Intelligent ecosystem to improve the governance, the sharing, and the re-use of health data for rare cancers

Deliverable 1.1

Quality Plan

29 February 2023

This project has received funding from the European Union's Horizon Europe research and innovation programme under grant agreement no. 101057048

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European Commission	Project Officer: and all concerned E.C. appointed personnel and external experts

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Revision History

Revision	Date of Issue	Author(s)	Brief Description of Change
0	04/11/2022	E. Gaeta (UPM)	ToC
0.1	14/11/2022	E. Martinelli (INT)	Revised ToC
0.2	24/11/2022	E. Martinelli (INT)	Draft
0.21	28/11/2022	E. Gaeta (UPM), A. Trama (INT)	Added contributions and comments
0.31	01/12/2022	E. Martinelli (INT)	
0.4	02/12/2022	E. Martinelli (INT)	
0.5	05/12/2022	E. Gaeta (UPM), E. Martinelli (INT)	Added contributions regarding technical management
0.6	11/12/2022	E. Martinelli (INT)	Added contributions from INT, UDEU and UPM
0.7	18/01/2022	E. Martinelli (INT)	Revised version
0.8	24/01/2023	A. Trama (INT)	Added contribution from INT, UDEU and UPM
09	26/01/2023	E. Martinelli	Integrated comments from Consortium
1	29/01/2023	E. Martinelli (INT)	Final version approved by Coordinator

Addressees of this document

This document is addressed to the whole IDEA4RC Consortium. It is an official deliverable for the project and shall be delivered at the European Commission and appointed experts.

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IDEA4RC

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Abbreviations and definitions

Definitions

Quality: the total set of characteristics of a product or service that affect its ability to satisfy a customer's stated or implied needs.

Quality system/Quality Assurance System (QS/QAS): the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.

Quality assurance (QA): the systematic and independent examination of all research-related activities and documents. These audits determine whether the evaluated activities were appropriately conducted and that the data were generated, recorded, analyzed, and accurately reported according to WPs and tasks described in the grant agreement, the clinical study protocol, standard operating procedures (SOPs), and good clinical practices (GCPs).

Quality control (QC): periodic operational checks within each functional department to verify that the activities set in the Annex I to the Grant Agreement are duly and timely performed and that clinical data are generated, collected, handled, analyzed, and reported according to protocol, SOPs, and GCPs.

Acronyms

CA	Consortium Agreement
DoA	Description of Action – Annex I to the Grant Agreement
EC	European Commission
EHDS	European Health Data Space
EU	European Union
GA	General Assembly
GCP	Good Clinical Practice
KPI	Key Performance Indicator
QA	Quality Assurance
QP	Quality Plan
QC	Quality Control
RAM	Risk Assessment Matrix
RC	Rare Cancers
SC	Steering Committee
SOP(s)	Standard Operating Procedure(s)
SSH	Social Sciences and Humanities
ToC	Table of Contents
WP	Work Package

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Abstract

This Quality Manual describes the procedures established to fulfill the above goals based on a quality-driven framework within which the project will be conducted and implemented. The quality framework incorporates three main dimensions: data quality monitoring, compliance to ethical and legal regulations and technical quality.
This document complements the quality provisions foreseen in the Technical Annex I DoA and in the Consortium Agreement (CA) for what concerns project responsibilities, coordination and decision-making. It has the objective to:

- provide methods, standards and procedures related to:
  - development, verification and maintenance of quality criteria;
  - acceptance and quality control;
  - risk assessment and monitoring;
  - control and recovery actions;
- advise and assist the project working team(s) in the achievement of high-quality results;

- plan, organize and perform controls aimed at a permanent and critical assessment of the progress of project activities vis-à-vis the expected results and the project goals.

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About IDEA4RC Quality Plan and procedures

1.1 Context and addressed quality aspects

IDEA4RC aims at establishing a trustable high-quality data space for the secondary use of rare cancer patients' data, accessible for research, healthcare service provision, healthcare management and monitoring, under controlled authorization procedures that ensure data subjects' rights. In this context, quality of data and quality and reliability of the tools that process, describe and give access to the data are fundamental not only for research purposes but also if used to inform the quality of healthcare services and to orient clinical decisions.

The above considerations underpin the quality framework and the quality plan established in IDEA4RC Consortium that addresses the following aspects:

- Quality of the involved actors/Consortium: this has been assessed during the preparation of the project and will be continuously monitored by the Coordinator throughout the project execution.
- Quality of management and project monitoring, including risks management
- Quality of technical and scientific results, in particular the developed tools, software and infrastructures (deliverables, software and any other expected results), that will be assessed by the Project Steering Committee and by the Coordinator as part of the Quality Assurance and Coordination activities as defined in the Technical Annex I DoA, and in the CA Section 6, and for what concerns the clinical and scientific aspects in the frame of WP8 and WP9.
- Quality of processes implemented in and proposed by the project for secure, legal and ethical data sharing. These aspects will be strictly monitored in particular in the frame of WP3, WP5, WP7 and will be assessed on a yearly basis by an external ethical advisor as established in WP12.
- Quality of data managed and shared by the project. This fundamental aspect is addressed and monitored during the system implementation as part of the developments in WP2, WP3, WP4, WP5 and WP6 and assessed in WP7, WP8 and WP9 as part of the pilots' measurement activities. Data quality aspects and recommendations from already running EU initiatives in the EHDS area (such as TEHDAS) as well as ongoing standards for data processing and integration (such as ISO/WD 20691 2019) will be considered in this respect.
- Quality of communications (internal to the project and external to the target audiences), which will be measured by the Coordinator according to the reactions of partners to important communications that involve deadlines, milestones, risks and/or critical decisions for the project execution.

These aspects are further detailed in the following sections of this document.

1.2 Quality policies

An effective quality assurance system (QAS) is established in the IDEA4RC project for the fulfillment of the following obligations described in the DoA:

- Achieve all project milestones within the relevant due date
- Produce all project deliverables, in conformance to the delivery date, resources and budget and quality levels established in the DoA
- Accomplish all ethics requirements related to the implementation of the project, according to EU regulations
- Achieve the promised quantitative KPIs, concerning the most relevant aspects of the project performance and results
- Monitor and control major risks that can potentially affect the achievement of the project objectives.

The project's quality plan establishes procedures that can and shall be implemented and applied by all Consortium partners and any involved third parties, and that are:

1. aligned with the strategic objectives of the project and of the participating organizations,
2. described in terms that are clear and easily understandable and interpreted,
3. designed to have measurable objectives,
4. evaluated on a yearly basis,
5. feasible based on available resources and on the foreseen timeframe.

1.2.1 Quality policies approval and revision

The Quality policies described in this deliverable have been approved by the project Consortium and authorized by the General Assembly at the date of issue, indicated in the cover page of the document.
Project procedures will be prepared by the responsible partner (WP leader/Task Leader) and will be reviewed for internal quality assurance by the Project Manager (PM).
Any Consortium partner may request the upgrade or the modification of the Quality Plan and relevant procedures as necessary at any time during the project execution, in the aim to increase the level of quality and to facilitate the quality assurance (QA) work. Modifications shall be agreed and approved by the Steering Committee and then distributed to all Consortium members.

The Quality Plan may be reviewed by the project Steering Committee and submitted for approval to the General Assembly during Consortium meetings to take into consideration:

- the adequacy of project partners staff for the tasks and activities foreseen and/or undertaken or the usage of resources,
- the results from project reviews and from internal audits,
- deficiencies or problems concerning any project deliverable,
- the preventive and/or corrective action requests from all the above,
- the eventual risks and the related corrective/mitigation actions.
- need for new quality procedures,
- users' dissatisfaction,

Records of such meeting decisions will be kept by the Coordinator. The actions decided will be followed and monitored through the Quality assurance and risk management (T1.3), Technical management (T1.2) and Ethics Coordination (T1.4) tasks.

1.3 Setup of quality plan and procedures

The Coordinator Team has proceeded fast to setup project monitoring procedures and anticipate quality assurance aspects management, by establishing organizational bodies, communication procedures and a collaborative documents' management space using Google Drive, accessible to all persons involved in the project (https://drive.google.com/drive/folders/1E4RgrhlLLZ_KmQwOXoIWH4u-WPF-XD0F).
The following timeline has been followed and milestones have been established to periodically check the Quality Plan throughout the project execution.

Activity / Milestone	Effective date	Related Milestone
Set-up Coordinator Team	May 2022	
Set up Steering Committee	July 2022	
Start of IDEA4RC	01/09/2022	M0
Set-up collaborative documents management space	14/09/2022	
Start Coordinator Team weekly meetings	03/10/2022	
General Assembly Meeting	28/09/2022	
Define templates for internal and official documents	15/10/2022	
Define project and activity monitoring tools	30/10/2022	
Define and setup technical collaborative environment	30/10/2022	
Start biweekly WP Leaders and Task Leaders online meetings	16/11/2022	
Periodic Steering committee Meeting	At least every three months	
Define Cluster work groups participants	11/11/2022	
Risk assessment and management	At least every three months	
Agree on Quality Plan and procedures and publish to Consortium	31/01/2023	
Deliver Quality Plan	28/02/2023	M1
Deliver Ethics Report N. 1	28/02/2023	M1
Revise quality plan and ethics report	On a yearly basis	

Table 1. Timeline for IDEA4RC Quality Plan and procedures setup

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2 Project management

2.1 The PM²: The Open Project Management methodology

PM² is a Project Management Methodology developed by the European Commission. Its purpose is to enable Project Managers (PMs) to deliver solutions and benefits to their organisations by effectively managing the entire lifecycle of their project.[1] IDEA4RC management quality will consider the recommendations offered by PM2.

2.2 Project Bodies and responsibilities

The EU Grant Agreement and the Consortium Agreement signed by project partners set the responsibilities of individual partners and of the Consortium as a whole. These are better described across the IDEA4RC organizational structure and bodies, defined by the Coordinator and agreed by the Consortium, represented by the figure below.

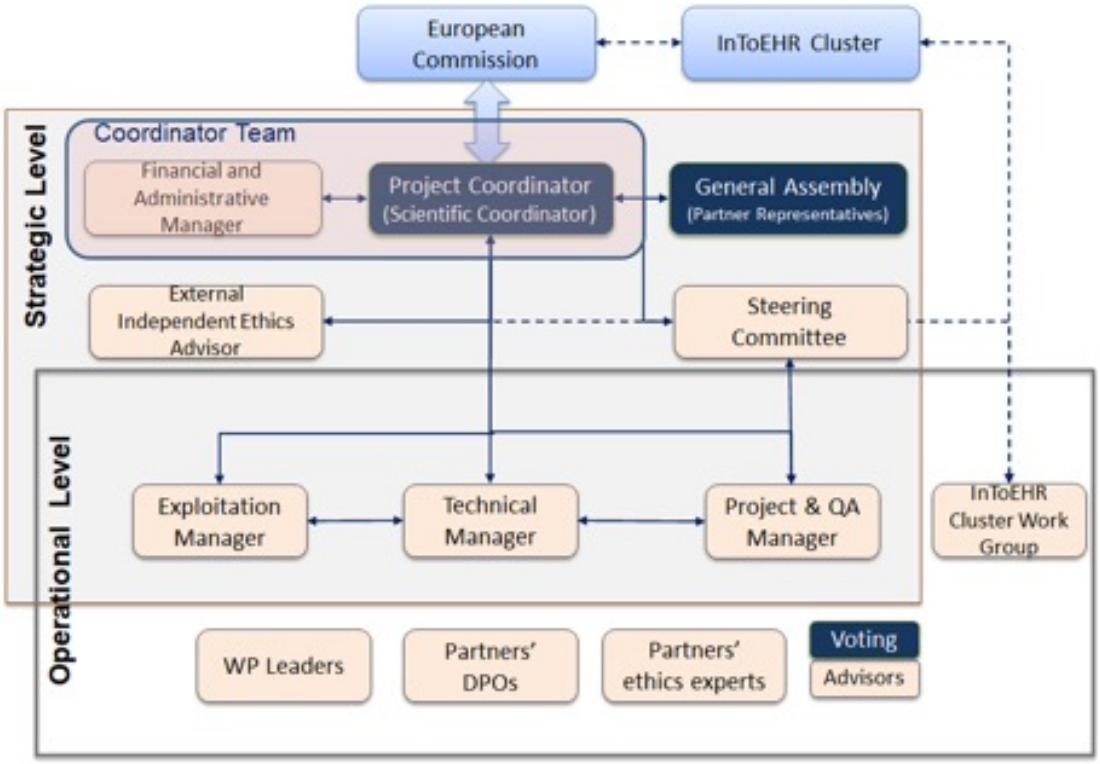

Figure 1. IDEA4RC Organizational structure

[1] European Commission, Directorate-General for Informatics, PM², Project management methodology : guide 3.0, Publications Office of the European Union, 2018, https://data.europa.eu/doi/10.2799/755246

2.2.1 General Assembly

The General Assembly (GA) represents the decisional Body for the project. Its responsibilities are described and defined in the Consortium Agreement Art. 6.3.1. and comprise decisions related to

- Content, finances and intellectual property rights
- Evolution of the Consortium
- Modifications to the Grant Agreement
- Management of disputes
- Management of under-performing / defaulting partners.

