Beyond One Million Genomes

D6.5

Project Handbook - 3v0 - final version and lessons learnt

Project Title (grant agreement No)	Beyond One Million Genomes (B1MG) Grant Agreement 951724		
Project Acronym	B1MG		
WP No & Title	WP6 - Coordination Office: Project Management, Communication, Governance and Sustainability		
WP Leaders	Juan Arenas (ELIXIR Hub), Esther Rodriguez (ISCIII)		
Deliverable Lead Beneficiary	1 - ELIXIR / EMBL / EBI		
Deliverable	D6.5 - Project Handbook - 3v0 - final version and lessons learnt		
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Authors	Nikki Coutts, Juan Arenas (ELIXIR Hub)		
Contributors			
Acknowledgements (not grant participants)			
Deliverable type	Report		
Dissemination level	Public		

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Document History

Date	Mvm	Who	Description
10/10/2023	2v1	Juan Arenas & Nikki Coutts (ELIXIR Hub)	Review and update of version 2v0
19/10/2023	2v2	Juan Arenas & Nikki Coutts (ELIXIR Hub)	Circulated to OG, Stakeholders and GB for review
27/10/2023	2v3	Juan Arenas & Nikki Coutts (ELIXIR Hub)	Final comments closed
27/10/2023	3v0	Nikki Coutts (ELIXIR Hub)	Version uploaded to the EC Portal

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1. Executive summary

This report provides an overview of the development of the second version of the B1MG Project Handbook.

The project handbook follows the Open PM[21] 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 objectives

The project handbook defines the project process that provides the framework to accomplish all projects objectives within the scope, budget and the required level of quality, therefore, we can say with confidence that this deliverable contributes to all objectives as listed below:

	Key Result No and description	Contributed
Objective 1 Engage local, regional, national and European stakeholders to define the requirements for cross-border access to genomics and personalised medicine data	**1.** B1MG assembles key local, national, European and global actors in the field of Personalised Medicine within a B1MG Stakeholder Coordination Group (WP1) by M6.	Yes
	2. B1MG drives broad engagement around European access to personalised medicine data via the B1MG Stakeholder Coordination Portal (WP1) following the B1MG Communication Strategy (WP6) by M12.	Yes
	3. B1MG establishes awareness and dialogue with a broad set of societal actors via a continuously monitored and refined communications strategy (WP1, WP6) by M12, M18, M24 & M30.	Yes
	4. The open B1MG Summit (M18) engages and ensures that the views of all relevant stakeholders are captured in B1MG requirements and guidelines (WP1, WP6).	Yes
Objective 2 Translate requirements for data quality, standards, technical infrastructure, and ELSI into technical specifications and implementation guidelines that captures European best practice	**Legal & Ethical Key Results**	
	1. Establish relevant best practice in ethics of cross-border access to genome and phenotypic data (WP2) by M36	Yes
	2. Analysis of legal framework and development of common minimum standard (WP2) by M36.	Yes
	3. Cross-border Data Access and Use Governance Toolkit Framework (WP2) by M36.	Yes
	Technical Key Results	
	4. Quality metrics for sequencing (WP3) by M12.	Yes
	5. Best practices for Next Generation Sequencing (WP3) by M24.	Yes

[1] https://webgate.ec.europa.eu/fpfis/wikis/display/openPM2

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	6. Phenotypic and clinical metadata framework (WP3) by M12, M24 & M36.	Yes
	7. Best practices in sharing and linking phenotypic and genetic data (WP3) by M12 & M24.	Yes
	8. Data analysis challenge (WP3) by M36.	Yes
	Infrastructure Key Results	
	9. Secure cross-border data access roadmap (WP4) by M12 & M36.	Yes
	10. Secure cross-border data access demonstrator (WP4) by M24.	Yes
Objective 3 Drive adoption and support long-term operation by organisations at local, regional, national and European level by providing guidance on phased development (via the B1MG maturity level model), and a methodology for economic evaluation	**1.** The B1MG maturity level model (WP5) by M24.	Yes
	2. Roadmap and guidance tools for countries for effective implementation of Personalised Medicine (WP5) by M36.	Yes
	3. Economic evaluation models for Personalised Medicine and case studies (WP5) by M30.	Yes
	4. Guidance principles for national mirror groups and cross-border Personalised Medicine governance (WP6) by M30.	Yes
	5. Long-term sustainability design and funding routes for cross-border Personalised Medicine delivery (WP6) by M34.	Yes

3. Introduction

- The aim of this deliverable was to produce the updated, final version of the project handbook following the Open PM² best practices. 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 within the Project Management Team (PMT) within the ELIXIR Hub that an initial version of the project handbook should be ready by the end of M4 (September 2020). The need for a project handbook during the early stages of a project was paramount for the successful project management of the project, therefore, it was prioritised. Using the PM² template[2] and previous knowledge from the Project Managers of managing H2020 projects, the template was adapted to accommodate the scope of the B1MG project and we were able to produce the first draft which, when ready, was circulated to the Operational Group for review.

[2] PM2

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- By M4 (September 2020) we had incorporated suggestions and addressed feedback completing a finalised initial version of the handbook.
- Version 2v0 of the handbook, including changes incorporated during the first year of the project, was submitted in November 2021.
- The live version of the Handbook is stored in the B1MG Google Drive, which all project participants have access to.

4. Description of work accomplished

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

The finalised Project Handbook 3v0 can be viewed in Appendix 1.

The live Project Handbook document, which has evolved throughout the project, 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^2 template[3] using the prior project handbook preparation experience of the Project Management Team. The PM^2 Methodology originated from the European Commission and Open PM^2 provides many guidelines and templates to facilitate the management and documentation of EC projects.

B1MG project handbook live document. Table of contents

[3] 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

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4.1 Update of processes as defined in the Project Handbook

All project participants have been welcome to, and actively encouraged to, suggest updates to the processes which were defined in the second version (2v0) of the Project Handbook. The Project Handbook was designed to be a living, adaptable resource and therefore was updated as new processes were refined and defined, with this being the final formal update.

5. Conclusions

The project handbook provided the framework for the management of the B1MG project. The Project Management Team monitored the relevance of the handbook regularly during the duration of the project and adapted it as required to ensure that it remained relevant, met the needs of the project participants and fulfilled the objectives of the deliverable.

6. Impact

The project handbook and the associated project assets (e.g. the project monitoring tool) have provided the framework for the monitoring and delivery of the tasks and objectives of each of the seven Work Packages at both the technical and financial level.

The project monitoring tool, designed and developed by ELIXIR for the ELIXIR-CONVERGE project, has been used in the B1MG project.

7. Next Steps

The project handbook has been kept as a live document, available for review and modification at any point during the project duration, ensuring it remained a valuable project resource. Project participants have had easy access to the document at all times from the project Google Drive and were recommended to rely on it as a first point of contact when they had project management related questions.

8. Deviation from Description of Action

N/A

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Appendix 1: B1MG Project Handbook 1v0

The project handbook copied here is a snapshot of the final version as of 19 October 2023. The latest version can be found linked to Appendix 2, below.

951724 – B1MG

Project Handbook

Date: October 2023
Version: 3v0

Document control information

Settings	Value
Document Title	Project Handbook
Project Title	B1MG
Document Author	Nikki Coutts, Juan Arenas Marquez
Project Owner	Serena Scollen
Project Manager	Juan Arenas Marquez
Doc. Version	3v0
Sensitivity	Public
Date	10/10/2023

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

To request a change to this document, contact the Document Author or Owner.
Changes to this document are summarised in the following table.

Revision	Date	Created by	Short description of changes
0v1	01/09/2020	Nikki Coutts	First draft of full handbook structure
0v2	24/09/2020	Juan Arenas Marquez & Nikki Coutts	Review of draft and closed comments and circulated to OG, and GB for review
0v3	08/10/2020	Juan Arenas Marquez & Nikki Coutts	Final comments closed
1v0	08/10/2020	Nikki Coutts	Finalised to submit as a deliverable
1v1	13/10/2021	Nikki Coutts	Revision of the handbook, for second iteration of the deliverable
1v2	20/10/2021	Juan Arenas Marquez & Nikki Coutts	Review of draft and closed comments and circulated to OG, and GB for review

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1v3	21/11/2021	Juan Arenas Marquez & Nikki Coutts	Final comments closed
2v0	12/11/2021	Nikki Coutts	Finalised to submit as a deliverable
2v1	09/10/2023	Nikki Coutts	Revision of the handbook, for second iteration of the deliverable
2v2	19/10/2023	Juan Arenas Marquez & Nikki Coutts	Review of draft and closed comments - circulated to OG, and GB for review
2v3	XX/10/2023	Juan Arenas Marquez & Nikki Coutts	Final comments closed
3v0	XX/10/2023	Nikki Coutts	Finalised to submit as a deliverable

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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 B1MG 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 through annual updates.

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)[4] and the Consortium Agreement[5].

[4] https://drive.google.com/file/d/1eX8ZUNPx3KqRxDdrJtz7pegd6X6y_SOa/view?usp=sharing
[5] https://drive.google.com/file/d/1Wov2zOWkY76CoVAkmF_d8XPTNmAXybw3/view?usp=drive_link

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2. Project overview

2.1. Basic project information

Project Call: H2020-SC1-DTH-2018-2020 (Digital transformation in Health and Care)
Project Title: Beyond One Million Genomes
Project Acronym: B1MG
Grant Agreement N°: 951724
Call topic: SC1-HCC-06-2020
Project start date: 1st June 2020
Project end date: Extended to 31st October 2023
Duration: 41 months
Project budget: €4,000,000
Number of beneficiaries: 32
Number of LTPs: 6

2.2. Short names of the consortium partners

Table 1. Beneficiaries

Beneficiary n°	Name of the consortium partner	Short name
1 (Coordinator)	EUROPEAN MOLECULAR BIOLOGY LABORATORY (FOR ELIXIR AND EMBL-EBI)	ELIXIR / EMBL-EBI
2	BIOBANKS AND BIOMOLECULAR RESOURCES RESEARCH INFRASTRUCTURE CONSORTIUM(	BBMRI-ERIC
3	FUNDACIO CENTRE DE REGULACIO GENOMICA	CRG
4	CSC-TIETEEN TIETOTEKNIIKAN KESKUS OY	CSC
5	UNIVERZITA KARLOVA	CUNI
6	STICHTING DTL PROJECTS	DTL-PROJECTS
7	EUROPEAN ALLIANCE FOR PERSONALISED MEDICINE ASBL	EAPM
8	EATRIS ERIC	EATRIS
9	ECRIN EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK	ECRIN
10	STICHTING HARTWIG MEDICAL FOUNDATION	HMF
11	Orszagos Onkologiai Intezet	NIO
12	INSTITUTO NACIONAL DE SAUDE DR. RICARDO JORGE	INSA
13	INSTITUTO DE SALUD CARLOS III	ISCIII
14	LEGAL PATHWAYS BV	Legal Pathways
15	KATHOLIEKE UNIVERSITEIT LEUVEN	KU Leuven
16	STICHTING NATIONAAL ICT INSTITUUT IN DE ZORG	Nictiz
17	KAROLINSKA INSTITUTET	KI
18	UNIVERSITETET I OSLO	UiO
19	STICHTING VUMC	VUmc
~~20~~	~~UNIVERSITE DU LUXEMBOURG~~	~~UNILU~~
21	UPPSALA UNIVERSITET	UU
22	TERVISE ARENGU INSTITUUT	TAI
23	TARTU ULIKOOL	UT

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24	UNIVERSITA DEGLI STUDI DI MILANO	UMIL
25	Centre National de la Recherche Scientifique(CNRS for Institut Français de Bioinformatique IFB)	CNRS
26	UNIVERSITAIR MEDISCH CENTRUM UTRECHT	UMC Utrecht
27	UNIVERZA V LJUBLJANI	UL
28	STICHTING LYGATURE	LYGATURE
29	OSPEDALE PEDIATRICO BAMBINO GESU	OPBG
30	ALLEANZA CONTRO IL CANCRO	ACC
31	HELSINGIN YLIOPISTO	FIMM
32	STICHTING HEALTH-RI	HRI
33	PNED GIE	PNED

2.3. Project acronyms

Table 2. Project Acronyms

Abbreviation	Meaning
1+MG	The European 1 Million Genomes initiative
B1MG	Beyond 1 Million Genomes
B1MG-CO	Beyond 1 Million Genomes Coordination Office
B1MG-OG	Beyond 1 Million Genomes Operational Group
B1MG-GB	Beyond 1 Million Genomes Governing Board
CA	Consortium Agreement - Agreement concluded amongst B1MG 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.
CDA	Confidential Disclosure Agreement
CEG	Commission Expert Group
Consortium	The B1MG Consortium, comprising the named legal entities.
CT	Coordination Team of the 1+MG initiative
DMP	Data Management Plan
DoA	Description of Action
EC	European Commission
GA	Grant Agreement - The agreement signed between the beneficiaries and the EC for the undertaking of the B1MG project
GA	General Assembly - all project participants
GB	Governing Board
GDI	European Genomic Data Infrastructure (Digital Europe project, also supporting the 1+MG initiative)
IC	Indirect Costs
KPI	Key Performance Indicator
MoU	Memorandum of Understanding
ODC	Other direct costs
OG	Operational Group (Work Package Leaders)
PM	Project Manager
PMs	Person months

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B1MG-CO	Project Management Team
Project	The sum of all activities carried out in the framework of the Grant Agreement.
QA	Quality Assurance
SEAB	Scientific & Ethics Advisory Board
SG	Special Group' (Equivalent to EC CEG but not tied to exact regulations)
WP	Work Package
WPL	Work Package Leader

2.4. Project summary

The Beyond 1 Million Genomes (B1MG) consortium is establishing the support and coordination structure for the European 1+ Million Genomes initiative (1+MG), which is based upon the commitment of 24 European Member States, the UK and Norway that signed the Declaration 'Towards access to at least 1 million sequenced genomes in the EU by 2022'. These countries have now given further commitment to the 1+MG roadmap 2023-2027 (see Figure 1 below).

