



Beyond One Million Genomes

# D1.7

## B1MG recommendation on citizens engagement and public trust in genomic data sharing.

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06/09/2023	0v2	Nikki Coutts (ELIXIR Hub)	Version circulated to B1MG-OG, B1MG-GB and 1+MG Stakeholders for feedback
02/10/2023	1v0	Nikki Coutts (ELIXIR Hub)	Comments addressed. Version uploaded to the EC Portal

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# 1. Executive Summary

The '1+ Million Genomes' (1+MG) initiative, coordinated by the Beyond 1 Million Genomes (B1MG) project, aims to enable secure access to genomic and corresponding clinical data across Europe for research, personalised healthcare, and policy making. It is a joint initiative of 24 EU countries, the UK, and Norway. Citizen engagement and public trust have been raised as critical components in the B1MG stakeholder forum meetings and country visits. To discuss these components, an online expert workshop was facilitated on January 18 2023.

14 Participants were invited to give a short presentation on their lessons learned regarding citizen engagement. They were selected for their expertise in bioethics, ELSI, governance, human genetics, patient representation, citizen engagement. After discussion they formulated recommendations to participating 1+MG countries.

Lessons learned from various engagement activities were shared under three subthemes: "When an ELSI framework is in place, what is the (additional) role of citizen engagement in fostering data sharing and public trust?"; "How does citizen engagement relate to (interests of) other stakeholders?"; "When and how to engage and at what level?". Recommendations stress the need for dedicated resources; acknowledging different views and interests; the need for capacity building to enable engagement; and creating meaningful participation via selected tools through early engagement with a careful choice of engagement strategy; having good and transparent governance for enabling trustworthiness to contribute to accountability; and the need to find ways to connect the relational trust established at the national level to the EU level.

Citizen engagement needs sustained resources and attention across projects and national and EU initiatives. Trust depends on citizens and patients, so a trustworthy data sharing infrastructure needs transparent governance to consider and incorporate citizen views.

## 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
<b>Objective 1</b>  Engage local, regional, national and European stakeholders to define the requirements for	<b>1.</b> 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
	<b>2.</b> 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



cross-border access to genomics and personalised medicine data	<p><b>3.</b> 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 &amp; M30.</p>	Yes
	<p><b>4.</b> The open B1MG Summit (M18) engages and ensures that the views of all relevant stakeholders are captured in B1MG requirements and guidelines (WP1, WP6).</p>	Yes
<p><b>Objective 2</b></p> <p>Translate requirements for data quality, standards, technical infrastructure, and ELSI into technical specifications and implementation guidelines that captures European best practice</p>	<p><b>Legal &amp; Ethical Key Results</b></p>	
	<p><b>1.</b> Establish relevant best practice in ethics of cross-border access to genome and phenotypic data (WP2) by M36</p>	Yes
	<p><b>2.</b> Analysis of legal framework and development of common minimum standard (WP2) by M36.</p>	No
	<p><b>3.</b> Cross-border Data Access and Use Governance Toolkit Framework (WP2) by M36.</p>	No
	<p><b>Technical Key Results</b></p>	
	<p><b>4.</b> Quality metrics for sequencing (WP3) by M12.</p>	No
	<p><b>5.</b> Best practices for Next Generation Sequencing (WP3) by M24.</p>	No
	<p><b>6.</b> Phenotypic and clinical metadata framework (WP3) by M12, M24 &amp; M36.</p>	Yes
	<p><b>7.</b> Best practices in sharing and linking phenotypic and genetic data (WP3) by M12 &amp; M24.</p>	Yes
	<p><b>8.</b> Data analysis challenge (WP3) by M36.</p>	No
	<p><b>Infrastructure Key Results</b></p>	
	<p><b>9.</b> Secure cross-border data access roadmap (WP4) by M12 &amp; M36.</p>	No
	<p><b>10.</b> Secure cross-border data access demonstrator (WP4) by M24.</p>	Yes
<p><b>Objective 3</b></p> <p>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</p>	<p><b>1.</b> The B1MG maturity level model ( WP5) by M24.</p>	No
	<p><b>2.</b> Roadmap and guidance tools for countries for effective implementation of Personalised Medicine (WP5) by M36.</p>	No
	<p><b>3.</b> Economic evaluation models for Personalised Medicine and case studies (WP5) by M30.</p>	No
	<p><b>4.</b> Guidance principles for national mirror groups and cross-border Personalised Medicine governance (WP6) by M30.</p>	No
	<p><b>5.</b> Long-term sustainability design and funding routes for cross-border Personalised Medicine delivery (WP6) by M34.</p>	No