The GA is composed by one member of each partner and is chaired by the Coordinator. IDEA4RC partners have appointed the following representatives:

Beneficiary No	Short name	Beneficiary name	Representative in the GA
1-Coord	INT	Fondazione IRCCS Istituto Nazionale dei Tumori di Milano	Annalisa Trama
2	UDEU	Universidad de la Iglesia de Deusto Entitad Religiosa	Aitor Almeida
3	MME	Multimed Engineers Srl	Franco Mercalli
4	UPM	Universidad Politecnica de Madrid	Eugenio Gaeta
5	HL7	HL7 International Foundation	Giorgio Cangioli
6	ECCP	European Centre for Certification and Privacy	Sébastien Ziegler
7	ENG	Engineering Ingegneria Informatica	Paolo Zampognaro
8	CERTH	Ethniko Kentro Erevnas kai Technologikis Anaptyxis	Konstantinos Votis
9	UU	Universiteit Utrecht	Wouter Boon
10	DIGICOR	Digital Institute for Cancer Outcomes Research	Claudio Lombardo
11	FBK	Fondazione Bruno Kessler	Alberto Lavelli
12	IKNL	Stichting Integraal Kankercentrum Nederland	Gijs Geleijnse
13	CLB	Centre de lutte contre le cancer Léon Bérard	Jean-Yves Blay Deputies: Hugo Crochet, Audrey Pons
14	APHA	Assistance Publique Hôpitaux de Paris	Bertrand Baujat
15	IIS-FJD	Instituto Investigacion Sanitaria Fundación Jimenez Diaz	Javier Martin Broto
16	VGR	Västra Götaladsregionen	Andreas Muth
17	NIO PIB	Narodowy Instytut Onkologii im. Marii Sklodowskiej-Curie - Panstwowy Instytut Badawczy	Iwona Lugowska
18	MUH	Facultni Nemocnice v Motole	Katerina Kopeckova
19	OUS	Oslo Universitetssykehus HF	Siri Larønningen
20	MMCI	Masarykuv Onkologicky Ustav	Jana Halamkova
21	CLN	Clininote Spolka z Organiczona Odpowiedzialnoscia	Rafal Szmuc
22	FPNS	Fundacion Frofesor Novoa Santos	Pablo Parente
23	TNO	Nederlands Organisatie voor Toegepast Natuurwetenschappelijk Onderzoek	Simon Dalmolen
24	INF	Inferenze Società Cooperativa	Maria Luisa Clementi
25	UKE	Universitaetsklinikum Essen	Sebastian Bauer

Table 2. Partners representatives in the General Assembly

Besides the General Assembly and the Coordinator, whose roles and responsibilities are detailed in the Grant Agreement and in the project Consortium Agreement, the following bodies have been established to manage and monitor the complex interlinks of IDEA4RC WPs.

2.2.2 Steering Committee

A Steering Committee has been established by the coordinator to orient the strategic decisions of the project. Given the multiple innovative technical and regulatory aspects addressed by the project, the Steering Committee is a rather large body that includes members from the following partners:

- Coordinator and Project Manager (INT),
- Technical Manager (UPM)
- UPM, ENG, CERTH: System architecture and data space ecosystem
- UU, ECCP: Users involvement, ethics and legal framework and data governance
- INT, MME: Pilots experimentation and assessment
- HL7, UDEU, FBK, IKNL: Data integration and standards

The Steering Committee meets at least every 3 months.

2.2.3 Coordinator Team

The Coordinator Team is in charge of the overall management of the Consortium from financial, administrative and day-by-day monitoring viewpoints. The Coordinator Team is basically composed by appointed members of the Coordinators' Unit, the Project Manager, and – for specific matters and for consultancy and advice – by representatives of the Coordinator's legal and Technology Transfer Office, Administrative Office and Grants Office.

The Coordinator Team is the first contact for Consortium partners in case of any issues relevant to the project's administrative, financial, legal, communication and exploitation (patenting and IPR protection) aspects.

Project Manager
The Project Manager (PM) oversees the project on a daily basis and is responsible for delivering high-quality results within the identified objectives and constraints, ensuring the effective use of the allocated resources. More widely, the Project Manager's (PM) responsibility also includes risk and issue management, project communication and stakeholder management. The PM is responsible for:

- Monitoring the execution of the project plans as approved by the Steering Committee (SC), and reporting achievements and status at specified time intervals.
- Ensuring the effective use of the allocated resources.
- Ensuring that project objectives are achieved within the identified constraints, taking preventive or corrective measures where necessary.
- Overseeing the creation, quality and approvals of all management documents and of project deliverables and results

- Ensuring the evolution of products delivered, through proper change management.
- Performing risk management activities for project-related risks.
- Escalating unresolvable project issues to the Steering Committee (SC) and to the General Assembly (GA).

2.2.4 Quality management and technical management

Given the high relevance of technical works in IDEA4RC, the Technical Manager shares with the Coordinator and the Project Manager the responsibility to monitor overall project quality and monitor the overall quality of the project's work, outcomes and committed objectives. To do that, the Technical Manager is supported by a technical and quality management team from UPM and by Steering Committee members as consultant in case of need.
Decisions relevant to quality aspects will be categorized as high, medium or low priority, assigning to each level a response time.

Priority	Time frame	Examples of decisions by criticism
High	1 day	Technical action that should be made due to issues with the clinical data collection.
Medium	1 week	Technical action of a needed solution with a close deadline
Low	1 month	Other situation, such as technical decisions of the activities to be conducted in the next months

Table 3. Categories of quality assurance decisions

The technical management, given the project scope, is focused on the technological developments of the project. To this aim, in addition to the biweekly conference calls involving WP Leaders and Task Leaders, the Technical Manager has established specific communication and monitoring tools (see section 3.2). Minutes from the meetings will be taken in real-time using online reporting tools (i.e. Etherpad2) and formally published in the project's documents repository (Biweekly meetings folder).

The technical manager also monitors – jointly with the Coordinator and the Coordinator Team – the correct use of resources and the achievement of contractual obligations. The Coordinator will be assisted in this task by the Steering Committee and the Work Package Leaders. Tasks and responsibilities of these persons and organisms are detailed in the Technical Annex I, DoA, and in the Grant Agreement and Consortium Agreement.

2.2.5 Work Package Leaders

For each work-package (WP), the Annex I to the Grant Agreement establishes a Lead beneficiary, i.e. a Consortium Partner responsible for the work in the respective work-package. Work Package Leader Beneficiaries for IDEA4RC are listed in Figure 2. The WP Lead Beneficiary appoints a WP Leader responsible (person or team), who will be in charge for the coordination of the WP activities and of the relevant QA and who will participate in the WP Leader communications and meetings and whose contact details are published in the relevant mailing-list in the project documents repository.

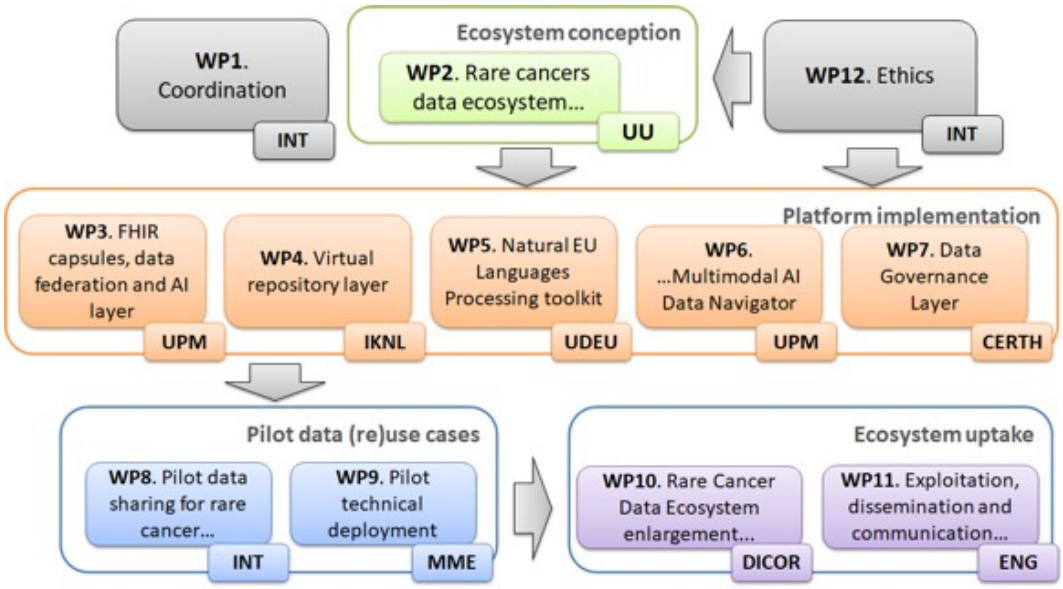

Figure 2. IDEA4RC WP Leader Beneficiaries

2.2.6 Deliverable responsible partner

For each deliverable, the Annex I to the Grant Agreement establishes a Lead beneficiary, i.e., a Consortium Partner responsible for coordinating the deliverable preparation work. The representative of the Beneficiary in charge of a deliverable is responsible for its quality and must deliver it to the WP leader on time for review, before the official delivery date. In particular they are responsible for:

- Proposing and agreeing with other contributors the structure of the deliverable (e.g., ToC for deliverables of type Report, architecture for deliverables of type Demonstrator, etc.) and the relevant individual contributions required
- Monitoring the production of contributions from involved Partners
- Ensuring the editing of the draft and final versions of the deliverable
- Promptly signal to the relevant WP Leader any potential risk for the deliverable, such as the possibility of delayed release or insufficient quality.
- Ensure that the deliverable is timely available for internal peer-review and that reviewers' comments are implemented.
- Ensure the timely release to the Coordinator for final approval and submission in the EU Participant portal.

The following table summarizes the IDEA4RC bodies, roles and responsibilities.

Role	Type	Members	Responsibility
General Assembly (GA)	Body	Consists of one Representative of each Party including the Coordinator PI and, when requested, the Financial Manager.	To deliberate, negotiate and decide on (see CA Art. 6.3.1.2) content, finances and intellectual property rights, evolution of the Consortium, risks, disputes, partners' under- or non-compliance.
Steering Committee	Body	Consists of the Project Coordinator PI, and representatives of partners in charge of the most relevant activities for the project, chaired by the Coordinator, the Project Manager and the Technical Manager (see section 2.2.2 above)	To orient and monitor the project works for the effective and efficient implementation of the project, in accordance with the decisions of the General Assembly and the overall project activities.
Coordinator and Scientific Coordinator (Dr. Annalisa Trama, INT)	Organization	Established in the Grant Agreement	To ensure that the Project is executed and the results are achieved in compliance with the Grant Agreement (see CA Art. 6.4.2). It is the primary responsible partner towards the European Commission. To coordinate the pilot experiments and the achievement of the expected scientific results.
Project Manager (E. Martinelli, INT)	Person	Appointed by the Coordinator	To manage the project on a day-by-day basis, chair meetings, ensure communications within the consortium, review deliverables, monitor risk mitigation actions, and ensure quality assurance in collaboration with the whole Coordinator Team, the Technical Manager and the External Independent Ethics Advisor, assisted by WP Leaders.
Technical/ Innovation Manager (Prof. E. Gaeta, UPM)	Person	Appointed by the General Assembly.	In charge of the overall coordination of the project's technical work, assisted by a technical management team at UPM.
Exploitation Manager (E. Mancuso and ENG Staff)	Person	Appointed by the Coordinator	To coordinate the external communications, and the project's exploitation and innovation work.
Work Package Leader (WPL)	Person	Appointed by the respective WP lead beneficiary	To coordinate the work of partners participating in WP execution, monitor their work and take decisions concerning the execution of WP tasks. To review all deliverables foreseen for the WP
Task Leader	Person	Appointed by the respective task lead beneficiary	To execute the expected works of the task, to monitor the activities of collaborators (including other beneficiaries) and to report to the WP Leader.
Deliverable lead beneficiary	Organization	Established in the Grant Agreement	To timely release the expected deliverables

Table 4. IDEA4RC Roles and responsibilities

2.3 Quality of coordination

The quality of coordination implies the measurement of progress and excellence of the work of the Consortium. The assessment of the quality of the work for the overall project is under the responsibility of the General Assembly, which meets usually three times a year, and by the Coordinator, through the Project Manager (PM) with the assistance of the Technical Manager. They will report and justify to the Coordinator, to the General Assembly and to the Steering Committee progress of activities vs. results and milestones, any deviations and any modifications to either the work results or the schedule of activities.

- Every 9 (nine) months the Project Manager collects reports on activities performed for each WP-Task and related resources devoted from all partners. WP Leaders are in charge of collecting such activity reports from all partners involved in their WPs, and to provide the summary to the PM. This will assess the progress of the project and the usage of resources and allow a correct planning for the next 9 months ahead. The 9 months periodic reports will be used internally to the Consortium and eventually presented and discussed during Consortium Meetings. They will also be used to verify the compliance of partners and of Third Parties.

Details of agreed quality assurance related actions are included in the following reference documents:

- Technical Annex I, part B section 3.2.2 through 3.2.5
- Consortium Agreement, Articles 6.2 (General operational procedures for all Consortium Bodies), 6.3 (Specific operational procedures for the Consortium Bodies), 7 (Financial provisions).

2.4 Project monitoring framework and procedures

The Coordinator Team has established a simple but strict monitoring procedure based on three pillars:

1. Internal monitoring and coordination checks performed on a weekly basis among the Coordinator Team, to highlight urgent pending issues to be addressed, to verify deadlines and to agree on reminders for partners and other actions (such as organizing online discussions if required).

2. Continuous monitoring as follows:
   - at the start of each month the PM sends an email to all involved WP leaders and partners representatives reminding of deadlines occurring in the next three months (tasks activities, deliverables and milestones) and asking for a workplan within two weeks;
   - at the start of the delivery month for any project deliverable or milestone, the PM issues a reminder to the interested WP leaders and task leaders, asking to receive a draft of the document to be approved at least one week before the official delivery date;
   - in case of any delays, the PM contacts the WP and/or the task leaders directly by phone or by any other videoconferencing method, in order to assess the status of work, any problems and to agree on the actions to be performed;

- biweekly conference calls are organized in any case to check all open tasks, to verify that all involved partners are informed and working and to check with the WP Leader possible risks and the related recovery actions.

3. Periodic activity and resources reporting on a 9 monthly basis (i.e., at the mid of each reporting period), to check the overall progress of the project activities, the availability and use of the resources required to fulfil the objectives set for each reporting period.

Details of agreed quality assurance related actions are included in the Consortium Agreement.
In addition to the above project monitoring procedures, the Technical Manager has established a punctual monitoring process described in section 3.2.
Financial monitoring (e.g., distribution of EU contributions) is managed by the Coordinator's Financial Offices and also monitored by the Coordinator Team by keeping records and documents of financial transactions.

2.4.1 Supporting tools

Day-by-day monitoring
The tools adopted by the Coordinator Team to monitor and report the progress of the project activities are based on textual and tabular representations, realized using standard Microsoft Office products (e.g. MS-Word and MS-Excel). Activity planning and monitoring will be performed by means of detailed plans covering 12 months issued by WP Leaders and – for the overall coordination – by the project manager, that are updated by WP and Task Leaders and periodically verified in the biweekly conference calls. The figures below provide an example of project management planning and monitoring tool.

