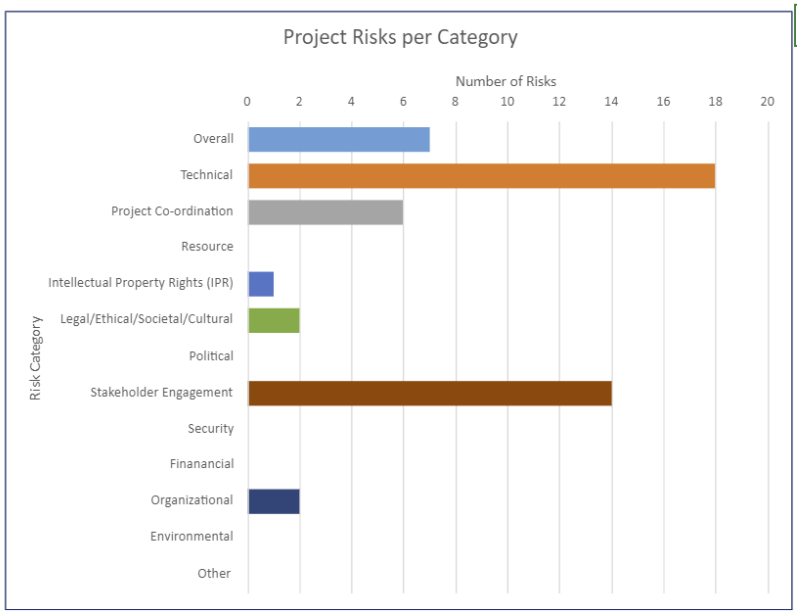


Figure 4: Risks per Category

RISKS Per WP	
WP No	Number of Risks
WP1	8
WP2	3
WP3	15
WP4	12
WP5	7
WP6	2
WP7	4

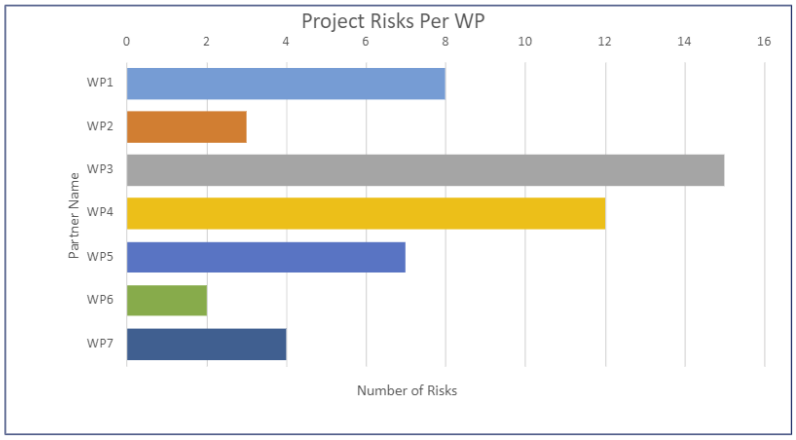


Figure 5: Risks per WP

RISKS Identified Per Quarter Period	
Risk per Q-period	Number of Risks
Q1|2023	13
Q2|2023	22
Q3|2023	3
Q4|2023	1
Q1|2024	12
Q2|2024	0
Q3|2024	0
Q4|2024	0
Q1|2025	0

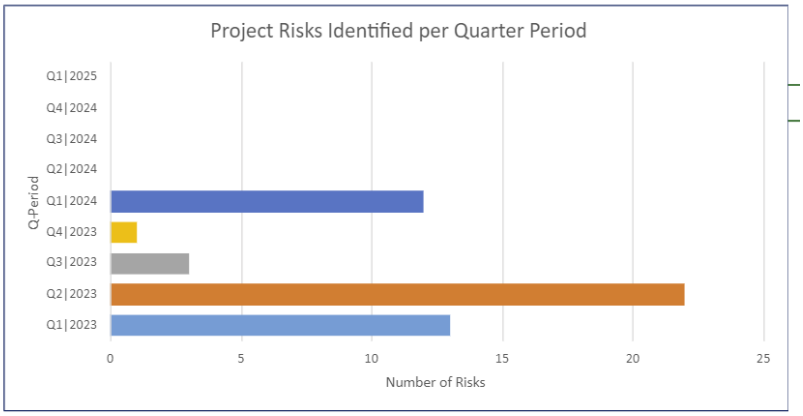
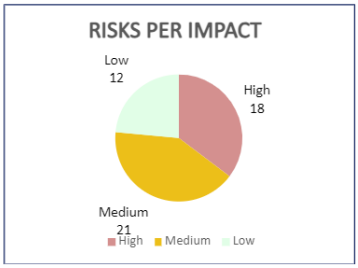


Figure 6: Identified Risks per Period

RISKS Per Impact	
Risk Category	Number of Risks
High	18
Medium	21
Low	12

RISKS Status	
Risk Status	Number of Risks
Open	49
Closed	0



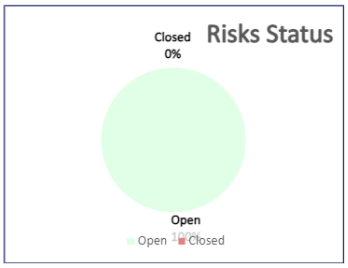
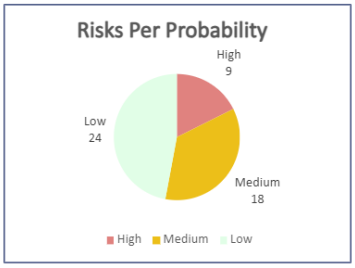


Figure 7: Overview of Risks per Impact and Status

RISKS Per Probability	
Risk Category	Number of Risks
High	9
Medium	18
Low	24

RISKS Per Severity	
Risk Category	Number of Risks
High	12
Medium	16
Low	21



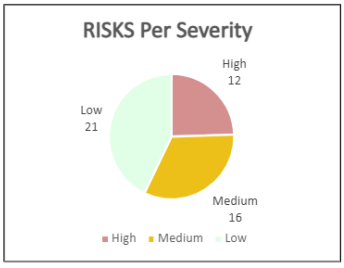


Figure 8: Overview of Risks per Probability and Severity

6.5 Risk Likelihood/Impact Matrix

The ONCOSCREEN project, in order to calculate the Likehood and Impact in the Risk Registry is using a Probability/Impact Matrix, similarly to the ones suggested by the PM² *Methodology*, as following:

		Impact		
		1=Low	2=Medium	3=High
Probability	3=High	4	5	6
	2=Medium	3	4	5
	1=Low	2	3	4

Legend:

	Risks can be accepted, contingency plans may be developed.
	Risks cannot be accepted, a risk response strategy should be developed (avoid, reduce, transfer/ share)
	Unacceptable – immediate risk reduction or avoidance response

Figure 9: Risk Probability/Impact matrix

The risk severity level is calculated by the summation of the probability and impact.

6.6 Risk Identification Activities

In this section, we describe the specific risk identification activities and tools that will be used in ONCOSCREEN.

Initial risk identification was first performed in the proposal writing phase (for high level risks). Therefore, this was the starting point of this step.

The identification of risks will result from: reviews, interviews, project team brainstorming, project meetings, feedback of the users' workshops, questionnaires, risk checklist analysis, and assumptions analysis.

The following risk categories have been included in the risk identification analysis, considering the type of the project:

- Administrative: related to the management and coordination of activities, on a partner and on a consortium level. This also includes project staffing, competences and coordination between teams;
- Technical/Technological: related to infrastructure, system development, security, and availability of IT services;
- External: related to external partners and macro environment, and competition;
- Legal: related to laws, regulations and rules, including GDPR;
- Communication and Information: related to communication methods and channels and to the quality and timeliness of information.

6.7 Risks Assessment Approach

The project will use the Risk Probability/Impact Matrix referred in section 6.3, which represents the different combinations of likelihood and impact of project risks on a scale from 1 to 3 and defines risk severity levels that suggest risk response strategies.

Risk level scale details:

Probability/Likelihood:

- **Low**: between 0% to 10% chance of occurrence;
- **Medium**: between 10% to 50% chance of occurrence;
- **High**: More than 50% chance of occurrence;

Impact:

- **Low**: low impact in project baselines, or/and only one milestone affected, or/and projects stakeholders may be affected, or/and sufficient project competencies to resolve the issue (if risk occurs).
- **Medium**: medium impact in project baselines, or/and one or more milestones affected, or/and projects stakeholders will be to some extent affected, or/and project objectives may be affected, or/and limited project competencies to resolve the issue (if risk occurs).

- **High**: high impact in project baselines, or/and several milestones affected, or/and projects stakeholders will be affected/concerned, or/and project objectives will be affected, or/and insufficient project internal competencies to resolve the issue (if risk occurs).

Risk levels thresholds:

- **Green**: risk level <=2;
- **Yellow**: risk level >=3 and <=4;
- **Red**: risk level >=5.

The Project Steering Committee approved / stated that the project risk appetite is limited to risk level <=2, and likelihood <10%.

6.8 Escalation

The risk escalation:

- All new risks, proposed risk response strategies and proposed actions are approved by the WP leader, if the risk level is < 2;
- If the risk level is>= 3 and <4, new risks, proposed risk response strategies and proposed actions are approved by the Project Coordinator;
- If the risk level is>= 5, new risks, proposed risk response strategies and proposed actions are approved by the Plenary Board.

6.9 Risk Response Strategies

The purpose of this section is to define the available risk response strategies to be used for the ONCOSCREEN project.

The risk response actions are documented and updated in the PM^2 *Risk Registry* throughout the project lifecycle (and then incorporated in the *Project Work Plan*) and revisited at least, in the weekly Project Follow-up Meeting.

The possible risk response strategies are:

- **Avoid**: risk avoidance, working the project or project plan around those conditions or activities which introduce the risk;
- **Reduce**: risk mitigation or reduction through the proactive implementation of risk reduction activities;
- **Accept**: acceptance of the risk (the impact/loss is accepted if the risk occurs). When accepting risks, there are two possible reactions:
    - Acceptance of the risk and no special action required, except continue to monitor the risk (passive acceptance);
    - Accept and develop contingency plans in case the risk occurs (active acceptance).
- **Transfer/Share**: transfer a risk to, or share a risk with other entities, e.g. through insurances, sub-contracting, partnering etc.

The following table describes the risk response approach for ONCOSCREEN:

Table 7 The ONCOSCREEN Risk Response Approach

Scenario	Risk Response Strategy
High impact and high likelihood/probability or high impact and medium likelihood.	Avoid **or** implement an immediate reduction
High impact and low likelihood.	Transfer/Share
All other risk levels.	Reduce
Low likelihood and low impact	Accept (monitor and plan contingency if deemed necessary)

6.10 Risk Control Activities

The purpose of this section is to define the activities performed for monitoring and controlling risks, as well as their frequency, within the ONCOSCREEN project.

The Project Coordinator monitors and controls risks based on Project Follow-up Meetings or on information received from other project stakeholders, in result of:

- Identification of new risks by project partners or by other project stakeholders, in consequence of changes in the project environment;
- New proposed ways to deal with a risk (adding/changing actions);
- Implementation of any of the given actions or on general events or developments that will change the values for likelihood and/or impact of the identified risks;
- Other changes.

Frequency of Revisiting the Risk Registry: The PM^2 *Risk Registry* is updated at least once a week, after the Project Follow-up Meetings, by the Project Coordinator.

Additionally, before each Plenary Board, there is a procedure in place to collect the status of each risk and action and the comments related to the effectiveness, quantification of resources spent, difficulties, potential problems and dependencies of the actions. This information is consolidated and updated in the *Risk Registry*, and presented to the PSC. The project review planned at the end of each milestone also includes a deep review of the *Risk Registry*.

The Risk Communication activities are part of the project *Communications Management Plan*.

The communication items identified are:

- Collection of new risks or changes to risks/actions in the weekly Project Follow-up Meeting;
- Report of risks (risk severity level>=2) and related actions status in plenary meetings or action approval to the plenary board in case of risks with a risk severity level >=4;
- Report risks list in the annual interim progress report;
- Communication of the risks that have turned into issues (i.e., have occurred) in the bi-weekly management board.

7 Ethical & Legal Aspects

In the context of ONCOSCREEN, the monitoring of ethical, legal, and societal aspects is of paramount importance. During the period from Month 1 (M1) to Month 18 (M18), significant efforts were undertaken by Timelex, the designated legal and ethical partner within the consortium, to ensure robust compliance and governance in these areas.

Effective communication and coordination were key to managing these activities. Timelex actively participated in the bi-weekly Management Board calls, which served as a platform for discussing progress, addressing issues, and planning future actions. Beyond these scheduled meetings, Timelex organized direct calls and engaged in regular email exchanges with relevant partners to ensure timely completion of tasks and address any emerging concerns.

Timelex maintained regular contact with EXUS, the project coordinator, to stay abreast of any developments and to address legal or ethical issues as they arose. This continuous engagement ensured that all project activities were aligned with the overarching ethical and legal framework, and that any potential issues were promptly identified and resolved.

7.1 Data Management Plan

Timelex prepared the first version of the Data Management Plan (DMP), which serves as a living document and will be continuously updated throughout the project's lifecycle. The DMP outlines the protocols for data collection, storage, and sharing, ensuring that all data-related activities adhere to the highest standards of integrity and confidentiality. This document is crucial for aligning the consortium’s data practices with both ethical guidelines and legal requirements, including those stipulated by the General Data Protection Regulation (GDPR).

7.2 Joint Controllership Agreement

A significant milestone in this period was the drafting and finalization of the Joint Controllership Agreement. This agreement delineates the rights and obligations of the consortium partners as joint controllers of the data processed within the project. The agreement ensures clarity and shared responsibility among partners, facilitating coordinated data handling practices and compliance with GDPR mandates.

7.3 Data Protection Impact Assessment

To further enhance the project's compliance framework, Timelex conducted a Data Protection Impact Assessment (DPIA). The DPIA identifies and mitigates potential risks associated with data processing activities. This proactive approach is essential for safeguarding personal data and upholding the trust of all stakeholders involved in the project.

7.4 Privacy Policy & Cookie Policy

In collaboration with CARR Communications, Timelex developed the privacy policy and cookie policy, as well as the cookie banner for the project's website. These documents are vital for informing website visitors about how their data is being used and ensuring transparency in line with GDPR requirements. Additionally, Timelex helped draft the privacy policy for the ONCO-CAWA mobile app, reinforcing the project's commitment to data protection and privacy, and advised on the implementation of two-factor authentication for app login.

7.5 Informed Consent Form

Timelex also played a crucial role in drafting the informed consent form, used to obtain explicit consent from participants involved in the project. This form provided clear and comprehensive information about the project's objectives, data usage, and participants' rights, thereby ensuring ethical standards are upheld. It also included information on the processing of personal data of the study participants (the so-called “double consent form”).

7.6 Cluster Activities

As part of the broader engagement within the Horizon Europe framework, Timelex, representing OncoScreen, initiated and led various activities within the Prevention and Screening Cluster. These activities aimed to foster collaboration and ensure consistency in data management practices across the cluster. Timelex was actively involved in the regular calls of the Cluster Data Management Task Force, held monthly or more frequently (when needed). These calls provided a platform for discussing common challenges, sharing best practices, and coordinating efforts to address data management issues collectively. Through active participation, Timelex contributed to shaping the data management strategies and policies within the cluster, spearheading efforts to draft the common chapter of the Data Management Plan. This common chapter is crucial for harmonizing data management protocols across different projects, ensuring that all cluster members adhere to a unified set of standards and practices. In addition to regular calls, Timelex participated in workshops organized by the Cluster Data Management Task Force. In summary, the period from M1 to M18 saw substantial progress in the monitoring and management of ethical and legal of the project. Through the diligent efforts of Timelex, supported by effective collaboration with other consortium partners, the project has established a strong foundation for ongoing legal compliance and ethical governance.

7.7 Ethic-by-design Approach

ONCOSCREEN has followed an Ethic-by-design approach in regards to the development of its tools. ONCOSCREEN has undertake the highest possible measures with a) its Zero Trust Framework Architecture for the protection of data b) ALTAI Framework Compliance in terms of requirements c) Joint Controllership Agreement sign up d) Ethical Risk Assessment & Monitoring through the risk registry e) GDPR Compliance by design of its technologies f) Clinical Trial Consent

forms g) System Co-design with patient and advocacy group to understand their concerns and expectations h) Cookie Policy & Privacy policy for its website i) privacy preservation tool development j) identification of Health inequalities as a secondary objective of its clinical study k) Setting up a plan to monitor the new EU AI Act and potential updates needed for the project.

The ERC acts in complementarity with the Local Ethic Committees for the approval of the clinical study protocol, which necessitates a strong compliance to ethic principles for the protection of citizens and their data.

It is noted that up to M18 no incident of ethic nature has been identified from the ERC. Based on the needs of the project, an External Ethic Advisory Board shall be formed to monitor the Ethic-by-design activities of the project and any updates shall be reported in the second iteration of this deliverable.

8 Conclusions

In this deliverable, we have described all the processes related to the coordination of the ONCOSCREEN project. More specifically, this document serves as a project handbook defining the administrative, technical, clinical/medical steering of the project and provides the management structures and methods ensuring the robust and qualitive implementation of all activities envisaged in the project including its continuous Risk Management, the Ethical/Legal monitoring and the overall Data management strategy.

This deliverable has also described the various registries used to monitor the various project management activities. In particular, this deliverable presents the KPI Registry, the Risk Registry, the Gender and Balance Registry, and depicts their complete version in the Annex. The deliverable mentions also other registries that are associated with the Communication and Technical activities like the Dissemination and Communication Registry, the Requirements Registry and the Integration Registry. Since these registries are analysed in detail in the respective deliverables of WP7, WP4 and WP5, respectively, are not provided in detail here to avoid duplication. This deliverable presents also templates such as the one used for keeping Minutes at each meeting.

In order to avoid the duplication of the reporting data, the latest registries and their data, which are live documents will be provided and analysed in the periodic project reports or relevant deliverables.

