



# Deliverable D1.1

## Project Handbook 1v0

<b>Project Title</b>	<b>Genomic Data Infrastructure</b>		
Grant agreement no	101081813		
<b>Project Acronym</b> (EC Call)	GDI		
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<b>WP Leaders</b>	Hannah Hurst (1. ELIXIR Hub)		
<b>Deliverable Lead Beneficiary</b>	1. ELIXIR Hub		
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## Log of changes

Date	Mvm	Who	Description
02/12/2022	ov1	Nikki Coutts (ELIXIR Hub)	Initial drafting template created
30/01/2023	ov2	Hannah Hurst (ELIXIR Hub)	Initial version finalised and ready to share with consortium for review & input
10/02/2023	ov3	Hannah Hurst (ELIXIR Hub)	Initial version reviewed by Consortium
17/02/2023	ov4	Hannah Hurst (ELIXIR Hub)	Comments and suggestions reviewed and incorporated
24/02/2023	1v0	Hannah Hurst (ELIXIR Hub)	Final version ready to submit

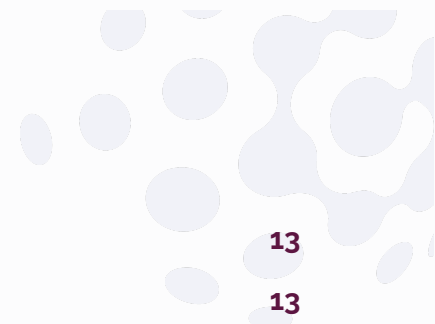
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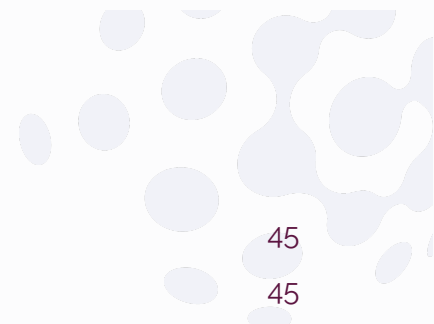


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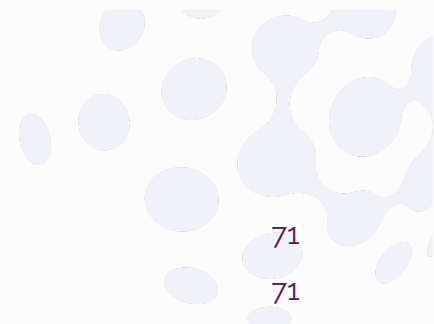
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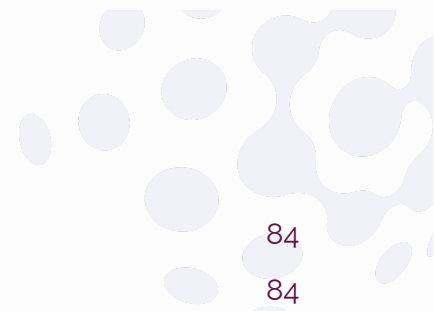
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## 1. Executive Summary

This report provides an overview of the development of the GDI Project Handbook.

The Project Handbook follows the Open PM<sup>21</sup> best practices to provide the board members and the project participants with a clear definition of their roles and responsibilities, as well as the relevant processes and assets the project will use, to ensure contractual commitments in the Grant Agreement are delivered on time and within the scope and budget, and with the expected level of quality.

## 2. Contribution towards project outcomes

With this deliverable, the project has reached or the deliverable has contributed to the following project outcomes:

	Contributed
<b>Outcome 1</b>  Secure federated infrastructure and data governance needed to enable sustainable and secure cross border linkage of genomic data sets in compliance with the relevant and agreed legal, ethical, quality and interoperability requirements and standards based on the progress achieved by the 1+MG initiative.	No
<b>Outcome 2</b>  Platform performing distributed analysis of genetic/genomic data and any linked clinical/phenotypic information; it should be based on the principle of federated access to data sources, include a federated/multi party authorisation and authentication system, and enable application of appropriate secure multi-party and/or high-end computing, AI and simulation techniques and resources.	No
<b>Outcome 3</b>	No

<sup>1</sup><https://webgate.ec.europa.eu/fpfis/wikis/display/openPM2>





Clear description of the roles and responsibilities related to personal data and privacy protection, for humans and computers, applicable during project lifetime and after its finalisation.	
<p><b>Outcome 4</b></p> <p>Business model including an uptake strategy explaining the motivation, patient incentives and conditions for all stakeholders at the different levels (national, European, global) to support the GDI towards its sustainability, including data controllers, patients, citizens, data users, service providers (e.g., IT and biotech companies), healthcare systems and public authorities at large.</p>	No
<p><b>Outcome 5</b></p> <p>Sustained coordination mechanism for the GDI and for the GoE multi-country project launched in the context of the 1+MG initiative.</p>	Yes
<p><b>Outcome 6</b></p> <p>Communication strategy – to be designed and implemented at the European and national levels.</p>	Yes
<p><b>Outcome 7</b></p> <p>Capacity building measures necessary to ensure the establishment, sustainable operation, and successful uptake of the infrastructure.</p>	Yes
<p><b>Outcome 8</b></p> <p>Financial support to the relevant stakeholders to enable extension, upgrade, creation and/or physical connection of further data sources beyond the project consortium or to implement the communication strategy and for capacity-building.</p>	No



### 3. Methods

The aim of this deliverable was to produce the Project Handbook combining the Open PM<sup>2</sup> methodology best practices and the expertise of the ELIXIR Project Management Office of running EC projects. It was defined that the Handbook must provide the board members and the project participants with a clear definition of their roles and responsibilities as well as the relevant processes and assets that the project must use to ensure the contractual commitments as defined in the Grant Agreement are delivered; not only on time but within the scope and budget and with the expected level of quality.

It was decided by the Project Manager during the proposal preparation phase that an initial version of the Project Handbook should be ready by the end of M3 (January 2023). The need for a Project Handbook during the early stages of a project is paramount for the successful project management of the project, therefore, it was prioritised. Using the PM<sup>2</sup> template and previous knowledge from the Project Managers of managing Horizon Europe projects, the template was adapted to accommodate the scope of the GDI project under the Digital Europe framework and we were able to produce the first draft which, when ready, was circulated to the Project Management Board for review.

By M3 (January 2023) we had incorporated suggestions and addressed feedback completing a finalised initial version of the Handbook. This version is stored in the GDI Project Shared Drive (Google), which all project participants have access to. The Handbook will be updated regularly throughout the project to ensure that guidance remains up-to-date and relevant.

In addition to the current project participants, during the course of the project the handbook will be shared with any new project participants in their welcome email upon successfully registering.

**Disclaimer:** live documents and assets mentioned throughout this document are stored within the project repository and therefore are only open to project participants. The ELIXIR PMO produced open versions of the assets listed here (funded by ELIXIR-CONVERGE) for the benefit of ELIXIR members and project management teams participating in EC projects.

### 4. Description of work accomplished

The description of work accomplished and results have been outlined below.

The finalised Project Handbook, up to date as of 27th January 2023, can be viewed in Appendix 1.

The live and evolving Project Handbook can be accessed in Appendix 2.

The table of contents below correspond and link with the live version of the Project Handbook which is adapted from the Open PM<sup>2</sup> template<sup>2</sup> using the prior project handbook preparation experience of

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<sup>2</sup>[https://webgate.ec.europa.eu/fpfis/wikis/display/openPM2/Artefacts?preview=/175357231/351800464/\(OPM2-04.P.TPL.v3.0\).Project\\_Handbook.\(ProjectName\).\(dd-mm-yyyy\).\(vx.x\).docx](https://webgate.ec.europa.eu/fpfis/wikis/display/openPM2/Artefacts?preview=/175357231/351800464/(OPM2-04.P.TPL.v3.0).Project_Handbook.(ProjectName).(dd-mm-yyyy).(vx.x).docx)



the Project Management Team. The PM<sup>2</sup> Methodology originated from the European Commission and Open PM<sup>2</sup> provides many guidelines and templates to facilitate the management and documentation of EC projects.

GDI Project Handbook live document. Table of contents:

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#### 4.1 Update of processes as defined in the Project Handbook

All project participants are welcome to, and actively encouraged to, suggest updates to the processes which are defined in the Project Handbook. The Project Handbook is designed to be a living, adaptable resource and therefore, as we refine and define new processes, the Project Handbook must be updated to avoid becoming stagnant and of no help to project partners.

### 5. Conclusions & Impact

The Project Handbook provides the framework for the management of the GDI project. The Project Management Team will monitor the relevance of the Handbook regularly during the duration of the project and adapt it as required to ensure that it remains relevant, meets the needs of the project participants and fulfils the objectives of the deliverable.

The Project Handbook and the associated project assets (e.g. the project monitoring tool) will provide the framework for the monitoring and delivery of the tasks and objectives of each of the nine work packages at both the technical and financial level.

The project monitoring tool, designed and developed by the ELIXIR Hub for the Horizon Europe ELIXIR-CONVERGE project, will also be used in the GDI project.



## 6. Next steps

The Project Handbook will be kept as a live document, available for review and modification at any point during the project duration, to ensure it remains a valuable project resource. Project participants will have easy access to the document at all times from the project Shared Drive and are recommended to rely on it as a first point of contact when they have project management related questions.

## 7. Deviation from Description of Action

Not applicable.



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## Appendix 1: GDI Project Handbook 1v0

The project handbook copied here is a snapshot of the initial version as of 27 January 2023. As the project handbook is a live and evolving document, the latest version can be found linked to Appendix 2, below.

# Project Handbook

101081813 — GDI

Date: January 2023

Version: 1v0

### *Document control information*

Settings	Value
Document Title	Project Handbook
Project Title	GDI
Document Author	Hannah Hurst, Nikki Coutts
Project Owner	Serena Scollen
Project Manager	Hannah Hurst
Doc. Version	1v0
Sensitivity	Public
Date	20/02/2023

### *Document history*

The Document Author is authorised to make the following types of changes to the document without requiring that the document be re-approved:

- Editorial, formatting, and spelling
- Clarification



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To request a change to this document, contact the Document Author or Owner by email to [gdi-coordination@elixir-europe.org](mailto:gdi-coordination@elixir-europe.org).

Changes to this document are summarised in the following table.

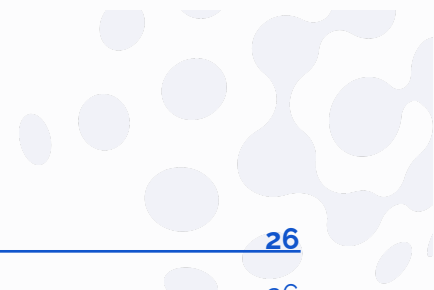
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17/02/2023	ov4	Hannah Hurst (ELIXIR Hub)	Comments and suggestions reviewed and closed
20/02/2023	1v0	Hannah Hurst (ELIXIR Hub)	Final version ready to submit as a deliverable

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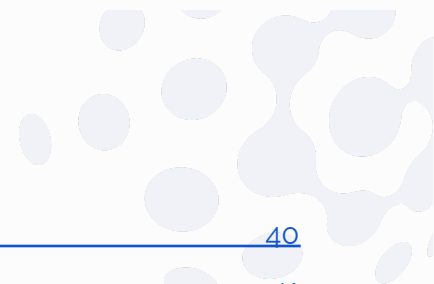
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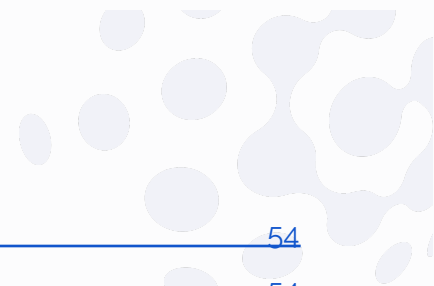






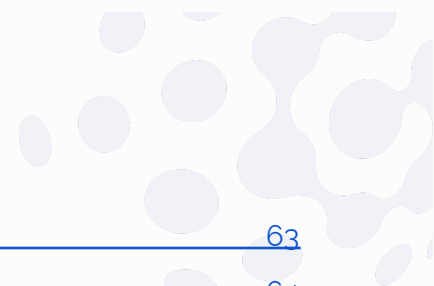
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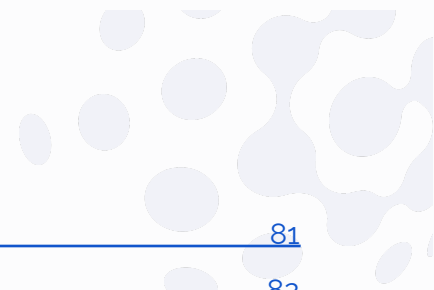
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## 1. About the project handbook

The Project Handbook provides a complete overview of the management and administrative procedures and principles to ensure an efficient execution of the European Genomic Data Infrastructure project (GDI) project, thus contributing to the production of high quality project results. The Project Handbook documents the selected approach for implementing the project goals, including the milestones and deliverables and relevant KPIs. It also highlights the key controlling processes to be used, the project policies and rules, and the overall management approach, including, but not limited to management structure, tasks, decision-making procedures, responsibilities and roles.

The Project Handbook is an important document since it contains all relevant planning information that the consortium partners will use as a framework for delivery during the course of the project.

The Project Handbook becomes the basis for managing the project throughout its lifecycle and is an important point of reference for all consortium partners and stakeholders. The Project Handbook is kept up to date throughout the life of the project.

Language adopted throughout the documents aims to be clear and concise.



Please note that this Project Handbook is circulated as a guidance document only. It should not be relied upon for making any legal assessments, for which Beneficiaries should always refer to the Grant Agreement (including its annexes)<sup>3</sup> and the Consortium Agreement<sup>4</sup>.

## 2. Project overview

### 2.1. Basic project information

Project Call: DIGITAL-2021-CLOUD-AI-01

Project Title: European Genomic Data Infrastructure

Project Acronym: GDI

Grant Agreement N°: 101081813

Project start date: 1st November 2022

Project end date: 31st October 2026

Duration: 48 months

Project budget: €40,000,000

EU Contribution: €20,000,000

Number of beneficiaries: 44

Number of AEs: 4

Number of APs: 6

### 2.2. Short names of the consortium partners

**Table 1.** Project Beneficiaries

Beneficiary n°	Name of the consortium partner	Short name
1 (Coordinator)	EUROPEAN MOLECULAR BIOLOGY LABORATORY (FOR ELIXIR AND EMBL-EBI)	EMBL

<sup>3</sup> GA: <https://drive.google.com/file/d/1k1M8tvPWqAXh-ElzZ7c5eTY5Z2yOxuox/view?usp=sharing>

<sup>4</sup> As of 27th January 2023 the Consortium Agreement is under negotiation by the project consortium



GDI project receives funding from the European Union's Digital Europe Programme under grant agreement number 101081813.

2	ERASMUS UNIVERSITAIR MEDISCH CENTRUM ROTTERDAM	ERASMUS MC
3	INSTITUTO DE SALUD CARLOS III	ISCI
4	INSTITUTO NACIONAL DE SAUDE DR. RICARDO JORGE	INSA
5	UNIVERSITE DU LUXEMBOURG	UNILU
6	CSC-TIETEEN TIETOTEKNIKAN KESKUS OY	CSC
7	UPPSALA UNIVERSITET	UU
8	VIB VZW	VIB
9	SCIENSANO	SC
10	MEDICAL UNIVERSITY SOFIA	MUS
11	UNIVERZA V LJUBLJANI	UL
12	UNIVERSITETET I OSLO	UIO
13	NATIONALT GENOM CENTER	NGC
14	RUDER BOSKOVIC INSTITUTE	RBI
15	Masarykova univerzita	MUNI
16	LATVIJAS BIOMEDICINAS PETIJUMU UN STUDIJU CENTRS	LBMC
17	FUNDACIO CENTRE DE REGULACIO GENOMICA	CRG-CERCA
18	TARTU ULIKOOL	UTARTU
19	EBERHARD KARLS UNIVERSITAET TUEBINGEN	UT
20	DEUTSCHES KREBSFORSCHUNGSZENTRUM HEIDELBERG	DKFZ



21	STICHTING HEALTH-RI	HRI
22	ASSOCIACAO BIP4DAB	BioData.pt
23	ROYAL COLLEGE OF SURGEONS IN IRELAND	RCSI
24	EMPIRICA GESELLSCHAFT FUR KOMMUNIKATIONS UND TECHNOLOGIEFORSCHUNG MBH	EMPIRICA
25	MINISTRY OF EDUCATION AND SCIENCE	MESBG
26	THE HEALTH RESEARCH BOARD	HRB
27	INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE	INSERM
28	UNIVERSITAETSKLINIKUM AACHEN	UKA
29	HELSINGIN YLIOPISTO	UH
30	UNIVERSITA CATTOLICA DEL SACRO CUORE	UCSC
31	STICHTING HET NEDERLANDS KANKER INSTITUUT-ANTONI VAN LEEUWENHOEK ZIEKENHUIS	NKI
32	INTERUNIVERSITAIR MICRO-ELECTRONICA CENTRUM	IMEC
33	LATVIJAS REPUBLIKAS VESELIBAS MINISTRIJA	MoH-LV
34	ACADEMISCH ZIEKENHUIS GRONINGEN	UMCG
35	VIESOJI ISTAIGA VILNIAUS UNIVERSITETO LIGONINE SANTAROS KLINIKOS	VULSK
36	CONSIGLIO NAZIONALE DELLE RICERCHE	CNR
37	BARCELONA SUPERCOMPUTING CENTER CENTRO NACIONAL DE SUPERCOMPUTACION	BSC
38	BIOBANKS AND BIOMOLECULAR RESOURCES RESEARCH INFRASTRUCTURE CONSORTIUM (BBMRI-ERIC)	BBMRI



39	ALBERT-LUDWIGS-UNIVERSITAET FREIBURG	ALU-FR
40	LIETUVOS SVEIKATOS MOKSLU UNIVERSITETO LIGONINE KAUNO KLINIKOS	KK
41	NACIONALINIS VEZIO INSTITUTAS	NVI
42	UNIVERZA V MARIBORU	UM
43	FONDAZIONE ISTITUTO ITALIANO DI TECNOLOGIA	IIT
44	UNIVERSITA VITA-SALUTE SAN RAFFAELE	UniSR

**Table 2.** Affiliated Entities

AE n°	Linked to	Name of the consortium partner	Short name
6.1	CSC	TERVEYDEN JA HYVINVOINNIN LAITOS	THL
22.1	BioData.pt	INSTITUTO SUPERIOR TECNICO	IST
22.2	BioData.pt	UNIVERSIDADE DE AVEIRO	UAVR
27.1	INSERM	CENTRE NATIONAL DE LA RECHERCHE SCIENTIFIQUE CNRS	CNRS

**Table 3.** Associated Partners

AP	Name of the consortium partner	Short name
45	BUNDESMINISTERIUM FUER BILDUNG UND FORSCHUNG	BMBF
46	BUNDESMINISTERIUM FUER GESUNDHEIT	BMG
47	SOTSIAALMINISTEERIUM	MSAE





48	VERKET FOR INNOVATIONSSYSTEM	Vinnova
49	MINISTERE DE L ENSEIGNEMENT SUPERIEUR ET DE LA RECHERCHE	MESR (LU)
50	HELSEDIREKTORATET	HDIR

## 2.3. Project acronyms

**Table 4.** Project Acronyms

Abbreviation	Meaning
<b>1+MG</b>	1+ Million Genomes Initiative
<b>1+MG CT</b>	1+ Million Genomes Coordination Team
<b>1+MG Group</b>	1+MG member states representatives and EC supporting the implementation of the 1+MG initiative
<b>AE</b>	Affiliated Entity
<b>AP</b>	Associated Partner
<b>B1MG</b>	Beyond 1 Million Genomes
<b>CA</b>	Consortium Agreement - Agreement concluded amongst GDI beneficiaries for the implementation of the Grant Agreement. Such an agreement shall not affect the parties' obligations to the Community and/or to one another arising from the Grant Agreement.
<b>CDA</b>	Confidential Disclosure Agreement
<b>CEG</b>	Commission Expert Group
<b>CSA</b>	Coordination and Support Action
<b>Consortium</b>	The GDI Consortium, comprising the named legal entities.



<b>DMP</b>	Data Management Plan
<b>DoA</b>	Description of Action
<b>EAB</b>	Ethics Advisory Board
<b>EC</b>	European Commission
<b>GA</b>	Grant Agreement - The agreement signed between the beneficiaries and the EC for the undertaking of the GDI project
<b>GA</b>	General Assembly - all project participants
<b>GB</b>	Governing Board
<b>GDI</b>	Genomic Data Infrastructure
<b>GDI-CO</b>	GDI Coordination office
<b>GDI-MB</b>	Genomic Data Infrastructure Managing Board (Coordination team + Pillar Leads)
<b>GoE</b>	Genome of Europe
<b>IAB</b>	Infrastructure Advisory Board
<b>IC</b>	Indirect Costs
<b>KPI</b>	Key Performance Indicator
<b>LTSB</b>	Long-Term Sustainability Board
<b>MoU</b>	Memorandum of Understanding
<b>NMG</b>	1+MG National mirror groups responsible for the national deployment of the recommendations endorsed by the 1+MG Group
<b>ODC</b>	Other direct costs



<b>PI</b>	Principal Investigator (lead researcher per Beneficiary)
<b>PM</b>	Project Manager
<b>PMs</b>	Person months
<b>PMT</b>	Project Management Team
<b>Project</b>	The sum of all activities carried out in the framework of the Grant Agreement.
<b>PO</b>	EC Project Officer handling the project
<b>Project Officer</b>	EC Project Officer handling the project
<b>QA</b>	Quality Assurance
<b>SIAB</b>	Scientific and Industry Advisory Board
<b>TBC</b>	To Be Confirmed
<b>TC</b>	Teleconference (telephone conference call)
<b>VC</b>	Videoconference (video conference call)
<b>WP</b>	Work Package

## 2.4. Project summary

The Genomic Data Infrastructure (GDI) project brings together national agencies, research organisations, and technology providers in 22 countries to provide a cross-border federated network of national genome collections, associated with other relevant data, for advancing data-driven biomedical research and personalised medicine solutions to benefit citizens of Europe. The project is designed to support the European 1+ Million Genomes (1+MG) Initiative.

Specifically, GDI will drive the development, deployment and operation of sustainable data-access infrastructures within each participating country including the legal frameworks, operational procedures and ethics principles required to foster and maintain citizens' trust in cross-border access



GDI project receives funding from the European Union's Digital Europe Programme under grant agreement number 101081813.

to highly sensitive personal data. It will unlock a data network of over 1 million genome sequences for research and clinical reference creating unprecedented opportunities for routine transnational, multi-stakeholder actions in personalised medicine for common, rare and infectious diseases. Authorised data users, such as clinicians, researchers and innovators, will be able to advance our understanding of genomics for more precise and faster clinical decision-making, diagnostics, treatments and predictive medicine, and for improved public health measures that will benefit citizens, healthcare systems and the overall economy.