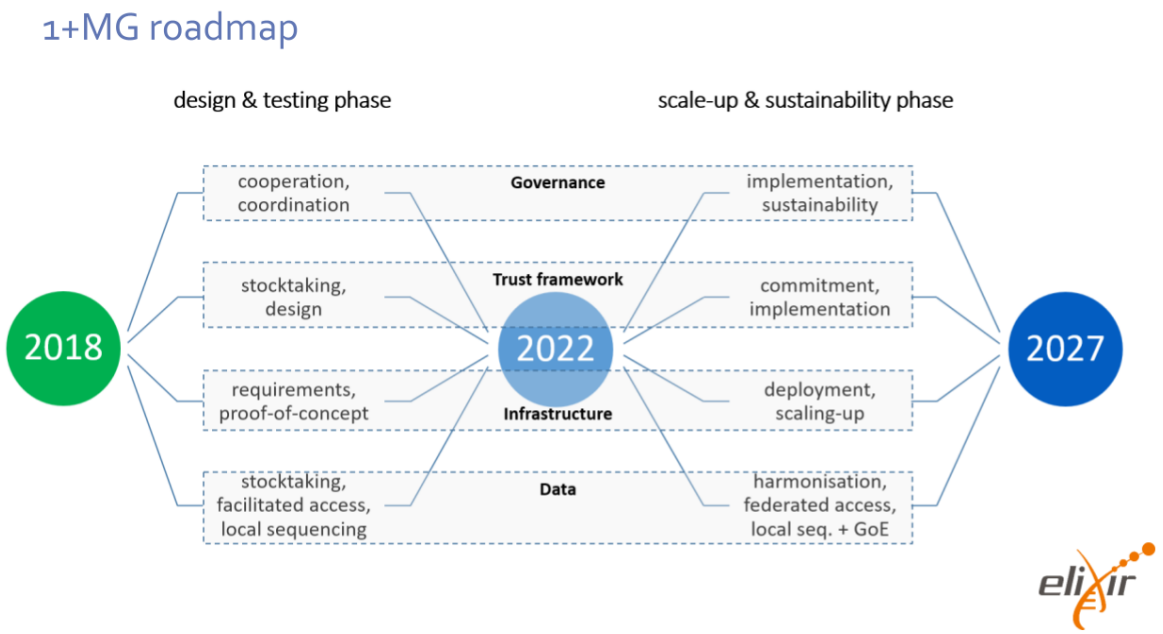

Figure 1 - High-level 1+MG Roadmap 2018-2027

Collectively, these countries have committed to establish a cross-border federated network of national genome collections associated with phenotypic data, consented for advancing health and medicine practices across Europe. Europe is uniquely placed to take on this challenge and position itself as a global leader in this field. B1MG is intended to go 'beyond' the 1M genome target and 'beyond' the original signatory countries. The project collaborates with an array of international initiatives and consults a range of stakeholders to support the creation of a pan-European genome-based health data infrastructure, encompassing data quality and exchange standards, access protocols and legal guidance. Recommendations are being translated to a B1MG maturity level model that provides concrete guidance on the steps required to implement personalised medicine, a healthcare approach that takes into account a person's genetic make-up, at local, regional and national-scale.

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Personalised medicine is expected to bring significant socio-economic benefits, including more efficient national health systems. Faster and more accurate diagnosis, the development of pharmacogenomics and advancement of preventative medicine will lead to better health, quality of life of patients and increased life expectancy. This will be captured in a methodology for economic evaluation, forming the basis of future business-cases for implementation in the health sector.

Detailed Project information :

- B1MG Description of Action Part A: Project summary, List of beneficiaries, Workplan (Work Packages, Deliverables), Milestones, Risks, Effort in PM, Review meetings.
- B1MG Description of Action Part B: Excellence, Impact, Implementation, Members of the Consortium, Ethics and security.
- Grant Agreement: Contract between the EC and the consortium establishing the obligations and conditions. An annotated version is available here.
- EC Grant Management Data: 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 the 1+MG initiative, the B1MG project, the GDI project, the EC and relevant stakeholders (Figure 2). Roles, synergies and differences will be outlined and clarified and, by doing so, any conflicts of interest will be identified.

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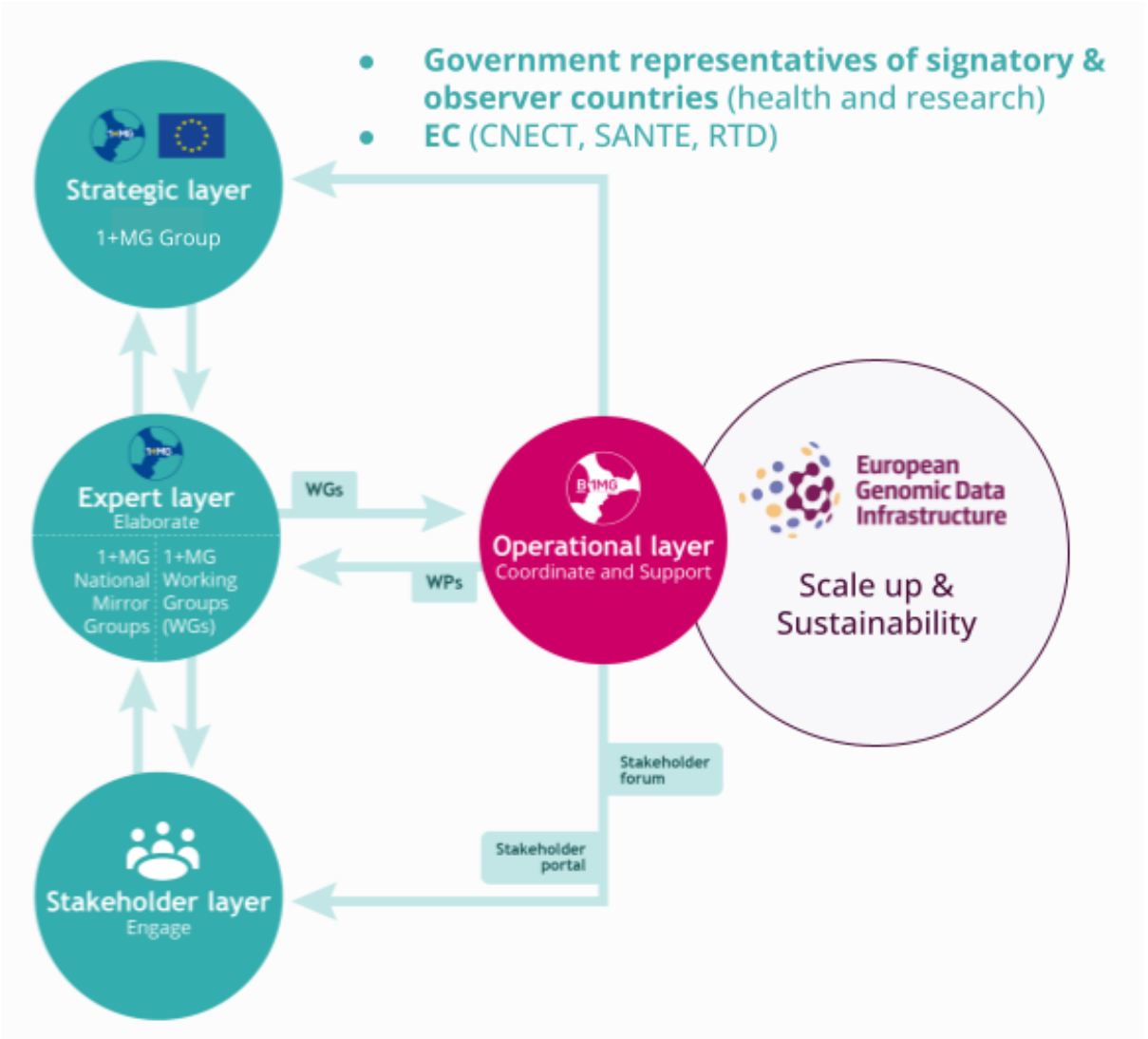

Figure 2. Model of the layers and interactions between the 1+MG initiative, the B1MG project, the GDI project, the EC and relevant stakeholders

1+MG

- Overarching role: 1+MG will drive 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

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to ensure its uptake by healthcare systems and integration into personalised healthcare and prevention.

- The initiative has unlimited duration to run - the 1+MG Initiative is expected to approve in November 2023 the roadmap that will cover the period 2023-2027.
- 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 B1MG Governing Board as outlined in the B1MG proposal (See Figure 3)

B1MG Project

The B1MG project now consists of seven Work Packages, an Operational level, a Coordination level and a Strategic level. Since the start of the project, a 7th WP has been added, focussed on helping to document the met and unmet needs of the Use Case Working Groups of the 1+MG initiative funded in B1MG.

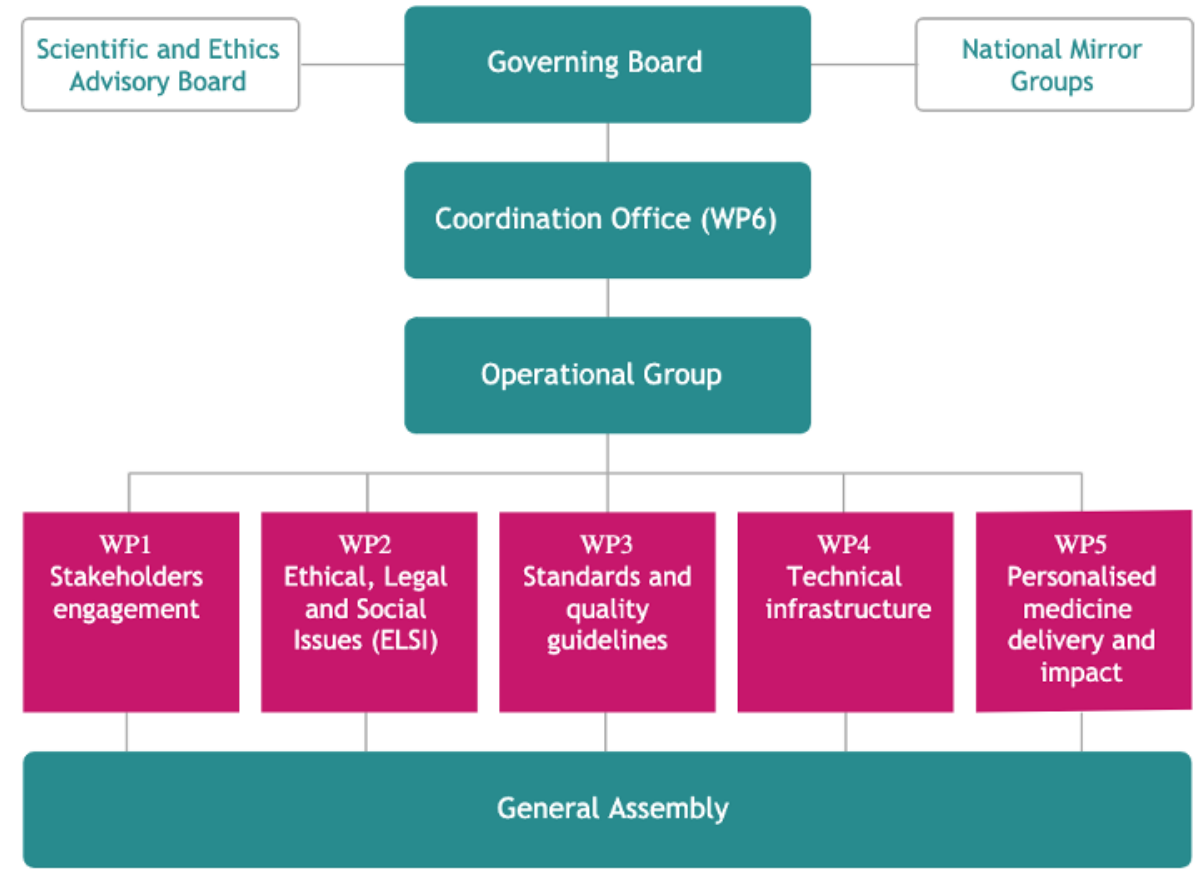

Figure 3. Governing Model of the B1MG project. WP7 (Support for the 1+MG Use Cases) has since been added to the WP layer

The B1MG project's primary role is to support the implementation of the 1+MG initiative by delivering the B1MG DoA. Amendments to the DoA have been sought to ensure the DoA remains aligned with 1+MG Roadmap. The B1MG WP structure ensures that 1+MG WGs, Stakeholders and NMG needs are taken into consideration via the participation in the different

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WPs while implementing the DoA (see Figure 4). In the same way as the other Use Case WGs, WG11 (infectious diseases) is also supported by the B1MG project. The coordination of WG12 (Genome of Europe) is supported by B1MG WP6.