MS-Word templates are established for minutes of meetings and discussions (both in presence and virtual) and are published in the relevant folders of the shared documents' repository IDEA4RC/Templates/ (https://drive.google.com/drive/folders/16hKv7dZTC6yRqvwcqix7ouKNc8WLidrM).
Besides continuous monitoring, the Coordinator will perform interim periodic assessment of the results achieved vis-à-vis those expected as defined in the Annex I at month 9 and month 27 (see Consortium Agreement Art. 7.2.2). These intermediate internal reports are intended to allow partners in keeping track of all the works and efforts devoted to the project, identify and report issues, risks and recovery actions, to monitor the use of their resources, report deviations and – if needed – propose modifications to the workplan, which might be discussed and addressed before the official reporting to the EU (established at month 18, 36 and 48).

Details are provided in the following section 5.2

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LEGENDA COLORS | Active task | work to be started in advance | Deliverable | Current date

WP	TASK	TASK ACTIVITY/ DELIVERABLE	RESP. PARTNER	MONTHS 1 2 3 4 5 6 7 8 9 10 11 12	Duration	% achieved at date
WP1	T1.1	Coordination: framework setup	INT		To M48	100%
	T1.2	Technical & Innovation Management: tasks start and coordidnation	UPM		To M48	50%
	T1.3	Quality Assurance and risks management	INT		To M48	20%
	T1.4	Scientific coordination	INT		To M48	6%
	T1.5	Clustering: cluster setup and activities	INT		To M48	6%
WP2	T2.1	Value-based and ethical data ecosystem governance scenario (see note)	UU		To M48	20%
	T2.2	Ethical data governance and reuse/ incentivization approach (M12)	ECCP		To M42	2%
	T2.3	D2.4 Data ecosystem architecture (M12)	UPM		end M12	25%
	T2.4	Metadata taxonomy	UDEU		end M12	8%
WP3	T3.1	FHIR Implementation definition (START THE WORKS)	HL7		To M36	
WP4	T4.1	Portable, secure and resilient and AI powered infrastructure	ENG		To M30	2%
	T4.2	Services meta-data annotation layer	UDEU		To M30	
	T4.3	Advanced services for data cleaning, data augmentation and federated AI	IKNL		To M36	
	T4.6	Building multi-lingual dictionaries for prospective NLP assistant	CLN		To M30	
WP5	T5.5	High quality NLP data collection engine for prospective NLP assistant	CLN		To M30	
WP6	T6.1	Specification of augmented analytics and multimodal navigation	UPM		To M21	
WP7	T7.1	Electronic DSA management	TNO		To M20	
	T7.2	Trust Management	CERTH		To M20	
	T7.3	Patients consent and data altruism	CERTH		To M20	
WP8	T8.1	Pilot studies identification and design (D8.1)	INT		to M19	
	T8.2	Setup of the Pilot in the EURACAN centres	NIOC		from M15	
WP9	T9.1	Pilot technical planning	UPM		from M13	
WP10	T10.1	Ethics data protection and management	ECCP		To M48	
	T10.2	Stakeholder engagement plan	DIGICOR		To M48	4%
WP11	T11.1	Communication, dissemination & exploitation activities	INF		To M48	6%
WP12	T12.1	Ethics report Requirements	INT (ETHICS EXPERT)		To M42	

Notes

T2.1	(i) review of relevant academic and grey literature for a first understanding of the rare cancer data eco-system and relevant issues related to RRI and valuation, to define a first draft of the bespoke RRI framework; (ii) interviews and co-creation workshops with rare cancer community stakeholders to define a baseline scenario of value positions and value-based incentivization. To be conducted in collaboration with: T2.2, T10.2 T1.3, T7.1.
T2.2	Define the data workflow and map all the data workflow, constitute the Data Protection Board of experts. Map the EHDS over IDEA4RC. Needed: DPOs of all clinical centres and technical partners. To be conducted in collaboration with T2.1, T2.4, T10.2, T8.1
T2.3	Define the use scenarios. To be done in parallel with T2.1, T2.2, T8.1, T2.4 and with strict interaction with T3.1, T4.1, T4.2 T5.1 and T7.1
T2.4	inks with T2.1, T2.2, T5.1 and WP7 (T7.1)
T3.1	Requested EURACAN reference centers, also the IT personnel of all centers are needed. Link to: T10.2, T8.1, T8.2
T9.2	Draft proposal for data sharing agreement for discussion
T10.1 T10.2	To be linked with T2.1, T2.2, T7.1, WP11

Figure 3. Example of project management timeline used for monitoring the progress of activities

WP Planning

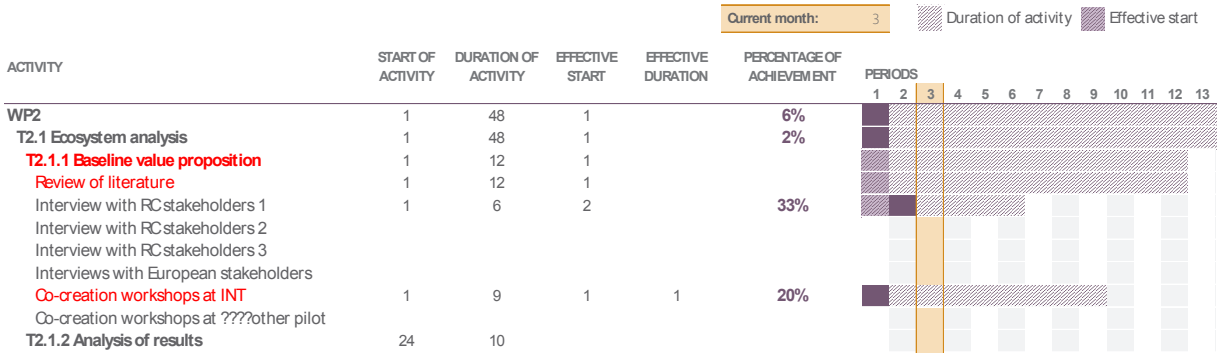

Figure 4. Example of detailed WP monitoring plan

The templates of the above GANTTs (see in shared documents repository at URL: https://drive.google.com/drive/folders/1ZLKYG5p4FdXGdU1CLcsP9nUhe-21cXMU) and the related minutes of biweekly online coordination meetings (template available in the shared documents' repository (URL: https://drive.google.com/drive/folders/16hKv7dZTC6yRqvwcqix7ouKNc8WLidrM) will support the continuous project monitoring. Specific actions required to address risks – if applicable – will also be managed and included in the above monitoring tools. Minutes of biweekly meetings are published in the shared documents repository at URL: https://drive.google.com/drive/folders/1fFaUyvZEECNMFl27yKJPmv1emroEMr-_.

2.4.2 Quality assurance of work performed by third parties

IDEA4RC foresees some activities that are subcontracted to third parties or services that are acquired from third parties as detailed in the Technical Annex I Part B section 3.1.
Monitoring of these activities is foreseen as follows:

- the responsible beneficiary will report to the Coordinator and to the Project Board on a quarterly basis concerning the status of the activities from third parties
- the Coordinator and the Technical Manager, as applicable depending on the subcontract, will verify with the responsible beneficiary that the third party is correctly performing the activities with the requested quality levels within the established deadlines
- in case of non-conformity detected, corrective actions will be implemented.

Partners' and third party's liability is established in the Consortium Agreement and in the Grant Agreement.
The Coordinator will periodically assess the work of third parties as part of the activities of the reference beneficiary, in the frame of the internal periodic reporting.

2.5 Project management and monitoring meetings

The following meetings are planned:

- Biweekly virtual meetings. Starting from 16/11/2022 WP and Task leaders and the Steering Board members will report on the status of activities, deadlines, milestones, risks. Decisions and action plan will be recorded in detailed minutes that are published in the shared documents' repository and used to check progress overtime.
- Steering Committee meetings. Every 3 months a virtual meeting of the Steering Committee will be organized by the Coordinator. The meeting agenda will be shared at least 1 week in advance and decisions will be proposed in the next biweekly meeting. Steering Committee meetings might be organized (online) for urgent matters. In this case the agenda will be published along with the SC meeting invitation. In case of aspects requiring strategic decisions as detailed in the Consortium Agreement, the General Assembly members will be informed and a dedicated meeting of the GA will be organized to discuss and vote on a decision.
- Consortium meetings will be held at least twice a year, possibly in person. Virtual or mixed modality meetings will also be possible. All Consortium partners should participate. In case a partner is unable to attend, a deputy may be appointed through written (email) communication to the Coordinator Team. Consortium meetings may also host General Assembly meetings whenever needed. The modalities for meeting decisions, invitation, recording and issue of minutes is the same as defined for the General Assembly meeting and detailed in the Consortium Agreement Art. 6.2.
- General Assembly meetings will be usually held twice a year in the frame of Consortium meetings. They are devoted to strategic decisions and are ruled according to the provisions of the Consortium Agreement Art. 6.2.

Details are provided in section 4 below.

2.6 Tasks and Work Packages

Tasks and Work Packages (WP) are detailed in the Technical Annex I part A, along with the responsible partners and the execution timing and deadlines. Tasks and WPs must be completed according to the committed timing and to the allocated resources, as described in the Technical Annex I, and in respect to the relevant ethical aspects.
Delays and exceeding the allocated resources (personnel and/or budget) shall be considered deviations and non-conformity vs. the plan and shall be addressed immediately and mitigation or recovery actions shall be put in place. Task/WP leaders are responsible to immediately inform the Coordinator and the Steering Committee of such occurrences. The risk management procedures detailed in the following address these cases.
Quality of tasks and WPs will be monitored internally at three levels:

- by the WP leader, through periodic assessment of the progress of the WP (e.g. during biweekly conference calls)
- by the General Assembly during Consortium meetings and through the agreed periodic internal reporting (month 9, month 27), as established in the Consortium Agreement
- and externally by the European Commission during periodic reviews.

Failures detected through internal quality assurance will be reported in the relevant internal periodic reports along with the agreed corrective actions and the results of such corrective actions. Quality problems that affect other tasks or WPs shall be evaluated jointly with the affected WP/Tasks leaders, relevant risks shall be assessed and addressed and a shared solution/recovery plan must be issued (see section 9). Major or unresolved failures shall be also reported in official periodic reports submitted to the EU. The Coordinator will report any major deviations from the Project objectives or the work plan to the EU Project Officer and will agree the necessary actions.
An insufficient quality rating at a project review is a serious non-conformity that should be immediately addressed through adequate corrective and preventive actions, in compliance with the recommendations received as part of the independent reviewers' report. Actions implemented will be described in the periodic report to be submitted to the European Commission Offices and – if required – in specific documents to be provided as required.

2.7 Ethics and legal aspects

Ethical aspects and concerns regarding the secondary use of health (personal) data are addressed in depth throughout the whole IDEA4RC development and the ethics and legal frameworks are established in Task T2,2. The quality of the proposed and implemented ethical and legal frameworks is specifically monitored by the Coordinator with the support of ECCP experts in task T1.4 and in WP12 by an independent external ethics advisor (IEEA). An ethics assessment report will be issued by the IEEA at months: 6, 18, 30 and 42.
Ethics assessment reports will consider the following ethical aspects:

- Compliance of the project's ethical and legal framework with existing and under discussion regulations at European and National level
- Quality of the ethical monitoring procedures implemented, including among others:
  - Completeness: whether the ethical procedures address all the relevant ethical and legal aspects for all the activities and results from IDEA4RC (i.e., the IDEA4RC ecosystem)
  - Effectiveness: how the effectiveness of the ethical and legal framework is measured
  - Monitoring and reporting: how the results of the implemented ethical procedures are verified and reported
  - Post-project maintenance and verification: methods for ethical aspects management and assessment criteria implemented in the system for continuous verification.

2.8 Quality of data

IDEA4RC aims to establish a reference data space for rare cancers, that makes data available for secondary use (for research in particular). Data quality is a cornerstone of IDEA4RC ecosystem and is specifically addressed in WP3 (T3.5), WP4 (T4.2), and WP5 (T5.5).
We foresee two layers of data quality. One that can be generally addressed in the metadata. The other layer is cohort specific.

Following the EHDS regulation, the metadata layer envisaged in IDEA4RC will provide indicators of data quality, and utility labels would inform data users about the characteristics of a dataset and enable them to choose the datasets that best fit their research needs. These labels will be mandatory for data generated within projects that received public funding.
The IDEA4RC data quality and utility labels will be designed to provide the data users the ability to perform a feasibility study on the research study he/she wants to perform without accessing the data. This functionality is commonly known as a cohort explorer. More details will be provided in the Data Management Plan (D1.2) and its updated versions.

3 Communication

IDEA4RC is a complex project that involves 25 partners, one affiliated entity and 2 linked third parties (hospitals). The project activities span over many domains (scientific, clinical, technical, regulatory and legal, ethical, social) that need collaborative work and development. In this context communications are fundamental to keep the project on track, to optimize and synchronize efforts and results.
The Coordinator has therefore established a sound communication framework well before the project start, in order to have it fully operational at the project's official start date.

3.1 Framework and procedures

The primary means of communication between the project partners is e-mail. IDEA4RC mailing lists have been set up for the partners to cover different content related communications about the project activities as well as inter-personal e-mail exchange. E-mails might also be used for remote decisions of the General Assembly of the project, as established by the Consortium Agreement.
Also, slack.com will be used in the project.
Moreover, the Project Steering Committee has agreed to hold quarterly (cross-work packages) online conferences to discuss progress of work.
Biweekly online meetings involving WP leaders will also be held to monitor the progress of the ongoing WP-specific activities and of the intertwined activities involving different WPs and tasks.
Specific communications will be directly managed by WP/Task leaders to organize online discussions on open and ongoing works and coordinate the relevant actions.
Minutes of all meetings will be recorded in the project documents repository in dedicated folders (see Shared documents repository structure in Annex 1 to this document).
Periodic online meetings and relevant email communications will also be organized among the projects involved in the InToEHR Cluster promoted by the EU Health Data Research team at the RTD-European Commission and HaDEA, to coordinate and progress joint actions of the established Working Groups.
All communications to the European Commission services will be handled by the Coordinator through the EU participants portal.