Overall, the presented management processes are essential for ensuring that the ONCOSCREEN project will be administered in an efficient, streamlined way. Any updates in regards to above process shall be documented and presented in the Final iteration of this deliverable.

Annex A – KPI Registry

It is noted that this annex shows the KPI Registry template. For avoidance of duplication the updates will be presented in the Periodic Report.

KPI Values Registry

WP	KPI Category	KPI	KPI Metric	KPI identifier	Overall Target	M01-M06	M07-M12	M13-M18	M19-M24	M25-30	M31-M36	M37-42	M43-M48	Overall Status	Comments
WP1 – Project Management & Innovation Development Coordination	Qualitative Deliverables submitted on time	1.1 On time submission of deliverables	1.1.1 In time project progress: Number of deliverables submitted on time	KPI-1.1.1	>75%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
		1.2 Quality of deliverables	1.2.1 Percentage of re-work requests (over total number of deliverables)	KPI-1.2.1	<20%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
WP2 – End User requirements and Evidence Based Studies	User Requirements	2.2 Risk Group Identification	2.2.1 High Risk groups identified <50 years old	KPI-2.2.1	>4	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
		2.3 CRC Biomarker Identification	2.3.1 New CRC Biomarkers identified and clinically validated	KPI-2.3.1	>4	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
		2.4 Reveal Inequalities retrospectively	2.4.1 Statistically Significant inequalities revealed retro and prospectively	KPI-2.4.1	>4	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
WP3 - Advancements on CRC Diagnostics	New CRC Screening Technologies	3.1 Develop Accurate VOC based CRC Diagnostics	3.1.1 Sensitivity of VOC based CRC Diagnostics	KPI-3.1.1	>90%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			3.1.2 Specificity of VOC based CRC Diagnostics	KPI-3.1.2	>95%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	

		3.2 Develop Accurate Metabolomics based CRC Diagnostics	3.2.1 Sensitivity of Metabolomics based CRC Diagnostics	KPI-3.2.1	>96%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			3.2.2 Specificity of Metabolomics based CRC Diagnostics	KPI-3.2.2	>95%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
		3.3 Develop Accurate CRISPR-Cas Dipstic based CRC Diagnostics	3.3.1 Sensitivity of CRISPR-Cas Dipstic based CRC Diagnostics	KPI-3.3.1	>90%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			3.3.2 Specificity of CRISPR-Cas Dipstic based CRC Diagnostics	KPI-3.3.2	>90%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
		3.4 Develop Accurate CRC Diagnostics based on Microfluidic Assay for CTCs with Antibody decoration	3.4.1 Sensitivity of Microfluidic Assay based CRC Diagnostics	KPI-3.4.1	>90%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			3.4.2 Specificity of Microfluidic Assay based CRC Diagnostics	KPI-3.4.2	>90%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
	AI-based Polyp Detection & Classification	3.5 AI-assisted Tissue Image Analysis Polyp Detection	3.5.1 Sensitivity of AI-assisted Tissue Image Analysis Polyp Detection	KPI-3.5.1	>98%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			3.5.2 Specificity of AI-assisted Tissue Image Analysis Polyp Detection	KPI-3.5.2	>98%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
	Bio-bank and FAIR access	3.6 Open Data Bio-bank	3.6.1 Number of Prospective Entries of combined diagnostics results	KPI-3.6.1	>4100	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			3.6.2 Number of Retrospective Entries of Algorithm Results	KPI-3.6.2	>250.000	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	

WP4 - Intelligent Platform & Tools for Citizens, Clinicians & Policy Makers	Risk Stratification	4.1 Develop Trustoworthy and Correct Personalised Risk Stratification	4.1 Percentage of Clinicians (from the clinical sites) who evaluate risk stratification as trustworthy and correct	KPI-4.1.1	>85%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
	Mobile App	4.2 Develop a Useful Personalised Mobile App	4.2 Percentageof Citizens/Patients enrolled for the studies positively evaluate the mobile app usage	KPI-4.2.1	>85%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
	Clinical Decision Support System (cDSS)	4.3 Clinical Decision Support System (cDSS) for issuing real time recommendations to Clinicians	4.3.1 Percentage of Clinicians rate recommendations as trustworthy and valuable	KPI-4.3.1	>85%	cDSS Task starts on M5	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			4.3.2 Percentage of Human Error reduction in polyp detection	KPI-4.3.2	>5%	cDSS Task starts on M5	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			4.3.3 Number of Junior histopathologists trained with the AI assisted polyp detection algorithms	KPI-4.3.3	>10	cDSS Task starts on M5	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
	Integrated Diagnostics Methodology	4.4 Develop an Integrated Diagnostics Methodology for CRC Detection	4.4.1 Sensitivity of Integrated Dignostics for CRC Screening	KPI-4.4.1	>95%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			4.4.2 Specificty of Integrated Dignostics for CRC Screening	KPI-4.4.2	>95%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
	Analytics Dashboard for Policy Makers	4.5 Intelligent Analytics Dashboard for Policy Makers	4.5.1 Percentage of Policy Makers rate provided evidence analytics trustworthy and valuable	KPI-4.5.1	>85%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	

WP5 - Clinical trials design implementation and validation	Upskill non-experts and junior colonoscopists	5.1 Train Upskilled non-experts and junior colonoscopists for AI-assisted polyp detection from colonoscopy sessions	5.1.1 Adenoma Detection Rate from Non-experts (e.g. Nurse Endoscopists; from ~25-35% current level)	KPI-5.1.1	>40%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			5.1.2 Improvement in Adenoma Detection Rate for Junior Colonoscopists	KPI-5.1.2	>5%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
		5.2 Train Upskilled personnel from Regional & National Authorities on Evidence-based Analysis	5.2.1 Number of People from National/Regional Authorities upskilled on Evidence-based Analysis	KPI-5.2.1	>20	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
		5.3 Train Upskilled Histopathologists from AI-assisted Tissue Image Analysis	5.3.1 Number of Junior Histopathologists upskilled on AI-Assisted Tissue Image Analysis	KPI-5.3.1	>15	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
	ONCOSCREEN Solutions validation	5.4 ONCOSCREEN solutions validated at Lab	5.4.1 Percentage of solutions validated at lab	KPI-5.4.1	100%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			5.4.2 Percentage of ONCOSCREEN solutions' results being integrated	KPI-5.4.2	100%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
		5.5 ONCOSCREEN solutions validated in short scale Clinical Trial	5.5.1 Number of CRC Patients participating in the small-scale clinical trial providing prospective data	KPI-5.5.1	>300	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	

			5.5.2 Percentage of Primary objective achieved	KPI-5.5.2	100%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			5.5.3 Percentage of ONCOSCREEN solutions validated in the small-scale clinical trial	KPI-5.5.3	100%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
		5.6 ONCOSCREEN solutions validated in large scale Clinical Trial	5.6.1 Number of different countries participating in the multi-centre clinical trial	KPI-5.6.1	7	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			5.6.2 Number of Different Clinical Settings participating in the trial	KPI-5.6.2	9	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			5.6.3 Number of countries involve patients from ≥ 2 different regions within the country	KPI-5.6.3	>2	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			5.6.4 Number of CRC Patients participating in the large-scale clinical trial	KPI-5.6.4	4100	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			5.6.5 Percentage of Primary objective achieved	KPI-5.6.5	100%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			5.6.6 Percentage of Secondary objectives achieved of	KPI-5.6.6	>80%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			5.6.7 Percentage of ONCOSCREEN solutions validated in the large-scale clinical trial	KPI-5.6.7	100%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
WP6 - Evaluation and Living Guidelines	Pathways for Solutions Updake	6.1 Living Guidelines for CRC Screening	6.1.1 Number of New High-Risk groups <50 years old recommended	KPI-6.1.1	>4	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	

for Solutions Uptake			to be monitored periodically												
			6.1.2 Number of Recommendation Conclusions for CRC screening commonly agreed from at least 50 CRC Clinical Experts across Europe	KPI-6.1.2	>10	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
		6.2 Low-Cost Breath Biopsy CRC Screening Solution	6.2.1 Cost/Examination	KPI-6.2.1	<3€	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
		6.3 Low-Cost CRISPR-based Liquid Biopsy Screening Solution	6.3.1 Cost/Examination	KPI-6.3.1	<9€	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
		6.4 Low-Cost CTC based Liquid Biopsy CRC Screening Solution	6.4.1 Cost/Examination	KPI-6.4.1	<35€	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
		6.5 Low-Cost NMR based liquid Biopsy CRC Screening Solution	6.5.1 Cost/Examination	KPI-6.5.1	<8.5€	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
		6.6 Reduced Cost AI-assisted Colonoscopy Sessions	6.6.1 % Cost reduction in colonoscopy sessions being conducted from non-experts	KPI-6.6.1	>20%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
		6.7 Reduced Cost AI-assisted Tissue Image Interpretations	6.7.1 % Cost reduction in tissue image analysis achieved through human error reduction and time-gained in Tissue Image	KPI-6.7.1	>5%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	

			analysis examination												
		6.8 Blended Financial Schemes Proposed for covering CRC screening cost	6.8.1 Number of financial schemes proposed for public private partnership and citizens for covering screening cost	KPI-6.8.1	>10	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
		6.9 Adoption of ONCOSCREEN CRC Screening Methodology from EU countries	6.9.1 Number of countries that adopt or partially adopt proposed methodology altering national guidelines and initiatives on CRC screening	KPI-6.9.1	>2	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			6.9.2 Number of MoUs signed between CRC diagnostics methods partners	KPI-6.9.2	≥ 5	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
		6.10 Financial & Life expectancy Evaluation of ONCOSCREEN CRC Screening Methodology as a whole	6.10.1 Expected Life Years (LYs) gained by citizens underwent ONCOSCREEN screening solutions	KPI-6.10.1	>6.5	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			6.10.2 Expected Quality-Adjusted Life-Years (QALYs) gained	KPI-6.10.2	>5.5	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	

			6.10.3 % Expected Mean Cost reduction of ONCOSCREEN diagnostics & Colonoscopy per LYs compared to Stool Test & Colonoscopy	KPI-6.10.3	>70%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			6.10.4 % Expected Mean Cost Reduction of ONCOSCREEN diagnostics & Colonoscopy per QALYs compared to Stool Test & Colonoscopy	KPI-6.10.4	>60%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
	Enhance citizen awareness, and acceptance of CRC screening programs	6.11 User Accepted Technologies	6.11.1 of patients participating in the trial are satisfied with proposed CRC screening solutions	KPI-6.11.1	>90%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
		6.12 Make Citizens Aware for New CRC Screening Technologies	6.12.1 People outreached (upon a robust and effective communication strategy, see S2.2.2) during the 48-month project period regarding the new CRC technologies proposed by the project	KPI-6.12.1	>10.000	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
		6.13 Citizen derived Ideas/prototypes for CRC Screening	6.13.1 Ideas/Prototypes proposed in virtual hackathons conducted by the Living Lab	KPI-6.13.1	>200	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	

		6.14 Targeted Prevention Campaign for High-Risk Target Groups	6.14.1 CRC prevention strategies developed in at least 2 countries for High Risk population groups with emphasis in vulnerable ones	KPI-6.14.1	>5	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
WP7 - Dissemination, Communication, Exploitation and Impact Creation	Dissemination	7.1 Scientific Publications in scientific, technological and medical Journals	7.1.1 Number of publications on novel diagnostics	KPI-7.1.1	>8	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			7.1.2 Number of articles submitted for publication on AI assisted Colonoscopy and Tissue Image Polyp detection	KPI-7.1.2	>4	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			7.1.3 Number of articles submitted for publication on relating environmental stressors with CRC	KPI-7.1.3	>3	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			7.1.4 Total Number of publications in scientific, technological and medical Journals of high impact	KPI-7.1.4	>15	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
		7.2 Attend Events/Conferences	7.2.1 Number of conferences covering all ONCOSCREEN technologies (Nanotechnology, Materials, Health Informatics, ICT, (Bio)Medical, Cancer Diagnostics)	KPI-7.2.1	>30	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	

		7.3 Organize Workshops (Virtual/Physical)	7.3.1 Number of workshops from Diagnostics and Software tools Developers (including Design thinking)	KPI-7.3.1	>5	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
		7.4 Publicize Data	7.4.1 Number of datasets from tech partners	KPI-7.4.1	>15	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			7.4.2 Number of Entries in Horizon Results Platform	KPI-7.4.2	≥2	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			7.4.1 Number of Dataset Entries in OpenAIRE	KPI-7.4.3	≥4	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
		7.5 Clustering with other projects	7.5.1 Joint Clustering Meetings	KPI-7.5.1	8	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			7.5.2 Joint White paper	KPI-7.5.2	1	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			7.5.3 Joint Virtual Public Events	KPI-7.5.3	≥2	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
		7.6 Organize ONCOSCREEN Final Conference with emphasis in exploitation of results	7.6.1 Final Conference (physical or virtual) targeting ≥ 250 participants with Key Representatives from Ministries, Experts and DGs (DG SANTE, DG REGIO, DG ENV) and other EU bodies like JRC, CINEA and ECHA	KPI-7.6.1	1	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
	Dissemination Outreach	7.7 Increase Outreach to scientific communities and relevant Stakeholders	7.7.1 Citations 5 years after the end of the project	KPI-7.7.1	>500	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			7.7.2 expected participants in events/conference	KPI-7.7.2	>5000	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			7.7.3 Distribution of leaflets at events, fairs and conferences	KPI-7.7.3	1500	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	

			7.7.4 Total Number of expected participants in organized workshops	KPI-7.7.4	> 400	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			7.7.5 MoUs signed between CRC diagnostics methods partners	KPI-7.7.5	≥ 5	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			7.7.6 Downloads of pubic datasets after 5 years	KPI-7.7.6	>500	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
	Communication	7.8 Meetings with National / Regional Health Authorities	7.8.1 Number of High level meetings	KPI-7.8.1	>20	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			7.8.2 Number of EU (regional, national) Health policy makers reached	KPI-7.8.2	>20	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
		7.9 Meetings with Cancer Patient Associations	7.9.1 Number of Meetings	KPI-7.9.1	>30	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			7.9.2 Number of Patient associations reached	KPI-7.9.2	>15	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
		7.10 Meetings with CRC HCPs Associations/Societies	7.10.1 Number of Meetings	KPI-7.10.1	>10	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			7.10.2 Number of CRC HCPs associations reached	KPI-7.10.2	>15	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
		7.11 Newsletters, Videos, Website	7.11.1 Number of websites	KPI-7.11.1	1	1	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			7.11.2 Number of visits per day after Y3	KPI-7.11.2	>50	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			7.11.3 Number of people hits from 60 countries	KPI-7.11.3	>25000	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			7.11.4 Number of Press releases	KPI-7.11.4	12	1	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			7.11.5 Number of emails via website per week received	KPI-7.11.5	>3	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	

			7.11.6 Number of media outlets at national and EU level	KPI-7.11.6	20	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			7.11.7 Number of videos	KPI-7.11.7	40 (10/y)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			7.11.8 Number of views in videos	KPI-7.11.8	>2000	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
		7.12 Social media, Blog, Stakeholders Database	7.12.1 Number of blog entries	KPI-7.12.1	≥40	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			7.12.2 Number of posts per month in social media accounts	KPI-7.12.2	5	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			7.12.3 Number of Twitter followers	KPI-7.12.3	≥2000	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			7.12.4 Number of followers on F/B	KPI-7.12.4	≥1000	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			7.12.5 Number of members onLinkedIn	KPI-7.12.5	1500	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			7.12.6 Number of stakeholders reached	KPI-7.12.6	≥700	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			7.12.7 Number of people outreach	KPI-7.12.7	≥10000	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
		7.13 Project logo & Visual material, White Papers	7.13.1 Number of logos	KPI-7.13.1	1	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			7.13.2 Number of PPT templates	KPI-7.13.2	1	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			7.13.3 Number of Short Presentations on Diagnostics and software tools	KPI-7.13.3	3	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			7.13.4 Number of White Papers	KPI-7.13.4	4	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			7.13.5 Number of banners	KPI-7.13.5	4	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			7.13.6 Number of posters	KPI-7.13.6	5	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			7.13.7 Number of brochures	KPI-7.13.7	3	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	
			7.13.8 Number of infographics	KPI-7.13.8	3	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not Achieved	

KPI Means of Verification

WP	KPI	KPI Metric	KPI identifier	M01-M06 Means of verification	M07-M12 Means of verification	M13-M18 Means of verification	M19-M24 Means of verification	M25-30 Means of verification	M31-M36 Means of verification	M37-42 Means of verification	M43-M48 Means of verification	Comments
WP1 – Project Management & Innovation Development Coordination	1.1 On time submission of deliverables	1.1.1 In time project progress: Number of deliverables submitted on time over total deliverables that are due during each period	KPI-1.1.1		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
	1.2 Quality of deliverables	1.2.1 Percentage of re-work requests (over total number of deliverables)	KPI-1.2.1		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
WP2 – End User requirements and Evidence Based Studies	2.2 Risk Group Identification	2.2.1 High Risk groups identified <50 years old	KPI-2.2.1		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
	2.3 CRC Biomarker Identification	2.3.1 New CRC Biomarkers identified and clinically validated	KPI-2.3.1		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
	2.4 Reveal Inequalities retrospectively	2.4.1 Statistically Significant inequalities revealed retro and prospectively	KPI-2.4.1		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
WP3 - Advancements on CRC Diagnostics	3.1 Develop Accurate VOC based CRC Diagnostics	3.1.1 Sensitivity of VOC based CRC Diagnostics	KPI-3.1.1		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
		3.1.2 Specificity of VOC based CRC Diagnostics	KPI-3.1.2		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
	3.2 Develop Accurate Metabolomics based CRC Diagnostics	3.2.1 Sensitivity of Metabolomics based CRC Diagnostics	KPI-3.2.1		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
		3.2.2 Specificity of Metabolomics based CRC Diagnostics	KPI-3.2.2		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
	3.3 Develop Accurate CRISPR-Cas Dipstic based CRC Diagnostics	3.3.1 Sensitivity of CRISPR-Cas Dipstic based CRC Diagnostics	KPI-3.3.1		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
		3.3.2 Specificity of CRISPR-Cas Dipstic based CRC Diagnostics	KPI-3.3.2		N/A	N/A	N/A	N/A	N/A	N/A	N/A	

