Beyond One Million Genomes

D2.1

Report of ELSI Stakeholder Meetings

Project Title (grant agreement No)	Beyond One Million Genomes (B1MG) Grant Agreement 951724		
Project Acronym	B1MG		
WP No & Title	WP2 - ELSI		
WP Leaders	Regina Becker (UNILU), Jasper Bovenberg (Legal Pathways)		
Deliverable Lead Beneficiary	9 - ECRIN		
Deliverable	D2.1 - Report of ELSI Stakeholder Meetings		
Contractual delivery date	30/09/2022	**Actual delivery date**	31/01/2023
Delayed	Yes		
Authors	Maria Panagiotopoulou (ECRIN), Regina Becker (UNILU)		
Contributors	Adrian Thorogood (UNILU), Susanne Rebers (NKI/BBMRI-NL), Signe Mežinska (University of Latvia/BBMRI-LV), Michaela Th. Mayrhofer (BBMRI), Olga Tzortzatou (BRFAA/BBMRI-GR), Marina Makri (BRFAA/BBMRI-GR), Mihaela Matei (ECRIN), B1MG WP2/1+MG WG2 members through discussions in project meetings and events		
Acknowledgements (not grant participants)	B1MG stakeholders for their valuable contributions during the project meetings and events		
Deliverable type	Report		
Dissemination level	Public		

B1MG has received funding from the European Union's Horizon 2020 Research and Innovation programme under grant agreement No 951724

Document History

Date	Mvm	Who	Description
12/01/2023	0v1	Maria Panagiotopoulou (ECRIN), Regina Becker (UNILU)	Initial draft circulated to WP participants for feedback
23/01/2023	0v2	Maria Panagiotopoulou (ECRIN), Regina Becker (UNILU)	WP comments addressed. Version circulated to B1MG-OG & B1MG-GB. Version uploaded to the B1MG Stakeholder Portal for feedback.
31/01/2023	1v0	Maria Panagiotopoulou (ECRIN) & Nikki Coutts (ELIXIR Hub)	Comments addressed. Version uploaded to the EC Portal

Table of Contents

B1MG has received funding from the European Union's Horizon 2020 Research and Innovation programme under grant agreement No 951724

1. Executive Summary

The 1+ Million Genomes (1+MG) initiative aims to enable secure access to genomics and the corresponding clinical data across Europe for better research, personalised healthcare and health policy making. The Beyond 1 Million Genomes (B1MG) project was funded under the Horizon 2020 Framework Programme (duration: June 2020-May 2023) with the objective to establish the support and coordination structure for the 1+MG initiative. More recently (November 2022), the Genomic Data Infrastructure (GDI) project was funded to build upon the work carried out in 1+MG and B1MG and provide the data infrastructure that will enable secure access to genomics and corresponding clinical data across Europe. A major challenge for 1+MG, B1MG and GDI is addressing adequately the Ethical, Legal, and Social Implications (ELSI) of genomic and health research and translating them into technical specifications and implementation guidelines that capture European best practice.

Stakeholders, defined as individuals, groups or organisations who may affect, be affected by or perceive themselves to be affected by a decision, activity, or outcome of a project can play a crucial role in the success of a scientific project for reasons such as helping to solve arising problems, achieving goals, increasing the availability of resources and improving the quality of products, services or outcomes. The B1MG project since its kick-off involved different groups of key stakeholders (patient organisations, HTA bodies, academics, national policy and decision makers, Research Infrastructures, clinicians and medical specialists, medicines authorities, industry, funders, EU Joint Actions) through annual B1MG Stakeholder Forum meetings, the creation of an interactive B1MG stakeholder portal, expert stakeholder consultation through regular meetings and workshops etc.

The present report describes the identification and prioritisation of stakeholders from the B1MG WP2 “ELSI” perspective and summarises the different meetings and consultations that took place for the period June 2020-December 2022. The mapping exercise of WP2 resulted in an internal project inventory of more than 100 ELSI stakeholders, several of which were invited to engage with the project through the WP2 sessions in the annual B1MG Stakeholder Forum meetings, thematic workshops or their inclusion to the monthly B1MG WP2/ 1+MG WG2 meetings. In addition, several members of the B1MG WP2/1+MG WG2 have participated in meetings of other European projects and initiatives as stakeholders, advisory board members or invited speakers, ensuring knowledge transfer and alignment.

B1MG has received funding from the European Union’s Horizon 2020 Research and Innovation programme under grant agreement No 951724

2. Contribution towards project objectives

With this deliverable, the project has reached or the deliverable has contributed to the following objectives/key results:

[Select 'Yes' (at least one) if the deliverable contributed to the key result, otherwise select 'No'.]

	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.	**No**
	5. Best practices for Next Generation Sequencing (WP3) by M24.	**No**
	6. Phenotypic and clinical metadata framework (WP3) by M12, M24 & M36.	**No**
	7. Best practices in sharing and linking phenotypic and genetic data (WP3) by M12 & M24.	**No**
	8. Data analysis challenge (WP3) by M36.	**No**
	Infrastructure Key Results	
	9. Secure cross-border data access roadmap (WP4) by M12 & M36.	**No**
	10. Secure cross-border data access demonstrator (WP4) by M24.	**No**

B1MG has received funding from the European Union's Horizon 2020 Research and Innovation programme under grant agreement No 951724

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.	**No**
	2. Roadmap and guidance tools for countries for effective implementation of Personalised Medicine (WP5) by M36.	**No**
	3. Economic evaluation models for Personalised Medicine and case studies (WP5) by M30.	**No**
	4. Guidance principles for national mirror groups and cross-border Personalised Medicine governance (WP6) by M30.	**No**
	5. Long-term sustainability design and funding routes for cross-border Personalised Medicine delivery (WP6) by M34.	**No**

3. Introduction: 1+MG, B1MG and GDI

The 1+ Million Genomes (1+MG) initiative aims to enable secure access to genomics and the corresponding clinical data across Europe for better research, personalised healthcare and health policy making. Since the Digital Day 2018, 24 EU countries, the United Kingdom and Norway signed the Member States' Declaration 'Towards access to at least 1 million sequenced genomes in the EU by 2022' that consists of stepping up efforts towards creating a European data infrastructure for genomic data and implementing common national rules enabling federated data access. The initiative forms part of the EU's agenda for the Digital Transformation of Health and Care[1] and is aligned with the goals of the European Health Data Space (EHDS)[2]. The 1+MG Roadmap, published in February 2020, sets out the priorities for the period 2020-2022[3].

The Beyond 1 Million Genomes (B1MG) project[4] is a 3-year (duration: June 2020-May 2023) Coordination and Support Action (CSA) implemented under the European Union's Horizon 2020 Research and Innovation programme with the aim to establish the support and coordination structure for the 1+MG initiative. It brings together 28 European partners from 25 countries, including participants both from academia and industry.

In summary, the project's goals are:

- To work with regional, national and European stakeholders to define the requirements for cross-border access to genomics and personalised medicine data.
- To translate requirements for data quality, standards, technical infrastructure, and Ethical, Legal, and Social Implications (ELSI) into technical specifications and implementation guidelines that capture European best practice.

[1] https://digital-strategy.ec.europa.eu/en/policies/ehealth
[2] https://ec.europa.eu/health/ehealth-digital-health-and-care/european-health-data-space_en
[3] https://b1mg-project.eu/docs/1mg-roadmap.pdf
[4] https://b1mg-project.eu/

B1MG has received funding from the European Union's Horizon 2020 Research and Innovation programme under grant agreement No 951724

- To drive adoption and support for long-term operations by providing guidance on phased development and a methodology for economic evaluation.

Building on the 1+MG initiative and the B1MG work, the Genomic Data Infrastructure (GDI) project[5] was launched in Brussels in November 2022. The aim of the GDI project is to realise the 1+MG initiative's data infrastructure that will enable secure access to genomics and corresponding clinical data across Europe.