3.1.1 Project mailing-lists

All partners have nominated persons for the different consortium-internal mailing lists. By creating the lists we ensure that all relevant figures within the consortium receive the information and no one is left out in the communication.
Partner Universidad Politecnica de Madrid (UPM) has appointed a responsible person set-up and will maintain the mailing lists required to facilitate communications among consortium partners. Partners can request changes to the lists at any time by informing the Coordinator and UPM responsible person.

The following mailing-lists have been activated:
Coordination mailing-list has been established by the Coordinator for administrative communications: idea4RCcoord@istitutotumori.mi.it, that connects the Consortium to the project Coordination Team.
Consortium: I4RC_partners@lst.tfo.upm.es. All contacts of the Consortium (scientific and clinical, technical, administrative, legal) have been included in the mailing-list (122 contacts overall)
General Assembly members: I4RC_GA@lst.tfo.upm.es. Representatives and deputies of each Consortium partner and linked third party are included in this mailing-list.
Steering Committee members: I4RC_SC@lst.tfo.upm.es. This mailing list comprises the representatives of partners leading the tasks supporting the most relevant aspects of the project: INT (Coordinator), UPM (Technical Manager), ENG (FHIR and system architecture), MME, IKNL, HL7 (Data integration and standards), ECCP (legal, ethical aspects, data governance), UDEU, FBK (NLP/NLU for unstructured data integration), CERTH (data infrastructure security and trust).
WP leaders: I4RC_WPL@lst.tfo.upm.es. The WP leaders of the 12 work packages are included in this mailing-list.
Clinicians: I4RC_Clinical@lst.tfo.upm.es. This mailing-list has been specifically conceived to facilitate the activities involving clinical centers in particular WP8 and WP9, but also to involve clinical partners in the system design and user requirements definition. All clinical centers participating in the project, as well as additional hospitals involved by Affiliated Entity ACC are included in this mailing-list.
Technical partners: I4RC_tech@lst.tfo.upm.es. This mailing-list supports the communications among the technical partners and University of Utrecht (expert in Social Sciences and Humanities) and ECCP (legal and ethics experts), in addition to the communication framework established by the Technical Manager using Slack (see below). Representatives of partners INT, UDEU, MME, UPM, HL7, ECCP, ENG, CERTH, UU, DIGICOR, CLN, TNO as well as IT reference staff in IDEA4RC clinical centers are included in this mailing-list.
In addition the Coordinator has established working groups for three main threads of the InToEHR cluster: 1. Governance and Data Permit, 2. Interoperable Data request protocol and 3. NLP, Data quality and labeling. For this work group a mailing-list has been set up: I4RC_WGL@lst.tfo.upm.es.
Legal and ethical: a separated mailing list has been established to facilitate the works related to data governance, data permit, data sharing incentivization and data altruism regulatory frameworks. This mailing-list includes partners' DPOs (or their appointed deputies) and experts from ethical committees. The external ethical advisor contracted by the Coordinator for WP12 may also be included.

All mailing lists and relevant contacts are published in the project 's shared documents' repository "Contacts" folder at URL:
https://drive.google.com/drive/folders/1_4E6IXwtEjHV4yYLC81SNr0h1OUiJ9A3.

3.1.2 e-conference and virtual meeting tools

The default solution adopted for e-conferences is zoom. The consortium might decide to use alternative options, such as Meet, Teams, Slack and Skype, as preferred by individual partners. Minutes of periodic online meetings (bi-weekly meetings and weekly coordination meetings) will be maintained in the shared documents' repository (URL: https://docs.google.com/spreadsheets/d/1jbej-nMrSyYxDgIk7g5rbewvb2Pk2jTmJs74LACUaNg/edit#gid=0)

3.2 Supporting tools for technical communications

Given the expected amount of technical communications that span across many work packages, the Technical Manager has set up dedicated tools to facilitate collaborative communications and development.

3.2.1 Slack

The Project Technical Manager will invite the technical members of the Consortium to join an IDEA4RC group on Slack. Dedicated channels will be activated for each WP and specific deliverables to allow direct and fast discussions and interactions among the partners involved.
Slack is a messaging app for businesses that connects people to the information they need by bringing people together to work as one unified team.
The Technical Manager has established specific recommendations on how to organize channels for a better communication among technical partners, which are detailed in Annex 4 to this document.

3.3 Communication with the EU

The Coordinator is the only authorized channel for submitting all documents to the European Commission (EC), and for general liaison between the Consortium and the EC. All general communications and all documentation for the European Commission must be through the Coordinator. Whenever possible the communications should be performed through the devoted functionality in the participant portal.

3.4 External communication and dissemination

Dissemination products include presentations and posters in conferences, scientific papers, and all public materials, including public deliverables.
Dissemination activities should:

- Adopt various dissemination methods: written text including illustrations, graphs and figures; electronic and web-based tools, and oral presentations at community meetings and scientific conferences.
- Comply with open science principles, i.e. be accessible for research and – more generally – non economic reuse. Exceptions are commercially sensitive communications that concern individual partner's IPRs or confidential business plans or patents: these might be directly addressed by the concerned Beneficiary to the relevant EU Offices (e.g. IPR helpdesk). This is only acceptable for communications that are commercially sensitive and confidential.

Communication materials include the web site (see below), social media accounts, brochures, videos, newsletters. Communication should:

- Address the needs of the audience, using appropriate language and information levels.
- Reach as many audiences as possible and raise awareness about the advances and results achieved from IDEA4RC.

The communication materials must therefore conform to the following quality principles:

- Tailored: i.e. adapted to each target audience.
- Concise: i.e. short and to the point; be sure that information is easy to find.
- Interesting: sort through all findings, and present just those that are new and/or compelling.
- Highlight key points: use bulleted lists, with one finding or conclusion per bullet.
- Useful: have clear conclusions and recommendations; if readers know what to do with the information, they will be more likely to apply it.
- Complete: must include all information necessary for a full understanding of the dissemination message.
- Attractive: have an attractive graphic design; attractive materials are more likely to be read. If possible, documents should be printed in colour.
- Accredited: include sources of data and information and contact details for clarifications requests.

The following quality requirements for language and design aimed at easy reading are also recommended:

- Use simple language
- Use uniform heading formats
- Use a clear and readable font
- Avoid overfilled pages; limit the amount of text, graphics, and bullet points to the essentials.
- For reports and printed materials, always include page numbers.

All communication and dissemination materials shall comply to the quality

requirements established by the European Commission for Horizon Europe projects (see: "Communicating EU research and innovation guidance for project participants") and to the quality requirements defined by the GA Art. 29 and Art. 38.
All public material shall bear the EU flag and include a disclaimer stating the EU contribution as follows: *"IDEA4RC has received funding from the European Union's Horizon Europe research and innovation programme under Grant Agreement number 101057048".*
The Coordinator and the Beneficiary in charge of communication (INF) will verify the quality of each dissemination and communication material before approving publication upon having verified that they comply to the above quality criteria.
The Steering Committee and the Coordinator will also ensure that no secret or confidential information belonging to any of the project participants is disclosed.
An official template for project presentations has been defined and published in the shared documents' repository (Templates folder). Other templates will be defined for standard public communications (e.g. newsletters, press releases), that will be published in the appropriate directory of the shared documents' repository.

3.4.1 Scientific papers

Scientific papers will be redacted according to the publisher's guidelines. The Main Author will be in charge of the quality of the paper. The writing of the paper must be approved by the Scientific Coordinator and by all involved PIs and must be authorized by the General Assembly. Quality of the paper will be assessed by the Coordinator and by the Technical Manager when applicable. Publications or disclosures using the data or results generated by the project must include at least one (1) co-author of the data providing partner and at least one (1) co-author of the data receiving/data processing partner.
Management of publications is ruled by Consortium Agreement provisions ex art. 8.4.2.1.

3.4.2 Project web site

IDEA4RC implements a distributed data space for rare cancers that aims to benefit not only the scientific and medical communities but also patients and their caregivers. Therefore, the quality of the web site is of primary relevance to the Consortium and will be measured and assessed based on the following criteria, compliant with the EC guidelines and according to the quality criteria defined by the EC for health-related web sites (Ref. https://www.ncbi.nlm.nih.gov/pubmed/12554546).

- Transparency of purpose of the site,
- Transparency of authorship/ownership of information,
- Transparency about financing and sponsorship,
- Clear separation of advertising and editorial,
- Transparency about use of personal information gathered by the site,
- Keeping information up-to-date.

These criteria should be applied in addition to relevant Community law.
INF is responsible to maintain the web site, of its integrity, backup and recovery, accessibility

from any client device (including mobile devices) and for the majority of browsers. INF will also produce the automatic quality indicators necessary for quality assessment (e.g. automatic measurements of access to the website, in an anonymous way).
The Coordinator and the Technical Manager are responsible for the quality of the scientific and technical information disclosed to the public. The Coordinator will ensure that appropriate disclaimers are included in the website, to correctly inform the public regarding the quality of information provided, the sources and the usage of such information.
All partners are responsible to provide high-quality contributions, including links to public domain documents of interest for the specific clinical and technical domains addressed by the project.
The Coordinator is responsible to monitor and periodically assess the quality of the web site.

3.4.3 Communications via social media

Communications through social media shall be managed by the Beneficiary responsible for communications activities (INFERENZE) and approved by the Coordinator prior publication. Beneficiaries willing to issue social media communications/posts shall adhere to the following procedure:

1. Carefully check any restrictions regarding the information to be published (e.g., embargo periods in case of papers under publications).
2. Check the coherence of the message vs. the objectives of the project and the terms used in the project.
3. Members of the partners institutions are encouraged to communicate about the project using their personal or institutional accounts. A short social media guide has been shared with all the partners by the INFERENZE indicating key words and accounts to include in order to maximize impact.

4 Meetings and webinars

4.1 Meeting modalities

Meetings will be held at different levels and with different modalities according to the needs for the optimum execution, conduction and monitoring of the project. The following modalities are foreseen:

- Physical meetings: this option is preferred for overall strategic discussions and decisions and for project planning and will be the standard modality for Consortium and General Assembly meetings.
- Online meetings: this option will be the standard for operational meetings of WPs and Tasks leaders, biweekly project management and monitoring, quarterly Steering Committee meetings and any WP or Task related discussion. Online meetings might also be the best option chosen by the European Commission for the periodic technical reviews.
- Mixed-modality meetings: these are foreseen in case some consortium members

might not be available for physical meetings. And will join by remote online connection. These cases will be strictly managed to avoid difficulties in interaction between the participants to the physical meeting and the online attendees.

- Asynchronous meetings: this option may be adopted in special cases when the participation of all partners is not feasible in reasonable times and applies in particular to online meetings.

Consortium and GA assembly meetings

- Consortium meetings will be held at least twice a year possibly in person (physical meeting) although mixed participation will also be possible in specific cases. Consortium meetings will be mainly devoted to:
  - Check the status of the activities
  - Highlight challenges, risks and propose solutions
  - Agree on next steps (tasks, contributions, actions, deadlines, responsibilities)
- General Assembly meetings will be organized any time a strategic or critical decision needs to be taken as foreseen in the Consortium Agreement (Article 6.2, 6.3) and at least twice a year, i.e. as part of the Consortium meetings. The GA is entitled to discuss and take decisions concerning the matters detailed in the Consortium Agreement Article 6.3.1.2:
- Content, finances and intellectual property rights:
  - proposals for changes to Annexes 1 and 2 of the Grant Agreement to be agreed by the Granting Authority;
  - changes to the Consortium Plan;
  - modifications or withdrawal of Background in Attachment 1 (Background Included);
  - additions to Attachment 3 (List of third parties related with the Beneficiaries);
  - additions to Attachment 4 (List of Third Parties for simplified transfer according to Consortium Agreement Article 8.3.2);
  - additions of affiliated entities and third parties
- Evolution of the consortium:
  - entry of a new Party to the Project and approval of the settlement on the conditions of the accession of such a new Party;
  - withdrawal of a Party from the Project and the approval of the settlement on the conditions of the withdrawal
  - identification of a breach by a Party of its obligations under this Consortium Agreement or the Grant Agreement;
  - declaration of a Party to be a Defaulting Party;
  - remedies to be performed by a Defaulting Party;
  - termination of a Defaulting Party's participation in the Project and measures relating thereto;
  - proposal to the Granting Authority for a change of the Coordinator;
  - proposal to the Granting Authority for suspension of all or part of the Project;
  - proposal to the Granting Authority for termination of the Project and the Consortium Agreement.
- Appointments: on the basis of the Grant Agreement, the appointment of an External Independent Ethics Advisor if necessary.

- Payments:
  - use of the common fund;
  - reallocation among the Parties of funds from the ones spending less than their allocated share of the budget.
- Software: implementing the introduction of Software under Controlled License Terms in the Project into the Consortium Plan.

The General Assembly meetings may also be organized online in case of urgent decisions to be taken. In such a case the decisions shall be taken by collecting votes during the meeting and confirmed in writing (email to the Coordinator / Coordinator Team). The voting results will be published to all Consortium partners in writing (official email is accepted).
The organization of these meetings and the relevant minutes shall be compliant to the provisions established in the Consortium Agreement Article 6.2 and shall be promptly published in the shared documents' repository.

4.1.1 Virtual meetings

Virtual meetings will be organized both according to an established schedule (e.g., biweekly for project monitoring) and whenever required to discuss and agree specific operational activities relevant for WPs and Tasks. Virtual meetings shall be agreed in advance with the needed participants.

4.1.2 Asynchronous meetings

This modality allows splitting the discussion among two or more groups of participants in order to collect feedbacks and proposals for decisions or votes on the same discussion items during separate discussion. The Coordinator will then sum up all the discussion issues, the opinions and the votes and possibly ask for a joint position via email. Although this is a sub-optimal meeting modality, we foresee the possibility to use it in extreme cases.