## 3. Methods

An expert workshop was organised for which scholars and professionals were invited to discuss citizen and patient engagement. 14 Experts were asked to give a short presentation in one of three thematic subgroups. In a concluding session participants formulated recommendations on the role of engagement in genomic data sharing and public trust.

## 4. Description of work accomplished

This report has been made based on the notes and recording of the expert workshop on 18 January 2023.

This deliverable falls under the heading of B1MG WP 1, but input was asked from WP 2 to present a short summary of the B1MG ELSI framework at the beginning of the workshop. The participants were asked about the relevance of citizen engagement in addition to ELSI frameworks, such as elaborated under WP 2. A representative of WP 2 attended the expert workshop and provided input in the discussions.

An abstract was submitted to the ESHG Conference in Glasgow, June 10-13, which was selected for presentation as a hybrid poster.

## 5. Recommendations

Please see the recommendations listed in the policy brief included in Annex 1.

## 6. Next steps

These Recommendations were presented at the ESHG meeting 2023 in Glasgow at a hybrid poster presentation.



# Annex 1



## Policy Brief

August 8th, 2023

# Genomic Data Sharing

## Recommendations for citizen engagement and public trust

Citizen engagement and public trust are critical components of responsible genomic research. Effective citizen engagement ensures that diverse perspectives are incorporated into research activities, leading to more inclusive and socially responsible outcomes. However, meaningful engagement requires dedicated funding and resources, effective ethical frameworks, and the development of capacity-building programs.

The '1+ Million Genomes' (1+MG) initiative, coordinated by the Beyond 1 Million Genomes (B1MG) project, aims to enable secure access to genomic and corresponding clinical data across Europe for research, personalised healthcare, and policy making. It is a joint initiative of 25 EU countries, the UK, and Norway. Citizen engagement and public trust have been raised as critical components in the B1MG stakeholder forum meetings and country visits. To discuss these components, an experts workshop was facilitated. The outcome of that workshop were a set of recommendations and this policy brief outlines these recommendations in six key categories aimed at promoting citizen engagement and fostering public trust in genomic research:

1. Resources & Infrastructure
2. Accountability
3. Goals and instruments
4. Connection between Initiatives
5. Inclusion of interests and diverse viewpoints
6. Capacity Building

**Trust depends on citizens and patients, so a trustworthy data sharing infrastructure needs transparent governance to consider and incorporate citizen views.**

On 18 January 2023 B1MG WP1 organised an expert workshop with 14 experts (in bioethics, governance, human genetics, ethical legal and social issues (ELSI) research, patient representation and citizen engagement, who shared their lessons learned on three themes:

"When an ELSI framework is in place, what is the (additional) role of citizen engagement in fostering data sharing and public trust?"  
"How does citizen engagement relate to (interests of) other stakeholders?"  
"When and how to engage and at what level?"

In a concluding session participants formulated recommendations on the role of engagement in genomic data sharing and public trust. A report from the workshop and the recommendations were distributed among the experts and comments were integrated.

The B1MG Expert workshop report can be accessed here: [B1MG D1.6 Citizen engagement and public trust in genomic data sharing | Zenodo](#)



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## Resources & Infrastructure

The European Commission and member states should allocate funding specifically for citizen engagement in genomic research and initiatives such as the 1+Million Genomes (1+MG) initiative and Genomic Data Infrastructure. This funding should be in addition to resources dedicated to ELSI (ethical, legal and social issues) research. Additionally, creating dedicated online facilities or portals will provide a platform for continuous engagement, enabling citizens to participate in ongoing discussions and decision-making processes.