4. Stakeholder engagement in B1MG

4.1 Stakeholder involvement in scientific research

Stakeholders can be defined as an individual, group or organisation who may affect, be affected by or perceive itself to be affected by a decision, activity, or outcome of a project [1]. Stakeholders include both those who are likely to be supportive of the research conducted and those who are likely to be less supportive or even critical of it. Stakeholder engagement refers to the process of involving stakeholders in the project for reasons such as helping to solve arising problems, achieving goals, increasing the availability of resources and improving the quality of products, services or outcomes [2]. *"Engaging stakeholders is an iterative process of soliciting the knowledge, experience, judgement and values of individuals selected to represent interests in an issue, to create a shared understanding and make relevant, transparent and effective decisions"* [3].

In scientific research, stakeholder involvement is considered an effective strategy for reducing the gap between research, practice and policy [4,5]. It helps to overcome the discrepancy between what organisations or projects see as important for their stakeholders, and what stakeholders themselves believe to be important. In addition, the complexity of certain projects, such as B1MG, requires *"the constructive input from various communities of knowledge"*, going beyond the project consortia. Stakeholders can provide expertise based on information from their field (e.g. academia, industry, regulatory), which helps to understand and reduce project constraints and risks, and increase the potential success and acceptance [6]. Building collaboration and trust may help to expand relationships between different stakeholder groups, which in turn can help to increase the experience of "ownership" (i.e. the project is taking their views and interests into account) and motivate them to sponsor the project and contribute to the sustainability of project outcomes once it has been completed. Moreover, involving stakeholders since the beginning of the project is a sign of transparency in the decision-making processes [7-9].

4.2 The B1MG stakeholder approach

The B1MG stakeholder organisation aimed to target and facilitate the engagement of stakeholders to the 1+MG initiative at the following major levels, and in the following manner:

1. Stakeholder experts are directly invited to register through the B1MG Stakeholder Portal[6]. Together they constitute the **B1MG Stakeholder Forum** as the body of known

[5] https://gdi.onemilliongenomes.eu/
[6] https://sites.google.com/ebi.ac.uk/b1mg-stakeholders-portal/home

B1MG has received funding from the European Union's Horizon 2020 Research and Innovation programme under grant agreement No 951724

experts informed and engaged in various activities organised within the framework of B1MG.

2. The **Stakeholder Portal** was developed as the central channel of communication among work package teams and stakeholders. Registered stakeholders get access to (draft) output documents of all B1MG WPs (e.g. deliverables) for their review and input. In this way B1MG informs and consults a broad range of key European, national and regional organisations that play an active role in implementation of genomics-based health strategies, and that can help co-create the guidelines and conditions that will facilitate secure cross-border access to genomic datasets ultimately assembled by the 1+MG National Mirror Groups.

   The stakeholder groups targeted in the B1MG Stakeholder Portal are:

   - Patient organisations
   - HTA bodies
   - Academics
   - National Policy and decision makers
   - Research Infrastructures
   - Clinicians and medical specialists
   - Medicines Authorities
   - Industry
   - Funders
   - EU Joint Actions

Figure 1. Screenshot of the B1MG Stakeholder Portal and the Stakeholder Groups identified as relevant for the B1MG project.

3. **Stakeholder Forum meetings** are held *once per year*, as part of the annual B1MG summit. These meetings are co-organised between WP1, the B1MG coordination and the teams of all B1MG WPs/1+MG WGs.

B1MG has received funding from the European Union's Horizon 2020 Research and Innovation programme under grant agreement No 951724

4. **Expert stakeholders** are invited to participate in workshops and other meetings/events organised in the 1+MG initiative: B1MG involves such stakeholders in B1MG work packages and 1+MG working groups. The work package leaders of WPs 2-7 are in the lead of selecting experts of key stakeholder organisations to be involved in their work packages.

5. The B1MG management and leads of WP2-7 identify a special category of stakeholders, so-called **Partner Projects** to be included in B1MG and in the B1MG Stakeholder Forum. Partner Projects are a selection of key stakeholder initiatives and specific (European) projects with funded capacity of experts who can actively contribute to the workstreams organised in the 1+MG initiative and help realise the 1+MG goals. Where applicable, B1MG WP2-7 teams involve such selected stakeholders in their work packages and 1+MG working groups.

6. Stakeholders are also involved in the WP-overarching subject of **citizen trust and public engagement**.

Figure 2 shows the position of the stakeholder layer in the 1+MG initiative. Identification of individual stakeholders is principally done through the expert network created around the international 1+MG WGs and B1MG WPs. Also, the governance bodies of the project and the 1+MG initiative, including the team of the European Commission supporting the 1+MG initiative, help in identifying key stakeholder organisations and individual experts across Europe, and beyond.

For more information on the B1MG stakeholder approach and the B1MG stakeholder portal the reader is referred to *D1.1 Document describing the operational organisation and processes for the Stakeholder Coordination Group (SCG)* [10] and *D1.2 Generation of a stakeholder portal within the project webpage containing the information resulting from the activities of the SCG* [11].

B1MG has received funding from the European Union's Horizon 2020 Research and Innovation programme under grant agreement No 951724

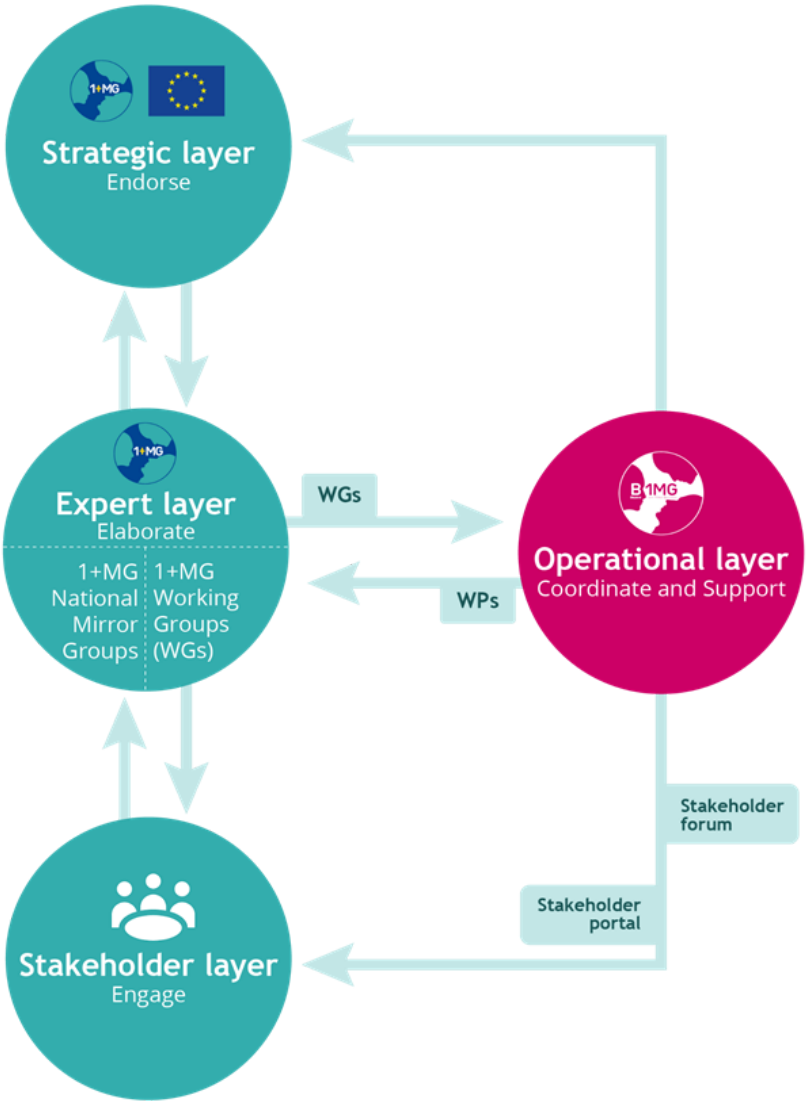


Figure 2. General overview of the 1+MG organisation and governance, showing the position of the body of Stakeholders in the 1+MG initiative which is primarily engaged via the workstreams organised in the 1+MG expert layer of working groups. The B1MG project facilitates optimal stakeholder engagement through the organisation of the Stakeholder Forum and the Stakeholder Portal. As such, it adds essential Stakeholder input to the output of 1+MG work processes that need to be endorsed by the 1+MG Group of country representatives in 1+MG (Strategic layer; policy perspective).