Thus, GDI is one critical component of Europe's ambition to lead the integration of genomics into healthcare and the GDI project is designed to interact with the other actors working towards this ambition via incremental milestones that drive alignment along a dynamic roadmap.

Detailed Project information:

- [GDI Description of Action Part A](#)<sup>5</sup>: Project summary, List of participants, List of Work Packages, Staff Effort, List of Deliverables, List of Milestones, List of Critical Risks, Project Reviews.
- [GDI Description of Action Part B](#)<sup>6</sup>: Relevance, Implementation, Impact, Work Plan, Timing & Subcontracting, Ethics and Security, and Annexes.
- [Grant Agreement](#)<sup>7</sup>: Contract between the EC and the consortium establishing the obligations and conditions. [An annotated version is available here](#)<sup>8</sup>.
- [EC Grant Management Data](#)<sup>9</sup>: Requires login into the EC portal

Note: Documents above are particularly important for new joiners to understand the ambition of the project and the framework in which we have to operate

## 2.5. Project scope and work structure

This section outlines the relationship between GDI and the 1+MG initiative, the B1MG project, the EC and relevant stakeholders ([Figure 1](#)). Roles, synergies and differences will be outlined and clarified and, by doing so, any conflicts of interest will be identified.

<sup>5</sup>[https://drive.google.com/file/d/1vKWhJolIHYb9Ok5RJVCO7g\\_7\\_ycXTXIBY/view?usp=share\\_link](https://drive.google.com/file/d/1vKWhJolIHYb9Ok5RJVCO7g_7_ycXTXIBY/view?usp=share_link)

<sup>6</sup>[https://drive.google.com/file/d/1T6U9shAXpW-YWpNZDNWgdyPReTCgMAul/view?usp=share\\_link](https://drive.google.com/file/d/1T6U9shAXpW-YWpNZDNWgdyPReTCgMAul/view?usp=share_link)

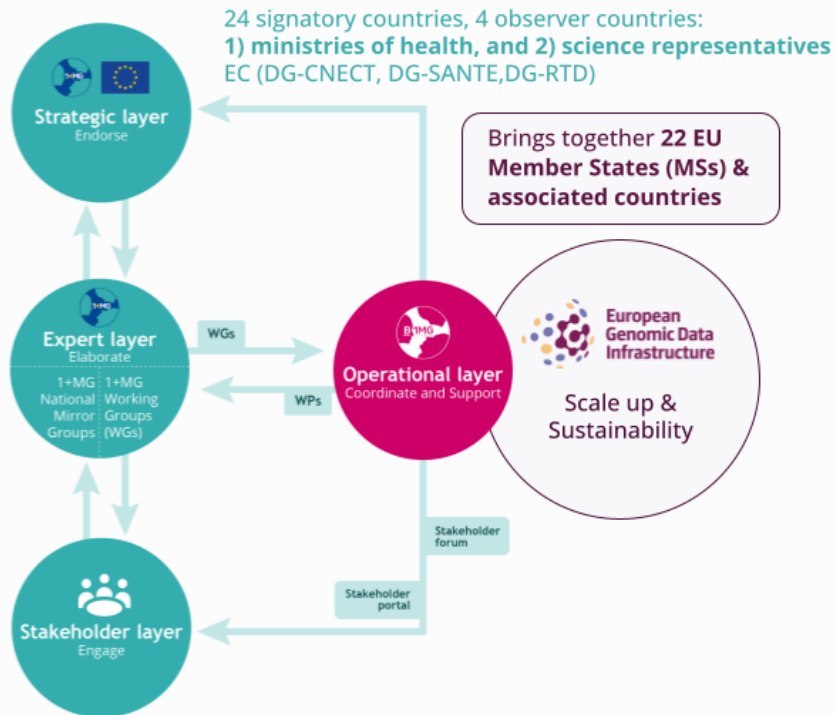
<sup>7</sup> <https://drive.google.com/file/d/1k1M8tvPWqAXh-ElzZ7c5eTY5Z2yOxuox/view?usp=sharing>

<sup>8</sup><https://drive.google.com/file/d/1rtHRX8znBUZ484qAkyWv26UnedYwuSG7/view?usp=sharing>

<sup>9</sup><https://ec.europa.eu/research/participants/grants-app/gap/h2020/GAP-101081813>



GDI project receives funding from the European Union's Digital Europe Programme under grant agreement number 101081813.



**Figure 1.** Model of the layers and interactions between GDI and the 1+MG initiative, the B1MG project, the EC and relevant stakeholders

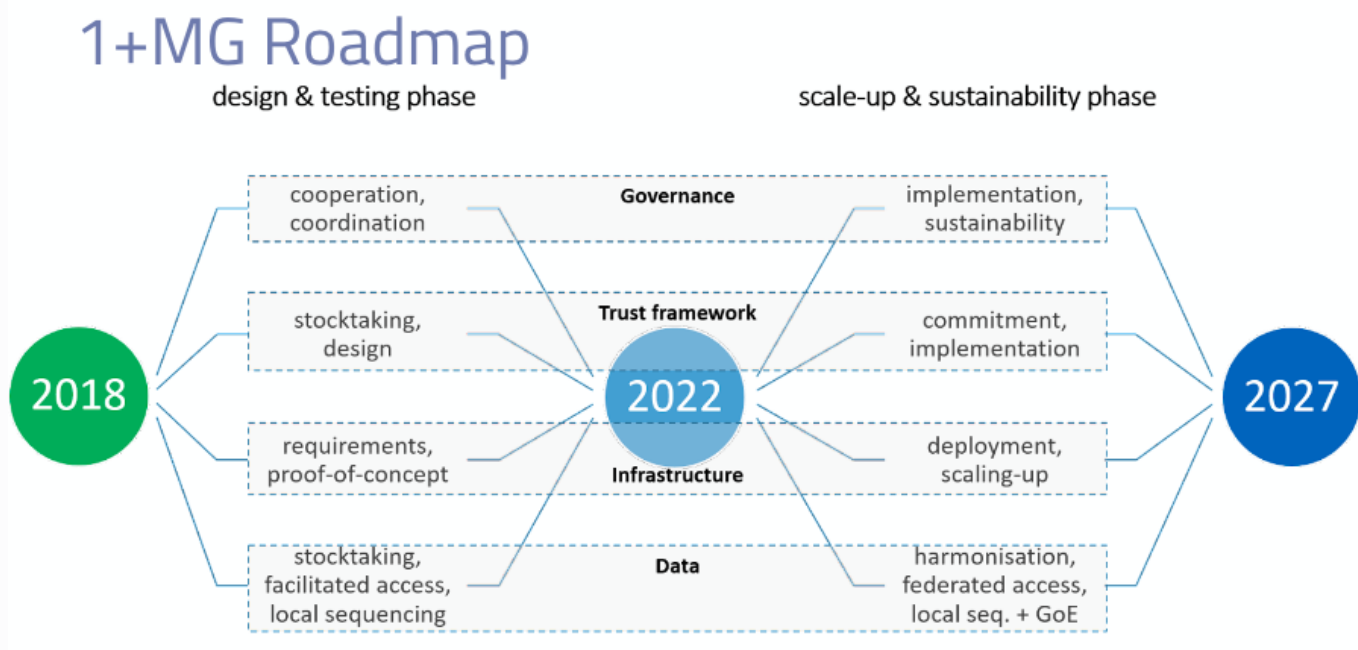
### 2.5.1. 1+MG

- Overarching role: 1+MG drives the development of a European infrastructure for federated and secure cross-border access to genomic and personalised medicine data by setting up a collaboration mechanism between signatory countries to:
  - ensure that appropriate technical infrastructure, allowing for secure, federated access to genomic data based on common standards that support applicable regulations, is available all over the EU;
  - ensure that ethical and legal implications of genomics, such as protection of personal data, security of stored data, ethical use of data and clear data ownership rules, are clear and taken into account, and are fully supported by the technical infrastructure;
  - ensure that the general public and policy makers in Member States and signatory countries are well informed about genomics and genomics-based health, in order to ensure its uptake by healthcare systems and integration into personalised healthcare and prevention.



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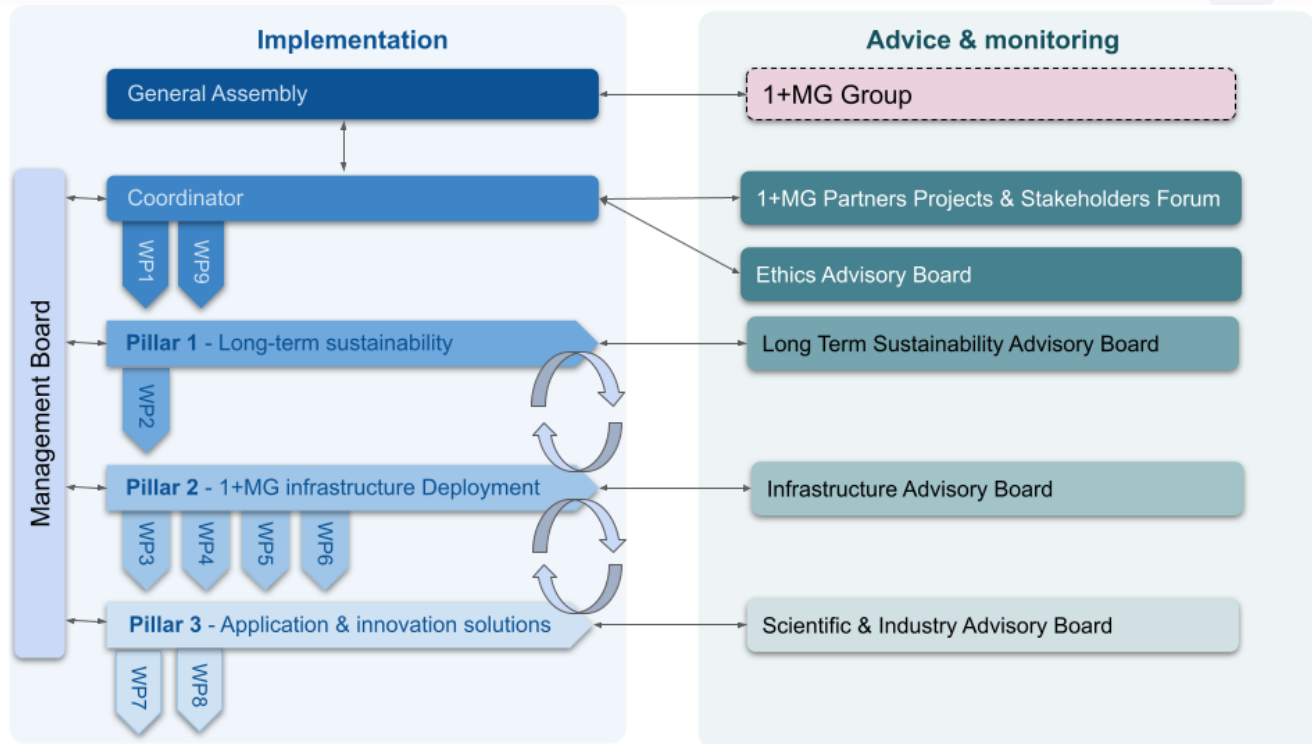
- Unlimited duration for the initiative to run but the initial promise was to deliver access to 1+ million genomes by 2022. This was a highly ambitious goal and has since been revised, with 2018 - 2022 being the design and testing phase (supported by the B1MG CSA) and 2022 - 2027 the scale-up and sustainability phase (supported by B1MG and GDI as well as various other projects) (See [Figure 2](#))
- Responsible for the relationships with signatory countries and EC, alignment among National Mirror Groups and the 12x 1+MG Working groups - activities and long term strategy
- 1+MG Signatory countries will be represented on the GDI Governing Board as outlined in the GDI proposal (See Figure 3).



**Figure 2.** 1+MG Roadmap, including the 2 phases: 'design and testing' and 'scale-up and sustainability'

### 2.5.2. GDI Project

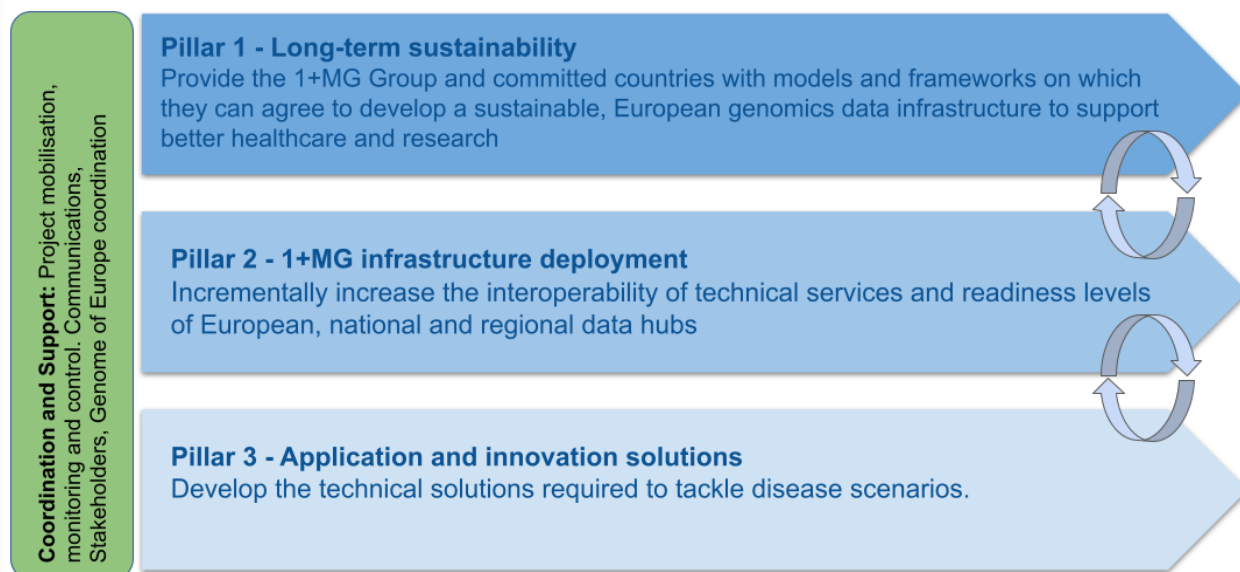
The GDI project consists of nine Work Packages, distributed across three technical pillars and a coordination pillar supporting and monitoring the project execution (Figure 3).



**Figure 3.** Governing Model of the GDI project

The GDI project's primary role is to develop the infrastructure that will fulfil the ambition of the 1+MG initiative by delivering the GDI DoA. Amendments to the DoA will be sought to ensure the DoA remains aligned with 1+MG Roadmap. The GDI consortium brings together 22 EU Member States (MSs) and associated countries (see Tables 1 & 2), who are involved in 1+MG and will collectively contribute to the deployment and development of the infrastructure.

The GDI project will make data accessible for research, clinical reference and policy development uses. To do this, the GDI project will be structured around three pillars with objectives outlined in [Figure 4](#).



**Figure 4.** GDI project objectives and the aligned project pillars.

Pillar I will establish the legal framework and the business models required to support European and national infrastructure operations, without preventing the infrastructure deployment. This pillar will look at the responsible sensitive data governance aspects providing additional requirements for pillar II. Pillar II will work on the establishment of the nodes and the European level services, initiating the deployment and operations of the 1+MG infrastructure ensuring it is fully operational and ready to enable access to data once the required agreements are in place. Pillar II will also assess the extension of the infrastructure to fulfil the 1+MG ambition - requirements received from pillar I and pillar III will be evaluated for their deployment in the infrastructure after the pillar generating the requirement has validated the implementation (change management process). Pillar III will guide implementation through key use cases (Genome of Europe demonstrator, rare disease, cancer, common complex diseases & infectious diseases), targeting users (clinicians, researchers, and innovators) and identifying standards and solutions that could be made part of the 1+MG infrastructure. With pillar II support, pillar III will evaluate whether the infrastructure provides services to fulfil the needs of use cases and targeted users. Innovative approaches will be explored, tested, and suggested to pillar II once they have been validated with use cases and the target users.

The coordination team of the GDI project has regular planned meetings with the 1+MG Coordination Team to ensure enough opportunity to align 1+MG and GDI activities at the strategic and operational levels (See [Table 5](#)).



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**Table 5.** GDI, 1+MG and EC coordination, via regular project meetings.

GDI	Period	How	Goal
<b>1+MG Coordination Group</b>	Weekly	VC. Attendance: 1+MG initiative Coordination Group Owner: 1+MG initiative (GDI coordinator as chair)	Strategic planning for the 1+MG initiative
<b>1+MG Group (external to GDI)</b>	Quarterly	Co-located with 1+MG signatories meeting. Attendance: 1+MG Group members, coordinator and relevant project participants Owner: EC	Alignment with 1+MG Group i.e. meeting template GB section
<b>Regular technical review meetings with PO (Project Officer) + EC internal Experts</b>	M9, M27.	VC or F2F @ EC premises - TBC. Technical report of project project. Attendance: PO, EC and external experts, coordinator and WP leaders Owner: EC	Technical Project Monitoring
<b>Regular technical and financial review meetings with PO (Project Officer) + EC internal Experts</b>	M18, M36 & M48	VC or F2F @ EC premises - TBC. Technical & financial report of project project. Attendance: PO, EC and external experts, coordinator and WP leaders Owner: EC	Technical and financial assessment of project performance
<b>GDI General Assembly</b>	Yearly	F2F. Attendance: Partners Owner: GDI Coordinator	GDI-GA GA meeting structure (TBC)
<b>GDI-CO (Coordination Office) (WP1)</b>	Monthly	VC. Attendance: WP1 Owner: GDI-CO	WP1 (Monitoring, Support, Communication, NMG Guidance, Sustainability)

<b>GDI Management Board</b>	Monthly	VC. Attendance: Coordinators (inc PMs) + Pillar Leaders & EC (Szymon Bielecki) Owner: GDI-CO	Coordinators/Pillar Leads <-> GDI WP alignment
<b>Board meetings (EAB, SIAB, LTSB, IAB)</b>	At least once a year (GA) or by GB request	F2F at annual GA + VC or F2F as needed, collocated another project meeting. Attendance: EAB, SIAB, LTSB, IAB, Coordinator Owner: GDI-CO	Independent advice.
<b>NMG (National Mirror Group) Coordinators</b>	At least once a year (GA) or by GB request	VC or collocated with another project meeting Attendance: NMG, CO Owner: GDI-CO	Ensure alignment with NMGs.
<b>WP1-WP8 TCs</b>	Monthly	VC. Attendance: WP members + unfunded external experts as required Owner: GDI WP Leaders	Align and implement GDI DoA with WP activities.
<b>Other WP level meetings (i.e. workshops)</b>	According to WP plan	VC or F2F. According to WP needs Owner: GDI WP Leaders	Progress on the delivery of project outputs

The pillar activities build on and complement the activities and outputs of the B1MG CSA project and of the 1+MG initiative WGs, including:

- sustainability briefs and support to establish National Mirror Groups (NMGs) that are a national reflection of the 1+MG WGs<sup>10,11</sup>
- stakeholder engagement
- the 1+MG Trust Framework<sup>12</sup>,
- use case needs<sup>13</sup>
- the maturity model that enables national or regional healthcare systems to self-evaluate the level of maturity of their genomic medicine practises and identify a path to optimisation

<sup>10</sup><https://zenodo.org/record/4813544#.YgVFhi-I30p>

<sup>11</sup><https://drive.google.com/file/d/1M2tgA3VmPN19Inabhr77W9t3e5qSh81Z/view>

<sup>12</sup>1+MG Trust Framework: brings together recommendations, guidelines and best practises to realise the 1+MG ambition encompassing the areas of ELSI, data standards, data quality and technical infrastructure

<sup>13</sup> 1+MG use cases: industry, rare diseases, cancer, common complex diseases, infectious disease



- 1+MG data infrastructure scoping report<sup>14</sup> and 1+MG/B1MG PoC<sup>15</sup>.

Building on consortia overlaps, the project coordination team will support pillar leads to establish working relationships with relevant projects and initiatives (additional to those previously mentioned), including Towards the European Health Data Space (TEHDAS)<sup>16</sup>, the European Health Data Space (EHDS)<sup>17</sup>, HealthyCloud<sup>18</sup>, Beyond COVID (BY-COVID)<sup>19</sup>, International Consortium for Personalised Medicine (ICPERMED)<sup>20</sup>, INTERVENE<sup>21</sup>, Solve-RD<sup>22</sup>. Links with Research Infrastructures (RIs) (EMBL-ELIXIR, The Biobanking and BioMolecular Resources Research Infrastructure (BBMRI-ERIC), Population Health Information Research Infrastructure (PHIRI), European Advanced Translational Research Infrastructure in Medicine (EATRIS) and European Clinical Research Infrastructure Network (ECRIN)) will be established either within the pillars for direct participation or at the board level to ensure RIs that could contribute and benefit from early understanding of the possibilities the 1+MG infrastructure has to offer.

**Time limited project:** expected November 2022 to October 2026

Support the 1+MG Coordination Team

- Maintaining the rolling agenda, taking minutes and follow-up actions
- Chairing 1+MG CT weekly meetings, including monthly meetings with 1+MG & WP Leaders.
- Note: physical meetings held regularly by the 12 1+MG WGs can not otherwise be supported by GDI. Participation of WG representatives in the individual WP meetings is encouraged based on agenda topics.

Support the 1+MG WGs via the GDI activities (see Figure 1 and Table 5) fostering 1+MG WG, Stakeholders and NMG participation in GDI WPs within the project limitations (Scope and Resources).

A common dissemination and communication strategy will be developed to ensure and maintain a high level of awareness, acceptance, and trust with the main groups of stakeholders. It is fundamental to give a voice to patients regarding the governance and use of their genomic data in the long-term, and for this purpose, representatives from cross-diseases umbrella patient organisations within Europe such as the European Patients Forum<sup>23</sup> will be included in the Long-Term Sustainability Board. There will also be a focused task to develop a framework and recommendations to raise awareness and enhance the knowledge of healthcare professionals

<sup>14</sup><https://zenodo.org/record/6089583#.YgusSd9Bw2x>

<sup>15</sup><https://www.youtube.com/watch?v=6MtlJA4xXdU>

<sup>16</sup><https://tehdas.eu/>

<sup>17</sup>[https://ec.europa.eu/health/ehealth-digital-health-and-care/european-health-data-space\\_en](https://ec.europa.eu/health/ehealth-digital-health-and-care/european-health-data-space_en)

<sup>18</sup><https://healthycloud.eu/>

<sup>19</sup><https://by-covid.org/>

<sup>20</sup><https://www.icpermed.eu/>

<sup>21</sup><https://www.interveneproject.eu/>

<sup>22</sup><https://solve-rd.eu/>

<sup>23</sup><https://www.eu-patient.eu/>



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regarding the potential of genomic medicine and genomic data sharing for clinical practice. Finally, content for communication directed at the general public will be developed for deployment by NMGs at the national level. Specific dissemination and communication actions will take place in pillar II towards the technical and scientific community that will be involved in the deployment and operation of the national nodes.

