Beyond One Million Genomes

D6.8 Policy briefs – 1v0

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Document History

Date	Mvm	Who	Description
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20/10/2021	0v2	Nikki Coutts (ELIXIR Hub)	Version circulated to B1MG-OG, B1MG-GB and Stakeholders for feedback
25/11/2021	0v3	Pepa López (ISCIII), Esther Rodríguez (ISCIII)	B1MG-OG, B1MG-GB and Stakeholders' comments addressed.
25/11/2021	1v0	Nikki Coutts (ELIXIR Hub)	Version uploaded to the EC Portal

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1. Executive Summary

Among 1+MG signatory countries, it is agreed to collectively develop a cohort of at least one million European citizens that have their genome determined via Whole Genome Sequencing (WGS). The goal is to make the personal genomic data and associated health information accessible in a secure manner for the different purposes in health care (prevention, diagnostics and therapy), research and innovation, and public health.

To achieve this goal, the Beyond 1 Million Genomes Project (B1MG)[1], will provide a set of recommendations for the long-term sustainability of the initiative beyond the B1MG including guidance for countries on how to **establish funding routes** to ensure the establishment and maintenance of the infrastructure to enable federated cross-border access to genomic and associated phenotypic data in the long term.

Long-term sustainability of the 1+MG initiative will require an appropriate organisational structure and plan. The Governing Board of B1MG will be crucial to this aim. Potential legal and financial frameworks for developing the initiative at national and international level will be explored together with its insertion/ institution as a major contributor to future initiatives.

Sustainability is built on the basis of four **dimensions** that we will have to consider beyond the proyect and beyond this task. This four dimensions are:

- **Financial dimension**: how the initiative will be financed at European, national, local and user level.
- **Legal dimension**: how the initiative will be used in compliance with legal and data protection standards.
- **Governance dimension**: in terms of Member States involvement and legal standing of the coordination entity for cooperation of Member States.
- **Data access dimension:** related with the governance of the data and the liability of data protection.

Also, particularly important, is that the initiative should work on establishing a **training and education plan on e-skills** for students and healthcare professionals, hospital managers and policy makers to be put in place at the same time as the infrastructure and technologies for data exchange are put in place within healthcare systems.

This **Policy Brief** is a first document (of three) that focuses on the dimensions of financial and legal aspects of sustainability and has been elaborated with main conclusions drawn from the first policy and legal context and mapping analysis.

[1] https://b1mg-project.eu/

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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	Contribute
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.	No
	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	No
	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.	No
	7. Best practices in sharing and linking phenotypic and genetic data (WP3) by M12 & M24.	No
	8. Data analysis challenge (WP3) by M36.	No
	Infrastructure Key Results	
	9. Secure cross-border data access roadmap (WP4) by M12 & M36.	No
	10. Secure cross-border data access demonstrator (WP4) by M24.	No

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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.	**Yes**
	3. Economic evaluation models for Personalised Medicine and case studies (WP5) by M30.	**Yes**
	4. Guidance principles for national mirror groups and cross-border Personalised Medicine governance (WP6) by M30.	No
	5. Long-term sustainability design and funding routes for cross-border Personalised Medicine delivery (WP6) by M34.	**Yes**

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3. Methods

For the preparation of this deliverable (Policy briefs – 1v0) 3 types of activities have been carried out:

- A **'Scoping paper for sustainability in 1+MG Initiative'**[2] (section 4.1) was prepared to decide the limits, steps to follow and methods that would be necessary in order to finally be able to establish the recommendations for the member states for the long-term sustainability of the initiative 1+MG.

- Analysis of the **Policy Framework of European priorities** in relation to the provision of cross-border Health services and access to health-related data (section 4.2).
  Namely, the place of the 1 + Million Genome Initiative within the European Health Data Space (EHDS), its development under the European Strategy for data and relevant funding opportunities such as the genomics call from Digital Europe Programme, calls connected to the Research Infrastructures programme of the Excellent Science pillar of Horizon Europe that will support the interoperability of use cases data or the opportunities within EU4Health for the sequencing effort. Also relevant is the current legal framework (GDPR, FFD, CSA, Open Data Directive, Artificial Intelligence Act[3]).

- Mapping[4] of European (and other relevant international and/or regional) programmes and initiatives related to, and with synergies with, the 1+MG initiative (section 4.3). This may include, but it will not be restricted to, the following parameters:
  - **Scope**: Line of activity/Intervention Area.
  - **Type**: Funding Programme/ Funded Project/ Infrastructure/ Service/ Political Framework/Other.
  - **Size/Dimension**: in terms of budget or another indicator.
  - **Geographical scope**: international, European, regional, other.

  This first mapping will help us to identify potential strategic alliances and gaps. It will be done in close cooperation with WP1 and partnering projects.

[2] https://docs.google.com/document/d/1zxaGUCUOUj2CFfleyfjl_sir0OlEH27l/edit
[3] Regulation (EU) 2016/679; Regulation (EU) 2018/1807; Regulation (EU) 2018/881; Directive 2019/1024; Regulation (EU) 2021/0106/COD
[4] https://docs.google.com/spreadsheets/d/16c0Vg__qe4j-8p_6ys86c4TsAjcNoc0l/edit#gid=1637622823

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4. Description of work accomplished

4.1 Scoping paper for sustainability

4.1.1 Scoping paper for sustainability in 1+MG Initiative

Background

Among 1+MG signatory countries, it is agreed to collectively develop a cohort of at least one million sequenced genomes of European citizens. The goal is to make the personal genomic data and associated health information accessible in a secure manner for the different purposes in health care (prevention, diagnostics and therapy), research and innovation, and public health.

The Beyond 1 Million Genomes Project (B1MG) will elaborate and propose potential governance and operational models for engagement and participation (e.g. for accessing/giving access to data). To this aim, it is essential to take into account the training requirements for infrastructure users, risk management, intellectual property models, citizen trust and sustainability. Continuous reflection on Use Cases (cancer, rare diseases, pharmacogenomics and infectious diseases) will ensure that the recommended infrastructure will have added value and impact. It will be essential to map the maturity of the healthcare systems and develop a roadmap to implement genomic information in healthcare (considering the specificities of each country), using a stepwise framework and a B1MG Maturity Level Model tool for healthcare systems. A harmonised methodology for economic evaluation of the cost and benefits of implementing Personalised Medicine, including a societal perspective, **will be key for informing sustainability options,** as well as the establishment of national mirror groups to coordinate implementation at a national level.

Scope and objectives

B1MG will provide a set of recommendations for the long-term sustainability of the initiative beyond the B1MG including guidance for countries on how to **establish funding routes** to ensure long term access to personalised medicine **cross-borders**.

Long-term sustainability of the 1+MG initiative will require an appropriate organisational structure and plan. The Governing Board of B1MG will be crucial to this aim. Potential legal and financial frameworks for developing the initiative at national and international level will be explored together with its insertion/ institution as a major contributor to future initiatives.

In this context, the project The Genome of Europe (GoE) is of great importance. The final goal of GoE is to build a high-quality European network of national genomic reference cohorts of at least 500,000 citizens, selected to be representative of the European population in 2022, with prospective data that will adhere to 1+MG standards. It will be important to consider this achievement of the GoE with the sustainability and expansion of this cohort in the long term by European countries.