5. ELSI stakeholder mapping

Within B1MG WP2 "ELSI" the *Task 2.1 Outreach to (and engagement of) relevant stakeholders and existing solutions* started by mapping and prioritising the stakeholders from an ELSI perspective.

The most relevant stakeholder groups for the WP2 activity and as identified by the WP2/WG2 members are:

B1MG has received funding from the European Union's Horizon 2020 Research and Innovation programme under grant agreement No 951724

- **Patient & societal organisations**

  Reasons for involvement:

  - Learn about concerns, hopes and best ways of communication.
  - Ensure and improve general ethical acceptability of the platform governance by patients and citizens, who are both risk-taking participants and the ultimate beneficiaries.
  - Ensure patients and citizens are appropriately represented on the governance bodies of the developed platform.

  Examples of identified stakeholders:

  European Patient Forum (EPF)[7], European Organisation for Rare Diseases (EURORDIS)[8], European Cancer Patient Coalition (ECPC)[9], European AIDS Treatment Group (EATG)[10], Patients Network for Medical Research and Health (EGAN)[11], The Synergist[12], Patvocates[13] etc.

- **Research Infrastructures, ELSI WGs of relevant alliances/initiatives/consortia, Projects, National personalised and genomic medicine initiatives and strategies, Individual Experts working on topics of relevance**

  Reasons for involvement:

  - Build upon existing knowledge and avoid reinventing the wheel. Learn from their experience on previous projects that address ELSI issues on genomics data sharing/cross-border sensitive data sharing for both research and healthcare.
  - Gain input on ethical, legal and societal challenges in different countries.
  - Ensure downstream scientific and ethical/legal compatibility between different large-scale resources to enable future international collaboration.

  Examples of stakeholders:

  Research Infrastructures: Biobanking and Biomolecular Resources Research Infrastructure (BBMRI)[14], European Clinical Research Infrastructure Network (ECRIN)[15], European Advanced Translational Research Infrastructure in Medicine (EATRIS)[16], European life-sciences Infrastructure for biological Information (ELIXIR) etc.[17]

[7] https://www.eu-patient.eu/
[8] https://www.eurordis.org
[9] https://ecpc.org/
[10] http://www.eatg.org/
[11] https://egan.eu/
[12] https://www.thesynergist.org/
[13] https://www.patvocates.net/
[14] https://www.bbmri-eric.eu/
[15] https://ecrin.org/
[16] https://eatris.eu/
[17] https://elixir-europe.org/

B1MG has received funding from the European Union's Horizon 2020 Research and Innovation programme under grant agreement No 951724

ELSI WGs of relevant alliances/initiatives/consortia: Global Alliance for Genomics and Health (GA4GH)[18], PHG Foundation[19], International Consortium for Personalised Medicine (ICPerMed)[20], Research Data Alliance (RDA)[21] etc.

Projects: HealthData@EU/EHDS2 pilot[22], TEHDAS Joint Action[23], EOSC-Life[24], EPND[25], SIENNA[26], SYNCHROS[27], HealthyCloud[28] etc.

National personalised and genomic medicine initiatives and strategies: Plan France Médecine Génomique 2025[29], Genomics England[30], National Human Genome Research Institute (NHGRI)[31] etc.

- **Industry: pharma, diagnostic companies,…**

  Reasons for involvement:

  - Learn about needs and obstacles from the private sector and get the "company point of view".

  Example of stakeholders:

  European Federation of Pharmaceutical Industries and Associations (EFPIA)[32]

- **Medicines authorities/Regulatory Bodies, Ministries of Health and Social Affairs**

  Reasons for involvement:

  - Learn about use case scenarios that they have for policy development.

  Example of stakeholders:

  European Medicines Agency (EMA)[33], Signatories of 1+MG Declaration

- **Supervisory authorities, Data Access Committees, Ethics Committees**

  Reasons for involvement:

  - Gain feedback on our suggested solutions.
  - Create a dialogue on modern genomic health and genomic research.
  - Gain them as supporters.

[18] https://www.ga4gh.org/
[19] https://www.phgfoundation.org/
[20] https://www.icpermed.eu/
[21] https://www.rd-alliance.org/
[22] https://www.ehds2pilot.eu/
[23] https://tehdas.eu/
[24] https://www.eosc-life.eu/
[25] https://epnd.org/partners
[26] https://www.sienna-project.eu/
[27] https://synchros.eu/
[28] https://healthycloud.eu/
[29] https://pfmg2025.aviesan.fr/en/
[30] https://www.genomicsengland.co.uk/
[31] https://www.genome.gov/
[32] https://www.efpia.eu/
[33] https://www.ema.europa.eu/en

B1MG has received funding from the European Union's Horizon 2020 Research and Innovation programme under grant agreement No 951724

Examples of stakeholders:

European Data Protection Board (EDPB)[34], European Network of Research Ethics Committees (EUREC)[35], Committee on Bioethics (DH-BIO) of the Council of Europe[36], UNESCO International Bioethics Committee[37]

- **European Commission and European Commission Expert groups**

  Reasons for involvement:

  - Learn what is going on in other policy areas (e.g. eHealth).
  - Gain input and inspiration.
  - Align activities (where relevant).

  Examples of stakeholders:

  Directorate-General for Health and Food Safety (DG SANTE), Directorate-General for Research and Innovation (DG RTD), Directorate-General for Communications Networks, Content and Technology (DG CNECT), European Group on Ethics in Science and New Technologies (EGE), eHealth Stakeholder Group, etc.

- **1+MG WGs (including the driving use cases, see 11. Appendix)**

  Reasons for involvement:

  - Translate the activity of the rest of the 1+MG working streams into ELSI requirements and recommendations.

B1MG WP2 maintains an ELSI stakeholder inventory listing information on more than 100 relevant stakeholders [12]. Since the beginning of the B1MG project, the stakeholders have been consulted for the organisation of different project meetings and events.

[34] https://edpb.europa.eu/edpb_en
[35] http://www.eurecnet.org/index.html
[36] https://www.coe.int/en/web/bioethics/dh-bio
[37] https://en.unesco.org/themes/ethics-science-and-technology/ibc/members

B1MG has received funding from the European Union's Horizon 2020 Research and Innovation programme under grant agreement No 951724

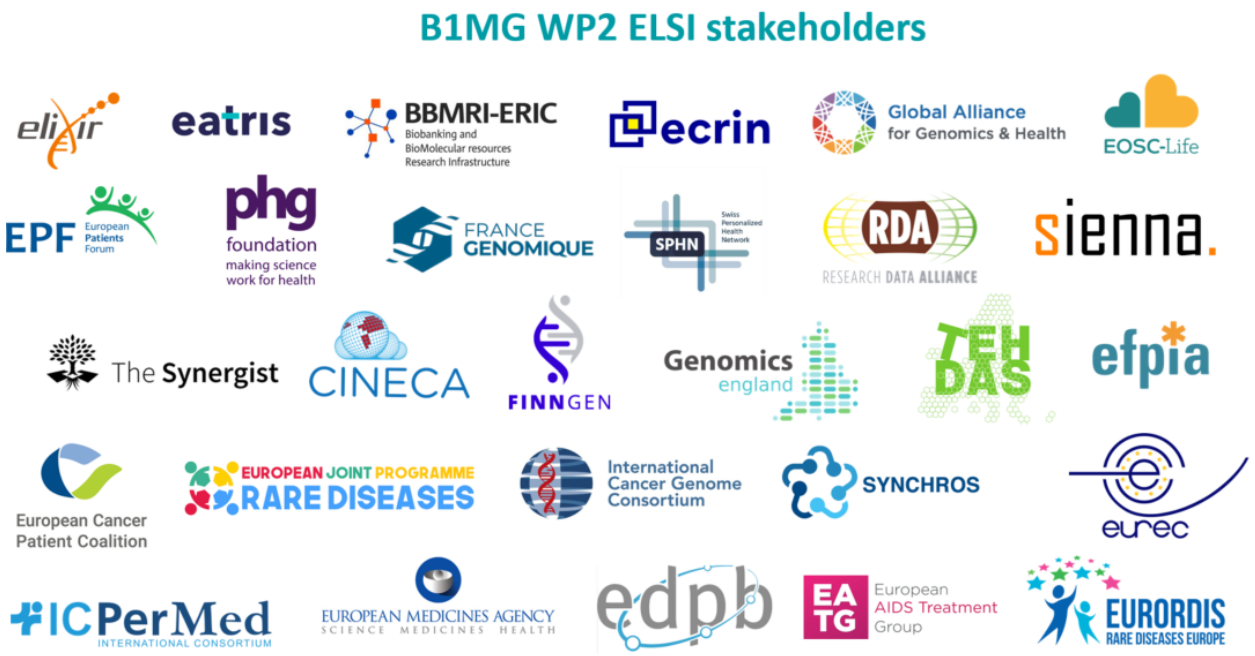


Figure 3. Examples of stakeholder organisations identified as relevant during the B1MG WP2 stakeholder mapping exercise.