**Table 6.** Summary of the overlapping objectives of the CSA B1MG project and the GDI project indicating the transition point of key activities between the projects that overlap by 1 year.

B1MG	GDI
Guidance, recommendations and development of the 1+MG Trust Framework	Enhancement of guidelines and recommendations, building on B1MG outputs beyond August 2023 (end of B1MG project)
	Deployment, operation, support and expansion of the 1+MG infrastructure (B1MG has no FTE capacity for this)
Definition of Proof of Concepts (PoCs)  - RD and Cancer (technical deployment demonstrated via partner projects)	PoCs:  - GDI Pillar II - implementation across multiple use cases based in mature solutions (e.g. Beacon v2)  - GDI Pillar III - implementation of innovative solutions (e.g. federated learning)
<b>Pre-September 2023</b>	<b>In the absence of a CSA beyond B1MG (beyond Sept 2023)</b>
Coordination of the 1+MG WGs	Coordination of the 1+MG WGs
Stakeholder activities (B1MG WP1/6)	Stakeholder activities (GDI WP6)
Coordination support to GoE (B1MG WP6)	Coordination support to GoE (GDI WP1)
1+MG website and European genome dashboard (B1MG WP1/3/6)	1+MG website and European genome dashboard (GDI WP1 & Pillar II)

GDI will provide different levels of support to 1+MG Working Group (WG), NMG Coordinator and Stakeholders within the project limited budget

- At the WP Level
  - Each WP is encouraged to reach out to additional WG members to contribute and shape project deliverables as they are produced, as part of outreach activities. To that end, WP Lead beneficiaries have been allocated budget to self-organise events (WP meetings, workshops) and reimburse WG members' travel costs (within the limits set in the GA) where they are not funded directly by GDI.



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- At the coordination level
  - The coordinator also has funds set aside to reimburse travel costs of WG members, not funded in GDI, to attend main project events that are open to external participation.
- Note: Maximum travel cost reimbursement amounts for WG members not funded in GDI: €375 (1 day event), €550 (2 days event) and €750 (3 days event).
  - Registration: Ask who will require support to attend meetings (to keep check on budget expenditure).

Support the National Mirror Groups via the B1MG Task 6.3 and GDI Task 1.6, led by (ISCI, ELIXIR).

Stakeholder management via GDI WP1 (ELIXIR).

### 2.5.3. EC (DG-CNECT, in alignment with DG-RTD and DG-SANTE)

- Strategically important initiative for EC to shape Europe's healthcare and digital future.
- Custodian of the 1+MG Declaration, co-drafting, promoting, facilitating implementation and supporting efforts to get new countries to sign.
- Link with other initiatives implementing the relevant EU priorities (digital agenda, data spaces, AI, cancer beating plan), with ongoing H2020 projects and with future funding opportunities.
- Role of EC team in 1+MG
- :
  - Facilitation of communication with Member State representatives in the framework of the regular 1+MG Signatory meetings.
    - Advise and facilitate actions of the 1+MG coordination group
    - Provide facilities for physical Member States and working group meetings when they are held in Brussels
    - Run surveys and written consultations of 1+MG signatory states on behalf of the 1+MG coordination group
    - Facilitate interaction with external stakeholders
  - Chairing of Signatory meetings and providing Secretariat for them, until a final governance of the 1+MG initiative has been developed and implemented. Preparation for these meetings is in conjunction with the 1+MG coordination group, part of WG1 and in GDI Pillar I.
- Funding authority for the GDI project



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- contractual relationship with the consortium,
- monitoring the progress and spending in the project
  - The responsible PO closely follows the project, organises periodic project reviews (every nine (9) months) and ultimately approves its deliverables and outcomes (supported by the assessment by independent experts).

## 2.6. Project coordination and management

The GDI Coordination Office (GDI-CO) will establish effective project governance and internal communication procedures to allow for the flow of information within the project. It will also fulfil the administrative tasks associated with management of the project.

The overall goal of this WP is to oversee the project execution ensuring an effective and efficient coordination across all activities and participants to deliver the project goals, benefits and expected impact within time, scope and budget.

The GDI-CO is implemented via WP1, where the objectives are established:

1. Mobilise the project (Task 1.1)
2. Project monitoring and control (Task 1.2)
3. Project communication strategy (Task 1.3)
4. Wider communication strategy and stakeholder engagement (Task 1.4)
5. Genome of Europe support (Task 1.5)
6. National mirror groups support (Task 1.6)

All tasks will contribute to the incremental version of the project handbook that will define and update the different plans and processes, including the monitoring of project metrics and lessons learned, which will contribute to the continuous improvement of EC funded projects.





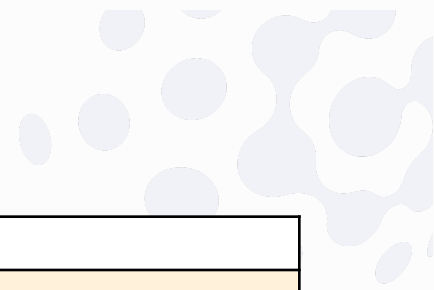
## 3. Project approach

### 3.1. Required project documentation

**Table 7.** Required Project Documentations

Artefact	Yes/No	Location	If No, briefly explain the reason
Description of Action - Part A	✓	<a href="https://drive.google.com/file/d/1vKWWhJoIHbYb9Ok5RJVCO7g_7_ycXTXIBY/view?usp=share_link">https://drive.google.com/file/d/1vKWWhJoIHbYb9Ok5RJVCO7g_7_ycXTXIBY/view?usp=share_link</a>	
Description of Action - Part B	✓	<a href="https://drive.google.com/file/d/1T6UgshAXpW-YWpNZDNWgdyPReTCgMAul/view?usp=share_link">https://drive.google.com/file/d/1T6UgshAXpW-YWpNZDNWgdyPReTCgMAul/view?usp=share_link</a>	
Grant Agreement	✓	<a href="https://drive.google.com/file/d/1k1M8tvPWqAXh-ElzZ7c5eTY5Z2yOxuox/view?usp=share_link">https://drive.google.com/file/d/1k1M8tvPWqAXh-ElzZ7c5eTY5Z2yOxuox/view?usp=share_link</a>	
Consortium Agreement - fully executed	X		Negotiations not yet finalised
Project Handbook (this document)	✓		
Project monitoring. Document includes: Technical (deliverables & milestones) & financial monitoring. Risk, issues and change management logs. Contacts and distribution lists	✓	<a href="https://docs.google.com/spreadsheets/d/1ioFrJO5PL5ZUFs5L_r3tQYT_KlUkw7ngjkoaUgNHO8cw/edit#gid=1662215412">https://docs.google.com/spreadsheets/d/1ioFrJO5PL5ZUFs5L_r3tQYT_KlUkw7ngjkoaUgNHO8cw/edit#gid=1662215412</a>	
Project Master File	✓	<a href="https://docs.google.com/spreadsheets/d/1nfXQtRcfnXsqiazqPoK3OGAeJja4no3h/edit#gid=1091682332">https://docs.google.com/spreadsheets/d/1nfXQtRcfnXsqiazqPoK3OGAeJja4no3h/edit#gid=1091682332</a>	
Data Management	X		Due month 6





Plan			
Other...			

## 3.2. Other standards

Holding place for future iteration.

## 3.3. Internal conflict resolution and escalation

Conflicts are situations in which one or both parties perceive a threat. They are considered to be critical issues and can be raised by any of the project stakeholders. The GDI-CO should proactively identify, log and raise such issues for resolution.

In the event that an internal conflict arises at a given time, the project coordination and the management structure is formulated to support a bottom-up approach with respect to its resolution.

- Conflicts amongst Beneficiaries in any given activity should be discussed at the Work Package (WP) level with the help of the respective Work Package Leaders (WPLs).
- If unresolved, the issue will escalate to the GDI-CO that will then use mediation to objectively aim to solve the issue involving all parties affected.
- If unresolved and when the issue is significant enough, the GDI-CO could then make a proposal:
  - To the GDI WPL impacted if the issue has very limited operational impact and can be resolved at this level.
  - To the GDI General Assembly (GA) if it is a non-strategic issue
  - To the Managing Board (GDI-MB), if it is a strategic issue, to amicably resolve the issue.
- In case no solution can be found which is acceptable to the Beneficiaries involved in the dispute, the dispute resolution mechanisms of the Consortium Agreement will apply.

At all stages, beneficiaries can reach out to the GDI-CO in case they feel a request has not been adequately dealt with.







## 4. Project processes

### 4.1. Risk management

#### 4.1.1. Risk identification and categorization

An initial list of key project risks has been identified during the preparation of the Action and a respective table of identified risks can be found in the DoA - Part A (p51)<sup>24</sup>.

All Beneficiaries are asked to screen their activities with regards to additional new risks and to promptly notify the GDI-CO of any significant new risk(s) having the potential to affect the completion of the assigned WP.

#### 4.1.2. Risk assessment, registry and action plan

The GDI-CO will add any new risks, including a description of the possible impact, to the risk register ([GDI Project Monitoring](#)<sup>25</sup> and EC Portal) and bring any additional risk(s) to the attention of the GDI Management Board.

Prioritisation of the risks will be based on the possible impact (I) and the probability (II) of realisation of the risk. Based on the prioritisation, appropriate mitigation activities and/or contingency plans will be developed.

Each identified risk is given a score from 1-5 for both risk likelihood and risk impact. These two scores are then multiplied to give a 'risk score'. A mitigation (for risks scoring 12 or above) and contingency plan for each identified risk has to be developed by the concerned owner (Work Package and the GDI-CO) and presented to the GDI MB as part of the risk management process. [The list of identified risks are stored in the GDI Project Monitoring](#)<sup>26</sup>. The management strategy should also be indicated for each risk: Avoid, Transfer, Manage, Accept, Archive.

#### 4.1.3. Risk monitoring

The [risk register](#)<sup>27</sup> will be reviewed by the GDI-CO on a monthly basis, informing the GDI MB of any significant change when it happens or at least every three months in the regular monthly meetings. WPLs and Task leads are asked to actively contribute to this activity which will be overseen by the GDI-CO.

An update of the risk assessment activity, including the major risks identified with their corresponding mitigation and contingency plans, will be included in the Periodic Reports to be

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<sup>24</sup> Risks. P51: [https://drive.google.com/file/d/1vKWhJoiHYb9Ok5RIVCO7g\\_7\\_ycXTXlBY/view?usp=share\\_link](https://drive.google.com/file/d/1vKWhJoiHYb9Ok5RIVCO7g_7_ycXTXlBY/view?usp=share_link)

<sup>25</sup> [https://docs.google.com/spreadsheets/d/1i0FrJO5PL5ZUFs5L\\_r3tQYTKlUkw7ngjk0aUgNHO8cw/edit#gid=915549057](https://docs.google.com/spreadsheets/d/1i0FrJO5PL5ZUFs5L_r3tQYTKlUkw7ngjk0aUgNHO8cw/edit#gid=915549057)

<sup>26</sup> [https://docs.google.com/spreadsheets/d/1i0FrJO5PL5ZUFs5L\\_r3tQYTKlUkw7ngjk0aUgNHO8cw/edit#gid=915549057](https://docs.google.com/spreadsheets/d/1i0FrJO5PL5ZUFs5L_r3tQYTKlUkw7ngjk0aUgNHO8cw/edit#gid=915549057)

<sup>27</sup> [https://docs.google.com/spreadsheets/d/1i0FrJO5PL5ZUFs5L\\_r3tQYTKlUkw7ngjk0aUgNHO8cw/edit#gid=915549057](https://docs.google.com/spreadsheets/d/1i0FrJO5PL5ZUFs5L_r3tQYTKlUkw7ngjk0aUgNHO8cw/edit#gid=915549057)



annually submitted to the European Commission. Newly identified risks will be communicated to the EC via the [EC project continuous monitoring tool](#)<sup>28</sup> (requires EC login).

The GDI-CO will drive the risk management process, dealing with the identification, assessment and follow-up of threats and opportunities likely to affect the project performance as a whole.

Concrete actions arising from the analysis of the risks will be included in the project monitoring tool and communicated to the relevant WPLs via email.

For any questions, contact [gdi-coordination@elixir-europe.org](mailto:gdi-coordination@elixir-europe.org).

## 4.2. Issue management

The project issue management process defines the activities related to identifying, documenting, assessing, prioritising, assigning, resolving and controlling issues. It is a four step process that the Project Management Team (GDI-CO) executes whenever required throughout the project lifecycle:

- Issue Identification: Issues can be identified by any project stakeholders throughout the project lifecycle, using different communication channels such as meetings, emails ([gdi-coordination@elixir-europe.org](mailto:gdi-coordination@elixir-europe.org)) and Slack (using the #coordination-team channel). The issues are registered in the [Issues log](#)<sup>29</sup> which forms part of the project monitoring tool.
- Issue Assessment and Action Recommendation: a first informal assessment by GDI-CO, considers the category, impact, urgency of the issue, followed by a more detailed analysis to identify the root cause and recommend a solution. This information is documented in the [Issues Log in the GDI Project Monitoring tool](#)<sup>30</sup> and used as input to the appropriate decision makers (based on the escalation process). The decision is also documented in the Issues Log.
- Actions Implementation: After issues are evaluated and the remediation actions approved, the GDI-CO will incorporate these actions into the appropriate project related documentation such as the [change log in the GDI Project Monitoring](#).
- Issue Control: During the monthly GDI-MB meetings the status of the issues related actions [incorporated into the GDI project monitoring](#) will be revised, and new issues identified.

The Issues log will be reviewed by the GDI-CO on a monthly basis, informing the GDI MB of any significant change when it happens or at least every three months in the regular monthly meetings.

Concrete actions arising from the analysis of the issues will be included in the project monitoring tool and communicated to participants and WPs involved via email.

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<sup>28</sup> <https://ec.europa.eu/research/participants/grants-app/reporting/DLV-101081813>

<sup>29</sup> [https://docs.google.com/spreadsheets/d/1i0FrJO5PL5ZUFs5L\\_r3tQYTKlUkw7ngjkoUgNHO8cw/edit#gid=1037062273](https://docs.google.com/spreadsheets/d/1i0FrJO5PL5ZUFs5L_r3tQYTKlUkw7ngjkoUgNHO8cw/edit#gid=1037062273)

<sup>30</sup> [https://docs.google.com/spreadsheets/u/0/d/1i0FrJO5PL5ZUFs5L\\_r3tQYTKlUkw7ngjkoUgNHO8cw/edit](https://docs.google.com/spreadsheets/u/0/d/1i0FrJO5PL5ZUFs5L_r3tQYTKlUkw7ngjkoUgNHO8cw/edit)





For any questions, contact [gdi-coordination@elixir-europe.org](mailto:gdi-coordination@elixir-europe.org).

### 4.3. Project change management

The project change management process defines the activities related to identifying, documenting, assessing, approving, prioritising, planning and controlling changes, and communicating them to all relevant stakeholders. It is a five step process that the Project Management Team (GDI-CO) executes whenever required throughout the project lifecycle:

- **Change Identification:** a request for a change can be submitted formally via an email to GDI-CO ([gdi-coordination@elixir-europe.org](mailto:gdi-coordination@elixir-europe.org)), or can be identified and raised during meetings as a result of decisions, issues or risks. The requested change should then be captured in the [Change Log section of the GDI Project Monitoring](#)<sup>31</sup> tool by the GDI-CO including information to identify the change, such as the requestor, a short description, identification date, etc.
- **Change Assessment and Action Recommendation:** the size and impact of the change on the project scope, schedule, cost, quality, risk, and other project boundaries is assessed, whereafter a recommended action will be documented by GDI-CO in the [Change Log section of the GDI Project Monitoring tool](#).
- **Change Approval:** the approval of a project change will be determined by the type and impact of the change requested and in line with best practice in EC grants. For low impact change requests, which do not require formal approval by the EC, GDI-CO will advise who must approve the change, be it GDI-CO, the GDI MB, or the General Assembly. If a formal change to the Grant Agreement is required then the GDI-CO will use the information provided in the Change Log as an input to the formal amendment request that will be submitted to the EC after the approval of the GA or the GDI-GB depending on the type of the change. Only when a significant change is requested or a number of smaller requests have been received, will an amendment request be submitted to the EC.
- **Change Implementation:** the activities related to the implementation of approved changes will be documented by the GDI-CO in close collaboration with the EC.
- **Change Control:** new or open changes will be identified/reassessed by the GDI-CO, using the [Change Log section of the GDI Project Monitoring tool](#) and will be brought to the attention of the GDI-MB or the GA in due course.

For any questions, contact [gdi-coordination@elixir-europe.org](mailto:gdi-coordination@elixir-europe.org).

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<sup>31</sup>[https://docs.google.com/spreadsheets/u/0/d/1i0FrJO5PL5ZUFs5L\\_r3tQYTKIUkw7ngjk0aUgNHO8cw/edit](https://docs.google.com/spreadsheets/u/0/d/1i0FrJO5PL5ZUFs5L_r3tQYTKIUkw7ngjk0aUgNHO8cw/edit)



## 4.4. Quality management

The implementation and execution of GDI follows the principles of the Digital Europe Programme and European Commission (EC) rules and are more specifically defined in the Grant Agreement, the Description of Action and in the Consortium Agreement provisions. The procedures described in this section shall not replace any of the established agreements within the consortium or with the EC, or any of the EC guidelines for project implementation. The project will be managed according to EC best practice with a dedicated communications effort.

GDI will explore the establishment and operation of a suite of high-quality communications channels, periodic project monitoring including work plan execution, quality assurance, data management, use of resources, innovation management activities, communication, issues, risks and change.

GDI quality objectives are to:

- Ensure that all the project related activities and deliverables are fulfilling the scientific and technical quality expectations and are following available quality and compliance standards issued by the EC under the Digital Europe Programme (DEP) funding scheme.
- To define the processes and assets to be utilised by all consortium partners to meet these objectives and to provide support to partners to achieve the required quality and to monitor adherence to the standards set for the project, in alignment with the DoA.
- Ensure compliance with agreed DEP and EC rules, applicable law and regulations, including, but not limited to, data privacy, handling of funds and ethics.

According to DEP rules the Project Coordinator is also asked to promote gender equality in the project and science and society issues related to the research activities conducted within the project.

### 4.4.1. Quality policy

The generic quality policy adopted by GDI builds upon the following set of principles:

- Quality and its pursuit are regarded as important for every individual activity within the project.
- Criteria and standards by which the quality of both the results of the project and the processes involved in their production will be identified.
- Description of the tools, methods and techniques to be employed in order to ensure quality will be disseminated.
- Allowance must be made for monitoring quality during the process and recording compliance and deviation.



GDI project receives funding from the European Union's Digital Europe Programme under grant agreement number 101081813.

Taking into consideration the overall quality policy, quality standards are to be applied to all the work undertaken throughout the project.

#### 4.4.2. Project quality control

The overall quality control of the project results includes the coordination of quality review for all project outputs prior to their submission to the EC.

It is crucial for the project to ensure that deliverables, as official results of the project, are reviewed and checked for quality. This may also apply to other outcomes of the project that are addressed to parties external to the project.

The present document is focusing only on the general methods implemented to ensure quality of written materials delivered to the EC and other partners external to the Consortium. A document produced in a project generally aims to provide information concerning the work, its progress or the derived results. Each document should thus be carefully drafted with rich content, a clear structure and a professional presentation. The three basic aspects for building quality into project documents are content, appearance and timing. It is generally accepted that the relative importance of each document varies, and it is important that overzealous quality criteria do not compromise timing if marginal benefit to the project is minimal.

Deliverables of relevance to the 1+MG Initiative will be shared with the 1+MG Group before submission to the EC.

For more information about the process, [see section 7.1.3. Deliverable review process](#).

### 4.5. Configuration management

#### 4.5.1. Storage of project management artefacts

##### 4.5.1.1. Project repository

The project management team (GDI-CO) have created a structured [GDI Google Shared Drive](#)<sup>32</sup> to store the project management artefacts following the same folder convention per sub-folder. Only those who have completed the project registration form will be able to access the repository. The PI for each project BEN, AP and AE must validate the list of individuals with access to the drive for their institution. If a PI doesn't or can't validate an individual then they will not be able to access the project repository. No one external to the project will be able to access the repository.

**Table 8.** Project repository structure.

Top Level Folders	Content
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<sup>32</sup> [https://drive.google.com/drive/folders/1h-dtZjiJ84OPlkCiKqSF6o7KpylqidaX?usp=share\\_link](https://drive.google.com/drive/folders/1h-dtZjiJ84OPlkCiKqSF6o7KpylqidaX?usp=share_link)



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<b>1. Project MASTER File</b>	<p>Master document with details from the project: contact lists, effort distribution, lists of deliverables &amp; milestones, Gantt chart etc</p> <p>Project monitoring spreadsheet - contains details of all actions, events, deliverables and milestones, along with due dates and templates - monthly reports are generated from this for all partners/WPs. It includes the email address of the partners' participants that are relevant for the monitoring and control activities: PIs, Deputies, administrative, financial and legal contacts.</p>
<b>2. Legal Documents</b>	Legal documents pertaining to the project: Consortium Agreement, Grant Agreement, Description of Action, amendments, contracts etc
<b>3. Pillars/WPs</b>	Working folders for the Pillars and WPs
<b>4. Deliverables &amp; Milestones</b>	Repository for project deliverables and milestones (templates, working drafts and submitted documents)
<b>5. Project meetings, Events &amp; TCs</b>	Details of all project meetings and events (agendas, minutes slide presentations etc)
<b>6. Periodic Reporting</b>	Financial and periodic reports from all project partners
<b>7. Guidance and Templates</b>	<p>Project handbook, containing guidance pertaining to all aspects of the project (processes, communications, management structure and responsibilities etc)</p> <p>Project templates: deliverables, milestones, agendas, minutes, slide presentations etc</p>
<b>8. Project Communications and Outreach Materials</b>	Project branding & style guidelines, press releases, articles, presentations, newsletters etc
<b>9. Grant Agreement Preparation</b>	Working documents for the preparation of the grant agreement

For any assistance with accessing or creating new folders, please contact [gdi-coordination@elixir-europe.org](mailto:gdi-coordination@elixir-europe.org).

Utilisation of project repository is covered in [4.6.3. File Exchange and Repository](#)



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#### 4.5.2. Naming convention of project management artefacts

Folders and documents within the repository will be named using the ISO 8601 standard<sup>33</sup> to represent dates. This means, dates will use the style “YYYYMMDD/ 20221117” in file names and in meeting notes.

Files names should adopt the following template:

**‘YYYYMMDD\_Title of document’**

#### 4.5.3. Versioning of project management artefacts

All project management artefacts are under version control.