One of the key aspects of sustainability for the 1+MG infrastructure is the definition of roles for stakeholders. Infrastructure of 1+MG is aiming to be a platform where researchers and medical practitioners could go and launch a query where to be sent some research questions to get value-added answers to apply to them in clinical practice. Having this in mind, it is important to take into account that collaboration and feedback of working groups dedicated to infrastructure

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(WG5), to implementation of healthcare (WG6) and to use cases (WG8-12) are crucial to develop this task in a proper way. It is also important to consider that this infrastructure will be used by different stakeholder that, in a first approach, can be divided into:

- **Data users**: as the actors who use this infrastructure (researchers, medical practitioners, etc.
- **Data Providers**: as the actors who provide data itself.
- **Platform managers**: as the actors who manage the data and the infrastructure and carry the liability and quality of analysis for the data.

The key questions on this relationship could include :

- Are the users expected to **pay for the use** of services after their construction?
- Are the service providers allowed to consume their own service capacity?
- How are common service access policies decided between the multiple signatory countries and European Commission?

These and other relevant questions need to be answered in the foreseeable (federated) framework. Financial transactions between the stakeholders will define the future sustainability prediction for the operational infrastructure services. A separately budgeted development programme of the integrated solutions can progress using public competitions (e.g. Horizon Europe, Digital Europe Programme, EU4Health), but, since the production cost and future value of the accumulated harmonised data is high, service operations making the data available in the 1+MG federation will have to be protected with multi-country contracts.

Within this frame, the sustainability task will map potential transitional routes towards the final infrastructure set-up and operation.

Working Plan

The work has been divided in gradual steps, as follows:

Step 1- The Policy Framework

Analysis of the current status of European priorities in relation to the provision of cross-border Health services and access to health-related data. Namely, the place of the 1 + Million Genome Initiative within the European Health Data Space (EHDS), its development under the European Strategy for data and relevant funding opportunities as the genomics call from Digital Europe Programme, calls connected to the Research Infrastructures programme of the Excellent Science pillar of Horizon Europe that will support the interoperability of use cases data or the opportunities within EU4Health for the sequencing effort. Also relevant is the current legal framework (GDPR, FFD, CSA, Open Data Directive, Artificial Intelligence Act).

Step 2 - Mapping of European (and other relevant international and/or regional) programmes and initiatives. This mapping exercise may include, but it will not be restricted to, the following parameters:

- Scope: Line of activity/Intervention Area.
- Type: Funding Programme/ Funded Project/ Infrastructure/ Service/ Political Framework/Other.
- Vision: short/medium/long term goals.
- Size/Dimension: in terms of budget or another indicator.
- Geographical scope: international, European, regional, other.

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This first mapping will help us to identify potential strategic alliances and gaps. It will be done in close cooperation with WP1 and partnering projects.

A first Policy Brief will be prepared with main conclusions drawn from the policy analysis.

Step3- Connection with the Maturity Level Model.

If the aim of the Maturity Level Model is to provide practical guidance on the steps required for an organisation to engage with the federated secure cross-border infrastructure to access personalised medicine data at local, regional, national and European level, the sustainability briefs should serve as a complement to identify potential funding routes and/or investment needs.

Step 4- Set of Recommendation both to the EC and Member States on how to fill in funding and implementation gaps, identifying potential funding routes and/or investment models.

These recommendations may include:

- Investment needs.
- Infrastructure needs.
- Training needs.
- Citizens engagement.
- Timeline.
- Governance & Cost Models.
- Potential Funding Routes.

4.2 The Policy and Legal Context

4.2.1 Policy Priorities[5]

4.2.1.1. Transformation of Digital Health and Care[6]

2018 Communication on Digital Health and Care[7]

The **Commission's Communication on the Transformation of Digital Health and Care[8]** of April 2018 aims to enhance the digitisation of the health and care sectors.

The Communication identifies 3 pillars around which activities will be based:

Pillar 1: Secure data access and sharing

To facilitate greater access to cross-border healthcare, the Commission is building the eHealth Digital Service Infrastructure to allow **e-prescriptions** and **patient summaries to** be **exchanged** between healthcare providers. The first cross-border exchanges started in 2019, with the goal of having all the other EU countries on board by 2025. In the longer term, the Commission is working towards establishing a European electronic **health record exchange format that is accessible to all EU citizens**.

[5] https://ec.europa.eu/health/ehealth/home_en
[6] https://ec.europa.eu/health/ehealth/home_en
[7] https://ec.europa.eu/health/ehealth/home_en
[8] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2018:233:FIN

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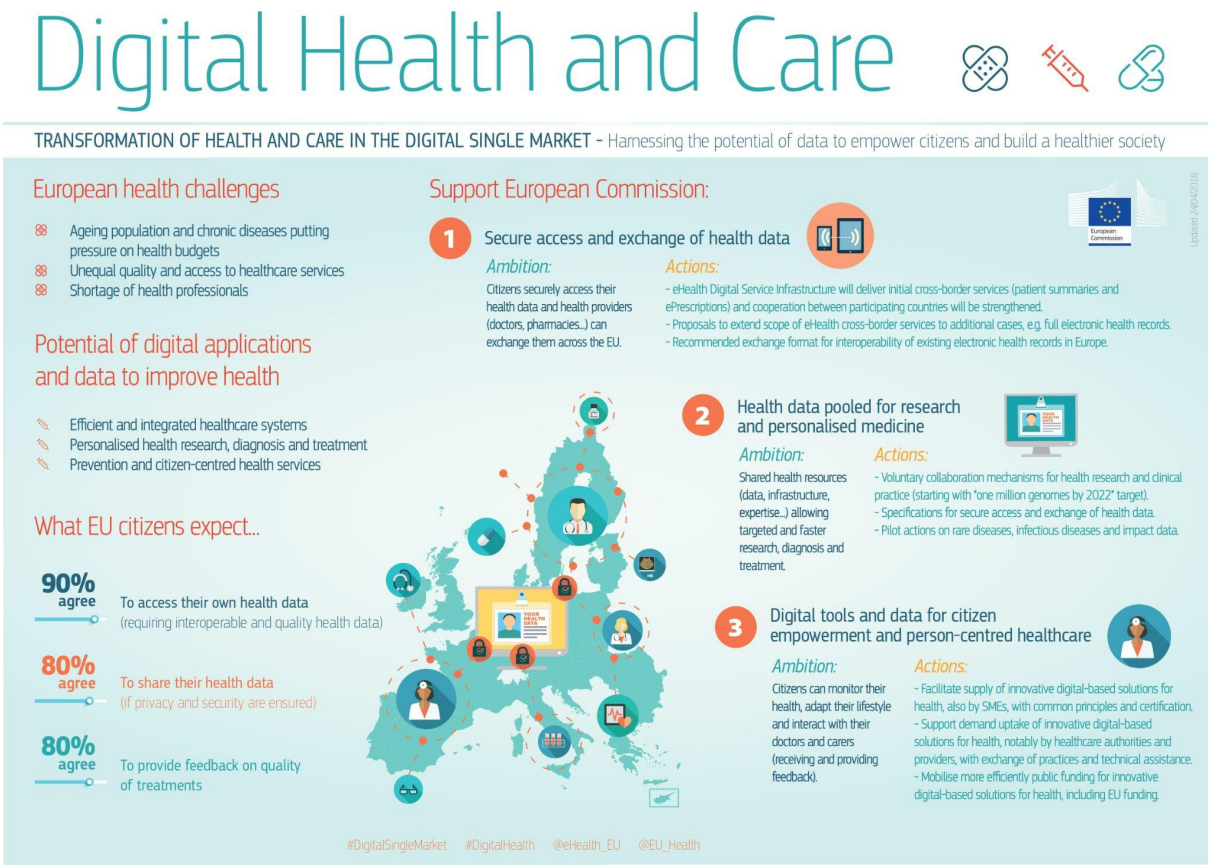

Figure 1. Infographics on Digital health and care.(Source: European Commission)[9]

Pillar 2: Connecting and sharing health data for research, faster diagnosis and improved health

This pillar intends to tap into the huge potential of health data to support medical research with the aim of improving prevention, diagnosis, treatments, drugs and medical devices.

