D1.4

Report of Stakeholders Forum 2022 including recommendations to the 1+MG Working Groups.

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		
WP Leaders	Denis Horgan (EAPM), Ruben Kok (DTL-Projects), Jan Korbel (EMBL Heidelberg), Toni Andreu (EATRIS).		
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Date	Mvm	Who	Description
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20/01/2023	0v2	Nina Habermann (EMBL) & Ruben Kok (DTL-Projects / Health-RI)	Review initial draft, addition of breakout session outcomes, Version circulated to B1MG-OG for feedback]
23/01/2023	0v3	Nikki Coutts (ELIXIR Hub)	Version circulated to B1MG-OG, B1MG-GB and Stakeholders for feedback
31/01/2023	1v0	Ruben Kok (DTL-Projects / Health-RI) & Nikki Coutts (ELIXIR Hub)	Comments addressed. Version uploaded to the EC Portal

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1. Executive Summary

The Beyond 1 Million Genomes (B1MG) project aims to facilitate the 1+MG initiative to provide access to genomics data and associated health data across borders and drive the development of personalised health strategies within Europe. The 1+MG/B1MG Stakeholder Forum 2022 held in October 2022, assembled for the third time a broad range of stakeholder experts, active in scientific and technical communities, international initiatives, projects, national healthcare systems, as well as industry to capture their input in the design of the infrastructure, the legal guidance and the best practices to realise the 1+MG infrastructure.

Being the last Stakeholder Forum (SF) organised by the B1MG project, this meeting centred on identifying how **stakeholders** could **contribute to the scale up and sustainability of the 1+MG/B1MG efforts**. The day included key updates on the progress of 1+MG/B1MG, specifically on the 1+MG Trust Framework (focussed on the ELSI and technical recommendations and guidelines for privacy-preserving access to genomics data), and including the B1MG Maturity Level Model as a tool for countries to assess progress towards implementation of genomics-based personalised health strategies into healthcare. This was then followed by a session on the next steps towards scale-up and implementation of the genomics data-sharing landscape by speakers from the recently established (1+MG-associated and EC-funded) Genomic Data Infrastructure (GDI) project, TEHDAS/EHDS and GAIA-X.

Acknowledging the role of industries in the scale-up and sustainability of these efforts, the day specifically included several ways to explore the role of companies as key stakeholders in realising cross-border genomic data sharing efforts and in developing a practice of genomics-based personalised health in 1+MG associated countries. A dedicated panel discussion included representatives from 1+MG WG7 (industry engagement), an umbrella industry organisation (EFPIA), an SME (Hyve - EHDEN project), as well as Australian Genomics, an initiative outside of Europe that has considered industry as part of their genomics activities. Clear recommendations were made to build a continuous exchange with industry to build mutual trust between public and private stakeholders. Further to this there was a proposal to explore the opportunity to establish a set of projects, such as under the framework of IHI. This clear output from the SF meeting should be explored further by the 1+MG initiative.

The second half of the day led into parallel workshops to consider scale up and sustainability in the context of rare diseases, cancer, common complex disease and infectious disease. The Trust Framework was regarded and the user communities addressed the question how stakeholders, including industry, could help realise these key components of the 1+MG infrastructure. It is clear that there are requirements specific to each disease community that are important to continuously review, discuss and understand in order to develop and sustain the 1+MG Trust Framework. The balance between how much research and care are entangled differs across use cases (rare diseases and cancer breakouts are already intertwined) and discussions stressed how the 1+MG infrastructure must be able to support primary and secondary use equally well.

The annual Stakeholder Forum meetings run by the B1MG project have all been very successful. They have strengthened the alignment of the stakeholders with the 1+MG initiative, enabling the leads of various activities to take on board suggestions and ensuring the outcomes of the project fit with stakeholder needs, encouraging innovation and alignment across a broader landscape. To continue stakeholder engagement and ensure further impact, these events will be continued as part of the GDI project.

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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	Yes
	2. Analysis of legal framework and development of common minimum standard (WP2) by M36.	No
	3. Cross-border Data Access and Use Governance Toolkit Framework (WP2) by M36.	No
	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.	Yes
	7. Best practices in sharing and linking phenotypic and genetic data (WP3) by M12 & M24.	Yes
	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.	Yes

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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. Methods

3.1. Methodology

The 1+MG/B1MG stakeholder forum (SF2022 from here on) was the third and last stakeholder forum organised by the B1MG project. To capitalise on this opportunity, members from B1MG WP1 and WP6 developed an agenda for the event that would bring forward the key elements needed to scale-up and make sustainable the work carried out by 1+MG/B1MG towards cross-border genomic data sharing across Europe.

Format

To ensure maximum participation, and due to the success of the SF2021, the meeting was organised virtually rather than in person.

Agenda

The agenda (see annex 1) was shaped with the active involvement of representatives from the B1MG project as well as the 1+MG initiative. The day was structured into 4 thematic sessions:

- **Updates from the project**: The morning session was dedicated to outlining the contribution of 1+MG/B1MG to develop the European genomic data sharing landscape. This included highlighting and presenting to the stakeholders the key updates from 1+MG/B1MG that were the 1+MG Trust Framework (central topic of the SF2021 meeting), the B1MG Maturity Model, as well as the efforts of 1+MG (WG7) towards engaging with industry through the initiative.
- **Next steps towards implementation**: The second session of the day focused on identifying ongoing, as well as upcoming efforts that complement the work of

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1+MG/B1MG towards the implementation of the genomic data landscape. This session included a presentation from the upcoming implementation project, The European Genomic Data Infrastructure (GDI). This was followed by a presentation from the TEHDAS/EHDS project and the GAIA-X Initiative.

- **Industry engagement:** The third session of the day focused on the role of industry in developing the genomic data landscape. The panel included experts who have engaged with industrial actors through umbrella industry organisations, SMEs, national, as well as international genomics efforts.
- **Scale-up and sustainability across 1+MG Use cases:** The afternoon session consisted of 4 parallel breakout sessions along the 1+MG use cases. Representatives from 1. Rare disease (1+MG W8); 2. Cancer (1+MG WG9); 3. Common and Complex disease (1+MG WG10) along with Genome of Europe (1+MG WG12); 4. Infectious disease (1+MG WG11). The goal of these sessions was to bring together the different stakeholders connected by a specific use case to identify the needs, as well as challenges in the scaling up and implementation of genomic data sharing efforts within the use case.

3.2. Relationship with other B1MG WPs and 1+MG WGs:

The SF2022 has been organised to address topics (figure above, pink labels) and allow direct involvement of all of the working groups in 1+MG and work packages in B1MG, as summarised in the figure. The green icons represent B1MG Work Packages and related Working Groups addressing technical/infrastructural aspects of the 1+MG initiative, with the proposed three key topics of the 1+MG Trust Framework highlighted in bold. Also the work on the Maturity Level Model carried out by the work package on Personalised medicine delivery and of Work Package 6 on sustainability of the initiative have been covered (top-right). The blue icons represent B1MG

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work packages and related 1+MG Working groups addressing use case aspects of the 1+MG initiative, including the perspective of industry involvement (WG7). The establishment of the Genome of Europe reference dataset proposed as part of the 1+MG endeavours was co-addressed in the afternoon use case session on Common & Complex diseases.

Below a summary of the involved B1MG work packages related to specific topics addressed:

- **Organising and communication:**
  - B1MG WP1 and WP6
- **1+MG Trust Framework updates:**
  - WP2: Updates on Data governance (ELSI)
  - WP3: Updates on Data standards and quality
  - WP4: Updates on technical infrastructural requirements
- **B1MG Maturity Level Model**
  - B1MG WP5
- **1+MG Industry engagement efforts:**
  - 1+MG WG7
- **Scale up and sustainability within use cases:**
  - 1+MG WG8, WG9, WG10, WG11

3.3. Communication

Communication and dissemination of the event took place through

- B1MG SF2022: A web page dedicated to the SF2022 was created and shared through the B1MG website, Linkedin, and Twitter.
- B1MG Stakeholder portal: Registered stakeholders were contacted via email to save the date, register and with further information on the event.

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- Regular updates and information was shared through social media platforms of Linkedin and Twitter.

Tools:

- To ensure an inclusive audience, the SF2022 was held in an online format via Zoom.
- Slido was used as an interactive tool for the participants to engage with the speakers and other participants, as well as raise questions and give feedback.

4. Description of work accomplished

4.1. Preparatory work and scope of session

4.1.1. Audience engagement

To initiate engagement with participants, registered participants were contacted and asked to respond to a broad question capturing the theme of the event with their ideas, thoughts and questions.

> "What is needed for scale up and sustainability of the trust framework in ELSI, Data Standards and/or Technical Infrastructure)? Besides the Trust Framework, what else is needed? (For your: Stakeholder group; Country; Institution; Use case)"

This option was opened for audience feedback from the 12th of Oct 2022 until the 15th of Oct 2022 in order to gather perspectives from before, during and after the event. Responses were gathered allowing the chairs of the meeting to include points in the relevant discussion (See annex 3). Whilst not many responses were submitted, the question posed allowed stakeholders to start considering the topic prior to the day.

4.1.2. Key objectives of the SF2022

The key objective of the SF2022 was to develop recommendations on how to scale up the 1+MG initiative and infrastructure, and how to make it sustainable from the perspective of the B1MG use cases. Specifically, the following two questions were raised and recommendations were formulated and collected:

1. How can stakeholders from each use case help scale up and make the work of 1+MG/B1MG in data governance, data standards and technical infrastructural aspects sustainable?
2. How can industry facilitate this process/ what gaps industry can fill?