6. ELSI stakeholder meetings

This section aims to provide an overview of the ELSI stakeholder meetings that were co-organised by B1MG WP2/1+MG WG2 and that took place over the period June 2020-December 2022.

B1MG Stakeholder Meeting 2020	
Date(s)	21/10/2020
Targeted stakeholder group(s)	All B1MG relevant stakeholder groups.
Objective/Outcome	To set the framework for stakeholder engagement in B1MG through the lens of the Work Packages and together with all the relevant stakeholders. It covered the topics: • Setting the Framework for Cooperation • Ethics, Legal, Societal Impact • Standards & Quality Guidelines • Federated Secure Cross-border Technical Infrastructure • Delivering Personalised Medicine cross-borders: Implementation in Healthcare systems and Societal

B1MG has received funding from the European Union's Horizon 2020 Research and Innovation programme under grant agreement No 951724

	Impact • Communication, Governance and Sustainability The recording, meeting minutes and slides are available and internal to the B1MG consortium. Based on compiled pre-information to the stakeholders and targeted questions, the meeting was used by WP2 to gain targeted input from different relevant stakeholder groups that could be used for the design of the work in WP2.

B1MG Stakeholder Meeting 2021	
Date(s)	17/11/2021
Targeted stakeholder group(s)	All B1MG relevant stakeholder groups.
Objective/Outcome	To gain stakeholder feedback and recommendations across all use cases on elements of the 1+MG Trust Framework. The sessions included: • Introduction to the Trust Framework (ELSI aspects, data standards and data quality aspects, infrastructure aspects) • Presentation on "Public trust and engagement: challenges for genomics and its implementation in healthcare" • Use case workshops (Industry-WG7, Rare Diseases-WG8, Cancer-WG9, Common and complex diseases-WG10, Infectious Diseases-WG11, Genome of Europe-WG12). During the use case workshops different stakeholders presented relevant work in projects and initiatives (e.g. the Screen4Care EU-IMI project[38], the FinnGen-study[39], the BY-COVID project[40], EJP RD[41] etc.) The recording, meeting minutes and slides are available and internal to the B1MG consortium.

[38] https://screen4care.eu/
[39] https://www.finngen.fi/en
[40] https://by-covid.org/
[41] https://www.ejprarediseases.org/

B1MG has received funding from the European Union's Horizon 2020 Research and Innovation programme under grant agreement No 951724

	D1.3 Report of Stakeholders Forum 2021 including recommendations to the 1+MG Working Groups[42] provides a detailed summary to the outcomes of the workshop and recommendations to the 1+MG WGs (including ELSI). This meeting was particularly relevant for the considerations of WP2 on the ELSI trust framework, reaching out beyond the members of the 1+MG WG2 (ELSI).

B1MG Stakeholder Meeting 2022	
Date(s)	13/10/2022
Targeted stakeholder group(s)	All B1MG relevant stakeholder groups.
Objective/Outcome	To discuss together with all relevant stakeholders how to scale up the work of 1+MG/B1MG and make it sustainable. The sessions included: ● Scale up and sustainability of 1+MG/B1MG efforts: - How can stakeholders facilitate the scale up and sustainability of the efforts of B1MG towards an infrastructure to share genomic data across borders? - How can the Maturity Level Model and the 1+MG Trust Framework be put to use by stakeholders? - What is the role of industry in the scale-up and sustainability efforts? - What is the role of National Mirror Groups in the scale- up and sustainability of the infrastructure? ● Key updates on 1+MG/B1MG ● Trust Framework - A brief overview of the 1+MG Trust Framework with updates on its 3 components - Data governance, data standards and quality, and technical infrastructure. ● Maturity Level Model

[42] https://zenodo.org/record/7590713#.Y9k_wezP30o

B1MG has received funding from the European Union's Horizon 2020 Research and Innovation programme under grant agreement No 951724

	- The efforts of 1+MG/B1MG in developing a Maturity Level Model to enhance the national healthcare systems towards the goal of precision medicine was introduced and progress on the pilot phase reported. ● 1+MG industry engagement - Learnings and experience from the efforts undertaken by 1+MG in engaging with industry as a key stakeholder in this initiative was shared. ● Implementation and next steps ● Genomic Data Infrastructure (GDI) presentation ● European Health Data Space (EHDS) presentation ● Gaia-X presentation ● Panel discussion on industry engagement The recording, meeting minutes and slides are available and internal to the B1MG consortium. *D1.4 Report of Stakeholders Forum 2022 including recommendations to the 1+MG Working Groups*[43] provides a detailed summary to the outcomes of the workshop and recommendations to the 1+MG WGs (including ELSI). This meeting provided input in particular to the envisaged data governance as proposed by WP2.

Implementation of the GDPR in the Nordic countries	
Date(s)	20/01/2021
Targeted stakeholder group(s)	Health researchers and legal and ethical experts from Denmark, Sweden, Norway, Finland. 1+MG WG2, B1MG WP2.
Objective/Outcome	To look into the specifics of the GDPR implementation in the Nordic countries: Denmark, Sweden, Norway, Finland. Invited speakers from the University of Turku (Finland), University of Copenhagen (Denmark), Norwegian Directorate of Health

[43] https://zenodo.org/record/7590743#.Y9k-_uzP30o

B1MG has received funding from the European Union's Horizon 2020 Research and Innovation programme under grant agreement No 951724

	(Norway), Stockholm University (Sweden). Meeting slides and recording are available and internal to the B1MG consortium. The outcomes of the "Implementation of the GDPR in the EU" workshop series have been submitted as a peer review open access publication.

Implementation of the GDPR across the South European countries	
Date(s)	19/05/2021
Targeted stakeholder group(s)	Health researchers and legal and ethical experts from Greece, Italy, Malta, Portugal, Spain. 1+MG WG2, B1MG WP2.
Objective/Outcome	To look into the specifics of the GDPR implementation in the South European countries. Presentations and discussion with representatives from Greece, Italy, Malta, Portugal, Spain. Invited speakers from the Biomedical Research Foundation of the Academy of Athens (Greece), University of Trento and University Milano Bicocca (Italy), Ethics Committee of ARS Centro (Portugal), Valencia Polytechnic University (Spain), University of Malta (Malta). Meeting slides and recording are available and internal to the B1MG consortium. The outcomes of the "Implementation of the GDPR in the EU" workshop series have been submitted as a peer review open access publication.

Implementation of the GDPR in central Europe	
Date(s)	19/11/2021
Targeted stakeholder group(s)	Health researchers and legal and ethical experts from the Netherlands, France, Germany, Belgium. 1+MG WG2, B1MG WP2.
Objective/Outcome	To look into the specifics of the GDPR implementation in the Central European countries. Presentations and discussion with representatives from the Netherlands, France, Germany, Belgium.

B1MG has received funding from the European Union's Horizon 2020 Research and Innovation programme under grant agreement No 951724

	Invited speakers from the Netherlands Cancer Institute (the Netherlands), the French Institute of Health and Medical Research - Inserm (France), the University of Heidelberg (Germany), KU Leuven (Belgium). Meeting slides and recording are available and internal to the B1MG consortium. The outcomes of the "Implementation of the GDPR in the EU" workshop series have been submitted as a peer review open access publication.