4.1.3 Webinars

In IDEA4RC webminars are foreseen especially in WP2 for the system co-creation to facilitate joint discussions of the stakeholders interested in the Rare Cancers data space and in WP10 as part of the ecosystem enlargement activities.
Webminars (as well as workshops and focus groups if needed) will take place both in person and online. To ensure quality the agenda, presentations and chairing will be defined at least 15 days in advance and invitations sent at least one month in advance in order to ensure the participation of the required audiences.
Minutes and results from discussions will be recorded and published in the shared documents repository and verified with participants before being used to shape the activities (e.g., ecosystem co-design, users' stories elicitation, design of the ecosystem architecture, identification of technical, legal and ethical aspects and constraints etc.).

The procedures described in the following for the meetings will also be followed.
If applicable, users' quality scores will be collected (e.g. webinar/workshop/focus group usefulness, interest, quality of participants, quality of presentations) and recorded. The collected feedbacks and relevant usability/usefulness scores will be important to inform the organization of the next events.

4.2 Preparation for meetings

Virtual meetings invite shall include specific information:

- date and time
- used web meeting platform and relevant link
- objectives
- agenda
- required participants

The agenda will be distributed at least 2 weeks before the meeting and might be refined according to partners' feedbacks and requirements.
Presentations and topics for discussions should be made available to the Consortium and published in the shared documents' repository at least one week before Consortium/GA meetings and at least 3 days before other meetings, so that participants and the Coordinator might be timely informed of the discussions and decisions to be taken.

4.3 Attendance and execution of meetings

All partners shall participate to Consortium and GA meetings. In case one partner is not able to attend a deputy shall be appointed and communicated to the Coordinator in writing (emails accepted).
All partners required as indicated in the meeting invite/agenda shall be present or – in exceptional cases - shall be represented by suitable deputies.

4.4 Meeting results reporting

The Coordinator Team with the support of the meeting organizer (any Consortium partner hosting the meeting) shall record all discussions and decisions in specific minutes, using the standard template published in the IDEA4RC shared documents' repository.
The minutes shall be issued as soon as possible after the meeting and shall include a list of the agreed actions, responsibilities and deadlines which will be used to check the execution of the works, the remedial activities to mitigate and address issues and risks, and to monitor the progress of the project (Action List).
Final presentations and any supporting documents, including signatures in scanned format, shall also be published in the shared documents' repository at least 2 weeks after the meeting closure.

4.5 Project's reviews

Project reviews will be agreed between the Consortium and the European Commission by means of official communications established by the Coordinator and the Project Officer via the Communication Centre in the participant portal. The reviews will take place 60 days after the end of each reporting period as established in Annex I DoA. Depending on the decision of the European Commission Offices, the reviews might be held through physical or online meetings.

4.5.1 Review preparation

The Coordinator and the Technical Manager will timely organize dedicated meetings (online or physical) to prepare the review and to finalize the presentations and the demonstrations to be delivered. The review agenda will also be prepared at least 3 weeks in advance and agreed by Consortium members and the Project Officer.
The review date and modalities will be defined at least one month in advance so that all partners will be able to attend.

4.5.2 Review results

As soon as the review results are available, the Coordinator will inform partners and start any actions required to reply to the reviewer's questions and requests and to address the recommendations received during the review. An action plan and timelines will be issued by the Coordinator to meet the EU requests.
Recommendations will be carefully addressed by the Consortium and the relevant actions reported to the European Commission at the next review and periodic/final report.

5 Planning and reporting

5.1 Planning responsibilities at WP and task levels

WP Leaders and Task Leaders are responsible to plan and monitor the activities of their WPs / Tasks respectively, in accordance with the general work plan established in the Technical Annex I and its revisions as agreed by the Steering Committee and the General assembly and – in case of major modifications – by the European Commission. Planning and monitoring tools and methods are defined and implemented by WP Leaders and may take advantage of the instruments proposed by the Project Manager and the Technical Manager and described in the section 2.4 above.

5.2 Interim report (mid-period report) for internal monitoring

The grant agreement sets official reporting at months 18, and 36 and a final report at the end of the project (month 48) and intermediate reviews at month 30 and 38 respectively. The Consortium has however agreed to perform intermediate assessments of the results achieved and of the resources devoted and required to complete the foreseen tasks. This internal reporting will take place at month 9 and month 27 and will be linked to installments of the EU funding as established in the Consortium Agreement (Art. 7.2.2). The concept behind this decision is to ensure partners' commitment and continuous monitoring of the progress and compliance to the assigned tasks and of the possible risks and recovery activities, as well as the periodic assessment of resources required and used. The periodic assessment would also prevent and early address possible under- or non-performance issues as well as requests for tasks/works re-organization among the consortium partners, in case of need.
Two contributions will be therefore collected from partners at these intermediate internal reporting deadlines:

1. one short, bullet-list, description of the activities performed by each partner for each task open in the reporting period (in MS-Word format), including possible risks and actions implemented to solve them, and a list of publications and dissemination activities
2. one tabular (MS-Excel) file listing the estimated resources devoted in the period (person months per WP) and – if possible and available –costs incurred (the latter are optional).

The internal reporting templates are published in the shared documents' repository. The Project Manager will request them at least one month before the internal deadline and will collect them no later than 2 weeks after the deadline so that the relevant interim payment can be timely distributed.

Content of the internal periodic reporting

The following data items will be provided by each beneficiary, with reference to the reporting period (see template in Annex 5 to this document):

- summary of the work performed and of objectives achieved for each WP/Task
- used resources (person months)
- description of activities performed by subcontractors / third parties
- brief description of the work and deliverables planned for the next reporting period
- dissemination activities performed, meetings attended

In addition, WP Lead Beneficiaries should provide a summary for the WP:

- summary of the work performed and of the objectives achieved
- official deliverables issued in the period
- list of major deviations from plan, risks and/or other elements affecting or likely to affect the project execution, applied corrective actions and results of such actions

The quality procedure for periodic reporting is detailed in Table 15 (Annex 8).

5.3 Periodic report

Official periodic reporting to the EU is required at the following months: 18, 36, 48 as stated in the Grant Agreement. The official reporting templates shall be submitted by the Coordinator on behalf of the Consortium within 60 days after the end of the reporting period. The report comprises the periodic technical report, according to the predefined format provided in the EU participants portal, the continuous monitoring data to be inserted in the specific sections of the EU participant portal, and the costs declaration forms submitted by each Beneficiary to the Coordinator through the EU participants portal. In case of cumulative costs declared exceeding 430.000€ a Certificate of Financial Statements issued by an independent auditor must also be provided (see Annex 5 of the Grant Agreement).

Content of the periodic reporting to EU

The templates used for internal periodic reporting (see Annex5 to this document) will also be used to guide Beneficiaries in providing the necessary information for the editing of the official periodic Activity (and Final) reports and to allow a verification of the correct costs' declarations prior to the official submission.

Each Beneficiary and WP Leaders are required to complete the reporting templates as specified at 5.1 above. Costs declared shall be coherent with the activities performed in the period by the Beneficiary. Additionally, the following information shall be indicated as justification of costs in the Costs Report for each Beneficiary:

- **personnel costs**: shall be indicated for each WP (total personnel costs by WP). For each person indicate the position in the organization, the person months devoted to the project in the reporting period.
- **subcontracts**: shall be indicated for each WP and subcontractor. The description of the subcontract and the sustained cost must be in line with the budget indicated in the Technical Annex I to the Grant Agreement part B section 4.2.
- **other costs:** shall be indicated for each WP and cost type (travel, consumables, etc.). Detailed description shall be indicated for each cost (e.g., name of provider, description of the purchase or of the cost, location and motivation of travels, etc.).

The Coordinator is responsible of verifying the coherency of costs vs. the declared and performed activities in the reporting period and may ask revisions (reject costs) to the Beneficiaries.

The process for periodic report to the EU is detailed in Annex 5 to this document.

5.3.1 Project review meetings by the European Commission

The Project will undergo three EC project reviews, according to the following tentative schedule, established in the Technical Annex I to the Grant Agreement:

- RV1, M18, Periodic Review #1
- RV2, M36, Periodic Review #2
- RV3, M48, Periodic Review #3 – Final.

The format and specific content of these reviews will be established by the EC in agreement with the Coordinator.

The corresponding review reports that the EC will forward to the Consortium will be

an input to the project Quality Assurance and Risk Management actions.
They will be analyzed by the Coordinator and by the Project Manager and possible identified non conformities (e.g. rejected project deliverables) will be addressed in the dedicated Quality reviews to be taken by the General Assembly during the next Consortium meeting.

5.3.2 Project Quality reviews

Quality reviews will be performed by the General Assembly during each Consortium meeting to ensure continuous monitoring of quality throughout the project. The Coordinator chairs such reviews. Quality reviews will consider the following inputs:

- Technical Annex I to the Grant Agreement (tasks, deliverables, KPIs, timings, costs)
- Non-conformities / risks detected during the period since last Quality review
- Reports from EC project reviews
- Official communications from the EC concerning project execution or additional requirements
- Additional contingency information, relevant to the project, including from sources external to the Consortium, when relevant.

The Coordinator and the Project Manager will assess and present to the General Assembly the status of the project and the quality achieved vs. the quality objectives and targets. All Beneficiaries will be requested to provide relevant additional technical, scientific and/or managerial information to identify non-conformities, risks and to agree on corrective measures.
The results of the Quality reviews will be recorded into the relevant meeting minutes and will include the following elements (when relevant) to be used for actions:

- Updated tables of milestones
- Revised KPIs and/or clinical impacts to be measured
- Updated Ethics requirements
- Updated Risks
- List of non-conformities (e.g. deliverables to be revised).

For each item a responsible Beneficiary will be appointed and corrective actions will be agreed and described.

5.3.3 Management of non-conformities

Non-conformities shall me monitored throughout the project execution by all participants. Examples of non-conformities are:

- Delay in the collection and harmonization of data to be shared in the IDEA4RC ecosystem
- Delay in the submission of a deliverable
- Deliverables of insufficient quality
- Missing a milestone
- Missing a KPI or a committed scientific/clinical impact
- Failure to satisfy an ethics requirement

- Overspending on a work-package
- Insufficient dissemination activities.

Besides the systematic QA process performed by the Project Manager and by the Coordinator on periodic reports and during Quality reviews, each member of the project team is encouraged to notify to the relevant WP Leader and to the Project Manager any non-conformity as soon as she/he detects it.

Addressing non conformity
The WP Leader and the Project Manager or the Technical Manager, within 7 days upon either a non-conformity detection or the reception of a non conformity notification from another team member, must analyze the non-conformity, assess its seriousness, prepare a proposal for a corrective action, and submit the proposal to the Coordinator for further follow up and removal of the non-conformity.

Preventive and corrective actions
Each member of the project team is encouraged to suggest to the Project Manager any preventive actions that may contribute to improve the capability of the project to achieve its stated quality objectives and to suggest corrective actions that may increase the success in risk recovery. Proposals for preventive or remedial actions may be advanced through email messages addressed to the Project Manager and to the Coordinator. The Project Manager will assess the applicability of the suggested actions and will decide which ones shall be proposed to the Steering Committee for initial action and, in case the non conformity is not solved, to the General Assembly. The GA will take further decisions regarding remedial actions that will be communicated to the Steering Board for implementation.

5.4 Final report

The final report will be issued in conformity with the official template provided by the EU and available in the participant portal. The format is similar to the periodic report. The **periodic report** consists of two parts, the Technical Report and Financial Report. The **Technical Report** is itself also divided in two parts, Parts A and B:

- Part A: contains the structured tables with project information (retrieved from the Grant Management System).
- Part B (the narrative part): mirrors the application form and requires the participants to report on differences (*delays*, *work not implemented*, *new subcontracts*, *budget overruns etc.*) It must be uploaded as a PDF document.

The **Financial Report** consists of the structured individual and consolidated Financial Statements (retrieved from the Grant Management System). In addition, most programs require either a detailed cost reporting table (Excel table) or the use of resources report (online wizard) and, for payments above a certain threshold, a certificate on the financial statements (CFS). The technical report Part A and the financial report is generated automatically on the basis of the data in the Grant Management System; Part B needs to be prepared outside the tools (using the template downloaded from the system) and then uploaded as PDF (together with Annexes, if any).

5.5 Responsibilities

All participants should contribute to the parts, but it is the Coordinator who will have to submit them as a single report.
The Coordinator shall:

- Check that the Continuous Reporting Module (in the EU participant portal) is updated in time (before the Periodic Report is Locked for review)
- Check that all participants have submitted their Financial Statements (and CFS, if needed)
- Check that the Report is coherent and that information in Part A and B is consistent.
- Make sure that the template has been followed and all sections are completed and no annexes are missing.

The Coordinator will review and submit the periodic report.

6 Document management

6.1 Framework and procedures

All project's documents shall be made available in the shared documents' repository established in Google Drive: https://drive.google.com/drive/folders/1E4RgrhlLLZ_KmQwOXoIWH4u-WPF-XD0F.
All persons involved in the IDEA4RC project have access to the repository. Access level (edit vs. view only) permissions are assigned by the Coordinator (operationally by a member of the Coordinator Team).
The shared documents' repository allows collaborative editing and production of documents.
Official documents / deliverables shall undergo internal peer-review and final approval by the Coordinator before submission in the EU participant portal.
Documents for internal use only shall be made available indicating whether they are final or in-progress. The standard templates established for all official documents (including minutes, deliverables, presentations, leaflets, logos, standard acknowledgement of the EU funding etc.) shall be used.
In particular for dissemination the EU guidelines for dissemination (https://rea.ec.europa.eu/system/files/2021-11/Communication%2C%20Dissemination%20and%20%20Exploitation-2021.pdf) shall be adopted.
The structure of the shared documents' repository is detailed in Annex1 to this document.

6.1.1 Access to the shared documents' repository for collaborative work

IDEA4RC Beneficiaries have communicated to the Coordinator Team the contact details of their staff that needs to access the shared documents' repository, specifying the role of the person and the access level to be granted. The default access level will be "edit" as we consider that staff needing access are those directly involved in the project activities.

Communications shall be done by email and new staff shall also be included in the Contacts list published in the IDEA4RC shared documents' repository. The Coordinator Team shall provide access at the earliest pace, possibly within 24 hours from the request.

6.1.2 Supporting tools

No specific tools are required besides a web browser.