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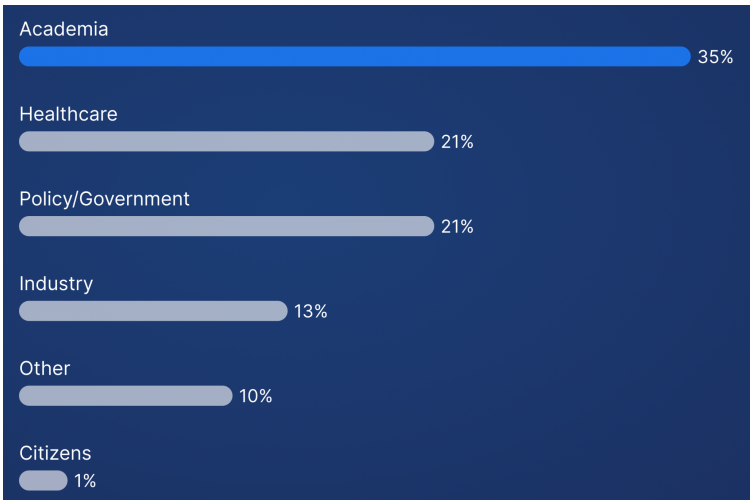
4.2. General outcome

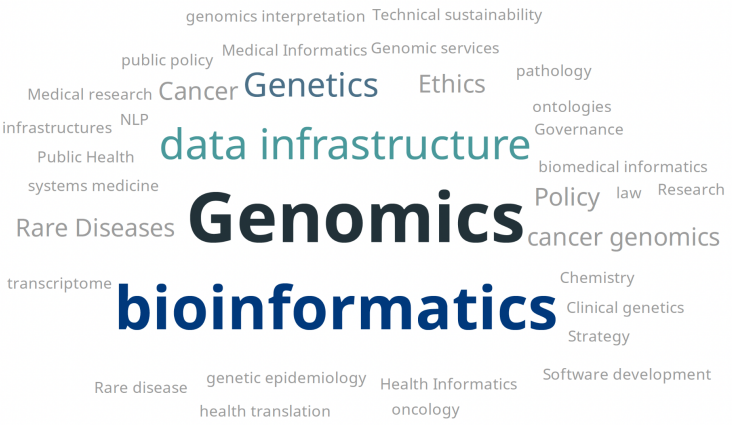
A general overview of the outcome of the SF2022 is as follows:

- Number of attendees: 184
- Participants who actively engaged in giving feedback: 152
- Engagement with different stakeholder groups: A diversity of stakeholder groups were represented by the attendees (see chart below): Academia (35%), Healthcare (21%), Policy/Government (21%), Industry (13%), Citizens (1%) and others (10%)



- Diverse areas of expertise:

  A large number of participants associated their expertise with genomics, followed by bioinformatics, data infrastructures, genetics and others that can be seen in the world cloud (see word cloud below)



- Broad country representation: The SF2022 involved participation from several nationalities (see word cloud below) within Europe (Spain, Italy, Netherlands, Finland, Sweden etc.) as well as outside Europe (UK and Australia)

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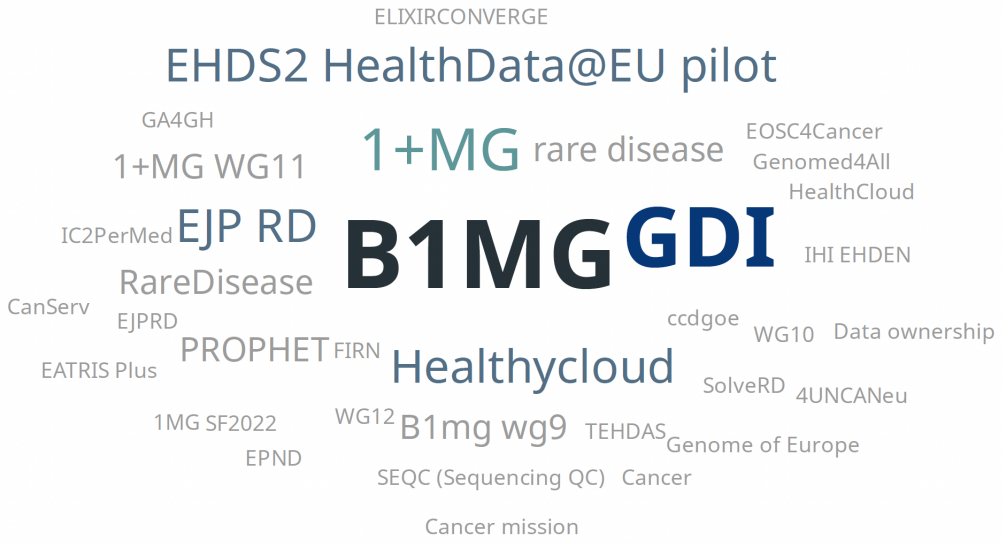
- Engagement with different projects and initiatives:

  The event was attended by participants affiliated with various projects besides 1+MG and B1MG as can be seen in the word-cloud figure below. These included Genomic Data Infrastructure (GDI), European Joint action for Rare Disease (EJPRD), Healthycloud, European Health Data Space2, PROPHET, CanSERV etc. Several of these projects are so-called *Partner Projects* to B1MG.



- Engagement with different institutions and initiatives:

  Participants included representatives from a broad variety of institutions (see word cloud below).

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- Most popular questions of the day: Participants had the option to raise questions and other concerns, as well as up-vote those asked by other participants through slido.com. Based on the response from the audience, the 5 most popular questions out of 49 questions asked across all the plenary sessions, as well as the panel discussion were:
  - ➢ How likely is it that Industry could co-invest in 1+MG data infrastructure service sustainability? Does the industry have a long-term strategy for data sharing?
  - ➢ Is industry considering adopting standards and tools to onboard 1+MG infrastructure and allow access to its own data?
  - ➢ Should 'industry' be broken down into different sectors rather than lumped together?
  - ➢ What can commercial entities do to demonstrate that they are compliant with the GDPR? As noted in previous presentations, legal barriers are major hurdles.
  - ➢ How can we work with Open Targets? (public-private partnership that uses human genetics data for systematic drug target identification and prioritisation)

4.3. Morning session

4.3.1. Introduction to the day: Marco Marsella (Head of DG CNECT, European Commission)

Speaker: Marco Marsella (Head of DG CNECT, European Commission)

Time 10:00-10:05

This session opened the 3rd 1+MG/B1MG Stakeholder Forum. Marco Marsella discussed the EC's continued support of the initiative and its implementation at a large scale. He spoke about keeping a balanced approach between health research and clinical benefit and identified its role in speeding up research in the clinical environment. He mentioned the linking role of the

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European Health Dataspace and its aim to provide access to data for secondary use with the intention that this can be also used for primary use and clinical decision making for patients.

4.3.2. Scale up and sustainability of 1+MG/B1MG efforts

Speaker: Ruben Kok, The Dutch Techcentre for Lifesciences (DTL, biography see Annex 2)
Link to Slides
Time 10:05-10:15

During the introduction, the strong support of the EC was acknowledged. This session set the stage for the main theme of the forum and the questions that were to guide the discussions of the day:

"What are the perceived challenges to the scale up and sustainability of the 1+MG infrastructure to provide access to genomic data across borders, and what stakeholders could help to address these challenges?" Related questions were:

- How can the Maturity Level Model be put to use by stakeholders?
- How can the 1+MG Trust Framework be put to use by stakeholders?
- What is the role of industry and of National Mirror Groups in the scale- up and sustainability of the infrastructure?

4.3.3. Key updates on 1+MG/B1MG

This session was focussing on the Trust Framework, the Maturity Level Model and 1+MG Industry engagement.

Trust Framework

Speaker: Serena Scollen (1+MG Coordination, ELIXIR Hub, biography see Annex 2)
Link to Slides
Time 10:15-10:30

This session included a brief overview of the 1+MG Trust Framework that was the focus of the previous stakeholder forum. Serena discussed the timeline of the B1MG project with its end in August 2023. She briefly introduced the 1+MG Trust Framework for genomics data developed by the B1MG project and its three aspects of data governance (ELSI), data standards and quality, and technical infrastructure. She specified how the data Governance policy being developed through the Trust Framework requires an analysis of the national legal situation, identification of possible legal bases for the operation, requirements for secondary use from the Data Governance Act, compatibility with the European Health Data Space, Transparency and Consent Guidance. In order for it to be adopted by countries to offer data subjects appropriate protection while ensuring ethical norms such as incidental findings, consideration of vulnerable subjects and groups.

The policy also needs to be compatible with national and EU legal frameworks and presents a homogeneous appearance as "one" resource towards users while supporting different national

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organisational and legal landscapes. Other aspects that need to be considered in developing this framework is drafting information and consent forms that ensure data subjects are informed, by giving the right level of choice to data subjects, providing "checklists" to validate consent forms, including 1+MG specific phrases to be used and example text for context specific elements, as well as the opportunity to opt-in or out of 1+MG ("re-consenting").

The framework should endorse data protection by design and default and offer protection to all stakeholders. The data quality and data standards aspect of the Trust Framework thus recommends organisational and technical safeguards to ensure secure processing at each step. The Trust Framework should incorporate translation of data governance into information management and IT infrastructure. Linking with the data governance aspect, ensuring data quality and compliance with data standards requires a standard definition of ELSI and associated metadata along the data life cycle, as well as planning workflows and tools with data protection / ELSI in mind.