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1+MG WG vs B1MG WP		B1MG (EC H2020)					
		WP1 Stakeholders	**WP2** ELSI	**WP3** Standards & Quality Guidelines	**WP4** Federated secure cross-border Technical infrastructure	**WP5** Delivering Personalised Medicine cross-borders	**WP6** Coordination Office
1+M Genome	Scope, stakeholders and governance (**WG1**)	Stakeholders					Governance, Sustainability
	Ethical, Legal, and Societal Issues (**WG2**)		Ethical, Legal, and Societal Issues				
	common standards for capturing clinical and phenotypic data requirements (**WG3**)			Common Standards + Phenotypic data requirements			
	good sequencing practice / development of standards for clinical interpretation (**WG4**)			Sequencing practices + standards for clinical interpretation			
	interoperability, transfer between countries, local/federated system incl. systems development and deployment and data access governance (**WG5**)				interoperability, transfer between countries, local/federated system incl. systems development and deployment and data access governance (Technical Aspects)		
	health economics and outcome research (**WG6**)					health economics and outcome research	
	involvement of the private sector (incentives, IP, contribution and access) (**WG7**)	involvement of the private sector					
	rare diseases (**WG8**)	rare diseases	rare diseases	rare diseases		rare diseases	
	cancer (**WG9**)	cancer	cancer	cancer		cancer	
	common, complex diseases (**WG10**)	common, complex diseases	common, complex diseases	common, complex diseases		common, complex diseases	
	National Mirror Groups (NMG)	Mirror Groups					Mirror Groups

Figure 4. 1+MG WG participation in B1MG WP

B1MG has reviewed the regular planned meetings with the 1+MG CT to ensure they provide enough opportunity to align 1+MG and B1MG activities at the strategic and operational levels (See Table 3).

Table 3.B1MG, 1+MG and EC coordination, via regular project meetings.

B1MG	Period	How	Goal
B1MG-GB (Governing Board) (B1MG Countries)	Quarterly	Co-located with 1+MG signatories meeting. **Attendance:** GB members **Owner**: B1MG-CO	Project oversight i.e. meeting template GB section
Regular meetings with PO (Project Officer) + EC internal Experts	Every 6 months or less.	VC. Content to be defined with PO. **Attendance:** EC, CO & WPL **Owner**: B1MG-CO	Project Monitoring 1+MG Needs.
B1MG-GA (General Assembly)	Yearly	Co-located with 1+MG WG meetings (WG, Stakeholders). **Attendance:** Partners + WG members. **Owner**: B1MG-CO	B1MG-GA GA meeting structure(TBD)
B1MG-CO (Coordination Office)	Monthly	TC or F2F collocated with other meetings. **Attendance:** WP6 **Owner**: B1MG-CO	WP6 (Monitoring, Support, Communication,

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(WP6)			NMG Guidance, Sustainability)
B1MG-OG (Operational Group) (WP Leaders)	Monthly TC, last friday	Combined with 1+MG CT + WG Leaders **Owner**: B1MG-CO	1+MG WG <-> B1MG WP alignment.
SEAB (Scientific & Ethic Advisory Board)	At least once a year (GA) or by GB request	TC or collocated with 1+MG meetings **Attendance:** SEAB, CO **Owner**: B1MG-CO	Independent advice.
NMG (National Mirror Group) Coordinators	At least once a year (GA) or by GB request	TC or collocated with 1+MG meetings **Attendance:** NMG, CO **Owner**: B1MG-CO	Ensure alignment with NMGs.
WP1-WP5 TCs	Monthly	TC with attendance by relevant WG experts on an agenda basis. **Attendance:** WP, WG **Owner**: B1MG-CO	Align and implement B1MG DoA with WG activities.
Other WP level meetings (i.e. workshops)	According to WP plan	According to WP needs **Owner:** WP Leaders	Progress on the delivery project outputs
Regular review meetings	M18 and M36	Face to face en EC premises **Attendance:** PO, EC and external experts , coordinator and WP leaders **Owner:** EC	Asset project performances

As the project is a Coordination and Support Action (CSA) project there will be no (or limited) Research and Innovation (RIA) driven activity.

B1MG expected outputs and participation from WGs:

- Stakeholders Coordination Group (WP1) <= WG1, WG7, WG8, WG9, WG10 , WG11+NMG + Stakeholders
- Minimum recommendation on ELSI and data protection (WP2) <= WG2
    - Use cases on agenda basis: WG8, WG9, WG10, WG11
- Minimum standards on data quality and analysis + data challenges (WP3) <= WG3, WG4
    - Use case on agenda basis: WG8, WG9, WG10, WG11
- Minimum common standards to implement the federated infrastructure (WP4) <= WG5
- Inventory of synthetic data + consented data available (WP4) <= WG5
- Maturity model to guide the implementation (WP5) <= WG5, WG6,
    - Use cases on agenda basis: WG8, WG9, WG10, WG11
- Economic models (WP5) <= WG6
- National mirror groups maturity model to guide their implementation (WP6) <= WG1, NMG
- Sustainability recommendations (WP6) <= WG1, WG6

Time limited project: June 2020 to October 2023

Support the 1+MG CoordinationTeam

- Maintaining the rolling agenda, taking minutes and follow-up actions

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- 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 B1MG. Participation of WG representatives in the individual WP meetings is encouraged based on agenda topics.

Support the 1+MG WGs via the B1MG activities (see Figure 3 and Table 4) fostering 1+MG WG, Stakeholders and NMG participation in B1MG WPs within the project limitations (Scope and Resources)

B1MG will provide different levels of support to 1+MG WG, NMG Coordinator and Stakeholders within the project limited budget

- At the WP Level
    - Each WP is encouraged to bring additional WG members into the discussion (particularly from use cases WGs: 8,9,10, 11) to contribute to the deliverables that will be produced. To that end, WP Lead beneficiary Institutions have been allocated budget to self-organise events (WP meetings, workshops) and reimburse WG members' travel costs (within the limits set on the GA) where not funded directly by B1MG.

- At the coordination level
    - The coordinator has also funds set aside to reimburse travel costs of WG members, not funded in B1MG, to attend main project events.

- Note: Maximum travel cost reimbursement amounts for WG members not funded in B1MG: €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 development of NMG Guidance in WP6 (ISCIII, ELIXIR).

Stakeholder Coordination Group via B1MG WP1 (EAPM, DTL-Projects/HRI, EATRIS).

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, such as the European Genomic Data Infrastructure (GDI) Digital Europe project

- 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

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        - Provide facilities for physical Signatory 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.

- Funding authority for the B1MG project
    - contractual relationship with the consortium,
    - monitoring the progress and spending in the project
        - The responsible PO closely follows the project, organises periodic project reviews and ultimately approves its deliverables and outcomes (supported by the assessment by independent experts).

2.6. Project coordination and management

The B1MG Coordination Office (B1MG-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. WP6 will also provide a set of recommendations for the sustainability of the initiative beyond the B1MG including guidance for countries on how to establish National Mirror Groups and funding routes to ensure long term access to personalised medicine cross-borders.

The B1MG-CO is implemented via WP6, where the objectives are established:

1. Establishment of the project governance structure mobilising the project resources and developing the project guidance
2. Efficient and effective project monitoring collecting KPIs and tracking risk and opportunities to assist the project boards on taking informed decisions at all levels
3. Develop and update the project data management plan along the project lifecycle
4. Develop and monitor the consortium communication plan that will facilitate internal and external communication
5. Facilitate the set up and operation of national mirror groups through guidelines and best practice identification
6. Develop and foster the adoption of a sustainability plan for the implementation of B1MG recommendations, identifying potential investments needs

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.

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3. Project approach

3.1. Required project documentation

Table 4. Required Project Documentations (access only available to project participants)

Artefact	Yes/No	Location	If No, briefly explain the reason
Description of Action — Part A (latest update)	✓	https://drive.google.com/file/d/1l2Xvrn-cg14iUvx5XHrOiY3aHcerzIRp/view?usp=drive_link	
Description of Action — Part B (latest update)	✓	https://drive.google.com/file/d/1QqqZ-4yFxi9779T8hs1M5VtWKa6ekwW2/view?usp=drive_link	
Grant Agreement	✓	https://drive.google.com/file/d/1eX8ZUNPx3KqRxDdrJtz7pegd6X6y_SOa/view?usp=sharing	
Consortium Agreement - fully executed	✓	https://drive.google.com/file/d/1Wov2zOWkY76CoVAkmF_d8XPTNmAXybw3/view?usp=drive_link	
Project Handbook (this document)	✓	https://docs.google.com/document/d/1OCOJJx7qhWp30kCfyFtzEKf6vE1QNTNp_pq4Y8UNKlo/edit#	
Project monitoring (Participants, Resources allocations, Deliverables, Milestones, Actions, Contacts, Issues, Risk and Change management)	✓	https://docs.google.com/spreadsheets/d/11wwGX34Qzfm-9ZyezYCi4VurTpTUFvYjpGZf3pZWXbU/edit?usp=sharing	
Project Master File	✓	https://docs.google.com/spreadsheets/d/1OYe-qwnrVZt4atMQ7NTQvcnnbaF9vGjrA6qNHFQyeEc/edit?usp=sharing	
Data Management Plan	✓	https://drive.google.com/file/d/1KozMgjs9LHUcUUvYH1mSCbcAYT7AMjey/view?usp=sharing	

3.2. Other standards

N/A

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 Project Management Team 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 B1MG-CO that will then use mediation to objectively aim to solve the issue involving all parties affected.

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- If unresolved and when the issue is significant enough, the B1MG-CO could then make a proposal :
    - To the B1MG-OG if the issue has very limited operation impact and can be resolved at this level.
    - To the B1MG General Assembly (GA) if it is a non-strategic issue
    - To the Governing Board (B1MG-GB), 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 B1MG-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 1.3.5 of the DoA - Part A (p41)[6].
All beneficiaries are asked to screen their activities with regards to additional new risks and to promptly notify the B1MG-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 B1MG-CO will add any new risks, including a description of the possible impact, to the risk register (B1MG Project Monitoring and EC Portal) and bring any additional risk(s) to the attention of the B1MG-OG.

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.

A mitigation plan for each identified risk has to be developed by the concerned work package and the BM1MG-CO and presented to the B1MG-OG as part of the risk management process.
The list of identified risks are stored in the B1MG Project Monitoring.

4.1.3. Risk monitoring

The risk register will be reviewed by the B1MG-CO on a monthly basis informing the B1MG-OG of any significant change when it happens or at least every six months in the regular meetings.
WPLs and Task leads are asked to actively contribute to this activity which will be overseen by the Project Coordinator and B1MG-CO.

[6] Risks. P41:https://drive.google.com/file/d/1wOjYzWH8IEyclXOftqSDC6mrefCmVn_9/view?usp=sharing

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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 annually submitted to the European Commission. Newly identified risks will be communicated to the EC via the EC project continuous monitoring tool (requires EC login).

The B1MG-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 distributed to participants and WP involved on a monthly basis via the automatic report generated and distributed by the B1MG Project Monitoring tool.

For any questions contact b1mg-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 (B1MG-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 and emails (b1mg-coordination@elixir-europe.org). The issues are registered in the Issue Log.
- Issue Assessment and Action Recommendation: a first informal assessment by B1MG-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 B1MG Project Monitoring tool 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 B1MG-CO will incorporate these actions into the appropriate project related documentation such as the change log in the B1MG Project Monitoring.
- Issue Control: During the regular B1MG-OG meetings the status of the issues related actions incorporated into the B1MG project monitoring will be revised, and new issues identified.

