Beyond One Million Genomes

D1.1

Document describing the operational organisation and processes for stakeholder engagement in B1MG

Project Title (grant agreement No)	Beyond One Million Genomes (B1MG) Grant Agreement 951724		
Project Acronym	B1MG		
WP No & Title	WP1–Framework for Cooperation through Stakeholders Engagement, Awareness & Alignment		
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Deliverable Lead Beneficiary	7–EAPM & DTL Projects		
Deliverable	D1.1–Document describing the operational organisation and processes for Stakeholder coordination in B1MG		
Contractual delivery date	31/10/2020	**Actual delivery date**	16/12/2021
Delayed	Yes		
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Acknowledgements			

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

(not grant participants)	
Deliverable type	Report
Dissemination level	Public

Document history

Date	Mvm	Who	Description
20/07/2020	0v1	Denis Horgan (EAPM)	Framework document circulated to all WP colleagues for feedback,
23/07/2020	0v2	Denis HORGAN (EAPM)]	Feedback received from WP1 team via conference call and recirculated
31/07/2020	0v3	WP1 Team	Presentation at the monthly Work Package meeting
04/08/2020	0v4	WP1 Team	B1MG-OG comments addressed. Version circulated to B1MG-GB for feedback through google shared drive
05/09/2020	0v5	Denis Horgan (EAPM)]	Feedback incorporated
23/10/2020	0v6	WP team	Presented to stakeholders
12/11/2020	0v7	WP team provided additional feedback taking into account Stakeholder Coordination meeting as well as alignment with B1MG which D. Horgan incorporated	Comments addressed and integrated
20/11/2020	0v8	Denis Horgan (EAPM)	B1MG-OB and GB comment addressed.
24/11/2020	1v0	Juan Arenas (ELIXIR Hub)	Final version uploaded to the EC Portal
09/02/2021	1v1	Juan Arenas (ELIXIR Hub)	Document open for suggestions to address EC reviewers comments received in the 1st six month consolidated report.

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10/02/2021	1v2	D. Horgan (EAPM)	Substantial Review in the line of the comments from reviewers
15/02/2021	1v2.1	D. Horgan (EAPM)	Development of Annex and additional content
05//03/2021	1v2.2	D. Horgan (EAPM)	Revision based on feedback from colleagues
1-4/03/2021	1v2.3	D. Horgan (EAPM)	Development of editorial report from conference
10/03/2021	1v2.4	R. Kok (DTL Projects)	Extensive review and revision
15/03/2021	1v2.41	D. Horgan (EAPM)	Extensive review and integration again
11/06/2021	1v3.0	M. van Rijswijk and R. Kok (DTL Projects)	Extensive review and revision
24/06/2021	1v4	Xenia Perez & Juan Arenas (ELIXIR Hub)	Template formatting issue fixed.
30/11/2021	1v5	R. Kok (DTL Projects)	Final revision based on team input
16/12/2021	2v0	Nikki Coutts (ELIXIR Hub)	Final version uploaded to the EC Portal

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1. Executive Summary

B1MG WP1 facilitates the engagement of stakeholders in the field of genomics-based health in the B1MG project and 1+MG initiative. Priority of the overall stakeholder engagement process in B1MG is to involve key stakeholders in the essential workstreams organised as part of the B1MG Work Packages (WPs) and their corresponding 1+MG Working Groups (WGs). Stakeholders are (experts of) organisations of a variable nature and scope, and B1MG chooses to organise their involvement at multiple levels.

Stakeholders are here defined as European/international, national and regional organisations and individuals active in and/or interested in the development and implementation of genomics-based health in national and regional healthcare systems. In particular, B1MG addresses stakeholders that have the expertise and capacities to play a role in the European 1+MG Initiative and are committed to realising the key goal of the 1+MG initiative: the ability to make genomics and related health data accessible across borders for trans-national use in research, diagnostics and/or innovation of healthcare.

The B1MG stakeholder organisation arranges for a general **Stakeholder Forum**, bringing together all stakeholders engaged in, or interested in the 1+MG initiative. **Stakeholder Forum meetings** are held once per year, co-organised with leads/teams of all B1MG WPs/1+MG WGs to discuss the progress in the project and 1+MG initiative. The WP1 team will co-organise, facilitate and report on the outcome of these yearly meetings in yearly reports.

Through a dedicated **Stakeholder Portal** arranged through WP1 in close collaboration with WP6 (technical implementation), B1MG arranges for a central communication channel with stakeholders on matters dealt with in the B1MG operational work packages. Experts of stakeholder organisations are invited to register to allow access to the portal, granted upon WP1 approval. All WPs of the B1MG project use the portal to inform and consult stakeholders in the design of scoping papers, recommendations, guidelines and other output.

B1MG facilitates the participation of (experts of) selected stakeholders in workstreams organised in the B1MG project WPs and corresponding WGs of the 1+MG initiative. In addition, a limited selection of specific stakeholder **Partner Projects** is engaged. These projects have important capacity and ongoing work that fully aligns with the 1+MG/B1MG ambitions. Only projects that can actively contribute to the workstreams organised in the 1+MG initiative and are committed to help realise the 1+MG goals can become B1MG Partner Projects.

Figure 1 below shows the three major levels of stakeholder engagement facilitated by the B1MG project.

Stakeholders are also involved in addressing the overarching subject of **citizen trust and public engagement**, crucial for the implementation of genomics-based health strategies across Europe. B1MG WP1 facilitates the B1MG process to establish recommendations to realise citizen engagement and build citizen trust across 1+MG.