7 Deliverables, milestones and KPIS

7.1 Deliverables

The official deliverables due by IDEA4RC Consortium are listed in the Technical Annex I Part A. They constitute the results of tasks/WPs.
Deliverables must be released to the European Commission by uploading them to the EU Participant Portal, within the due date indicated in the Technical Annex I and in the portal. Late delivery is a non-conformity that must be immediately addressed.
Deliverables must be completed within the resources allocated to the work-package to which they belong. Exceeding the allocated resources is a relevant risk that should be carefully monitored throughout the project execution.
Quality of deliverables will be controlled at two levels:

- Internally to the Consortium and prior to delivery, through an internal reviewing procedure.
- By the European Commission after delivery, through contractual project reviews.

Same as WP/Tasks, insufficient quality evaluation of a deliverable received after a project review is a major risk that shall be addressed as recommended by the evaluators in the shortest time.
The overall quality of the IDEA4RC ecosystem and infrastructure will be measured as part of task T8.4.

7.1.1 Deliverable production and acceptance procedure

Deliverables shall be produced timely and according to the standards and the templates established by the Consortium. This document is an example of a standard deliverable.
Deliverables shall be managed according to the templates and standards established by the Consortium.
They shall be managed and published in the shared documents' repository. The final version shall be submitted for internal peer-review according to the timing detailed in section 7.2. All technical deliverables will also be verified by the Technical Manager before release to the Coordinator for final approval.
Final approval shall be done by the Coordinator who will submit the deliverable in the EU participant portal.

7.1.2 Deliverable Standard

Deliverables should:

- Have a cover page with the following data: ID, version number, contractual delivery date, actual delivery date, status, dissemination level (as established in Technical Annex I Part A), short name of the Leading Beneficiary, short names of contributors, project logo, Reference project documents.
- Include a history of changes, which, for each version of the document, lists: the version number, the version issuing date, the author(s) of the version, a description and motivation of the modifications made in comparison with the previous version.
- Include a list of addresses for the document.
- Include a table with definition and abbreviations.
- Include an executive summary or abstract.
- Include a header on every page with the Project Acronym and the Grant Agreement number.
- Include a footer on every page with the title of the deliverable and the page number and version and date of issue.

7.1.3 Deliverables templates

The templates are published in the shared documents repository: https://drive.google.com/drive/folders/16hKv7dZTC6yRqvwcqix7ouKNc8WLidrM.

7.1.4 File naming for deliverables

The deliverables shall be named as follows:
<Deliverable number> <Deliverable title> <extension (either .docx or .pdf)

7.2 Quality assurance and peer-review procedures

7.2.1 Quality of deliverables

The internal quality check of deliverables is a mandatory step that will be performed at three levels:

- The deliverable Lead Beneficiary
- The relevant WP leader
- The internal peer-reviewer(s)
- The Project Manager
- The Coordinator.

The objective is to provide deliverable authors with comments and suggestions on the deliverable, that can help in improving quality. The quality check is initially applied to a sufficiently completed draft of the deliverable, that allows significant assessment of its content. Comments and suggestions of the internal quality check are shared among deliverable contributors using email and the collaborative document management system.

The Coordinator has the last word for the approval of a deliverable and its submission to the EU.

Quality requirements for deliverables

- **Content.**
  The responsibility for the content of each deliverable is always with the author(s). The following quality requirements must be met regarding all information included in reports and deliverables.
  - ***Relevance***. Only information relevant for the scope of the deliverable must be provided. Accessory information or data may be provided in Annexes.
  - ***Completeness***. Information provided in the deliverable must be reliable and must correspond to reality. All background information must be supported by references; foreground must be supplied in clear statements and supported by evidence as much as possible (supporting data, measurements, comparisons etc.). Clarity is fundamental in order to avoid misinterpretation.
  - ***Accuracy***. Content of deliverables must be focussed on the scope of the deliverable and present the key facts and issues. The content must include all the necessary information to enable verifications by readers and to be well understood by the specific target addressees.
- **Document structure and appearance.**
  - ***Uniformity and standardization.*** Deliverables shall conform to unique standards characteristics for the project, such as uniform structure, documents organization and appearance. To this aim specific templates are foreseen for the different types of deliverables, which must be used by all staff involved.
  - ***Adherence to standards***. In specific cases such as publications for journals/books, videos or other forms of documentation, international or de-facto standards must be adopted.
- **Timing**
  - ***Punctuality.*** Deliverables and information in general must be provided to the relevant addressees and especially to the European Commission in relation to the particular phase of the project's development and according to the project work plan. Punctuality in official delivery of documents and project results is mandatory.

Although the editor(s) are responsible for the above quality criteria of their deliverables, the WP Leaders and the Project Manager are in charge of further assessment of such quality.

The quality criteria indicated above are measured by the key indicators, summarized in the following table. They relate to the defects or points that require amendments in the documents and are categorized as non-conformities.

Quality aspects	Quality criteria	Quality indicators (non-conformance)	Importance[4]
Content	Completeness	Missing content / Lack of information	Very High
		Redundancy	High
		Lack of details	High
	Relevance	Error in content	Very High
		Missing /wrong references	High
		Insufficient documentation	High
		Ambiguity	High
	Accuracy	Non-relevant information	Medium
		Confusing text	High
Document structure and appearance	Uniformity and standardization	Spelling errors	Medium
		Non-conformance to documents templates	Medium
		Usage of different fonts and types of presentations	Medium
	Adherence to standards	Non-compliance to EU or de-facto standards	High
Timing	Punctuality	Delay	Very High

[4] +++: very important; ++: important; +: to be corrected but not very important

Table 5. Quality indicators for deliverables

7.2.2 Process for the quality assurance of deliverables

- The WP leader verifies the document and then releases it to the Project Manager;
- The PM revises the document and
  - in case of medium/high non-conformance indicators, rejects the document and sends it back to the author and Deliverable Responsible and in CC to the WP Leader with comments regarding the required revisions;
  - if approved, accepts the document and delivers it (upload on participants portal).

The process is iterative until the requested quality is reached. The process is detailed in Annex 6 to this document.
Internal peer-review will be required for all deliverables, including a first revision of the Table of Content, and a final revision of the "final" deliverable. In such cases:

- The expert revises the document, send comments and recommendations to the Project Manager
- The PM forwards the peer-review to the relevant WP leader and verifies that the recommendations are considered and applied, then sends back for final approval the document to the internal reviewer.

7.3 Minutes of the meetings

Minutes of the meeting are collected as defined in the Consortium Agreement section 6.3. The minutes of meetings have the same format of project deliverables and shall include these mandatory items:

- Type of meeting (Consortium, General Assembly, Steering Board, WP meeting, etc.)
- Date and venue of meeting, meeting duration
- List of participants
- Scanned signatures of participants
- Results of the meeting
- List of actions, deadlines and responsibilities agreed.

7.4 Risk registry

Risks are collected and monitored though a Risk Registry table / Risk log (See Annex 6. Risk Log template in Annex 7 to this document).
The table is managed by the Risk management procedure (see Section 9).

7.5 Other documents

Partners can produce other documents, beyond those listed above, as they see fit for the activities at hand. These "working documents" have a free format, however they should use a similar header and footer as indicated for deliverables, in order to identify the project, the scope of the document and the dissemination level. Versioning management is also recommended when applicable.

7.6 Version control

Each project document should have a version number, in the format vx.y, and have a edition date in the document footer. Deliverables should also have a history of changes, that track changes from one version to the next.

7.7 Documents approval and change management

Each official version of a document is subjected to the approval by a responsible project role, as illustrated in the following table.

Type of document	Responsible Partner(s) Role	Quality approval process
Minutes of meetings	Meeting participants Coordinator	The minutes are submitted to all participants and finally approved by the Coordinator
General Assembly decisions	GA member Coordinator	Decisions are approved by the GA as established in the Consortium Agreement and officially by the Coordinator
Internal documents	1. Task leader & WP Leader 2. Technical Manager/ Coordinator	The task leader and the WP leader check the correctness of the version and the presence of version number, date of issue and list of modifications, and then submit to the technical manager (if technical documents) or to the Coordinator (if scientific documents) for final approval according to quality parameters (see Table 5 above)
Official deliverables (final version)	1. Task leader & WP leader 2. Peer-reviewers 3. Technical manager/ Coordinator	Task and WP leaders check quality parameters (see Table 5 above). Internal reviewers check overall quality and send comments. Technical Manager and Coordinator check adherence to the expected results as in Annex I and perform formal check
Financial reports	1. Partners' Financial Offices & Auditors (in case of CFS) 2. Final approval by Coordinator	Quality shall be assessed against time sheets and receipts for other costs. The Coordinator checks the coherence of costs and resources claimed vs. the activities reported and verified through periodic monitoring of project progress and delivery of results
Periodic Technical Reports	1. WP leader 2. Coordinator	WP leader checks activities vs. results for each partner/task Coordinator checks consistency vs. results and claimed resources/ costs
Dissemination & Communication materials / documents	1. WP11 Leader 2. Coordinator	WP11 leader checks the content adequacy vs. target audience and the conformity with the standards set for the project The Coordinator and the Technical Manager check the content accuracy and trustiness, the presence of the agreed authors names (if applicable) and of the EU disclaimers
Scientific papers	1. Main author 2. Coordinator	Main author check compliance vs. requested standards for scientific papers The Coordinator checks the presence of all authors and contributors as agreed by Consortium partners and established in the Consortium Agreement and verifies the presence of mandatory disclaimers of EU funding

Table 6. Quality Assurance process for project documents

7.8 Milestones

The milestones committed by IDEA4RC Consortium are described in the table reported in the Technical Annex I Part A. Milestones define the results to be achieved and have a committed delivery date, and indicate how to measure the degree of achievement for the milestone, which constitutes the measure of quality for the milestone.
Failure in achieving a project milestone is a major risk that should be carefully monitored along the project duration and constitutes a non-conformity that should be addressed through adequate actions.

7.9 Key Performance Indicators (KPI)

The KPIs defined for IDEA4RC (see Technical Annex I section 2.1) provide quantitative quality objectives that relate to the impacts foreseen from the project. Each KPI indicates the indicator to be measured, measurement criteria and a quantitative threshold for quality achievement.
Missing a KPI objective should be carefully monitored along the project duration and should be immediately addressed through adequate corrective and preventive actions. The Coordinator, the Project Manager and the Technical Manager with the support of the Steering Committee are in charge of monitoring the achievement of KPIs.

7.9.1 Quality levels

The level of quality required is important to establish the acceptability of project outputs as defined in the previous paragraphs. To assess the quality level the quality responsible persons at all levels shall be assigned a list of metrics that will be used for quality evaluation, similar to what is usually applied by the European Commission during project reviews. This scale indicates the level of achievement of the expected result as follows:

- Unacceptable: quality level is unsatisfactory, achievement ratio is below 60% of target
- Acceptable: quality level is sufficient, achievement level is between 60% and 70% of target
- Good: the project output/result quality satisfies the expectations and is in line with the commitments, achievement level ranges between 70% and 100% of target
- Excellent: the quality of the output/result goes beyond commitments and expectations, achievement level exceeds the committed target.

8 Development process management and quality assurance

As one of the main outcomes of the IDEA4RC project is a software product, it is important to properly manage its source code and implement appropriate Methods of Quality Assurance. The development project will follow DevOps and MLOps methodologies, as such, we will provide tools to aid in all of the phases of development, for individual components as well as the platform as a whole. This infrastructure is coordinated through T4.1 (DevOps) and T4.5 (MLOps).

8.1 Source Code management

GIT instances such as GitLab or GitHub will be the tool to manage source code repositories. This tool will be used to plan through the embedded issue management system and milestone features.
Repositories will be organized coherently with the implementation requirements,

which may differ from project structures. This will help the code adapt to the actual design as well as future developments beyond the project. Each repository will be governed by a set of rules:

1. Every module/microservice will be its own repository, with the main objective that users can clone or fork it and start working directly with it. In this context every module should be as self-contained as possible, i.e.: you would not need to clone several repositories to work with it, and it should also contain all the information for developers and maintainers to work on it. However, it is also acceptable to have folders for submodules, in the cases where the submodules are intrinsically linked to the whole module. In such cases it is preferred to operate with git-submodule feature.

2. Use any form of project or package management, this will facilitate coding, building, testing, and even deploying DevOps phases; by automatising dependency management (download libraries), IDE configurations, build toolchains, testing frameworks and testing execution, as well as general execution. Examples include Maven for Java, PIP for Python, NPM for node js, Make for C, gradle for Android. Another benefit is that the source code should build independently of the state of other repositories (by using fixed or ranged versions).

3. Every repository must contain a README.MD (preferably all capitalized) file in the root of the repository, in markdown format, containing at the following sections:
   a. Getting started / Use. A short guide for end users to start using the module.
   b. How to build, Install, deploy. A short guide for developers, maintainers and deployers.
   c. Testing (optional): A short guide for developers and maintainers.
   d. Contributing (optional): A short guide for developers and maintainers including code conventions, code incorporation process (e.g. pull request), branch workflow, and general etiquette.
   e. Credits / Getting help (optional): A list of contributors to this project, so they can be directly contacted in case of problems. Alternatively cite the services through which to report issues, get support or feedback.
   f. Licence: A short summary of the licence which applies to the module.

4. Every repository must contain a LICENCE.TXT (preferably all capitalized) file, containing the full licence under which the module is distributed. The short version of the license is disclosed in the README.MD (see rule 3). Also the NOTICE.TXT (preferably all capitalized) file should explain the dependencies, application, IPR owners, etc.

5. Dockerfile should be in the root directory, whenever it is necessary to build the containerized version of the module. If your module needs to contain several Dockerfiles, this could be indicative that there is more than one module in the same repository, which is not advised (see rule 1). Alternatively, the Dockerfile may be created as a result of project management (see rule 2), in which case it should be clearly explained in the README.MD (see rule 3).

It is generally recommended to follow GIT best practices when committing and operating with the Source Code Management System (SCM). These practices include:

- Make Commits atomic, one logical change per commit.
- Do not commit generated/compiled/binary nor big files, whenever possible. Properly use the ".gitignore" file to avoid accidental commit of these files. There are many relevant templates available .
- Do not commit dependencies. Use package management or git-submodule instead.
- Don't commit local configuration such as passwords, or absolute file system references.
- Write useful commit messages.
- Adhere to the agreed workflow, like tagging releases, using branch naming convention and avoiding rewriting history.
- Test before pushing.