The Commission will, while ensuring full compliance with data protection legislation and ethical principles also:

- Set up a mechanism for the voluntary **coordination** of authorities and other stakeholders **to share data and infrastructure** for prevention and personalised medicine research
- Support the **development of technical specifications for secure access and cross-border** exchange of genomic and other health datasets to facilitate **interoperability** and to support **personalised medicine research**.
- Launch **pilot actions** to demonstrate the benefits of advancing research, disease prevention, personalised medicine and health technology assessment.
- Support all the above by **mobilising funds** from Horizon Europe and the Connecting Europe Facility within the current envelopes, and consider **further support** from the next multi-annual financial framework.

[9] https://ec.europa.eu/health/sites/health/files/ehealth/docs/2018_ehealth_infographic_en.pdf

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Pillar 3: Strengthening citizen empowerment and individual care through digital services

Digital services can empower citizens, making it easier for them to take a greater role in the management of their own health. Health systems will also benefit from innovative care models that use telehealth and mHealth to address the rising demand for healthcare, **helping to shift progressively towards integrated and personalised care systems**.

4.2.1.2. '1 + Million Genomes' Initiative

2018 Declaration of Cooperation **'Towards access to at least 1 million sequenced genomes in the European Union by 2022'**[10]

The Declaration on genomics cooperation, 'Towards access to at least 1 million sequenced genomes in the EU by 2022'[11], was launched on Digital Day 2018 and was signed by 22 EU countries, the UK and Norway (currently already signed by 24 countries). From the signing of the declaration came the **'1 + Million Genomes' Initiative (1+MG)** where a collaborative mechanism was established with the potential to improve disease prevention, enable more personalised treatments and provide sufficient scale for new clinical practices.

The initiative is open to countries of the European Economic Area and the European Free Trade Association and **it is part of the EU's agenda for the Digital Transformation of Health and Care**.

This cooperation mechanism is supported and facilitated by the European Commission, which works closely with the Member States in order to ensure that in 2022 there will be at least a cohort of 1 million sequenced genomes accessible for research and personalised medicine in the EU.

The signatory countries had their kick-off meeting on 21 September 2018 in Brussels. Since then, they meet regularly with each other and in 11 specialised working groups to make sure that **by 2022 there will be a research cohort of at least 1 million sequenced genomes accessible in the EU**.

In late 2020, the Commission created a **special expert group (1+MG Group[12])** with a view to formalising and facilitating the cooperation and coordination at the level of national representatives of the signatory countries. The group is co-chaired by the Commission and an EU country representative.

4.2.1.3. Europe's Digital Decade

"A Europe fit for the digital age" is one of the six political priorities of the Commission for the period 2019-2024. The Digital Transition[13] should be something that benefits everyone, putting people first and opening new opportunities for business. In this sense, **health is one of the sectors included in this agenda**, given the potential benefits that digital services have to offer citizens and enterprises in this area.

[10] https://digital-strategy.ec.europa.eu/en/policies/1-million-genomes
[11] https://digital-strategy.ec.europa.eu/en/news/eu-countries-will-cooperate-linking-genomic-databases-across-borders
[12] https://digital-strategy.ec.europa.eu/en/policies/1mg-group
[13] Shaping Europe's digital future

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Indeed, the **Europe's Digital Decade Political Programme** envisions that, by 2030, 100% of citizens will have access to medical records through the electronic health records (EHR) and that the forthcoming "European Health Data Space" will help to achieve this objective.

The **European Strategy for Data** foresees the creation of such **"European Health Data Space"** [14] to foster targeted research, diagnosis and treatment.

As a key pillar of the European strategy for data[15], the Data Governance Act will increase trust in data sharing, strengthen mechanisms to increase data availability and overcome technical obstacles to the reuse of data.

We cannot ignore the fact that genomics has the potential to revolutionise healthcare in many ways. It could lead to the development of more targeted personalised medicines, therapies and interventions. It could also enable better diagnostics, boost prevention and make more efficient use of scarce resources. From cancer to rare diseases to neurodiseases and prevention, genomics can greatly improve health conditions of EU citizens.

Equally important, genomics has the potential to improve the effectiveness, accessibility, sustainability and resilience of health systems in the European Union.

4.2.1.4. Europe's Beating Cancer Plan[16]

On **World Cancer Day 2021**, the European Commission is presenting **Europe's Beating Cancer Plan**[17] – a main priority in the area of health of the von der Leyen Commission and a key pillar of a strong **European Health Union**[18].

With new technologies, research and innovation as the starting point, the Cancer Plan sets out a new EU approach to cancer prevention, treatment and care. It will tackle the entire disease pathway, from prevention to quality of life of cancer patients and survivors, focusing on actions where the EU can add the most value.

Europe's Beating Cancer Plan will be supported by actions spanning across policy areas from employment, education, social policy and equality, through marketing, agriculture, energy, the environment and climate, to transport, cohesion policy, and taxation.

The Cancer Plan is structured around **four key action areas** (prevention, early detection, diagnosis and treatment and improvement of quality of life) with 10 flagship initiatives and multiple supporting actions[19].

It will be implemented using the whole range of Commission funding instruments, with a total of €4 billion being earmarked for actions addressing cancer, including from the EU4Health programme, Horizon Europe and the Digital Europe programme.

[14] https://ec.europa.eu/health/ehealth/dataspace_en
[15] https://digital-strategy.ec.europa.eu/en/policies/strategy-data
[16] https://ec.europa.eu/commission/presscorner/detail/en/ip_21_342
[17] https://ec.europa.eu/health/sites/default/files/non_communicable_diseases/docs/eu_cancer-plan_en.pdf
[18] https://ec.europa.eu/commission/presscorner/detail/en/ip_20_2041
[19] https://ec.europa.eu/commission/presscorner/detail/en/fs_20_341

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4.2.2 EU cooperation[20]

Although the development and deployment of eHealth solutions in healthcare systems is a national competence, **the EU is committed to providing support through funding and platforms where EU countries can collaborate on eHealth-related issues (including genomic data)**. Some aspects like interoperability or **quality standards are addressed at European level** through coordinated action and digital alignment.

4.2.2.1 Policy Cooperation Platforms

Several structures provide a platform for collaboration and cooperation:

- The eHealth Network[21] set up under Directive 2011/24/EU on patients' rights in cross-border healthcare connects national authorities responsible for eHealth. Through this voluntary network, EU countries can give direction to eHealth developments in Europe and help shape policy on eHealth interoperability and standardisation. The eHealth Network's activities are based on priorities set out in its **2018-2021 Multiannual Work Plan (MWP)[22]**.