	3.4 Develop Accurate CRC Diagnostics based on Microfluidic Assay for CTCs with Antibody decoration	3.4.1 Sensitivity of Microfluidic Assay based CRC Diagnostics	KPI-3.4.1		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
		3.4.2 Specificity of Microfluidic Assay based CRC Diagnostics	KPI-3.4.2		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
	3.5 AI-assisted Tissue Image Analysis Polyp Detection	3.5.1 Sensitivity of AI-assisted Tissue Image Analysis Polyp Detection	KPI-3.5.1		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
		3.5.2 Specificity of AI-assisted Tissue Image Analysis Polyp Detection	KPI-3.5.2		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
	3.6 Open Data Bio-bank	3.6.1 Number of Prospective Entries of combined diagnostics results	KPI-3.6.1		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
		3.6.2 Number of Retrospective Entries of Algorithm Results	KPI-3.6.2		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
WP4 - Intelligent Platform & Tools for Citizens, Clinicians & Policy Makers	4.1 Develop Trustoworthy and Correct Personalised Risk Stratification	4.1 Percentage of Clinicians (from the clinical sites) who evaluate risk stratification as trustworthy and correct	KPI-4.1.1		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
	4.2 Develop a Useful Personalised Mobile App	4.2 Percentageof Citizens/Patients enrolled for the studies positively evaluate the mobile app usage	KPI-4.2.1		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
	4.3 Clinical Decision Support System (cDSS) for issuing real time recommendation s to Clinicians	4.3.1 Percentage of Clinicians rate recommendations as trustworthy and valuable	KPI-4.3.1		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
		4.3.2 Percentage of Human Error reduction in polyp detection	KPI-4.3.2		N/A	N/A	N/A	N/A	N/A	N/A	N/A	

		4.3.3 Number of Junior histopathologists trained with the AI assisted polyp detection algorithms	KPI-4.3.3		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
	4.4 Develop an Integrated Diagnostics Methodology for CRC Detection	4.4.1 Sensitivity of Integrated Dignostics for CRC Screening	KPI-4.4.1		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
		4.4.2 Specificty of Integrated Dignostics for CRC Screening	KPI-4.4.2		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
	4.5 Intelligent Analytics Dashboard for Policy Makers	4.5.1 Percentage of Policy Makers rate provided evidence analytics trustworthy and valuable	KPI-4.5.1		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
WP5 - Clinical trials design implementation and validation	5.1 Train Upskilled non-experts and junior colonoscopists for AI-assisted polyp detection from colonoscopy sessions	5.1.1 Adenoma Detection Rate from Non-experts (e.g. Nurse Endoscopists; from ~25-35% current level)	KPI-5.1.1	Double check by senior physician	N/A	N/A	N/A	N/A	N/A	N/A	N/A	
		5.1.2 Improvement in Adenoma Detection Rate for Junior Colonoscopists	KPI-5.1.2	Double check by senior physician	N/A	N/A	N/A	N/A	N/A	N/A	N/A	
	5.2 Train Upskilled personnel from Regional & National Authorities on Evidence-based Analysis	5.2.1 Number of People from National/Regional Authorities upskilled on Evidence-based Analysis	KPI-5.2.1	Questionnaire/Validation session	N/A	N/A	N/A	N/A	N/A	N/A	N/A	
	5.3 Train Upskilled Histopathologists from AI-assisted Tissue Image Analysis	5.3.1 Number of Junior Histopathologists upskilled on AI-Assisted Tissue Image Analysis	KPI-5.3.1	Questionnaire/Validation session	N/A	N/A	N/A	N/A	N/A	N/A	N/A	

	5.4 ONCOSCREEN solutions validated at Lab	5.4.1 Percentage of solutions validated at lab	KPI-5.4.1	Double check by an expert	N/A	N/A	N/A	N/A	N/A	N/A	N/A	
		5.4.2 Percentage of ONCOSCREEN solutions' results being integrated	KPI-5.4.2	Double check by an expert	N/A	N/A	N/A	N/A	N/A	N/A	N/A	
	5.5 ONCOSCREEN solutions validated in short scale Clinical Trial	5.5.1 Number of CRC Patients participating in the small-scale clinical trial providing prospective data	KPI-5.5.1	Comparison with proposal	N/A	N/A	N/A	N/A	N/A	N/A	N/A	
		5.5.2 Percentage of Primary objective achieved	KPI-5.5.2	Double check of the calculation	N/A	N/A	N/A	N/A	N/A	N/A	N/A	
		5.5.3 Percentage of ONCOSCREEN solutions validated in the small-scale clinical trial	KPI-5.5.3	Double check of the percentage calculation	N/A	N/A	N/A	N/A	N/A	N/A	N/A	
	5.6 ONCOSCREEN solutions validated in large scale Clinical Trial	5.6.1 Number of different countries participating in the multi-centre clinical trial	KPI-5.6.1	Dashboard by task leader	N/A	N/A	N/A	N/A	N/A	N/A	N/A	
		5.6.2 Number of Different Clinical Settings participating in the trial	KPI-5.6.2	Dashboard by task leader	N/A	N/A	N/A	N/A	N/A	N/A	N/A	
		5.6.3 Number of countries involve patients from ≥ 2 different regions within the country	KPI-5.6.3	Dashboard by task leader	N/A	N/A	N/A	N/A	N/A	N/A	N/A	
		5.6.4 Number of CRC Patients participating in the large-scale clinical trial	KPI-5.6.4	Dashboard by task leader	N/A	N/A	N/A	N/A	N/A	N/A	N/A	
		5.6.5 Percentage of Primary objective achieved	KPI-5.6.5	Dashboard by task leader	N/A	N/A	N/A	N/A	N/A	N/A	N/A	
		5.6.6 Percentage of Secondary objectives achieved of	KPI-5.6.6	Dashboard by task leader	N/A	N/A	N/A	N/A	N/A	N/A	N/A	

		5.6.7 Percentage of ONCOSCREEN solutions validated in the large-scale clinical trial	KPI-5.6.7	Dashboard by task leader	N/A	N/A	N/A	N/A	N/A	N/A	N/A	
WP6 - Evaluation and Living Guidelines for Solutions Uptake	6.1 Living Guidelines for CRC Screening	6.1.1 Number of New High-Risk groups <50 years old recommended to be monitored periodically	KPI-6.1.1		N/A	N/A	N/A	N/A	N/A	N/A	Dashboard by task leader	
		6.1.2 Number of Recommendation Conclusions for CRC screening commonly agreed from at least 50 CRC Clinical Experts across Europe	KPI-6.1.2		N/A	N/A	N/A	Dashboard by task leader	Dashboard by task leader	Dashboard by task leader	Dashboard by task leader	
	6.2 Low-Cost Breath Biopsy CRC Screening Solution	6.2.1 Cost/Examination	KPI-6.2.1		N/A	N/A	N/A	N/A	N/A	N/A	Results of Phase B clinical trial	
	6.3 Low-Cost CRISPR-based Liquid Biopsy Screening Solution	6.3.1 Cost/Examination	KPI-6.3.1		N/A	N/A	N/A	N/A	N/A	N/A	Results of Phase B clinical trial	
	6.4 Low-Cost CTC based Liquid Biopsy CRC Screening Solution	6.4.1 Cost/Examination	KPI-6.4.1		N/A	N/A	N/A	N/A	N/A	N/A	Results of Phase B clinical trial	
	6.5 Low-Cost NMR based liquid Biopsy CRC Screening Solution	6.5.1 Cost/Examination	KPI-6.5.1		N/A	N/A	N/A	N/A	N/A	N/A	Results of Phase B clinical trial	
	6.6 Reduced Cost AI-assisted Colonoscopy Sessions	6.6.1 % Cost reduction in colonoscopy sessions being conducted from non-experts	KPI-6.6.1		N/A	N/A	N/A	N/A	N/A	N/A	Results of Phase B clinical trial	
	6.7 Reduced Cost AI-assisted Tissue Image Interpretations	6.7.1 % Cost reduction in tissue image analysis achieved through human error	KPI-6.7.1		N/A	N/A	N/A	N/A	N/A	N/A	Results of Phase B clinical trial	

		reduction and time-gained in Tissue Image analysis examination										
	6.8 Blended Financial Schemes Proposed for covering CRC screening cost	6.8.1 Number of financial schemes proposed for public private partnership and citizens for covering screening cost	KPI-6.8.1		N/A	N/A	N/A	Based on the analysis performed	Based on the analysis performed	Based on the analysis performed	Based on the analysis performed	
	6.9 Adoption of ONCOSCREEN CRC Screening Methodology from EU countries	6.9.1 Number of countries that adopt or partially adopt proposed methodology altering national guidelines and initiatives on CRC screening	KPI-6.9.1		N/A	N/A	N/A	Dashboard by task leader	Dashboard by task leader	Dashboard by task leader	Dashboard by task leader	
		6.9.2 Number of MoUs signed between CRC diagnostics methods partners	KPI-6.9.2		N/A	N/A	N/A	Dashboard by task leader	Dashboard by task leader	Dashboard by task leader	Dashboard by task leader	
	6.10 Financial & Life expectancy Evaluation of ONCOSCREEN CRC Screening Methodology as a whole	6.10.1 Expected Life Years (LYs) gained by citizens underwent ONCOSCREEN screening solutions	KPI-6.10.1		N/A	N/A	N/A	N/A	N/A	N/A	Based on the results of Phase B clinical trial	
		6.10.2 Expected Quality-Adjusted Life-Years (QALYs) gained	KPI-6.10.2		N/A	N/A	N/A	N/A	N/A	N/A	Based on the results of Phase B clinical trial	
		6.10.3 % Expected Mean Cost reduction of ONCOSCREEN diagnostics & Colonoscopy per LYs compared to Stool Test & Colonoscopy	KPI-6.10.3		N/A	N/A	N/A	N/A	N/A	N/A	Based on the results of Phase B clinical trial	

		6.10.4 % Expected Mean Cost Reduction of ONCOSCREEN diagnostics & Colonoscopy per QALYs compared to Stool Test & Colonoscopy	KPI-6.10.4		N/A	N/A	N/A	N/A	N/A	N/A	Based on the results of Phase B clinical trial	
	6.11 User Accepted Technologies	6.11.1 of patients participating in the trial are satisfied with proposed CRC screening solutions	KPI-6.11.1		N/A	N/A	N/A	Dashboard by task leader	Dashboard by task leader	Dashboard by task leader	Dashboard by task leader	
	6.12 Make Citizens Aware for New CRC Screening Technologies	6.12.1 People outreached (upon a robust and effective communication strategy, see S2.2.2) during the 48-month project period regarding the new CRC technologies proposed by the project	KPI-6.12.1		N/A	N/A	N/A	Dashboard by task leader	Dashboard by task leader	Dashboard by task leader	Dashboard by task leader	
	6.13 Citizen derived Ideas/prototypes for CRC Screening	6.13.1 Ideas/Prototypes proposed in virtual hackathons conducted by the Living Lab	KPI-6.13.1		N/A	N/A	N/A	Dashboard by task leader	Dashboard by task leader	Dashboard by task leader	Dashboard by task leader	
	6.14 Targeted Prevention Campaign for High-Risk Target Groups	6.14.1 CRC prevention strategies developed in at least 2 countries for High Risk population groups with emphasis in vulnerable ones	KPI-6.14.1		N/A	N/A	N/A	Dashboard by task leader	Dashboard by task leader	Dashboard by task leader	Dashboard by task leader	
WP7 - Dissemination, Communication, Exploitation and Impact Creation	7.7 Increase Outreach to scientific communities and relevant Stakeholders	7.7.1 Citations 5 years after the end of the project	KPI-7.7.1		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
		7.7.2 expected participants in events/conferences	KPI-7.7.2		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
		7.7.3 Distribution of leaflets at events, fairs and conferences	KPI-7.7.3		N/A	N/A	N/A	N/A	N/A	N/A	N/A	

		7.7.4 Total Number of expected participants in organized workshops	KPI-7.7.4		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
		7.7.5 MoUs signed between CRC diagnostics methods partners	KPI-7.7.5		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
		7.7.6 Downloads of pubic datasets after 5 years	KPI-7.7.6		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
	7.8 Meetings with National / Regional Health Authorities	7.8.1 Number of High level meetings	KPI-7.8.1		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
		7.8.2 Number of EU (regional, national) Health policy makers reached	KPI-7.8.2		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
	7.9 Meetings with Cancer Patient Associations	7.9.1 Number of Meetings	KPI-7.9.1		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
		7.9.2 Number of Patient associations reached	KPI-7.9.2		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
	asqw-	7.10.1 Number of Meetings	KPI-7.10.1		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
		7.10.2 Number of CRC HCPs associations reached	KPI-7.10.2		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
	7.11 Newsletters, Videos, Website	7.11.1 Number of websites	KPI-7.11.1		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
		7.11.2 Number of visits per day after Y3	KPI-7.11.2		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
		7.11.3 Number of people hits from 60 countries	KPI-7.11.3		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
		7.11.4 Number of Press releases	KPI-7.11.4		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
		7.11.5 Number of emails via website per week received	KPI-7.11.5		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
		7.11.6 Number of media outlets at national and EU level	KPI-7.11.6		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
		7.11.7 Number of videos	KPI-7.11.7		N/A	N/A	N/A	N/A	N/A	N/A	N/A	

		7.11.8 Number of views in videos	KPI-7.11.8		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
	7.12 Social media, Blog, Stakeholders Database	7.12.1 Number of blog entries	KPI-7.12.1		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
		7.12.2 Number of posts per month in social media accounts	KPI-7.12.2		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
		7.12.3 Number of Twitter followers	KPI-7.12.3		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
		7.12.4 Number of followers on F/B	KPI-7.12.4		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
		7.12.5 Number of members on LinkedIn	KPI-7.12.5		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
		7.12.6 Number of stakeholders reached	KPI-7.12.6		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
		7.12.7 Number of people outreach	KPI-7.12.7		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
	7.13 Project logo & Visual material, White Papers	7.13.1 Number of logos	KPI-7.13.1		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
		7.13.2 Number of PPT templates	KPI-7.13.2		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
		7.13.3 Number of Short Presentations on Diagnostics and software tools	KPI-7.13.3		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
		7.13.4 Number of White Papers	KPI-7.13.4		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
		7.13.5 Number of banners	KPI-7.13.5		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
		7.13.6 Number of posters	KPI-7.13.6		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
		7.13.7 Number of brochures	KPI-7.13.7		N/A	N/A	N/A	N/A	N/A	N/A	N/A	
		7.13.8 Number of infographics	KPI-7.13.8		N/A	N/A	N/A	N/A	N/A	N/A	N/A	

Tracking of KPI Revisions

KPI identifier	Initial Target	New Target	Justification
KPI-1.1.1	>75%	-	-
KPI-1.2.1	<20%	-	-

KPI-2.2.1	>4	-	-
KPI-2.3.1	>4	-	-
KPI-2.4.1	>4	-	-
KPI-3.1.1	>90%	-	-
KPI-3.1.2	>95%	-	-
KPI-3.2.1	>96%	-	-
KPI-3.2.2	>95%	-	-
KPI-3.3.1	>90%	-	-
KPI-3.3.2	>90%	-	-
KPI-3.4.1	>90%	-	-
KPI-3.4.2	>90%	-	-
KPI-3.5.1	>98%	-	-
KPI-3.5.2	>98%	-	-
KPI-3.6.1	>4100	-	-
KPI-3.6.2	>250.000	-	-
KPI-4.1.1	>85%	-	-
KPI-4.2.1	>85%	-	-
KPI-4.3.1	>85%	-	-
KPI-4.3.2	>5%	-	-
KPI-4.3.3	>10	-	-
KPI-4.4.1	>95%	-	-
KPI-4.4.2	>95%	-	-
KPI-4.5.1	>85%	-	-
KPI-5.1.1	>40%	-	-
KPI-5.1.2	>5%	-	-
KPI-5.2.1	>20	-	-
KPI-5.3.1	>15	-	-
KPI-5.4.1	1	-	-
KPI-5.4.2	1	-	-
KPI-5.5.1	>300	-	-
KPI-5.5.2	1	-	-

KPI-5.5.3	1	-	-
KPI-5.6.1	7		
KPI-5.6.2	9	-	-
KPI-5.6.3	>2	-	-
KPI-5.6.4	4100	-	-
KPI-5.6.5	1	-	-
KPI-5.6.6	>80%	-	-
KPI-5.6.7	1	-	-
KPI-6.1.1	>4	-	-
KPI-6.1.2	>10	-	-
KPI-6.2.1	<3€	-	-
KPI-6.3.1	<9€	-	-
KPI-6.4.1	<35€	-	-
KPI-6.5.1	<8.5€	-	-
KPI-6.6.1	>20%	-	-
KPI-6.7.1	>5%	-	-
KPI-6.8.1	>10	-	-
KPI-6.9.1	>2	-	-
KPI-6.9.2	≥ 5	-	-
KPI-6.10.1	>6.5	-	-
KPI-6.10.2	>5.5	-	-
KPI-6.10.3	>70%	-	-
KPI-6.10.4	>60%	-	-
KPI-6.11.1	>90%	-	-
KPI-6.12.1	>10.000	-	-
KPI-6.13.1	>200	-	-
KPI-6.14.1	>5	-	-
KPI-7.1.1	>8	-	-
KPI-7.1.2	>4	-	-
KPI-7.1.3	>3	-	-
KPI-7.1.4	>15	-	-

KPI-7.2.1	>30	-	-
KPI-7.3.1	>5	-	-
KPI-7.4.1	>15	-	-
KPI-7.4.2	≥2	-	-
KPI-7.4.3	≥4	-	-
KPI-7.5.1	8	-	-
KPI-7.5.2	1	-	-
KPI-7.5.3	≥2	-	-
KPI-7.6.1	1	-	-
KPI-7.7.1	>500	-	-
KPI-7.7.2	>5000	-	-
KPI-7.7.3	1500	-	-
KPI-7.7.4	> 400	-	-
KPI-7.7.5	≥ 5	-	-
KPI-7.7.6	>500	-	-
KPI-7.8.1	>20	-	-
KPI-7.8.2	>20	-	-
KPI-7.9.1	>30	-	-
KPI-7.9.2	>15	-	-
KPI-7.10.1	>10	-	-
KPI-7.10.2	>15	-	-
KPI-7.11.1	1	-	-
KPI-7.11.2	>50	-	-
KPI-7.11.3	>25000	-	-
KPI-7.11.4	12	-	-
KPI-7.11.5	>3	-	-
KPI-7.11.6	20	-	-
KPI-7.11.7	40 (10/y)	-	-
KPI-7.11.8	>2000	-	-
KPI-7.12.1	≥40	-	-
KPI-7.12.2	5	-	-

KPI-7.12.3	≥2000	-	-
KPI-7.12.4	≥1000	-	-
KPI-7.12.5	1500	-	-
KPI-7.12.6	≥700	-	-
KPI-7.12.7	≥10000	-	-
KPI-7.13.1	1	-	-
KPI-7.13.2	1	-	-
KPI-7.13.3	3	-	-
KPI-7.13.4	4	-	-
KPI-7.13.5	4	-	-
KPI-7.13.6	5	-	-
KPI-7.13.7	3	-	-
KPI-7.13.8	3	-	-

Annex B – Risk Registry

It is noted that the following registry represent only the template and not the latest updates value of risks. The latest values and the final Risk Registry will be included in the EC Periodic Reporting process.