8.2 Continuous Integration and QA

Continuous Integration will be set up through specific automation tools like Gitlab CI/CD or Jenkins. It will be accessible using developer credentials. Jenkins will perform a nightly "Pipeline", a process ensuring the source code repositories can be built and are thoroughly tested, and in case all is good: package a release, and even deploy to production (generally a test server).
The build process will consist of building the standard Dockerfile, where the concrete compiling toolchain for each module will be correctly configured. If the build fails, the developers will be informed about this event.
A standard battery of tests will be set up, concretely checking the rules and best practices mentioned in section 7.1. Additional tests can be set up in the pipeline for the project, Jenkins is able, in many cases, to instrumentalize the code, an derive certain metrics such as code coverage. In the interest of providing the best quality product developers should strive to provide tests with as higher code coverage as possible, while also considering the most important features and factors for each module. In the event of a test failure, the developers will be notified. Jenkins will also provide an historical log, as well as graphs of test success rate, code coverage and other general metrics for the performance of each module.
In addition to testing, code conventions can be checked, because IDEA4RC is expected to be a polyglot product, where each microservice module can be written using a different programming language; no specific code convention can be provided, however in the interest of general readability and uniformity across the project, general guidelines can be provided.

8.3 Releases

There will be at least 2 types of software releases: intermediate and stable. Intermediate releases will consist of releases with small changes, bug fixes, new features, or just plain improvement. Nightly releases will be an example of intermediate releases. Stable releases, on the other hand, are intended to be fully integrated releases aligned with the overall platform version.

Releases will follow a Semantic Versioning approach. Modules will not have to follow the exact version schema of the platform; however, it is highly recommended they do. The platform release will be accompanied, through documentation or through its build files, with a full list of the modules with their specific version. Stable releases of the platform will only contain stable releases of all modules (i.e. no rolling references such as "nightly" or "snapshot"). Each stable release will be tagged in SCM so it can always be built from the source.
Additionally, to the version type, there are two products which could be released. The first product is the Community Edition (CE) where all modules are open source, the second product is the Enterprise Edition (EE) which will extend CE with modules which are proprietary by the different partners of the consortium. These editions will be marked in the versioning as build, thus a stable release for Community Edition will be in the form of "x.y.z+CE" the same stable release for the Enterprise Edition will be "x.y.z+EE".
The binary releases of the modules will be deployed in the private Docker registry of the project. Access to this service will be granted through the developer credentials.

8.4 Open Source

The decision of making the software project, fully or partially, open source will be examined throughout the running of the project and reported in the exploitation deliverables, Open Source and open data will be preferred whenever possible. Thus, until this analysis is made technological developments need to follow an agnostic approach. The approach is to consider all developments which either stem from an already open source project, or are developed within the project as Open Source; whereas there might be proprietary components, provided by consortium partners, which might be incorporated or integrated into the platform. As stated in 8.2, the platform will have 2 editions: Community Edition (CE) and the Enterprise Edition (EE), depending on whether the release contains
The development services, Source Code Management, Continuous integration, Release and other servers such as documentation and ticketing will need to be private. All of the content will be considered confidential with only free access by consortium members and other necessary third parties (such as open callers).
These services and content, particularly the content that is deemed part of the CE, will however need to be prepared for migration to common open-source communities such as GitHub or docker hub.
More details will be provided in the Data Management Plan throughout the project execution.

8.5 Products support

Every software product needs to be extensively documented and support need to be provided in different ways. Channels in Slack for support and help of platform and products will be created.

9 Risk management

Risk management refers to all activities undertaken to detect, analyze, monitor, and control potential risks that could affect the execution of the project. Risk management is a continuous process that will be undertaken throughout the lifetime of the project with the objective to prevent risks and minimize their impacts in case risks occur. Risks will be minimized and managed by using well-established methodologies for project planning and monitoring. The Project Coordinator and the Technical Manager in cooperation with the Steering Committee will overview risks monitoring and management.

9.1 Risk Management Roles and Responsibilities

Risk monitoring and management involves the overall management structure of IDEA4RC and may involve a bottom-up or a top-down approach, depending on the type of risks and of the impacts on the project execution.

Key participant(s)	Responsibility and actions
Task Leader / WP Leader	Timely identify and evaluate the risk (probability, severity, impact) connected to specific task/WP and inform the Project Manager.
Execute the recovery actions and report results to the Project Manager and the Steering Committee.	
Project Manager	Timely inform all the involved actors (Task Leaders, WP Leaders) and the Steering Committee
Monitor and control the risks	
Steering Committee	Monitor high level risks and inform on strategic actions
Other stakeholders	Identify and communicate risks in their areas of expertise to Task/WP Leaders

Table 7. Risk management roles and responsibilities

9.2 Risk management procedure

Risk management involves the following steps:

Initiating risks management

1. Risk identification. The purpose of this step is to identify and document the risks that can have impact on the project's objectives. New risks that may arise at any point during the project should be added to the Risk Table / Risk Log for further analysis/action.
2. Risk assessment. The purpose of this step is to assess the likelihood of each risk and the severity of its impact on project objectives or on the consortium interests.

This assessment is necessary before any risk response is planned. Medium to high level risks will be dealt with at a higher priority level.

Risks response planning

3. Develop a risk-response strategy. The purpose of this step is to choose the best possible strategy to address an identified risk and to plan actions necessary to implement this strategy (includes appointment of responsibilities, verification checkpoints etc.).

Risk mitigation execution

4. Execute the actions proposed in the strategic plan and record the activities, challenges and the intermediate results

Risks monitoring & control

5. Control risk-response activities: The purpose of this step is to monitor and control the implementation of risk-response activities and to revise/update the Risk Log based on a regular reassessment. This step might involve the refinement/re-definition of the risk mitigation actions and responsibilities.
6. Record. Update the project Work Plan with clear risk-response tasks whenever deemed necessary.

Risks closing and solving

7. Report. Regularly inform the Steering Committee (SC) about risk-related activities and record and report in the project activity (periodic) reports the status of risks, the implemented actions, the effects of the applied strategies and the impacts, if any, on the project Work Plan and expected project results.

9.3 Tools & Techniques

9.3.1 Risk management plan

The Risk Management Plan outlined here defines and documents the Risk Management Process for a project. It describes how risks will be identified and assessed, what tools and techniques can be used, what the evaluation scales and tolerances are, 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 Log, which is used to document and communicate the risks and their response actions.
Risks shall be promptly communicated to the Project Manager and the Technical Manager (usually within one week after risk detection and first evaluation inside the task members and the WP participants).

9.3.2 Risk Log

A Risk Table / Risk Log is used to document and communicate the risks and relevant risk-response actions and responsibilities and the results and impacts of the implemented mitigation/solution actions.
The following documents support the overall risks management process:

Related documents	Initiating	Planning	Executing	Monitoring	Closing
Risk Management Plan	Risk log	Risk management plan/strategy	Project Reports / Risk Log	Project Work Plan	Project Reports / Risk Log

9.3.3 Risk Assessment Matrix

Each identified risk will be evaluated according to a Risk Assessment Matrix (RAM) that considers risk probability and risk severity and impacts. The RAM is an easy-to-use tool that measures the overall relevance and impacts of the risks, informing rids addressing priorities. Depending on the overall score (color) of the risk according to the RAM, adequate mitigation measures will be planned and implemented.

		IMPACT				
		very low	low	medium	high	very high
PROBAPILITY	very likely					
	likely					
	possible					
	unlikely					
	rare					

Figure 5. Example of Risk Assessment Matrix

The level of likelihood and of impacts are defined based on scores agreed by Consortium partners:

Level	Likelihood	Probability	Impact
1	Rare	<10%	Negligible
2	Unlikely	Between 10% and 25%	Minor
3	Possible	Between 25% and 50%	Moderate
4	Very likely	Between 50% and 75%	Significant
5	Almost certain	>75%	Severe

Table 8. Scoring guideline for the use of the Risk Assessment Matrix

The risk level (color-related) is calculated based on the combination of likelihood and impact, where the "impact" weighs highest.

Risk level	Description
LOW	Has little impact on costs, schedule and results. Normal effort or minor interventions would be sufficient to overcome the difficulties.
MODERATE	Can disrupt timings, costs, and efforts required to achieve the expected results and performance. Special effort and a dedicated recovery strategy will most probably overcome the problems.
HIGH	Will likely cause significant impacts on resources and disruption of the time schedule potentially affecting the performance and the expected results even if dedicated effort and close monitoring are applied.

Table 9. Risk levels

9.3.4 Revision frequency of the Risk Log file

The risk log file shall be updated whenever a new risk is detected and addressed and whenever actions are implemented and the risk is solved or remains unsolved and alternative solutions are proposed. Descriptions of the risk, of the implemented actions and of the results / solutions achieved and the relevant effort devoted shall be included in the Risk Log file.
The biweekly conference calls foreseen as part of usual management are the main checkpoint for risk log updating, however the risk log can be updated anytime by the actors involved in the risk management process (see Table 7 above). In all cases the Risk Log shall be translated into the relevant risk table in the participant portal at least on the occasion of the periodic reports (both internal periodic reporting and official periodic reporting as established by the Grant Agreement).

9.4 Escalation

Escalation to the Steering Committee and – if needed – to the General Assembly shall be done in case the risk cannot be solved by implementing the planned recovery actions or in case the new risk is of high level. Any person involved in IDEA4RC tasks or activities is entitled to escalate the risk.
Risks escalation shall however be adopted only in case the usual procedure might result too lengthy or insufficient to address the risk. In case the risk cannot be solved, the problem shall be brought to the attention of the European Commission by the Coordinator, who will timely inform the Project Officer firstly informally (via usual email) and if needed formally through the communication services available in the EU participant portal.

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ANNEXES

Annex 1.
Structure of the Shared Documents Repository

Meetings. In this folder all the IDEA4RC meetings will be collected, including agenda, minutes and presentations. It is divided into:

- Cluster meetings
- Consortium meetings

Project Administration. In this folder, the administrative details of the IDEA4RC will be grouped. It is divided into:

- Amendments
- Consortium agreement
- Contacts
- Funds and financial reports
- Financial and technical reporting
- Grant agreement

General Assembly: this folder contains the list of partners' representatives in the GA and may contain any relevant information regarding any permanent or occasional appointment of new representatives/deputies for specific General Assembly meetings and decisions.
Steering committee: this is a work space for the Steering Committee members' works, meetings and decisions.

- Steering Committee Meetings

Templates

- Minutes template
- Deliverable template
- Presentation template
- Logo
- Periodic report template
- WP plans & monitoring forms

WPx folders. Each WP has a dedicated folder that might include:

- Periodic meetings folder, when applied is to include agenda, minutes and link.
- Folder for each individual task that should contain working documents but also a folder with every deliverable assigned to each task (in .doc and .pdf formats)
- Any other working folder or document the WP leader may require.

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Annex 2.

Template of meeting agenda

<name of meeting>
<*Date of meeting*>

<Location and address>
n

<time, duration of meeting>

GENERAL OBJECTIVES
The meeting intends to:
1. List of objectives
2.…

AGENDA

Time	Presented/Chair	Description of session and objectives
	Objectives:	
	Coordinator	**Any Other Business, meeting wrap-up,** ***next meeting*** ***End of meeting***

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Annex 3.

Template of minutes of meeting

The template is similar to the template of deliverables. Sections shall cover the meeting sessions/objectives and the relevant discussions and decisions.
The minutes shall include an action list according to the following format (see example below):

Action	Resp. Partner(s)	Deadline
Finalize the CA signature	INT	
(all consortium)	asap	
Start T2.1 and state of art recognition	UU (support MME)	1 October 2022
Distribute ToC D1.1, D1.2	INT	15 October 2022
Payment of prefinancing (1st instalment)	INT	Possibly mid October 2022
Publication of kick-off meeting minutes	INT	12 October 2022
Circulation of Consortium Agreement draft	INT	Asap
Consolidation of mailing lists	UPM	Asap
Answers to EU cluster requests	INT (WP Leaders)	End of October 2022
First biweekly webconf with WP leaders	UPM/INT	16/11/2022 2.30 p.m.
ECCP seminar	ECCP	Spring 2023
Next Consortium Meeting	INT	15-16 May 2022
Etc.		

Table 10. Example of action list to be included in the minutes

No	Title	Resp.	Status and contributions	Deadline
D1.1	Quality Plan	INT	To be drafted, main contributors: UPM, ECPC, MME, HL7, ENG	28 Feb 2023
D1.2	Data Management Plan	INT	To be drafted, main contributors: CERTH, UPM, ECPC, clinical centres	28 Feb 2023
D11.1	Plan for dissemination….	INF	To be drafted, main contributors: ALL partners	28 Feb 2023
D12.1	Ethics report 1	INT	To be issued by Ethics external expert. Main contributor: ECCP	28 Feb 2023
D10.2	Stakeholders Engagement Plan	DIGICOR	To be issued. Main contributors: UU, INT, clinical partners	28 Feb 2023

Table 11. Example of action list (pending deliverables) to be included in the minutes

Annex 4.

Rules of conduct for technical communication with Slack

This section provides several recommendations on how to organize channels for a better communication among technical partners.

Recommendation #1: prefix
Slack does not show the list of all the channels in a workspace, such list is hidden and a user needs to know which is the name of the channel he want to join. In order to provide the functionality for all user to preview all the available channels the usage of a prefix is a best practice.
In this regards as recommendations #1 - Use always the prefix "i4rc"
for instance:
i4rc-general.

Recommendation #2: Operational channels
In order to identify discussions related to specific WP, task, WG it's a best practice to follow the structure of the project.
In this regards as recommendations #2 - Create all channels for work packages, tasks, Working Groups, deliverable. Using the following rules:
i4rc-wpx -> i4rc-wp1
i4rc-tx.y -> i4rc-t2.3
i4rc-dx.y -> i4rc-d2.3
i4rc-wgx -> i4rc-wg1

Recommendation #3: Discussion channels
Channels on specific topic. To be used for cross task and work packages issues.
i4rc-discussion-<topic> -> i4rc-discussion-datastorage

Recommendation #4: Teams
Channels to reach specific organization
i4rc-team-<org> -> i4rc-team-upm

Recommendation #5: Support channels
Channels for support on specific topic.
i4rc-help-<topic> -> i4rc-help-login

Recommendation #6: Event channels
Channels for specific event.
i4rc-event-<topic> -> i4rc-event-privacysympsium

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Annex 5.