Data standards should promote data interoperability and the Trust Framework should offer advice on which standards are of preference or mandatory in the management of genomic data. The Trust Framework should also support an approach for working with common standards and outline documented best practices in sharing and linking phenotypic and genetic data.

Maturity Level Model (MLM):

Speaker: Astrid Vicente (Instituto Nacional de Saúde Dr. Ricardo Jorge (INSA), biography in Annex 2)
Link to Slides
Time 10:30-10:45

This session introduced the efforts of 1+MG/B1MG in developing a MLM (WP5) to enhance the national healthcare systems towards the goal of precision medicine and reported on the progress on the pilot phase.

Astrid introduced the tool that has been developed within WP5 to assess the maturity of personalised medicine delivery and the scientific and societal impact of personalised medicine. She described this model as a tool for national (or regional) healthcare systems to self-evaluate the level of maturity of their genomic medicine practices according to a common matrix and to define a path to optimization. The aim of the model is to promote and facilitate the adoption of genomics in healthcare systems to make personalised medicine accessible to citizens and patients across Europe.

The development and validation of the model has been done through a literature review, consultation and brainstorming with B1MG WP5 and 1+MG WGs. A MLM framework draft was prepared and experts evaluated this through 2 rounds of delphi surveys. The Delphi surveys were launched in July 2021 where 21 high level experts were invited from which 14 experts completed the validation using the Welphi online platform. The model consists of 8 domains - governance and strategy; investment and economic model; ethics, legislation and policy; public awareness and acceptance; workforce skills and organisation, clinical organisation, infrastructure and tools; clinical genomics guidelines and infrastructure; and data management, standards and infrastructure.

Discussion on the MLM included its use beyond healthcare and by other organisations; how this model assesses economic benefits that are often analysed after genomics is used in healthcare

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instead of before or during its implementation; the domains and indicators that have been identified as particularly strong or weak across countries within Europe.

1+MG industry engagement:

Speaker: Sandra Liede (1+MG WG7, Healthtech Finland, biography see Annex 2)
Link to Slides
Time 10:45-11:00

During this session, the efforts undertaken by the 1+MG initiative in exploring the role of industry in cross-border genomic data sharing were presented. Sandra discussed the role of industry in facilitating the scale-up and sustainability of the cross 1+MG vision and the B1MG coordination efforts. 1+MG nominated 21 members from 16 signatory states with the original focus of exploring industry involvement as a concept.

The aim of WP7 was to identify the various roles of industry in the initiative. Examples of industry roles include - project support, as partners in scaling up the initiative, project management support, advice and access to a network of experts to ensure we can identify gaps in infrastructure and successful scale up, data solutions provider, develop and provide solutions and bioinformatics platforms, technology solutions provider, providing e.g. sequencing and array technology, as well as reagents, scientific innovator, develop and manufacture new innovative solutions to improve and enable genomic testing and analysis, data for research and development with necessary checks in place, stringent consent and privacy measures, industry could also access the data to advance innovation. Moreover, these efforts had to be undertaken without directly involving private organisations or industry as nominated experts due to sensitivities of commercial issues of genomics. Yet, what those sensitivities are remain unclear.

Identifying where trust is lacking in terms of industry requires breaking down the role of industry in the overall vision of genomics cross-border data sharing. There is a clear need to add industry in the National Mirror Groups in each signatory country. To document relevant use cases for industry involvement in the 1+MG initiative covering rare disease, cancer, common/population -level diseases and COVID-19 and other emerging infectious diseases. Additionally, WG7 identified the need to gather examples of organisations which have invested in Europe, why they have done so, why have they remained and the loss of certain investments.

Further discussions during the session raised concerns around the fear of engaging with industry specifically in the context of sensitive data such as genomics data; and the impact on the 1+MG initiative by increasing collaboration with industry in different roles.

4.3.4. First instruments for scale-up and sustainability

This session brought forward the first instruments that have been or will be taking forward the efforts of 1+MG/B1MG towards the implementation, scale-up and sustainability of the infrastructure for cross-border genomic data sharing within Europe.

Genomic Data infrastructure (GDI)

Speaker: Juan Arenas Marquez (ELIXIR Hub, biography see Annex 2)
Link to Slides
Time 11:15-11:30

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In this session, Juan introduced the European Genomic Data Infrastructure (GDI) project which is aimed at taking forward the coordination and support efforts of the B1MG project towards the implementation stage. The project will kick off in November and rests on the premise that 1+MG has the potential to improve and realise the practice of personalised medicine & health.

The structure of the GDI project was explained which consists of three pillars:

- Pillar I which focuses on long-term sustainability relies on member states representatives and their direct involvement as this is crucial to ensure adoption and sustainability of the infrastructure. Country representatives will agree on a long-term governance plan, a legal entity and a business model for the infrastructure. These will ensure that the infrastructure continues to operate after the end of the GDI project.
- Pillar II focuses on infrastructure deployment and will implement the infrastructure by increasing the interoperability of European data resources, ensuring resources form a part of the 1+MG infrastructure and are readily accessible once the required agreements are in place. Resources include - European level services, user portal (including data catalogue), data discovery services, helpdesk, data management services, "Real" synthetic data and metadata, data management support to Nodes, technical outreach and technical capacity building.
- Pillar III involves use cases for example, the Genome of Europe, cancer data and infectious disease data and guides the implementation of the project through these use cases. It works with users like clinicians, researchers and innovators to identify solutions that could form part of the infrastructure.

Discussions included the role of GDI in ensuring the commitment of countries towards putting data into the infrastructure where it was clarified that GDI is not looking at data generation, except in the use case of GoE where the goal is to make data from 500.000 participating citizens available as a reference for research, innovation and in healthcare.

EHDS - SANTE, TEHDaS: Towards the European Health Data Space

Speaker: Markus Kalliola (Sitra Finland, biography see Annex 2)
Link to Slides
Time 11:30-11:45

Markus discussed the various measures undertaken by the European Union with regards to data and its protection. Within this context, he defined the European Health Data Space (EHDS) as a data ecosystem specific to health data that consisted of rules, common standards and practices, infrastructures and a governance framework. This ecosystem will also combine health data with different types of data such as environmental. He highlighted the commonalities between the EHDS proposal and the 1+MG vision, the common objective being the effective use of health data. He discussed the four pillars of EHDS - Legal and governance, Data quality, Infrastructure, and Capacity building.

The Joint Action towards the European Health Data Space (TEHDAS) supports the Member States and the Commission and develops and promotes concepts for sharing of data in secondary use. It includes authorities from 25 European countries and will extend for 30 months from February 2021 – Summer 2023. He also reported on some of the key barriers to cross-border genomic

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data sharing of health data for secondary use which included - legal issues, semantic/data related issues, infrastructural and trust issues.

Discussions with the audience were focused on the potential of secondary use of health data to foster better healthcare, as well as the concept of data altruism according to the Data Governance Act and the apprehensions around the concept regarding return of engagement and investment value proposition. Finland, France and Denmark amongst others were mentioned as models for best practices for secondary sharing of data systems.

Gaia-X: Health

Speaker: Bert Verdonck (Luxembourg Institute of Health, biography see Annex 2)
Link to Slides
Time 1145-1200

Gaia-X is a membership association which brings together a lot of players: industry, research, technology providers. The European Data Strategy involves a lot of legislation (Data Act, Data Governance Act, European Health Data Space) providing the legal framework. Gaia-X is working on the cloud infrastructure side and on the data spaces side by providing a framework concept covering the governance structure as well as technical frameworks. The aim for the Gaia-X Cloud infrastructure is to be more transparent, controllable and interoperable with the option to use different providers in different countries.

The Gaia-X Data Spaces are working on Use cases, Data Connectors and interoperability to create sustainability. Gaia-X Cloud infrastructure is distinct from the traditional cloud approach for data storage and sharing. Gaia-X offers users the option of choosing between different providers without much effort in order to avoid adverse effects of monopolies. While traditional cloud approaches are concentrated, proprietary and opaque, Gaia-X endorses an open, transparent and distributed infrastructure. Gaia-X Data Side promotes existing standards to allow interoperable sharing between different domains. Gaia-X's core essence is the compliance area with the aim of providing decentralised services to enable objective and measurable trust, involving data management and permission management. Bert also discussed the Trust framework developed by Gaia-X to ensure trust in data sharing ecosystems. Bert was inviting an open and active dialogue with Gaia-X, in particular with the Data Space Support Centre.

4.4. Afternoon Session

The afternoon session was split in two sessions: the afternoon started with a 1 hour panel discussion on industry engagement in supporting cross border genomic data sharing: benefits, challenges, and risks for 1+MG/B1MG in engaging with industry. This panel discussion was followed by four parallel breakout sessions to suggest recommendations to scale up and make the work of 1+MG/B1MG more sustainable and on how industry can facilitate this process. Recommendations of the breakout session were presented afterwards and the SF2022 was wrapped up at 16:30.