Concrete actions arising from the analysis of the issues will be included in the project monitoring tool and distributed to participants and WP involved on a monthly basis via the automatic report generated and distributed by the B1MG Project Monitoring tool.

For any questions contact b1mg-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 (B1MG-CO) executes whenever required throughout the project lifecycle:

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- Change Identification: a request for a change can be submitted formally via an email to B1MG-CO (b1mg-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 B1MG Project Monitoring tool 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 B1MG-CO in the Change Log section of the B1MG 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, B1MG-CO will advise who must approve the change, be it B1MG-CO, the Operational Group, the B1MG GB or the General Assembly. If a formal change to the Grant Agreement is required then the B1MG-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 or the GA or the B1MG-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 B1MG-CO in close collaboration with the EC.

- Change Control: new or open changes will be identified/reassessed by the B1MG-CO, using the Change Log section of the B1MG Project Monitoring tool and will be brought to the attention of the B1MG-OG, the B1MG-GB or the GA in due course.

For any questions contact b1mg-coordination@elixir-europe.org.

4.4. Quality management

The implementation and execution of B1MG follows the principles of Horizon 2020 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.

B1MG 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 and risks.

B1MG 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 Horizon 2020 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 Horizon 2020 and EC rules, applicable law and regulations, incl. but not limited to data privacy, handling of funds and ethics.

According to Horizon 2020 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 B1MG 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.

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.

For more information about the process, see section 7.1.3. Deliverable review process.

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4.5. Configuration management

4.5.1. Storage of project management artefacts

Project repository

The Project Management Team have created a structured B1MG Google Drive to store the project management artefacts following the same folder convention per sub-folder.

Table 5. Project repository structure.

Top Level Folders	Content
0. Grant Agreement Preparation	Working documents for the preparation of the grant agreement
1. Project MASTER File	Master document with details from the project: contact lists, effort distribution, lists of deliverables & milestones, GANTT chart etc 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.
2. Legal Documents	Legal documents pertaining to the project: Consortium Agreement, Grant Agreement, Description of Action, amendments, contracts etc
3. WPs	Working folders for the WPs
4. Deliverables & Milestones	Repository for project deliverables and milestones (templates, working drafts and submitted documents)
5. Project meetings, Events & TCs	Details of all project meetings and events (agendas, minutes slide presentations etc)
6. Periodic Reporting	Financial and periodic reports from all project partners
7. Guidance and Templates	Project handbook, containing guidance pertaining to all aspects of the project (processes, communications, management structure and responsibilities etc) Project templates: deliverables, milestones, agendas, minutes, slide presentations etc
8. Project Communications and Outreach Materials	Project branding & style guidelines, press releases, articles, presentations, newsletters etc

For any assistance with creating new folders, please contact b1mg-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

The latest version of a detailed, controlled Documents Version Policy outlining the project naming conventions and other configuration management guidance will be included in D6.2 Data Management Plan.

4.5.3. Versioning of project management artefacts

All project management artefacts are under version control.

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 3.

The B1MG communication strategy is a formal project deliverable that is due in M06 (D6.3 Consortium communication strategy) once submitted this document will link to the deliverable.

4.6.1. Communication Plan

The B1MG consortium will adopt the following approach to communications:

- Use of electronic mail as the main tool for communication within the consortium.
- Google Chat room area available for instant message, sharing and group VC communication channels will be created by B1MG-CO following WP Leaders or WG leader requests.
- Documentation of discussions, agreements and decisions made by phone is encouraged. Specifically, phone conferences should always have an agenda and minutes, which should be made available through the B1MG Google Drive and in the appropriate folder..
- Several distribution lists have been 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 B1MG-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 6. Distribution Lists

Distribution list	Description
b1mg-coordination@elixir-europe.org	ELIXIR Hub B1MG Coordination team
b1mg-all@elixir-europe.org	All project participants signed up to B1MG mailing lists
b1mg-project-administrators@elixir-europe.org	B1MG admin contacts + ELIXIR Hub B1MG Coordination team

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b1mg-finance@elixir-europe.org	B1MG Finance contacts + ELIXIR Hub B1MG Coordination team
b1mg-legal@elixir-europe.org	B1MG Legal contacts + ELIXIR Hub B1MG Coordination team
b1mg-gb@elixir-europe.org	B1MG Governing Board + ELIXIR Hub B1MG Coordination team
b1mg-og@elixir-europe.org	B1MG Operating Group (WPLs) + ELIXIR Hub B1MG Coordination team
b1mg-pi@elixir-europe.org	B1MG PIs + ELIXIR Hub B1MG Coordination team
b1mg-sab@elixir-europe.org	B1MG SEAB + ELIXIR Hub B1MG Coordination team
b1mg-stakeholders-coordination-group@elixir-europe.org	B1MG Stakeholders Coordination Group + ELIXIR Hub B1MG Coordination team
b1mg-nmg-coordinators@elixir-europe.org	B1MG NMG coordinators (Esther, Pepa & Marta) + ELIXIR Hub B1MG Coordination team
b1mg-nmg-representatives@elixir-europe.org	B1MG National Mirror Group Representatives + ELIXIR Hub B1MG Coordination team
b1mg-WP1-stakeholders@elixir-europe.org	B1MG WP1, leads and members + ELIXIR Hub B1MG Coordination team
b1mg-WP2-elsi@elixir-europe.org	B1MG WP2, leads and members + ELIXIR Hub B1MG Coordination team
b1mg-WP3-standards@elixir-europe.org	B1MG WP3, leads and members + ELIXIR Hub B1MG Coordination team
b1mg-WP4-infrastructure@elixir-europe.org	B1MG WP4, leads and members + ELIXIR Hub B1MG Coordination team
b1mg-WP5-personalisedmedicine@elixir-europe.org	B1MG WP5, leads and members + ELIXIR Hub B1MG Coordination team
b1mg-WP6-coordination@elixir-europe.org	B1MG WP6, leads and members + ELIXIR Hub B1MG Coordination team
b1mg-WP7-usecasesupport@elixir-europe.org	B1MG WP7, leads and members + ELIXIR Hub B1MG Coordination team

4.6.2. Email guidelines

Good practice when using email is essential.

- Project related mails should be tagged with project short name “B1MG:” and also indicate when action is required (ACTION REQUIRED, FEEDBACK REQUIRED).
- 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.
- All emails sent to any of the mailing lists created so far should start with “B1MG:” 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. B1MG: 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.
- No relevant issues for the work to be performed should remain unclear.

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- When feasible avoid sending emails out of working hours or indicate a reply is not expected outside of working hours.

4.6.3. File Exchange and Repository

4.6.3.1 B1MG Repository

A Google Drive instance has been created for B1MG 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 B1MG Google 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 B1MG Google Drive once they have signed up to the mailing lists. New accesses can be requested by filling in the registration form[7].

- The latest version of the B1MG contact list is uploaded on the B1MG Google Drive, in the Registered Contacts section of the Project Monitoring spreadsheet[8]. The up-to-date participants' contact information with clear information of who is included in every mailing list mentioned above will be based on the periodic updates by each of the Work Package Leaders.

- 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.
  B1MG uses Google Drive as a project management tool that is simultaneously used as a document management system. The B1MG Google 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 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.

B1MG uses Google 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.

[7] https://docs.google.com/forms/d/e/1FAIpQLSfU2qVLaN_8E9t-bttmQ-npU--bmaSiEwk_dyN0Xfv1yM_o5Q/viewform
[8] https://docs.google.com/spreadsheets/d/11wwGX34Qzfm-9ZyezYCi4VurTpTUFvYjpGZf3pZWXbU/edit?usp=sharing

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Any publication in B1MG is governed by Article 29 of the Grant Agreement and Article 7.5 of the Consortium Agreement. Scientific Publications and Communication to the public will be covered by D6.3 Consortium communication strategy due in M06.

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.

4.6.3.2 1+MG Initiative Repository

In addition to the project repository the B1MG Coordination Office (B1MG-CO) provides the 1+MG repository for the coordination group. If required by the WG leaders, repositories for the different WGs can also be provided.

The B1MG-CO can provide 1+MG WG repositories 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[9], 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.

All partners must follow the dissemination circulation procedure set out in Clause 7.5.2.2 of the Consortium Agreement[10].

The Commission also provide a Horizon 2020 guide to communicating EU research and innovation for project participants[11].

4.6.5. Open Access policy and requirements

Article 29.2 of the EC Annotated Model Grant Agreement (AMGA)[12] details the obligations related to the provision of open access to scientific publications.

We must ensure open access (free, online access for any user) to all peer-reviewed scientific publications relating to our B1MG project results.

Further explanations can be found in the EC Annotated Model Grant Agreement. The EC have also prepared the following guide to help steer this process.

Published articles (peer-reviewed or not) have to be submitted to B1MG-CO in PDF format. The document(s) will be made available to the consortium on the B1MG Google Drive in the Articles folder[13] and listed in the publications and dissemination activities spreadsheet[14].

[9] https://drive.google.com/file/d/1eX8ZUNPx3KqRxDdrJtz7pegd6X6y_SOa/view?usp=sharing
[10] https://drive.google.com/file/d/1Wov2zOWkY76CoVAkmF_d8XPTNmAXybw3/view?usp=drive_link
[11] https://ec.europa.eu/research/participants/data/ref/h2020/other/gm/h2020-guide-comm_en.pdf
[12] https://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/amga/h2020-amga_en.pdf
[13] https://drive.google.com/open?id=1MuGeU21sfV6BwReSqooIT2boiM2kqqTq
[14] https://docs.google.com/spreadsheets/d/1MIJwZlD7JoyRcoEHGZRv5ShLHHEkn2BiUWOhUwR0iqg/edit#gid=0

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4.6.6. EU Funding Acknowledgement

As set out in Article 38 of the Grant Agreement[15], unless the Commission requests or agrees otherwise or unless it is impossible, any communication activity related to the B1MG project (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the EU emblem and

To be used for B1MG:

- Download the EU emblem[16] 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 38 of the GA, the beneficiaries may use the EU emblem without first obtaining approval from the Commission.

(b) include the following text:

B1MG acknowledgement:

For communication activities:

"This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 951724".

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 Horizon 2020 research and innovation programme under grant agreement No 951724."

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 (B1MG) and the grant agreement number (951724) 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 Commision 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.

B1MG 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.

[15] https://drive.google.com/file/d/1eX8ZUNPx3KqRxDdrJtz7pegd6X6y_SOa/view?usp=sharing
[16] https://europa.eu/european-union/about-eu/symbols/flag_en

4.6.7. Project Branding

The B1MG project must follow the ELIXIR branding and communication guidelines. The ELIXIR branding guidelines, font and project logo are all available on the project Google Drive[17].

The branding and style guide should be used in all project communications without alteration. For any questions related to branding and communications please contact Xènia Pérez Sitjà, xenia.sitja@elixir-europe.org.

Figure 5. The B1MG logo

4.6.8. Project Website

The project web pages[18] 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 Martin Cook, martin.cook@elixir-europe.org with b1mg-coordination@elixir-europe.org in cc.

4.6.9. Social Media

B1MG has dedicated social media accounts,:

Twitter: @B1MG_Project

LinkedIn: https://www.linkedin.com/company/b1mg-project/

4.6.10. Project Newsletter

The ELIXIR Hub will publish a B1MG newsletter quarterly. All B1MG 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 Operational Group/WGLs TCs.

[17] https://drive.google.com/drive/folders/1H6A7tEZ6T64URbe22CgAT_oRLloCKK6z
[18] https://b1mg-project.eu/

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Content ideas can be emailed to xenia.sitja@elixir-europe.org with b1mg-coordination@elixir-europe.org in cc.

4.6.11. Templates

Presentations for internal or external communication should use the B1MG PowerPoint/Google Slide template.

All internal and external documents should use the B1MG Word/Google Doc template.

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

- Pre-filled Deliverables report templates per WP.
- Pre-filled Milestones report templates.

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, Horizon 2020 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 with Xènia Pérez Sitjà, xenia.sitja@elixir-europe.org.

A deliverable template has been prepared and can be found in the Templates folder on the B1MG Google Drive, but please note that an individually tailored template has been created by the Project Management Team for all project deliverables and are circulated in the monthly project monitoring emails which are automatically sent to WPLs. 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).