- The **Joint Action supporting the eHealth Network**, called eHAction[23] (eHealth Action), was launched in 2018. Its primary aims are to support the eHealth Network with technical and scientific advice, to facilitate cross-border healthcare across the EU and to provide the necessary policy support to the eHealth Digital Service infrastructure (eHDSI). It is financed through the EU Health Programme with the expressed goals of:
  - empowering people
  - contributing to the innovative use of health data
  - enhancing continuity of care
  - overcoming implementation challenges

- The **eHealth stakeholder group** (eHSG) is composed of representatives of European umbrella organisations/associations or organisations with a European outreach in the fields of research, industry, standardisation and associations representing users (patients, professionals, providers etc.) active in the eHealth sector. Its primary objective is to contribute to the development of eHealth policy at EU level. Established in 2012 and with a **mandate until the end of 2022**, it has 30 members.
  European cooperation is currently being developed in the following technical areas, with the purpose of promoting the benefits and added value of digital health in concrete operational fields:
  - Setting-up of the eHealth Digital Service Infrastructure for the cross-border exchange of health data, to allow continuity of care for citizens when they travel abroad in the EU
  - Setting-up of the European Health Data Space to allow the secure use of health data to support delivery of care, research and policy making

- The **Joint Action (JA) for the European Health Data Space**, called **TEHDAS** (Towards the European Health Data Space) was launched in 2021. It brings together 26 European countries (22 EU Member States and 4 other European countries). This JA will support the Commission's work on the European Health Data Space by:
  - bringing together actors relevant to the use of health data for research and policy making (**secondary use of data**) in the EU

[20] https://ec.europa.eu/health/ehealth/cooperation_en
[21] https://ec.europa.eu/health/ehealth/policy/network_en
[22] Multi Annual Work Programme (MWP) 2018-2021
[23] http://ehaction.eu/

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- collecting the best practice available in the EU on the **secondary use of data**
- developing concepts and options necessary for efficient **secondary use of health data**

These concepts and options will focus on governance, data quality, infrastructure and empowering citizens with regards to secondary health data use in the EU. The Joint Action is set up under the Third EU Health Programme.

4.2.2.2 Commision Special Group on Genomics

- **Special Group "Signatories of the Declaration «Towards access to at least 1 million sequenced genomes in the EU by 2022»" ("1+MG Group")[24].** On 6 June 2020, the signatories' countries of Declaration endorsed the proposal to reinforce the strategic layer of 1+MG by transforming the signatories' meetings into a more formal group with well-defined terms of reference and rules of procedure and a balanced representation of all signatory and observer countries. Subsequently, on 30 July, the Commission created the **Special Group "Signatories of the Declaration «Towards access to at least 1 million sequenced genomes in the EU by 2022»" ("1+MG Group")**. The group's mandate shall be to:
  (a) ensure good coordination and cooperation between the Commission and Member States on the implementation of the 1+MG Declaration;
  (b) build consensus and commitment among the signatory countries as regards the formulation and implementation of strategic choices/orientations related to the priorities and actions outlined in the 1+MG Declaration;
  (c) endorse/give feedback on the outcomes and outputs of the work in the operational/expert layer (1+MG working groups);
  (d) formulate strategic steer to the operational/expert layer working on the detailed aspects of the implementation of the 1+MG Declaration;
  (e) occasionally, advise the Commission on policies, legislative proposals and other instruments or regulatory frameworks related to genomic data.
  The group is **co-chaired** by the Commission and an EU signatory country representative.

4.2.2.3 Funding Programmes

- **Horizon Europe**[25]: is the ambitious EU research & innovation framework programme for 2021-2027 with a budget of €95.5 billion. Its overarching goals are:
  - ➢ to strengthen the EU's scientific and technological bases and the European Research Area (ERA);
  - ➢ to boost Europe's innovation capacity, competitiveness and jobs;
  - ➢ to deliver on citizen's priorities and sustain our socio-economic model and values.
  - ➢ with a particular focus on creating impact or the European Green Deal, the digital and sustainability transition and recovery from the coronavirus-crisis.

  Of particular importance are the **Missions** which set out measures to achieve bold, inspirational and measurable goals within a set timeframe. There are 5 main mission areas as part of Horizon Europe (with a particular relevance in this scope the **Cancer Mission**[26]).
- **Digital Europe programme**: is a new EU funding programme for the period 2021-2027 focused on bringing digital technology to businesses, citizens and public administrations. provides funding for projects in five crucial areas:

[24] https://digital-strategy.ec.europa.eu/en/policies/1mg-group
[25] https://ec.europa.eu/info/research-and-innovation/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe_en
[26] https://ec.europa.eu/info/research-and-innovation/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/missions-horizon-europe/cancer_en

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➢ supercomputing
➢ artificial intelligence
➢ cybersecurity
➢ advanced digital skills
➢ ensuring the wide use of digital technologies across the economy and society

The programme is **designed to bridge the gap between digital technology research and market deployment**. It will benefit Europe's citizens and businesses, especially SMEs. Investment under the Digital Europe Programme supports the European Union's twin objectives of a green transition and digital transformation while strengthening the Union's resilience and digital sovereignty.

4.2.3 Ethical & Legal Aspects[27]

The European Commission sponsored two studies on **telemedicine**[28] and **big data**[29] to guide policies on digital health and care.

The proposed Regulation on data governance[30] (**Data Governance Act**[31]), adopted by the Commission on 25 November 2020, aims to boost data sharing across sectors and Member States.

The data governance act will also support the set-up and development of common European data spaces in strategic domains, involving both private and public players, enabling cross-border data use within the Union and the emergence of data pools covering several Member States (such as the European Health Data Space). It is worth mentioning that both healthcare and scientific research are highlighted in the text as general interest purposes for which there is a strong potential in the use of data made available voluntarily by data subjects.

The Commission has also commissioned a study for an **"Assessment of the EU countries' rules on health data in the light of GDPR"**[32]. The study provides a mapping of how the **GDPR is implemented in the health sector in the different countries**. It also gives an overview of the legal and technical modalities in place in the EU countries to share health data as well as the governance mechanisms established to facilitate third parties' access to health data for its re-use.

The EC is also conducting a study on regulatory gaps, aimed at identifying barriers to the provision of digital health services, the use of Artificial Intelligence in health with a particular focus on liability and the use of health data. The study also looks at Article 14 of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.

Also to consider are the following regulations related to legal aspects of data processing:

- **Regulation (EU) 2016/679** of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on

[27] https://ec.europa.eu/health/ehealth/cooperation_en
[28] Market study on telemedicine
[29] Study on Big Data in public health, telemedicine and healthcare
[30] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020PC0767
[31] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020PC0767
[32] Assessment of the EU countries' rules on health data in the light of GDPR

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the free movement of such data, and repealing Directive 95/46/EC (**General Data Protection Regulation**)[33]

- **Regulation (EU) 2018/1807** of the European Parliament and of the Council of 14 November 2018 on a **framework for the free flow of non-personal data** in the European Union[34]
- **Council Decision (EU) 2018/881** of 18 June 2018 requesting the Commission to submit a **study on the Union's options for addressing the findings of the Aarhus Convention Compliance Committee in case ACCC/C/2008/32** and, if appropriate in view of the outcomes of the study, a proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1367/2006[35]
- **Directive (EU) 2019/1024** of the European Parliament and of the Council of 20 June 2019 on **open data and the re-use of public sector information**[36]
- **COM (2021) 206**: Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL LAYING DOWN HARMONISED RULES ON ARTIFICIAL INTELLIGENCE (**ARTIFICIAL INTELLIGENCE ACT**) AND AMENDING CERTAIN UNION LEGISLATIVE ACTS[37]

4.2.4 Capacity building and Digital skills[38]

The Commission strives to support building Member State capacity in the use of new technologies, such as telehealth and Artificial Intelligence and to help optimise their health systems through the development of indicators and benchmarking, and short term peer reviews/twinnings. As an important part of the digitalisation of the health and care sector, the Commission is working with EU countries to provide digital skills training and education, including upskilling, reskilling and opportunities for knowledge sharing, to students and health care professionals, hospital managers and policy makers.