4.4.1. Panel discussion on Industry engagement

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Time: 12:45-13:45

Building on the efforts undertaken by 1+MG to engage with industry stakeholders, this session was organised as a panel discussion. Under the theme of scale-up and sustainability, the aim was to explore the role of industry as a key stakeholder group towards the vision of the 1+MG initiative. While the involvement of industrial actors is integral to achieving this vision, doing so has also presented challenges that are often unique to this stakeholder group. As a first step towards addressing these challenges within the scope of this project, this panel discussion brought together representatives from an umbrella industry organisation, SME, a patient/citizen advocacy group, as well as national genomics initiatives outside Europe to discuss the benefits, risks and challenges of industry involvement in cross border genomic data sharing efforts.

The panel was chaired by Sandra Liede (1+MG WG7) and co-chair Ruben Kok (1+MG Coordination Group) and consisted of

- **Magda Chlebus** representing the European Federation of Pharmaceutical Industries and Associations (EFPIA), an umbrella organisation for industrial stakeholders
- **Julia Kurps** representing the perspective of SMEs (The Hyve) based upon experiences in the IMI Project - European Health Data and Evidence Network (EHDEN))
- **Tiffany Boughtwood** covering the perspective of a national genomics data initiative outside Europe, namely Australian Genomics
- **Fernando Martin-Sanchez** adding the perspective of patient and citizen advocates, ("Carlos III" Health Institute of Spain (ISCIII), 1+MG CG).

The panellists' biographies are collected in Annex 2.

The session began with a round of introductions from the panellists where they also briefly discussed their positions and experience with industry engagement through their respective roles.

Following her introduction, Magda Chlebus from EFPIA which is an umbrella organisation for Research and Development-based pharmaceutical industries, explained that activities around engaging with industry are often influenced by myths and uninformed as these activities frequently are held in the absence of industrial stakeholders. She suggested engaging in a dialogue not just about the risks of data misuse from industry engagement, but also acknowledging that these risks may not be unique to the industry and are valid concerns with other stakeholders as well. In this context, the work done by 1+MG/B1MG and the outcome is relevant to identify the common risks as well as all the stakeholders who are involved in addressing these risks.

Julia Kurps described the EHDEN project as one that brings together both industry and research. She stressed the importance of creating evidence: what can we do when the data is available. For instance, by mapping clinical data to a common data model so it can be used without the data leaving the hospital. She showcased that this model works and has an impact. Input from the public is needed (what are the fears) and development of ways to mitigate fears.

Tiffany Boughtwood from Australian Genomics discussed the potential opportunities and challenges to involve industries from the Australian perspective. Fernando Sanchez from ISCII shared his experience from the "All of US" project where data was offered from over 500,000 participants (biospecimen, genomics data, health data, digital sensors) and made available through a resource. This project took a different approach by NIH in 2015 where academia and

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industry was invited to join, the outcome of which was that 4 WPs were led by academia while 3 WPs were led by private companies.

Discussions during this session raised several interesting questions on the challenges to industry engagement.

For instance, recommendations to break down industry into different sectors than it being considered one stakeholder would be dependent on how the data is being used by the industry. Another topic of discussion was the incentive model that needs to be considered when engaging with industry. Are industries being considered users or would they be ensuring data quality and taking the role of data providers.

The panellists also acknowledged the public-private nature of several national genomics efforts (eg. Australian Genomics) which help build better relationships between stakeholders working towards the same goal. Additionally, while the tradition of public-private initiatives at national level, based upon specific and open goals and aims has worked, there is no one solution that fits all. Open Targets, which is a public-private partnership that uses human genetics data for systematic drug target identification and prioritisation was another topic of interest and was a good example of this. Working with core-groups to be more effective without involving all initiatives to avoid slowing down the efforts was another recommendation offered by the panel.

Questions around aspects that industry should *not* be involved were also discussed during this session. The panel recommended trying to address this by more granular consent on the use of data. There are communities that may have particular sensitivities to industry engagement, which should be respected. As long as we ensure that privacy is conserved and data is used for better health, then industry involvement is good. Overall, regulating who can access data is very important (‘good use’, not ‘bad use’).

Discussions also addressed the role of industry in 1+MG. Concerns included how and when industry would consider adopting standards and tools to onboard 1+MG infrastructure and allow access to its own data. Another aspect to consider is what the likeliness of industry is towards co-investing in 1+MG data infrastructure services and sustainability and industry’s long-term strategy for data sharing. The panel recommended creating an ecosystem that is sustainable by providing training for industries and ensuring continual exchange through a structured dialogue as collaboration is key for sustainability. Creating a ***‘comfort-zone’*** where public and private interests meet, also requires acknowledging concerns to build trust mutually. To which the panel recommended, a “Sandbox” approach to start a discussion for concrete problems / intents.

GDPR concerns were another topic that the panel discussion touched upon. What can commercial entities do to demonstrate that they are compliant with GDPR? As noted in the previous sessions, legal barriers prove to be major hurdles towards industry involvement in genomic data sharing efforts. The panel shared their experience from several projects involving sensitive data where a European checklist can be used as substantial proof for industry to comply with GDPR.

Fear around industry engagement was also discussed. These fears often stem from the different i.e. commercial purpose, culture, traditions, priorities industries have when compared to other stakeholders. However, examples have proven that both still can work together in research if this is acknowledged, so a collaboration is possible. A good example is the IMI programme in which public and private partners are working towards identifying and addressing these differences.

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It was concluded that the 1+MG WG7 has done a good job in kicking off the conversation on industry engagement. Identifying industry's motivations to get involved in the 1+MG initiative would be another next step to pursue.

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4.4.2. Breakout sessions

Time: 13:45-15:00

This session was organised into four parallel breakout sessions. Each session centred on a specific 1+MG use case

1. Breakout 1: Rare disease (WG8)
2. Breakout 2. Cancer (WG9)
3. Breakout 3. Common and complex disease (+GoE) (WG10)
4. Breakout 4. Infectious diseases (WG11)

The goal of this 1 hour and 15 mins breakout session was to identify challenges stakeholders could face in scaling up the 1+MG Trust Framework and engaging with industry, as well as recommending how these challenges can be navigated within the use case. The breakout session were asked to answer the following questions:

1. How can stakeholders from each use case help scale up and make the work of 1+MG/B1MG in data governance, data standards and technical infrastructural aspects sustainable?
2. How can industry facilitate this process/ gaps industry can fill?

Each session started with a summary presentation on the 1+MG use case. Then, the questions above were discussed amongst the participants of the breakout sessions, recommendations were collected on slides and presented to all SF2022 participants during a feedback session (15:00-15:45).

Breakout 1: Rare disease (WG8)

Chair: Katrin Õunap (Univ Tartu, EE)
Co-Chair: Ruben Kok (DTL/Health-RI, NL)
Number of participants: 35
Link to Slides

For an introduction, previous activities of this working group were presented, this was followed by a discussion. The focus of the breakout session was to formulate recommendations for 1+MG/B1MG from the perspective of the Rare Disease use case along the three aspects of the 1+MG Trust Framework (ELSI & Data Governance, Data & Quality Standards, Technical Infrastructure).

The following challenges were formulated:

ELSI & Data Governance: Which challenges to the scale up (within this Use Case) could be addressed by industry?	**ELSI & Data Governance: Which challenges to the scale up (within this Use Case) could be addressed by other stakeholders (please specify stakeholder)?**
• Implementation of an electronic and dynamic consent system • Sharing knowledge from multinational	• Gap between clinical actors and the FAIR principles (understanding, mindset, solutions, and

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studies • Their collaboration on machine readability of consent and use condition of collected data (different from electronic consent) • Transparency on how patient data benefits the company. It could for instance help to train algorithms, or help as proof of function to boost sales.	implementation). Funders and academic organisations could help! • Allow for secondary use of genomic data (data sharing) outside of research studies (EU and government) and share with other nations (such as US) • We should know who is addressing what issue. For example GA4GH is addressing many of the ethical and legal issues surrounding genomic data. • National DPBs should come up with suggestions on how data can be used responsibly, and allow collaboration between industry and health care institutes.

Data & Quality Standards: Which challenges to the scale up (within this Use Case) could be addressed by industry?	**Data & Quality Standards: Which challenges to the scale up (within this Use Case) could be addressed by other stakeholders (please specify stakeholder)?**

• Automated extraction of minimal dataset
  ○ Have plug-ins from all local hospital systems and facilitate those conversions through tools and software we use
  ○ Enable the capture of data from clinical systems to feed into research and vice versa
• Tools to facilitate data entry with HPO, ORDO within EHRs
• Translation of ontologies
• Standards, tools, and requirements developed and adopted by industry
  ○ https://github.com/ejp-rd-vp
	• HTA and regulators (EMA and EUnetHTA)
	  ○ They are developing their own processes and data spaces and guiding on the type of data
	  ○ EMA through the DARWIN initiative and have provided a lot of guidelines and data
	• Usage of tools already implementing standards (eg. EJPRD virtual platform)
	• Quality control, accredited lab/centres
	• Strong guidelines on data standardisation on EU level, forcing national implementations to follow the EU guidelines.