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5. Project management structure and responsibilities

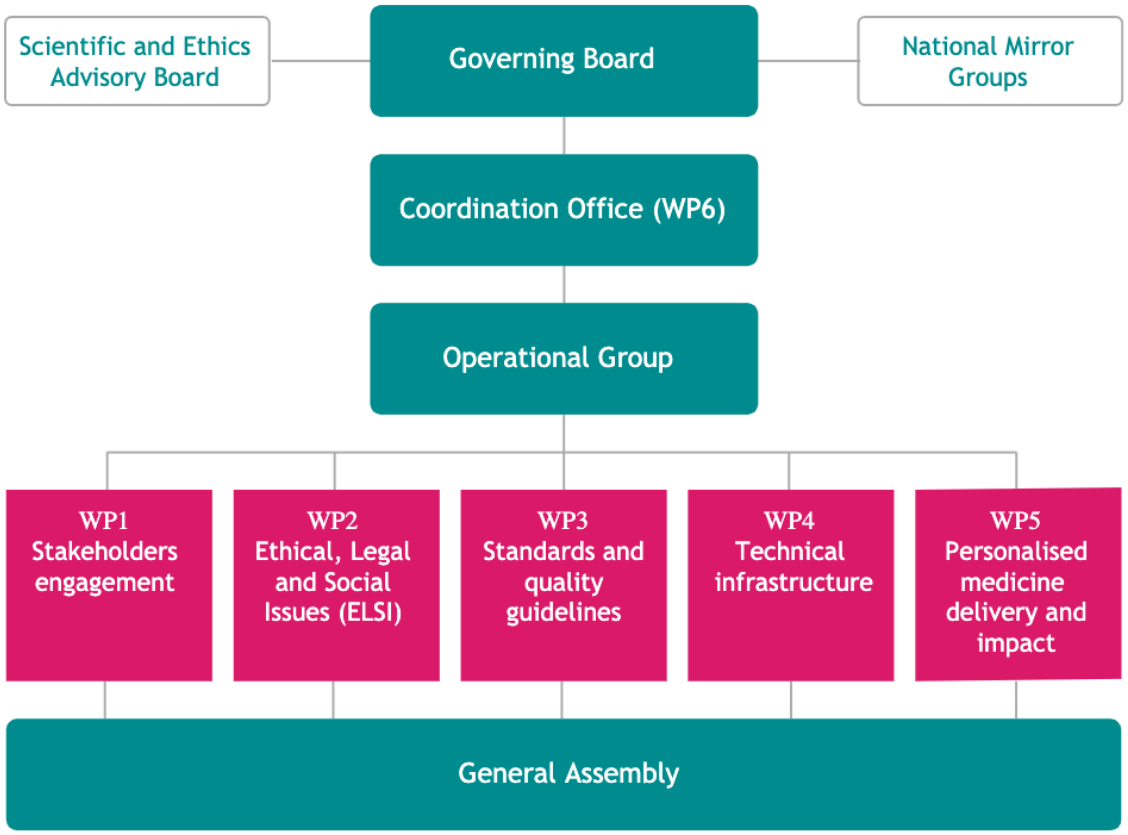

Figure 6. Management Structure. WP7 (Support to 1+MG Use Cases) has since been added

5.1. Description of project roles and responsibilities

In the following section, the roles of major stakeholders in the B1MG project are described alongside the responsibilities, expectations, rights and duties of each participant in the project.

5.1.1. Project coordinator

Table 7. Project Coordinator details

Name	Serena Scollen
Organisation	ELIXIR Hub
Email	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. The Coordinator is and shall be a central point of contact between the Beneficiaries and the EC in particular regarding the management of the Grant Specific duties: Legal signatory, legal responsibility for contract, budget oversight and control, submission of deliverables and milestones to EC, chair of GA and OG. The Coordinator is supported by the Project Management Team in regards to financial and contractual administration of the project.

5.1.2. General Assembly

The General Assembly (GA) is composed of representatives of all project beneficiaries that have delegated the decision making to the OG. The GA will be informed of the project progress in a timely manner (Operational Group meeting minutes circulated to all partners).

If necessary, each Beneficiary shall also be entitled to nominate a replacement Representative in the event that the original Representative is unable to attend any scheduled meetings of the General Assembly.

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.

Table 8. General Assembly members

Participant	GA member
ELIXIR / EMBL-EBI	Serena Scollen, Jan Korbel, Thomas Keane
BBMRI-ERIC	Michaela Th. Mayrhofer
CRG	Ivo Gut, Sergi Beltran
CSC	Tommi Nyrönen, Ilkka Lappalainen
CUNI	Milan Macek
DTL-PROJECTS	Ruben Kok
EAPM	Denis Horgan
EATRIS	Toni Andreu
ECRIN	Jacques Demotes
HMF	Edwin Cuppen
NIO	Attila Patocs, Janos Papp
INSA	Astrid Vicente

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ISCIII	Gonzalo Arevalo, Esther Rodriguez
Legal Pathways	Jasper Bovenberg
KU Leuven	Gert Matthijs
Nictiz	Pim Volkert, Maarten Ligtvoet
KI	Valtteri Wirta
UiO	Eivind Hovig
VUmc	Jeroen Belien
UNILU	Regina Becker, Reinhard Schneider
UU	Bengt Persson, Niclas Jareborg
TAI	Helen Lepa
UT	Andres Metspalu
UMIL	Matteo Chiara
CNRS	David Salgado
UMC Utrecht	Geert Frederix
UL	Brane Leskosek
LYGATURE	Ilse Custers
OSPEDALE PEDIATRICO BAMBINO GESU	Marco Tartaglia
ALLEANZA CONTRO IL CANCRO	Giovanni Tonon
HELSINGIN YLIOPISTO	Andreas Scherer
STICHTING HEALTH-RI	Ruben Kok
PNED GIE	Regina Becker

See Clause 11.3 of the Consortium Agreement[19] for further information regarding the General Assembly.

5.1.3. 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 Operational Group and Governing Board. The Work Package Leaders collectively make up the Operational Group. 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 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 Operational Group during the monthly meetings. The WPLs, as the Operational Group and via the Coordinator, report on the project progress to the GB at least every 12 months.

WPLs are responsible for filtering project information from the Operational Group meetings to their work packages via their dedicated WP distribution lists, during their regular meetings, or

[19] https://drive.google.com/file/d/1Wov2zOWkY76CoVAkmF_d8XPTNmAXybw3/view?usp=drive_link

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 are expected to promptly document the situation and raise it with the B1MG-CO in order to swiftly address reputational or technical risk for the consortium.

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

Contact: b1mg-coordination@elixir-europe.org

For more information, please refer to the ELIXIR Hub document Work Package Leader's Good Practice Guide[20]. Please be aware, as of 15/04/2020, that this is currently a working draft.

5.1.4. Operational Group

The Operational Group (OG) is composed of the Project Coordinator, the 1+MG coordination group, the 1+MG WG Leaders, EC representatives and the Work Package Leaders and is responsible for ensuring alignment and coordination across Work Packages and with the 1+MG initiative and for the successful execution of the project.

The Operational Group 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 OG 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. The responsibilities are fully detailed in the B1MG Consortium Agreement[21].

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

The Operational Group will be supported by the Project Management Team (B1MG-CO).

Meetings

The Operational Group will meet at least every month. In addition to the monthly teleconferences, the OG shall meet twice a year face to face making use of regular ELIXIR events such as the ELIXIR All Hands and HoN face to face meetings.

A Representative of the Project Coordinator will act as the chairperson of the Operational Group (the "Chairperson of the Operational Group") and shall:

A. with assistance from the BM1G-CO, be responsible for the convening of meetings, preparation and distribution of the agenda and minutes for meetings of the Operational Group;
B. and chair meetings of the Operational Group.

[20] https://docs.google.com/document/d/1jZAhcO4wYMsm8pdd22vO7wNaiowg83H7Fm_Ro8EL_FQ/edit#heading=h.d7mglv9j5el8

[21] https://drive.google.com/file/d/1Wov2zOWkY76CoVAkmF_d8XPTNmAXybw3/view?usp=drive_link

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

See Clause 11.4 of the Consortium Agreement[22] for further information regarding the Operational Group.

Table 9. Operational Group members

Role	Operational Group Member
Project Coordinator	Serena Scollen (ELIXIR Hub)
WP1 Leader	Denis Horgan (EAPM), Ruben Kok (DTL-Projects), Jan Korbel (EMBL Heidelberg), Toni Andreu (EATRIS).
WP2 Leader	Regina Becker (UNILU), Jasper Bovenberg (Legal Pathways)
WP3 Leader	Ivo Gut (CRG), Jeroen Belien (VUmc)
WP4 Leader	Tommi Nyrönen (CSC), Ilkka Lappalainen (CSC), Bengt Persson (UU), Sergi Beltran (CNAG-CRG)
WP5 Leader	Astrid Vicente (INSA), Serena Scollen (ELIXIR Hub)
WP6 Leader	Juan Arenas (ELIXIR Hub), Esther Rodriguez (ISCIII)
WP7 Leader	Serena Scollen (ELIXIR Hub), Giselle Kerry (ELIXIR Hub)

Contact: b1mg-coordination@elixir-europe.org

5.1.5. SAB (Scientific Advisory Board)

B1MG will make use of the Scientific Advisory Board (SAB) for progress review. The SAB will provide recommendations for the scientific strategy of this project in the context of overall 1+MG Strategy. The SAB includes experts in the biological and biomedical life science area whose backgrounds cover science and industry.

Meetings

The SAB meets once a year or ad hoc by request of the B1MG-CO or the GB. They provide direct feedback to the GB.

See Clause 11.6 of the Consortium Agreement[23] for further information regarding the SAB.

Table 10. SAB members

SEAB member	Affiliation
Augusto Rendon	Chief Bioinfomatician, Genomics England, UK
Christine Chomienne	Former Director, Institut National du Cancer, France
Bartha Knoppers	Director of the Centre of Genomics and Policy, Faculty of Medicine, Department of Human Genetics, McGill University, Canada
Mark McCarthy	Senior Director Human Genetics, Genentech, US
Mark Lawler	Associate Pro-Vice-Chancellor and Professor of Digital Health, Chair in Translational Cancer Genomics, Queen's University, Belfast, Northern Ireland
Ele Zeggini	Director, Institute of Translational Genomics, Munich, Germany
Aarno Palotie	Faculty member, Center for Human Genome Research, Massachusetts General Hospital; associate member at the Broad Institute of MIT and Harvard, US and

[22] https://drive.google.com/file/d/1Wov2zOWkY76CoVAkmF_d8XPTNmAXybw3/view?usp=drive_link

[23] https://drive.google.com/file/d/1Wov2zOWkY76CoVAkmF_d8XPTNmAXybw3/view?usp=drive_link

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	Research Director of the Human Genomics Program at the Institute for Molecular Medicine Finland (FIMM) in Helsinki, Finland - to be confirmed
Anne Cambon-Thomsen	Emeritus Research Director at CNRS, Director of Research Université Paul Sabatier Toulouse III

Contact: b1mg-sab@elixir-europe.org

5.1.6. Project Management Team (B1MG-CO)

The Project Management Team (B1MG-CO) will be led by the ELIXIR Project Management Unit 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.

Table 11. B1MG-CO

Name	Serena Scollen / Juan Arena Marquez / Nikki Coutts/ Arshiya Merchant
Organisation	ELIXIR Hub
Email	b1mg-coordination@elixir-europe.org
Role	The B1MG-CO is responsible for the day-to-day execution of the Project, providing the necessary project management support to deliver the Project. In particular, the B1MG-CO is responsible for the following tasks and activities: • implementation of all management and organisational tasks • scheduling of decisions • monitoring the achievement of set milestones • timely submission of deliverables • organisation and documentation of the meetings of the Consortium Bodies • dissemination of all relevant information and action items across the Consortium • accounting for all financial aspects of the Project and ensuring timely submission of all required reports to the EC. A full list of Project Management roles and responsibilities is available on the B1MG Google Drive.

The B1MG-CO will support and report on the execution of the project work plan and budget utilisation, providing the mechanism to identify and manage project risks and opportunities.

A consortium communication strategy will be established (WP6) 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.

Meetings

The B1MG-CO Team meet on a weekly basis.

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5.1.7. 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.

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 designated Task Leaders are presented in Table 12 below.