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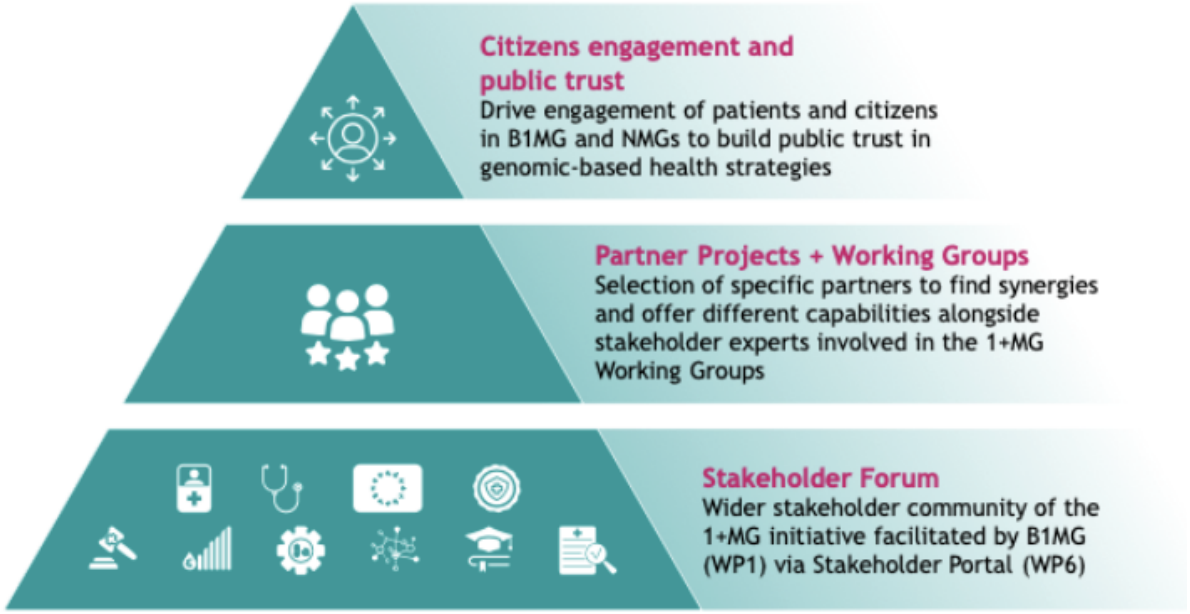

Figure 1. Levels of stakeholder engagement organised in B1MG.

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2. Contribution towards project objectives

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

	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	N/A
	2. Analysis of legal framework and development of common minimum standard (WP2) by M36.	N/A
	3. Cross-border Data Access and Use Governance Toolkit Framework (WP2) by M36.	N/A
	Technical Key Results	
	4. Quality metrics for sequencing (WP3) by M12.	N/A
	5. Best practices for Next Generation Sequencing (WP3) by M24.	N/A
	6. Phenotypic and clinical metadata framework (WP3) by M12, M24 & M36.	N/A
	7. Best practices in sharing and linking phenotypic and genetic data (WP3) by M12 & M24.	N/A
	8. Data analysis challenge (WP3) by M36.	N/A
	Infrastructure Key Results	

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	9. Secure cross-border data access roadmap (WP4) by M12 & M36.	N/A
	10. Secure cross-border data access demonstrator (WP4) by M24.	N/A
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.	N/A
	2. Roadmap and guidance tools for countries for effective implementation of Personalised Medicine (WP5) by M36.	N/A
	3. Economic evaluation models for Personalised Medicine and case studies (WP5) by M30.	N/A
	4. Guidance principles for national mirror groups and cross-border Personalised Medicine governance (WP6) by M30.	N/A
	5. Long-term sustainability design and funding routes for cross-border Personalised Medicine delivery (WP6) by M34.	N/A

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3. Scope of stakeholder engagement in B1MG

As the Coordination and Support Action (CSA) supporting the 1+MG initiative, the B1MG consortium regards stakeholder engagement as a crucial activity. The B1MG project acts as a key platform of interaction and consultation between all active stakeholders in the European genome-based health field, including stakeholders in signatory countries of the 1+MG initiative and at the European level. Collecting input and discussing viewpoints from diverse stakeholder groups, such as patient organisations, clinicians, regulators and policy organisations, industry and infrastructures at the European and Member State level will be crucial to shape the work of B1MG. Primary approach is to capture best practices and expertise of a broad range of international stakeholders and channel them towards the workstreams organised in the European Working Groups of the 1+MG initiative (and associated B1MG Work Packages (WP2, WP3, WP4 and WP5). Stakeholder engagement also addresses the so-called **National Mirror Groups** who are progressively taking shape in individual countries and work towards implementation of national genomics programmes.

Essentially, WP1 supports the other operational WPs in their stakeholder engagement and does not take a lead role. It rather facilitates the communication with stakeholders so that they can help the output of B1MG, both in quality (stakeholder experts engaging in design and review steps) and in volume (working with partner projects that have funded capacity to contribute to the realisation of 1+MG ambitions). In doing so, WP1, in close alignment with the coordinating WP6 and 1+MG Coordination Group, has a cross-connecting role to facilitate and streamline stakeholder engagement across B1MG/1+MG.

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4. Approach in B1MG stakeholder engagement

Collecting input and discussing viewpoints from a variety of stakeholders (e.g. patient organisations, clinicians, medical specialists, regulators, industry and others, see Figure 2 below) is crucial to shape the work and output of the B1MG project. The project takes a staged approach to engage the broader community of stakeholders at the EU, country and regional level and to actively inform the stakeholders about the output of the B1MG Work Packages.