Technical Infrastructure: Which challenges to the scale up (within this Use Case) could be addressed by industry?	**Technical Infrastructure: Which challenges to the scale up (within this Use Case) could be addressed by other stakeholders (please specify stakeholder)?**
• Support to find the “right” fit for	• Heterogenous maturity levels among

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integration/ "make whatever we need" adaptable to personal local situation
• On what level are we sharing data with industry
  ○ Much easier to share data with industry if you do not have to return results to an individual person.
  ○ There are different local regulations if the data is being returned for the benefit of specific individuals
• Industry infrastructures made interoperable with 1+MG Infrastructure
• (Financial/ technical) Support to find "right" fit for integration/ "make whatever we need" adaptable to personal/local situations.
	MS in digital data storage and HCP infrastructure
	  ○ Belongs to people who are investigated and the national governing body should decide how to keep that data
	• Cloud-based tools and software can be provided locally - no internet access - it requires HPC platforms to engage with providers
	• GA4GH toolkits for responsible data sharing (e.g file formats, APIs, standards, recommendations, etc.)
	• Critical Path Institute, Data processing/Analysis Platform: https://portal.rdca.c-path.org/

In addition, there were some general comments raised:

- There will be a workshop focussing on technical hands-on and dissemination/sustainability planning by EJP RD and next phase RD partnership, there had been many examples already been piloted and proven successful (such as EJP-RD and SOLVE-RD),
- There is a need for patient initiatives donating data, national requirements and resources to build up germline genomic data at clinical level,
- A guidebook would be needed containing the relevant resources and tools for researchers just starting or Member States looking to start implementing genomics into healthcare systems.

Breakout 2. Cancer (WG9)

Chair: Giovanni Tonon (ACC/HSR, IT)
Co-chair: Astrid Vicente (INSA, PT)
Number of participants: 28
Link to Slides

The focus of this breakout session was to formulate recommendations for B1MG from the Cancer use case perspective along three aspects of the 1+MG trust framework. For an introduction, previous activities of B1MG WG9 were presented. The following challenges were collected:

ELSI & Data Governance: Which challenges to the scale up (within this Use Case) could be addressed by industry?	**ELSI & Data Governance: Which challenges to the scale up (within this Use Case) could be addressed by other stakeholders (please specify stakeholder)?**
• Harmonisation	• Patient organisations

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• After harmonisation we will need data quality control, this is an expensive chapter • Data ownership • Confidentiality • ELSI terminology/contracts only open to one interpretation	• Policy makers • Citizen • Creating trust: all relevant stakeholders

Data & Quality Standards: Which challenges to the scale up (within this Use Case) could be addressed by industry?	**Data & Quality Standards: Which challenges to the scale up (within this Use Case) could be addressed by other stakeholders (please specify stakeholder)?**
• Incorporate standards into their products (e.g. EHR, equipments) and provide easy means of use • Transparent adoption of FAIR data standards • Limited return on engagement for effort required • capacity	• Data curators: working in semantic interoperability • Hospital IT personnel • Patients having access to their own data is a food leverage to data standards • Make text mining / natural language processing a reality (not all is structured data)

Technical Infrastructure: Which challenges to the scale up (within this Use Case) could be addressed by industry?	**Technical Infrastructure: Which challenges to the scale up (within this Use Case) could be addressed by other stakeholders (please specify stakeholder)?**
• Develop doctor-friendly user interfaces for tools in federated infrastructure • pseudonymization/key management/persistent identifiers • Trusted working / research environments • Linguistic technologies	• Connecting hospitals with the European HPS environment - connectivity and security issues • IT storage • Hospitals • Academia and research

In addition, a set of general recommendations were formulated:

- It is important to engage with citizens, in particular patients.
- At the same time it is also important to engage with doctors and health care professionals who enter the data.
- There should be agreement on a date that all stakeholders apply the standards which were agreed.

Breakout 3: Common and complex disease (+GoE) (WG10)

Chair: Andres Metspalu (UT, EE)
Co-chair: Serena Scollen (B1MG, ELIXIR Hub)

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Number of participants: 20
Link to Slides

The aim of this session was to gather recommendations to 1+MG/ B1MG WGs/WPs from the perspective of the use case Common and complex diseases (WG10). The session was introduced by a presentation on WG10 activities. The participants of the breakout session made the following recommendations along the three aspects of the Trust Framework:

ELSI & Data Governance: Which challenges to the scale up (within this Use Case) could be addressed by industry?	**ELSI & Data Governance: Which challenges to the scale up (within this Use Case) could be addressed by other stakeholders (please specify stakeholder)?**
• WGS dataset can be used almost a lifetime • We need good clinically accepted software medical genetest devices to work on the WGS data • Policy makers on EU level could provide more financial instruments for WGS data generation • From the industry good market overview on software medical genetic tests could be provided centrally on EU level	• National policy makers/public health authorities should develop vision and strategy (including financing) for using genomic testing for secondary prevention • If a whole genome costs 100EUR including proper sampling, how much would a data analysis service request by a doctor cost? • Education for professionals and citizens should be developed (by professional organisations from clinical genetics?) and their needs should be studied and used.

Data & Quality Standards: Which challenges to the scale up (within this Use Case) could be addressed by industry?	**Data & Quality Standards: Which challenges to the scale up (within this Use Case) could be addressed by other stakeholders (please specify stakeholder)?**
• Healthcare - needs to set the quality etc. regulation to be set at a government level • Inter lab quality assessment: industry can produce chips that respond to the quality control set • Example: Screen4Care is EFPIA supported on newborn screening using genomics - this could be extended.	• For the industry inside the EU market quality assessment system and standards should be the same, otherwise it's a waste if just on a national level. • EHDS implementation needs to set common standards also in genetic data - good input is needed there. • Newborn screening at national level - will scale up samples and data rapidly

Technical Infrastructure: Which challenges to the scale up (within this Use Case) could be addressed by industry?	**Technical Infrastructure: Which challenges to the scale up (within this Use Case) could be addressed by other stakeholders (please specify stakeholder)?**
• https://health.ec.europa.eu/medical-devices-sector/new-regulations_en - more clarity needed!	• No input was formulated to this question, but the discussion following related to the role of (national) policy

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• Dream to have a European Genome Centre (like EMBL) - need it to keep going and be successful, extension of 1+MG . make healthcare science-based!	makers, see below.

During the discussion, some recommendation pertaining the needs from policy for responsible implementation were formulated:

A. Public and professional trust: ensuring that the general public, researchers, clinical professionals and policy makers are well informed about genomics and feel empowered to make decisions, in order to ensure its uptake by (public) healthcare systems and integration into personalised healthcare
B. Focus on inclusion and equity: avoiding an increase in unequal access to health services
C. Sequencing facilities and personnel: ensuring that facilities and workforce are facilitated for sequencing, but also counselling and support
D. IT-infrastructure:
    a. ensuring that appropriate technical infrastructure is available, allowing for secure, federated access to genomic data,
    b. implementing interoperability guidelines to achieve data of internationally agreed standards
E. Legal framework allowing safe data-exchange and informed choice:safeguarding privacy and personal control
F. Financial arrangements/reimbursement of testing: ensuring access to testing for citizens
G. Piloting implementation: assessing evidence and identifying and overcoming practical and remaining ethical, legal and societal issues.

Breakout 4: Infectious diseases (WG11)

Chair: Katja J. Kivinen,
Co-chair: Juan Arenas
Number of participants: 10
Link to Slides

The aim of this session was to list recommendations for scale up and sustainability around ELSI, Data standards and Infrastructure from WG11 Infectious diseases use case perspective. The work of WG11 was presented at the beginning of the session, this was followed by a discussion and the following recommendations were collected:

ELSI & Data Governance: Which challenges to the scale up (within this Use Case) could be addressed by industry?	**ELSI & Data Governance: Which challenges to the scale up (within this Use Case) could be addressed by other stakeholders (please specify stakeholder)?**
• Data privacy • Economically • Infrastructure solutions	• Data types, data use, sharing (consent of use) (hospital, patient organisations) • National initiatives • Hospitals

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	• Know what is the interest of sequencing in infectious diseases

Data & Quality Standards: Which challenges to the scale up (within this Use Case) could be addressed by industry?	**Data & Quality Standards: Which challenges to the scale up (within this Use Case) could be addressed by other stakeholders (please specify stakeholder)?**
• Collaboration to recommend and use standards • Data sharing • Sequencing capacity • Definition of data standards	• Integration and linking of host and pathogen data (academia, scientific services, hospitals) • Availability of bioinformaticians

Technical Infrastructure: Which challenges to the scale up (within this Use Case) could be addressed by industry?	**Technical Infrastructure: Which challenges to the scale up (within this Use Case) could be addressed by other stakeholders (please specify stakeholder)?**
• Solutions for automation • Technical experts • Clouds servers • Cybersecurity resources	• Sustainability (MS) • Metadata organisation and interoperability (hospitals) • Sequencing devices in public health agencies

As a general comment, the need of funding for sequencing and data analysis (by hospitals and researchers) was pointed out.

5. Results

5.1 Recommendations from Breakout sessions

Recommendations from the afternoon breakout session to scale up and make the work of 1+MG/B1MG sustainable have been summarised per breakout / use case below along the three aspects of the 1+MG Trust Framework.

Breakout 1: Rare disease (WG8)

ELSI & Data Governance: The industry was identified by the breakout session to be useful for different aspects of the consent recording system and fostering the availability of patient metadata, also the industries' knowledge on multinational collaborations could be useful. Other stakeholders can be of help as well: funders and academic organisations can help educate (clinical) actors on FAIR principles.

Data & Quality Standards: The group valued the tools available at industry stakeholders to be

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useful also in the context of 1+MG: an automated extraction of minimal datasets can facilitate the data entry by capturing of clinical and/or local datasets, also in general the use of standards, tools, and requirements developed by the industry are available. Other stakeholders such as HTA, EMA, EUnetHTA are developing their own standards, already implemented standards (EJPRD as an example) is ready to use, however, guidelines on data standardisation are needed on EU level.