Risk ID	Risk Title	Risk Category	Risks Description	Related Task	Responsible Partner Organization	Risk Owner	Current Escalation Level	Risk Trigger	Probability	Impact	Severity Score	Severity Status	Period Identified	Risk Period	Risk Result	Risk Status	Risk Response Type	Mitigation Plan	External ID linkage	Comments
	Description of the risk	**Select the appropriate Risk Category**	**Provide a Description of the Risk**	**Linkage with a specific Task**	**What organization is responsible for this Task (and for this risk)**	**Name of person who monitors the risk**	**Define the current level of escallation within project**	**How you know the risk is becoming an issue or has reached a point that requires action.**	**Estimate how likely is to occur**	**Estimate of how significant the impact of this risk will be if/when occurs**	**Automatic Score Status. Do not fill.**	**Automatic Status. Do not fill.**	**Which Q-period (3-month) was identified**	**Which year is going to take place? Is it for the entire period of the project?**	**What will happen if the risk becomes an issue and no action is taken**	**Is this risk still Open, Materialised or Closed?**	**Decision made by group on how to respond to this risk**	**What is the mitigation measures in order to prevent the risk from happening?**	**Link with an ID which will be a hyperlink to another log file e.g. Issue Log or Requirements Log**	**Are there any other Comments?**
1	Partner Active Participation	Project Co-ordination	Partner underperforms or leaves the consortium	T1.1	EXUS	Anaxagoras Fotopoulos (EXUS)		Different level of understanding in project plennary meetings & TELCOs. Delays in schedule. Wrong focus in deliverable outcomes.	Low	Medium	3	Low	Q1| 2023	Lifetime of Project	If partner activities are not allocated to other partners fast eventually it may lead to delays in schedule.	Open	No Action	The Consortium Agreement will foresee such situations and will describe measures to be taken to prevent non-compliance to project activities		
2	Key milestones or deliverables are delayed	Project Co-ordination	Project execution failure	T1.1	EXUS	Anaxagoras Fotopoulos (EXUS)		No clear structure regarding the information that needs to be included in the Deliverables. As such, delays are noticed in work allocation among partners involved.	Low	Medium	3	Low	Q1| 2023	Lifetime of Project	Reaching project milestones on time may be jeopardised.	Open	No Action	The Project Coordination Team will be aware in advance about delays or issues due to daily project monitoring, implemented tight working relationships and quality control. Milestones and deliverables with a		

																	critical path will be handled with a special attention.		
3	Effort needed for the technical realisation of the tools is underesti mated	Project Co-ordination	Effort required for achieving technical project goals is under-estimated.	T1.2	ICCS			These issues will become evident initially during the individual tool development, and during the integration process.	M ed iu m	Low	3	Low	Q1| 202 3	Lifetim e of Project	This could result in individual tools not achieving their projected goals, as well as in delays in the project schedule (in the case that other tools expect specific outputs from the underperforming tool)	Ope n	No Action	Project partners are committed to this line of work and R&I as this is important for their own products and/or research. Therefore, they have an incentive to cover additional resources that may be required to achieve certain goals. In addition, the project structure and implementation approach, aims to identify such issues early on and to help direct partners properly to re-allocating resources to tasks and goals.		
4	Lack of interaction between technical/c linician/en d-users	Stakeholder Engagement	This risk involves lack of relevant partners' engagement in the meetings between technical and clinician users and unresponsiveness to requests for information	T1.3	ICCS				Lo w	Medi um	3	Low	Q1| 202 3	Lifetim e of Project		Ope n	No Action			
5	Policy-makers & citizens/pa tients not fully responsive due to operationa l overload	Stakeholder Engagement	This risk involves lack of relevant partners' engagement in the workshops organizedand unresponsiveness to requests for information	T1.3	UMC				Lo w	Medi um	3	Low	Q1| 202 3	Lifetim e of Project		Ope n	No Action			
6	Deliverabl es and performed work are of reduced quality	Project Co-ordination	The prepared deliverables are of reduced quality and do not follow the set format, lack results and explanations	T1.4	EXUS	Anaxagoras Fotopoulos (EXUS)		Deliverables do not follow the template and formats set in the project, they lack explanations and results	M ed iu m	Low	3	Low	Q1| 202 3	Lifetim e of Project	This could result in deliverables needed to be resubmitted and spending extra time at a later time when other tasks are active	Ope n	No Action	Each deliverable will be reviewed by at least two relevant reviewers. The techical and project coordinator will be checking the quality of the deliverable in terms of the technical content and the adoption of the set standards and formats		
7	Ethical concerns, and intellectual property rights	Legal/Ethical /Societal/Cul tural	Risk of potentially ingesting sensitive data and sharing them with other components or stakeholders	T1.5	TIMEL EX				Lo w	Medi um	3	Low	Q1| 202 3	Lifetim e of Project		Ope n	No Action			
8	Data privacy and intellectual	Intellectual Property Rights (IPR)	Risk of potentially ingesting sensitive data and sharing them with other components or stakeholders	T1.6	TIMEL EX				Lo w	Medi um	3	Low	Q1| 202 3	Lifetim e of Project		Ope n	No Action			

	property rights																		
9	Lack of end user engagement	Stakeholder Engagement	This risk involves lack of end-user partners' engagement in the organised workshops and unresponsiveness to requests for information.	T2.2	UMC			If a partner is not responsive by the given deadlines.	Low	High	4	Medium	Q1|2023	Y1	We will not be able to collect the required end-user feedback which will cause a delay of deliverables and subsequently the formulation of technical speficiations and the development of the tools	Open	No Action	Establish good and regular communication between all involved partners in WP2. Keep them updated on the progress of the task and their required input and send regular reminders.		
10	Lack of contributors engagement	Stakeholder Engagement	This risk involves lack of relevant partners' engagement	T2.4	SERVTECH			If a partner is not responsive by the given deadlines.	Low	High	4	Medium	Q1|2023	Lifetime of Project	We will not be able to collect the required information from project partners and external stakeholders	Open	No Action	Establish good and regular communication with involved users. Keep them updated on the progress of the task and their required input and send regular reminders.		
11	Lack of partner engagement	Stakeholder Engagement	This risk involves lack of end-user partners' engagement and response to sent out questionnaires	T2.5	POLA			If a partner is not responsive by the given deadlines.	Low	High	4	Medium	Q1|2023	Lifetime of Project	We will not be able to collect the required information from end users	Open	No Action	Establish good and regular communication with end users. Keep them updated on the progress of the task and their required input and send regular reminders.		
12	Innacurate sensors	Technical	Limited accuracies of developed sensor arrays might be expected during the training process	T3.1	TECHNION				Medium	Medium	4	Medium	Q2|2023	Lifetime of Project		Open	No Action	The array is likely to be affected by environmental and/or background clinical factors or diseases; if this is the case, we will use training sets including VOCs related to each confounding factor to establish calibration curves between the confounding factor and the sensing response. These calibrations curves will be fed into the algorithm to neutralize the effect.		
45	Sample collection problems	Technical	Sample collection problems	T3.1	TECHNION	Gidi shani	Task Level		Medium	Medium	4	Medium	Q4|2023	Lifetime of Project	Possible delays in measuring and evaluating the samples and thus the further development of the tool.	Open	Open	Identify the causes of the sample collection problems and resolve these causes. Otherwise, find alternative ways to collect samples or conduct a large-scale search for existing samples in biobanks or similar sources		

13	Undetected CTCs due to inaccurate processor	Technical	The proposed architecture for the chip platform based on size exclusion may fail to isolate and detect individual CTCs	T3.2	UMINHO				High	Low	4	Medium	Q2|2023	Lifetime of Project		Open	No Action	CTCs-containing samples can be incubated with an antibody targeting the desired surface marker and then introduced into a microfluidic chip with a herringbone structured ceiling. Thus, CTCs can be effectively immobilized on the array, while other cell types leave the microfluidic chip on the outlet.		
14	No CTC Isolation	Technical	Failure of approaches 1 and 2 for CTCs isolation/ detection based on size exclusion.	T3.2	UMINHO				High	High	6	High	Q2|2023	Lifetime of Project		Open	No Action	Develop advanced chip devices decorated with different antibodies for antibody and magnetic separation, and dielectric exclusion techniques.		
20	Delayed samples	Technical	Delayed delivery of samples	T3.2	UMINHO				Medium	Medium	4	Medium	Q2|2023	Lifetime of Project		Open	No Action	Looking for another supplier or adjusting the protocol by replacing the enzyme or changing the enzyme concentration. Quality control of samples		
15	Low number of sequences	Technical	Number of target sequences is too low to detect	T3.3	MUI				Medium	Medium	4	Medium	Q2|2023	Lifetime of Project		Open	No Action	Amplify the target sequences or to concentrate the samples.		
17	Issues with samples	Technical	Batch-effects by samples from different sites	T3.3	MUI				Medium	Medium	4	Medium	Q2|2023	Lifetime of Project		Open	No Action	Establish standard operating procedures and distribute among clinical sites. Computational correction.		
18	Insufficient storage, processing resources	Technical	De-Central sample processing and storage insufficient.	T3.3	MUI				Low	Medium	3	Low	Q2|2023	Lifetime of Project		Open	No Action	Establish SOPs and distribute information. Provide point of contacts for questions. Quality control		
19	Low Specificity	Technical	Lower numbers of specificity sensitivity of ONCOSCREEN diagnostics	T3.3	MUI				Medium	Low	3	Low	Q2|2023	Lifetime of Project		Open	No Action	Apply a) tandem measurements b) combined measurements with 2 or more diagnostics c) multianalyte kits		
21	Supply chain disruption	Technical	Disruption of supply chain due to a crisis	T3.3	MUG				High	High	6	High	Q2|2023	Lifetime of Project		Open	No Action	Build up inventory, diversify supply base		

42	Missing annotations due to inactive partner	Technical	Necessary annotations for training of an AI algorithm are not provided	T3.3	MUI	Paul Torke (MUG)	Task Level	No annotations are available. No feedback from the partner regarding the annotation plan. No suggestions for solutions from the corresponding partner.	High	High	6	High	Q3| 2023	Lifetime of Project	The planned algorithm cannot be trained reliably due to a lack of annotated data. The tool that is based on the AI algorithm cannot be completed.	Risk Materialised	Open	Immediate delivery of the first annotated data. (Meanwhile beginning of October 2023) Clear answer from the partner regarding the annotation plan and the further procedure. Otherwise, search for other open source data to enable at least some training of the AI algorithm. (We are not aware that similar data currently exists)		
43	Lack of information about responsible partner	Project Co-ordination	Currently no information about responsible contact persons and personal investigators from the partner	T3.3	MUI	Paul Torke (MUG)	Task Level	No answer to the questions about the current personnel investigator and /or current responsible persons.	High	Medium	5	High	Q3| 2023	Lifetime of Project	No coordination with the partner regarding joint tasks and organizational matters possible	Open	Open	Partner reacts on requests and clarifies open questions. Otherwise, partner should be viewed as inactive and evasive actions regarding an inactive partner should be initiated.		
44	Inactivity of a task leader	Project Co-ordination	The partner is not fulfilling the tasks as a task leader	T3.3	MUI	Paul Torke (MUG)	Task Level	Partner does not fulfill the tasks as a task leader, such as informing the included partners about meetings and organizational points. No presence in meetings. No feedback on task-specific questions.	High	Medium	5	High	Q3| 2023	Lifetime of Project	The function of the task leader cannot be fullfilled and/or the tasks of the task leader have to be assigned to another partner.	Risk Materialised	Open	Partner restarts to fullfill the tasks as task leader. Otherwise, the tasks of the task leader should be distributed among other partners.		
16	Sample collection problems	Technical	Sample collection problems	T3.4	MUG				Medium	High	5	High	Q2| 2023	Lifetime of Project		Open	No Action	In Case of delays/ not enough samples, use of synthetic DNA or RNA samples to test the diagnostic tool		
22	Ethical concerns, Data privacy	Legal/Ethical /Societal/Cultural	Risk of potentially ingesting sensitive data and sharing them with other components or stakeholders	T3.4	MUG				Low	Medium	3	Low	Q1| 2023	Lifetime of Project		Open	No Action	All Ethical/legal aspects will be prepared and monitored in WP1. In the unlikely event of unclear aspects, a reassessment of the framework will be deployed. The collected data will be secured, stored and processed under the ethical framework that will be formed.		
23	Lack of partner engagement	Stakeholder Engagement	Lack of interaction technical/end-user	T4.1	ICCS				Low	Medium	3	Low	Q1| 2023	Lifetime of Project		Open	No Action	Composition of mixed working groups. Agile development methodology with frequent iterations and incremental releases. Regular planning of feedback moments. Bilateral outreach to (frequent) non-responders.		Though ICCS is listed responsible partner in the Risk Registry, it falls to all

																			ONCO-EVIDA partners to interact with end-users to gauge progress towards the URs.
24	Mismatch between user, technical reuiremen ts	Technical	Technical requirements not user-compatible. URs with no TR counterpart or vice-versa.	T4.1	ICCS				Lo w	Medi um	3	Low	Q2| 202 3	Lifetim e of Project		Ope n	No Action	We will include citizens, clinicians and policy makers during tech developments in a cocreation approach, to address their needs. Linkage and alignment of TRs and URs through identifiers and similar wording.		
25	Unsuitable cancer models	Technical	Difficulties in delivering suitable cancer-related data models	T4.2	CERTH				M ed iu m	Medi um	4	Me diu m	Q2| 202 3	Lifetim e of Project		Ope n	No Action	Conduct extensive literature study and extensive surveys with the ONCOSCREEN policy-makers. Emphasise further the interdisciplinary dimension and consider additional correlating factors to improve predictions. Collect more datasets and iterate based on synthetic data.		
27	Issues with System Integration	Technical	System level integration or interoperability difficulties due to unforeseen complexity	T4.2	CERTH				M ed iu m	High	5	Hig h	Q2| 202 3	Lifetim e of Project		Ope n	No Action	Clear description of system architecture, data models and interfaces following a standard modelling language. Modular software approach and well-defined interfaces between components from the very beginning. Structured and systematic approach to integration and verification activities, allowing sufficient time for tests. Close monitoring by the WP leaders and the Technical Coordinator to ensure smooth integration and interoperability		
26	Inefficient tools	Technical	Difficulties in delivering suitable and efficient tools, including dashboard, mobile app and recommendation engines.	T4.4	iSPRIN T				Lo w	High	4	Me diu m	Q2| 202 3	Lifetim e of Project		Ope n	No Action	The Project team is composed of highly skilled and motivated researchers with impressive track records of achievement,		

																	including successful participation in challenging RIA projects, publications and software development. Adherence to requirements. Close monitoring of scientific and technological progress through the Technology Steering task. More tests before deployment to the clinical sites will be performed.		
28	End User engangement with the mobile app	Stakeholder Engagement	Low adherence to data collection protocol in trials	T4.4	iSPRINT				Low	High	4	Medium	Q2|2023	Lifetime of Project		Open	No Action	End-user education: Demonstration of ONCO-CAWA to the end-users; hands-on training sessions. Gamification features in the app to make it more appealing.		
46	High-resolution data not supported	Technical	High-resolution maps are not supported by the platform. Low geospatial levels (town or below) lead to cluttered visualization attempts due to a large number of units.	T4.6	VITO	Jos Bessems Simon Van den bergh	Task Level	Issue raised during biweekly meeting	High	Medium			Q1|2024	Lifetime of Project	Only high aggregation levels can be visualized; end-users cannot draw strong conclusions.	Open	Open	Increased emphasis on analysis results rather than visual representations for queries going below municipal level. Recommendation engine limits itself to mentioning only “worst performers”.		This is primarily a front-end issue for which is managed by Catalink (CTL).
47	Underwhelming implementation by policymakers	Stakeholder Engagement	The tool is finished and works properly but few end-users are actually using it.	T4.6	VITO	Jos Bessems Simon Van den bergh	WP level		Low	High			Q1|2024	Lifetime of Project	No impact on CRC outcomes or screening	Open	Open	Internal outreach through regular contact with end-user partners. External outreach through publications, poster sessions, presence at conferences and summits...		Probability difficult to assess at this point
29	Issues with clinical studies	Other	COVID-19, causes unavailability of partners to be involved in project's clinical studies.	T5.1	FIRALIS			COVID cases reaching a critical threshold.	High	Medium	5	High	Q2|2023	Lifetime of Project	Clinical study will be delayed.	Open	No Action	WP5 partners and the medical steering committee will monitor closely and any needed preventive actions will be followed		
30	Low participation in clinical trials	Stakeholder Engagement	Low/delayed enrolment rate in the clinical trials producing low data volume that does not allow digital phenotyping	T5.4	UMC				Medium	Low	3	Low	Q1|2024	Lifetime of Project		Open	No Action	Synthetic data generation in the Healthentia platform to facilitate the digital phenotyping algorithms		