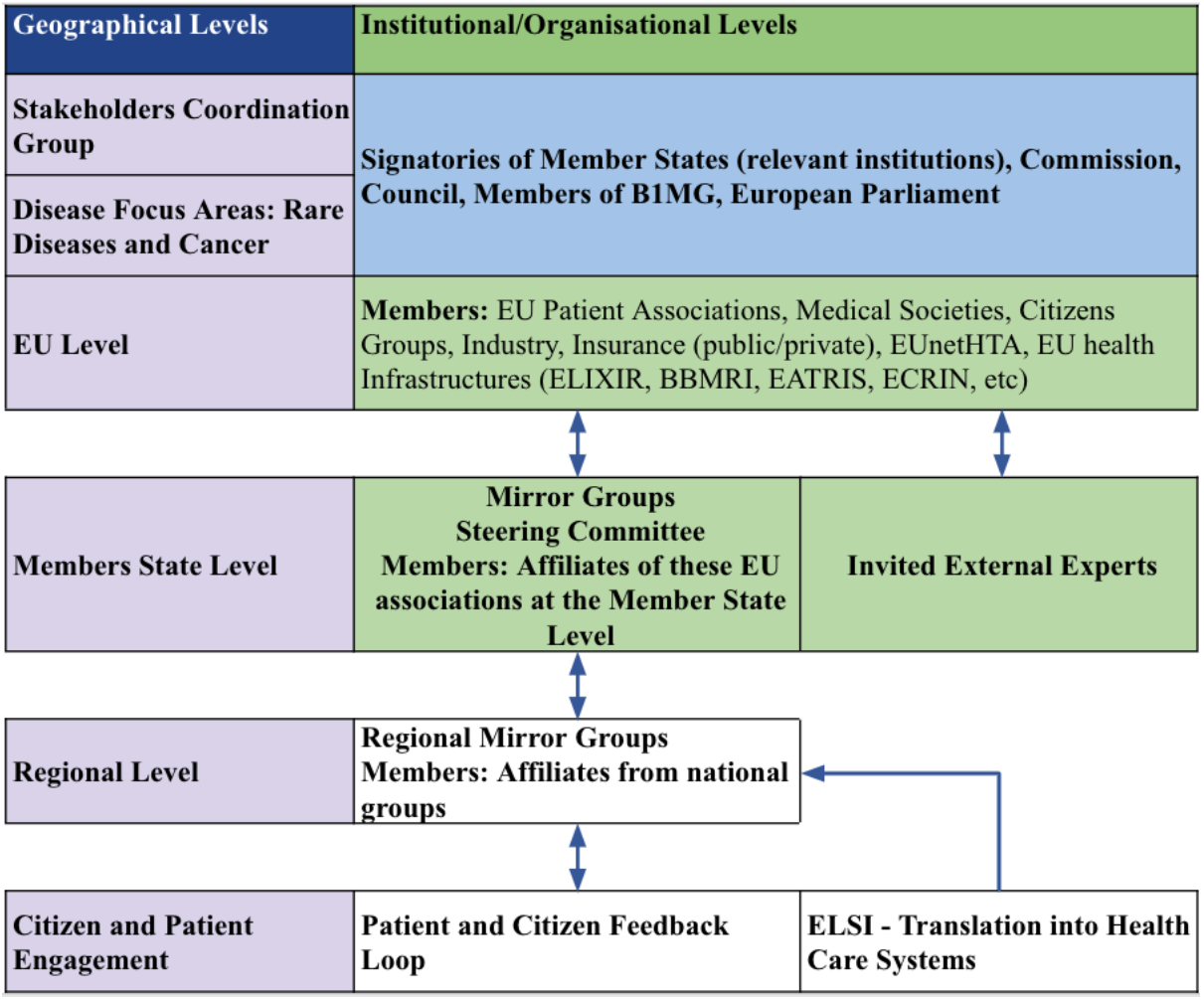

Figure 2. Overview of the stakeholders engaged in the B1MG project, showing the types of stakeholders from the local to the European Level.

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Figure 3 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.

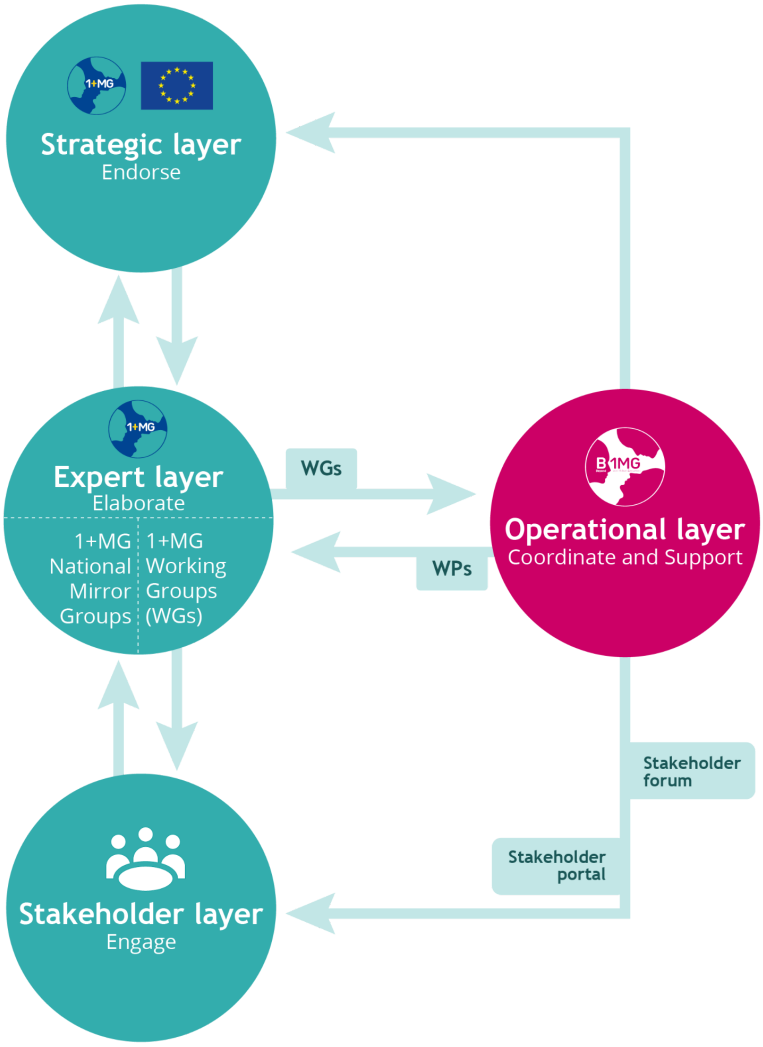

Figure 3. General overview of the 1+MG organisation and governance, showing the position of the body of Stakeholders in the 1+MG initiative which is primarily engaged via the workstreams organised in the 1+MG expert layer of working groups. The B1MG project facilitates optimal stakeholder engagement through the organisation of the Stakeholder Forum and the Stakeholder Portal organised by B1MG WP1. 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).

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The B1MG stakeholder organisation targets and facilitates engagement of stakeholders to the 1+MG initiative at the following major levels, and in the following manner (further elaborated in Table 1 below):

1. Stakeholder experts are directly invited to register through the B1MG Stakeholder Portal. Together they constitute the B1MG **Stakeholder Forum** as the body of known experts informed and engaged in various activities organised within the framework of B1MG.
2. The **Stakeholder Portal** will be 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 for their review and input. In this way we work to inform and consult 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.
3. **Stakeholder Forum meetings** are held once per year, as part of the annual B1MG summit. WP1 co-organises these meetings with leads/teams of all B1MG WPs/1+MG WGs. The WP1 team facilitates and assembles reports on the outcome of these yearly meetings in yearly reports (Deliverables 1.3 to1.5). Separate from these B1MG-organised stakeholder meetings, the B1MG team connects with specific groups of stakeholders (e.g. the TEHDAS consortium and the eHealth Stakeholder Group) to arrange for a dialogue or find their advice on matters of interest to realising the B1MG goals.
4. **Expert stakeholders are invited to participate in workshops and other workstreams** 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. WP1 assists to identify relevant stakeholders and ensure a balanced representation of stakeholder types across the initiative.
5. The B1MG management and leads of WP2-7 identifies 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 will 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**. B1MG WP1 will assist in designing scoping documents (D1.6) and co-organise workshops with relevant stakeholders to help design recommendations to 1+MG National Mirror Groups on how to address this important topic.