Technical Infrastructure: Involvement of industry can support finding the right fit for the needed infrastructure, interoperability aspects are crucial to allow data sharing between industry and 1+MG. Other stakeholders can also help overcome challenges: owners of HPC, cloud-based tools and software, the use of the GA4GH toolkit for responsible data sharing.

Breakout 2. Cancer (WG9)

ELSI & Data Governance: Also the group related to the cancer use case valued the involvement from industry for e.g. quality control, which was identified as expensive but crucial. All stakeholders involved are needed for an open discussion to create trust.

Data & Quality Standards: The group made the point that for using data standards from the industry industry has to adopt FAIR data standards. Data curators as additional stakeholders were mentioned to keep up on developing semantic interoperability. And it would be useful for data collection purposes to make text mining / natural language processing a reality.

Technical Infrastructure: This group discussed that industry should develop doctor friendly user-interfaces. Other aspects discussed were focussing on situations in clinics: in order to speed up, clinics need to be connected to the European HPC environment, they need scaled-up IT storage.

Breakout 3: Common and complex disease (+GoE) (WG10)

ELSI & Data Governance: This group discussed the fact that a WGS dataset can be used for almost a lifetime. They addressed the need for national policy makers / public health authorities to develop a strategy for genomic testing for secondary prevention.

Data & Quality Standards: The industry was identified as a powerful partner for inter lab quality assessments in producing respective chips. Newborn screening at national level was discussed as a measure to scale up samples and data rapidly.

Technical Infrastructure: This group was mentioning that it would be enormously helpful to create a European Genome Centre to make the efforts sustainable and to make healthcare science-based.

Breakout 4: Infectious diseases (WG11)

ELSI & Data Governance: During the discussion of the group industry input was discussed to be of value, e.g. on data privacy but also on available solutions by industry infrastructures. Stakeholders such as hospitals, patient organisations can help to identify available metadata and clauses of data use and sharing.

Data & Quality Standards: The group discussed the need for an open discussion with the industry on standards, and industry can also be a partner in scaling up sequencing capacities. Other stakeholders such as academia, scientific service providers, hospitals are key in integrating and linking datasets / metadata.

Technical Infrastructure: This group valued the technical expertise by the industry which are

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also useful in the context of 1+MG: automation, cloud servers, but also resources for cybersecurity. Other stakeholders potentially could add sequencing devices too (public health agencies etc.)

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6. Discussion

The online Stakeholder Forum 2022 again offered an excellent platform for stakeholder interaction around 1+MG progress in general and in particular around the topics addressed by Working Groups in the 1+MG framework (and supporting B1MG Work Packages). Over 180 participants from a broad range of backgrounds, expertise areas and nationalities were involved in the various sessions in the morning and in the panel discussion, breakouts and feedback session in the afternoon. Of the attendees, 152 actively participated and gave feedback showing that the individuals who attended were highly engaged. As expected, academics were the most represented stakeholder group, but healthcare and policy/government were also well represented. Industry representatives were fairly low considering one of the topics was industry engagement. The SF2022 session offered a good platform to discuss how to improve this situation, see below..

Given the fact that this was the last of three broader Stakeholder Forum meetings organised under the B1MG project, the Stakeholder Forum centred around the question of how to scale up the 1+MG initiative and make it sustainable, and how stakeholders could contribute to this process. This topic was also chosen as the 1+MG initiative is transitioning into a phase of scale up and sustainability, after the first period of design and testing of approaches following the first signatures under the 1+ million genomes declaration in 2018, meanwhile signed by 25 countries (Autumn 2022, Ireland and France have also joined).

A few important European developments were also covered in the SF2022 programme, since they offered opportunities to help realise the 1+MG ambitions, and the European digital environment for embedding of 1+MG:

1. November 2022, as part of the Digital Europe Programme, the first major project was to be launched some weeks after the SF2022 meeting: the Genomics Data Infrastructure (GDI) project recently started with 50% financial support from the European Commission via DG-CNECT. This project will provide a great opportunity for the scale up and sustainable development of the federated 1+MG data infrastructure. It will focus on implementation in a large part of the 1+MG signatory countries and therefore will help to realise an essential part of the backbone of the European genomics data infrastructure. The project will run for four years, is taking along many partners now already associated in the 1+MG Working Groups and B1MG work packages, and therefore is ideally positioned to secure continuation of work launched in B1MG. The Stakeholders were informed about the GDI project by the project coordinator.
2. May 2022, the proposed (draft) regulation on the European Health Data Space (EHDS) was published by DG-SANTE, offering a view on the future European framework and infrastructure for cross-border access to healthcare data, both for primary use in healthcare, and for secondary use in research, innovation and policy development. This made it more and more apparent that 1+MG as an initiative focussing on genomics-based personalised health strategies will need to be well embedded in – or connected to – the future EHDS. More generally, the 1+MG infrastructure and Trust Framework will need to be fully interoperable with other future data spaces, including the FAIR-based European Open Science Cloud and the emerging European GAIA-X public cloud infrastructure. In the SF2022 plenary part of the programme, EHDS (via the TEHDAS project) and GAIA-X were presented as initiatives to engage with for 1+MG.

The role of industry in the (scale up and sustainability of the) 1+MG initiative was a key element of the SF2022 stakeholder exchange. This topic had been on the table of 1+MG's Working Group

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7 from the onset of the bottom-up programme of work in 2019, but was suffering from the perceived sensitivity of the idea that companies would get access to genomics data as the most sensitive form of personal data for their own private businesses. This led to a duality in the approach of engaging companies, which was held back at the level of the European initiative, but was stimulated at the local (regional/national) level of initiatives connected to the 1+MG framework. These aspects, were clearly expressed during the day, first in the form of a summary of the outcomes of the work of Working Group 7 by WG-lead Sandra Liede, subsequently by a panel discussion offering the perspectives of major pharma and biotech industries, SME's, and the perspective of genomics initiative outside Europe (Australia and USA), and in the afternoon through the focus of breakout groups on the potential role of industry in scaling up 1+MG and making it sustainable.

Throughout the presentations and subsequent discussions during the SF2022 meeting, the great importance of engaging industry in 1+MG was clearly raised. Industry must be seen in its wide variety of stakeholders and roles to play potentially. Multiple aspects of the industry to be involved into 1+MG were thus acknowledged, including but not limited to providing professional services, developing software and tools for data management (including cybersecurity), provisioning of training, provisioning of (cloud) infrastructure and (contribution to) development of standards. Lastly, but importantly, Industry would also be a source of important (pre-clinical) data to be tapped into for 1+MG. With the right legal arrangements of data access as part of the 1+MG Trust Framework, it will be critical for the future of personalised medicine and health strategies to involve companies at multiple stages in the European 1+MG network of national, regional and local initiatives.

The panel discussion clearly stipulated that a continuous exchange with the industry (involving all stakeholders) will be needed in order to develop a ***comfort zone*** to engage industry in 1+MG, to help demystify the basis of hesitations about industry's engagement and to build mutual trust between public and private stakeholders. It was proposed to move away from vague sentiments and build a working relationship with industry partners in the form of a growing set of tangible projects that could help to build the required level of trust in the skills and services offered by companies. EFPIA chair Magda Chlebus clearly offered the IHI framework as a possible environment to realise such projects. Another recommendation was to develop an "***Industry Forum***" associated with the 1+MG initiative and the (European) projects realising it.

The 1+MG Trust Framework (common choices/recommendations on ELSI, data standards and infrastructure) again offered a common set of major aspects to reflect on with stakeholders, especially from the perspective of the four disease areas covered by working groups in 1+MG. The parallel breakout sessions in the afternoon were essentially used to review the necessary elements of the future 1+MG Trust Framework and how they would best support the primary (clinical) and secondary (research) use of the 1+MG associated data resources. In capturing the recommendations from the experts involved in the SF2022 meeting, it proved very useful to have these discussions first summarise specific requirements from the perspective of each community and then focus on the question how stakeholders (including industry) would be in a position to help scale up and make these elements as sustainable components of the 1+MG infrastructure.

The first part showed again that there are elements specific to each disease community, and differences in how much research and care are already entangled. The rare diseases and oncology breakouts showed a clear need to engage both researchers and health care professionals (physicians / hospitals) and patients, while the other two disease domains seem to operate more on the research side still, certainly if it comes to the role of genomics aspects and how they offer biomarkers to develop personalised health strategies. Again this stressed that the

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1+MG infrastructure must be able to support primary and secondary use equally well. Genomics also brings in a particular case of re-using primary healthcare data of one patient in diagnostics of other patients (hence secondary use in primary care), with the Rare Diseases practice of clinical genetics offering everyday examples. The field works on designing better processes to find similar patients (in phenotype and genotype) across borders and to ameliorate diagnosis, and seed the development of potential avenues to cure patients with (often) rare genetic variants. The breakout discussions also illustrate that 1+MG (and genomics-based healthcare) requires a high level of complexity in access to various data types (including data outside the healthcare setting). Such aspects provide an important element of feedback to the EHDS framework of the future, in which the 1+MG infrastructure will have to be embedded, and can be positioned as a front-running platform connecting European countries.