34	Limited available data from trials	Technical	Effectiveness data will be collected from the trials execution and therefore it depends on the maturity of the trials.	T5.4	UMC			Delaed progress of the trials.	Medium	High	5	High	Q1|2024	Lifetime of Project	Incomplete cost-effectiveness analysis.	Open	No Action	Cost-effectiveness analysis will be conducted incementally as per trial execution progress.		
35	Patient number for trials	Stakeholder Engagement	The recruited number of patients for trials are considered inefficient	T5.4	UMC			If we have not reached xx patients by Mxx (as our KPI is xxx by Mxx)	Medium	Medium	4	Medium	Q1|2024	Lifetime of Project	We will not meet our KPIs and the project cannot be demonstrate and showcase its potential	Open	No Action	a) Partners already have a plan to quickly raise awareness about the project and engage the target groups in participating in the trial. b) clinical partners have a strong network of hospitals/clinics making feasible to manage the recruitment of patients, c) Include backup clinical partners and focus on specific subgroups (e.g. particular high risk for cancer development)		
31	Engengement with technology assesment	Stakeholder Engagement	Low adherence to data collection protocol in trials	T5.5	LSMU				Low	Low	2	Low	Q1|2024	Lifetime of Project		Open	No Action	Include a virtual coaching module based on principles of persuasive technology in the Healthentia app to enhance engagement with the application		
32	User Acceptance	Overall	Not meeting end-user requirements	T5.5	LSMU				Low	High	4	Medium	Q1|2024	Lifetime of Project	We will not meet our KPIs and the project cannot be exploited to its potential	Open	No Action	Agile development approach in the work plan with multiple iterations and incremental releases, comprising effective feedback cycles.		
33	Ineffective Diagnostics	Overall	Lower numbers of specificity sensitivity of ONCOSCREEN diagnostics	T5.5	LSMU				Medium	Low	3	Low	Q1|2024	Lifetime of Project	We will not meet our KPIs and the project cannot be exploited to its potential	Open	No Action	Be I close contact with technical partners that develop the diagnosits and pursue altrnative solutions e.g. a) tandem measurements b) combined measurements with 2 or more diagnostics c) multianalyte kits		
36	End-users/Patients not reponsive	Stakeholder Engagement	Policy-makers & citizens/patients not fully responsive due to operational overload.	T6.1	URIOJA	Marino Gonzalez (URIOJA)	WP level	Systematic absence of contact and participation in the meetings defined with end-users and patient organizations, in agreement with the specific responsible parties.	Medium	High	5	High	Q1|2024	Lifetime of Project	We will not meet our KPIs and the project cannot be demonstrate and showcase its potential	Open	No Action	Sufficient timeframes allocated to end-user tasks (e.g. demonstration and evaluation). Fair distribution of workloads and proactive monitoring of performance. High number of policymakers and citizens/patients involved		

37	Lack of enduser acceptance of ONCOSCREEN solutions	Overall	Trial and medical committees express mismatch between solutions and use requirements. Difficulty in adoption of solutions in national/ EU health strategies	T6.4	MoH-GR				Low	High	4	Medium	Q1|2024	Lifetime of Project	No or limited acceptance of solutions by endusers	Open	No Action	Strong interaction between endusers/solution developers. Agile development approach in the work plan with multiple iterations and incremental releases, comprising effective feedback cycles.		
38	Project Dissemination	Stakeholder Engagement	Failure to disseminate/exploit project outcomes	T7.1	CARR			We will know if this is a problem that needs addressing if during our first year we have no or low dissemination and media coverage	Medium	Low	3	Low	Q2|2023	Lifetime of Project	Low dissemination and low audience attention	Open	No Action	All partners have significant expertise in impact creation activities. Dissemination metrics and progress will be monitored regularly each quarter. We have Strong participation from industry, academia, healthcare		
40	Participation from partners in dissemination and impact creation activities	Organizational	The risk is not getting active participation for dissemination and communication from all partners.	T7.1	CARR			If partners aren't responding to emails or completing designated dissemination tasks.	Low	Low	2	Low	Q2|2023	Lifetime of Project	The project will not be adequately disseminated or communicated meaning a lack of awareness of the project from potential stakeholders.	Open	No Action	Clearly articulate key messages and methods of contribution. There shall be regular meetings including all partners that involve discussions about dissemination and planning activities. Send timely and regular reminders to partners when specific contributions are needed		
39	Audience/ Citizens response	Stakeholder Engagement	The risk is not achieving engagement/impact for the project for lack of awareness or lack of results that are interesting for our audiences.	T7.2	ECPT			If we do not have people subscribing to our newsletter, contacting us via email or the website, engaging with social media posts, or participating in webinars and events.	Low	Low	2	Low	Q2|2023	Lifetime of Project	Lack of awareness of the project and its results	Open	No Action	Produce a variety of engaging content and invite potential stakeholders to events. Leverage partners' and cluster projects's channels and networks to promote ONCOSCREEN further.		
41	Face-to-face events	Organizational	Not being able to attend or organise face-to-face events due to COVID-19 restrictions or any other reason for the duration of the project. .	T7.4	EXUS	Anaxagoras Fotopoulos (EXUS)		If partners are not attending or organising online events. If alternative online events aren't gaining the responses we need to meet our KPIs or a negative response.	Low	Low	2	Low	Q2|2023	Lifetime of Project	The project will not be adequately disseminated or communicated meaning a lack of awareness of the project from potential stakeholders.	Open	No Action	Covid pandemicand relevant restrictions are over in almost all Europe. In the unlike event of another pandemic partners will attend and organise virtual events in order to be able to present results and engage with relevant stakeholders. We will research ways to make virtual sessions engaging and interactive through the use of different platforms, thus limiting the negative impact of not being able to organise face-to-face events.		

48	Availability of early diagnostic data	Overall	The data from tools of WP3 will be available very late in the project affecting development of AI tools	T4.5	KONN			If we are reaching the later stages of the projects development and we have still not collected the needed data.	Medium	High	5	High	Q2| 2023	Lifetime of Project	The development of tools based on these data will be stalled.	Open	No Action	Continuous monitoring of the progress of data collection together with the project coordination and possible use of only initially collected data as a placeholder until the total amount is collected.		
49	Quality of early diagnostic data	Overall	The data collected from the early diagnostic methods of WP3 might be of low quality	T4.5	KONN			This can only be known during the data collection itself	Low	Low	2	Low	Q2| 2023	Lifetime of Project	It can affect the performance of suggestions based on these data	Open	No Action	Selection of specific algorithms that take into consideration any data quality limitations.		
50	Availability of traditional diagnostic data	Overall	Some data need to be acquired from traditional diagnostic methods, and the clinical partners might be unwilling or unable to provide them due to the sensitive nature of them.	T4.5	KONN			By communicating with the project coordination together with the clinical partners	High	High	6	High	Q1| 2024	Lifetime of Project	Classificasion into a cancer stage might be impossible without access to this data	Open	No Action	There have been two approaches considered as a resolution to this. The first is to avoid any complicated integration and have manual input fields on the cDSS platform.The second is to run a different local server on each clinical center so no data leaves the hospital		
51	Participation of clinical partners	Overall	The intelligent suggestions that we are going to implement, are partially based on empirical observations of the clinical staff, so their participation is crucial to achieve this.	T4.5	KONN			If there is a lack of participation on relevant telchos and assigned tasks	Low	High	4	Medium	Q1| 2024	Lifetime of Project	The tool will not have sufficient suggestions	Open	No Action	With communication from the project coordination and constant channels of communication		

Risk Trends

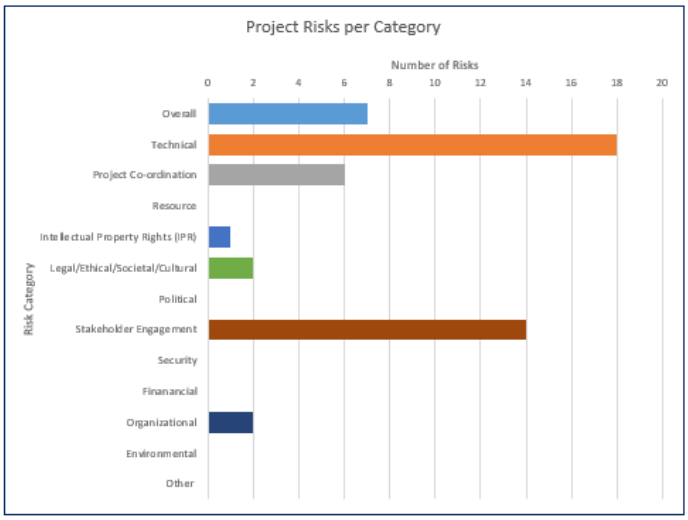
Risk ID	Risk Title	Risk Category	Risk Trend per Period															
			Q1|2023	Q2|2023	Q3|2023	Q4|2023	Q1|2024	Q2|2024	Q3|2024	Q4|2024	Q1|2025	Q2|2025	Q3|2025	Q4|2025	Q1|2026	Q2|2026	Q3|2026	Q4|2026
1	Partner underperforms or leaves the consortium	Project Co-ordination	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**
2	Project execution failure	Project Co-ordination	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**
3	Effort required for achieving technical project goals is under-estimated.	Project Co-ordination	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**
4	This risk involves lack of relevant partners' engagement in the meetings between technical and clinician users and unresponsiveness to requests for information	Stakeholder Engagement	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**
5	This risk involves lack of relevant partners' engagement in the workshops organizedand unresponsiveness to requests for information	Stakeholder Engagement	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**
6	The prepared deliverables are of reduced quality and do not follow the set format, lack results and explanations	Project Co-ordination	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**
7	Risk of potentially ingesting sensitive data and sharing them with other components or stakeholders	Legal/Ethical/Societal/Cultural	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**
8	Risk of potentially ingesting sensitive data and sharing them with other components or stakeholders	Intellectual Property Rights (IPR)	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**
9	This risk involves lack of end-user partners' engagement in the organised workshops and unresponsiveness to requests for information.	Stakeholder Engagement	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**
10	This risk involves lack of relevant partners' engagement	Stakeholder Engagement	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**
11	This risk involves lack of end-user partners' engagement and response to sent out questionnaires	Stakeholder Engagement	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**
12	Limited accuracies of developed sensor arrays might be expected during the training process	Technical	N/A	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**
45	Sample collection problems	Technical	N/A	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**
13	The proposed architecture for the chip platform based on size exclusion may fail to isolate and detect individual CTCs	Technical	N/A	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**
14	Failure of approaches 1 and 2 for CTCs isolation/ detection based on size exclusion.	Technical	N/A	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**
20	Delayed delivery of samples	Technical	N/A	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**
15	Number of target sequences is too low to detect	Technical	N/A	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**

17	Batch-effects by samples from different sites	Technical	N/A	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**
18	De-Central sample processing and storage insufficient.	Technical	N/A	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**
19	Lower numbers of specificity sensitivity of ONCOSCREEN diagnostics	Technical	N/A	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**
21	Disruption of supply chain due to a crisis	Technical	N/A	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**
42	Necessary annotations for training of an AI algorithm are not provided	Technical	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**
43	Currently no information about responsible contact persons and personal investigators from the partner	Project Co-ordination	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**
44	The partner is not fulfilling the tasks as a task leader	Project Co-ordination	N/A	N/A	N/A	N/A	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**
16	Sample collection problems	Technical	N/A	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**
22	Risk of potentially ingesting sensitive data and sharing them with other components or stakeholders	Legal/Ethical/Societal/Cultural	N/A	N/A	N/A	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**
23	Lack of interaction technical/end-user	Stakeholder Engagement	N/A	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**
24	Technical requirements not user-compatible. URs with no TR counterpart or vice-versa.	Technical	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**
25	Difficulties in delivering suitable cancer-related data models	Technical	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**
27	System level integration or interoperability difficulties due to unforeseen complexity	Technical	N/A	N/A	N/A	N/A	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**
26	Difficulties in delivering suitable and efficient tools, including dashboard, mobile app and recommendation engines.	Technical	N/A	N/A	N/A	N/A	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**
28	Low adherence to data collection protocol in trials	Stakeholder Engagement	N/A	N/A	N/A	N/A	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**
46	High-resolution maps are not supported by the platform. Low geospatial levels (town or below) lead to cluttered visualization attempts due to a large number of units.	Technical	N/A	N/A	N/A	N/A	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**
47	The tool is finished and works properly but few end-users are actually using it.	Stakeholder Engagement	N/A	N/A	N/A	N/A	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**
29	COVID-19, causes unavailability of partners to be involved in project's clinical studies.	Other	N/A	N/A	N/A	N/A	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**
30	Low/delayed enrolment rate in the clinical trials producing low data volume that does not allow digital phenotyping	Stakeholder Engagement	N/A	N/A	N/A	N/A	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**
34	Effectiveness data will be collected from the trials execution and therefore it depends on the maturity of the trials.	Technical	N/A	N/A	N/A	N/A	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**

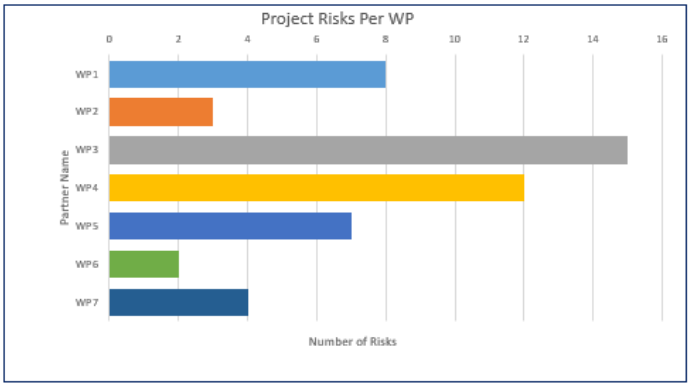
35	The recruited number of patients for trials are considered inefficient	Stakeholder Engagement	N/A	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**
31	Low adherence to data collection protocol in trials	Stakeholder Engagement	N/A	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**
32	Not meeting end-user requirements	Overall	N/A	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**
33	Lower numbers of specificity sensitivity of ONCOSCREEN diagnostics	Overall	N/A	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**
36	Policy-makers & citizens/patients not fully responsive due to operational overload.	Stakeholder Engagement	N/A	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**
37	Trial and medical committees express mismatch between solutions and use requirements. Difficulty in adoption of solutions in national/ EU health strategies	Overall	N/A	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**
38	Failure to disseminate/exploit project outcomes	Stakeholder Engagement	N/A	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**
40	The risk is not getting active participation for dissemination and communication from all partners.	Organizational	N/A	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**
39	The risk is not achieving engagement/impact for the project for lack of awareness or lack of results that are interesting for our audiences.	Stakeholder Engagement	N/A	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	Falling	Falling	Falling	**Closed**
41	Not being able to attend or organise face-to-face events due to COVID-19 restrictions or any other reason for the duration of the project. .	Organizational	N/A	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	**Closed**
48	The data from tools of WP3 will be available very late in the project affecting development of AI tools	Overall	N/A	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	**Closed**
49	The data collected from the early diagnostic methods of WP3 might be of low quality	Overall	N/A	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	**Closed**
50	Some data need to be acquired from traditional diagnostic methods, and the clinical partners might be unwilling or unable to provide them due to the sensitive nature of them.	Overall	N/A	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	**Closed**
51	The intelligent suggestions that we are going to implement, are partially based on empirical observations of the clinical staff, so their participation is crucial to achieve this.	Overall	N/A	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Steady	Falling	**Closed**

Risk Report

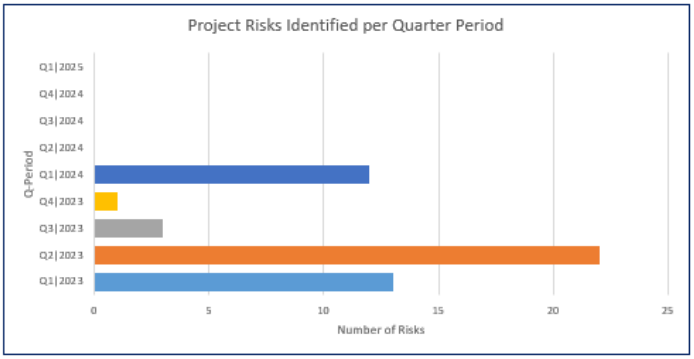
RISKS Per Categorg	
Risk Category	Number of Risks
Overall	7
Technical	18
Project Co-ordination	6
Resource	0
Intellectual Property Rights (IPR)	1
Legal/Ethical/Societal/Cultural	2
Political	0
Stakeholder Engagement	14
Security	0
Finanancial	0
Organizational	2
Environmental	0
Other	0



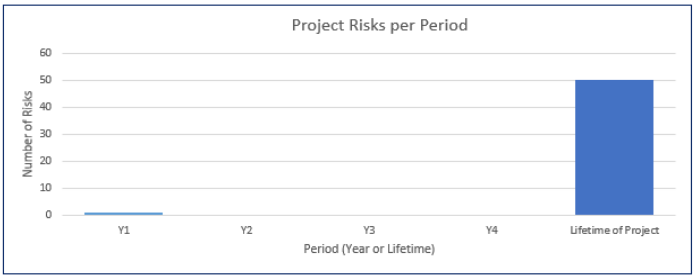
RISKS Per WP	
WP No	Number of Risks
WP1	8
WP2	3
WP3	15
WP4	12
WP5	7
WP6	2
WP7	4



RISKS Identified Per Quarter Period	
Risk per Q-period	Number of Risks
Q1|2023	13
Q2|2023	22
Q3|2023	3
Q4|2023	1
Q1|2024	12
Q2|2024	0
Q3|2024	0
Q4|2024	0
Q1|2025	0