For example, the versioning table at the start of each project Deliverable:

Date	Mvm	Who	Description
02/12/2022	ov1	Nikki Coutts (ELIXIR Hub)	Initial drafting template created
30/01/2023	ov2	Hannah Hurst (ELIXIR Hub)	Initial version finalised and ready to share with consortium for review & input
10/02/2023	ov3	Hannah Hurst (ELIXIR Hub)	Initial version reviewed by Consortium
17/02/2023	ov4	Hannah Hurst (ELIXIR Hub)	Comments and suggestions reviewed and incorporated
20/02/2023	1v0	Hannah Hurst (ELIXIR Hub)	Final version ready to submit

<sup>33</sup> <https://www.iso.org/iso-8601-date-and-time-format.html>







## 4.6. Communications management

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

The regular project meetings are identified in [Table 5](#).

The GDI communication strategy is a formal project deliverable that is due in M06 (D1.2 Project communication strategy). Once submitted this document will link to the deliverable.

### 4.6.1. Communication Plan

The GDI consortium will adopt the following approach to communications:

- Use of electronic mail as the main tool for communication within the consortium.
- Slack workspace available for instant message & sharing. Group communication channels will be created by the GDI-CO following a request by a WP or Task Leader. Access to the Slack workspace will only be granted when an individual has completed the project registration form.
- Documentation of discussions, agreements and decisions made by phone is encouraged. Specifically, phone and video conferences should always have an agenda and minutes, which should be made available through the GDI project Shared Drive in the appropriate folder.
- Video conferences should be scheduled using the project Zoom accounts which will be made available to the Pillar Leaders as soon as they are available. At the time of publishing the Handbook, the accounts aren't yet in place but are expected in the coming weeks. The following accounts have been requested:
  - [gdi-pillar\\_i\\_zoom@elixir-europe.org](mailto:gdi-pillar_i_zoom@elixir-europe.org)
  - [gdi-pillar\\_ii\\_coord\\_zoom@elixir-europe.org](mailto:gdi-pillar_ii_coord_zoom@elixir-europe.org)
  - [gdi-pillar\\_ii\\_tech\\_zoom@elixir-europe.org](mailto:gdi-pillar_ii_tech_zoom@elixir-europe.org)
  - [gdi-pillar\\_iii\\_zoom@elixir-europe.org](mailto:gdi-pillar_iii_zoom@elixir-europe.org)
- Several distribution lists have been initially created which can be used by any participant depending on the subject of the message. Additional lists may be created as the project evolves, if necessary. The GDI-CO team will be responsible for updating the below-mentioned lists with the information received from participants. When a list is used, care should be taken





by participants to use the “reply to all” feature only when relevant. The table below shows the distribution lists created by the time of publishing this Handbook.

**Table 8.** Distribution Lists

Distribution list	Description
<a href="mailto:gdi-msreps@elixir-europe.org">gdi-msreps@elixir-europe.org</a>	Member State Representatives + their deputies following the nominations from the MS concerned + Project Coordinators + Empirica
<a href="mailto:gdi-pillar1@elixir-europe.org">gdi-pillar1@elixir-europe.org</a>	Pillar I leads + members as nominated by the MS Reps + Project Coordinators + Empirica
<a href="mailto:gdi-pillar2@elixir-europe.org">gdi-pillar2@elixir-europe.org</a>	Pillar II leads + members as nominated by the MS Reps + Project Coordinators + Empirica
<a href="mailto:gdi-pillar3@elixir-europe.org">gdi-pillar3@elixir-europe.org</a>	Pillar III leads + members as nominated by the MS Reps + Project Coordinators + Empirica
<a href="mailto:gdi-pillar-leaders@elixir-europe.org">gdi-pillar-leaders@elixir-europe.org</a>	Pillar leads + Project Coordinators + Empirica
<a href="mailto:gdi-coordination@elixir-europe.org">gdi-coordination@elixir-europe.org</a>	Serena Scollen, Hannah Hurst, Juan Arenas, Nikki Coutts
<a href="mailto:gdi-eb@elixir-europe.org">gdi-eb@elixir-europe.org</a>	Editorial Board Members + Project Coordinators
<a href="mailto:gdi-all@elixir-europe.org">gdi-all@elixir-europe.org</a>	All those signed up to any of the GDI mailing lists + Project Coordinators
<a href="mailto:gdi-scientific@elixir-europe.org">gdi-scientific@elixir-europe.org</a>	All those signed up to any of the WP mailing lists + Project Coordinators
<a href="mailto:gdi-mb@elixir-europe.org">gdi-mb@elixir-europe.org</a>	Pillar Leads (and deputies) + Project Coordinators
<a href="mailto:gdi-wpls@elixir-europe.org">gdi-wpls@elixir-europe.org</a>	Work Package Leads (and deputies) + Project Coordinators
<a href="mailto:gdi-wp1@elixir-europe.org">gdi-wp1@elixir-europe.org</a>	All those signed up to the WP1 mailing list + Project Coordinators
<a href="mailto:gdi-wp2@elixir-europe.org">gdi-wp2@elixir-europe.org</a>	All those signed up to the WP2 mailing list + Project Coordinators

<a href="mailto:gdi-wp3@elixir-europe.org">gdi-wp3@elixir-europe.org</a>	All those signed up to the WP3 mailing list + Project Coordinators
<a href="mailto:gdi-wp4@elixir-europe.org">gdi-wp4@elixir-europe.org</a>	All those signed up to the WP4 mailing list + Project Coordinators
<a href="mailto:gdi-wp5@elixir-europe.org">gdi-wp5@elixir-europe.org</a>	All those signed up to the WP5 mailing list + Project Coordinators
<a href="mailto:gdi-wp6@elixir-europe.org">gdi-wp6@elixir-europe.org</a>	All those signed up to the WP6 mailing list + Project Coordinators
<a href="mailto:gdi-wp7@elixir-europe.org">gdi-wp7@elixir-europe.org</a>	All those signed up to the WP7 mailing list + Project Coordinators
<a href="mailto:gdi-wp8@elixir-europe.org">gdi-wp8@elixir-europe.org</a>	All those signed up to the WP8 mailing list + Project Coordinators
<a href="mailto:gdi-admin@elixir-europe.org">gdi-admin@elixir-europe.org</a>	GDI Admin contacts + Project Coordinators
<a href="mailto:gdi-finance@elixir-europe.org">gdi-finance@elixir-europe.org</a>	GDI Finance contacts + Project Coordinators
<a href="mailto:gdi-legal@elixir-europe.org">gdi-legal@elixir-europe.org</a>	GDI Legal contacts + Project Coordinators

For any questions, please contact [gdi-coordination@elixir-europe.org](mailto:gdi-coordination@elixir-europe.org).

#### 4.6.2. Email guidelines

Good practice when using email is essential.

- Project related mails should be tagged with project short name "GDI:" and also indicate when action is required (ACTION NEEDED, FEEDBACK NEEDED, FOR INFORMATION etc.).
- Participants must respond promptly to any email received. When that is not possible, at least acknowledgement of receipt of all messages is strongly recommended, especially when answering an explicit request.
- Carefully consider whether "reply to all" is required and used. For example, the following do not need to be sent as a "reply to all":
  - Beneficiary bank details. If responding to a request from the coordinator, please send to [gdi-coordination@elixir-europe.org](mailto:gdi-coordination@elixir-europe.org)



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- Any other personal data. If responding to a request from the coordinator, please send to [gdi-coordination@elixir-europe.org](mailto:gdi-coordination@elixir-europe.org). If the request is from someone else, please send it to the sender only following the instructions provided in the email
- Meeting apologies. If you are unable to attend a meeting, please inform the meeting host(s) in advance of the meeting.
- All emails sent to any of the mailing lists created so far should start with "GDI:" in the subject section and senders should add the subject of the message.
- When individual messages between participants are exchanged, use of the same tag is strongly encouraged (e.g. GDI: WPL meeting\_agenda).
- Messages need to be concise but clear, especially when requests are made.
- Message text should include the content needed for the recipient to action the requests.
- Deadlines must be made explicit.
- All relevant issues for the work to be performed should be clarified/clear.
- Be considerate of diverse working schedules and recognise that there is no obligation for people to respond to emails outside of their typical working hours.

### 4.6.3. File Exchange and Repository

#### 4.6.3.1 GDI Repositories

##### 4.6.3.1.1 GDI Google Shared Drive

A Google Shared Drive instance has been created for GDI to be used as a repository of relevant information and files which facilitates the exchange of documents within the consortium (i.e. meeting minutes, documents in progress, final versions and other relevant reports or announcements). The GDI Google Shared Drive also provides the possibility of discussion between participants through messages, maintenance of a calendar of meetings and events, upload of files, and tracking of important milestones and events at both the project and Work Package level.

- All beneficiaries have been enabled access to the GDI project Shared Drive once they have signed up to the mailing lists. New accesses can be requested by completing the project registration form<sup>34</sup>.
- The latest version of the GDI contact list is uploaded on the GDI project Shared Drive, in the Registered Contacts section of the Project Monitoring spreadsheet<sup>35</sup>. The up-to-date

<sup>34</sup>[https://docs.google.com/forms/d/e/1FAIpQLSfgQ7XfxsgzNLmsU6IZq8ZzcbVgGlpBcoQqg7uxrp9x\\_adU6g/viewform](https://docs.google.com/forms/d/e/1FAIpQLSfgQ7XfxsgzNLmsU6IZq8ZzcbVgGlpBcoQqg7uxrp9x_adU6g/viewform)

<sup>35</sup>[https://docs.google.com/spreadsheets/d/1ioFrJO5PL5ZUF55L\\_r3tQYTKIUkw7ngjkoaUgNH08cw/edit#gid=1662215412](https://docs.google.com/spreadsheets/d/1ioFrJO5PL5ZUF55L_r3tQYTKIUkw7ngjkoaUgNH08cw/edit#gid=1662215412)



participants' contact information, with clear information of who is included in every mailing list mentioned above, will be based on periodic reviews of the mailing list subscribers in consultation with the project PIs..

- The use of de facto standards based on Google Docs for electronic document exchange among participants is required when possible. PDF format can alternatively be used to avoid excessive size of files when no editing is required.  
GDI uses a Google Shared Drive as a project management tool that is simultaneously used as a document management system. The GDI project Shared Drive provides a place to store, secure and organise the consortium documentation which helps to ultimately control the quality of documents and conformity of processes.
- The GDI Google calendar will be regularly maintained and will include core project meetings (e.g. MB monthly meetings, WP monthly meetings, Pillar meetings) and important project deadlines (such as technical/financial reporting).

The tool has capabilities available to set permissions on a file or folder. These clear access rights can be rapidly degraded or defeated entirely by the sysadmin (coordinator) of the consortium. Users with proper visibility rights and access permission can fuel quality control of the project.

Additionally, a document version history is an efficient way to track who has edited files and when. This platform allows users to revert to an earlier version if the file becomes corrupted or if errors are introduced.

With the notification feature available, each person with permission can invite other consortium participants on document edits and to track changes to a document stored in a shared folder simultaneously.

GDI uses Google Shared Drive to manage quality of the documents and processes by enhancing the centralization of digital assets, promote maintenance of quality and support backup and data protection.

The Documents Versioning Policy outlined in Section 4.5.2. (Configuration Management), is key to clean and consistent archiving; especially towards the mid/end phase of the project when an increasing number of digital outputs and documents are created. Using the same tag for email subjects and for the documentations in attachments, fuels clear communication and leads to reduced email burden and duplication of work.





#### 4.6.3.1.2 GDI - Pillar I GOV Teams Drive

As with the project Google Shared Drive described above, a Microsoft Teams Drive has been created by the GDI-CO at the request of Pillar I leads, specifically for the purpose of sharing confidential information with the members of the Pillar I GOV meetings.

- The Pillar I leads maintain a list of those project participants who require access to the confidential repository. Only the members of the Pillar I GOV meetings and GDI-CO members may have access to the drive.
- The drive is owned and maintained by the GDI-CO and only they have permissions to grant access to the drive.
- GDI-CO will only provide or revoke access to the drive at the request of Pillar I leads.

#### 4.6.3.2 1+MG Initiative Repository

In addition to the project repository, the GDI Coordination Office (GDI-CO) will provide the 1+MG repository for the Coordination Group (after the B1MG CSA has finished).

If required by the WG leaders, the GDI-CO can provide 1+MG WG members with their own repositories upon request.

#### 4.6.4. Dissemination

Dissemination is an important activity for all EC projects, a fact that is recognised in the project Grant Agreement<sup>36</sup>, which requires that we make our scientific work and results openly available, as early as possible and in a form that is easily accessible, understandable and reusable.

Any publication in GDI is governed by Article 17 - Communication, Dissemination and Visibility<sup>37</sup> of the Grant Agreement and Article 8.4 of the Consortium Agreement<sup>38</sup>. Scientific Publications and Communication to the public will be covered by D1.2 Project communication strategy due in Mo6.

All partners must follow the dissemination circulation procedure set out in Clause 8.4.2.1 of the Consortium Agreement<sup>39</sup>.

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<sup>36</sup>[https://drive.google.com/file/d/1k1M8tvPWqAXh-ElzZ7c5eTY5Z2yOxuox/view?usp=share\\_link](https://drive.google.com/file/d/1k1M8tvPWqAXh-ElzZ7c5eTY5Z2yOxuox/view?usp=share_link)

<sup>37</sup><https://drive.google.com/file/d/1k1M8tvPWqAXh-ElzZ7c5eTY5Z2yOxuox/view?usp=sharing>

<sup>38</sup> As of January 2023 the Consortium Agreement is under negotiation

<sup>39</sup> As of January 2023 the Consortium Agreement is under negotiation



The European Commission also provide a guide on '[Communicating about your EU-funded project](https://rea.ec.europa.eu/communicating-about-your-eu-funded-project_en)'<sup>40</sup> and this [informative flyer](https://op.europa.eu/en/publication-detail/-/publication/41da9b1e-1c45-11ed-8fa0-01aa75ed71a1/language-en/format-PDF/source-264404113)<sup>41</sup> which is relevant for all recipients of EU project funding.

#### 4.6.4.1 External talks and presentations

To track all dissemination activities contributed by GDI partners, we created a [Google spreadsheet \(Dissemination activities tracker\)](https://docs.google.com/spreadsheets/d/1dtQwIS_LapIU5NQH7WHFADb2Nb2FHxG-DFZYH8GJwSI/edit#gid=0)<sup>42</sup> for partners to input information on external activities, including events that partners have attended, spoken or presented at. Project partners should fill in the spreadsheet once they have delivered a talk or presented a poster at an external event. The information needed includes:

- Name of the event
- Date and location
- Website link
- Who attends or speaks
- Topic of the presentation
- Type of presentation (talk, panel discussion, poster presentation or others)
- Type of audience (industry, academia, policy maker, public or others)

With the [Dissemination activities tracker](https://op.europa.eu/en/publication-detail/-/publication/41da9b1e-1c45-11ed-8fa0-01aa75ed71a1/language-en/format-PDF/source-264404113), we also aim to track GDI publications submitted during the project period. Project partners should fill in the tracker when they have published a GDI project-related paper. The information needed includes:

- Paper title
- Authors
- Paper URL or DOI
- Publication date and year
- Publication type (GDI-led publication, GDI cited paper or others)

#### 4.6.5. Open Access policy and requirements

Annex 5 (p.151) of the EC Annotated Model Grant Agreement (AMGA)<sup>43</sup> details the obligations related to the provision of open access to scientific publications. Please review this section for a full explanation of the dissemination expectations.

<sup>40</sup> [https://rea.ec.europa.eu/communicating-about-your-eu-funded-project\\_en](https://rea.ec.europa.eu/communicating-about-your-eu-funded-project_en)

<sup>41</sup> <https://op.europa.eu/en/publication-detail/-/publication/41da9b1e-1c45-11ed-8fa0-01aa75ed71a1/language-en/format-PDF/source-264404113>

<sup>42</sup> [https://docs.google.com/spreadsheets/d/1dtQwIS\\_LapIU5NQH7WHFADb2Nb2FHxG-DFZYH8GJwSI/edit#gid=0](https://docs.google.com/spreadsheets/d/1dtQwIS_LapIU5NQH7WHFADb2Nb2FHxG-DFZYH8GJwSI/edit#gid=0)

<sup>43</sup> <https://drive.google.com/file/d/1rtHRX8znBUZ484qAkyWv26UnedYwuSG7/view?usp=sharing>



We must ensure open access (free, online access for any user) to all peer-reviewed scientific publications relating to our GDI project results.

Published articles (peer-reviewed or not) have to be submitted to GDI-CO in PDF format. The document(s) will be made available to the consortium on the GDI project Shared Drive in the Articles folder<sup>44</sup> and listed in the publications and dissemination activities spreadsheet<sup>45</sup>.

#### 4.6.6. EU Funding Acknowledgement

As set out in Article 17 of the Grant Agreement<sup>46</sup>, unless otherwise agreed with the granting authority, communication activities of the beneficiaries related to the GDI project (including media relations, conferences, seminars, information material, such as brochures, leaflets, posters, presentations, etc., in electronic form, via traditional or social media, etc.), dissemination activities and any infrastructure, equipment, supplies or major result funded by the grant must acknowledge EU support and display the European flag (emblem) and funding statement (translated into local languages, where appropriate):

1. display the EU emblem and

To be used for GDI:

- Download the EU emblem<sup>47</sup> in different versions and formats



- When displayed together with another logo, the EU emblem must have appropriate prominence.
- For the purposes of our obligations under Article 17 of the GA, the beneficiaries may use the EU emblem without first obtaining approval from the Commission.

2. include the following text:

GDI acknowledgement:

For communication activities:

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<sup>44</sup> <https://drive.google.com/drive/folders/13x-uyVGxZDmyFQEa28ofTyMWpNUHceai>

<sup>45</sup>

<sup>46</sup> [https://drive.google.com/file/d/1k1M8tvPWqAXh-ElzZ7c5eTY5Z2yOxuox/view?usp=share\\_link](https://drive.google.com/file/d/1k1M8tvPWqAXh-ElzZ7c5eTY5Z2yOxuox/view?usp=share_link)

<sup>47</sup> [https://europa.eu/european-union/about-eu/symbols/flag\\_en](https://europa.eu/european-union/about-eu/symbols/flag_en)



GDI project receives funding from the European Union's Digital Europe Programme under grant agreement number 101081813.

***“GDI project receives funding from the European Union’s Digital Europe Programme under grant agreement number 101081813.”***

For infrastructure, equipment and major results:

***“This [infrastructure][equipment][insert type of result] is part of a project that has received funding from the European Union’s Digital Europe Programme under grant agreement number 101081813”***

A copy of the funding acknowledgement is stored on the GDI project Shared Drive<sup>48</sup>. The funding acknowledgement should be translated into local languages, where appropriate.

If it is not possible to use this exact statement (e.g. if numerous grants are cited), please ensure that at least the grant's name (GDI) and the grant agreement number (101081813) are specified in the Acknowledgements or Funding Statement of the publication, as this helps with detecting articles using text-mining.

- A formal acknowledgement of EC support

Disclaimer excluding Commission responsibility: Any communication activity related to the action must indicate that it reflects only the author's view and that the Commission is not responsible for any use that may be made of the information it contains.

GDI disclaimer:

***This communication reflects the views of the authors and neither the European Union or any Associated Partners are liable for any use that may be made of the information contained herein.***

#### 4.6.7. Project Branding

The GDI project must follow the ELIXIR branding and communication guidelines related to the GDI project. The branding guidelines, font and project logo are all available on the GDI project Shared Drive<sup>49</sup>.

The branding and style guide should be used in all project communications without alteration. For any questions related to branding and communications please contact Zippy Tseng ([yun-yun.tseng@elixir-europe.org](mailto:yun-yun.tseng@elixir-europe.org)).

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<sup>48</sup>

<https://docs.google.com/document/d/1XWRFrXy6Z88QsxUkoXMZA3tXHtE4pzgVZH1PbGxolQU/edit#heading=h.gjdqxs>

<sup>49</sup> [https://drive.google.com/drive/folders/1-5\\_QTmwHoBnlwZBPMDK94BhSGA\\_lk3fV](https://drive.google.com/drive/folders/1-5_QTmwHoBnlwZBPMDK94BhSGA_lk3fV)







**European  
Genomic Data  
Infrastructure**

**Figure 4.** The GDI logo

#### 4.6.8. Project Website

The project web pages<sup>50</sup> provide an overview of the project, consortium and Board members, and the project timeline. In addition, visitors can find details of upcoming events, and our project outputs. Publications, press releases and submitted public deliverables are also available via the site.

For any updates to the project website, contact Raj Mitra ([prithviraj.mitra@elixir-europe.org](mailto:prithviraj.mitra@elixir-europe.org)), with [gdi-coordination@elixir-europe.org](mailto:gdi-coordination@elixir-europe.org) in cc.

#### 4.6.9. Social Media

GDI has dedicated social media accounts:

Twitter: [@GDI\\_EUproject](https://twitter.com/GDI_EUproject)

LinkedIn: <https://www.linkedin.com/company/gdi-euproject/>

#### 4.6.10. Project Newsletter

The ELIXIR Hub will publish a GDI newsletter quarterly. All GDI project partners who sign up to receive this will be added to the mailing list and receive it. Every issue provides the recipient with the option to update their preferences or unsubscribe from the list. Content for the newsletter is gathered by the ELIXIR Hub communications team. All project partners are encouraged to suggest any project content ideas either by email to the communications team or during the monthly WP or Management Board TCs.

Content ideas can be emailed to Zippy Tseng ([yun-yun.tseng@elixir-europe.org](mailto:yun-yun.tseng@elixir-europe.org)) with [gdi-coordination@elixir-europe.org](mailto:gdi-coordination@elixir-europe.org) in cc.

#### 4.6.11. Templates

Presentations for internal or external communication should use the GDI Google [Slide template](#).

All internal and external documents should use the GDI Google [Doc template](#).

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<sup>50</sup> <https://gdi.onemilliongenomes.eu/>



GDI project receives funding from the European Union's Digital Europe Programme under grant agreement number 101081813.