Table 1 below shows the levels of involvement of stakeholders in the B1MG project Work Packages and/or corresponding Working Groups of the 1+MG initiative and indication of the lead role in B1MG of engaging with these stakeholders.

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	Engagement of stakeholders	Lead role **(role of WP1)**
1	Select and register stakeholders to become involved in overall B1MG and 1+MG process	All B1MG teams **(WP1 to design Stakeholder Portal to facilitate stakeholder engagement process and register selected stakeholder experts)**
2	Consulting registered stakeholders wrt draft WP/G output	WPs 2-7 **(through Stakeholder Portal and through WP1-organised Stakeholder Forum–yearly-events at yearly B1MG Summits)**
3	Experts of stakeholders in WP 2-7-organised workshops and other workstreams	WP2-7 leads **(WP1 registers experts in B1MG portal and involves them in the Stakeholder Forum)**
4	Stakeholder projects contributing working capacity to WP/Gs (selected projects engaged as B1MG 'Partner Projects')	WP2-7 leads **(WP1 registers experts in B1MG portal and involves them in the Stakeholder Forum)** WP6 communicates role of Partner Projects on B1MG website
5	National stakeholders in National Mirror Group meetings	NMGs **(Upon request, WP1 invites national experts to register in B1MG portal and involves them in the Stakeholder Forum)**
6	Yearly B1MG Summits (Oct 20 see section 7, Nov 21, Nov 23) (1 day is Stakeholder Forum meeting)	All WPs and NMGs **(WP1 co-organises, co-chairs and reports on Stakeholder Forum meetings as indicated in the Description of Action)**
7	WP-overarching topic of citizen trust and public engagement	All WPs and 1+MG CG **(WP1 co-organising role)**

Table 1: Levels of involvement of stakeholders in the B1MG project Work Packages and/or corresponding Working Groups of the 1+MG initiative and indication of the lead role in B1MG of engaging with these stakeholders. **(WP1 roles are shown in pink)**.

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5. Description of working framework

In this chapter we provide a short overview of major Stakeholder types engaged in the B1MG project, and of the operational mode of working around the key layers of stakeholder engagement as highlighted in chapter 3.

5.1. Stakeholder types

As depicted in Figure 2 above, a variety of stakeholder types are identified and registered according to these types in the Stakeholder Portal. Below, a short description is provided of the major stakeholder types identified in B1MG.

5.1.1. Patient and citizen organisations

Patient organisations are identified by the disease areas which include at least the areas of oncology and rare diseases, preferably extended to cover also disease fields of common and complex diseases and infectious diseases, to cover all use-cases in the 1+MG initiative. B1MG also targets the engagement of citizen organisations, both at the European as well as at the national level.

5.1.2. Specialists, clinicians

Clinicians preferably cover all four 1+MG disease areas. Target stakeholders are the relevant medical societies at the EU level such as the European Society of Medical Oncology, European Society of Pathology and corresponding affiliates at the country level.

5.1.3. Scientists

Researchers involved in 1+MG, from academia and private sectors, come from the research domains of oncology, rare disease, common complex disorders and infectious diseases as well as data science. Target stakeholders are relevant academic centres from the 1+MG disease areas such as medical universities, as well as scientists from cross-cutting initiatives that will deal with issues such as ELSI aspects of genomics in health.

5.1.4. HTA bodies and projects

Through 1+MG WG6 (HEOR working group) and B1MG WP5 we will involve a representation of national HTA bodies and experts from across Europe. This ensures that there is a thorough understanding of processes and policies to evaluate the viability of the use of genomics in healthcare. The B1MG team already has a good connection with EUnetHTA and projects like HEcoPerMed and will connect with other relevant European projects as appropriate.

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5.1.5. Pharmaceutical, Diagnostic and ICT industry

This category will be derived from the umbrella associations that are active in the sphere of the B1MG project and will work closely with 1+MG WG7, which is assessing industry involvement possibilities and challenges in the 1+MG initiative.

Target stakeholders are both industry associations (e.g. COCIR, EFPIA, MedTech Europe) and individual companies active in the Pharmaceutical, Diagnostic, Biotech plus ICT and data science industries.

5.1.6 European (research) data infrastructures and e-infrastructures

Key European research infrastructures in the biomedical field include hubs of the infrastructures from the ESFRI programme, such as the EATRIS ERIC–European Infrastructure for translational medicine , BBMRI ERIC–Biobanking and Biomolecular Resources Research Infrastructure, ECRIN ERIC–European Clinical Research Infrastructures Network and ELIXIR, European Distributed Infrastructure for Biological data. In the framework of the development of the European data spaces, also the European Health Data Space will be closely aligned with (see also 5.1.7 below). Affiliated national nodes to such European infrastructures may also be engaged as stakeholders through the National Mirror Groups. Besides these actors, the 1+MG infrastructure WG5/B1MG WP4 may involve European e-Infrastructure programmes such as GEANT and PRACE where necessary.

5.1.7 EU Joint Actions

Joint Actions are a type of funding instrument under the third EU Health Programme. They encourage and support cooperation between Member States to improve the health policies that benefit their citizens. Examples include Joint Actions in the area of cancer and rare disease, in alignment with the prioritised use-cases within the 1+MG initiative.

Target stakeholders include THEDAS, the Joint Action towards establishment of the European Health Data Space, Joint Action on Cancer, Joint Action on Rare Disease, etc.

5.1.8 International project consortia and standardising bodies

International consortia include networks such as the International Genome Consortium, International Cancer Genome Consortium etc, as well as global standard setting organisations such as the Global Alliance for genomics and Health (GA4GH), that will allow the B1MG to engage with the relevant international communities.