Implementation of the GDPR in Eastern Europe	
Date(s)	21/02/2022
Targeted stakeholder group(s)	Health researchers and legal and ethical experts from the Czech Republic, Poland, Estonia, Latvia. 1+MG WG2, B1MG WP2.
Objective/Outcome	To look into the specifics of the GDPR implementation in the Eastern European countries. Presentations and discussion with representatives from the Czech Republic, Poland, Estonia, Latvia. Invited speakers from the Masaryk Memorial Cancer Institute (Czech Republic), the Estonian Ministry of Social Affairs (Estonia), the University of Latvia (Latvia), the University of Warsaw (Poland). Meeting slides and recording are available and internal to the B1MG consortium. The outcomes of the "Implementation of the GDPR in the EU" workshop series have been submitted as a peer review open access publication.

Data Protection by Design and Default	
Date(s)	11/03/2021 (1st session) & 26/03/2021 (2nd session)
Targeted stakeholder group(s)	Technical experts involved in 1+MG WG5 (infrastructure) and WG2 (ELSI).
Objective/Outcome	1st session Discussion around: • The concept of Data Protection by Design and Default (DPbDD) and how

B1MG has received funding from the European Union's Horizon 2020 Research and Innovation programme under grant agreement No 951724

	to apply it in 1+MG (e.g. how to compile the data protection principles of Transparency, Lawfulness, Fairness, Purpose Limitation, Data Minimisation, Accuracy, Storage limitation, Integrity and confidentiality, Accountability for the data processing in 1+MG). 2nd session The 1+MG WG5 and WG2 will be called to provide recommendations to the Member States on infrastructure aspects that consider DPbDD. The meeting allowed to WG2 & WG5 to align and analyse the full operations with the mind-set of a controller: - How to design the entire 1+MG infrastructure and tools to ensure compliance with DPbDD? - Determine the infrastructure blueprint: What functionalities? What set-up? What are the requirements? Meeting slides for both sessions are available and internal to the B1MG consortium. A full day face-to-face workshop is planned on 14/02/2023, based on the DPbDD requirements list compiled following the data governance compilation and the various policies developed in WP2.

Use case workshop - Healthcare	
Date(s)	15/10/2020
Targeted stakeholder group(s)	B1MG consortium, 1+MG use cases (Rare Diseases, Cancer, Common/Complex Disease).
Objective/Outcome	Healthcare uses are one of three envisaged applications of the 1+MG, along with health research and policy-making. The objective of this workshop was to better understand the needs of healthcare providers seeking to access genomic and related health data from the 1+MG. The needs of these users will in turn inform the design of technical infrastructure, and the ethical and legal governance needed to ensure data is shared responsibly and securely.

B1MG has received funding from the European Union's Horizon 2020 Research and Innovation programme under grant agreement No 951724

	The disease areas covered were Rare Diseases, Cancer, and Common/Complex Diseases. The 1+MG WG lead of these disease areas was invited to present a few detailed, anecdotal situations where healthcare providers would seek access to genomic and related health data to answer a clinical question. The presenters were asked beforehand to complete a detailed questionnaire: Who is the user seeking to access the 1+MG? What is his/her purpose? What questions is he/she trying to answer? What kinds of data does he/she need to access? What results will be generated? Will the user need to recontact the original data provider or data subject? Meeting slides are available to the B1MG consortium and 1+MG WG members. The meeting summary is available to the registered stakeholders of the B1MG Stakeholder portal[44].

Use case workshop - Research	
Date(s)	29/04/2021
Targeted stakeholder group(s)	B1MG consortium, 1+MG use cases (Rare Diseases, Cancer, Common/Complex Diseases and Infectious Diseases).
Objective/Outcome	The workshop aimed to better understand the needs of potential users of a genome data resource for secondary use. It looked at anecdotal portrayals of likely situations in data use that elucidate the actors, their need in data and IT infrastructure, the kind of questions that need to be answered and the hurdles that have currently been observed. The collected feedback will give input into the design of the legal, ethical, technical and data design of the planned 1+MG infrastructure. The presenters were asked beforehand to complete a detailed questionnaire (similar to the one for the use case workshop for healthcare): Who is the user seeking to access the 1+MG? What is his/her purpose? What questions is he/she trying to answer? What

[44] https://drive.google.com/drive/u/1/folders/1pLP7M6phyZVjFhfQipPI76OmUKWjK4mu

B1MG has received funding from the European Union's Horizon 2020 Research and Innovation programme under grant agreement No 951724

	kinds of data does he/she need to access? What results will be generated? Will the user need to recontact the original data provider or data subject? Meeting slides are available to the B1MG consortium and 1+MG WG members. The meeting summary is available to the registered stakeholders of the B1MG Stakeholder portal[42].

Joint 1+MG WG2-WG8 Workshop on Rare Diseases and ELSI	
Date(s)	20/12/2022
Targeted stakeholder group(s)	B1MG consortium, 1+MG WG8 (Rare Diseases use case) and 1+MG WG2 (ELSI).
Objective/Outcome	From a data protection and privacy point of view, there are several issues specific to the Rare Diseases field, including: i) the heightened vulnerability of the data subjects, which often include minors; ii) low numbers of subjects with a particular Rare Disease means there is an inherently high risk identifiability; iii) an overlap between research and healthcare delivery when dealing with Rare Disease patients makes it challenging to clearly delineate purposes of data processing operations. The workshop focused mainly on the definition of research versus healthcare data processing purposes in the field of rare diseases. The feedback collected will help to design the 1+MG infrastructure while considering the specific needs from the rare diseases community.

Meetings of the B1MG WP2/1+MG WG2 including key stakeholders	
Date(s)	Regular (monthly) meetings Dedicated workshops as relevant: - 19/10/2021: "1+MG Ethical challenges workshop" - 17/12/2021 "1+MG Governance Framework (Data Inclusion/Data Access) workshop"

B1MG has received funding from the European Union's Horizon 2020 Research and Innovation programme under grant agreement No 951724

	- 13/05/2022 "Presentation of the European Health Data Space (EHDS)"
Targeted stakeholder group(s)	B1MG WP2, 1+MG WG2, Working Group of national delegated ELSI experts (This group includes members of ministries, legal consultants advising the government, data protection authorities, Ethics Committees and internationally renowned ELSI experts.) Invited also to attend: representatives of the EC, ELSI experts involved in other projects and initiatives (e.g. TEHDAS Joint Action, GA4GH, PHG Foundation).
Objective/Outcome	Regular (monthly) meetings: To discuss the Ethical, Legal and Social Implications in the context of the 1+MG initiative and the B1MG project. Through these monthly meetings, WP2 reaches out to the countries involved in 1+MG and through national representatives in the 1+MG ELSI Working Group also to the National Mirror Groups of the countries. All the outcomes of B1MG WP2 have been reviewed by the 1+MG ELSI Working Group. Specific workshops: ● 1+MG Ethical challenges workshop - Policy on Incidental Findings including Background information [13, 14] - Policy on feedback provision of general research results [15] - Policy on special (vulnerable) subjects [16] - Policy on consent [17] ● 1+MG Governance Framework (Data Inclusion/Data Access) workshop - Policy for data access [18] - Policy for data inclusion [19] ● Presentation of the European Health Data Space (EHDS) - To discuss with EC DG SANTE the implications of the EHDS on the 1+MG initiative and align.