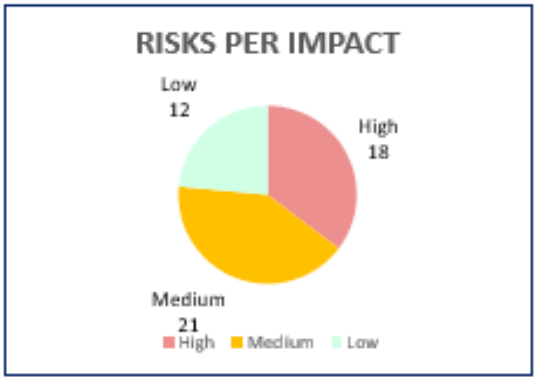


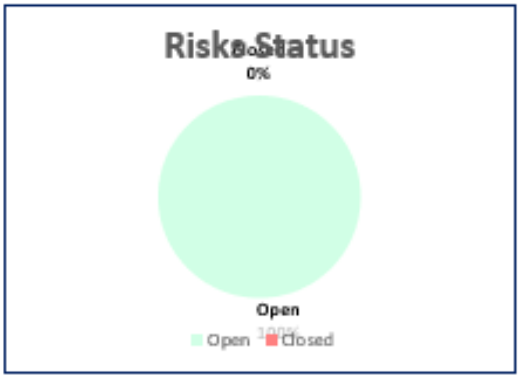
RISKS Per Period	
Risk per Q-period	Number of Risks
Y1	1
Y2	0
Y3	0
Y4	0
Lifetime of Project	50



RISKS Per Impact	
Risk Category	Number of Risks
High	18
Medium	21
Low	12

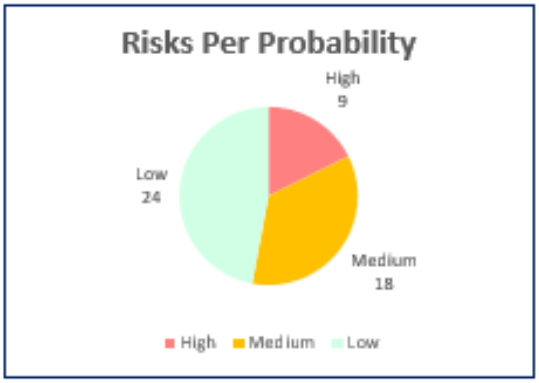
RISKS Status	
Risk Status	Number of Risks
Open	49
Closed	0

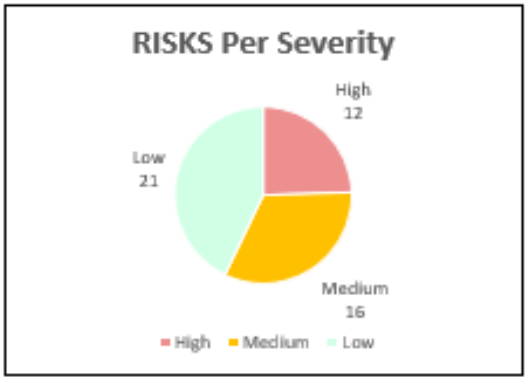




RISKS Per Probability	
Risk Category	Number of Risks
High	9
Medium	18
Low	24

RISKS Per Severity	
Risk Category	Number of Risks
High	12
Medium	16
Low	21





Annex C – Minutes of Meeting Template

ONCOSCREEN

Minutes of Meeting

DATE & TIME	27.03.2022
PROJECT	ONCOSCREEN
DISTRIBUTION	CONFIDENTIAL/PUBLIC
EDITOR	ANAXAGORAS FOTOPOULOS
MEETING TYPE	VIRTUAL/PHYSICAL

SUBJECT	Minutes of Management Board Telco (

Participant	Organisation
Anaxagoras Fotopoulos	EXUS

Agenda

1. New Procedures Explanation
2. WP Status Update
3. Other Issues

Discussion Results

1. Coordinator explained the new documents and tools and answered partners' questions regarding the overall process.
2. XXX

List of Actions

No.	WP	DESCRIPTION	PERSON/PARTNER IN CHARGE	DEADLINE
1	WP1	Provide the Template for the Minutes of Meeting		28/11/2019
2	WP1			
3	WP2			
4	WP3			
5	WP1			
6	WP5			
7	WP4			
8	WP7			

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Annex D – 1st Plenary Meeting Minutes

Minutes of 1st Plenary Meeting

DATE & TIME	01.02.2024 – 02.02.2024
PROJECT	ONCOSCREEN
DISTRIBUTION	CONFIDENTIAL
EDITOR	EXUS
MEETING TYPE	Physical, Paris, France

SUBJECT	Minutes of 1st Plenary Meeting

Participants
59 staff from the partner organizations attended the meeting. An attendance list is signed by all participants, which can be found in in the dedicated ONCOSCREEN sharepoint folder.

Agenda
The 2-day meeting agenda included presentations about the progress updates, the challenges and next steps in all WPs along with 5 workshops focusing on system architecture, clinical trials, end-user requirements, exploitation and citizen engagement. The detailed 2-day agenda can be found in the dedicated Oncoscreen sharepoint folder.

Key Discussion Topics
An overview of each WP was presented by a representative of each WP leader complemented with a detailed task presentations from task leaders and/or contributors followed by WP specific questions and discussions. At the end of each WP key aspects that need attention were highlighted by the coordinator. The detailed overview of each WP, the topics of discussions in each WP and the organized workshops can be found in the dedicated Oncoscreen folder. Key topics of discussion are summarized below as a quick reference. **WP1** An overview of the WP1 activities was presented, stressing the achieved submission of all due deliverables on time during this period and highlighting the key aspects that need attention (ref. slide 9, WP1 presentation) which include: • Significant Delays in Trial Submission Folder • Missing inputs in the internal periodic report • Collaboration between End user & Technical Partners • Poor participation of consortium to dissemination activities & scientific publications • Delays in concluding and understanding of the system architecture • Communication across WPs and utilisation of their outputs • Exploitation initiatives

WP2

An overview of the WP2 activities and what was achieved during the first year was presented. Key topics and results among others include the Risk Stratification Results Overview (ref. slide 7, WP2 presentation), the developed Clinical Knowledge Base including publications, datasets, risk studies, trials results (ref. slide 16, WP2 presentation), the identified CRC Biomarkers (ref. slide 19, WP2 presentation), and the End User Requirements and Laboratory Integration Test (LIT) outcomes (ref. slide 28, WP2 presentation).

Main points of discussion some of which need attention are highlighted below:

- There is a need to connect end-users with technical partners. To facilitate this technical partners need to complete the relevant information sheets from LIT 1 and 2 and send information and links to the end-users.
- May worth to compare the current WP2 results with other existing studies - e.g. WP2 results suggest that smoking is a low risk factor, but this contradicts general opinion and need further investigation before concluding it as a project outcome.
- The CRC risk factors results of different partners need to be present in a common/coherent way, especially for the upcoming midterm review.
- Each risk level needs to be defined clearly and be explained better such that everyone understands what it means.
- There is a need to discuss emerging Polygenic risk factors and was suggested to include results that cover them.
- In case of an identified critical factor partners must work towards writing a white paper (e.g. for asbestos or any other identified factor)
- WP2 partners shall work closer with ONCO-CLIDE
- Relevant standards need to be emphasized in the presentation

WP3

An overview of the WP3 activities and what was achieved during the first year was presented. Key topics and outcomes among others include the development of an ONCO-VOC prototype, of an ML (RFC) based model and of an ONCO-CTC device. Furthermore, the ONCO-NMR and ONCO-CRISP prototypes were presented along with the ONCO-AICO (tool link, ref. slide 33, WP3 presentation), ONCO-AITI and ONCO-BIOBA (tool link, ref. slide 40, WP3 presentation) urging partners to utilize the features of the developed platforms. New risks were identified about at least 2 tools which need attention.

Main points of discussion some of which need attention are highlighted below:

- Samples, data from partners/trials are needed for ONCO-NMR, ONCO-CRISP, ONCO-AICO, ONCO-AITI such that the prototypes can be refined.
- There is a need for harmonized data description (e.g. for ONCO-BIOBA).
- There is a need to clarify how privacy issues are addressed where relevant? E.g. how in ONCO-BIOBA, key features/identifiers are not revealed.
- Closer contact with clinical partners is desirable and must be sought in the next period to refine the tools and get any needed data.
- Need to explain clearer the need for alternative CRC diagnostics and motivate the performed research work. Underline why a tested/detected feature is needed. What is its significance for the clinicians? E.g. why methylation is important?
- The innovation of each tool needs to be clearly described in the presentations

- The introduced terms need to be defined and used consistently by partners (e.g. ONCO-VOC vs breath analysers)
- The collaboration with end-users (feedback, refinement cycle) during the development of each tool need to be emphasized
- What is the innovation related with the AI use in this context? How ONCOSCREEN AI methods compare with existing FDA approved AI methods? There is a need to emphasize that our novelty is on the training platform. In addition, there is a need to emphasize the trustworthiness, robustness of AI and clarify if/how the training process is transparent, e.g. can we provide metadata for others to double check/validate?

WP4

An overview of the WP4 activities and what was achieved during the first year was presented. Key topics and outcomes among others include the developed system architecture, the privacy preserving system integration, the preliminary stratification engine, the developed self-assessment mobile app, the clinical decision support system and the analytics for evidence-based decisions by policy makers.

Main points of discussion some of which need attention are highlighted below:

- In T4.1, more data are needed for ensuring that the reached conclusions and identified risk factors make sense (e.g. claiming that smoking is not a risk is controversial and may cause issues and doubts to the overall work). There is a need to compare with other recent CRC risk analysis studies.
- In T4.2, Datalake needs to be realized and be integrated with the rest.
- In T4.3, ONCO-CAWA must present the innovation and briefly explain how it differs from other apps (e.g. even at least as a tool that utilizes and combines information).
- In T4.4, there is a need to finalize what data need to be collected; preparation of a data collection plan is required in the next period (when, how often, what to ask). There is also a need to collect relevant risks and finalize their assessment and visualization based on feedback that be collected from partners.
- In T4.5, the innovation may be clearly described but there is a need to explain clearly (even on a separate slide) how the work from other tasks e.g. data analysis, AI methods developed by the rest Tasks/Tools are utilized by the cDSS.
- In T4.5, there is a need for inputs/data from clinicians to guide the recommendations of the tool, as well as feedback from end users to help refine it
- In T4.6, there was a good brief presentation of the collaboration between partners, innovation and the impact of the task. There is a need to perform geospatial visualization rather than only country wide focused analysis.

WP5

An overview of the WP5 activities and what was achieved during the first year was presented. Key topics among others include the clinical study protocol preparation (ref. slide 7-8, WP5 presentation), the completion of the 1st and 2nd lab integration tests and the collection of feedback from end users, the preparation of clinical trials and patient recruitment. The challenges associated with the protocol approval, and patient recruitment under a tight timeline were highlighted.

Main points of discussion some of which need attention are highlighted below:

- In the planned clinical study, it was stressed that the recruitment requires approval within the target countries.
- Case control needs to be applied during recruitment to ensure adequate cases are available.

- There are many challenges associated with the management of supplies and shipment to sites most of which are addressed (ref. slide 9, WP5 presentation)
- In T5.2, there is a need for more collaboration between technical and medical partners
- In T5.3, LIT 1 and 2 completed and most technical partners have filled the relevant information about each tool such that end users can check and evaluate them. However, there is a need for some more info by some tools and feedback to be filled by more end users (ref. slide 24, WP5 presentation, link to the LIT2 folder)
- A target number of patients per country was set, but there is still a need to finalize the numbers for some sites such that the target numbers are reached.
- There is a need to pay attention on the target countries for recruitment that is presented in WP2 and WP5 and ensure that are the same.
- There are recruitment issues as stressed by Rosenbaum- in some sites that need to be addressed in order to meet the promised clinical trial number.
- There is a need to clarify if polygenic factors are considered in the study
- There is a need to urgently conclude on the cost per patient within each country/site and ensure that the study will be within budget and finalize who pays for what
- It is stressed that Onco-CAWA can also collect questionnaires and be utilized in the clinical study
- It would be useful to link the recruitment with the cancer awareness month – MARCH '24
- UMINHO needs to arrange with end users and ICCS a separate session LIT2 activity.

WP6

An overview of the WP6 activities and what was achieved during the first year was presented. Key topics among others include the identification of deficiencies in existing studies/programs and methodologies and the targeted novel proposals by ONCOSCREEN partners.

Main points of discussion some of which need attention are highlighted below:

- There is strong dependency of WP6 on WP2 and WP5 outputs (T2.4, T5.5), thus there is a need for closer collaboration.
- There is a need to stress how Oncoscreen is going to help e.g. address the fact that some countries do not have a national CRC program?
- There is a need to highlight what is important and what is the introduced novelty
- In T6.3, it would be useful to add some screenshots/material from the held meetings; mention briefly with whom did you meet, what are the outputs as examples (at least for some meetings)
- Presentation wise, the introduction must be kept smaller and focus more on the work done
- There is a need to clarify what do we propose against the deficiencies identified
- It would be useful to explore based on current policies who is best to pay
- There is a need to explain what are the constraints? How we make decisions/policies based on them (e.g. financial constraints)
- It seems that the work in this WP is a parallel activity on risk factors. There is a need to differentiate from WP2; Focus on the socioeconomic factors in WP6
- There is a need to clarify how to address issues like transportation; what do we propose?
- It will be useful to highlight what is the impact/benefits of an applied policy; how did it help to improve an issue? What must be adopted/changed?

WP7

An overview of the WP7 activities and what was achieved during the first year was presented. Key topics among others include the dissemination and exploitation plans and outcomes during this period, along with the citizen engagement and clustering activities.
Main points of discussion some of which need attention are highlighted below:

- All partners need to actively engage with the dissemination activities, prepare posts on social media and blog articles relevant to the performed work.
- There is a need to engage with the planned citizen engagement activities especially in March 2024 when is the cancer awareness month.
- There is a need to connect the patient recruitment with the communication/dissemination
- In the presentation there is a need to show the targeted KPIs and where we stand

WORKSHOPS

The 5 organized workshops aimed at engaging partners on interactive discussions for resolving open issues relevant with the system architecture and clinical trials and making them familiar with tools and procedures that will be applied for end-user and citizen engagement as well as exploitation.

System Architecture Workshop

The open issues and details relevant with the refinement of the system architecture were presented with all technical partners participating in a discussion. The key points discussed included the need to clarify the Federated Data storage and what metadata will be able to be transferred. The data flow details and need for certain connections between some tools were also discussed. It would be useful to follow up with a practical example about metadata that can be provided by a virtual hospital and request from all partners what data they need to use and get access to for refining their tools.

Clinical Trials Workshop

The open issues on the preparation of the clinical protocol study were discussed. There is a need to finalize the protocol, ensure that the planned study can be performed within budget such that it can be shared for approval as soon as possible.

Co-Design Workshop on End-Users Requirements

An interactive session was organized based on round discussion tables between technical partners and end users in an effort to clarify the end-user questions about each tool and request feedback about the end-user needs and possible tool refinements.

Exploitation Workshop

Key exploitation tools like the IPR registry, the SWOT and PESTLE analysis and business Canvas were presented. The current status of the IPR management and exploitation route in the project was presented along with a timeline for filling in the relevant templated for the key exploitable results of the project. In the next 6 months partners involved in the development of the key exploitable results of the project will be asked to engage in the presented processes.

Citizen Awareness Workshop

The planned activities for citizen engagement were shared and inputs from partners were discussed. The idea of engaging influencers for dissemination and citizen awareness was interesting and was suggested to investigate it. It was suggested to collaborate with other relevant projects e.g. Dioptra/Oncodir to accelerate the impact of the activities. It was also suggested to raise awareness about the risk factors identified in WP2 in the next period and relevant partners to engage in planned activities.

List of Actions				
No.	**WP**	**DESCRIPTION**	**PERSON/PARTNER IN CHARGE**	**DEADLINE**
1	1	All partners should finalize their contributions about their work in the internal periodic report (2023)	All partners	01.03.2024
2	1	Sign the joint controllership agreement according to guidelines shared via email from TIMELEX	TIMELEX, all partners	05.03.2024
3	1	Fill in the evaluation form	All partners	05.03.2024
4	2	Technical partners and end users who have not yet done so, complete the relevant information about the tools and feedback sheets from LIT 1 and LIT2. End-user requirements spreadsheet. Laboratory integration tests (LIT) spreadsheet	Technical Partners and End Users	05.03.2024
5	2	Lead technical partners complete end user co-design workshop spreadsheet	Technical Partners involved	05.03.2024
6	3, 4	Technical partners discuss, refine and finalize the system architecture	Technical Partners involved	30.03.2024
7	2,3,4	Provide Synthetic data and examples of metadata from virtual hospital	WP2 partners under guidance of SERVTECH	30.03.2024
8	5	Finalize the clinical trial budget sheet	FIRALIS, UMC-MAINZ	01.03.2024
9	5	Finalize the clinical trial protocol	All Clinical trial partners	01.03.2024
10	7	Finalize Citigen engagement plan and partner contributions for Cancer awareness month (March 2024)	LSMU, relevant partners	05.3.2024
11	7	All partners make brief posts on social media and/or prepare blog articles about your work for posting on the website during the cancer awareness month	All partners	30.03.2024
12	4	ONCOEVIDA team needs to clarify their planning	ONCOEVIDA Development Team, ICCS, MoH-GR, MoH-LT	15.03.2024
13	5	UMINHO needs to organize a LIT2 session with end users and ICCS	UMINHO, ICCS, Assigned End Users	15.03.2024

Annex E – ONCOSCREEN Deliverable Review Plan

It is noted that this annex shows the template creation and its usage.