Templates for all deliverables and milestones report have been created and have been pre-filled with the required administration information and are available here:

- [Pre-filled Deliverables report templates per WP.](#)
- [Pre-filled Milestones report templates.](#)

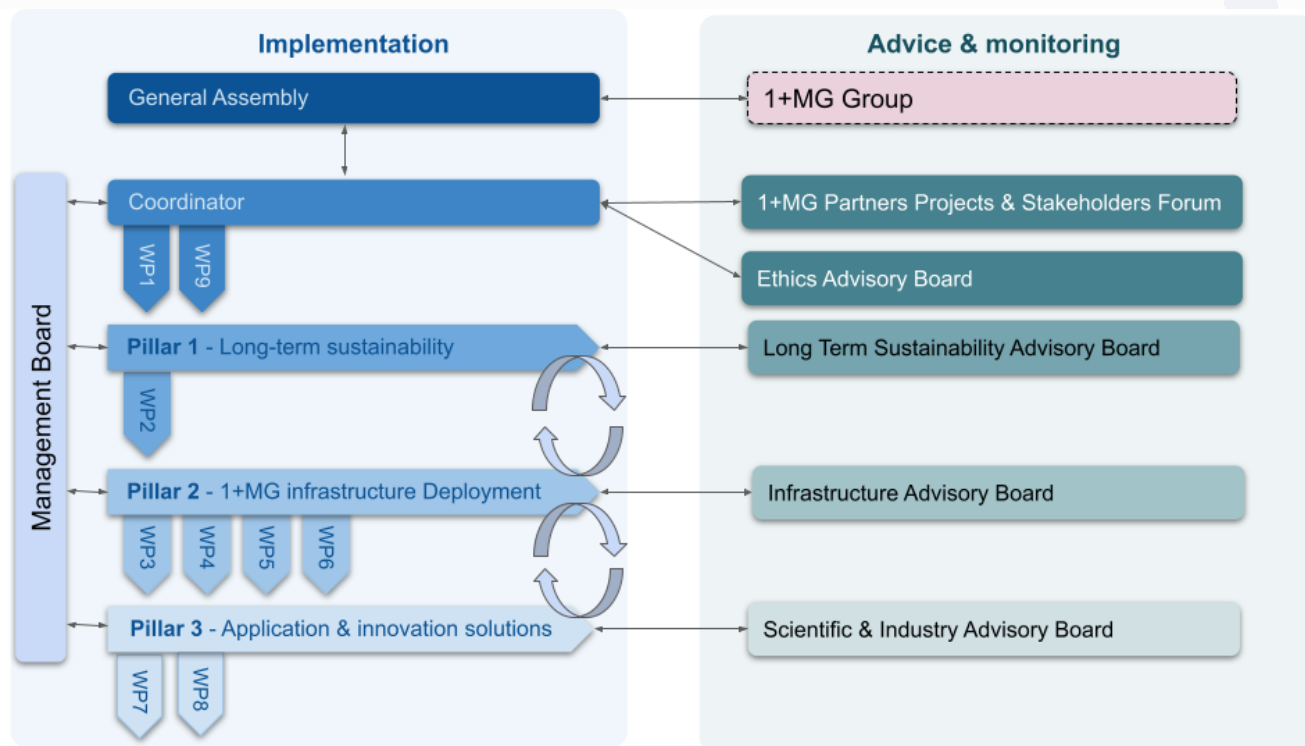
To find your deliverable or milestone template, you will need to navigate to the correct reporting period, then to subfolders: 'working documents' --> '[your WP e.g. WP1]'.

All Deliverable Authors shall use the approved deliverable template for the production of deliverables. For more information about how to prepare a deliverable report, please see section 7.1. (Deliverable).

All presentations, posters, media briefings and event documentation should display the European flag, besides the project logo. In line with the European Commission's policy on corporate visual identity, Digital Europe is being promoted as a verbal brand, meaning no 'visual mark' or logotype is needed. More information about displaying the correct logos and funding acknowledgements can be found in the EU Funding Acknowledgement section above, but for any questions, contact should be made to Zippy Tseng ([yun-yun.tseng@elixir-europe.org](mailto:yun-yun.tseng@elixir-europe.org)) with [gdi-coordination@elixir-europe.org](mailto:gdi-coordination@elixir-europe.org) in cc].



## 5. Project management structure and responsibilities



**Figure 5.** Management Structure.

### 5.1. Description of project roles and responsibilities

In the following section, the roles of major stakeholders in the GDI project are described alongside the responsibilities, expectations, rights and duties of each participant in the project.

#### 5.1.1. Project coordinator

**Table 9.** Project Coordinator details

<b>Name</b>	Serena Scollen
<b>Organisation</b>	ELIXIR Hub
<b>Email</b>	serena.scollen@elixir-europe.org



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## Role

The ELIXIR Hub is appointed as Coordinator. The Coordinator shall act through a designated Representative, Serena Scollen, Head of Human Genomics and Translational Data.

The Coordinator is and shall be a central point of contact between the project participants, the 1+MG Group and the funding agency (EC) in particular regarding the management of the Grant

Specific duties: Legal signatory with legal responsibility for contract. The project coordinator coordinates the project implementation, the overall reporting and financial management of the project and makes recommendations to the General Assembly when changes to the project plans become necessary. They maintain budget oversight and control, submission of deliverables and milestones to EC, and chair the GA and MB.

The Coordinator is supported by the Management Board in regards to financial and contractual administration of the project and in order to execute the project plans

### 5.1.2. Project Management Team (GDI-CO)

The Project Management Team (GDI-CO) will be led by the ELIXIR Project Management Office and leverage their experience and processes for managing large, international consortia to ensure timely delivery and effective communication and collaboration across WPs, and towards internal and external stakeholders.

The GDI-CO will support and report on the execution of the project work plan and budget utilisation and maintain oversight of the infrastructure deployment, providing the mechanism to identify and manage project risks and opportunities.

A consortium communication strategy will be established (WP1) making appropriate use of digital resources. Communication dynamics will be promoted across the project, keeping the right level of engagement among stakeholders. Specific collaboration tools will be enabled from the first stages of the Project. These tools will guarantee the means for efficient communication within the Consortium, fulfilling internal communication needs, and external stakeholders needs.

#### 5.1.2.1. Meetings

The GDI-CO Team meet on a monthly basis via the WP1 meetings.

Contact: [gdi-coordination@elixir-europe.org](mailto:gdi-coordination@elixir-europe.org).

### 5.1.3. Implementation Coordinator

The implementation coordinator is responsible for:



GDI project receives funding from the European Union's Digital Europe Programme under grant agreement number 101081813.

- coordinating the monitoring of the deployment of the infrastructure ensuring information is gathered from project participants, reviewed by the project Management Board and presented to the 1+MG Groups as required
- liaising with country representatives and the institutions they have nominated to support them to reach the targeted level of implementation for their GDI Node
- liaising with partner projects, in collaboration with the Project Coordinator, ensuring GDI outcomes are disseminated in the relevant forums as well as establishing links between experts across projects.

Contact: [juan.arenas@elixir-europe.org](mailto:juan.arenas@elixir-europe.org).

#### 5.1.4. General Assembly

The General Assembly (GA) is composed of representatives of all project beneficiaries that have delegated the decision making to the General Assembly voting members who are the ultimate decision making body with one (1) vote per country + one (1) vote per institution not selected by countries cast by ELIXIR. The GA will be informed of the project progress in a timely manner.

##### 5.1.4.1. Meetings

The GA will meet face to face once a year to be updated on the project progress and plans.

A Representative of the Coordinator shall chair the General Assembly. The Chairperson of the General Assembly shall:

- be responsible for the convening of meetings, preparation and distribution of the agenda and minutes for meetings of the General Assembly; and
- chair meetings of the General Assembly.

Where the Chairperson of the General Assembly cannot attend a General Assembly meeting, the General Assembly shall nominate a replacement to chair the meeting for the purposes of such meeting of the General Assembly only, provided that the replacement must be a Representative. Such replacement shall be deemed Chairperson of the General Assembly.

##### 5.1.4.2. General Assembly members

All project Beneficiaries are members of the General Assembly and are welcome to attend the annual General Assembly meeting. Affiliated Entities and Associated Partners are not members of the General Assembly but may be invited to attend the annual General Assembly meetings.



GDI project receives funding from the European Union's Digital Europe Programme under grant agreement number 101081813.

At minimum, the named PIs for each project Beneficiary will be expected to attend a General Assembly meeting, along with the GA voting member for their country (where different), and can be accompanied by other representatives of their respective institutions at the GA meetings..

#### *5.1.4.3. General Assembly Voting Members & Deputies*

All project beneficiaries will be a member of the General Assembly, however, only one named individual may have a voting right per country. Each voting member may have one named proxy for instances when they are unable to attend a General Assembly meeting.

The GA voting members and proxies were nominated per country with the decision taken with agreement of all project beneficiaries within each country. An up to date list of the [GA voting members and proxies](#)<sup>51</sup> is available on the project shared drive.

Any GA voting member may nominate a substitute to attend and vote at any meeting. In that respect, any change in a GA voting member must be informed by the original representative, in writing (including electronic mail), to the Chair (Coordinator) at least one week before an ordinary meeting of the GA takes place, indicating the reason for substitution and identifying the new representative.

Should you need to update the General Assembly voting member or proxy nomination for your country, please complete the [nomination form](#)<sup>52</sup> and return it to [gdi-coordination@elixir-europe.org](mailto:gdi-coordination@elixir-europe.org).

#### *5.1.4.4. General Assembly Voting Rules*

Any decision which requires a vote will be sent to the voting member at least two weeks prior to the vote taking place, allowing them time to discuss the topic(s) with other partners from within the country.

The voting member will be expected to socialise the topic within the country and seek agreement before casting a vote.

When a vote needs to take place via written procedure (when a face to face meeting isn't scheduled), a private link will be sent to each voting member to cast their vote using [Balotilo](#)<sup>53</sup>. A supporting document will accompany the voting link which will provide information regarding the vote topic(s).

When a vote will take place during a face to face meeting, a request will be sent to the General Assembly at least two weeks prior to the vote taking place, allowing them time to discuss the topic(s) with other partners from within the country.

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<sup>51</sup> [https://docs.google.com/spreadsheets/d/1NNl9pQKdN768JE\\_4FhaELCb78oFkuQcd\\_EmSHRMeVoM/edit#gid=0](https://docs.google.com/spreadsheets/d/1NNl9pQKdN768JE_4FhaELCb78oFkuQcd_EmSHRMeVoM/edit#gid=0)

<sup>52</sup> <https://docs.google.com/document/d/1yqP53qdGUOpYJylXw82sGkRJGn2xcyav/edit>

<sup>53</sup> <https://www.balotilo.org/>



One vote is required per General Assembly voting members on behalf of the beneficiaries within their country.

Two-thirds ( $\frac{2}{3}$ ) of the voting members must cast a vote by the vote deadline (for votes by written procedure) or during the face to face vote for a decision to be taken.

A decision shall be taken per voting item by a majority of two-thirds ( $\frac{2}{3}$ ).

Abstention from voting shall not prevent a decision from being considered as taken with specified majority.

See Clause 6.4 of the Consortium Agreement<sup>54</sup> for further information regarding the General Assembly.

#### 5.1.5. Management Board

The Management Board (MB) brings together the project coordinator, the project management team and the pillar leaders to oversee the technical delivery of the project, evaluating the progress (quarterly reports) and recommending actions when required that will then be discussed with the 1+MG Group and presented to the General Assembly for approval.

The MB shall be responsible for the overall execution of the Action, the quality of the Action, alignment across all Work Packages, decision making and the initial finding of amicable solutions for any disputes between the Beneficiaries relating to the execution of the Action. The MB will ensure the smooth operation of the Action and guarantee that all efforts are focused towards the Action Objectives, Deliverables and Milestones. This will be achieved by regular meetings, at least every month, and thorough reviews of progress reports. It will also ensure that all Beneficiaries are regularly updated on the scientific progress of the project. The responsibilities are fully detailed in the GDI Consortium Agreement<sup>55</sup>.

An up to date list of the [Management Board members and deputies](#)<sup>56</sup> is available on the project shared drive.

MB members shall have named deputies to ensure proper representation in all meetings.

The Management Board will be supported by the Project Management Team (GDI-CO).

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<sup>54</sup> As of January 2023 the Consortium Agreement is under negotiation

<sup>55</sup> As of January 2023 the Consortium Agreement is in the final rounds of negotiations

<sup>56</sup> <https://docs.google.com/spreadsheets/d/1C-ivf2N8ltYk6LAp8uvWp5i4TBnAcnD4yrC84Z07zYg/edit#gid=1726849619>



#### 5.1.5.1. Meetings

The Management Board will meet at least every month. In addition to the monthly teleconferences, the MB shall meet twice a year face to face making use of pre-existing meetings such as the annual General Assembly meeting. The Management Board meetings may be attended by EC representatives from DG CNECT as co-chair of the 1+MG Group which would benefit the alignment with the 1+MG initiative as well as related projects and activities. For similar purpose, representatives from other EC DGs can be invited to attend when appropriate (e.g. SANTE for alignment with EHDS).

A Representative of the Project Coordinator will act as the chairperson of the Management Board and shall:

- A. with assistance from the GDI-CO, be responsible for the convening of meetings, preparation and distribution of the agenda and minutes for meetings of the Management Board;
- B. and chair meetings of the Management Board.

Where a Pillar Leader is unable to attend a meeting they may send their predefined Deputy Pillar Leader.

An up to date list of the [Pillar Leaders](#)<sup>57</sup> is available on the project shared drive.

Contact: [gdi-mb@elixir-europe.org](mailto:gdi-mb@elixir-europe.org)

#### 5.1.6. Pillar Leaders

The Pillar Leaders are responsible for overseeing the technical progress of the project and ensure interoperability and alignment of co-dependent tasks across pillars. They are also responsible for presenting the work carried out by the pillars to the European Commission and for the content of their pillar activities within the periodic reports.

Pillar Leaders are responsible for the proper execution of the DoA and the implementation of the decisions of the Management Board and General Assembly. The Pillar Leaders collectively make up the Management Board along with the GDI-CO. They are expected to identify issues, risks and opportunities within the technical tasks of the Project and take appropriate actions to ensure the project delivers the anticipated benefits both at pillar and project level. Risks or opportunities that cut across more than one pillar should, together with a suggested action, be elevated to the Management Board during the monthly meetings. The Pillar Leaders, as the Management Board and via the Coordinator, report on the project progress to the General Assembly at least every 12 months.

Pillar Leaders are responsible for filtering project information from the Management Board meetings to the Work Package Leader to in turn, filter to the work package teams via their dedicated WP distribution lists, during their regular meetings, or via other communication means they deem fit, e.g. Slack.

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<sup>57</sup> <https://docs.google.com/spreadsheets/d/1C-iVf2N8ltYk6LAp8uvWp5i4TBnAcnD4yrC84Zo7zYg/edit#gid=1726849619>





In case of beneficiaries not performing their roles, Pillar and WPLs are expected to promptly document the situation and raise it with the GDI-CO in order to swiftly address reputational or technical risk for the consortium.

#### *5.1.6.1. Meetings*

The Pillar Leaders shall meet with their pillar once per month and are responsible for scheduling their own pillar meetings, creating and circulating an agenda, and taking and disseminating minutes.

As described in section 5.1.5.1., the Pillar Leaders will meet during the Management Board meeting at least every month. In addition to the monthly teleconferences, the MB shall meet twice a year face to face making use of pre-existing meetings such as the annual General Assembly meeting.

Where a Pillar Leader is unable to attend a Management Board or General Assembly meeting, they may deputise to their predefined Deputy Pillar Leader.

An up to date list of the [Pillar Leaders](#)<sup>58</sup> is available on the project shared drive.

Contact: [gdi-pillar-leaders@elixir-europe.org](mailto:gdi-pillar-leaders@elixir-europe.org).

#### **5.1.7. Work Package Leaders**

The Work Package Leads (WPLs) are responsible for overseeing the technical progress of the project and ensure interoperability and alignment of co-dependent tasks across work packages. They are also responsible for presenting the work carried out by the WP to the European Commission and for the content of their WP activities within the periodic reports.

WPLs are responsible for the proper execution of the DoA and the implementation of the decisions of the Management Board and General Assembly. The WPLs are expected to identify issues, risks and opportunities within the technical tasks of the Project and take appropriate actions to ensure the project delivers the anticipated benefits both at work package and project level. Risks or opportunities that cut across more than one work package should, together with a suggested action, be elevated to the Pillar Leaders for escalation to the Management Board during the monthly meetings. The WPLs, and via the Coordinator, report on the project progress to the General Assembly at least every 12 months.

WPLs are responsible for filtering project information from the Pillar Leaders to their work packages via their dedicated WP distribution lists, during their regular meetings, or via other communication means they deem fit, e.g. Slack. WPLs are responsible for scheduling their own WP meetings, creating and circulating an agenda, and taking and disseminating minutes.

In case of beneficiaries not performing their roles, WPLs, in cooperation with the Pillar Leads, are expected to promptly document the situation and raise it with the GDI-CO in order to swiftly address reputational or technical risk for the consortium.

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<sup>58</sup> <https://docs.google.com/spreadsheets/d/1C-iVf2N8ltYk6LAp8uvWp5i4TBnAcnD4yrC84Zo7zYg/edit#gid=1726849619>

Where a WPL is unable to host one of their Work Package meetings or attend an annual General Assembly meeting, they may deputise to their predefined Deputy Work Package Leader.

Contact: [gdi-wpls@elixir-europe.org](mailto:gdi-wpls@elixir-europe.org).

For more information, please refer to the ELIXIR Hub document Work Package Leader's Good Practice Guide<sup>59</sup>.

### 5.1.8. Task Leaders

Each Work Package is broken down into tasks and sub-tasks.

Each Task Lead is responsible for prompt and on time performance and fulfilment of the assigned task and subtask as per the Description of Action (DoA) in cooperation with all task participants and liaising with the respective WPL and/or Pillar Leader.

The Task Leads must ensure that the fulfilment of their task activities are accomplished in due time in line with the commitments identified in the DoA.

Task Leads shall promptly notify the WPL of any significant problem or delay likely to affect the completion of the assigned task.

Each participant must ensure timely contribution to the allocated tasks, as requested by each Task Leads and/or WPLs. Any encountered issue should be discussed with the Task Lead and, if needed, escalated to the WPL level.

The most up-to-date list of designated Task Leaders are available on the GDI Google Shared Drive in the [Project Master File → Work Package tabs](#)<sup>60</sup>.

### 5.1.9. Deliverable Authors

The most up-to-date list of deliverables and designated deliverable authors (owners) is available on the GDI Google Shared Drive in the [Project Master File](#)<sup>61</sup>.

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<sup>59</sup>

[https://docs.google.com/document/d/1jZAhcO4wYMsm8pdd22vO7wNaiowg83H7Fm\\_Ro8EL\\_FQ/edit#heading=h.d7m9lvvj5el8](https://docs.google.com/document/d/1jZAhcO4wYMsm8pdd22vO7wNaiowg83H7Fm_Ro8EL_FQ/edit#heading=h.d7m9lvvj5el8). (Last updated November 2021)

<sup>60</sup> <https://docs.google.com/spreadsheets/d/1nfXQtRcfnXsqiazqPoK3OGAeJja4n03h/edit#gid=2035076543>

<sup>61</sup> <https://docs.google.com/spreadsheets/d/1nfXQtRcfnXsqiazqPoK3OGAeJja4n03h/edit#gid=312411306>





### 5.1.10. GDI named Country Contact Points & Deputies

During the project proposal phase the GDI Country Contact Points were known as Member State Representatives, however, we were asked to rename the group during the grant agreement preparation phase (GAP) in order to differentiate the group from the Governing Board.

During the proposal phase the Country Contact Points committed their country to attain a stage of infrastructure deployment and operations during the 4 year project (onboarding, deployment, operations) and provided beneficiary (+AE and AP) nominations for Pillars I-III.

They are the first point of contact for the coordinator when Member State involvement is required.

The Country Contact Points do not need to be a member of a project beneficiary, Affiliated Entity or Associated Partner.

The Country Contact Points are named in Table 1 of the [Grant Agreement](#)<sup>62</sup>, up to date as of the day of submission, and an [up to date list](#)<sup>63</sup> is maintained on the GDI Google Shared Drive.

If a country needs to update their named Country Contact Point or deputies, they may do so by emailing [gdi-coordination@elixir-europe.org](mailto:gdi-coordination@elixir-europe.org).

### 5.1.11. Pillar I Nominated Representatives

The Pillar I Nominated Representatives meet once per month to discuss and decide on how to make the genomic data infrastructure sustainable, both financially and legally.

A Pillar I Nominated Representative does not need to be a member of a project beneficiary, Affiliated Entity or Associated Partner. Each country who has at least one beneficiary in the project may nominate one or several representatives to the Pillar I GOV meetings who are authorised to vote on behalf of the country on the decisions taken in Pillar I. The group comprises a large overlap of members with the GDI named Country Contact Points and the delegates of the 1+MG group.

The list of all nominated representatives of each country is maintained by the Pillar I leads that, together with the selected chair, supports the members in organising the meetings. This list will be available on the GDI Google Shared Drive to inform project participants of their country's representative(s).

The rules of procedures for the Pillar I GOV meetings are available to its members on the shared [Microsoft Teams Drive](#)<sup>64</sup>.

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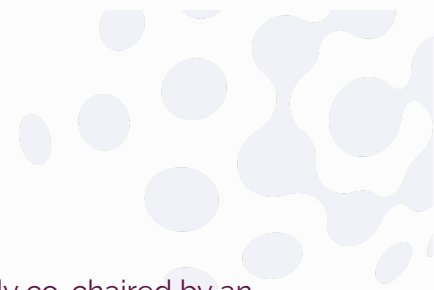
<sup>62</sup> <https://drive.google.com/file/d/1k1M8tvPWqAXh-ElzZ7c5eTY5Z2yOxuox/view?usp=sharing>

<sup>63</sup> [https://docs.google.com/spreadsheets/d/1oVqqH3piHpw9E7k2IXLL\\_k8u0lqEFXQe/edit#gid=479343071](https://docs.google.com/spreadsheets/d/1oVqqH3piHpw9E7k2IXLL_k8u0lqEFXQe/edit#gid=479343071)

<sup>64</sup>

<https://emlebi.sharepoint.com/:f:/r/sites/EuropeanGenomicDataInfrastructureGDI/Shared%20Documents/General/General?csf=1&web=1&e=KgeJLp>





#### 5.1.12. Governing Board / 1+MG Group

The 1+MG Group (formerly known as the 1+MG Special Group) is an external body co-chaired by an EC representative from DG CNECT, created by the EC to support the coordination and cooperation regarding the implementation of Member States' 2018 Declaration 'Towards access to at least 1 million sequenced genomes in the European Union' by 2022.

The group maintain an advisory role to the project and comprises a large overlap of participants with our GDI named Country Contact Points.

The 1+MG Group will be responsible for the GDI project's strategic direction and as such, will endorse, approve, or be consulted by the General Assembly regarding progress and project activities while acting on behalf of Member States. In addition, as per call requirements, the project will update the 1+MG Group in each of the 1+MG Group meetings. This will ensure alignment with the overall 1+MG vision and provide the 1+MG Group the opportunity to provide frequent feedback to the consortium and influence the project direction.

It is important to note that whilst the project will make progress on the recommended options and required agreements for the long-term sustainability of the resulting 1+MG infrastructure, long-term participation will remain a country's decision.

Deliverables of relevance to the 1+MG Initiative will be shared with the 1+MG Group before submission to the EC.

The EC maintains a list of 1+MG members which can not be shared with the GDI consortium.

Please direct any questions to [gdi-coordination@elixir-europe.org](mailto:gdi-coordination@elixir-europe.org).

#### 5.1.13. 1+MG Coordination Group

The 1+MG Coordination Group ensure alignment between 1+MG initiative and GDI via weekly meetings.