With respect to the roles of stakeholders, there is a clear demand to engage companies in multiple aspects of realising a practice of genomics-based personalised health, and at the same time to design better policies at the level of national genomics programmes (referring to the important role of National Mirror Groups in 1+MG) to build the capacity in genomics-based health and implement a range of novel technologies. From the Common and Complex Diseases community, a clear call for a more massive exploration of the potential of Polygenic Risk Scores (PRS) was voiced once more, with the mounting evidence that PRS-based analysis can also help to implement affordable diagnostics (arrays) that would avoid expensive whole genome sequencing for prevention-oriented population screening practices.

The field of infectious diseases focussing on the host-genomics-aspects of susceptibility of citizens to infectious viral and bacterial ailments showed a basic need to harmonise data management strategies, improve metadata schemas and build the capacity towards FAIR implementation in connected fields of pathogen research and healthcare. This can be translated into a general need to implement FAIR approaches to data and associated metadata across clinical and research communities. With the help of the involved genomics expert communities, 1+MG and important stakeholders such as ELIXIR and the Global Alliance for Genomics and Health (GA4GH) can play a crucial role to improve this practice of FAIR-based data stewardship.

7. Conclusions

Stakeholders are supportive of the fact that the 1+MG initiative is now scaling up after a first period of design and testing of the 1+MG Trust Framework. There is a great desire to make 1+MG a sustainable multicountry initiative to allow for rich and high quality genomic health data to be accessed across borders for shared use in clinical settings, research and innovation, and policy development.

The GDI project started in November 2022 offers great opportunities to ramp up activities and implement a significant part of the collective 1+MG data access infrastructure, building on the ELSI framework, standards and infrastructure design prepared in B1MG. The Stakeholder Forum 2022 confirmed the necessity to make 1+MG fully interoperable with EHDS and other data spaces, including EOSC and GAIA-X.

A clear role of industry is wanted, and building on the first basis created by WG7, the initiative is advised to build help countries build up a strong working relationship with a broad range of companies, ranging from pharma and biotech to AI and medtech companies, and to create a platform in which a strong level of trust can be reached among public and private stakeholders.

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A common platform needs to be created that will offer the *comfort zone* to explore the synergies with other stakeholders and define the best roles of industry in strengthening the 1+MG endeavours. An open and structured dialogue should be achieved within the setup of an *industry forum* where public and private interests meet and where also concerns are shared. Industry is foreseen to be providing professional services on many aspects of genomics based health, including access to private data resources. Trust needs to be built based upon tangible time-bound projects, and it is advised to work towards creating programmes that can help realise such public private collaborations.

Other stakeholders must be enabled to be part of the 1+MG initiative, including health care professionals and citizens. Health care professionals as data holders (e.g. in hospitals) must be trained in data management based upon the FAIR data principles, and it must be ensured they have (secure) access to infrastructures for their clinical work. Citizens will need to be involved more directly at the national level of implementation, and the initiative should try to build a strong expertise base on how to engage citizens and patients in an open manner.

The 1+MG Trust Framework still offers a strong basis to work from, and the different disease fields share many common requirements to the ELSI, standards and infrastructure teams, jointly calling for a closer interaction between healthcare and research. Recommendations from the use case break out sessions are listed in a table per use case in chapter 4 and not repeated here. Recommendations are shared with the relevant B1MG work packages and related 1+MG Working Groups, and are directly fed into the GDI project teams.

8. Follow up and Impact

The SF2022 has been an important platform to collect feedback and recommendations from stakeholders with diverse expertise across Europe (and beyond) for scaling up and making 1+MG sustainable.

There is a clear need for continuous stakeholder engagement. This has been taken into consideration in the design of the next implementation project, the European Genomics Data Infrastructure (GDI) where further similar annual stakeholder meetings will be run. This will ensure the impact of the series of annual events established by B1MG is maximised. In addition, 1+MG partner projects are also working to engage stakeholders and by expert overlap and discussions, the outcomes of these meetings will also be considered in future implementation projects (e.g. Healthycloud is running three stakeholder meetings all before March 2023).

The 1+MG WG7 activity should now be increased. Many of the outcomes of the SF2022 meeting could lead to work in this sector to ensure innovation and engagement. One opportunity could be to create an IHI programme, or similar programme of tangible PPP projects. This will need to be explored further by the 1+MG initiative with interested industry partners.

It is clear that there is one category of stakeholders that still needs particular attention - the citizens. The B1MG project (WP1) meanwhile has set up a workshop specifically to outline recommendations for what is required for citizen engagement in considering implementation of genomics into healthcare across Europe.

The three stakeholder reports will remain accessible for review in the B1MG stakeholder portal and website.

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10. Annex

Annex 1: Agenda of the SF2022

Time	Duration	Session
0930 -1000	30 mins	**Arrival & registration** Waiting room will be open
1000 - 1005	5 mins	**Welcome** Marco Marsella, European Commission
Introduction to the theme of the day: Scale up and sustainability of 1+MG/B1MG		
1005-1015	10 mins	**Introduction on Scaling up and making 1+MG/B1MG sustainable** *Ruben Kok, DTL/Health-RI, 1+MG CG*
Key updates from 1+MG/B1MG		
1015-1100	15 mins	**Overview of 1+MG Trust Framework** *Serena Scollen, ELIXIR, 1+MG CG, B1MG Coordinator*
	15 mins	**Overview of the B1MG Maturity level model** *Astrid Vicente, INSA*
	15 mins	**1+MG/B1MG engagement with industry** *Sandra Liede, 1+MG WG7, Healthtech Finland*
1100-1115	**Coffee Break**	
First instruments for scale-up and sustainability		
1115 -1200	15 mins	**Genomic Data Infrastructure (GDI)** *Juan Arenas, ELIXIR, B1MG / GDI*
	15 mins	**European Health Data Space (EHDS)/ Joint action Towards the European Health Data Space (TEHDAS)** *Markus Kalliola, Sitra, Finland*
	15 mins	**GAIA-X** *Bert Verdonck, National Data Exchange Platform, Luxembourg*

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1200 - 1245	**Lunch break**	
Panel discussion: **Industry engagement in supporting cross border genomic data sharing:** Benefits, challenges, and risks for 1+MG/B1MG in engaging with industry		
1245-1345	1 hr	*Chair:* Sandra Liede, representing WG7, 1+MG *Co-Chair:* Ruben Kok Panellists: • Magda Chlebus, EFPIA • Julia Kurps, The Hyve Project, EHDEN • Tiffany Boughtwood, Australian Genomics • Fernando Martin-Sanchez, Instituto de Salud Carlos III
Outcome: to come up with a set of recommendations on 1. **How can stakeholders from each use case help scale up and make the work of 1+MG/B1MG in data governance, data standards and technical infrastructural aspects sustainable?** 2. **How can industry facilitate this process/ gaps industry can fill?**		
1345-1500	1 hr and 15 mins	**4 parallel breakout sessions**: **Room 1. Rare disease** Chair: Katrin Õunap, Co-Chair: Ruben **Room 2. Cancer** Chair: Giovanni Tonon, Co-chair: Astrid Vicente **Room 3. Common and complex disease + Genome of Europe** Chair: Andres Metspalu, Co-chair: Serena Scollen **Room 4. Infectious diseases** Chair: Katja J. Kivinen, Co-chair: Juan Arenas
1500-1515		**Break**
1515 - 1600		**Feed back** Breakout sessions to feed back key points from discussion to the entire forum

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1600 - 1630		**Wrap up**

Annex 2: Speakers' and panellists' biographies

Ruben Kok, The Dutch Techcentre for Lifesciences (DTL)

Biography:Dr. Ruben Kok received his PhD in microbial genetics in 1995 at the University of Amsterdam and followed his scientific career at Yale University, Gist Brocades (now DSM) and Wageningen University and Research. In 2005, dr. Kok was appointed director of the Netherlands Bioinformatics Centre (NBIC). 9 Years later, with several colleagues in the field, Ruben Kok co-founded DTL, the Dutch Techcentre for Lifesciences and became its first director. Meanwhile DTL connects over 40 public and private organisations in a national digital life sciences platform, supporting strategies towards data stewardship, data analytics and data sharing in molecular life sciences. DTL is host to the Dutch node in ELIXIR, and has been foundational for the development and global advocacy of the FAIR principles for data stewardship, later taken over by the GO FAIR initiative. Dr. Kok has co-initiated the development of Health-RI, set up to realise the national Dutch data infrastructure for health research and innovation. He is formal Board member of the Health-RI Foundation. Dr. Kok also chairs the international coordination group of the 1+ Million Genomes initiative (1+MG) since 2019. In 2020 he was appointed as coordinator of the FAIR Data pillar of the Dutch National Programme Open Science (NPOS).

Serena Scollen (1+MG Coordination, ELIXIR Hub)

Biography: Serena is the Head of Human Genomics and Translational Data at ELIXIR, the European infrastructure for bioinformatics and life-science data, based in Hinxton, UK. Her vision is to ensure data that can be shared, will be shared responsibly. She is working with scientists across Europe to establish standards and infrastructure to facilitate discoverability, access, sharing and analysis of genomics data, linked to other data types and at a scale that has not previously been achieved. Developing infrastructure will unleash new possibilities for genomics and health. Serena is the coordinator of the B1MG project, a €4M EU H2020 Coordination and Support Action and an upcoming €40M EU H2020 Genomic Data Infrastructure project that are both aligned with the 1+ Million Genomes Initiative (1+MG), which she also co-chairs. This initiative is a commitment of 24 European countries to give cross-border access to one million sequenced genomes. She is also project lead for the Innovative Medicine Initiative (IMI) FAIRplus project, an €8.3M collaboration that sets out to improve data sharing and reuse in life science research. Prior to joining ELIXIR, she was a Director within the Human Genetics and Computational Biomedicine group at Pfizer. In this role, she led and implemented a genetic and precision medicine strategy to support drug target selection and clinical programmes for the Pain and Sensory Disorders Research Unit. Earlier in her career, she worked within the Toxicogenomics group at GlaxoSmithKline. She gained postdoctoral experience at the University of Cambridge and Imperial College London and a PhD from the University of Cambridge, with a focus on the genetic susceptibility to disease.