5.1.9 ELSI specialists

Individual experts and expert working groups in ethical, legal and social issues of genomics (often associated with national sequencing initiatives), data protection supervisory authorities, networks of research ethics committees (RECs). In addition, the patient and citizen organisations need to be engaged specifically on aspects of ethical data governance.

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5.2. Major instruments for stakeholder engagement

5.2.1 Stakeholder Forum

The B1MG stakeholder organisation arranges for a general Stakeholder Forum, bringing together all stakeholders engaged in, or interested in the 1+MG initiative. Key persons representing identified stakeholders are invited to register through the Stakeholder Portal (see section 5.2.2) to be informed about the work in the B1MG work packages and to be involved in the expert layer of the 1+MG initiative as appropriate. The Stakeholder Forum will have access to relevant documents through the repository space in the stakeholder portal and they are invited to provide feedback and suggestions.

B1MG strives to have a strong representation of the stakeholder types of the stakeholder categories mentioned above (section 5.1). The key to successful and effective stakeholder engagement is the generation of relevant recommendations to support decision-making in relation to the areas of work of the B1MG workstreams. WP leads of the B1MG work packages are in the lead to select relevant stakeholders, and will be facilitated by WP1 to liaise with these stakeholder clusters to understand viewpoints, concerns and requirements which support the work in B1MG.

The Stakeholder Forum discussion and consultations with stakeholders will consider the outcomes needs to improve coordination with respect to the B1MG technical and other Work Packages:

- WP2–Ethics, Legal, Societal Impact
- WP3–Standards & Quality Guidelines
- WP4–Federated Secure Cross-border Technical Infrastructure
- WP5–Delivering Personalised Medicine cross-borders: Implementation in Healthcare systems and Societal Impact
- WP6–Communication, Governance and Sustainability
- WP7–Four use cases: 1] Rare Diseases, 2] Cancer, 3] Common and Complex Diseases, 4] Infectious Diseases.

Stakeholder Forum meetings are held once per year, co-organised with leads/teams of all B1MG WPs/1+MG WGs to exchange with stakeholders on the progress made in the 1+MG initiative, and to gather feedback from the broader stakeholder field. The WP1 team will co-organise, facilitate and report on the outcome of these yearly meetings in yearly reports (and deliverables to the project). An initial Stakeholder Forum meeting has been held in October 2020, while further Stakeholder Forum meetings are planned alongside the B1MG general assemblies/annual meetings in November 2021 and November 2022.

- D1.3: Report of Stakeholder Forum 2021 including recommendations to the 1+MG Working Groups and B1MG Work Packages (M19)
- D1.4: Report of Stakeholder Forum 2022 including recommendations to the 1+MG Working Groups and B1MG Work Packages. (M31)

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5.2.2 Stakeholder Portal

Through a dedicated Stakeholder Portal arranged through WP1, B1MG acts as a central communication channel with external stakeholders on matters dealt with in the B1MG work packages. Developed by WP1 in close relationship with the communication and coordination teams (WP6) as detailed described in D1.2, it supports the development of a stakeholders network within the B1MG project.

A specific domain in the B1MG project webpage (www.b1mg-project.eu[1]) allows access to the portal, possible upon registration. Experts of stakeholder organisations are invited to register to allow access to the portal. Applications are reviewed by WP1 and, after approval, the applicant receives an email notification and the portal access is granted. Main inclusion criteria are the contribution and added value that the stakeholder can bring to B1MG.

In the portal, stakeholders are organised in clusters according to their expertise with the possibility of users to create transversal sub-communities and heterogeneous working groups. All WPs of the B1MG project use the portal to upload documents in a dedicated repository space, inform and consult stakeholders in the design of scoping papers, recommendations, guidelines and other output.

The Stakeholder Portal thus aims to efficiently deliver timely analysis of challenges, opportunities and solutions resulting from the Work Packages to the Stakeholder Forum, and receive input from stakeholders. The portal is a living space that will be shaped according to the needs of the users and their access is possible upon registration. The result will be the creation of a vibrant community, organised and focused, that can collaborate in an effective and advantageous way for improving the project outcomes.

In summary, the Stakeholder Portal meets the following requirements:

1. Facilitate community participation and engagement
2. Facilitate communication and collaboration
3. Facilitate documents sharing and management

The main portal functionalities were presented in a dedicated webinar on February 18th 2021. Over 40 participants among stakeholders and WP leaders attended the webinar, whose recording is available on the portal. Stakeholders and WP leaders have been invited to actively build the portal together with WP1 and WP6 according to their needs. In addition, after the webinar, WPs leaders have been engaged via email and encouraged to have an open dialogue with the stakeholders, through the portal.

5.2.3 Involvement of stakeholders in activities organised by the B1MG Work Packages

As described in the project data management plan and the project handbook, work package leaders can invite external (unfunded) experts to contribute to the drafting of the guidelines and recommendations. In addition, all members of the Stakeholder Forum will be invited to

[1] http://www.b1mg-project.eu

contribute to the mature versions of the documents before they are submitted to the EC as described in the quality assurance process (project handbook). Their feedback will be shared with the authors who would then finalise the documents.

5.2.4 Partner Projects Partner Projects

Due to the absence of a central fund to realise the 1+MG initiative, we have chosen to engage key stakeholder projects in the workstreams organised as part of the B1MG Work Packages (and their corresponding 1+MG Working Groups). Such partner projects[2] provide capacity, expertise, technology or other output to contribute to realising the ambitions of the B1MG Work Packages WP2 (ELSI), WP3 (data standards and quality), WP4 (technical infrastructure) and WP5 (implementation in healthcare) and thus help realise the 1+MG Roadmap. Only projects that can actively contribute to the workstreams organised in the 1+MG initiative and are committed to help realise the 1+MG goals can become B1MG Partner Projects. Selection of such stakeholder projects will be done as part of Work Packages 2-5. WP1 will facilitate the communication with this important subset of Stakeholders through the Stakeholder Portal.

6. Conclusions and Impact

This document describes the levels of stakeholder engagement strived for in the B1MG project, in support of the implementation of the 1+MG Roadmap.

The structure of the stakeholder engagement process deviates from what was originally foreseen when drafting the B1MG proposal, and from the first version of this document. The complex environment of organising genomics-based health and realising the infrastructure for cross-border access to over 1+ million genomic datasets has led to progressive insight in the best way to involve stakeholders.