Both Digital Europe and EU4Health will fund the design and delivery of specialised programmes and traineeships for future experts in key capacity areas.

In particular, the Digital Europe work programme for 2021-2022 includes €166 million for actions related to advanced digital skills in key capacity areas through specialised education programmes and other actions; also EU4Health. Horizon Europe at its turn, has some programmes, such as MSCA that could also partially cover these training needs, although RIAs & CSAs do not include, in general terms, training or upskilling activities.

It is still not clear how or which of these funds could benefit the future of the initiative. Also the skill portfolio is still to be defined. In this regard, 1+MG initiative should work on establishing a training and education plan on e-skills for students and healthcare professionals, hospital managers and policy makers to be put in place at the same time as the infrastructure and technologies for data exchange are put in place within healthcare systems.

4.3 Mapping of programmes and initiatives

4.3.1 European Programmes and Partnerships

As the purpose of this document is to identify potential funding routes for the future, this section refers only to programmes corresponding to the new MFF 2021-2027 or initiatives with funding

[33] https://eur-lex.europa.eu/eli/reg/2016/679/oj
[34] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32018R1807
[35] https://eur-lex.europa.eu/eli/dec/2018/881/oj
[36] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2019.172.01.0056.01.ENG
[37] https://eur-lex.europa.eu/procedure/EN/2021_106
[38] https://ec.europa.eu/health/ehealth/cooperation_en

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still to be committed. In that regard, the main **European Programmes** relevant for 1+MG initiative are:

Programme	Scope	Principal organization	Budget	Sources of funding	Geographical Scope
Digital Europe programme (DIGITAL)[39]	EU's programme to accelerate the recovery and drive the digital transformation of Europe. The programme will boost investments in supercomputing, artificial intelligence, cybersecurity, advanced digital skills, and ensure a wide use of digital technologies across the economy and society, including through Digital Innovation Hubs.	EC	€7.6 billion	MFF	European
Connecting Europe Facility (CEF2)[40]	aims to support and catalyse investments in digital connectivity infrastructures of common interest, during the period 2021-2027. CEF2 Digital will deliver important contributions to the Union's strategic connectivity objectives as well as to the President Von der Leyen's policy goals, specifically: "A Europe fit for the digital age", "A European Green Deal" and "An economy that works for people".	EC	€2.07 billion	MFF	European
Horizon Europe[41]	the research and innovation framework programme running from 2021-2027	EC	€95.5 billion	MFF	European
EU4Health[42]	EU4Health will: • boost EU's preparedness for major cross border health threats by creating • strengthen health systems so that they can face epidemics as well as long-term challenges by stimulating • make medicines and medical devices available and affordable, advocate the prudent and efficient use of antimicrobials as well as	EC	€5.1 billion	MFF	European

[39] https://ec.europa.eu/digital-single-market/en/europe-investing-digital-digital-europe-programme
[40] https://digital-strategy.ec.europa.eu/en/library/connecting-europe-facility-cef2-digital-draft-orientations-towards-implementation-roadmap
[41] https://ec.europa.eu/info/horizon-europe_en
[42] https://ec.europa.eu/health/funding/eu4health_en

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	promote medical and pharmaceutical innovation and greener manufacturing. • Our work on urgent health priorities such as the fight against cancer, reducing the number of antimicrobial-resistant infections and improving vaccination rates will also be boosted. • The EU will expand successful initiatives like the European Reference Networks for rare diseases and continue to pursue international cooperation on global health threats and challenges.				

The main **European Partnerships** relevant for 1+MG initiative are:

European Partnership	Scope	Principal organization	Budget	Sources of funding	Geographical Scope
Innovative Health Initiative (IHI)[43]	The partnership intends to • create an EU-wide health research and innovation ecosystem that facilitates translation of scientific knowledge into innovations • foster the development of safe, effective, people-centred and cost-effective innovations that respond to strategic unmet public health needs currently insufficiently served by industry • drive cross-sectoral health innovation for a globally competitive European health industry. It will cover prevention, diagnostics, treatment and disease management.	tbd	tbd	HE and industry	European
Health and Care Systems Transformation[44]	The partnership aims to contribute to the transition towards more sustainable, resilient, innovative and high-quality people-centred health and care systems. It will pool a critical mass of European, national and regional scientific resources to more	tbd	tbd	HE	European

[43] https://ec.europa.eu/info/files/european-partnership-innovative-health_en
[44] https://ec.europa.eu/info/files/european-partnership-health-and-care-systems-transformation_en

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	efficiently address similar challenges related to health and care systems transformation. As a result, the context relevant evidence will meet the needs of national/regional health and care systems by facilitating the transfer and uptake of cost-effective technological, service, organisational and policy innovations.				
Rare Diseases[45]	The partnership will coordinate national, local and European research and innovation programmes, combining research funding and implementation of research supportive activities such as training, data access infrastructures, data standards etc. The main goal is to improve the life of patients with rare diseases by developing diagnostics and treatments for rare diseases through multidisciplinary research and innovation programmes with all relevant stakeholders. This will increase impact and uptake of research results as well as increase the visibility of EU leadership in rare diseases research.	tbd	tbd	HE	European
Personalised Medicine[46]	The partnership aims to coordinate research in personalised medicine between the EU, EU countries and regions. Aims • faster uptake of research and innovation results into clinical practice, secure Europe's position in state-of-the-art healthcare provision • facilitate a shift from a 'one size fits all' approach towards taking into account individual differences and better utilising the accumulating data to manage health, disease and its predisposition • sustainable health systems	tbd	tbd	HE	European

[45] https://ec.europa.eu/info/files/european-partnership-rare-diseases_en

[46] https://ec.europa.eu/info/files/european-partnership-personalised-medicine_en

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	and independence in data intensive healthcare				
EOSC Partnership [47]	The partnership will enable a trusted, virtual, federated environment in Europe to store, share and re-use research data across borders and scientific disciplines. Besides, it will bring together institutional, national and European initiatives and engage all relevant stakeholders to co-design and deploy a European Research Data Commons where data are Findable, Accessible, Interoperable, Reusable (FAIR).	EOSC Association and EC	€1 billion (co-investment) to 2021-2027.	MS and AC	International
EJP RD[48]	The European Joint Programme on Rare Diseases (EJP RD) sets out to improve the integration, the efficacy, the production and the social impact of research on RD through the development, demonstration and promotion of Europe/world-wide sharing of research and clinical data, materials, processes, knowledge and know-how	INSERM	€100 million	H2020-Co funded	European
ERA PerMed [49]	ERA-Net Cofund, supported by 32 partners from 23 countries and cofunded by the European Commission. To align national research strategies, promote excellence, reinforce the competitiveness of European players in PM, and enhance the European collaboration with non-EU countries, national funding organisations have agreed to launch Joint Transnational Calls for collaborative innovative research projects in Personalised Medicine (PM).	ISCIII	€32 million	H2020	European