B1MG has received funding from the European Union's Horizon 2020 Research and Innovation programme under grant agreement No 951724

7. Interactions with European projects and initiatives

Apart from the meetings organised by B1MG/1+MG that are detailed above, the B1MG WP2/1+MG WG2 members have joined meetings/workshops/events organised by other European projects and initiatives that seek alignment with or input from our work:

Project/Initiative	B1MG WP2/1+MG WG2 contribution
EOSC-Life (https://www.eosc-life.eu/)	EOSC-Life brings together the 13 Life Science 'ESFRI' research infrastructures to create an open, digital and collaborative space for biological and medical research. The project will publish 'FAIR' data and a catalogue of services for the management, storage and reuse of data in the European Open Science Cloud (EOSC). B1MG WP2/1+MG WG2 members exchange with EOSC-Life on best practices for sensitive data management and seek alignment in the developments of the 1+MG platform and the EOSC.
HealthyCloud (https://healthycloud.eu/)	HealthyCloud aims to define the Strategic Agenda for the European Health Research and Innovation Cloud (HRIC). It has been organised around 4 pillars: - interaction with stakeholders - the inclusion of ELSI aspects in the design of the HRIC - sustainable access - use and re-use of health-related data and technological solutions to enable distributed health data analysis in Europe. The project is guided by two real-world use cases on cancer and atrial fibrillation. B1MG WP2/1+MG WG2 members exchange with HealthyCloud on ethical, legal and social challenges of establishing a pan-European HRIC and discuss possible solutions. There may be the opportunity to reach out to Data Protection Authorities on data protection related subjects discussed in B1MG in a collaborative effort with HealthyCloud.
TEHDAS Joint Action (https://tehdas.eu/)	TEHDAS Joint Action focuses on: - engaging other European projects and policymakers in a dialogue about the European Health Data Space;

B1MG has received funding from the European Union's Horizon 2020 Research and Innovation programme under grant agreement No 951724

TEHDAS Towards European Health Data Space	- ensuring sustainability of the secondary use of health data in Europe; - developing a governance model for cross-border cooperation in the secondary use of health data between European countries; - promoting the reliability and compatibility of and access to health data for secondary use; - clarifying the role of individuals in the secondary use of health data and including them in dialogue about the use of health data for research and policymaking. B1MG WP2/1+MG WG2 members interact directly with TEHDAS Joint Action WP5 "Sharing data for health" but have contributed also to overarching project activities (e.g. through the project Advisory Groups) and in joint workshops organised by TEHDAS with participation of the HealthData@EU/EHDS2 Pilot and the DARWIN[45] project of the European Medicines Agency.
EHDS2/HealthData@EU pilot (https://www.ehds2pilot.eu/) EHDS HealthData@EU Pilot	The HealthData@EU/EHDS2 pilot project brings together national data permit authorities, public health infrastructures and health research infrastructures, in order to enable linking and integrating data between different data sources. This pilot project is a major first step towards the realisation of the European Health Data Space for secondary use. The project started in July 2022. ELIXIR and BBMRI-ERIC members of 1+MG ensure the knowledge transfer between the two projects.
PHIRI (https://www.phiri.eu/) PHIRI Population Health Information Research Infrastructure	PHIRI allows for better coordinated European efforts across national and European stakeholders to generate the best COVID-19 population health knowledge. In doing so, PHIRI is laying the foundation to build a Research Infrastructure on Population Health to be used to overcome future crises. The intent is to support research across Europe through the identification, access, assessment and reuse of population health and non-health data to underpin public health policy decisions.

[45] https://www.ema.europa.eu/en/about-us/how-we-work/big-data/data-analysis-real-world-interrogation-network-darwin-eu

B1MG has received funding from the European Union's Horizon 2020 Research and Innovation programme under grant agreement No 951724

	B1MG WP2/1+MG WG2 members exchange with PHIRI on best practices to responsibly and securely access and reuse sensitive data (population health & genomics data).
SYNCHROS (https://synchros.eu/)	SYNCHROS aimed to: - map the cohort landscape in Europe and large international initiatives; - identify the best methods for integrating cohort data; - identify solutions for addressing practical, ethical and legal challenges in integrating data across patient, clinical trial and population cohorts; - evaluate the use of emerging and new data collection technologies and types of data. B1MG WP2/1+MG WG2 members exchanged with SYNCHROS partners on the identification of the ELSI barriers to the integration of cohort data in cross-border and international settings.
SIENNA (https://www.sienna-project.eu/)	Human genomics, human enhancement, artificial intelligence and robotics offer benefits for both individuals and society. But these technologies also challenge our notions of what is ethical. SIENNA provided frameworks to help develop research ethics protocols, professional ethical codes and better legal frameworks. B1MG WP2/1+MG WG2 members discussed with SIENNA on the outcomes of the project with regards to human genomics and built upon their lessons learned.
EJP RD (https://www.ejprarediseases.org/)	EJP RD is a programme aiming to create an effective rare diseases research ecosystem for progress, innovation and for the benefit of everyone with a rare disease. It supports rare diseases stakeholders by funding research, bringing together data resources & tools, providing dedicated training courses, and translating high quality research into effective treatments. B1MG WP2/1+MG WG2 members collaborate with EJP RD to better understand the specific ethical and legal challenges in the field of rare diseases and how to best overcome them in the design of the 1+MG platform.
EPND (https://epnd.org/)	Despite the prevalence of neurodegenerative

B1MG has received funding from the European Union's Horizon 2020 Research and Innovation programme under grant agreement No 951724

epnd European Platform for Neurodegenerative Diseases	disorders, there is a lack of accurate diagnostic tools or effective treatments to prevent or modify disease progression. EPND addresses this growing challenge with transcontinental data sharing and collaboration, creating a powerful collective effort to accelerate biomarker discovery, development, and validation across Europe and the world. B1MG WP2/1+MG WG2 members share their experience on cross-border data sharing policies and best practices and learn from the approaches taken in the field of neurodegenerative diseases.
BY-COVID (https://by-covid.org/) BY-COVID beyond covid	BY-COVID aims to provide comprehensive open data on SARS-CoV-2 and other infectious diseases across scientific, medical, public health and policy domains. The project contributes resources to the European COVID-19 Data Portal[46]. B1MG WP2/1+MG WG2 members collaborate with BY-COVID to exchange upon best practices for sharing/re-using different types of sensitive data in the area of infectious diseases and in emergency settings (e.g. pandemics).
CINECA (https://www.cineca-project.eu/) CINECA Common Infrastructure for National Cohorts in Europe, Canada, and Africa	CINECA develops a federated cloud-based infrastructure for making genomic and biomolecular data accessible. It has assembled a virtual cohort of 1.4 million individuals from population, longitudinal and disease studies and will develop solutions both to the challenges of delivering transcontinental security requirements for data access, and to the ethical, legal, and societal commitments where data cannot move outside a legal jurisdiction. B1MG WP2/1+MG WG2 members built upon the efforts of CINECA when developing the policies for the 1+MG platform.
PANELFIT (https://www.panelfit.eu/) PANELFIT PARTICIPATORY APPROACHES TO A NEW ETHICAL AND LEGAL FRAMEWORK FOR ICT	PANELFIT aimed at facilitating the adaptation processes between new technical advances and legal frameworks, by producing a set of editable, openly accessible guidelines, as well as offering operational standards capable of reducing ethical and legal problems posed by information and communication technologies.

[46] https://www.covid19dataportal.org/

B1MG has received funding from the European Union's Horizon 2020 Research and Innovation programme under grant agreement No 951724

	B1MG WP2/1+MG WG2 members have contributed to the different discussions and consultations of the PANELFIT project.
EULAC PerMed (https://www.eulac-permed.eu/)	EULAC PerMed aims to integrate countries from the Latin American and Caribbean (LAC) region in the ICPerMed (International Consortium of Personalised Medicine (PerMed) and the ERANet ERAPerMed, as a means to widen the international scope of PerMed Research & Innovation related policies, increasing and encouraging a worldwide implementation of PerMed approaches across the whole healthcare value chain. B1MG WP2/1+MG WG2 members have exchanged with EULAC PerMed on the ELSI challenges and workable solutions for international cooperation.
ECRAID (https://www.ecraid.eu/)	The European Clinical Research Alliance for Infectious Diseases - ECRAID - advances clinical research in the field of infectious diseases by establishing a long-term, financially self-sustainable, clinical research network in Europe. This is happening through a series of projects such as ECRAID-Plan, ECRAID-Base, ECRAID-Prime. B1MG WP2/1+MG WG2 members are part of the ECRAID projects and ensure the knowledge transfer through their participation in project meetings and events.
EUCANCan (https://eucancan.com/)	EUCANCan is a European Canadian cooperation aimed at enhancing modern oncology, by implementing a cultural, technological and legal integrated framework across Europe and Canada, to enable and facilitate the efficient analysis, management and sharing of cancer genomic data. B1MG WP2/1+MG WG2 members have participated in the EUCANCan initiative and provided insights on the cancer use case for the 1+MG platform.
EuCanImage (https://eucanimage.eu/)	EuCanImage builds a highly secure, federated and large-scale European cancer imaging platform that will greatly improve capabilities of artificial intelligence (AI) in oncology. The EuCanImage platform will be populated with a new data resource totaling over 25,000

B1MG has received funding from the European Union's Horizon 2020 Research and Innovation programme under grant agreement No 951724