In close alignment with the Work Package leads and the leadership of the 1+MG we have now modelled our stakeholder engagement process to snuggly fit the overall governance of 1+MG and its processes of work. The result is a tiered level of steps, methods and tools to engage stakeholders in the work processes of the initiative, with WP1 in the role to facilitate these processes. The overarching theme of citizen engagement and public trust has now been included and will be specifically addressed as a novel task within WP1, bringing new teams to the WP, and working along with the other Work Packages.

The active engagement of stakeholders will greatly impact the output of B1MG Work Packages, and will greatly strengthen the 1+MG Initiative.

[2] https://b1mg-project.eu/1mg/partner-projects

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7. Annexes update of stakeholder activities

In this annexe we describe an update of stakeholder activities that have been taken up in the first six months of the B1MG project.

7.1 1st Stakeholder Forum meeting (Oct-2020)

The first Stakeholder Forum meeting took place on Oct 21st, 2020. The agenda is available here[3] as well as the minutes of the meeting here[4]. 182 stakeholders participated which were from the patients/citizens organisations, medical associations, member state representatives, researchers, as well as policy makers. The geographical breakdown is evenly distributed across the EU.

A breakdown is as follows: 35 from patient organisation, 70 from the research community, 29 from countries representatives, 8 from institutions, 20 citizens and 28 clinicians

The meeting was divided into a format that maximised the potential of the Working Groups to engage with the stakeholders. Each Working Group of the B1MG had a dedicated session where the WP leaders presented as well as key stakeholders. This was followed by a discussion as well as questions and answers from the floor.

Key conclusions are set out in the minutes[5] (access restricted to project participants and external experts) for each session as well as followed up by the respective WP leaders.

A summary of these are:

- Despite the wide range of backgrounds and interests, there is great adhesion of stakeholders to the mission and approach of 1+MG/B1MG
- To allow 'going clinal and personal' in each disease field we need cross-border access to larger numbers of datasets, even beyond 1+MG
- Multi-level approach is recognised and there are many organisations and projects that can and want to contribute

Collaboration is the spirit!

- 1+MG/B1MG to organise stakeholder alignment and collaboration
- Make stakeholders visible as partners of the 1+MG endeavour

1+MG/B1MG will not reinvent wheels but will help align agendas, ongoing projects and (emerging) solutions of major stakeholders

Stakeholder organisation to facilitate the involvement of stakeholders in 1+MG working groups

[3] https://drive.google.com/file/d/1u5UClGSiKKmZ95bGSoFhsReJW_WLpXGq/view
[4] https://docs.google.com/document/d/1C17SYFF2YnU0fiVmXy6HsDSW4p7XXOgHVM36EaY32v4/edit
[5] https://docs.google.com/document/d/1C17SYFF2YnU0fiVmXy6HsDSW4p7XXOgHVM36EaY32v4/edit

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Assist in mapping stakeholder activities/solutions/experts to collective topical 1+MG workstreams, using selected use cases as guidelines

- WP2 ELSI framework,
- WP3 Quality and Standards,
- WP4 Infrastructure,
- WP5 Implementation in health care
- WP6 National mirror groups

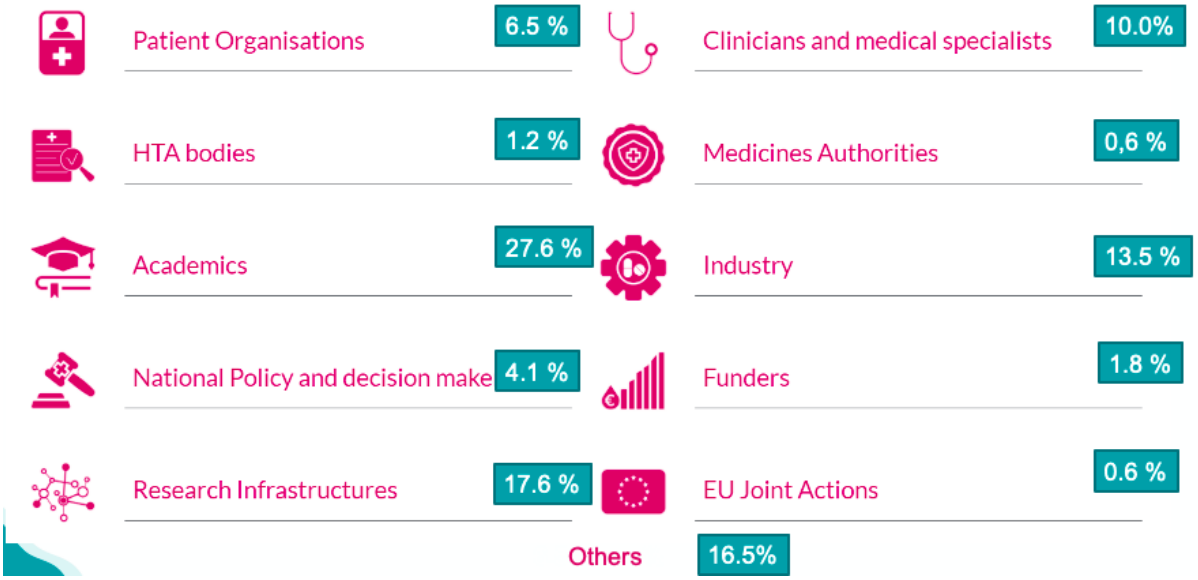
Developing a common federated framework to make genomics and health data accessible in a trusted and secure manner across borders binds all stakeholders

- Need for a common ethical and legal framework that can be adopted in national legislation and policies
- Interoperability is key at multiple levels
- cf EOSC model: Legal & Organisational & Semantic & Technical interoperability

Many stakeholders provide good building blocks

- E.g. in RD field: EJP-RD, ERN's, Orphanet … also the involvement of patients
- E.g. Federated EGA now rolled out for research

Regarding the Stakeholder Portal, the percentage of the breakdown of members registered in February 2021 is as follows:



On **February 18 at 14:00-15:00 CET**, WP1 of B1MG project organised a virtual **webinar** focusing on everything you need to know about the Stakeholders Forum portal (presentation here[6]). **42 participants** among stakeholders and WP leaders attended the webinar, whose recording is available on the portal. Stakeholders and WP leaders have been invited to actively build the portal together with WP1 and WP6 according to their needs.