WP N°	Del. N°	Deliverable Name	Accountable Partner	Planned Delivery Month	Review Level 1 (RL1) Month	RL1 Status	Review Level 2 (RL2) Month	RL2 Status	Reviewer 1 Organization	Reviewer 2 Organization	RL1 Suggestions Adopted?	RL2 Suggestions Adopted?	WP Leader Check	Technical Manager Check	Legal, Ethical and Security Check	Quality Manager Check	Project Coordinator Check	Submission to EC Status
1	D1.1	Report on Project Management and Cross activities (First version)	EXUS	18	16	Not Done	18	Not Done	ICCS	CERTH			Not Done			Not Done	Not Done	Not Done
1	D1.2	Report on Project Management and Cross activities (Final version)	EXUS	42	40	Not Done	42	Not Done	CERTH	ICCS			Not Done			Not Done	Not Done	Not Done
1	D1.3	Data Management Plan (First Version)	time.lex	6	5	Not Done	6	Not Done	MUG	SERVTECH			Not Done			Not Done	Not Done	Not Done
1	D1.4	Data Management Plan (Final version)	time.lex	48	46	Not Done	48	Not Done	iSPRINT	EXUS			Not Done			Not Done	Not Done	Not Done
2	D2.1	ONCOSCREEN clinical knowledge base (First version)	UMC-MAINZ	12	10	Not Done	12	Not Done	UzL (3rd Party)	LSMNU			Not Done			Not Done	Not Done	Not Done
2	D2.2	ONCOSCREEN clinical knowledge base (Final Version)	UMC-MAINZ	29	27	Not Done	29	Not Done	IPO	IOB			Not Done			Not Done	Not Done	Not Done
3	D3.1	ONCOSCREEN CRC diagnostics (First version)	TECHNION	13	11	Not Done	13	Not Done	UMINHO	CC RL			Not Done			Not Done	Not Done	Not Done
3	D3.2	ONCOSCREEN CRC diagnostics (Final Version)	TECHNION	29	27	Not Done	29	Not Done	BEIA	CC SV			Not Done			Not Done	Not Done	Not Done
3	D3.3	ONCOSCREEN bio bank	MUG	47	45	Not Done	47	Not Done	SERVTECH	FIRALIS			Not Done			Not Done	Not Done	Not Done
4	D4.1	ONCOSCREEN Co-Designed System Architecture (First Version)	ICCS	13	11	Not Done	13	Not Done	CATALINK	EXUS			Not Done			Not Done	Not Done	Not Done
4	D4.2	ONCOSCREEN Co-Designed System Architecture (Final Version)	ICCS	29	27	Not Done	29	Not Done	iSPRINT	TECHNION			Not Done			Not Done	Not Done	Not Done

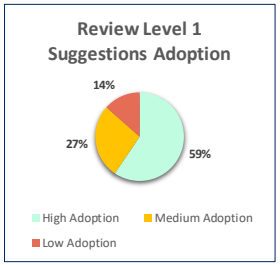
4	D4.3	ONCOSCREEN Integrated Intelligent Platform for Citizens, Clinicians & Policy Makers (First version)	CERTH	13	11	Not Done	13	Not Done	VITO	TLBG			Not Done			Not Done	Not Done	Not Done
4	D4.4	ONCOSCREEN Integrated Intelligent Platform for Citizens, Clinicians & Policy Makers (Final version)	CERTH	29	27	Not Done	29	Not Done	KT	AINIGMA			Not Done			Not Done	Not Done	Not Done
5	D5.1	Phase A Clinical Study - Initiation package	FIRALIS	8	6	Not Done	8	Not Done	UMC-MAINZ	ROSENBAUM			Not Done			Not Done	Not Done	Not Done
5	D5.2	Phase B Clinical Study - Initiation package	FIRALIS	23	21	Not Done	23	Not Done	HSGO	GERCOR			Not Done			Not Done	Not Done	Not Done
5	D5.3	Phase A Clinical Study - Midterm recruitment report	FIRALIS	18	16	Not Done	18	Not Done	IPO	EXUS			Not Done			Not Done	Not Done	Not Done
5	D5.4	Phase B Clinical Study - Midterm recruitment report	FIRALIS	36	34	Not Done	36	Not Done	UKSH	UFC			Not Done			Not Done	Not Done	Not Done
5	D5.5	Phase A Clinical Study - Post clinical results	UMC-MAINZ	29	27	Not Done	29	Not Done	LSMNU	IOB			Not Done			Not Done	Not Done	Not Done
5	D5.6	ONCOSCREEN Laboratory tests and evaluation	ICCS	29	27	Not Done	29	Not Done	TECHNION	VITO			Not Done			Not Done	Not Done	Not Done
5	D5.7	Phase B Clinical Study - Post clinical results	UMC-MAINZ	48	45	Not Done	48	Not Done	UFC	UNIRIOJA			Not Done			Not Done	Not Done	Not Done
6	D6.1	ONCOSCREEN Holistic Evaluation & Solutions Uptake	UNIRIOJA	48	45	Not Done	48	Not Done	CSIC	EY			Not Done			Not Done	Not Done	Not Done
6	D6.2	ONCOSCREEN CRC Screening Living Guidelines	LSMNU	48	45	Not Done	48	Not Done	UMC-MAINZ	IPO			Not Done			Not Done	Not Done	Not Done
6	D6.3	Addressing inequalities recommendations	LSMNU	48	45	Not Done	48	Not Done	IOB	MoHGR			Not Done			Not Done	Not Done	Not Done
7	D7.1	ONCOSCREEN Project Website	CARRCOMMS	6	5	Not Done	6	Not Done	time.lex	EXUS			Not Done			Not Done	Not Done	Not Done
7	D7.2	ONCOSCREEN Dissemination, Communication and Exploitation Plan	CARRCOMMS	6	5	Not Done	6	Not Done	ESDO	YCE			Not Done			Not Done	Not Done	Not Done

7	D7.3	ONCOSCREEN Dissemination and Communication activities (First version)	CARRCOMMS	18	16	Not Done	18	Not Done	ECPT	POLA			Not Done			Not Done	Not Done	Not Done
7	D7.4	ONCOSCREEN Exploitation and IPR Management (First version)	EXUS	18	16	Not Done	18	Not Done	CARRCOMMS	BEIA			Not Done			Not Done	Not Done	Not Done
7	D7.5	ONCOSCREEN Living Lab Performance Evaluation	LSMNU	29	27	Not Done	29	Not Done	EY	TECHNION			Not Done			Not Done	Not Done	Not Done
7	D7.6	ONCOSCREEN Dissemination and Communication activities (Final version)	CARRCOMMS	48	46	Not Done	48	Not Done	MoHGR	GIE AXA			Not Done			Not Done	Not Done	Not Done
7	D7.7	ONCOSCREEN Exploitation and IPR Management (Final version)	EXUS	48	46	Not Done	48	Not Done	GERCOR	MUG			Not Done			Not Done	Not Done	Not Done
7	D7.8	Initial common work plan for scientific collaboration under the 'Prevention, including Screening' cluster	EXUS	6	5	Not Done	6	Not Done	ICCS	TECHNION			Not Done			Not Done	Not Done	Not Done
7	D7.9	Progress report and updates on the common annual meeting of the 'Prevention, including Screening' cluster (version 1)	EXUS	12	10	Not Done	12	Not Done	TLBG	KT			Not Done			Not Done	Not Done	Not Done
7	D7.10	Progress report and updates on the common annual meeting of the 'Prevention, including Screening' cluster (version 2)	EXUS	24	22	Not Done	24	Not Done	AINIGMA	CATALINK			Not Done			Not Done	Not Done	Not Done
7	D7.11	Progress report and updates on the common annual meeting of the 'Prevention, including screening' cluster (version 3)	EXUS	36	34	Not Done	36	Not Done	UMC-MAINZ	CERTH			Not Done			Not Done	Not Done	Not Done
7	D7.12	Progress report and updates on the common annual meeting of the 'Prevention, including	EXUS	48	46	Not Done	48	Not Done	FIRALIS	UMINHO			Not Done			Not Done	Not Done	Not Done

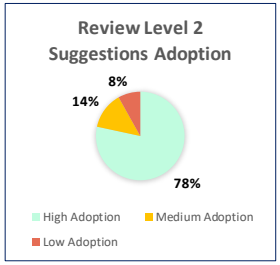
		Screening' cluster (final version)																
7	D7.13	Citizen engagement summary report	ECPT	48	46	Not Done	48	Not Done	POLA	MoHLT			Not Done			Not Done	Not Done	Not Done
7	D7.14	Mission Cluster EU-Projects Common video and brochure	CARRCOMMS	12	10	Not Done	12	Not Done	EXUS	YCE			Not Done			Not Done	Not Done	Not Done

	Total RL1s	Total RL2s	Total Reviews	Total PMs	% PM	% Reviews	Total Deliverables
EXUS	1	4	5	149	9%	7%	9
UMC-MAINZ	3	0	3	80	5%	4%	4
ICCS	2	1	3	77	5%	4%	3
FIRALIS	1	1	2	84	5%	3%	4
UKSH	1	0	1	37	2%	1%	0
UzL (3rd Party	1	0	1	21	1%	1%	0
LSMNU	1	1	2	58	3%	3%	3
MUG	1	1	2	44	3%	3%	1
IPO	2	1	3	60	4%	4%	0
IOB	1	2	3	47	3%	4%	0
TECHNION	1	3	4	86	5%	5%	2
UMINHO	1	1	2	42	2%	3%	0
TLBG	1	1	2	34	2%	3%	0
VITO	1	1	2	28	2%	3%	0
CERTH	1	2	3	77	5%	4%	2
iSPRINT	2	0	2	30	2%	3%	0
SERVTECH	1	1	2	22	1%	3%	0
AINIGMA	1	1	2	36	2%	3%	0
CATALINK	1	1	2	33	2%	3%	0
KT	1	1	2	36	2%	3%	0
BEIA	1	1	2	34	2%	3%	0
UNIRIOJA	0	1	1	37	2%	1%	1
time.lex	1	0	1	21	1%	1%	2
CARRCOMMS	1	0	1	27	2%	1%	5
MoHGR	1	1	2	30	2%	3%	0
POLA	1	1	2	28	2%	3%	0
ECPT	1	0	1	23	1%	1%	1
HSGO	1	0	1	17	1%	1%	0
ESDO	1	0	1	35	2%	1%	0
YCE	0	2	2	19	1%	3%	0
MUI	0	0	0	36	2%	0%	0
MoHLT	0	1	1	29	2%	1%	0
EY	1	1	2	20	1%	3%	0
CSIC	1	0	1	29	2%	1%	0
UFC	1	1	2	46	3%	3%	0
ROSENBAUM	0	1	1	55	3%	1%	0
GIE AXA	0	1	1	26	2%	1%	0
GERCOR	1	1	2	82	5%	3%	0
CC RL	0	1	1	14	1%	1%	0
CC SV	0	1	1	14	1%	1%	0
Total			**74**	**1703**			**24**

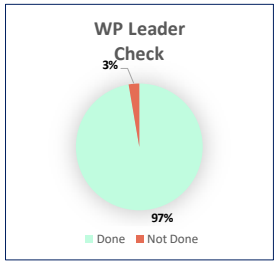
Review Level 1 Suggestions Adoption	
Status	Total Number
High Adoption	22
Medium Adoption	10
Low Adoption	5



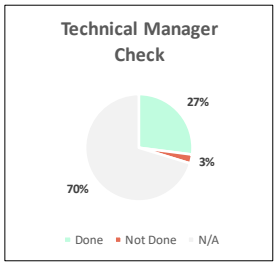
Review Level 2 Suggestions Adoption	
Status	Total Number
High Adoption	29
Medium Adoption	5
Low Adoption	3



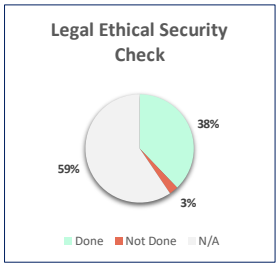
WP Leader Check	
Status	Total Number
Done	36
Not Done	1



Technical Manager Check	
Status	Total Number
Done	10
Not Done	1
N/A	26

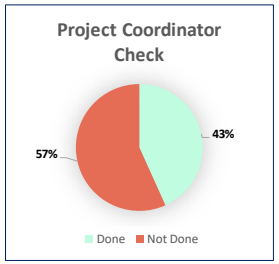


Legal Ethical Security Check	
Status	Total Number
Done	14
Not Done	1
N/A	22

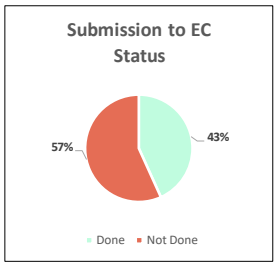


Quality Manager Check	
Status	Total Number
Done	37
Not Done	0

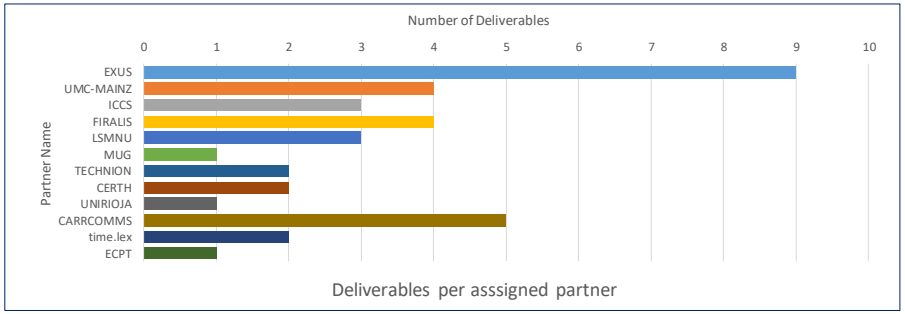
Project Coordinator Check	
Status	Total Number
Done	16
Not Done	21



Submission to EC Status	
Status	Total Number
Done	16
Not Done	21



Deliverables per Assigned Partner	
Partner Name	Number of Del.
EXUS	9
UMC-MAINZ	4
ICCS	3
FIRALIS	4
LSMNU	3
MUG	1
TECHNION	2
CERTH	2
UNIRIOJA	1
CARRCOMMS	5
time.lex	2
ECPT	1

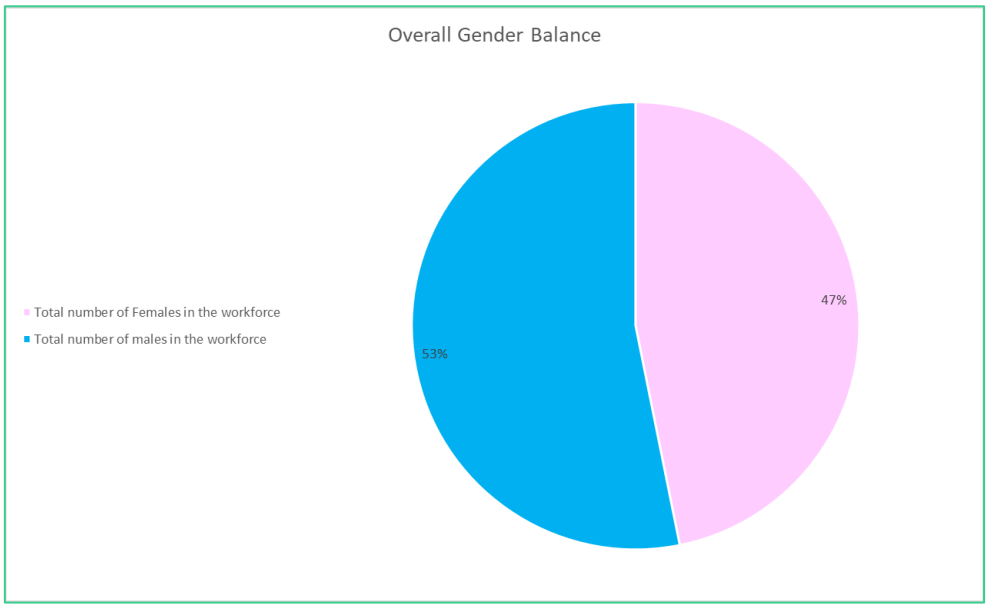


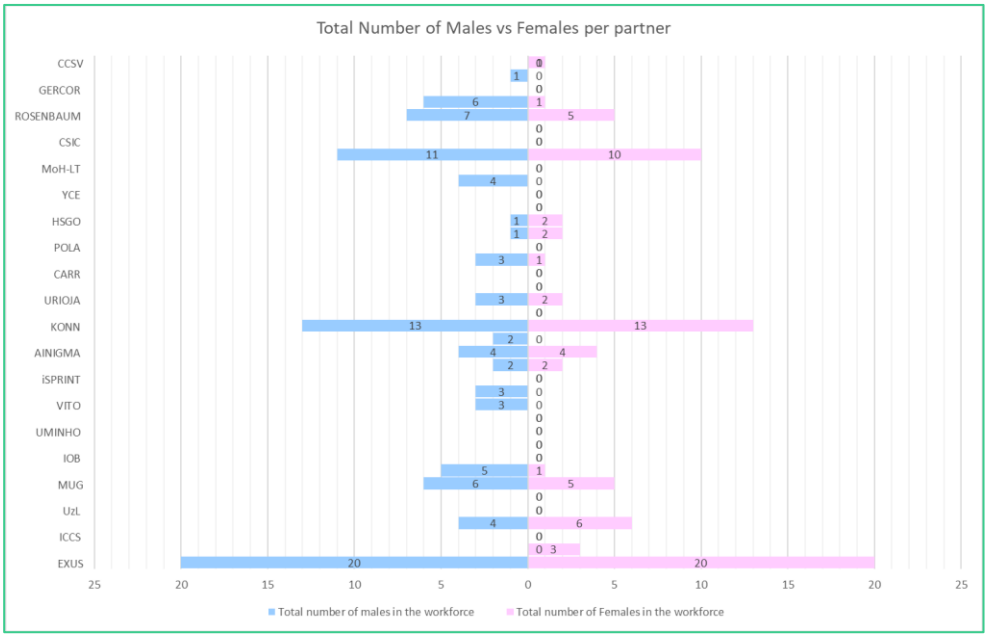
Annex F – Gender Balance Registry

The following registry do not represent the current state. The final updates will be documented in the periodic report.