EUCAN IMAGE	single subjects, which will allow to investigate unmet clinical needs e.g., the detection of small liver lesions and metastases of colorectal cancer, or estimating molecular subtypes of breast tumours and pathological complete response. The cancer imaging platform will be cross-linked to biological and health repositories through the European Genome-phenome Archive, allowing to develop multi-scale AI solutions that integrate organ-level, molecular and other clinical predictors into dense patient specific cancer fingerprints. B1MG WP2/1+MG WG2 members participate in EuCanImage and make bridges between the ELSI recommendations of 1+MG and the policy solutions of the EuCanImage platform.
EU-STANDS4PM (https://www.eu-stands4pm.eu/) EU-STANDS4PM standards for in silico models for personalised medicine	EU-STANDS4PM has initiated an EU-wide mapping process to assess and evaluate strategies for data-driven *in silico* modelling approaches. A central goal is to develop harmonised transnational standards, recommendations and guidelines that allow a broad application of predictive *in silico* methodologies in personalised medicine across Europe. B1MG WP2/WG2 members and EU-STANDS4PM members both collaborate through GA4GH working group meetings on setting the framework for *in silico* methodologies in personalised medicine across Europe.
ReCoDID (https://recodid.eu/) ReCoDID	ReCoDID develops a sustainable model for the storage, curation, and analyses of the complex data sets collected by infectious disease-related cohorts. It combines groundbreaking work on data sharing in public health emergencies, equitable sample sharing, and statistical methods for leveraging high-dimensional laboratory data in the context of high levels of heterogeneity and limited sample sizes with long-term investments in cloud-computing and OMICS data curation to develop and implement a new model for collaborative research in epidemic response. B1MG WP2/WG2 members are also part of ReCoDID and thus interactions have focused on ethical and legal guidance in cross-border genomics data sharing.

B1MG has received funding from the European Union's Horizon 2020 Research and Innovation programme under grant agreement No 951724

eCREAM (website under development) 	The central aim of the project is to enable clinical and quality of care assessment research using data extracted directly from electronic health records (EHR) of emergency departments (ED). Its three main objectives are: - to develop new technical solutions to extract reliable clinical information from structured and unstructured data contained in different electronic patient files; - to FAIRify the established databases for clinicians, researchers, health policymakers and citizens while respecting the European and national legislations; - to pilot the exploitation of the established databases in two relevant use cases: i) assessment of ED propensity to hospitalise a patient, and ii) development of a dashboard to be used by citizens and policymakers to improve the quality of care in ED B1MG WP2/WG2 members are taking part in the ELSI discussions of the project on how to make healthcare data available for research in an ethically and legally compliant manner and taking into account the challenges of data collection in emergency healthcare settings.
BBMRI Code of Conduct Working Group[47]	The initiative for drafting a code of conduct for health research was launched in 2015, pushed by scientific and legal experts of BBMRI-ERIC. Now the initiative brings together more than 160 individuals representing roughly 90 organisations in the field of health research. This effort includes members of B1MG WP2/1+MG WG2.
European Reference Networks (ERNs)	European Reference Networks (ERNs) are virtual networks involving healthcare providers across Europe. They aim to facilitate discussion on complex or rare diseases and conditions that require highly specialised treatment, and concentrated knowledge and resources. They review the diagnosis and the best possible treatments for patients from all over Europe. In addition, they aim to set up repositories for secondary use of the data exchanged in the primary use.

[47] http://code-of-conduct-for-health-research.eu/

B1MG has received funding from the European Union's Horizon 2020 Research and Innovation programme under grant agreement No 951724

	Legal experts of the ERNs are taking part in the B1MG WP2/1+MG WG2 ELSI meetings and documents compiled by B1MG WP2 proved to be helpful also for ERNs.

8. Conclusions

Since June 2020, the EC has provided funding to establish the B1MG project as a Coordination and Support Action to strengthen the 1+MG initiative. Coordinated by the European life science data infrastructure ELIXIR, the B1MG project assembles a consortium of expert organisations across Europe to support the 1+MG Working Groups and help reach the 1+MG targets. B1MG as a whole and the WP2 "ELSI" in particular have included a strong stakeholder element to ensure the co-design of the 1+MG infrastructure and the wider acceptability of the 1+MG proposed solutions.

At the beginning of the project, an ELSI stakeholder mapping and prioritisation exercise took place, which resulted in an inventory of more than 100 stakeholders: Patient & societal organisations, Research Infrastructures, ELSI WGs of relevant alliances / initiatives / consortia, Projects, National personalised and genomic medicine initiatives and strategies, Individual Experts working on topics of relevance, Industry, Medicines authorities/Regulatory Bodies, Ministries of Health and Social Affairs, Supervisory authorities, Data Access Committees, Ethics Committees, EC and EC's Expert Groups, the 1+MG WGs. These stakeholders have been invited to interact with the B1MG teams through different meetings (e.g. the annual B1MG Stakeholder meetings, the regular B1MG WP2/WG2 meetings extended to key stakeholders, thematic workshops etc.) and their inclusion in the B1MG stakeholder portal. The present document lists the most relevant meetings that took place until December 2022. In addition, it details the links of the B1MG WP2/1+MG WG2 members with a plethora of relevant European projects and initiatives.

Further meetings are already planned and/or will be scheduled as the exchange on proposed solutions increases the need for further stakeholder exchange.

9. References

[1] Project Management Institute. (2017). A guide to the Project Management Body of Knowledge (PMBOK guide) (6th ed.). Project Management Institute.

[2] Krstic, N. (2014). Stakeholder management from the business perspective. Megatrend Revija, 11(2), 165–182. https://doi.org/10.5937/megrev1402165

[3] Deverka, P. A. et al. (2012). Stakeholder participation in comparative effectiveness research: Defining a framework for effective engagement. Journal of Comparative Effectiveness Research, 1(2), 181–194. https://doi.org/10.2217/cer.12.7

B1MG has received funding from the European Union's Horizon 2020 Research and Innovation programme under grant agreement No 951724

[4] Nyanchoka, L. et al. (2020). Key stakeholders' perspectives and experiences with defining, identifying and displaying gaps in health research: A qualitative study. BMJ Open, 10(11), 1–8. https://doi.org/10.1136/bmjopen-2020-039932

[5] Slunge, D. et al. (2017). Stakeholder interaction in research processes - a Guide for Researchers and Research groups. March, 1–35. https://doi.org/10.13140/RG.2.2.28518.22080

[6] Lang, D. J. et al. (2012). Transdisciplinary research in sustainability science: Practice, principles, and challenges. Sustainability Science, 7(SUPPL. 1), 25–43. https://doi.org/10.1007/s11625-011-0149-x

[7] Martinez, J. et al. (2019). Stakeholder engagement in research : a scoping review of current evaluation methods. Journal of Comparative Effectiveness Research, 8(15), 1327–1341. https://doi.org/10.2217/cer-2019-0047

[8] Peters, D. H. et al. (2017). Engaging stakeholders in implementation research: Lessons from the Future Health Systems Research Programme experience. Health Research Policy and Systems, 15(Suppl 2), 4–6. https://doi.org/10.1186/s12961-017-0269-6

[9] Ray, K. N., & Miller, E. (2017). Strengthening stakeholder-engaged research and research on stakeholder engagement. Journal of Comparative Effectiveness Research, 6(4), 375–389. https://doi.org/10.2217/cer-2016-0096

[10] Horgan, D. et al. (2020). B1MG D1.1 Document describing the operational organisation and processes for the Stakeholder Coordination Group (SCG). Zenodo. https://doi.org/10.5281/zenodo.5786736

[11] Oldoni, E. et al. (2021). B1MG D1.2 - Generation of a stakeholder portal within the project webpage containing the information resulting from the activities of the SCG. Zenodo. https://doi.org/10.5281/zenodo.5018381

[12] Panagiotopoulou, M., & Mayrhofer, M. Th. (2021). B1MG M2.1 Inventory of relevant stakeholders, initiatives and policies that can give inputs to B1MG WP2. Zenodo. https://doi.org/10.5281/zenodo.5006455