[6] https://docs.google.com/presentation/d/1kBZKwbI-NETfFSh3RQhcOmUB49YgxPun/edit#slide=id.p1

in order to support the implementation of the 1+MG Roadmap.

7.2 Report of Stakeholder Meeting, October, 2020

Master multi-stakeholder collaboration and it will be possible for the EU to master genomic data sharing

Brussels, March 15th, 2021: Close collaboration across national borders and reciprocal consultation with stakeholders have to be at the very centre of systemising the contribution of genomic data to the development of personalised medicine. How to achieve this was the focus of discussion at the virtual kick-off conference with stakeholders of the European plan to improve citizens' health and boost medical research with the Beyond 1 Million Genomes project.

The European 1+ Million Genomes (1+MG) initiative is the EU's answer to some of the most pressing challenges in developing the potential of genomics more fully. The insights that genomics offers are not only transforming approaches to medical research; they are also increasingly enriching clinical operations and informing personalised medicine.

But exploiting the ability of genomics to deliver earlier diagnosis, more effective prevention programmes and more precise targeting of therapies depends crucially on data. To capture the full benefits of genomic data, it must be shared with multiple actors: researchers to support academic and clinical research; health providers to support delivery of health services and public health activities; and commercial organisations involved in developing and implementing new health technologies or delivering health care services. This in turn raises numerous logistical questions about data acquisition and exchange, and important ethical, social and legal issues (ELSI) relating to the treatment of data

In these conspicuously sensitive areas, the conference underlined the need for developing wider links across the healthcare community, for careful development of the necessary mechanisms and safeguards, and for achieving the right balance in generating common approaches across borders while still respecting national, local and private interests.

The discussions and recommendations of the stakeholders at this kick-off conference in late 2020 take on particularly topical relevance in the current context, as the EU forges ahead with its plans for the joint development of the European Health Union and the **European Health Data Space**, with their own emphases on collaboration. And equally significantly, the conference discussions also reflect the spirit of collaboration that has been intrinsic to this project from its very origins.

The role of B1MG is to establish the support and coordination structure for the quintessentially joint European 1+ Million Genomes (1+MG), the cross-border federated network for sharing data from national genome collections. And 1+MG itself arose from a multi-stakeholder initiative created, led and organised by a stakeholder organisation, the European Alliance for Personalised Medicine, which acted as a bridge, working closely with the European Commission and European Parliament as well as Member States and other stakeholders.

Thus from the outset this exercise has been truly stakeholder driven.

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Consequently, this B1MG stakeholders kick-off conference featured healthcare professionals, researchers, decision makers, patient organisations, and European umbrella groups representing associations and initiatives engaged in personalised medicine. Europe is uniquely placed to position itself as a global leader in genomics and personalised medicine, because of its capacity to harness its critical mass of 27 Member States and the scientific and technological expertise and assets they possess at local, regional and national level. The participation at this kick-off conference exemplified the approach to ensuring that stakeholders remain at the centre of B1MG's activities, with its plans for an effective Stakeholder Coordination Group and Stakeholder Forum.

7.2.1 The importance of links

The range of links that have been built up in this stakeholder approach was saluted by all participants, who underlined the importance of working together on this common approach. **Daria Julkowska**, *Coordinator of the European Joint Project on Rare Diseases*, fully endorsed the concept and indicated willingness to integrate into the project. She proposed that rare diseases might provide a valuable case study, through its existing strong connections with the healthcare community across Europe, and particularly through its links to the European Reference Networks and their 900 healthcare units across the member states. The EJP RD was already constructing an ecosystem for rare diseases through federated systems including genomic data and biosamples, and was working in the ethics and regulatory space to facilitate creating of the registries so that data can be used in research. The idea of integrating RD into B1MG was welcomed by the meeting.

Francesco Florindi, *Strategy and Partnership Manager of BBMRI-ERIC*, similarly expressed interest in providing support to the project through its 600 biobanks in 20 European countries, facilitating access to over 1 million samples and data. This could, he suggested, bring in expertise on FAIRification of data, standards, interoperability, and ELSI. He also favoured reaching out to healthcare as well as to research. He recognised, however, that there are complications in sharing and protecting data that do not apply so acutely in respect of samples, and he looked forward to collaborating on the search for solutions.

Lydia Makaroff, *CEO of Fight Bladder Cancer*, welcomed the project's recognition of the importance of citizen engagement: 'Patients and privacy need to be at the centre of this,' she said, since patients are custodians of their medical records and have the right to show them to their choice of clinical provider. She applauded the intention of the 1+MG project to help to build good legal, ethical, and logistical foundations to enable the sharing of data and to create related best practices, in the interests of ensuring that every patient gets the best treatment at the right time.

Tit Albreht of the *Joint Action on Cancer* noted that the Covid pandemic had generated greater interest in genomics and had motivated moves towards its increasing use in personalised medicine. Denis Hogan of EAPM, chairing the conference, remarked that the role of the Joint Action on Cancer was crucial in guiding the project towards links with national cancer plans. And **Albreht** saw an opportunity that should be seized in the creation of a cancer knowledge centre at the European Commission's Joint Research Centre.

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Mario Romao, *Global Director of Health & Data Policy at Intel*, noted that 'a long political journey' had preceded the attainment of this point in collaboration, and applauded the approach the project was taking to the technical infrastructure that would be needed so that data governance could build trust and secure data privacy while permitting researcher access to data.

Virginie Bros-Facer, *Scientific Director of EURORDIS* also emphasised the importance of gaining trust from consultation to provide the reassurance that can encourage patients and the general population to share their data for research. **Dirk Lanzerath**, *Secretary General of EUREC*, pointed to the need to bring the research ethics committee into the picture, and to reflect with them who would have access to the data.

Thomas Keane, *Team Leader of the European Genome Phenome Archive and of Archive Infrastructure at EMBL-EBI*, said it was 'great to hear that B1MG/1+MG is looking to leverage EGA.' **Ejner Moltzen**, *Chair of ICPerMed*, also indicated support could be forthcoming from ICPermed's 'unique collaboration among its 40 member organisations, including funding agencies, ministries, and public policy organisations.' There were already close links to B1MG, he added, through overlaps in membership. **Astrid Vicente**, *Coordinator of the Department of Health Promotion and Prevention of Non- communicable Diseases Principal Investigator at the Instituto Nacional de Saude Doutor Ricardo Jorge*, insisted on the importance of wide collaboration in developing the project, which will need input from national and regional healthcare systems.