Periodic report (internal) template

This template is used for the periodic reports, both the internal ones foreseen every 9 months and the official ones requested at the end of each reporting period.

Cover page

Project Number: 101057048
Project Acronym: IDEA4RC
Project title: Intelligent Ecosystem to improve the governance, the sharing, and the re-use of health Data for Rare Cancers

9 months Periodic Report
Part B

Funding Scheme:
HORIZON-HLTH-2021-TOOL-06-03: Innovative tools for use and re-use of health data

Date of latest version of Annex I against which the assessment will be made:
[insert date]

Period covered by the report:
from [insert dd/mm/yyyy] to [insert dd/mm/yyyy]

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Table of contents

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Explanation of the work carried out by the beneficiaries and overview of the progress (coordinator)

Participant portal Periodic Report Template:

- Explain the work carried out during the reporting period in line with the Annex 1 to the Grant Agreement.
- Include an overview of the project results towards the objective of the action in line with the structure of the Annex 1 to the Grant Agreement including summary of deliverables and milestones, and a summary of exploitable results and an explanation about how they can/will be exploited .
  (No page limit per work package but report shall be concise and readable. Any duplication should be avoided).

Additional guidelines:

Please refer to the Description of the Action (DoA).
When describing the advancement of your project, please include reference (brief description) to the following:

Results:

- main scientific and/or technological achievements of the project
- main innovation outputs (if applicable)
- contribution to the state of the art
- scientific and/or technological quality of the results
- impact on technology and/or society
- impact on the researcher career (if applicable)
- dissemination activities and results: publications, users involved, etc.
- protection of the acquired intellectual property (patents applications, etc.)

Progress of the activities:

- main research / innovation (if applicable) / training (if applicable) / transfer of knowledge activities (if applicable)
- summary of the achieved objectives, compliance with the workplan, any deviations (whether justified) and corrective actions (whether acceptable).
- milestones for the period and submission and acceptance of deliverables (if applicable).
- use of resources (are they in line with the DoA, do they represent good value for money?) (if applicable).

Objectives and results achieved in the period
To be completed by Coordinator

Explanation of the work carried per WP

WPX: WP Title(resp. beneficiary short name)
Explain the work carried out in WPX during the reporting period giving details of the work carried out by each beneficiary/linked third party involved.
Summary by WP Leader

Partners contributions (Resp: all partners involved in the WP)
Example to be completed by each partner involved in the WP

Beneficiary n. 1 INT	**Fondazione IRCCS Istituto Nazionale dei Tumori di Milano**
Person months	
Tasks	**Activities performed and results achieved**
T.1 Project Management	•
T1.2 Technical and Innovation Management	•
T1.3 Quality Assurance and Risks Management	•
T1.4 Scientific and Ethics Coordination	•
T1.5 Clustering	•

Deliverables:

- D1.x – Title - Delivered month xx
-

Problems encountered & recovery actions
List problems and recovery actions implemented
Etc.

Annex 6.

Process for QA of project deliverables

Step	Description	Timing	Input	Output
1	The deliverable Lead Beneficiary circulates a proposal for the table of contents (TOC) of the deliverable to the Consortium	At least 2 months before the delivery date		Deliverable TOC and guidelines for contributions
2	Assigned-peer reviewers will provide their comments to the TOC	Within 5 working days, after receipt of the deliverable TOC	Proposed TOC	Comments to the TOC
3	The Author appointed by the deliverable Lead Beneficiary circulates the final TOC and indications for partners' contributions	Upon receipt of reviewers comments on TOC	Final TOC	Draft deliverable to be completed
4	Partners' contributions are delivered to the Author	Within 30 working days before the official delivery date	Draft deliverable to be completed	Deliverable contributions by co-authors
5	Author check the draft deliverable and – if required - asks for revisions/complementary information	Within 5 days from receipt of contributions	Deliverable contributions by co-authors	Deliverable draft
6	Contributors shall provide the missing information plus their comments	Within 10 working days	Deliverable draft	
	Additional contributions by co-authors			
7	The Author sends the draft to the peer reviewers for first assessment	Within 15 days before the delivery date	Additional contributions by co-authors	Integrated draft of deliverable
8	The peer reviewers return the draft with comments to the Author	Within 5 days from receipt of the draft document	Integrated draft of deliverable	Commented draft of deliverable
9	The Author sends a final revision to contributors, to the WP Leader and to the PM for approval	Within 5 days before the delivery date	Document with implemented revisions	Final deliverable for approval
10	The PM performs a final reading and revision. The Coordinator checks and approves the document. Deliverable is submitted	Within 1 day before delivery date	Final deliverable to be checked	Finalized and approved deliverable for submission

Table 12. Process for QA of project deliverables

At the end of the process the deliverable is delivered on the participants portal and uploaded on the shared documents' repository and to the participant portal documents management system. If the document is public, it will also be accessible from the public area of the IDEA4RC web site.
This procedure applies to all deliverables which can be presented in electronic format, including videos and animations.
The following figure presents the process timeline.

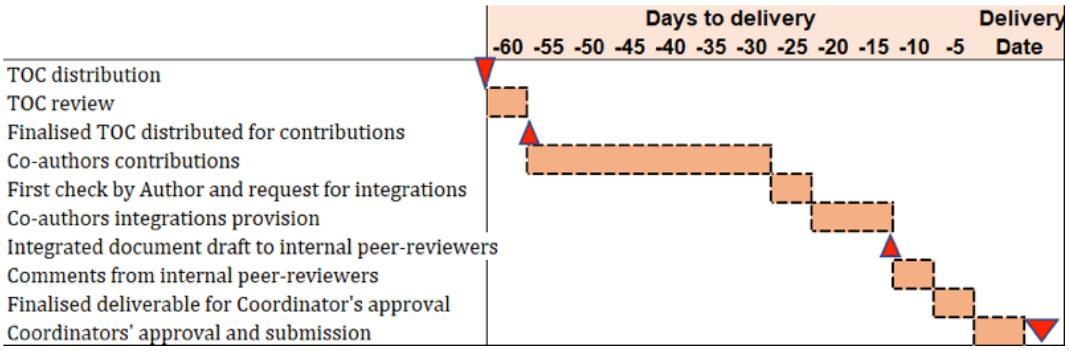

Figure 6. Deliverable production and QA timeline

Assignments of the peer-reviewers by deliverable

Del No.	Deliverable Title	Lead Beneficiary	Reviewer 1
D1.1	Quality Plan	INT	MME
D1.2	Data Management Plan	INT	ECCP
D1.3	Innovation management plan	UPM	ENG
D2.1	Data Ecosystem baseline value positions	UU	CERTH
D2.2	Data Ecosystem final guide	UU	DICOR
D2.3	Ethical data governance and reuse incentivization approach	ECCP	MSCI (Polonia)
D2.4	Data Ecosystem reference architecture	UPM	UDEU
D2.5	Metadata taxonomy	UDEU	IKNL
D3.1	FHIR Implementation Guide	HL7	UDEU
D3.2	Policy Manager API implementation	UPM	CERTH
D3.3	Transaction Data Layer API implementation	ENG	IKNL
D3.4	Analytics and trustworthy AI layer API implementation	IKNL	MUH (Motol)
D3.5	NLP NLU Integration module	UPM	FBK
D4.1	Data Ecosystem infrastructure	ENG	TNO
D4.2	Metadata annotation and meta-query engine	UDEU	INT (Baili)
D4.3	Data cleaning, augmentation and federated AI algorithms and services	IKNL	FJD (Madrid)
D4.4	API Gateway and service broker	UPM	CERTH
D4.5	Secure MLOps Pipeline implementation	UPM	CLN
D4.6	Multilingual dictionaries	CLN	FBK

D5.1	Structured Data Model to support NLP NLU	UDEU	IKNL
D5.2	Structured extraction	FBK	ENG
D5.3	Question-answering module	FBK	CLN
D5.4	Prospective natural language data collector	CLN	ENG
D6.1	Specification of multimodality navigation	UPM	INT (Provenzano, Cavalieri)
D6.2	Pluggable interfaces for AI models implementation	UPM	CLB
D6.3	Data provisioning driver	UDEU	HL7
D6.4	Multimodal AI navigator	UPM	FJD (Madrid)
D6.5	NLP Guided Assistant UI	CLN	FBK
D7.1	e-DSA Management	TNO	CERTH
D7.2	Toolkit trust management	CERTH	ECCP
D7.3	Data altruism manager	CERTH	ECCP
D7.4	Data usage tracking and auditing system	CERTH	TNO
D8.1	Rare Cancer Pilots selection	INT	VGR
D8.2	Pilot data governance	NIOC	DICOR
D8.3	Pilots results intermediate report	IIS-FJD	MUH (Motol)
D8.4	Pilots' evaluation report	INT	FPNS
D9.1	Pilot deployment plan	UPM	CLB
D9.2	Rare Cancer Data Ecosystem deployed	UPM	DICOR
D9.3	Rare Cancer Data Ecosystem toolkit usage guidelines	MME	UKE
D9.4	Rare Cancer Data Ecosystem Final release	UPM	MME
D10.1	Ethics guidelines for enlargement	ECCP	CERTH
D10.2	Stakeholder Engagement Plan	DICOR	UU
D10.3	Standards for a Rare Cancer Data Ecosystem	HL7	DICOR
D10.4	Plan for the uptake of a Rare Cancer data hub	DICOR	FJD (Madrid)
D11.1	Plan for communication, dissemination and exploitation activities	INF	MME
D11.2	Communication materials	INF	N/A
D11.3	Exploitation prospects	ENG	FJD (technical person)
D11.4	Launch plan and IPR Agreements	ECCP	ENG/INT (Cannarozzo)
D12.1	OEI Requirement No.1	INT	NA
D12.2	OEI Requirement No.2	INT	NA
D12.3	OEI Requirement No.3	INT	NA
D12.4	OEI Requirement No.4	INT	NA

Table 13. Peer Reviewers of the Project Deliverables

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Annex 7.

Risk Log template

Risk ID 1			
Risk identification			
Description of the problem	**Risk**		**Involved WP**
	Describes the risks for the project in terms of: - results (affects results). - management - other…		
Risk analisys			
Likelihood of the risk	**Impact on project**	**Foreseen period/timing for impact on project**	
		Describe when and for which activities the risk has impact on the projec	
Risk management			
Priority	**Contingency Plan**	**Consequences of mitigation**	**Resp. Partners**
Describe the contingency plan identify to minimise/ solve the risk. Possible to indicate a reference to a document describing the contingency plan.	Describe the consequences of the mitigation on the project's workplan or outcomes	Partners responsible for the contingency actions implementation	
Monitoring			
Status and Date			

[6] probability of the risk to materialize (100% if the risk has materialized) or probability level as defined in Table 8 above

[7] 1= Negligible; 2=Minor, no major problems; 3=Moderate, corrective actions recommended; 4=Significant, corrective actions mandatory; 5=Severe: need immediate action

[8] 1= very low; 2= low but necessary before impact time; 3=moderate, to be addressed asap; 4=high, urgent; 5=very high, needs immediate reaction

[9] Status: open , in process, closed. Date refers to the status.

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Annex 8.

Process for periodic reporting

Internal periodic reporting

The process for internal reporting foresees these activities and timing:

Step	Description	Input	Output
1	Within 30 days from the expiration of a project's semester, the Project Manager will circulate the templates for the periodic reporting	Periodic reporting templates	
2	Within 15 days from the expiration of a project's semester, WP Leaders and all Beneficiaries will send to the Project Manager the reporting information described above using the provided templates		Periodic reporting templates filled (see in Annex I)
3	Within 5 working days from receipt of the contributions from Beneficiaries, the Project Manager checks quality of contributions and sends requests for integration to the concerned beneficiaries	Completed reporting forms	
	Individual reporting forms plus requests for integration		
4	Within 5 working days the concerned Beneficiaries should send the required integrations to the PM for document integration and approval	Individual reporting forms plus requests for integration	Integrated periodic report forms
5	The Project Coordinator makes available to the Consortium a consolidated version, in order to support Steering Committee / General Assembly decision making.		Consolidated version of internal project reporting to be presented to the General Assembly

Table 14. Process for internal periodic reporting (month 9, month 27)

Official periodic reporting to the EU

The following steps are performed to ensure the quality of official periodic reporting to the EU:

Step	Description	Input	Output
1	Within 15 days before the expiration of a reporting period, the PM will circulate the templates for the periodic reporting. The EM will circulate a template for the collection of publications materials	Official periodic reporting templates. Excel sheets for costs declaration	
2	Within 20 days after the expiration of the reporting period, all Beneficiaries will send to the Project Manager the reporting information described above using the provided templates		Official periodic reporting and detailed costs
3	Within 10 working days from receipt of the contributions from Beneficiaries, the Project Manager checks quality of contributions and sends requests for integration to the concerned beneficiaries	Completed reporting forms	Individual reporting forms plus requests for integration
4	Within 10 working days the Beneficiaries should provide integration to the periodic report and upload costs in the EU portal.	Integrated periodic report forms, final costs for each Beneficiary	Integrated periodic report forms plus Forms C in the participants portal
5	Within 45 days after the expiration of the reporting period, the Project Manager checks costs, asks for revisions and produces the periodic report for partners approval.	Forms C and CFS when applicable	Requests for revisions Forms C and official Periodic (Final) report
6	Within 55 days after the expiration of the reporting period the Beneficiaries consolidate their costs, the relevant part of the gender table, the SME impacts table in the EU portal, and the official periodic (final) report	Forms C and official Periodic (Final) report and CFS when applicable SME impacts, Gender table, publications, Patents etc.	Consolidated Costs reports and Periodic (Final) report all sections available in the EU participants portal
7	By day 60 after the expiration of the reporting period the Coordinator submits the Periodic Cost and Activity Report	Consolidated Forms C and Periodic (Final) report	Submitted Periodic costs and activity report

Table 15. Process for periodic reporting to the EU (Month 18, month 36, month 48)