[47] https://eosc-portal.eu/news/european-commission-enters-partnership-eosc-association
[48] https://www.ejprarediseases.org/
[49] https://erapermed.isciii.es/

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4.3.2 Initiatives

The main **Initiatives** relevant for 1+MG initiative are:

Initiative	Scope	Principal organization	Budget	Sources of funding	Geographical Scope
European Health Data Space (EHDS)[50]	The European health data space will: • promote safe exchange of patients' data (including when they travel abroad) and citizens' control over their health data • support research on treatments, medicines, medical devices and outcomes • encourage the access to and use of health data for research, policy-making and regulation, with a trusted governance framework and upholding data-protection rules • support digital health services • clarify the safety and liability of artificial intelligence in health.	EC	tbd	**EU Level:** EU4Health, HE, DEP **National level:** RRF, ERDF, ESF, InvestEU.	European
Cancer Mission[51]	Targets by 2030: more than 3 million lives saved, living longer and better, achieve a thorough understanding of cancer, prevent what is preventable, optimise diagnosis and treatment, support the quality of life of all people exposed to cancer, and ensure equitable access to the above across Europe.	EC	~€125.65 million* (2021-2022)	HE	European
Europe's Beating Cancer Plan[52]	The Cancer Plan sets out a new EU approach to cancer prevention, treatment and care. It will tackle the entire disease pathway, from prevention to quality of life of cancer patients and survivors, focusing on actions where the EU can add the most value.	EC	€4 billion	EU4Health Programme HE DEP	European
Genome of Europe[53]	Multi-country project brings together European countries to build a high-quality European network of national genomic reference cohorts of at least 500.000 citizens, selected to be	1+MG signatory countries	tbd	RRF, tbd	European

[50] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12663-A-European-Health-Data-Space
[51] https://ec.europa.eu/info/horizon-europe/missions-horizon-europe/cancer_en
[52] https://ec.europa.eu/commission/presscorner/detail/en/IP_21_342
[53] https://digital-strategy.ec.europa.eu/en/policies/1-million-genomes#:~:text=The%20Genome%20of%20Europe%20is,representative%20of%20the%20European%20population

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	representative for the European population by 2022				
European Research Networks (ERNs)[54]	Virtual networks involving healthcare providers across Europe. They aim to facilitate discussion on complex or rare diseases and conditions that require highly specialised treatment, and concentrated knowledge and resources.	Member States	-	EU4Health, CEF, Horizon Europe	European
ICPerMed 'Family'[55]	The ICPerMed international consortium is an effort to support synergies and align and encourage efforts in Personalised Medicine research, funding and implementation across the whole healthcare value chain developing strategic publications, providing a forum to explore policy recommendations and promoting joint initiatives. ICPerMed works in close collaboration with ERA PerMed, several CSAs funded by the European Commission (SAPHIRe, Regions4PerMed, EULAC PerMed, SINO-EU PerMed, EU-Africa PerMed, PERMIT, HEco PerMed), as well as with an increasing number of associated and related initiatives, research infrastructures and capacities. This so-called **ICPerMed 'Family'** has an important role in supporting the research and implementation of personalised medicine in Europe and beyond.	DLR Project Management Agency (as coordinator of ICPerMed project)	**ICPerMed**: €2 M **ERA PerMed**: €32 M **SAPHIRe**: €2 M **Regions4PerMed**: €2 M **EULAC PerMed**: €2 M **SINO-EU PerMed**: €2 M **EU-Africa PerMed**: €2 M **PERMIT**: €2 M **HEco PerMed**: €2 M **TOTAL: €48 M**	H2020	International

4.3.3 Infrastructures and Platforms

The main **Platforms** relevant for 1+MG initiative are:

Platform	Scope	Principal organization	Budget	Sources of funding	Geographical Scope
Clinical Patient Management System (CPMS)[56]	Is a secure Software as a Service (SaaS) that enables health professionals to enroll patients using comprehensive data models. Health professionals can use the CPMS to collaborate actively and	ERN	-	Co-financed - CEF	European

[54] https://ec.europa.eu/health/ern_en
[55] https://www.icpermed.eu/en/related-initiatives.php
[56] https://cpms-training.ern-net.eu/login/?next=/insight/

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	share patient within and across ERNs				
COVID-19 Data Portal[57]	To facilitate data sharing and analysis in order to accelerate coronavirus research	EBI	-	tbd	European

The main **Infrastructures** relevant for 1+MG initiative are:

Infrastructure	Scope	Principal organization	Budget	Sources of funding	Geographical Scope
eHealth Digital Service Infrastructure (eHDSI)[58]	infrastructure ensuring the continuity of care for European citizens while they are travelling abroad in the EU. This gives EU countries the possibility to exchange health data in a secure, efficient and interoperable way. Citizens can easily recognise the availability of the services under the brand "MyHealth @ EU".	EC	€35 million	Variety of different programmes, such as CEF and (INTERREG)	European
Testing and experimentation facilities for artificial intelligence (TEFs)[59]	To provide a common, highly specialised resource to be shared at European level and foster the deployment of trustworthy AI in the following areas: 1) a common European platform to design and manufacture edge intelligence components and systems based on neuromorphic and quantum technologies 2) reference sites for applications in essential sectors such as health, agri-food, manufacturing, smart cities and smart mobility (including environment and climate perspective).	EC - Work Programme DEP	-	DEP	European
BBMRI-ERIC[60]	European research infrastructure for biobanking. We bring together all the main players from the biobanking field –	-		MS	European

[57] https://www.covid19dataportal.org/
[58] https://ec.europa.eu/health/ehealth/electronic_crossborder_healthservices_en
[59] https://ec.europa.eu/information_society/newsroom/image/document/2020-19/200507_workshop_report_tef_edge_public_version_50D5372E-0FEC-8D05-E7F7B1E31DD0390F_66635.pdf
[60] http://www.bbmri-eric.eu/

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	researchers, biobankers, industry, and patients – to boost biomedical research.				
EATRIS[61]	EATRIS is the European infrastructure for translational medicine. To bring resources and services for research communities to translate scientific discoveries into benefits for patients.	-	€2.5 million (2020 revenue)	MS	European
ECRIN[62]	ECRIN is a public, non-profit organisation that links scientific partners and networks across Europe to facilitate multinational clinical research. We provide sponsors and investigators with advice, management services and tools to overcome hurdles to multinational trials and enhance collaboration.	-	€4.2 million (2020 revenue)	MS	European
ELIXIR[63]	Managing and safeguarding the increasing volume of data being generated in LS by publicly funded research. Including a specific Human Genomic and Translational Data Programme.	ELIXIR Hub	€7.3 million	MS	European

4.3.4 Policy Organisations

The main **Policy Organisations** relevant for 1+MG initiative are:

Policy Organisation	Scope	Principal organization	Budget	Sources of funding	Geographical Scope
GA4GH[64]	Policy-framing organisation creating open standards to enable responsible genomic data sharing within a human rights framework.	-	-	-	International
RDA Alliance[65]	Social platform where international research data experts meet to exchange views and to agree on topics including social hurdles on data sharing, education and training	Research Data Alliance (RDA) Foundation	-	-	International

[61] https://eatris.eu/
[62] https://www.ecrin.org/
[63] https://elixir-europe.org/
[64] https://www.ga4gh.org/
[65] https://www.rd-alliance.org/rda-europe

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	challenges, data management plans and certification of data repositories, disciplinary and interdisciplinary interoperability, as well as technological aspects.				
ESHG[66]	The European Society of Human Genetics is a non-profit organization that promotes research, facilitates communication and encourages best practice in applications of human and medical genetics, particularly in Europe.	-	-	-	European

4.3.4 Projects

Some examples of **Projects** relevant for 1+MG initiative are:

Project	Scope	Principal organization	Budget	Sources of funding	Geographical Scope
EUSTANDS4PM[67]	Project to establish a European standardisation framework for data integration and data-driven in silico models for personalised medicine	FORSCHUNG SZENTRUM JULICH GMBH	€2 million	H2020	European
CINECA[68]	CINECA project aims to build towards a platform for cohort level federated genetic discovery and analysis (Common Infrastructure for National Cohorts in Europe, Canada and Africa).	EUROPEAN MOLECULAR BIOLOGY LABORATORY	€6.6 million	H2020	International
EUCANCan[69]	EUCANCan project aims at enhancing modern oncology, by implementing a cultural, technological and legal integrated framework across Europe and Canada, to enable and facilitate the efficient analysis, management and sharing of cancer genomic data.	BSC	€6.5 million	H2020	International
ELIXIR-CONVERGE[70]	Translational Federated EGA & COVID-19 Data Platform	ELIXIR	€ 9.8 million	H2020	European

[66] https://www.eshg.org/index.php?id=home
[67] https://www.eu-stands4pm.eu/
[68] https://www.cineca-project.eu
[69] https://eucancan.com/
[70] https://elixir-europe.org/about-us/how-funded/eu-projects/converge

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CORBEL[71]	CORBEL is an initiative of thirteen new biological and medical research infrastructures (BMS RIs), which together will create a platform for harmonised user access to biological and medical technologies, biological samples and data services required by cutting-edge biomedical research	ELIXIR	€14 million	H2020	European
EOSC-Life[72]	The project will publish 'FAIR' data and a catalogue of services provided by participating RIs for the management, storage and reuse of data in the European Open Science Cloud (EOSC).	ELIXIR	€26 million	H2020	European
EATRIS-Plus[73]	Deliver a multi-omic toolbox to support cross omic analysis and data integration in clinical samples	EATRIS ERIC	€5 million	H2020	European
Healthy Cloud[74]	Strategic Agenda including a Ready-to-implement Roadmap for the HRIC (European Health Research and Innovation Cloud)	IACS	€3 million	H2020	European
PHIRI[75]	To facilitate and support open, interconnected, and data-driven research through the sharing of cross-country COVID-19 population health information	Sciensano	€5 million	H2020	European
TEHDAS[76]	To develop and promote concepts for the secondary use of health data to benefit public health and health research and innovation in Europe.	Finnish Innovation Fund., Sitra	€4.16 M (EU €2.5 + MS €1.66)	3rd EU Health Programme	European
KATY[77]	KATY project will develop an AI-empowered personalised medicine system that will greatly assist medical professionals and researchers in their daily work. As a stress test, the KATY project will initially experiment with data from patients with a rare and complex form of kidney cancer.	UNITOV	€8.5 million	Horizon 2020	European
GenoMed4ALL[78]	The project represents a quantum leap in advanced personalised medicine, pooling genomic/ '-omics' health data through a secure and trustworthy Federated Learning	UPM	€10 million	Horizon 2020	European

[71] https://www.corbel-project.eu/home.html
[72] http://www.eosc-life.eu/
[73] https://eatris.eu/projects/eatris-plus/
[74] https://cordis.europa.eu/project/id/965345
[75] https://www.phiri.eu/
[76] https://tehdas.eu/
[77] https://katy-project.eu/

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	platform. A disruptive AI model, scaled up by HPC, will boost the processing capacity of data repositories from 10 clinical sites across Europe, empowering forward-thinking research of common and Haematological RD				
PANCAIM[79]	PANCAIM will combine genomics and imaging phenomics using AI to generate breakthrough knowledge to increase understanding of PDAC biology and patient stratification. It will develop trusted impactful AI applications for regular clinical use to help clinical decision-makers to give the right treatment to the right patients at the right time, and at the right cost and improve treatment outcomes of PDAC patients.	Radboud UMC	€8.2 million	Horizon 2020	European
INTERVENE[80]	INTERVENE seeks to advance AI-facilitated analyses of complex medical data to develop genetic risk scores, which summarize the estimated effect of an individual's genetic makeup on the risk of developing a particular disease.	FIMM	€10.5 million	Horizon 2020	European

[78] https://genomed4all.eu/
[79] https://pancaim.eu/
[80] https://www.interveneproject.eu/

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5. Results

5.1. The Policy and Legal Context

The European Commission has manifested through various policy priorities its commitment to that it intends to support the pooling of the EU's data resources and to facilitate their use for research and health policy. One of its main objectives is to connect national initiatives with European networks of scientific and clinical expertise related to personalised medicine, cancer, rare diseases and other relevant initiatives.

Moreover, the link with the data collected in the electronic health records and the registries developed by the European Reference Networks should be an important aspect to be considered in the genome initiative. This will help European research and industry remain at the forefront, bringing new personalised medical solutions to the market. Any initiatives in this area should take full account of other EU Policy and technological developments on healthcare products. We especially note that the Commission intends to step up coordination between authorities across the EU to implement the secure exchange of genomic and other health data in order to advance research and personalised medicine, always in compliance with legal and ethical aspects.

5.2. Mapping of programmes and initiatives

After mapping the main European (and other relevant international and/or regional) programmes, initiatives, infrastructures, policy organisations and projects related to and with synergies with the initiative 1+MG, we have classified them based on their relationship with the 5 main pillars of the initiative: ELSI, Data (Standards and Quality Guidelines), Infrastructure, Personalised Medicine Delivery and Use Cases (Cancer, Rare Diseases, Common Complex Diseases, Infectious Diseases, Population Genetics).

This classification is shown in **Figure 2**. As can be seen there are currently a large number of programs, initiatives, infrastructures, political organizations and projects that could interact and collaborate directly or indirectly in the activities of the 1 + MG initiative.

In each of the pillars they must be considered and collaborate with:

- **ELSI**: initiatives such as the EHDS and projects such as TEHDAS and EOCS-Life.
- **Infrastructure**: programs such as the Digital Europe Program or the Connecting Europe Facility; initiatives such as the European Health Data Space; research infrastructures such as ELIXIR and eHealth; and projects such as CINECA, EOSC-Life and PHIRI.
- **Personalized Medicine Delivery**: the European partnership of Health and Care Transformation and ERA PerMed; initiatives such as ICPerMed 'Family'; and projects such as EU-STANDS4PM, Healthy Cloud, INTERVENE, KATY, GenoMed4ALL and PANCAIM.
- **Data and Uses Cases**[81]: programs such as Horizon Europe and EU4Health; European partnerships such as Innovative Health Initiative, EOSC, EJP RD, Rare Diseases and Personalized medicine; initiatives such as Cancer Mission, Genome of Europe, Europe's Beating Cancer Plan and ERNs; research infrastructures such as EATRIS, ECRIN, ELIXIR and BBMRI-ERIC; platforms such as COVID-19 Data Portal; policy organizations such as RDA,

[81] Since many of the European (and international) programmes, initiatives, infrastructures, policy organisations and projects relevant for use cases are largely based on data collection (genomic, clinical, phenotypic, etc.), we have represented them together in the figure.