Astrid Vicente (Instituto Nacional de Saúde Dr. Ricardo Jorge (INSA))

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Astrid M. Vicente is a senior researcher in biomedical sciences and public health, Head of the Department of Health Promotion and Non-Communicable Disease Prevention at the National Institute of Health Doutor Ricardo Jorge, in Lisbon, Portugal, and Associate Professor at the Faculty of Sciences, University of Lisbon. She holds a degree in Biochemistry and a PhD in Molecular Biology from University of Coimbra, and previously worked at the University of Coimbra and was a Genetic Epidemiology group leader at Instituto Gulbenkian de Ciência. Astrid Vicente represents the Ministry of Health of Portugal in the International Consortium for Personalised Medicine (ICPerMed) and in the European 1+Million Genomes Initiative (1+MG), and coordinates the development of the strategy for Genomic Medicine in Portugal. She served two terms as elected Vice-Chair of ICPerMed (2018-2022), is a member of the Steering Board and leader of the Working Group on Clinical Studies. She is also a member of the 1+MG Initiative Coordination Team, and leads the work package on Personalised medicine delivery, scientific and societal impact for the associated coordination and support action Beyond One Million Genomes. Her research focuses on understanding the aetiology and biological processes underlying complex non-communicable diseases, with a particular interest in pathologies of the nervous system, like Autism Spectrum Disorder. She pursues a broad perspective of interactions between factors at various levels, including genomics, lifestyle and the environment, to clarify the origins of multifactorial disorders and promote progress towards translation of knowledge into personalised medicine approaches. She previously participated in large international genomics consortia, as a lead investigator for the Autism Genome Project (AGP), and as a collaborator of the Psychiatric Genomics Consortium and the International Stroke Genetics Consortium. She has contributed extensively to the scientific literature in her research area, particularly in ASD. Currently she is very interested in promoting progress towards the implementation of personalised strategies for diagnostics, medical care and prevention in health systems, through public health policies for Personalised Medicine, and on the promotion of equitable access to Personalised Medicine for all.

Sandra Leide (1+MG WG7, Healthtech Finland)

Biography: Senior Legal Specialist, Sandra Liede, Healthtech Finland is a Finnish lawyer with wide-ranging expertise in the different areas of medical and bio law. She is professionally experienced in public policy and regulatory issues of health technology and medical devices, including software and artificial intelligence (AI), genomics, biobanking, health data processing and data governance. During her career Sandra has been involved in legislating and supervising biobanking and genomics as well as partnering with national & EU institutions and stakeholder groups on these issues. As a part of her current role at Healthtech Finland Sandra coordinates the work of an industry forum involving the main stakeholders of the genome industry in Finland.

Juan Arenas Marquez (ELIXIR Hub)

Juan is the Head of the Project Management Office at ELIXIR, the European infrastructure for bioinformatics and life-science data, based in Hinxton, UK. With a computer Science background, he worked at Accenture for twelve years, leading ICT projects for global leaders in their market and contributing to the establishment of the Spain Delivery centre in Malaga. While running his own SME providing ICT and project management services, he participated in startups and research projects with the University of Malaga and University Pompeu Fabra (Barcelona) before tacking on a CTO position for the University of Sheffield, leading ICT components of biomedical imaging research projects on dementia and musculoskeletal domains as well as in the technical development of generic federated cloud infrastructure for researchers across domains. Since joining ELIXIR, he has been acting as Head of PMO and Financial Manager, contributing to growing the ELIXIR Portfolio from €40M to €340M. He contributes to the development of the B1MG and the GDI proposal, where he will support the development, rollout and operations of the 1+MG infrastructure across 18 countries.

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Markus Kalliola (Sitra Finland)

Markus Kalliola is the project director in Health data 2030 project in The Finnish Innovation Fund Sitra and the coordinator of Joint Action Towards The European Health Data Space (TEHDAS). Prior to Sitra he worked in the European Commission in DG Health and food safety where he was responsible for cross-border healthcare IT projects. Mr. Kalliola has vast experience in data economy and in the next years he will work towards a healthier and fairer data economy for Europe as well as towards a more competitive health data ecosystem in Finland. Mr. Kalliola holds a position of trust in HMA-EMA joint big data steering group, HMA-EMA Darwin EU advisory board and DNV Digital health advisory board.

Bert Verdonck (Luxembourg Institute of Health)

Bert Verdonck has a 25+ year career in healthcare informatics and eHealth. He earned a PhD in signal and image processing from Telecom Paris and a MS in electro technical engineering of the university KU Leuven. He has a lifelong career at Philips which started in clinical software applications for radiology, cardiology and oncology. He extended experience into care solutions outside the hospital: home monitoring, regional eHealth solutions and population health management. His geographic focus has been global, including focus on North America, International markets as well as EMEA. He held positions in clinical science, advanced development, product management, marketing, sales, business transformation, software engineering and general management. Since 2020 he is an active contributor to the Gaia-X initiative, in multiple committees and working groups. From October 2022 onwards he will work for the Luxembourg government, leading a new national data sharing initiative.

Magda Chlebus (European Federation of Pharmaceutical Industries and Associations (EFPIA))

Magda Chlebus is Executive Director Science Policy & Regulatory Affairs at the European Federation of Pharmaceutical Industries and Associations (EFPIA), representing the R&D-based pharmaceutical industry in Europe. Magda and her team are in charge of following policy and legislative developments that influence the research and regulatory environments for the healthcare industry in Europe. This includes public private collaborations (inter alia the Innovative Medicines Initiative), enabling sensitive technologies and the interface between new science and technology and regulation. She joined EFPIA in 1995. Her experience covers public and government affairs mainly at EU level, on a range of legislative and non-legislative files in the area of research, development and access to medicines and enabling technologies. Magda, a Polish national, holds a Master Degree in Applied Linguistics from the University of Warsaw.

Julia Kurps (The Hyve Project - European Health Data and Evidence Network (EHDEN))

Before joining The Hyve in 2016, Julia obtained her Ph.D. in Neuroscience at the Free University of Amsterdam, where she studied exocytosis in neuroendocrine cells. Since the beginning of 2021, Julia leads the Real World Data team, focusing on streamlining the work of the teams around RADAR-base and OMOP/OHDSI. Important aspects of her role are implementation of processes, alignment of expectations and tasks of different roles and ensuring personal growth of team members. In the IMI EHDEN project, Julia co-leads the technical work package, focusing on providing the infrastructure to enable real world evidence generation across Europe.

Tiffany Boughtwood (Australian Genomics)

Tiffany Boughtwood is the Managing Director of Australian Genomics, an Australian Government initiative supporting genomic research and its translation into clinical practice through broad engagement and a collaborative national approach. Tiffany has 25 years' experience in molecular

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biology and management: leading academic and diagnostic genomic programs; collaborating internationally in genetic and genomic research; and consulting in health genomic implementation. She has served on the World Economic Forum Global Future Council for Biotechnology and the WHO Collective Global Network for Rare Disease; is an advisor to the UAE Genomic Program and is a founding Director of the Childhood Dementia Initiative.

Fernando Martin-Sanchez (Instituto de Salud Carlos III (ISCIII), 1+MG CG)

Dr. Fernando Martin-Sanchez is a research professor at the National School of Public Health of the "Carlos III" Health Institute of Spain. His field of specialisation is biomedical informatics and more specifically its application in digital health and precision medicine. From 2015 to 2017 he was Full Professor at the Division of Health Informatics at Weill Cornell Medicine and participated in the US Precision Medicine Initiative (AllofUs). Prior to this (2011-2015), he was the Chair of Health Informatics at the Melbourne Medical School and foundational Director of the Health and Biomedical Informatics Centre (HaBIC) at the University of Melbourne. He holds PhDs in Informatics and Medicine; an MSc in Knowledge Engineering and a BSc in Biochemistry and Molecular Biology. He is a Fellow of the American College of Medical Informatics (ACMI) and the Australasian College of Health Informatics (ACHI). He has served as a Vice-President of the International Medical Informatics Association (IMIA) and is an inaugural Fellow of the International Academy for Health Sciences Informatics (IAHSI). With more than 200 peer-reviewed publications (h-index:30), his research has been funded by some 40 grants from the European Commission, and main agencies from Spain, Australia and the USA.

Annex 3: Responses prior to the meeting

The following responses were gathered before the SF2022 to the question "What is needed for scale up and sustainability of the trust framework in ELSI, Data Standards and/or Technical Infrastructure)? Besides the Trust Framework, what else is needed? (For your: Stakeholder group; Country; Institution; Use case)":

- Common implementation on data management; gene testing and software medical devices, standards for clinical use and strong input to EHDS implementation acts!
- To make it sustainable we need to INVEST IN PEOPLE and actively engage policy makers and national politicians in the decision processes since the beginning.
- Citizens having access to their OWN data
- The 1+MG WG7 has done a good job in kicking off the conversation on industry engagement. The next step should be to create a permanent table for discussion!

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