Table 12. Task Leaders

Task #	Task Leader	Email	Organisation
T1.1	Denis Horgan	denishorgan@euapm.eu	EAPM
T1.2	Toni Andreu Anne-Charlotte Fauvel	toniandreu@eatris.eu annecharlottefauvel@eatris.eu	EATRIS
T1.3	Ruben Kok GertJan B. van Ommen	ruben.kok@dtls.nl gjvo@lumc.nl	DTL-Projects
T2.1	Jacques Demotes Mihaela Matei	jacques.demotes@ecrin.org Mihaela.MATEI@ecrin.org	ECRIN
T2.2	Marjanka Schmidt Susanne Rebers	mk.schmidt@nki.nl s.rebers@nki.nl	BBMRI-NL
T2.3	Jasper Bovenberg	jabovenberg@xs4all.nl	Legal Pathways
T2.4	Regina Becker	regina.becker@uni.lu	UNILU
T3.1	Ivo Gut	ivo.gut@cnag.crg.eu	CRG
T3.2	Ivo Gut	ivo.gut@cnag.crg.eu	CRG
T3.3	Ivo Gut	ivo.gut@cnag.crg.eu	CRG
T3.4	Jeroen Belien	jam.belien@vumc.nl	VUmc
T3.5	Jeroen Belien	jam.belien@vumc.nl	VUmc
T4.1	Tommi Nyronen Ilkka Lappalainen	tommi.nyronen@csc.fi ilkka.lappalainen@csc.fi	CSC
T4.2	Thomas Keane	tk2@ebi.ac.uk	EMBL-EBI
T4.3	Bengt Persson	bengt.persson@icm.uu.se	UU
T4.4	Bengt Persson	bengt.persson@icm.uu.se	UU
T4.5	Tommi Nyronen Ilkka Lappalainen	tommi.nyronen@csc.fi ilkka.lappalainen@csc.fi	CSC
T5.1	Astrid Vicente Teresa C. Almeida Mafalda Bourbon Alexandra Costa	astrid.vicente@insa.min-saude.pt teresa.almeida@insa.min-saude.pt mafalda.bourbon@insa.min-saude.pt alexandra.costa@insa.min-saude.pt	INSA
T5.2	Astrid Vicente Teresa C. Almeida	astrid.vicente@insa.min-saude.pt teresa.almeida@insa.min-saude.pt	INSA

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	Mafalda Bourbon Alexandra Costa	mafalda.bourbon@insa.min-saude.pt alexandra.costa@insa.min-saude.pt	
T5.3	Ilse Custers	ilse.custers@lygature.org	Lygature
T5.4	Astrid Vicente Teresa C. Almeida Alexandra Costa	astrid.vicente@insa.min-saude.pt teresa.almeida@insa.min-saude.pt alexandra.costa@insa.min-saude.pt	INSA
T6.1	Hannah Hurst Juan Arenas Nikki Coutts	hannah.hurst@elixir-europe.org juan.arenas@elixir-europe.org nikki.coutts@elixir-europe.org	ELIXIR Hub
T6.2	Hannah Hurst Juan Arenas Nikki Coutts	hannah.hurst@elixir-europe.org juan.arenas@elixir-europe.org nikki.coutts@elixir-europe.org	ELIXIR Hub
T6.3	Hannah Hurst Juan Arenas Nikki Coutts	hannah.hurst@elixir-europe.org juan.arenas@elixir-europe.org nikki.coutts@elixir-europe.org	ELIXIR Hub
T6.4	Andrew Smith Erin Haskell Martin Cook	andrew.smith@elixir-europe.org erin.haskell@elixir-europe.org martin.cook@elixir-europe.org	ELIXIR Hub
T6.5	Esther Rodriguez	erodriguez@eu-isciii.es	ISCIII
T7.1	Marco Tartaglia	marco.tartaglia@opbg.net	OPBG
T7.2	Giovanni Tonon	tonon.giovanni@hsr.it	ACC/HSR
T7.3	Andres Metspalu	andres.metspalu@ut.ee	UT
T7.4	Andreas Scherer	andreas.scherer@helsinki.fi	FIMM

The most up-to-date Task Leader list is available on the B1MG Google Drive[24].

5.1.8. Deliverable Authors

The most up-to-date list of Deliverable Authors ist is available on the B1MG Google Drive[25].

5.2 How and when the project bodies meet

The Coordinator, supported by the B1MG-CO Team, is responsible for convening meetings of the management and governance bodies at the B1MG overall level (i.e. GA, OG, SAB), complying with the minimum frequency of ordinary meetings as defined in the B1MG Consortium Agreement (CA) and detailed above. Work Package leaders have the responsibility of calling meetings within their respective WPs as needed.

The meeting frequency is defined in Table 3.

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 B1MG meetings

[24] https://docs.google.com/spreadsheets/d/1B_sK9Q8uwAQEOGY-PRBG08HbMgSrlKGE-MCrArKdXW0/edit#gid=1122316636

[25] https://docs.google.com/spreadsheets/d/1B_sK9Q8uwAQEOGY-PRBG08HbMgSrlKGE-MCrArKdXW0/edit#gid=858182447

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- distribution of minutes following the meeting and follow-up of points agreed at the meetings.

5.3. Beneficiaries

5.3.1. How Beneficiaries change their representatives to the General Assembly (GA)

Beneficiaries' representatives in the General Assembly (GA) are expected to be maintained throughout the project. Any representative in the GA may nominate a substitute to attend and vote at any meeting. In that respect, any change in a representative in the GA 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.

GA members can be accompanied by other representatives of their respective institutions at meetings, but only one vote per institution is allowed in the GA.

5.3.2. 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 B1MG project and act in cooperation and mutual trust. Beneficiaries shall also provide their respective contributions to deliverables, information, and reports as required by the WPLs, the OG, the PM Team, and the Coordinator, so as to help these bodies to fulfil their obligations.

Beneficiaries shall promptly notify the Coordinator and the B1MG-CO Team 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.
- Notify promptly the relevant governance body of any potential issue affecting performance. The normal chain of reporting would be, in this order: WPL → PM → OG.
- Notify the B1MG-CO Team 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 B1MG, and report it faithfully.

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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 June 2020 and has the GA # 951724.

The Grant Agreement core document includes a standard text (i.e. it is essentially the same for any EC Horizon 2020 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 B1MG Project and includes the budget details for all project beneficiaries. This document is automatically generated by the EC Participant Portal.

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 B1MG Grant Agreement. If a new beneficiary joins the project, this form will be requested to be signed by the new institution joining the project.

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6.1.4. Annex 4. 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 7.3.3. (Financial Reporting) for more details.

6.1.5. Annex 5. Model for the Certificate on Financial Statements

This Annex is required for those partners that request a total EC funding of €325,000 or more, as reimbursement of actual costs calculated based on its usual cost accounting practices. Please see section 7.3.3. (Financial Reporting) for more details.

6.1.6. Annex 6. Model for the Certificate on the Methodology

Beneficiaries 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. "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.

The Grant Agreement and its Annexes are available on the B1MG Google Drive[26].

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 B1MG-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 (B1MG-CO) will keep track of all needed amendments. Meetings and communications with the beneficiaries affected will enable the B1MG-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.
3. The B1MG-CO will prepare the following documentation:
    a. A new version of the DoA with the modifications in track changes.
    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.

[26] https://drive.google.com/drive/folders/1fnSik__m6fmVA-0RIZki_Nh5H5I15F30

4. The B1MG-CO will circulate an amended version of the DoA to the Operational Group for validation. The approval by the Operational Group will be required for any Amendment to the Grant Agreement.
5. As a final step the Coordinator, supported by the B1MG-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 B1MG Google Drive[27] 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 PM Team to confirm the procedure to follow for any modification needed.

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

6.2. The consortium agreement

The Consortium Agreement (CA) is concluded between the B1MG 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 B1MG Google Drive[28].

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 PM Team.

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.

[27] https://drive.google.com/drive/folders/1GoVIPU5DO0WEvaU_Dd3h-W0KyOPh3xHu
[28] https://drive.google.com/drive/folders/1xt_Kfz0ALIQ0mp2L3eQOxpffq0g3uI9X

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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 WPL. 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 PM Team based on the official EC template, and it is available on the B1MG Google Drive in the Guidance and Templates folder[29].

When naming the document it is expected that the document naming convention is adhered to, all deliverables template has been created following the appropriate name convention.

7.1.2. Deliverable structure, guidance and tips

Project deliverables are to be submitted at specific times stated in the DoA (Part A Section 1.3.2 WT2 list of deliverables[30]).

Note: The "expected delivery date" listed in the DoA always refers to the last date of any month. e.g. 'June 2020' means '30th June 2020' / 'Feb 2021' means '28th Feb 2021'.

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 B1MG-CO and shared in the monthly Project Monitoring report. In addition, a clean copy of the deliverable template can found in the Templates folder on the B1MG Google Drive[31].

The template has six predefined sections:

- Executive Summary (Max ½ page, should provide an overview of the work carried out and the conclusion)
- Contribution Towards Project Objectives (indicate with Yes/No if the deliverable contributes to the key result)
- Introduction (1-1 ½ pages, describe deliverable scope and the methodology to be applied)
- Description of Work Accomplished (Describe what has been done. Interactions with other WPs? Collaboration with external partners/projects? Dissemination activities carried out?)
- Results (Present and discuss the results obtained)

[29] https://drive.google.com/drive/folders/1PNEtZzOKk7Gp_GH84KYc9Ur4yMqInG8T
[30] https://drive.google.com/file/d/1wOjYzWH8IEyclXOftqSDC6mrefCmVn_9/view?usp=sharing
[31] https://drive.google.com/drive/folders/1cxSNL4oxRVw-dsLPUI7p6QpIKdifD8GR

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- Conclusion
- Impact (Present and discuss the impact obtained)
- Next Steps
- Deviation from Description of Action (If applicable, describe the deviation from the Description of Action and the justification and plans to avoid this deviation impacting the work plan)

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 B1MG project, the review process shall be coordinated by the B1MG-CO.

As and when a deliverable approaches due, it will appear in the monthly 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.

If the WPL 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).

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The Deliverable Lead must nominate a minimum of two reviewers. Before informing the B1MG-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 B1MG project may also be asked to be a reviewer.

The deliverable author(s) should work on their deliverable within their Work Package folder on the B1MG Google 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 WPL(s) do 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 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 4.1.3.1. above. Any suggested edits or comments should be made within the 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 B1MG-CO, by emailing them a link to the Google Doc version on the B1MG Google Drive. The B1MG-CO will distribute the link to the OG for a final review, allowing the OG seven (7) days to review it. Once approved, the B1MG-CO (on behalf of the Project Coordinator) will convert the Google Doc to PDF and submit the final document to the EC via the Participant Portal. In addition, the B1MG-CO will upload all public deliverable reports to Zenodo (see also Section 4.6.6, Open Access policy and requirements) and notify the Consortium. The final document will also be available on the B1MG Google Drive in the Deliverables and Milestones folder[32].

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 monthly project monitoring report with a link to the pre-prepared deliverable template.
2. Two months (60 days) prior to the due date, author(s) identify the reviewers and inform the B1MG-CO.
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 WPLs, they must have the WPLs review the deliverable report.
6. 1 month (30 days) prior to the due date, author(s) must send the draft report to the B1MG-CO by emailing them a link to the Google Doc version on the B1MG Google Drive. The B1MG-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.

[32] https://drive.google.com/drive/folders/1i8WQ7BR6fAObvDJg4MJi8MNq7t53oQx9

8. Author(s) generate a revised version of the document taking on board the suggestions and comments of the reviewers.
9. 1.5 weeks (10 days) prior to the due date, author(s) must send the final version to the B1MG-CO emailing them a link to the Google Doc version on the B1MG Google Drive. The B1MG-CO will then circulate the document (via emailed link) to the OG (all WPLs) and the GB (Countries) for final review, allowing them seven (7) days to review the document. The OG are encouraged to make any suggestions or comments directly within the Google Doc.
10. Three days prior to the due date, the author(s) provide the B1MG-CO with the consolidated, final version.
11. The Coordinator (or the B1MG-CO on their behalf) will convert the Google Doc to PDF and upload the final version in Participant 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. RP1, RP2, RP3) in the 04. Deliverables and Milestones folder[33] on the B1MG Google Drive.

04. Deliverables and Milestones→ RP1→ Submitted

Note: 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.

In case of time constraints, an exceptional streamlined procedure for the deliverables may apply upon agreement with the OG.

A tracker with the deliverable due dates is available on the B1MG Google Drive[34].

7.2. Milestones

Each milestone must use a clean copy of the milestone template[35] and must not exceed one slide.

It is the responsibility of the Milestone Lead organisation[36] to produce the milestone report or to deputise the responsibility to someone else upon their agreement.

7.2.1. Illustrative timelines

1. 3 months prior to the due date, the milestone will appear in the monthly project monitoring report with a link to the pre-prepared milestone template
2. 1.5 months (45 days) prior to the due date, if the author(s) are not the WPLs, they must have the 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 B1MG-CO by emailing them a link to the Google Doc version on the B1MG Google Drive. The B1MG-CO will then circulate the document (via emailed link) to the OG (all WPLs) for final review, allowing them seven (7) days to provide any comment. The OG are encouraged to make any suggestions or comments directly within the Google Doc however, this shouldn't be a time consuming process for the OG.