#### 5.1.14. Unfunded External Experts

The GDI project structure and the design of the advisory groups ensures that each pillar has direct access to critical external experts and stakeholders. It is expected that Work Packages would need to consult with additional experts to deliver the project outputs, but under the Digital Europe restrictions that apply to the grant, it became quite cumbersome to bring unfunded experts to contribute. To overcome this situation, the project would organise as part of WP5 technical outreach activities, regular meetings (monthly initially) to gather the required inputs from experts beyond the project. External experts won't get access to the project repository and won't be able to directly



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contribute to project deliverables that will be the responsibility of the project partners, but they could be listed as contributors to them.

### 5.1.15. Ethics Advisory Board

#### 5.1.15.1 Scope

The Ethics Advisory Board (EAB) is an external and independent body of recognised experts in the field that provides advice and recommendation on the ethical aspects and issues that could arise during the life-time of the project.

The EAB will be required to produce an ethics report annually which will be submitted to the EC as a deliverable report in Months 12, 24, 36 & 48.

An up to date list of EAB members is available on the project shared drive in the [Project Master Document](#)<sup>65</sup>.

#### 5.1.15.2. Meetings

The EAB meets once a year during the annual GA meeting or ad hoc by request of the GDI-CO or the GA. They provide direct feedback to the GA.

See Clause 6.8 of the Consortium Agreement<sup>66</sup> for further information regarding the EAB.

Contact: as of January 2023 a mailing list hasn't yet been created for the EAB. Please contact [gdi-coordination@elixir-europe.org](mailto:gdi-coordination@elixir-europe.org).

### 5.1.16. Long-Term Sustainability Board

The Long-Term Sustainability Board (LTSB) will advise the Pillar I leaders regarding establishing a business model, including recommendations for legal and governance structures, allowing the 1+MG infrastructure to run sustainably over the long-term and enabling the continuous access to genomics data across borders. Its members will include relevant actors, such as patient representatives, research funders, other genome initiatives, user representatives, and other stakeholders or experts as necessary.

An up to date list of LTSB members is available on the project shared drive in the [Project Master Document](#)<sup>67</sup>.

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<sup>65</sup> <https://docs.google.com/spreadsheets/d/1nfXQtRcfnXsqiazqPoK3OGAeJja4n03h/edit#gid=1058026394>

<sup>66</sup> As of January 2023 the Consortium Agreement is under negotiation

<sup>67</sup> <https://docs.google.com/spreadsheets/d/1nfXQtRcfnXsqiazqPoK3OGAeJja4n03h/edit#gid=897898827>





#### 5.1.16.1. Meetings

The LTSB meets once a year during the annual GA meeting or ad hoc by request of the GDI-CO or the GA. They provide direct feedback to the Pillar I Leaders and to the GA.

See Clause [update when CA is finalised] of the Consortium Agreement<sup>68</sup> for further information regarding the LTSB.

Contact: as of January 2023 a mailing list hasn't yet been created for the LTSB. Please contact [gdi-coordination@elixir-europe.org](mailto:gdi-coordination@elixir-europe.org).

#### 5.1.17. Infrastructure Advisory Board

The Infrastructure Advisory Board (IAB) will advise the pillar II leaders on the 1+MG infrastructure being deployed to ensure the interoperability by design with other key infrastructures. It is composed of technical experts who would contribute or benefit from an early involvement in the project providing advice to Pillar II.

An up to date list of IAB members is available on the project shared drive in the [Project Master Document](#)<sup>69</sup>.

##### 5.1.17.1. Meetings

The IAB meets once a year during the annual GA meeting or ad hoc by request of the GDI-CO or the GA. They provide direct feedback to the Pillar II Leaders and to the GA.

See Clause [update when CA is finalised] of the Consortium Agreement<sup>70</sup> for further information regarding the IAB.

Contact: as of January 2023 a mailing list hasn't yet been created for the IAB. Please contact [gdi-coordination@elixir-europe.org](mailto:gdi-coordination@elixir-europe.org).

#### 5.1.18. Scientific and Industry Advisory Board

The Scientific and Industry Advisory Board (SIAB) will advise the Pillar III leaders regarding the use cases requirements and the best options for the technical implementation, taking into account the needs of the exemplar users, the interoperability needs to support them, and the innovative solutions related to the use-cases proposed at national and European level initiatives and projects. The board will be formed of scientific experts involved in the 1+MG Use Cases WGs (industry, rare disease,

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<sup>68</sup> As of January 2023 the Consortium Agreement is under negotiation

<sup>69</sup> <https://docs.google.com/spreadsheets/d/1nfXQtRcfnXsqiazqPoK3OGAeJja4n03h/edit#gid=1911351765>

<sup>70</sup> As of January 2023 the Consortium Agreement is under negotiation



cancer, common and complex diseases, infectious diseases, GoE) and related initiatives and projects already running (e.g., EOSC4Cancer, HealthyCloud) or awarded, which need to be connected. Additional industry representation will be sought as necessary. The number of members of the Scientific and Industry Advisory Board can be increased to add experts in other relevant domains.

An up to date list of SIAB members is available on the project shared drive in the [Project Master Document](#)<sup>71</sup>.

#### 5.1.18.1. Meetings

The SIAB meets once a year during the annual GA meeting or ad hoc by request of the GDI-CO or the GA. They provide direct feedback to the Pillar III Leaders and to the GA.

See Clause [update when CA is finalised] of the Consortium Agreement<sup>72</sup> for further information regarding the SIAB.

Contact: as of January 2023 a mailing list hasn't yet been created for the SIAB. Please contact [gdi-coordination@elixir-europe.org](mailto:gdi-coordination@elixir-europe.org).

## 5.2 How and when the project bodies meet

The Coordinator, supported by the GDI-CO Team, is responsible for convening meetings of the management and governance bodies at the GDI overall level (i.e. GA, MB, SIAB, EAB, LTSB, IAB), complying with the minimum frequency of ordinary meetings as defined in the GDI Consortium Agreement (CA) and detailed above. Pillar Leaders have the responsibility of calling meetings within their respective pillars and Work Package Leaders have the responsibility of calling meetings within their respective WPs as needed.

The meeting frequency is defined in [Table 5](#).

Organisation of meetings comprises the following tasks:

- professional convocation and on time distribution of the agenda according to the terms of the Grant Agreement;
- organisation of facilities or conference venues with the required infrastructure and catering, to ensure the smooth running of the conference (when face-to-face);
- organisation and steering of decision-making processes at GDI meetings
- distribution of minutes following the meeting and follow-up of points agreed at the meetings.

<sup>71</sup> <https://docs.google.com/spreadsheets/d/1nfXQtRcfnXsqiazgPoK3OGAeJia4n03h/edit#gid=1908318607>

<sup>72</sup> As of January 2023 the Consortium Agreement is under negotiation







### 5.3. Beneficiaries, Affiliated Entities and Associated Partners

All project Beneficiaries are members of the General Assembly (normally the PI). Affiliated Entities and Associated Partners are not members of the General Assembly but may be invited to attend the annual General Assembly meetings.

#### 5.3.1. Beneficiaries

Project beneficiaries in Pillar I and II were nominated by the GDI named Country Contact Points. Pillar III Beneficiaries have been selected following Pillar Leaders and consortium recommendations to bring in use cases and technology experts.

Beneficiaries:

- Do the work
- Sign the GA
- Sign the CA
- Receive funding, up to 50% of eligible cost of the total budget

##### *5.3.1.1 What are the main Beneficiaries' responsibilities?*

Beneficiaries must use all reasonable endeavours to perform and fulfil, promptly, and on time, all of their obligations under the Grant Agreement and the Consortium Agreement, to accomplish the purpose and objectives of the GDI project and act in cooperation and mutual trust. Beneficiaries shall also provide their respective contributions to deliverables, information, and reports as required by the Pillar Leaders, WPLs, the Management Board, the GDI-CO, and the Coordinator, so as to help these bodies to fulfil their obligations.

Beneficiaries shall promptly notify the Coordinator and the GDI-CO through the appropriate WPL or directly of any significant problem or delay likely to affect the success of the project.

To summarise, each Beneficiary must:

- Do the work assigned to it in the Description of Action, and any other detailed work plan derived from it, on time, on budget, and with an appropriate level of quality.
- Collaborate with all other Beneficiaries as required by the tasks, including contributing to relevant deliverables.
- Not hinder the work of others or delay it unnecessarily.
- Attend meetings and teleconferences as required.



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- Notify promptly the relevant governance body of any potential issue affecting performance. The normal chain of reporting would be, in this order: WPL → GDI-CO → MB.
- Notify the GDI-CO about any risk that may be detected in the course of the work, and that may affect future performance.
- Fulfil the administrative and financial reporting obligations according to EC rules.
- Spend the costs foreseen only for the work expected in GDI, and report it faithfully.

### 5.3.2. Affiliated Entities (AEs)

Project Affiliated Entities in Pillar I and II were nominated by the GDI named Country Contact Points. Pillar III AEs have a legal link with one of the Beneficiaries and have been selected following Pillar Leaders and consortium recommendations to bring in use cases and technology experts.

Affiliated Entities:

- Have a legal link with one of the project beneficiaries
- Do the work
- Do not sign the GA
- Do not sign the CA
- Receive funding, up to 50% of eligible cost of the total budget

#### 5.3.2.1 What are the main Affiliated Entities' responsibilities?

The Affiliated Entities (AEs) have the same responsibilities as project Beneficiaries, as described in [section 5.3.1.1](#), however. AEs shall promptly notify the Beneficiary they have a legal link with of any significant problem or delay likely to affect the success of the project, who will in turn, notify the Coordinator and the GDI-CO through the appropriate WPL or directly.

To summarise, each AE must:

- Do the work assigned to it in the Description of Action, and any other detailed work plan derived from it, on time, on budget, and with an appropriate level of quality.
- Collaborate with all other project partners as required by the tasks, including contributing to relevant deliverables.
- Not hinder the work of others or delay it unnecessarily.
- Attend meetings and teleconferences as required.



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- Notify promptly the relevant governance body of any potential issue affecting performance. The normal chain of reporting would be, in this order: the Beneficiary you have a legal link with → WPL → GDI-CO → MB.
- Notify the Beneficiary you have a legal link with and the GDI-CO about any risk that may be detected in the course of the work, and that may affect future performance.
- Fulfil the administrative and financial reporting obligations according to EC rules.
- Spend the costs foreseen only for the work expected in GDI, and report it faithfully.

### 5.3.3. Associated Partners (APs)

Project Associated Partners in Pillar I and II were nominated by the GDI named Country Contact Points.

Associated Partners:

- Do the work
- Do not sign the GA
- Do not sign the CA
- Do not receive EC funding, they bring their own funding
- Have obligations to deliver towards the consortium

#### 5.3.3.1 *What are the main Associated Partners' responsibilities?*

Associated Partners (AP) shall promptly notify the Coordinator and the GDI-CO through the appropriate WPL or directly of any significant problem or delay likely to affect the success of the project.

To summarise, each AP must:

- Do the work assigned to it in the Description of Action, and any other detailed work plan derived from it, on time, on budget, and with an appropriate level of quality.
- Collaborate with all other project partners as required by the tasks, including contributing to relevant deliverables.
- Not hinder the work of others or delay it unnecessarily.
- Attend meetings and teleconferences as required.



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- Notify promptly the relevant governance body of any potential issue affecting performance. The normal chain of reporting would be, in this order: WPL → GDI-CO → MB.
- Notify the GDI-CO about any risk that may be detected in the course of the work, and that may affect future performance.
- Fulfil the reporting obligations according to EC rules.

For more information about the role of the project Beneficiaries, Affiliated Entities and Associated Partners, please refer to section 4.1 and Attachment 5<sup>73</sup> of the Consortium Agreement<sup>74</sup>.

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<sup>73</sup> TBC

<sup>74</sup> As of January 2023 the Consortium Agreement is under negotiation



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## 6. Key legal documents

### 6.1. The grant agreement

The Grant Agreement (GA) is the main legal document underpinning the project's execution – effectively, a contract between the beneficiaries and the EC. It is first signed by the EC and the Coordinator. Each beneficiary then accedes to the Grant Agreement by executing an accession form. The Grant Agreement mainly provides information on the grant (parties, duration, start date, budget, etc.), obligations of the Beneficiaries towards the EC (such as reporting requirements), as well as the intellectual property framework and other legal conditions. The Grant Agreement is dated 1st November 2022 and has the GA # 101081813.

The Grant Agreement core document includes a standard text (i.e. it is essentially the same for any EC Digital Europe project) describing the general rules and regulations governing EC projects, including financial rules (e.g. which costs are acceptable, how payments are handled, etc.), Intellectual Property Rights (who owns the results, how access to such results is enabled, etc.) and other general conditions applicable to EC projects. These generic provisions can be supplemented (but not contravened) with project-specific provisions via a Consortium Agreement (see below), which enables projects to set out their specific IPR detailed rules, governance mechanisms, etc.

Beyond its core terms and conditions, mostly standard text, the Grant Agreement also includes the following annexes, which form an integral part of the contract:

#### 6.1.1. Annex 1. Description of the action (DoA)

The most extensive and important Annex to the Grant Agreement is the Description of Action (DoA), which comprises the technical description of the work to be undertaken in the project (work packages, tasks, deliverables, milestones), the description and roles of the different partners, allocated effort in person-months, and budget details. The DoA is derived from the original proposal submitted to the EC for evaluation and approval, and it is the benchmark against which project progress will be judged. Compared to the rest of the Grant Agreement and annexes, which are mostly model texts, the DoA is specific for each project. It is important to remember that the DoA is an integral part of the Grant Agreement, and therefore it is a contractual commitment of all beneficiaries.

#### 6.1.2. Annex 2. Estimated Budget for the action

This Annex refers to the overall budget for the GDI Project and includes the budget details for all project beneficiaries and affiliated entities. This document is automatically generated by the EC Participant Portal.

##### *6.1.2.1. Annex 2a Additional information on unit costs and contributions (if applicable)*

Beneficiaries and AEs may submit to the EC, for approval by the Commission, a certificate on the methodology to state that their usual cost accounting practices comply with specific conditions (e.g.



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"unit costs" instead of actual costs). Once the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

### 6.1.3. Annex 3. Accession form for beneficiaries

This form is required to be signed by all the project beneficiaries to formally accede to the GDI Grant Agreement. If a new beneficiary joins the project, this form will be requested to be signed by the new institution joining the project.

#### 6.1.3.1. Annex 3a Declaration on joint and several liability of affiliated entities (if applicable)

N/A to the GDI project. This annex is not included in the GA.

### 6.1.4. Annex 4. Model for the financial statement

This form refers to the summary of costs to be reported by those partners receiving EC funding for each reporting period. Please see section 7.3.2. (Financial Reporting) for more details.

### 6.1.6. Annex 5 Specific rules

This annex provides details on rules specific to the GDI project, as listed below:

#### CONFIDENTIALITY AND SECURITY (— ARTICLE 13)

- Sensitive information with security recommendation
- EU classified information

#### ETHICS (— ARTICLE 14)

- Ethics

#### INTELLECTUAL PROPERTY RIGHTS (IPR) — BACKGROUND AND RESULTS — ACCESS RIGHTS AND RIGHTS OF USE (— ARTICLE 16)

- Definitions
- List of background — Background free from restrictions
- Results free from restrictions
- Ownership of results
- Protection of results
- Exploitation of results
- Transfers and licensing of results
- Access rights — Additional rights of use

#### COMMUNICATION, DISSEMINATION AND VISIBILITY (— ARTICLE 17)

- Communication and dissemination plan
- Dissemination of results
- Additional communication activities



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## SPECIFIC RULES FOR CARRYING OUT THE ACTION (— ARTICLE 18)

- Implementation in case of restrictions due to security or EU strategic autonomy
- Specific rules for PAC Grants for Procurement
- Specific rules for Grants for Financial Support
- Specific rules for JU actions
- Specific rules for blending operations

The Grant Agreement and its Annexes are available on the GDI project Shared Drive<sup>75</sup>.

### 6.1.7. Changes to the Grant Agreement

The Grant Agreement can and must be changed whenever any important project parameter changes: partnership, project duration, budget, etc. Implementation of such changes must follow a specific procedure called 'Grant Agreement amendment'. Most changes that trigger Grant Agreement amendments relate to updates in the Description of Action (DoA) (e.g. changes in tasks and deliverables, changes in efforts allocated, changes in partner's teams, budget transfers across beneficiaries, etc.). These can be relatively minor, in which case they tend to be grouped and implemented together in one go, or major, which might trigger an amendment on their own, especially if it is urgent that the change is officially entered into the contract.

Grant Agreement amendments are submitted to the EC by the Coordinator on behalf of the Consortium. This implies that the Consortium must be aware of and approve any proposed changes before the amendment is requested.

The GDI-CO will be responsible for following-up on amendments to the Grant Agreement during the project.

The procedure is as follows:

1. The Project Management Team (GDI-CO) will keep track of all needed amendments in the project [Change Management log](https://drive.google.com/drive/u/0/folders/13yvEVcinOeyJfwogvHFX1FZfqtExZpc)<sup>76</sup>. Meetings and communications with the beneficiaries affected will enable the GDI-CO to compile all the necessary information to support the changes.
2. The list of modifications will be circulated to the General Assembly for their information and approval of the GA voting members.
3. The GDI-CO will prepare the following documentation:
  - a. A new version of the DoA with the modifications in track changes.

<sup>75</sup> <https://drive.google.com/drive/u/0/folders/13yvEVcinOeyJfwogvHFX1FZfqtExZpc>

<sup>76</sup> [https://docs.google.com/spreadsheets/d/1ioFrJO5PL5ZUFs5L\\_r3tQYTKlUkw7ngik0aUgNH08cw/edit#gid=1430036108](https://docs.google.com/spreadsheets/d/1ioFrJO5PL5ZUFs5L_r3tQYTKlUkw7ngik0aUgNH08cw/edit#gid=1430036108)



- b. A first version of a "Request Letter" to be sent to the EC Project Officer including the changes.
  - c. Other documents needed to request modifications.
4. The GDI-CO will circulate an amended version of the DoA to the Management Board for validation. The approval by the Management Board will be required for any Amendment to the Grant Agreement.
5. As a final step the Coordinator, supported by the GDI-CO, will submit on behalf of the Consortium, the Request Letter, the new version of the DoA and all the additional documentation required by EC for the changes submitted.
6. Once approved, the new version of the DoA will also be accessible in the GDI project Shared Drive<sup>77</sup> in the appropriate amendment folder.

The Grant Agreement may be affected by other types of minor changes which do not constitute an amendment, but which must be communicated to the consortium or to the EC through an information procedure. In any case, beneficiaries should contact the GDI-CO to confirm the procedure to follow for any modification needed.

For more information about the procedure, review [section 4.3. Project Change Management](#).

## 6.2. The Consortium Agreement

The Consortium Agreement (CA) is concluded between the GDI Beneficiaries in order to provide a legal framework for their collaboration within the boundaries of the Grant Agreement. The CA includes provisions on, for instance, governance, intellectual property, dissemination, and liability. The EC is not a party to the CA. The fully executed CA is accessible in the GDI project Shared Drive<sup>78</sup>.

Amendments to the CA may also be necessary in the course of the project, sometimes purely as a consequence of Grant Agreement amendments. These CA amendments will be handled separately by agreement of all beneficiaries, under the coordination of the Coordinator with the support of the GDI-CO.

The Project Coordinator shall keep records of the Consortium Agreement together with (i) all amendments to the Grant Agreement amending the Consortium Agreement, and (ii) any other amendments to the Consortium Agreement.

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<sup>77</sup> <https://drive.google.com/drive/folders/19YVEWraO4hlZgZVlBoYcpoYZiXxKokgl>

<sup>78</sup> As of January 2023 the Consortium Agreement is under negotiation





## 7. Project reporting

### 7.1. Deliverables

#### 7.1.1. Who generates project deliverables?

As official results of the project, deliverables deserve special attention and are generated and reviewed according to specific procedures. As a general rule, the generation of deliverables is a responsibility of the corresponding work package lead beneficiary and the process will be supervised by the corresponding Work Package Leader. The lead beneficiary will be responsible for drafting the deliverable and gathering contributions from work package participants as appropriate. Prior to submission to the EC, deliverables will undergo an internal review process that is detailed below.

In order to ensure uniformity in the presentation across the project and facilitate the consolidation of contributions from different partners, the template for deliverables has been generated by the GDI-CO based on the official EC template, and it is available on the GDI Shared Drive in the Guidance and Templates folder<sup>79</sup>.

When naming the document it is expected that the document naming convention is adhered to. All deliverable templates have been created following the appropriate naming convention.

#### 7.1.2. Deliverable structure, guidance and tips

Project deliverables are to be submitted at specific times stated in the DoA. A full list of the project deliverables and the deliverable deadlines is available in the Project Master Document<sup>80</sup>.

Note: The “expected delivery date” listed in the DoA always refers to the last date of any month. e.g. ‘June 2023’ means ‘30th June 2023’ / ‘March 2025’ means ‘31st March 2025’.

Deliverables reflect the results achieved during the lifetime of the project, and they are important documents to assess the progress achieved.

Each deliverable must use the deliverable template pre-prepared by the GDI-CO and shared in the Project Monitoring report, in the deliverable reminder emails and available on the GDI project Shared Drive<sup>81</sup>. In addition, a clean copy of the deliverable template can found in the Templates folder on the GDI project Shared Drive<sup>82</sup>.

The template has eight predefined sections:

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<sup>79</sup><https://drive.google.com/drive/folders/1apd5mWWw4gDBLsOmaqmiBDmBHh5oY4lw>

<sup>80</sup> <https://docs.google.com/spreadsheets/d/1nfXQtRcfnXsqiazqPoK3OGAeJja4n03h/edit#gid=312411306>

<sup>81</sup> [https://drive.google.com/drive/folders/1Dt3o4YMqnVx3f15n5zoTA\\_B2hdeonSM\\_](https://drive.google.com/drive/folders/1Dt3o4YMqnVx3f15n5zoTA_B2hdeonSM_)

<sup>82</sup> <https://drive.google.com/drive/folders/1apd5mWWw4gDBLsOmaqmiBDmBHh5oY4lw>





- Executive Summary (Max ½ page, should provide an overview of the work carried out and the conclusion)
- Contribution Towards Project Outcomes (indicate with Yes/No if the deliverable contributes to the key result)
- Method (1-1 ½ pages (on average) to cover deliverable scope, relationship with other WPs and methodology)
- Description of Work Accomplished (Try to keep this section to below 10 pages. Describe what has been done. Interactions with other WPs? Collaboration with external partners/projects? Problems encountered and how they have been solved?)
- Results (½ - 1 page. Present and discuss the results obtained. Dissemination activities carried out?)
- Discussion (½ to two pages. Discussion of results)
- Conclusion & Impact (½ to one page. Present and discuss the conclusion and impact obtained)
- Next Steps (½ to one page)
- References (Optional field - delete if not applicable)

### 7.1.3. Deliverable review process

#### 7.1.3.1. Review for quality

The review process must use the following quality criteria as reference.

As regards to content:

- **Completeness:** Information must address all aspects related to the purpose for which the information is produced. On the other hand, redundancy of information must be avoided, as it obscures the clarity of documents.

Related indicators: Missing content, Redundancy.