*Citizen engagement needs dedicated funding and resources.*

*Ethical, legal and social issues (ELSI) research is often funded as part of or in addition to scientific research projects. Such funding is not aimed nor sufficient to allow for meaningful citizen engagement.*





## Accountability

While the ELSI framework provides essential ethical guidance, it should be complemented by mechanisms to ensure accountability and enhance trustworthiness. Engagement is necessary to explore what accountability and trust means according to citizens.

Data users should commit to the uptake and utilization of results before engagement events begin, demonstrating a genuine commitment to value citizen input.

If broad consent is used, this should serve as consent for participatory governance, allowing citizens to hold data users accountable and establishing a social license for genomic data sharing.

*B1MG is laying the foundation for a sound ELSI framework, elaborating ethical, legal and social issues in procedures for consent for data sharing and storage, access et cetera.*

*Having such an ELSI framework may help establish trustworthiness but does not necessarily lead to participants having trust in an institution.*

*However, an ELSI framework alone does not automatically achieve trust.*

*The addition of citizen engagement can help create preconditions for accountable research and trust but may not automatically result in more trust or cooperation in data sharing, people may sometimes become more worried and feel vulnerable.*





## Goals & Instruments

Engagement may have various goals, and participants may have various roles (e.g. data subjects or co-developers), which should be clearly outlined before starting engagement. Reflection on 'why are we engaging' is key to developing the most relevant questions for the audience to address.

In choosing instruments for engagement, such as a patient forum or public consultation, we must consider their effect on balancing inclusion of various groups and publics, aiming for empowerment and equal partnership.

*The tools used for citizen engagement need to be appropriate for the different contexts and goals:*

- *a citizen board, or patient forum, which allow for interaction and influence;*
- *consultations via questionnaires, focus groups, interviews;*
- *social media and online tools have become more prominent, and may especially be useful to engage youth.*





## Connect National Initiatives

Transparent communication about the European context of data sharing is crucial for building on relational trust. Efforts should be made to connect engagement activities across multiple organizations and countries. To achieve this, it is important to tie continuous engagement to infrastructures like the Genomic Data Infrastructure, rather than individual projects. This approach will promote transparency, consistency, and coherence in citizen engagement efforts.

*Trust is relational and context specific and dependent on many factors such as desires and hopes, socio-political factors and developments, knowledge and experience, and the relation to the professionals or institutions asking for data sharing and trust.*

*Citizen engagement across multiple organisations and across countries will be a step further than most of our current national engagement activities.*



*Engagement is a process in which various sides can learn from each other's perspective and interest. Dialogue can be fostered to explore diverging views, address concerns and potentially find common ground.*

## Interests & Diverse Viewpoints



Stakeholder engagement reveals divergence of ideas and values. Engagement activities should explicitly recognize and explore the divergence of ideas and values among stakeholders. This includes acknowledging potential conflicts of interest, power differences, and priorities between publicly accountable researchers and private companies. By making these factors explicit, dialogue can be fostered to address concerns and find common ground, contributing to responsible research practices.



## Capacity building

To enhance the quality and outcomes of engagement processes, capacity building initiatives should be established. This includes providing training and support to those involved in ongoing dialogue, as well as actively involving healthcare professionals and professional organizations, particularly in the field of medical genetics, in engagement activities related to genomic research and medicine. Furthermore, integrating genomics and dialogue on healthcare innovations into students' curricula will foster a culture of informed participation and responsible engagement from an early stage.

*Capacity building is necessary to improve the quality of the process of engagement and its outcomes.*

## Conclusion

Citizen engagement and public trust are critical components of responsible genomic research. By implementing the recommendations outlined in this policy brief, the European Commission can facilitate the necessary conditions for meaningful citizen engagement and support building public trust. Allocating dedicated funding, moving beyond the legal requirements of the ELSI framework, connecting diverse contexts, fostering stakeholder engagement, and capacity building will lead to more transparent, accountable, and socially responsible genomic research practices. These efforts will support building public trust but also help ensure that genomic advancements benefit society as a whole.



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