[33] https://drive.google.com/drive/folders/1i8WQ7BR6fAObvDJg4MJi8MNq7t53oQx9
[34] https://docs.google.com/spreadsheets/d/1abzvqo3sLsF1e0o7tGIYgsybAa9yJAQInSv0ciU--fk/edit#gid=1091470126
[35] https://drive.google.com/drive/folders/1cVxZtW5UyunJP4ISPzrv4p_7qc7CRsur
[36] https://docs.google.com/spreadsheets/d/1abzvqo3sLsF1e0o7tGIYgsybAa9yJAQInSv0ciU--fk/edit#gid=1091470126

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4. Three days prior to the due date, the author(s) provide the B1MG-CO with the final version.
5. The Coordinator (or the B1MG-CO on their behalf) will convert the Google Doc to PDF and upload it in Participant Portal.
6. The final version of the document is also uploaded to the 'Submitted' folder within the respective reporting period subfolder (e.g. RP1, RP2, RP3) in the 04. Deliverables and Milestones folder[37] on the B1MG Google Drive.

A tracker with the milestone due dates is available on the B1MG Google Drive[38].

7.3. Progress reporting

7.3.1. EC Project Periodic Technical Reports

Throughout the entire project execution period (1st June 2020 until 31st May 2023), the Consortium is required to submit, in due time, two periodic technical reports to the EC using the template periodic report[39] provided in the EC Participant Portal[40]. The project is officially divided into 2 periods for both progress and financial reporting to the EC:

- RP1: 1st Feb 2020 to 31st July 2021 (M1-18)
- RP2: 1st August 2021 to 31st Oct 2023 (M19-41)

In compliance with the rules specified in Clause 20.3 of the B1MG Grant Agreement (Periodic reports – Request for interim payments)[41], 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 Horizon 2020 key performance indicators and EC and the Horizon 2020 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 B1MG-CO, within 30 calendar days after the end of the reporting period. Effort figures can however be requested by the B1MG-CO at any point during the project. For the purpose of

[37] https://drive.google.com/drive/folders/1RwHcsPXTaXKhIMtnaYbuzTVRIT1_8J06
[38] https://docs.google.com/spreadsheets/d/1abzvqo3sLsF1e0o7tGIYgsybAa9yJAQInSv0ciU--fk/edit#gid=1091470126
[39] https://drive.google.com/open?id=1silKGIyW_wzvHQUJn-TweWoX3MCtEcBE
[40] https://ec.europa.eu/research/participants/docs/h2020-funding-guide/grants/grant-management/reports/periodic-reports_en.htm#partB
[41] https://drive.google.com/open?id=1gLhclTzFumCGuobTsZBPcZKFcPB2m5Qn

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.

The Periodic Technical Report template provided by the EC can be found on the B1MG Google Drive[42]. This template will be used for each of the two Periodic Technical Reports unless the EC produces an amended version throughout the course of the B1MG project.

Detailed instructions on the submission of the periodic technical report will be provided by the B1MG-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. See the Financial Reporting Guidelines available on the EC Participant Portal[43] for further information.

As with all EC Horizon 2020 projects, each B1MG project beneficiary has a budget, which comprises the estimated costs that will be incurred during the project lifecycle. 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 B1MG project a maximum 100% 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 OG, 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

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:

- they must be actually incurred by the beneficiary;
- they must be incurred in connection with the action as described in the DoA and necessary for its implementation;
- they must be determined in accordance with the usual accounting principles of the beneficiary;
- they must be incurred during the duration of the project, with the exception of costs relating to the submission of the periodic report for the last reporting period and the final report;
- they must be recorded in the beneficiaries' accounts;

[42] https://drive.google.com/open?id=1silKGlyW_wzvHQUJn-TweWoX3MCtEcBE
[43] https://ec.europa.eu/research/participants/docs/h2020-funding-guide/grants/grant-management/reports/periodic-reports_en.htm#partB

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- they must comply with the applicable national law on taxes, and social security;
- they must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency;
- they must be indicated in the estimated overall budget in the DoA.

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 100% 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:

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.

The personnel costs are normally calculated by the hourly rate multiplied by the number of actual hours worked for the project.

The hourly rate (based on actual costs) can be calculated as: actual annual personnel costs, divided by the number of annual productive hours. The number of annual productive hours that makes a person-month can vary between partners. All partners must calculate their specific productive hours according to the internal accounting practice for their organisation. In case different categories of personnel have different working conditions, individual productive hours may be calculated. The productive hours per year should exclude annual leave, public holidays, training (if not project related) and sick leave.

In addition, for personnel costs, the beneficiaries must keep time records for the number of hours 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:

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- 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 hours worked for the action in the period covered by the time record; it is highly recommended that the number of hours is detailed per day (hours worked for the action in each day);
- short description of the work carried out during the month;
- the supervisor's full name and signature.

According to Article 18.1.2 of the Grant Agreement: "as an exception, for persons working exclusively on the action, there is no need to keep time records, if the participant signs a declaration confirming that the persons have worked exclusively on the action". Nonetheless, institution rules need to be consulted first.

Other direct costs

Travel and subsistence costs

- 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 "other direct 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 provide decision trees for determining who pays for travel and meeting costs - the hosting organisation or the beneficiary:

Who pays what? Event organiser or external source?

Venue costs:

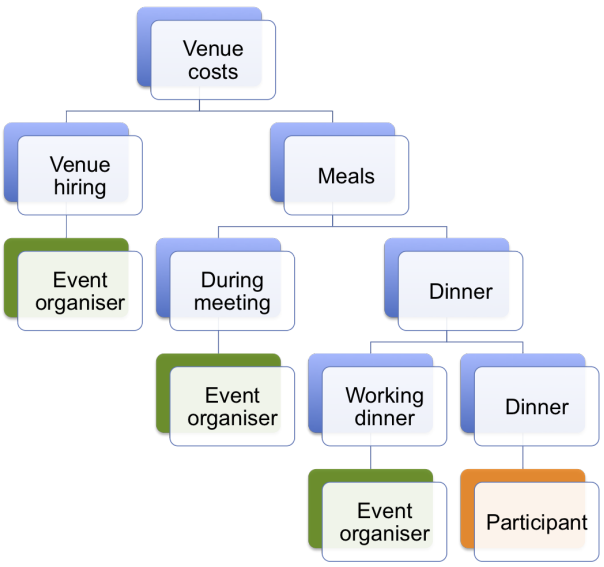

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Figure 7. Venue costs decision tree

Travel costs

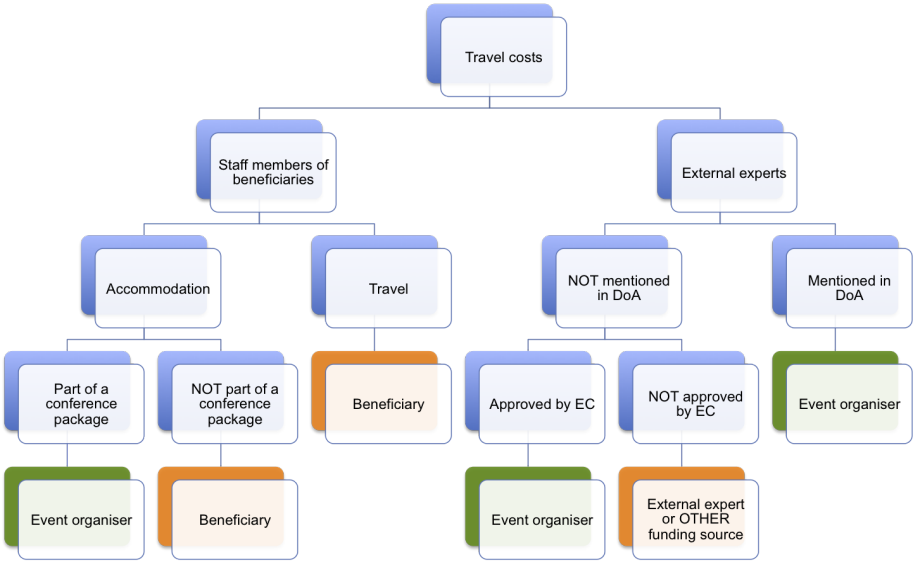

Figure 8. Travel costs decision tree

For more information, see ELIXIR's Guidelines and Tips for Events - for event organisers[44]

The depreciation costs of equipment, infrastructure or other assets (new or second hand) as recorded in the beneficiary's accounts are eligible, if they are purchased and written off in accordance with the beneficiary's usual accounting principles. The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and the rate of actual use for the purpose of the action.

Costs of other goods and services (consumables, supplies, dissemination, protection of results, certificates on the financial statements, certificates on the methodology, translations, publications) are eligible if they are purchased specifically for the project.

Subcontracting and other third parties' costs.

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" described in Article 13.1 of the Grant Agreement ("Subcontracting")[45].

Indirect costs

Indirect costs or overheads (e.g. heating, lighting, security, office supplies, etc.), which represents a fair apportionment of the overall overheads of the institution, are to be added to the above-mentioned categories. As they are indirect, these costs are not justified using invoices,

[44] https://docs.google.com/document/d/12YrPsuwEuUywSRaYdjUDjaq-bvhm_e_gOqd1pM44vmc/edit#
[45] https://drive.google.com/open?id=1gLhclTzFumCGuobTsZBPcZKFcPB2m5Qn

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etc., but are simply stated in the financial statement as a 25% flat rate of the direct costs (except for subcontracting and the costs of resources made available by third parties which are not used on the premises of the beneficiary, which bear no overheads).

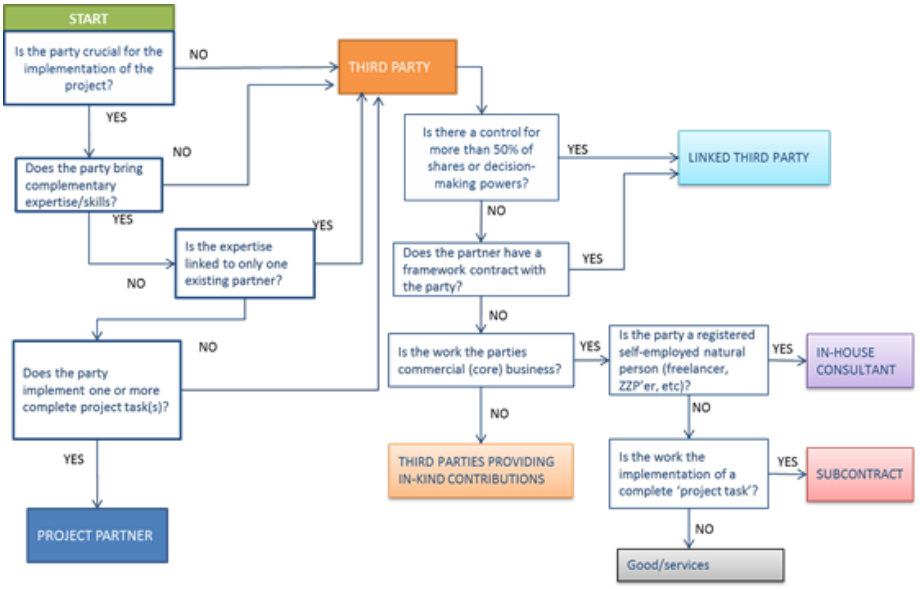

Figure 9. An overview of how to determine a subcontractor, linked third party, third party providing in-kind contributions or in-house consultant.

If in doubt, we encourage you to email b1mg-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.

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 6.1 to 6.4 of the Grant Agreement, in particular:

- Costs related to return on capital
- Debt and service debt charges
- Provisions for possible future losses or charges
- Interest owed
- Doubtful debts
- Currency exchange losses
- Bank costs charged by the beneficiary's bank for transfers from the Commission
- Excessive or reckless expenditure
- Deductible VAT
- Costs incurred during suspension of the implementation of the action.
- Any costs which do not meet the conditions established in the previous section.

Costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Commission for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period, unless it can demonstrate that the operating grant does not cover any costs of the action.

7.3.2.3. Submitting the financial statement

The financial statement is an official statement submitted by the beneficiary. Any Linked Third Parties (LTP) 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 & Tenders Opportunities Portal 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 Portal[46].

Cost 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. 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 B1MG-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.

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.

[46] https://ec.europa.eu/research/participants/data/ref/h2020/gm/reporting/h2020-tmpl-periodic-rep_en.pdf#page=23

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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 B1MG-CO and the OG with input from all WPs.

The B1MG-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 B1MG-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 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.

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.

As a guideline, Annex 5 of the Grant Agreement includes the terms of reference and independent report of factual findings for the certificate of financial statements.