- **Accuracy:** Information contained in the document must be reliable and must correspond with reality. This means that all background information used in the reports should be appropriately supported by references. Foreground information should be sufficiently supported so that misinterpretation is avoided. Use of statistically validated objective data is to be prioritised.

Related indicators: Error, Insufficient references/objective supporting data, Ambiguity.

- **Relevance:** Information used in the document should be focused on the key issues and be written in a fashion that takes into consideration its target audience.

Related indicators: Irrelevant information.

- **Depth:** all information used should be provided to the depth needed for the purpose of the document.



Related indicators: Lacking detail, Excessive detail.

As regards to appearance and structure:

- Adherence to standards: it is important that deliverables are prepared with uniform appearance and structure so that, even if they are produced by different authors, they appear as originating from a single initiative.

Related indicators: Lack of uniformity in presentation.

### *7.1.3.2. The review process*

Within the GDI project, the review process shall be coordinated by the GDI-CO.

As and when a deliverable approaches due, it will appear in the project monitoring report three months prior to submission deadline. A link to the deliverable template will be provided, as well as guidelines for producing the document. This will be emailed to the appropriate Deliverable Lead (owner) with the associated WPLs on copy.

If the Deliverable Lead themselves will not be drafting the deliverable, it is their responsibility to forward the request to the appropriate team member(s) who will be undertaking the task of drafting the deliverable (the deliverable authors).

The Deliverable Lead must nominate a minimum of two reviewers. Before informing the GDI-CO of who the reviewers will be they should seek agreement from the nominated reviewers. The reviewers should ideally be from a different WP and have a thorough understanding of the deliverable topic so they can provide sufficient technical critique/review. If it is deemed that the review by someone with additional expertise is required, e.g. such as a case where a deliverable has a focus on ethical or regulatory/legal issues, members of any of the Advisory Boards of the GDI project may also be asked to be a reviewer.

A list of the nominated deliverable reviewers will be maintained in the [project monitoring tool](#)<sup>83</sup>.

The deliverable author(s) should work on their deliverable within their Work Package folder on the GDI project Shared Drive.

Where more than one person is producing the deliverable, the lead deliverable author should create a Table of Contents and assign responsibilities to the other authors.

If the Deliverable Lead does not draft the report themselves, once the first draft of the document is produced by the author(s), they will be expected to have the Deliverable Lead and WPLs review it to assess the content from a scientific/technical perspective.

Reviewers will be expected to check the deliverable against the quality criteria described in [section 7.1.3.1](#) above. Any suggested edits or comments should be made using Suggesting Mode within the

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<sup>83</sup> [https://docs.google.com/spreadsheets/d/1ioFrJO5PL5ZUFs5L\\_r3tQYTKlUkw7ngikoaUgNHO8cw/edit#gid=296328137](https://docs.google.com/spreadsheets/d/1ioFrJO5PL5ZUFs5L_r3tQYTKlUkw7ngikoaUgNHO8cw/edit#gid=296328137)

Google Doc which allows for a collaborative working environment. The deliverable author(s), must then proceed with the amendments or comments on the reviewed document.

1.5 weeks prior to the deliverable due date, the final draft of the document should be submitted to the GDI-CO, by emailing them a link to the Google Doc version on the GDI Shared Drive. The GDI-CO will distribute the link to the Management Board for a final review, allowing the MB seven (7) days to review it. Once approved, the GDI-CO (on behalf of the Project Coordinator) will convert the Google Doc to PDF and submit the final document to the EC via the Funding and Tenders Portal. In addition, the GDI-CO will upload all public deliverable reports to Zenodo (see also [Section 4.6.5, Open Access policy and requirements](#)) and notify the Consortium. The final document will also be available on the GDI project Shared Drive in the Deliverables and Milestones folder<sup>84</sup>.

During the whole process, it is recommended that there is one responsible author that acts on behalf of all authors and communicates with them for evolving the document.

#### 7.1.3.3. Illustrative timelines

1. Three months prior to the due date, the deliverable will appear in the project monitoring tool with a link to the pre-prepared deliverable template and a reminder will also be emailed directly to the Deliverable Lead (owner) with the WPL(s) on copy.
2. Two months (60 days) prior to the due date, author(s) identify the reviewers and inform the GDI-CO (where they are not already identified).
3. If multiple people will be producing the deliverable, the lead author should create a Table of Contents and assign responsibilities to the other authors.
4. Author(s) produce the first draft of the deliverable report.
5. If the author(s) are not the Deliverable Owner or WPLs, they must have the Deliverable Owner WPLs review the deliverable report.
6. 1 month (30 days) prior to the due date, author(s) must send the draft report to the GDI-CO by emailing them a link to the Google Doc version on the GDI project Shared Drive. The GDI-CO will review the draft for formatting before forwarding it to the pre-identified reviewers, allowing them two weeks to provide comments directly within the Google Doc.
7. Reviewers' input is gathered within the Google Doc using suggested edits and comments (Suggesting Mode).
8. Author(s) generate a revised version of the document taking on board the suggestions and comments of the reviewers (in instances where the reviewer(s) identify quality issues which cannot be resolved by the submission deadline, the deliverable submission would need to be delayed).

<sup>84</sup> [https://drive.google.com/drive/folders/1Dt3o4YMqnVx3f15n5zoTA\\_B2hdeonSM](https://drive.google.com/drive/folders/1Dt3o4YMqnVx3f15n5zoTA_B2hdeonSM)

9. 1.5 weeks (10 days) prior to the due date, author(s) must send the final version to the GDI-CO emailing them a link to the Google Doc version on the GDI Shared Drive. The GDI-CO will then circulate the document (via emailed link) to the Management Board (all Pillar Leaders and Coordinator) and to the 1+MG Group (only in those instances where the deliverable is of relevance to the 1+MG Initiative) for final review, allowing them seven (7) days to review the document. The Management Board are encouraged to make any suggestions or comments directly within the Google Doc using Suggesting Mode.
10. Three days prior to the due date, the author(s) provide the GDI-CO with the consolidated, final version.
11. The Coordinator (or the GDI-CO on their behalf) will convert the Google Doc to PDF and upload the final version in the Funding and Tenders Portal and to Zenodo.
12. The final version of the document is also uploaded to the 'Submitted' folder within the respective reporting period subfolder (e.g. RV01 M1-9, RV02 M10-18) in the 04. Deliverables and Milestones folder<sup>85</sup> on the GDI Shared Drive.

*E.g. 04. Deliverables and Milestones → RV01 M1-9 → Submitted*

**Note:**

1. Although the illustrative timeline starts three months prior to the due date with drafting beginning two months prior to the due date, this process can begin earlier if the authors wish, and deliverables can be submitted ahead of schedule.
2. Where the deliverable due date falls over a Christmas period (e.g. 31st December) or over a summer period, please consider adjusting the illustrative timeline to allow for times when colleagues may be on annual leave. The Management Board and GDI-CO won't appreciate reviewing deliverables over their Christmas break.
3. In case of time constraints, an exceptional streamlined procedure for the deliverables may apply upon agreement with the Management Board.

A tracker listing all deliverables, owners and due dates is available in the [Project Master Document](#)<sup>86</sup>.

## 7.2. Milestones

Each milestone must use a clean copy of the milestone template<sup>87</sup> and must not exceed one slide.

It is the responsibility of the Milestone Lead organisation to produce the milestone report or to deputise the responsibility to someone else upon their agreement. A tracker listing all milestones, owners and due dates is available in the [Project Master Document](#)<sup>88</sup>.

<sup>85</sup> [https://drive.google.com/drive/folders/1Dt304YMqnVx3f15n5zoTA\\_BzhdeonSM\\_](https://drive.google.com/drive/folders/1Dt304YMqnVx3f15n5zoTA_BzhdeonSM_)

<sup>86</sup> <https://docs.google.com/spreadsheets/d/1nfXQtRcfnXsqiazqPoK3OGAeJja4n03h/edit#gid=312411306>

<sup>87</sup> <https://docs.google.com/presentation/d/1Zdo8X7JCgQy6wzQpRWPU1gkTxlspkcFoBKVk5-oG3oc/edit?usp=sharing>

<sup>88</sup> <https://docs.google.com/spreadsheets/d/1nfXQtRcfnXsqiazqPoK3OGAeJja4n03h/edit#gid=1645851001>



### 7.2.1. Illustrative timelines

1. 3 months prior to the due date, the milestone will appear in the project monitoring report with a link to the pre-prepared milestone template and a reminder will also be emailed directly to the Milestone Lead (owner) with the WPL(s) on copy.
2. 1.5 months (45 days) prior to the due date, if the author(s) are not the Milestone Owner or WPLs, they must have the Milestone Owner and WPLs review the milestone before submitting it.
3. 1.5 weeks (10 days) prior to the due date, author(s) must send the final version to the GDI-CO by emailing them a link to the Google Doc version on the GDI Shared Drive. The GDI-CO will then circulate the document (via emailed link) to the Management Board (all Pillar Leaders and Coordinator) for final review, allowing them seven (7) days to provide any comment. The MB are encouraged to make any suggestions or comments directly within the Google Doc using Suggesting Mode, however, this shouldn't be a time consuming process for the MB.
4. Three days prior to the due date, the author(s) provide the GDI-CO with the final version.
5. The Coordinator (or the GDI-CO on their behalf) will convert the Google Doc to PDF and upload it in the Funding and Tenders Portal.
6. The final version of the document is also uploaded to the 'Submitted' folder within the respective reporting period subfolder (e.g. RV01 M1-9, RV02 M10-18) in the 04. Deliverables and Milestones folder<sup>89</sup> on the GDI Shared Drive.

*E.g. 04. Deliverables and Milestones → RV01 M1-9 → Submitted*

A tracker listing all milestones, owners and due dates is available in the [Project Master Document](#)<sup>90</sup>.

## 7.3. Progress reporting

### 7.3.1. EC Project Periodic Technical Reports

Throughout the entire project execution period (1st November 2022 until 31st October 2026), the Consortium is required to submit, in due time, three periodic technical reports to the EC using the template periodic report provided in the EC Participant Portal<sup>91</sup>. The project is officially divided into three periods for both progress and financial reporting to the EC:

- RP1: 1st Nov 2022 to 30th April 2024 (M1-18)
- RP2: 1st May 2024 to 31st Oct 2025 (M19-36)
- RP3: 1st Nov 2025 to 31st Oct 2026 (M37-48)

<sup>89</sup> [https://drive.google.com/drive/folders/1Dt3o4YMqnVx3f15n5zoTA\\_BzhdeonSM](https://drive.google.com/drive/folders/1Dt3o4YMqnVx3f15n5zoTA_BzhdeonSM)

<sup>90</sup> <https://docs.google.com/spreadsheets/d/1nfXQtRcfnXsqiazqPoK3OGAeJja4n03h/edit#gid=1645851001>

<sup>91</sup> <https://webgate.ec.europa.eu/funding-tenders-opportunities/pages/viewpage.action?pageId=1867970>



In compliance with the rules specified in Clause 4.2 of the GDI Grant Agreement (Periodic reporting and payments)<sup>92</sup>, periodic reports have to be submitted to the EC within 60 days after the end of each reporting period.

The periodic technical report must include the following:

- an explanation of the work carried out by the beneficiaries;
- an overview of the progress towards the objectives of the action, including milestones and deliverables identified in Annex 1;
  - an explanation justifying any differences between work expected to be carried out in accordance with Annex 1 and that actually carried out;
  - an overview of the exploitation and dissemination of the results and, if required in Annex 1, an updated 'plan for the exploitation and dissemination of the results'.
  - an overview of the communication activities;
- a summary for publication by the EC;
- the answers to the 'questionnaire', covering issues related to the action implementation and the economic and societal impact, notably in the context of the EC and the Digital Europe key performance indicators and EC and the Digital Europe monitoring requirements.

Each partner shall send or provide within the technical report template, as requested, information about the work performed and efforts devoted in the corresponding period to the GDI-CO, within 30 calendar days after the end of the reporting period. Effort figures can however be requested by the GDI-CO at any point during the project. For the purpose of accountability, beneficiaries are requested to keep track of their efforts at the task/activity level. This facilitates the linkage between effort and progress when reporting to the EC in the technical reports and during the review meetings when we are asked to report progress at the task level.

The Periodic Technical Report template provided by the EC will be available on the GDI project Shared Drive<sup>93</sup> once available. This template will be used for each of the three Periodic Technical Reports unless the EC produces an amended version throughout the course of the GDI project.

Detailed instructions on the submission of the periodic technical report will be provided by the GDI-CO to all partners in advance of the reporting deadline.

### 7.3.2. Financial Reporting

Disclaimer: Beneficiaries must always ensure they follow the EC financial reporting guidelines. The details provided here are valid at the date of the document submission but may be superseded by changes to EC rules.

<sup>92</sup> <https://drive.google.com/file/d/1k1M8tvPWqAXh-ElzZ7c5eTY5Z2yOxuox/view?usp=sharing>

<sup>93</sup> [https://drive.google.com/drive/folders/19716il\\_r6oRWFyT4Vl7EYhpw8LoFpgkJm](https://drive.google.com/drive/folders/19716il_r6oRWFyT4Vl7EYhpw8LoFpgkJm)





As with all EC Digital Europe projects, each GDI project beneficiary has a budget, which comprises the estimated costs that will be incurred during the project lifecycle. 50% of these costs can be covered with EC funding. Total funding received by a beneficiary cannot exceed its costs (i.e. it cannot yield a profit derived from participation in the project).

EC funding follows EC reimbursement rules, which imply in the GDI project a maximum 50% of the costs reimbursed for eligible project activities. EC funding is paid in several instalments: an advance payment (pre-financing) at the beginning of the project, periodic interim payments reimbursing the costs reported and accepted in each Periodic Report (up to a total amount of 85% of the total funding for a beneficiary), and a final payment of the remaining 15% of the total funding.

Budgeted efforts and costs are available in the DoA. When agreed by the Management Board, budgets can be adjusted by transfers of amounts between beneficiaries or between budget categories (or both) during the project life. This may not require an amendment, if the action is implemented as described in DoA. In case of subcontracting, these costs should be included in the DoA (via Amendment if needed) to make sure they are accepted by the EC as costs claimed.

#### *7.3.2.1. Eligible costs*

Co-funding will be based on actually incurred costs. The EU funding rate of 50% applies to the project's eligible costs that have actually been incurred within the duration of the project (see Article 6 of the General Model Grant Agreement<sup>94</sup> for more information on the cost eligibility conditions).

Moreover, as stated in section 13 of the Call document<sup>95</sup>, grants may not give a profit (i.e. surplus of revenues + EU grant over costs). Any given action may receive only one grant from the EU budget and cost items may under no circumstances be declared to two different EU actions (except under EU Synergies actions). This is particularly important when reporting effort to the GDI and B1MG projects.

Combination with EU operating grants is possible, if the project remains outside the operating grant work programme and it is made sure that cost items are clearly separated in the accounting and not declared twice, see Article 6.3.b.ii of the General Model Grant Agreement<sup>96</sup>. Financial contributions from non-EU funding can be used to co-fund the action.

Costs which are categorised as eligible may be claimed for reimbursement. In order to consider project costs as eligible and therefore be approved by the EC, they must fulfil the following general conditions:

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<sup>94</sup> <https://drive.google.com/file/d/1rtHRX8znBUZ484qAkyWv26UnedYwuSG7/view?usp=sharing>

<sup>95</sup>

[https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/digital/wp-call/2021/call-fiche\\_digital-2021-cloud-ai-01\\_en.pdf](https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/digital/wp-call/2021/call-fiche_digital-2021-cloud-ai-01_en.pdf)

<sup>96</sup> <https://drive.google.com/file/d/1rtHRX8znBUZ484qAkyWv26UnedYwuSG7/view?usp=sharing>



Actual costs that were actually incurred for your project, in-line with budgeted costs (same cost categories as budgeted), including:

- A. Personnel costs
  - Inc. average personnel costs (unit cost according to usual cost accounting practices)
- A.1 Employees / A.2 Natural persons under direct contract / A.3 Seconded persons / A.4 SME owners and natural person beneficiaries
- B. Subcontracting costs (subcontracted work must be performed in the eligible countries)
- C. Purchase costs
- C.1 Travel and subsistence (actuals only)
- C.2 Equipment:
  - depreciation + full cost for listed equipment for topic
- C.3 Other goods, works and services
- D. Other cost categories:
  - D.1 Financial support to third parties
  - D.2 Internally invoiced goods and services (unit cost according to usual cost accounting practices)
- E. Indirect costs flat-rate: 7% of the eligible direct costs
  - VAT: non-deductible VAT is eligible (but please note that since 2013 VAT paid by beneficiaries that are public bodies acting as public authority is NOT eligible)
- in-kind contributions for free are allowed, but cost-neutral, i.e. they cannot be declared as eligible cost
- kick-off meeting: costs for kick-off meeting are eligible

NOTE: See the Grant Agreement for more details on Eligible Costs

Beneficiaries should take into account, in the day-to-day administration of the project, some practical advice that may facilitate their financial management.

Beneficiaries need to:

- be aware of their own budget distribution;
- coordinate their financial flows: budget, funding, expenditure, justification, payments;
- avoid inconsistencies between efforts spent in the project (recorded in time sheets) and personnel cost justification.

'Budget' refers to costs that each partner is expected to incur, as declared in the DoA. The amount contributed by the EC is called 'funding' or 'EC contribution', and corresponds to 50% of the eligible costs. A beneficiary has to justify its total budget in order to get the expected funding in full. The actual costs incurred during the project (the 'practical' implementation of the planned budget) is called the 'expenditure'. These costs will conform to EC rules and therefore be justifiable. Lastly, 'payments' refer to the actual amounts transferred to the partners' accounts during the project. These





depend on the funding of each partner and the justification accepted by the EC, and cannot exceed the total funding of each beneficiary.

Identification of eligible costs:

#### **7.3.2.1.1. Personnel Costs**

The EC follows a policy of full cost justification for all beneficiaries. This means that the hours devoted by all of the personnel involved in a project can be justified, irrespective of them being newly hired for the project or permanent staff.

For the justification of personnel costs in the periodic financial statement, beneficiaries must take into account the efforts (expressed in person-months) reported for the same period so that these are consistent with the amounts justified. Personnel costs are understood to include salaries, social charges, etc.; all of the actual costs that the person represents for the institution.

According to Article 6.2 of the Grant Agreement<sup>97</sup>, the following calculations should be used:

The personnel costs are normally calculated by the daily rate for the person multiplied by the number of day-equivalents worked on the action (rounded up or down to the nearest half-day).

The daily rate must be calculated as: annual personnel costs for the person divided by 215. The number of day-equivalents declared for a person must be identifiable and verifiable. The total number of day-equivalents declared in EU grants, for a person for a year, cannot be higher than 215.

The personnel costs may also include supplementary payments for personnel assigned to the action (including payments on the basis of supplementary contracts regardless of their nature), if:

- it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required
- the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

If the beneficiary uses average personnel costs (unit cost according to usual cost accounting practices), the personnel costs must fulfil the general eligibility conditions for such unit costs and the daily rate must be calculated:

- using the actual personnel costs recorded in the beneficiary's accounts and excluding any costs which are ineligible or already included in other budget categories; the actual personnel costs may be adjusted on the basis of budgeted or estimated elements, if they are relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information

and

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<sup>97</sup> <https://drive.google.com/file/d/1k1M8tvPWqAXh-ElzZ7c5eTY5Z2yOxuox/view?usp=sharing>

- according to usual cost accounting practices which are applied in a consistent manner, based on objective criteria, regardless of the source of funding.

In addition, for personnel costs, the beneficiaries must keep time records for the number of days declared for all actual work performed for the project. The time records must be in writing and approved by the persons working for the action and their supervisors, at least monthly. It is advised that time records should include:

- the title and Grant Agreement number of the project, as specified in the GA;
- the beneficiary's full name, as specified in the GA;
- the full name, date and signature of the person working for the action;
- the number of days worked for the action in the period covered by the time record
- short description of the work carried out during the month;
- the supervisor's full name and signature.

Your institution may choose to use the EC template Time Declaration<sup>98</sup> if this is inline with usual accounting and timekeeping practices.

#### 7.3.2.1.2. Subcontracting costs.

Subcontracting costs for the action (including related duties, taxes and charges, such as non-deductible or non-refundable value added tax (VAT)) are eligible, if they are calculated on the basis of the costs actually incurred, fulfil the general eligibility conditions and are awarded using the beneficiary's usual purchasing practices — provided these ensure subcontracts with best value for money (or if appropriate the lowest price) and that there is no conflict of interests.

The beneficiaries must ensure that the subcontracted work is performed in the eligible countries or target countries set out in the call conditions — unless otherwise approved by the granting authority.

Subcontracting may cover only a limited part of the action.

Regarding subcontracting costs, it is paramount that the DoA includes a specification that enables approval by the EC.

The EC lay a ground rule that all partners must have the technical and financial resources needed to carry out the project themselves, but if it is necessary to implement the project, a beneficiary may call upon subcontractors to implement "action tasks" as described in Article 9.3 of the Grant Agreement ("Subcontractors")<sup>99</sup>.

- FTEs are to help create national capacity that remains after the end of the project. Therefore, subcontracting should be avoided when possible
- Only subcontracting defined in the the DoA is eligible

<sup>98</sup>

[https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/temp-form/report/time-declaration\\_en.docx](https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/temp-form/report/time-declaration_en.docx)

<sup>99</sup> <https://drive.google.com/file/d/1k1M8tvPWqAXh-FlzZ7c5eTY5Z2yOxuox/view?usp=sharing>



- Subcontracted work must be performed in the eligible countries and by validated institutions (ownership declaration)

### 7.3.2.1.3. Purchase costs

Purchase costs for the action (including related duties, taxes and charges, such as non-deductible or non-refundable value added tax (VAT)) are eligible if they fulfil the general eligibility conditions and are bought using the beneficiary's usual purchasing practices — provided these ensure purchases with best value for money (or if appropriate the lowest price) and that there is no conflict of interests.

Beneficiaries that are 'contracting authorities/entities' within the meaning of the EU Directives on public procurement must also comply with the applicable national law on public procurement.

#### 7.3.2.1.3.1. Travel and subsistence costs

Purchases for travel, accommodation and subsistence must be calculated as follows:

- travel: on the basis of the costs actually incurred and in line with the beneficiary's usual practices on travel
- accommodation: on the basis of the costs actually incurred and in line with the beneficiary's usual practices on travel
- subsistence: on the basis of the costs actually incurred and in line with the beneficiary's usual practices on travel.

As a general rule, common meetings expenses (catering, meeting rooms, etc.) shall be paid and justified by the host partner/s in the corresponding reporting period under the "Travel and subsistence costs " category.

- Travel costs must be needed for the work in the project, or for activities related to it (e.g. presentation of a paper explaining the results of the project in a conference). Travel costs related to a conference where no specific project-related work will be performed or presented by the beneficiary would not be eligible. Travel costs should be limited to the necessity for the project; any extension of the travel for other professional or private reasons is not an eligible cost.
- Each partner must apply the travel rules of their own organisation (i.e. some organisations reimburse a flat rate allowance for meal expenses while others reimburse actual costs).