[13] Rebers, S., Thorogood, A., B1MG WP2, & 1+MG WG2. (2022). Draft version for stakeholder interaction and discussion - 1+MG Incidental Findings Policy - Summary and Recommendations. Zenodo. https://doi.org/10.5281/zenodo.6362089

[14] Rebers, S., Thorogood, A., B1MG WP2, & 1+MG WG2. (2022). Draft version for stakeholder interaction and discussion - 1+MG Incidental Findings Policy - Background and References. Zenodo. https://doi.org/10.5281/zenodo.6362131

[15] Rebers, S. (2022). Draft version for stakeholder interaction and discussion - B1MG Policy Document - B1MG WP2 - Recommendation of minimal standards for feedback provision of results of research studies conducted with data provided through 1+MG to data subjects. Zenodo. https://doi.org/10.5281/zenodo.6362164

[16] Mežinska, S., Becker, R., Matei, M., Rebers, S., & Thorogood, A. (2022). Draft version for stakeholder interaction and discussion - B1MG Policy Document - B1MG WP2 - Recommendations for a 1+MG Minimal Standards for Inclusion of Special Subjects. Zenodo. https://doi.org/10.5281/zenodo.6362184

B1MG has received funding from the European Union's Horizon 2020 Research and Innovation programme under grant agreement No 951724

[17] Matei, M., Panagiotopoulou, M., Thorogood, A., Chokoshvili, D., Becker, R., 1+MG WG2, & B1MG WP2. (2022). Draft version for stakeholder interaction and discussion - 1+MG Consent Recommendations. Zenodo. https://doi.org/10.5281/zenodo.6363194

[18] Thorogood, A., Becker, R., 1+MG WG2, & B1MG WP2. (2022). Draft version for stakeholder interaction and discussion - 1+MG Recommendations for a Data Access Governance Framework (Research Purposes). Zenodo. https://doi.org/10.5281/zenodo.6363157

[19] Thorogood, A., Becker, R., B1MG WP2, & 1+MG WG2. (2022). Draft version for stakeholder interaction and discussion - Recommendations for a 1+MG Data Inclusion Governance Framework. Zenodo. https://doi.org/10.5281/zenodo.6363179

B1MG has received funding from the European Union's Horizon 2020 Research and Innovation programme under grant agreement No 951724

10. Abbreviations

AI	Artificial Intelligence
BBMRI	Biobanking and Biomolecular Resources Research Infrastructure
BY-COVID	BeYond-COVID (project acronym)
B1MG	Beyond 1 Million Genomes (project acronym)
CINECA	Common Infrastructure for National Cohorts in Europe, Canada and Africa (project acronym)
CSA	Coordination and Support Action
DARWIN	Data Analysis and Real World Interrogation Network (project acronym)
DG CNECT	Directorate-General for Communications Networks, Content and Technology
DG RTD	Directorate-General for Research and Innovation
DG SANTE	Directorate-General for Health and Food Safety
DPbDD	Data Protection by Design and by Default
EATG	European AIDS Treatment Group
EATRIS	European Advanced Translational Research Infrastructure in Medicine
EC	European Commission
ECPC	European Cancer Patient Coalition
ECRAID	European Clinical Research Alliance for Infectious Diseases
eCREAM	enabling Clinical Research in Emergency and Acute care Medicine (project acronym)
ECRIN	European Clinical Research Infrastructure Network
ED	Emergency department
EDPB	European Data Protection Board
EFPIA	European Federation of Pharmaceutical Industries and Associations
EGAN	Patients Network for Medical Research and Health
EGE	European Group on Ethics in Science and New Technologies
EHDS	European Health Data Space
EHR	Electronic Health Records
EJP RD	European Joint Programme on Rare Diseases

B1MG has received funding from the European Union's Horizon 2020 Research and Innovation programme under grant agreement No 951724

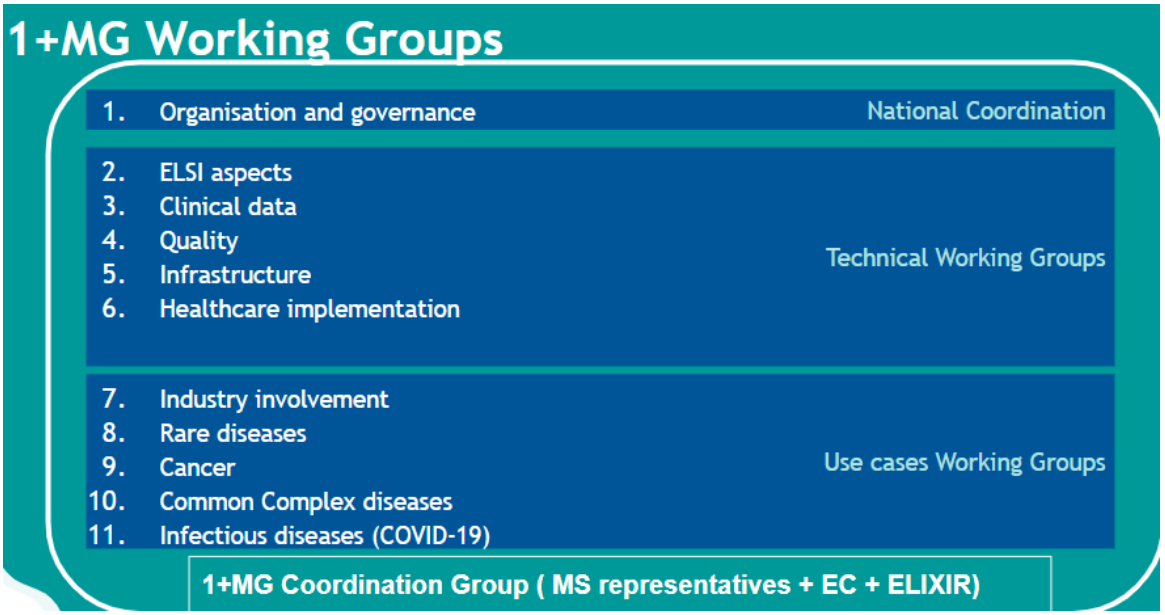
ELIXIR	European life-sciences Infrastructure for biological Information
ELSI	Ethical, Legal, and Social Implications
EMA	European Medicines Agency
EOSC	European Open Science Cloud
EPF	European Patients' Forum
EPND	European platform for neurodegenerative disorders (project acronym)
ERN	European Reference Network
ESFRI	European Strategy Forum on Research Infrastructures
EU	European Union
EUCANCan	European-Canadian Cancer Network (project acronym)
EUREC	European Network of Research Ethics Committees
EURORDIS	European Organisation for Rare Diseases
FAIR	Findable, Accessible, Interoperable, Reusable
GA4GH	Global Alliance for Genomics and Health
GDI	Genomic Data Infrastructure (project acronym)
HTA	Health Technology Assessment
HRIC	Health Research and Innovation Cloud
ICPerMed	International Consortium for Personalised Medicine
IMI	Innovative Medicines Initiative
LAC	Latin American and Caribbean
NHGRI	National Human Genome Research Institute
PANELFIT	Participatory Approaches to a New Ethical and Legal Framework for Information and Communication Technologies (project acronym)
PerMed	Personalised Medicine
PHIRI	Population Health Information Research Infrastructure (project acronym)
RDA	Research Data Alliance
ReCoDID	Reconciliation of Cohort data in Infectious Diseases (project acronym)
SIENNA	Stakeholder-Informed Ethics for New technologies with high socio-ecoNomic and human rights impAct (project acronym)
SCG	Stakeholder Coordination Group

B1MG has received funding from the European Union's Horizon 2020 Research and Innovation programme under grant agreement No 951724

SYNCHROS	SYNergies for Cohorts in Health: integrating the Role of all Stakeholders
TEHDAS	Towards the European Health Data Space (project acronym)
WG	Working Group
WP	Work Package
UNESCO	United Nations Educational, Scientific and Cultural Organization
1+MG	1+ Million Genomes (initiative)

B1MG has received funding from the European Union's Horizon 2020 Research and Innovation programme under grant agreement No 951724

11. Appendix: The 1+MG WGs



'Genome of Europe'[48] was more recently included as WG12.

[48] https://b1mg-project.eu/docs/genome-europe.pdf

B1MG has received funding from the European Union's Horizon 2020 Research and Innovation programme under grant agreement No 951724