7.2.2 Constructing with care

The evident enthusiasm for engaging in the project was matched by general insistence on the need to move with sensitivity in planning the next steps – a point that Julkowska emphasised. Or as Anna Middleton of the Wellcome Trust Sanger Institute and the 'Your DNA, Your Say' Project, expressed it, 'There will be many different stakeholders, and everyone must be careful so as to get the best out of this collaboration.' Lanzerath echoed the sentiment: 'Winning trust from consultation is not easy.' Keane noted that it had been a multi-year challenge to scale up to 1+MG – and would continue to be so.

The wide range of regulatory agencies across Europe and internationally was highlighted by Dr **Joaquin Mateo**, *Principal Investigator in the Prostate Cancer Translational Research Group at Vall d'Hebron Institute of Oncology*, who is also *Chair of the European Society for Medical Oncology Translational Research and Precision Medicine Working Group*. It cannot be assumed that they and other national and regional authorities are all fully comfortable with the changes that genomics and personalised medicine imply for healthcare delivery, which requires ensuring that each of them is treated with due attention. **Moltzen** counselled that since the numerous challenges cannot be solved immediately and simultaneously, there will be a need to run different types of projects and go step by step, bearing in mind that ultimately politicians will have to be involved to put new policies in place.

At the forefront of everyone's mind at the conference were the identifiable current gaps, both in terms of logistics and of adequate and appropriate communication with and among the many stakeholders who will need to come on board and remain on board.

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7.2.3 Filling the logistics gaps

The gaps are numerous in terms of infrastructure, data acquisition and sharing, standards, and operability, with questions outstanding too on issues of quality.

There is no centralised sequencing facility in Europe, observed **Andres Metspalu**, *Professor of Biotechnology and Head of the Estonian Biobank in the Institute of Genomics of the University of Tartu*, arguing that in order to implement personalised medicine, we need more data, and the initial target of 1 million genomes is a good reference point. But it is necessary also to set standards for minimum quality for all facilities for sequencing, existing and new. Clear understanding is vital of how the samples are being acquired by the facilities, and pre-sequencing information is required too, for which standards must also be agreed. The challenge, he said, will be to ensure all countries have the same approach, standards, and technology to ensure everyone benefits from genomic medicine. For **Mark Caulfield**, *Chief Scientist at Genomics England*, the future lies in a federation of data: 'You can never have enough clinical data on patients–the more clinical definitions you have, the more likely to get a diagnosis,' he said. And **Julkowska** suggested that to establish a real federated space to share genomic data, a bridge will have to be crossed in going from the national to the international level, which underlines the importance of standards set across Europe.

Gennaro Ciliberto, *Scientific Director of IRCCS's Istituto Tumori Regina Elena in Rome* offered the experience of the Alliance against Cancer, as indicative of how to approach issues of quality and interoperability of data, through tumour specific studies, joint work on pathology and informatics, and agreeing an infrastructure for molecular and clinical outcomes in addition to genomic. **Ilkka Lappalainen**, *Biomedical Service Development Manager at the CSC – IT Center for Science*, suggested that seeking common ground across use cases was a valuable method to develop interoperability, with a focus on ensuring that the infrastructure is built in an ELSI-compliant way. And as **Denis Horgan**, *Executive Director of the European Alliance for Personalised Medicine* pointed out, one of the current unknowns is how to develop the ecosystem of trust with interpretation of the EU's General Data Protection Regulation still varying from country to country.

7.2.4 Filling the communication gaps

Success will also depend on finding the right forms of communication – and the right messages – with a wide range of specific audiences. From the outset, it had to be recognised, said Middleton, that there is generally low awareness of genomics and of the potential of utilising genomic data. Communication with the widest audience will be necessary – and that means pre-eminently patients and citizens – to make B1MG function. Information may not be enough in itself: Hans **Peter Dauben**, *Director of DAHTA, the German Agency for Health Technology Assessment*, suggested it may be necessary to actively advocate in order to raise the level of acceptance for genetic therapies and for the sharing of data across Europe, and with citizens as the principal audience, as they will be the final beneficiaries of the advances that will come from sharing data. This will require a new level of cooperation between experts developing the advances and societal organisations in a position to influence the opinions of populations.

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Regina Becker, a *research scientist at Luxembourg University's Centre for Systems Biomedicine*, raised some of the practical questions that this implies: how can we best reach people? How much information should we share? and how differently should we communicate to different publics? she mused. This was another area where **Albreht** saw the need for building broader coalitions, and Middleton candidly suggested exploring the retention of communication professionals to advise on the delicate tasks involved.

Bros-Facer reported on how Eurordis had used focus groups to get the perspective of rare disease patients on sharing genomic data – and how involvement of patients tended to increase their readiness to share data, once they were reassured over consent, governance, privacy protection and feedback on use of their data. 99% of rare disease patients polled agreed that data should be shared, and would be willing to share theirs, she said – a higher proportion than the 37-80% of the general population who are willing to share their data according to diverse recent polls.

But ultimately, the communication will have to be effective too at the policy level, and attention will have to be paid to the political class. **Dr Ilda Hoxhaj**, *Department of Life Sciences and Public Health at the Università Cattolica del Sacro Cuore*, reported how the Italian health ministry had introduced a plan on developing policies on implementing genomic medicine, and **Tuula Helander** of the *Ministry of Social Affairs and Health in Finland* said that a steering group for health strategy already existed in her country, with representation from key ministries.

7.2.5 Concluding remarks

As **Horgan** observed in closing the conference, it has played its role in triggering the debate over how stakeholders should be involved in setting the framework for cooperation within 1+MG/B1MG. It is vital that the exchanges with stakeholders should now ensure adequate attention to ethics, legal, societal impact; to standards and quality guidelines; to federated secure cross-border technical infrastructure; to delivering personalised medicine cross-border; and to clear and targeted communication with all relevant groups, without which the impetus for success will be weakened. Outlining a plan is one step. The next steps, of agreeing and then implementing plans is what attention must now turn to. **ends**

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