7.3.5. EC Funding

The EC funding is paid to the Coordinator (ELIXIR Hub), who distributes it to the beneficiaries without unjustified delay.

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Some general rules apply with respect to the payments:

- The EC paid a pre-financing amount at the start of the project which was distributed to the beneficiaries receiving funding;
- 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. The Coordinator has the right to reject costs reported by any beneficiary if they are not in line with the work performed.

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:
    - 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 impact of the project in relation to the call text will be assessed against Key Performance Indicators (See table 13). Relating to all WPs, these KPIs can easily be monitored, from the project onset and will be refined in Task 5.3. Progress against these KPIs must be 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.

A full list of the KPIs as identified in the Description of Action Part B[47] can be viewed in the table below:

[47] https://drive.google.com/open?id=1K66wzojDS3K6VypdzyV67P9AIMPpKduW

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Table 13. B1MG KPIs.

Expected Impact (Call text) and B1MG approach to deliver and go beyond
Agreed standards and mechanisms for the cross-border linking and analysis of genomic and other health data with potential for wide-spread adoption across Europe.
Standards and mechanisms for the cross-border linking and analysis of genomic and other health data will be developed under W2 and WP3, informed by WP5, and co-designed with stakeholder input (under WP1). The latter will help ensure that the standards and mechanisms are agreed at the pan-European scale. Relevant deliverable(s): D2.2 Policy document for a genome data sharing initiative, D2.3 Report on legal set-up including Data Protection Impact Assessment (DPIA), D3.1 Quality metrics for sequencing, D3.2 Best practices for Next Generation Sequencing (NGS), D3.3 The B1MG data analysis challenge, D3.5 Phenotypic and clinical metadata framework, D3.8 Documented best practices in sharing and linking phenotypic and genetic data, D5.1 B1MG maturity level model and country-specific alignment within the model, D5.2 Roadmap and guidance tool for countries. Barrier(s): Sequencing capacity and effort, as well as policy and legal contexts, vary across countries. KPI(s): Proportion of countries involved in co-designing the standards and mechanisms; proportion of countries positively supporting the standards and mechanisms. Target(s): All countries that have signed the Declaration are involved in co-designing the standards and mechanisms, as well as positively supporting them. Overall buy-in from non-signatory countries. Adequate basis for developing a cross-border digital infrastructure for linking genomic and other health data in Europe. The federated cross-border digital infrastructure for linking genomic and other health data will be designed under WP4, informed by WP2 WP3 and stakeholder feedback (under WP1). Relevant deliverable(s): D2.4 Report on data access and governance framework, Report on current landscape and limitations and the benefits of developing cross-border digital infrastructure to link genomic and health data in Europe, via surveys, interviews and expert group meetings. A key assessment is the engagement of the signatory Member States and their respective national mirror groups that ensured a link to national and regional expertise and competence. D4.1 Secure cross-border data access roadmap, D4.2 Secure data access demonstrator, and D4.3 Secure cross-border data access roadmap updated. Barrier(s): Countries have varying infrastructure capacities. A large group of stakeholders needs to be consulted. KPI(s): Proportion of countries providing feedback on the design of the proposed cross-border digital infrastructure. Target(s): All countries that have signed the Declaration support the design of the proposed cross-border digital infrastructure. Overall buy-in from non-signatory countries.
Best possible and secure use of genomic and other health data for personalised medicine.

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Building on the work of relevant initiatives and informed by WP1, WP2, WP3 and WP5 will produce standards and quality guidelines that will form a solid foundation for the best possible and secure use of genomic and other health data for personalised medicine.

Relevant deliverable(s): D2.4 Report on data access and governance framework, D3.8 Documented best practices in sharing and linking phenotypic and genetic data, D5.1 B1MG maturity level model and country-specific alignment within the model, D5.2 Roadmap and guidance tool for countries

Barriers: Reaching consensus across a range of stakeholders. Varying set-ups for health data systems at national-level.

KPIs: Proportion of countries in support of the standards and guidelines.

Targets: All countries that have signed the Declaration support the proposed standards and guidelines. Overall buy-in from non-signatory countries.

Adequate basis for investment decisions in personalised medicine (both private and public) based on expected returns.

WP5 will develop a harmonised methodology for economic evaluation of the cost and benefits of implementing personalised medicine, which will inform investment decisions in this sector.

Relevant deliverable(s): D5.3 Economic models methodology and case studies. Report on harmonisation of economic evaluation models for application of genomic medicine in cancer, rare diseases, and for prevention of complex diseases.

Barrier(s): Limited body of knowledge on the cost and benefits of personalised medicine. Varying set-ups for health data systems at national-level. Buy-in of the approach and results by stakeholders.

KPI(s): Proportion of countries in support of the methodologies

Target(s): All countries that have signed the Declaration support the methodology. Overall buy-in from non-signatory countries.

Support Europe's global leadership in personalised medicine.

Work under WP1, WP5 and WP6 will result in a set of recommendations on how a cross-border infrastructure can unleash the potential of personalised medicine, in collaboration with key players in the public and private sectors, thereby demonstrating Europe's global leadership in this area.

Relevant deliverable(s): D1.1 Document describing the operational organisation and processes for the SCG, D1.5 Yearly report on recommendations to facilitate genome/clinical data integration to the EJR-RD and Cancer Mission, SCG Roundtable meeting and Thematic framework, D5.1 B1MG maturity level model and country-specific alignment within the model, D5.2 Roadmap and Guidance tool for countries, D5.3. Economic models methodology and case studies. D6.7 Guiding principles and best practices examples for mirror groups, D6.10 Report on sustainability design and funding routes for the delivery of Personalised Medicine cross-border

Barrier(s): Uptake of personalised medicine approaches differ by country and sector.

KPI(s): Proportion of countries in support of the recommendations.

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Target(s): All countries that have signed the Declaration support the recommendation in principle. Overall buy-in from non-signatory countries.

In addition, Communications KPIs will be detailed in the B1MG communication strategy.

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

- M6.2 Project KPIs presented to OG - Month 12
- D6.4 Project Handbook V2 - Month 16
- M6.3 Project KPIs presented to OG - Month 24
- D6.5 Project Handbook final version - Month 41
- M6.4 Final project KPIs available and presented to EC as part of final report to EC - Month 36

As and when new metrics are available, it is the responsibility of the WPLs to inform the B1MG-CO who will then include them in the dashboard to be monitored monthly.

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8. Data management plan

The Data Management Plan (DMP) will be defined and updated throughout the project lifecycle as part of Task 6.3. The initial version of the DMP must be created by the ELIXIR Hub in the first six months of the project within WP6 (D6.2) according to the project scope and the EC requirements.

Any questions regarding the DMP should be directed to the ELIXIR Hub (juan.arenas@elixir-europe.org).

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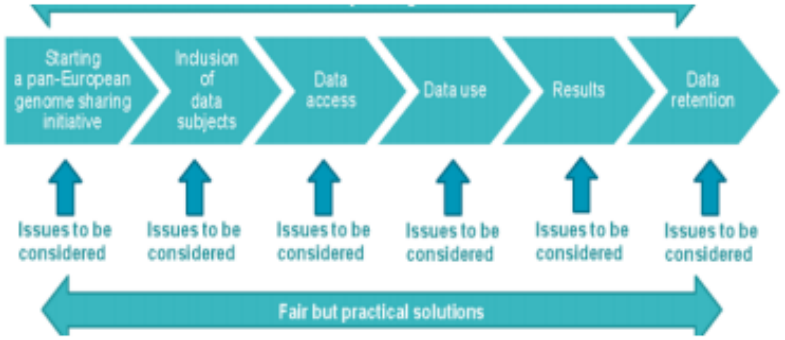
9. Ethical considerations

Within B1MG, no sensitive personal data will be processed. Where IT infrastructures will be tested for accessing genome and health data, such processing will be based on synthetic data that has been created outside the project. Such data does no longer count as personal data and can therefore be used without restrictions from a legal or ethical point of view.

Human participants are involved to the extent that a major stakeholder involvement will be part of the project and surveys will be conducted. In this context, it will be necessary to process personal data. However, the risk in terms of rights and freedom of the stakeholders involved will be minimal and the handling of their data will be explained to them upfront.

Nevertheless, while work in the B1MG does not imply any critical ethical issue, its ultimate goal to enable a sharing of genomic and health data on a large scale across Europe will come with major ethical, legal and social implications. For this reason, an ELSI WP has been set up to study the legal, ethical and social implications of this initiative and provide a framework of policies, guidelines and legal analyses as well as practical recommendations that can be translated into technical solutions.

We will analyse issues at stake across the entire life cycle of the data in the initiative and relevant use cases (see Figure below).



We will explore the ethical-legal situation in the different countries to identify the need to adapt already otherwise developed policies and procedures as well as the necessity for harmonisation to allow an efficient pooling of genomes. As evidenced by the General Data Protection Regulation (GDPR), which leaves the regulation of data processing of health and genomic data as well as many aspects of processing personal data for research to the Member States, achieving consensus on ELSI issues among participating Member States may be hard to achieve and require political action. Rather, deploying the European regulatory mechanism of common minimum standards and mutual recognition, we will identify the legal, ethical requirements for making nationally compliant data sets accessible for pan-European use.

An important element in the development of the rules and procedures to underlie the 1+MG initiative will be the performance of a data protection impact assessment. This will allow us to evaluate the risks to the data subjects associated with the initiative and the role of the procedures and rules suggested to mitigate such risks. The ultimate aim is to develop a framework that allows harmonised access procedures based on thresholds and requirements, that defines a data governance across the 1+MG and that gives input to the technical realisation of such governance allowing ethically and legally compliant data sharing.

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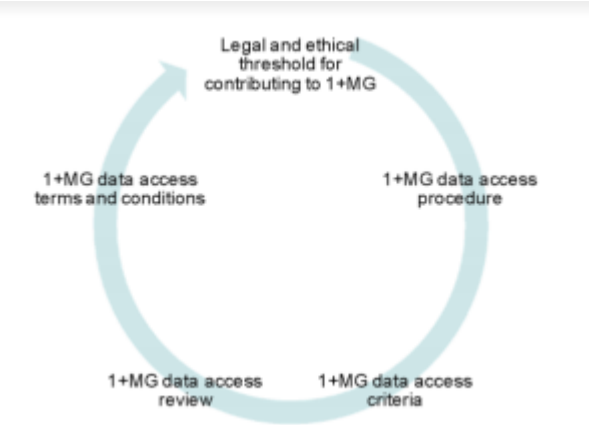

WP2 and WP4 will work closely together on the design of this framework. More detailed information can be found in these WPs as well as in the concept and methodology section 1.3. The B1MG will further be accompanied by a Scientific and Ethics Advisory Board with recognised experts in the field. Building on the 1+MG Initiative, there will be the ELSI experts Working Group across the members to the initiative to reflect the work performed in the project. These experts will further be backed up by national mirror groups on ELSI.

The B1MG consortium will apply the "data minimisation" principle while collecting personal data (i.e. stakeholder workshops) and handle it in compliance with the applicable GDPR regulations. Besides, data to be imported to/exported from the EU (limited to contact data and mail distribution list memberships) will be kept on a file managed by the B1MG coordinator that will be listed in the project data management plan (D6.2)

9.1. Equal Opportunities

In accordance with Article 33 — Gender Equality, of the Grant Agreement[48], 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 B1MG 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 ensure a cadre of future leaders. The B1MG-CO and Operational Group will monitor participation and representation.

[48] https://drive.google.com/file/d/1gLhcITzFumCGuobTsZBPcZKFcPB2m5Qn/view

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10. Intellectual property rights

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

1. Section 8 (Intellectual Property - Access Rights) of the B1MG Consortium Agreement[49]
2. Article 23a (Management of Intellectual Property) of the B1MG Grant Agreement[50]

Or contact the B1MG-CO: b1mg-coordination@elixir-europe.org

[49] https://drive.google.com/file/d/1Wov2zOWkY76CoVAkmF_d8XPTNmAXybw3/view?usp=drive_link
[50] https://drive.google.com/file/d/1gLhcITzFumCGuobTsZBPcZKFcPB2m5Qn/view

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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 B1MG Google Drive[51].

Appendix 2: B1MG Project Handbook - live version

The Project Handbook is accessible to all project Partners on the B1MG Google Drive: B1MG_PROJECT HANDBOOK_LIVE document[52]

[51] https://docs.google.com/spreadsheets/d/1B_sK9Q8uwAQEOGY-PRBG08HbMgSrlKGE-MCrArKdXW0/edit#gid=434949238
[52] B1MG Project Handbook: https://docs.google.com/document/d/1OCOIJx7qhWp30kCfyFtzEKf6vE1QNTNp_pq4Y8UNKlo/edit#

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