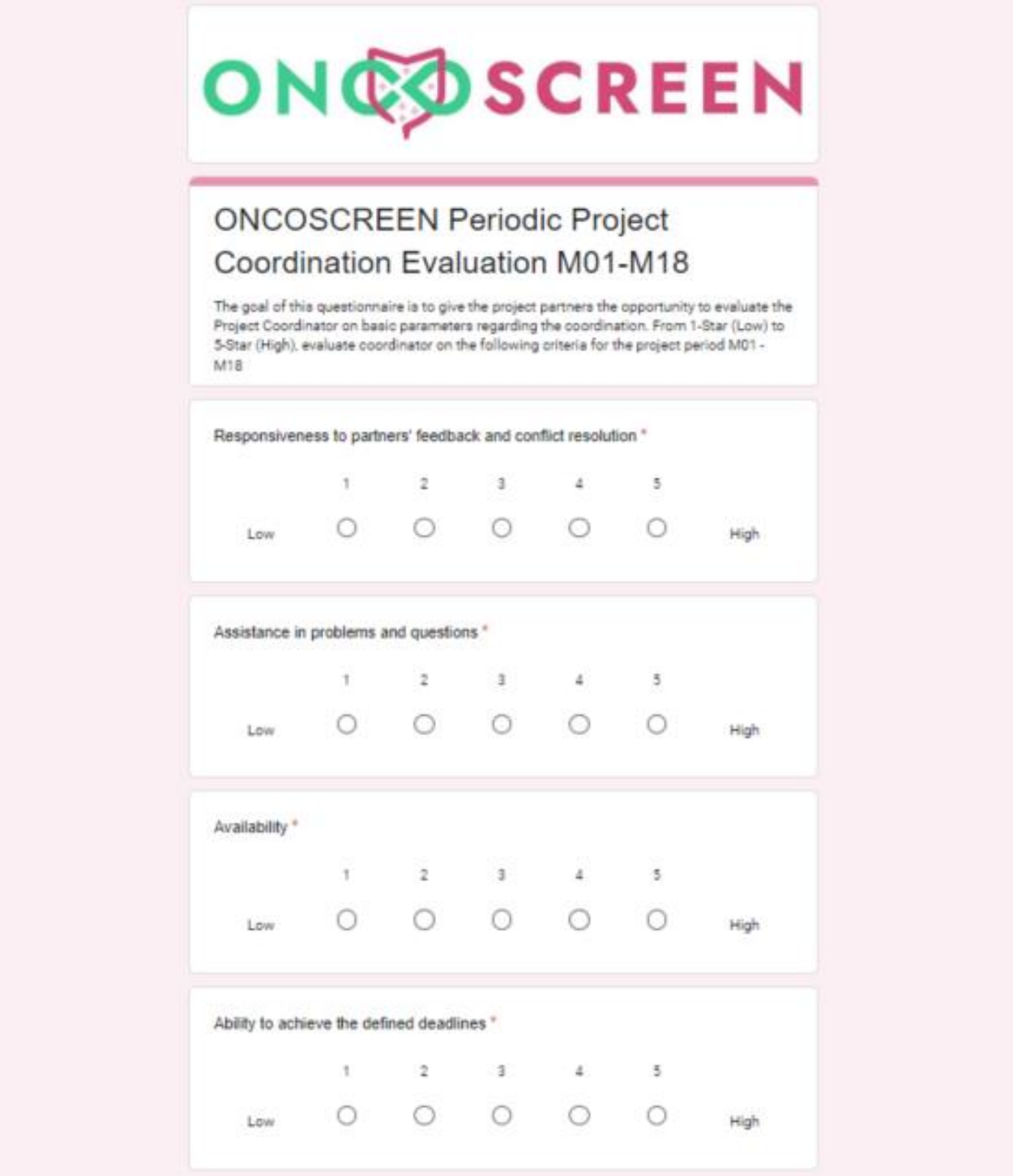
Beneficiaries	Number of Female Researchers	Number of Male Researchers	Number of females in the workforce other than researchers	Number of males in the workforce other than researchers	Total number of Females in the workforce	Total number of males in the workforce
EXUS	10	10	10	10	20	20
UMC-Mainz	3	0			3	0
ICCS					0	0
FIRALIS	5	2	1	0	6	2
UzL					0	0
LSMU					0	0
MUG	5	6			5	6
IPO	1	0			1	0
IOB					0	0
TECHNION					0	0
UMINHO					0	0
TLBG					0	0
VITO		3	0	0	0	3
CERTH					0	0
iSPRINT					0	0
SERVTECH	2	2	0	0	2	2
AINIGMA	4	4	0	0		4
CTL					0	0
KONN	13	13	0	0	13	13
BEIA					0	0
URIOJA	2	3			2	3
TIMELEX					0	0
CARR					0	0
MoH-GR	1	2	0	1	1	3
POLA					0	0
ECPT	0	0	2	3	2	3
HSGO	0	2	2	3	2	5
ESDO					0	0
YCE					0	0
MUI					0	0
MoH-LT					0	0
EY			10	11	10	11
CSIC					0	0
UFC					0	0
ROSENBAUM	2	4	3	3	5	7
AXA	1			1	1	1
GERCOR					0	0
CCRL	0	0	0	1	0	1
CCSV	0	0	1	0	1	0
Total	49	51	29	33	74	84

Number of Female Researchers (%)	Number of Male Researchers (%)	Number of females in the workforce other than researchers (%)	Number of males in the workforce other than researchers (%)	Total number of Females in the workforce (%)	Total number of males in the workforce (%)
50%	50%	50%	50%	50%	50%
100%	0%	-	-	100%	0%
-	-	-	-	-	-
71%	29%	100%	0%	75%	25%
-	-	-	-	-	-
-	-	-	-	-	-
45%	55%	-	-	45%	55%
100%	0%	-	-	100%	0%
-	-	-	-	-	-
-	-	-	-	-	-
-	-	-	-	-	-
-	-	-	-	-	-
0%	100%	-	-	0%	100%
-	-	-	-	-	-
-	-	-	-	-	-
50%	50%	-	-	50%	50%
50%	50%	-	-	0%	100%
-	-	-	-	-	-
50%	50%	-	-	50%	50%
-	-	-	-	-	-
40%	60%	-	-	40%	60%
-	-	-	-	-	-
-	-	-	-	-	-
33%	67%	0%	100%	25%	75%
-	-	-	-	-	-
-	-	40%	60%	40%	60%
0%	100%	40%	60%	29%	71%
-	-	-	-	-	-
-	-	-	-	-	-
-	-	-	-	-	-
-	-	-	-	-	-
-	-	48%	52%	48%	52%
-	-	-	-	-	-
-	-	-	-	-	-
33%	67%	50%	50%	42%	58%
100%	0%	0%	100%	50%	50%
-	-	-	-	-	-
-	-	0%	100%	0%	100%
-	-	100%	0%	100%	0%


Overall Gender Balance
Total number of Females in the workforce
Total number of males in the workforce
47%
53%


Total Number of Males vs Females per partner
CCSV
GERCOR
ROSENBAUM
CSIC
MoH-LT
YCE
HSGO
POLA
CARR
URIOJA
KONN
AINIGMA
iSPRINT
VITO
UMINHO
IOB
MUG
UzL
ICCS
EXUS
25 20 15 10 5 0 5 10 15 20 25
Total number of males in the workforce
Total number of Females in the workforce

Annex G – Coordination Evaluation Survey



ONCOSCREEN Periodic Project Coordination Evaluation M01-M18

The goal of this questionnaire is to give the project partners the opportunity to evaluate the Project Coordinator on basic parameters regarding the coordination. From 1-Star (Low) to 5-Star (High), evaluate coordinator on the following criteria for the project period M01 - M18

Responsiveness to partners' feedback and conflict resolution *

	1	2	3	4	5	
Low	○	○	○	○	○	High

Assistance in problems and questions *

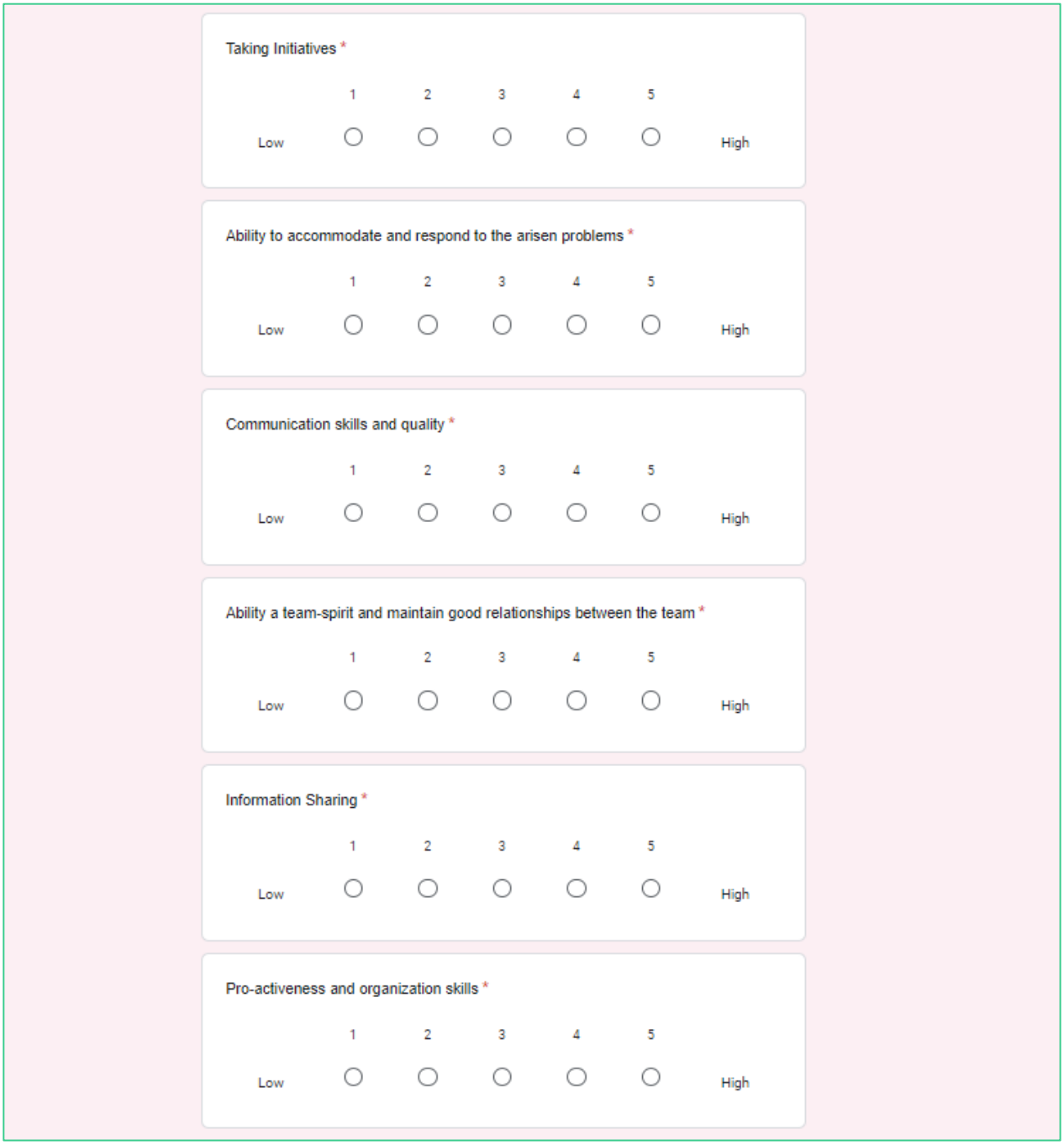
	1	2	3	4	5	
Low	○	○	○	○	○	High

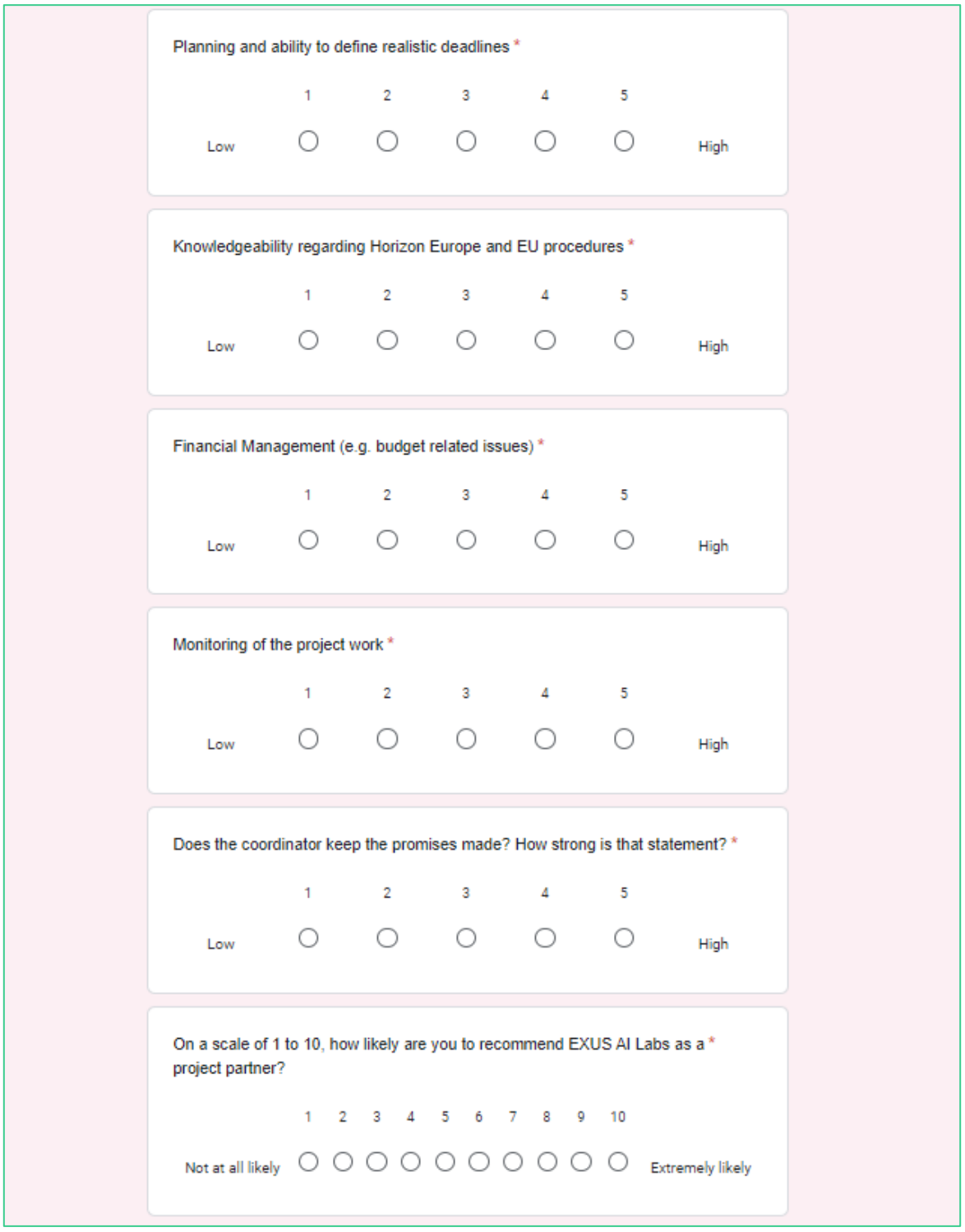
Availability *

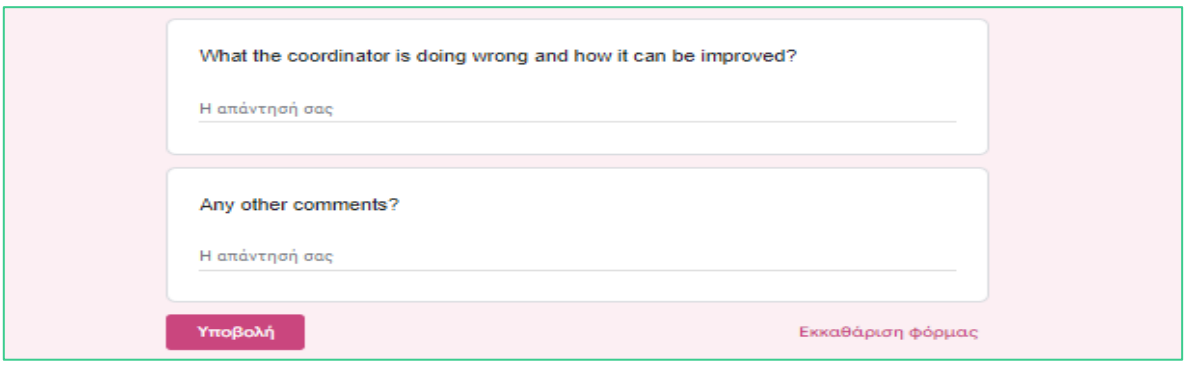
	1	2	3	4	5	
Low	○	○	○	○	○	High

Ability to achieve the defined deadlines *

	1	2	3	4	5	
Low	○	○	○	○	○	High


Taking Initiatives *
1 2 3 4 5
Low High
Ability to accommodate and respond to the arisen problems *
1 2 3 4 5
Low High
Communication skills and quality *
1 2 3 4 5
Low High
Ability a team-spirit and maintain good relationships between the team *
1 2 3 4 5
Low High
Information Sharing *
1 2 3 4 5
Low High
Pro-activeness and organization skills *
1 2 3 4 5
Low High


Planning and ability to define realistic deadlines *
1 2 3 4 5
Low High
Knowledgeability regarding Horizon Europe and EU procedures *
1 2 3 4 5
Low High
Financial Management (e.g. budget related issues) *
1 2 3 4 5
Low High
Monitoring of the project work *
1 2 3 4 5
Low High
Does the coordinator keep the promises made? How strong is that statement? *
1 2 3 4 5
Low High
On a scale of 1 to 10, how likely are you to recommend EXUS AI Labs as a * project partner?
1 2 3 4 5 6 7 8 9 10
Not at all likely Extremely likely


What the coordinator is doing wrong and how it can be improved?
Η απάντησή σας
Any other comments?
Η απάντησή σας
Υποβολή
Εκκαθάριση φόρμας