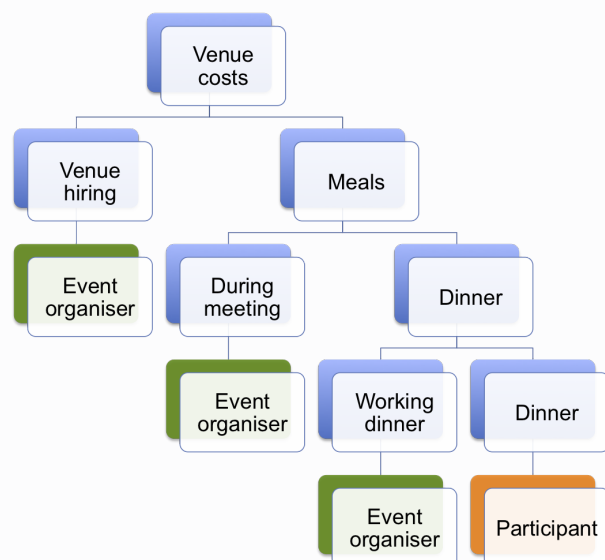
The ELIXIR Hub provides decision trees for determining who pays for travel and meeting costs - the hosting organisation or the beneficiary:

#### 7.3.2.1.3.2. Who pays what? Event organiser or external source?

Venue costs:

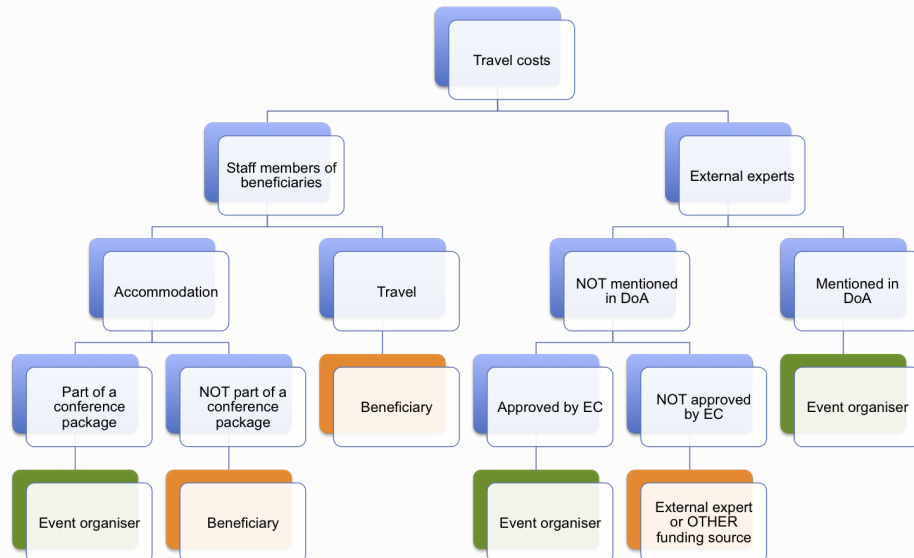


GDI project receives funding from the European Union's Digital Europe Programme under grant agreement number 101081813.



**Figure 6.** Venue costs decision tree

### 7.3.2.1.3.3. Travel costs



**Figure 7.** Travel costs decision tree

For more information, see ELIXIR's Guidelines and Tips for Events - for event organisers<sup>100</sup>

<sup>100</sup> [https://docs.google.com/document/d/12YrPswFuUywSRaYdjUDjaq-bvhm\\_e\\_gQqd1pM44vmc/edit#](https://docs.google.com/document/d/12YrPswFuUywSRaYdjUDjaq-bvhm_e_gQqd1pM44vmc/edit#)



#### **7.3.2.1.5. Equipment**

Purchases of equipment, infrastructure or other assets used for the action must be declared as depreciation costs, calculated on the basis of the costs actually incurred and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.

Only the portion of the costs that corresponds to the rate of actual use for the action during the action duration can be taken into account.

Costs for renting or leasing equipment, infrastructure or other assets are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.

#### **7.3.2.1.6. Other goods, works and services**

Purchases of other goods, works and services must be calculated on the basis of the costs actually incurred.

Such goods, works and services include, for instance, consumables and supplies, promotion, dissemination, protection of results, translations, publications, certificates and financial guarantees, if required under the Agreement.

#### **7.3.2.1.7. Indirect costs**

Indirect costs will be reimbursed at the flat-rate of **7%** of the eligible direct costs (categories A-D, except volunteers costs and exempted specific cost categories, if any).

As they are indirect, these costs are not justified using invoices, etc., but are simply stated in the financial statement as a 7% flat rate of the direct costs.

For more information on all cost categories, please refer to Article 6 (Eligible and ineligible costs and contributions) of the Grant Agreement<sup>101</sup>.

If in doubt, we encourage you to email [gdi-coordination@elixir-europe.org](mailto:gdi-coordination@elixir-europe.org) for further guidance or clarification.

#### **7.3.2.2. Non-eligible costs**

Non-Eligible costs: costs which can not be claimed.

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<sup>101</sup> <https://drive.google.com/file/d/1k1M8tvPWqAXh-ElzZ7c5eTY5Z2yOxuox/view?usp=sharing>



The EC state that there are some costs which cannot be considered eligible and therefore, can not be included in the financial statement.

Costs that do not comply with the conditions set out in Articles 6.3 ("Ineligible Costs and Contributions") of the Grant Agreement<sup>102</sup>, in particular:

- costs or contributions that do not comply with the conditions set out above (Article 6.1 and 6.2), in particular:
  - costs related to return on capital and dividends paid by a beneficiary
  - debt and debt service charges
  - provisions for future losses or debts
  - interest owed
  - currency exchange losses
  - bank costs charged by the beneficiary's bank for transfers from the granting authority
  - excessive or reckless expenditure
  - deductible or refundable VAT (including VAT paid by public bodies acting as public authority)
  - costs incurred or contributions for activities implemented during grant agreement
  - suspension (see Article 31)
  - in-kind contributions by third parties
- costs or contributions declared under other EU grants (or grants awarded by an EU Member State, non-EU country or other body implementing the EU budget), except for the following cases:
  - (i) Synergy actions: not applicable
  - (ii) if the action grant is combined with an operating grant running during the same period and the beneficiary can demonstrate that the operating grant does not cover any (direct or indirect) costs of the action grant
- costs or contributions for staff of a national (or regional/local) administration, for activities that are part of the administration's normal activities (i.e. not undertaken only because of the grant)
- costs or contributions (especially travel and subsistence) for staff or representatives of EU institutions, bodies or agencies
- other:
  - costs or contributions for activities that do not take place in one of the eligible countries or target countries set out in the call conditions — unless approved by the granting authority
  - costs or contributions declared specifically ineligible in the call conditions.

If a beneficiary declares costs or contributions that are ineligible, they will be rejected (see Article 27) and this may also lead to other measures described in Chapter 5 of the Grant Agreement<sup>103</sup>.

<sup>102</sup> <https://drive.google.com/file/d/1k1M8tvPWqAXh-ElzZ7c5eTY5Z2yOxuox/view?usp=sharing>

<sup>103</sup> <https://drive.google.com/file/d/1k1M8tvPWqAXh-ElzZ7c5eTY5Z2yOxuox/view?usp=sharing>



For more information on all cost categories, please refer to Article 6 (Eligible and ineligible costs and contributions) of the Grant Agreement<sup>104</sup>.

#### *7.3.2.3. Submitting the financial statement*

The financial statement is an official statement submitted by the beneficiary. Any Affiliated Entities (AEs) must provide their financial statement to the project beneficiary who in turn, must submit the report to the EC on their behalf. In the financial statement the beneficiary must declare any costs incurred during the specific reporting period for which they wish to be reimbursed by the EC, where applicable.

The EC uses an online application tool called the Funding & Tender Opportunities Portal<sup>105</sup> for the submission of financial statements. Each beneficiary has access to the portal and are expected to submit their costs there. A sample Financial Statement is available in the Grant Agreement, Annex 4<sup>106</sup>.

Draft costs must be filled in the Funding & Tender Opportunities Portal within 20 calendar days after the end of the reporting period together with the explanation of use of resources. After review by the GDI-CO, the final figures should be ready to submit 46 calendar days after the end of the reporting period. It is advised that beneficiaries prepare in advance for reporting and liaise with any relevant financial or administrative department in their respective institution at least one month in advance of the end of the reporting period.

Specific guidelines for accessing the Participant Portal will also be provided by the GDI-CO in the months leading up to the reporting period. These guidelines will include complete instructions and recommendations for adequate reporting.

#### *7.3.2.4. Adjustments to previous periods*

Any adjustment (retroactive modification of costs submitted in previous periods) requires the submission of a supplementary Financial Statement for the period, where the details of that adjustment will appear.

Together with the new financial statement, the details and justification for the adjustment must be provided by the participant in the periodic report.

Therefore, for correction of financial statements submitted in previous reporting periods, the following need to be submitted:

- One Financial Statement for the current period;
- One separate Financial Statement for every previous period where adjustments are needed, which will include those adjusted (negative/positive) costs of that specific previous period.

<sup>104</sup> <https://drive.google.com/file/d/1k1M8tvPWqAXh-ElzZ7c5eTY5Z2yOxuox/view?usp=sharing>

<sup>105</sup> <https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/home>

<sup>106</sup> <https://drive.google.com/file/d/1k1M8tvPWqAXh-ElzZ7c5eTY5Z2yOxuox/view>



If these costs need to be covered by a Certificate on Financial Statements (CFS), they could be supported within the CFS for the current period but with a specific indication by the auditor certifying both the supplementary costs incurred in previous periods and those claimed in the current one.

### 7.3.3. Final Report

Within 60 days after the end of the project, and in addition to the periodic report for the last reporting period, the Consortium must also submit a final report to the EC. This final report must include the following:

1. A 'final technical report' with a summary for publication containing:
  - a. an overview of the results and their exploitation and dissemination;
  - b. the conclusions on the action, and;
  - c. the socio-economic impact of the action.
2. A 'final financial report' containing:
  - a. a 'final summary financial statement', created automatically by the electronic exchange system, consolidating the individual financial statements for all reporting periods and including the request for payment of the balance and;
  - b. a 'certificate on the financial statements' for each beneficiary, if it requests a total contribution of €325,000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices.

This final report will be prepared by the GDI-CO and the Management Board and WPLs with input from all WPs.

The GDI-CO will also coordinate the elaboration of the final financial report that accompanies the technical report and in which reported figures from all participants throughout the project are consolidated.

Detailed instructions on the submission of the final report will be provided by the GDI-CO to all partners in advance of the reporting deadline.

### 7.3.4. Certificate on the Financial Statement (CFS)

A certificate on the financial statement (CFS), also named audit certificate, is a statement from a competent, external auditor in which correctness and compliance with EC rules of a cost justification is certified.

A CFS must be submitted together with the corresponding financial cost statement at the end of the project by all beneficiaries if the beneficiary requests a total contribution of 325,000 Euro or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices.



GDI project receives funding from the European Union's Digital Europe Programme under grant agreement number 101081813.



Auditors eligible to deliver audit certificates must be "external auditors" or "public competent officers" who are "independent" and "qualified to carry out statutory audits of accounting documents". It is highly recommended to determine an adequate auditor well before the end of the reporting period to ensure his/her availability for a timely generation of the audit certificate.

See Article 24.2 of the Grant Agreement<sup>107</sup> for more information about the certificate on the financial statement.

### 7.3.5. EC Funding

The EC funding (50% of the total eligible costs) is paid to the Coordinator (ELIXIR Hub), who distributes it to the beneficiaries without unjustified delay and within 30 days of receipt from the EC.

Payments will be made in accordance with the schedule and modalities set out in the Data Sheet (see Point 4.2 - page 10 of the Grant Agreement<sup>108</sup>).

Some general rules apply with respect to the payments:

- The EC paid a pre-financing amount (80%) at the start of the project which was distributed to the beneficiaries receiving funding. A tracker of pre-financing payments is available on the project Shared Drive<sup>109</sup>;
- interim payments will be depending on costs justified and accepted after each reporting period, and distributed after receipt from the EC;
- a final payment will be released by the EC corresponding to the costs accepted for the last reporting period, plus any adjustment needed.

Total payments during the project cannot exceed 85% of the total funding. 15% of the funding will only be paid after final reports are approved.

The most important notion for beneficiaries to bear in mind is that payments follow costs reported – and costs reported follow work done for the project.

See the Grant Agreement Articles 21 ("Reporting") and 22 ("Payments and Recoveries")<sup>110</sup> for more information concerning the reporting process and financial payments.

### 7.3.6. Receipts of the project

The receipts (in lay terms, 'income received due to the project') of the project are:

- Resources made available by third parties to the partner by means of financial transfers or contributions in-kind which are free of charge:

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<sup>107</sup> <https://drive.google.com/file/d/1k1M8tvPWqAXh-ElzZ7c5eTY5Z2yOxuox/view>

<sup>108</sup> <https://drive.google.com/file/d/1k1M8tvPWqAXh-ElzZ7c5eTY5Z2yOxuox/view?usp=sharing>

<sup>109</sup> <https://docs.google.com/spreadsheets/d/155MGTZuDjHkjt9l8j2of9Rlp1dMq9Mmd/edit#gid=654093336>

<sup>110</sup> <https://drive.google.com/file/d/1k1M8tvPWqAXh-ElzZ7c5eTY5Z2yOxuox/view?usp=sharing>



- Shall be considered a receipt of the project if they have been contributed by the third party specifically to be used on the project.
- Shall not be considered a receipt of the project if their use is at the discretion of the participant's management.
- Income generated by the project:
  - Shall be considered a receipt for the participant when generated by actions undertaken in carrying out the project and from the sale of assets purchased under the grant agreement up to the value of the cost initially charged to the project by the participant;
  - Shall not be considered a receipt for the participant when generated from the research use or direct exploitation of foreground resulting from the project.

## 7.4. Key Performance Indicators (KPIs)

The outcomes and deliverables of the project in relation to the call text will be assessed against the four Key Performance Indicators defined in the Call Text:

KPIs to measure outcomes and deliverables:

1. Number of different databanks and platforms connected to the European genomic data infrastructure – at least 20 from at least 13 different EU/associated countries by the end of the project.
  - Due to high interest from countries to participate in the GDI consortium, GDI is going beyond this KPI (13 operational countries). The consortium has decided to prioritise the funding to enable countries participating (and those that have deferred their participation) to reach their target stage (via pillar II) and to fund the expansion of the 1+MG/B1MG PoC targeting new disease areas and identifying innovative solutions that will support the exemplar users (pillar III).
2. Volume of genomic data accessible through the project – with the objective to achieve at least 1 million by 2022, and further sizeable increase by the end of the project.
3. Number of authorised users connected to the European genomic data infrastructure in operational mode – at least 100 by the end of the project.
4. Number of countries in which the communication strategy has been implemented – at least all EU/associated countries where databanks/platforms have been connected to the European genomic data infrastructure.



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These KPIs can easily be monitored from the project onset and will be refined in Task 5.3 Technical coordination. Progress against these KPIs must be tracked in each deliverable report and reported to the governance boards, to inform project planning and management, looking forwards (rather than post-hoc assessment), ensuring corrective actions are taken as and when they are needed. Some of these indicators already form part of ELIXIR's suite of indicators, which are used to monitor the infrastructure's performance (mostly internally-facing) and impact (mostly externally-facing), in line with ESFRI's current work on ensuring that the infrastructures it has recognised are adequately monitored.

In addition, Communications KPIs will be detailed in the GDI communication strategy.

The KPIs must be formally reviewed and updated as part of:

- D3.2 – Node deployment roadmap (Updated development and deployment roadmap for each node including node KPIs and gap analysis) - month 12
- D3.5: Final report on production system meeting defined KPIs (Final report on production infrastructure measured against defined KPIs) - Month 48
- D4.5 – Report on European operations (Report on operation of the GDI, including KPIs and metrics) - Month 48

As and when new metrics are available, it is the responsibility of the WPLs to inform the GDI-CO who will then include them in the dashboard to be monitored monthly.



## 8. Data management plan

The Data Management Plan (DMP) will be defined and updated throughout the project lifecycle as part of Work Package 6: Data Management. WP6 provides the data management plans for onboarding of 1+MG genomic datasets and technical implementation of data governance. The initial version of the DMP must be created by VIB in the first six months of the project as Deliverable *D6.1: Draft data management policy published including ELSI best practice* according to the project scope and the EC requirements.

Any questions regarding the DMP should be directed to WP6, [gdi-WP6@elixir-europe.org](mailto:gdi-WP6@elixir-europe.org), or the coordination team, [gdi-coordination@elixir-europe.org](mailto:gdi-coordination@elixir-europe.org).





## 9. Ethical considerations

GDI will drive the development, deployment and operation of sustainable data-access infrastructures within each participating country including the legal frameworks, operational procedures and ethics principles required to foster and maintain citizens' trust in cross-border access to highly sensitive personal data.

A mandatory Ethics Work Package, WP9 – Ethics requirements, was included in the Description of Action during the Grant Agreement Preparation phase. This WP comprises five deliverables:

1. Dg.1: H - AI - POPD - Requirement No. 1 (Establishment of an external ethics and legal advisory board) - Due Month 1
  - The scale and the importance of the raised ethic issues (raised by the proposal reviewers) requires the establishment of an external ethics and legal advisory board. Members of this board must include data protection related legal expertise, e.g. representatives from data protection authorities, technical expertise on data protection and privacy by design, expertise on the use of AI technologies for health purposes as well as representatives of civil society and patient organisations.
2. Dg.2: POPD - AI - H - Requirement No. 3 (First annual report of the external ethics and legal advisory board covering M1-M12) - Due Month 12
3. Dg.3: POPD - H - AI - Requirement No. 4 (Second annual report of the external ethics and legal advisory board covering M13-M24) - Due Month 24
4. Dg.4: POPD - AI - H - Requirement No. 5 (Third annual report of the external ethics and legal advisory board covering M25-M36) - Due Month 36
5. Dg.5: H - AI - POPD - Requirement No. 2 (Fourth annual report of the external ethics and legal advisory board covering M37-M48) - Due Month 48

In line with the mandatory Ethics Requirements, the coordinator will ensure sufficient consultation and support to address the ethical issues that could appear during the execution of the project. The objective of Work Package 9 is to ensure compliance with the 'ethics requirements' which are included as deliverables in the work package. No budget is assigned to the work package.

By month 1 of the project an external ethics and legal advisory board will have been established. Members of this board will include data protection related legal expertise, for example, representatives from data protection authorities, technical expertise on data protection and privacy by design, expertise on the use of AI technologies for health purposes as well as representatives of civil society and patient organisations. See section [5.1.15. Ethics Advisory Board](#) for more information.



Reports on the treatment of ethical and legal issues within the GDI project will be submitted as annual deliverables.

It is important to note that actual cross-border access to real sensitive human data can only be enabled where legal agreements between countries are in place. Until such agreements are in place, use cases will demonstrate impact by relying on data provided through partner projects that have already addressed the ethical aspects for such data access.

See the Grant Agreement, Annex 2 - Ethics Issues Table<sup>111</sup> for a list of ethical issues of concern to the GDI project and where they are addressed in the Description of Action and the GDI Ethics self-assessment.

Finally, as stipulated in the Grant Agreement (Article 14: Ethics<sup>112</sup>):

- The beneficiaries must pay particular attention to the principle of proportionality, the right to privacy, the right to the protection of personal data, the right to the physical and mental integrity of persons, the right to non-discrimination, the need to ensure protection of the environment and high levels of human health protection.
- Before the beginning of an action task raising an ethical issue, the beneficiaries must have obtained all approvals or other mandatory documents needed for implementing the task, notably from any (national or local) ethics committee or other bodies such as data protection authorities.
- The documents must be kept on file and be submitted upon request by the coordinator to the granting authority. If they are not in English, they must be submitted together with an English summary, which shows that the documents cover the action tasks in question and includes the conclusions of the committee or authority concerned (if any).

## 9.1. Equal Opportunities

Beneficiaries have an obligation to aim for gender equality and must take all measures to promote equal opportunities between men and women in the implementation of the action. They must aim, to the extent possible, for a gender balance at all levels of personnel assigned to the action, including at supervisory and managerial level.

It is acknowledged by GDI project partners that equal opportunities include: gender balance in research teams; gender balance in decision-making; and integrating gender/sex analysis in R&I content. The consortium is also aware of the well-known underrepresentation of women in higher-level positions in the academic sciences. A key action to address underrepresentation is to ensure that women and other underrepresented groups have equal opportunities to lead ad-hoc project working groups and present the outcome of project activities to external stakeholders to

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<sup>111</sup> <https://drive.google.com/file/d/1k1M8tvPWqAXh-ElzZ7c5eTY5Z2yOxuox/view?usp=sharing>

<sup>112</sup> <https://drive.google.com/file/d/1k1M8tvPWqAXh-ElzZ7c5eTY5Z2yOxuox/view?usp=sharing>



ensure a cadre of future leaders. The GDI-CO and Management Board will monitor participation and representation.

## 10. Intellectual property rights

For all matters relating to Intellectual Property Rights please refer to:

1. Section 9 (Intellectual Property - Access Rights) of the GDI Consortium Agreement<sup>113</sup>
2. Article 16 (INTELLECTUAL PROPERTY RIGHTS (IPR) — BACKGROUND AND RESULTS — ACCESS RIGHTS AND RIGHTS OF USE) of the GDI Grant Agreement<sup>114</sup>

Or contact the GDI-CO: [gdi-coordination@elixir-europe.org](mailto:gdi-coordination@elixir-europe.org).

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<sup>113</sup> As of January 2023 the Consortium Agreement is under negotiation

<sup>114</sup> <https://drive.google.com/file/d/1k1M8tvPWqAXh-ElzZ7c5eTY5Z2yOxuox/view?usp=sharing>



## Annex 1: Project gantt chart

The full project Gantt chart and other project planning information can be found in the Project Master File on the GDI project Shared Drive<sup>115</sup>.

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<sup>115</sup> <https://docs.google.com/spreadsheets/d/1nfXQtRcfnXsqiazqPoK3OGAeJja4n03h/edit#gid=1706897384>



GDI project receives funding from the European Union's Digital Europe Programme under grant agreement number 101081813.



## Appendix 2: GDI Project Handbook - live version

The Project Handbook is accessible to all project Partners on the GDI project Shared Drive:  
[GDI\\_PROJECT HANDBOOK\\_LIVE document](https://docs.google.com/document/d/1EfiFxDylODJgNmaTZluz0DhDOt4kGL5Fg3G4p9IKvjk/edit#)<sup>116</sup>

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<sup>116</sup> GDI Project Handbook:

<https://docs.google.com/document/d/1EfiFxDylODJgNmaTZluz0DhDOt4kGL5Fg3G4p9IKvjk/edit#>



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