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GA4GH and ESHG; and projects such as EUCANCan, EATRIS +, ELIXIR-CONVERGE and CORBEL.

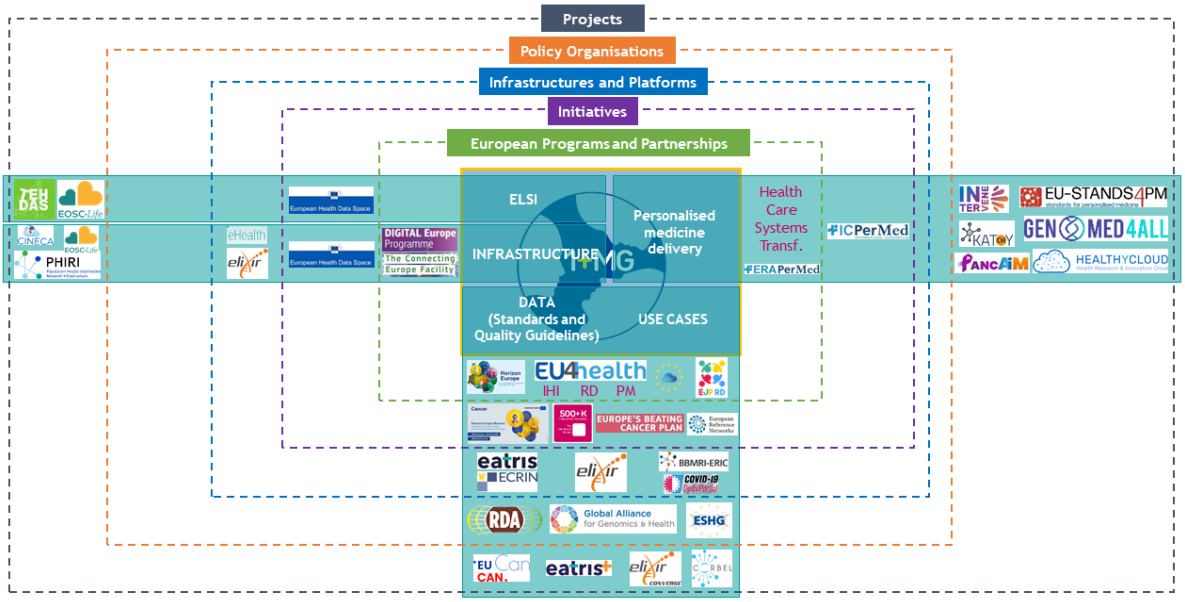

Figure 2. Classification of European (and international) programmes, initiatives, infrastructures, policy organisations and projects relevant for and with synergies with the 1+MG initiative, in the 5 main pillars of the initiative: ELSI, Data, Infrastructure, Personalised Medicine Delivery and Use Cases.

For a correct development of the initiative, it will be necessary to identify the gaps and overlaps that occur within the ecosystem of European programs, initiatives, infrastructures, political organizations and projects relevant for the initiative in order not to duplicate efforts and to leverage existing resources towards the same goal in a more efficient way.

Finally, in terms of funding, as **potential funding sources at EU level**, have been identified the following programmes and partnerships:

- Digital Europe, Connecting Europe Facility and EU4Health -for its connection to Health Data Services (ERNs) and the European Health Data Space (EHDS)- for the pilot **infrastructure**.
- Horizon Europe, EU4Health, the Innovative Health Initiative, the Cancer Mission and the Rare Diseases Partnership for the **use cases**.
- Horizon Europe, Digital Europe and EU4Health for the **data**.
- Personalized Medicine and Health and Care Systems Transformation Partnerships for personalized **medicine delivery.**

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6. Discussion

For genomic data use to be successfully adopted by healthcare, it is fundamental that a close collaboration is established with healthcare systems stakeholders in each country to deeply understand the challenges and expectations of effective data sharing and data usage so that the generated framework becomes effectively useful and sustainable. This can be achieved by identifying the specific challenges and barriers in health systems to the efficient and sustainable use of shared genomic data – for instance, in infrastructure, in capacity building and in legislative framework. The 1+MG approach is to identify national and European gaps and needs to ensure that ongoing initiatives have the means to deliver and that additional efforts needed to achieve the goal are highlighted and addressed. The process is set up to facilitate capacity building at a national level through support to the signatory countries to develop genome sequencing, data analytics and professional capacity in the framework of the National Mirror Groups.

6.1. The Policy Framework

The coordination between authorities across the EU to implement the secure exchange of genomic and other health data in order to advance research and personalised medicine will help European research and industry remain at the forefront, bringing new personalised medical solutions to the market. Any initiatives in this area should take full account of other EU Policy and technological developments on healthcare products.

Besides, an alignment with the plans for the European Health Data Space (EHDS) is very important as it may influence the legal space for the implementation of the 1+MG. A close interaction and exchange with the Joint Action Towards a European Health Data Space (JA TEHDAS) will be pursued to establish a mutual exchange on findings and strive for common solutions.

6.2. Mapping of programmes and initiatives

As shown in section 5.3, there are currently a large number of programs, initiatives, infrastructures, policy organizations and projects that are directly or indirectly relevant for 1+MG initiative and with which it would be advisable to start working and collaborate with them to take advantage of their work and and there are no duplications within the initiative.

There is also a great fragmentation and little coordination with the programs, initiatives, infrastructures, policy organizations and projects existing and yet to come.

It is considered necessary to start now to establish forms of collaboration and enrichment between the programs, initiatives, infrastructures, policy organizations and projects and the 1+MG initiative. It is important that all the funding that is available and that is going to be put in place serves to launch and maintain the initiative together with what the member states are willing to put into the maintenance of the national structure.

Additionally, the Initiative has only just started to collect requirements from expert stakeholders, analyse gaps and identify inconsistencies to ensure reuse of existing research infrastructure capacities.

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Currently, a major bottleneck is the development of expertise for developing further European data infrastructures, or for operating existing services that support secure cross-border genome data management services.

In addition to competence building at the national level, there is a clear need for European-level actions that fully exploit the competence acquired within the existing and potential new Horizon Europe research projects.

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7. Conclusions

After analyzing the results we can give the following recommendations:

Identification of funding programmes that could fill the gaps at EU level

It is necessary to continue to identify, apply and use the remaining funding opportunities that arise outside the identified programmes in order to finalise the necessary investment to complete the development and establishment of the infrastructure and start its operation at European level, as well as to establish possible collaborations with other related international initiatives.

Identification of related projects/initiatives

There is a wide variety of projects and initiatives related to the initiative that overlap and do not work in a coordinated manner. It is necessary to try to establish a linkage and collaboration in order not to duplicate efforts and to leverage existing resources towards the same goal in a more efficient way (It is particularly important to coordinate with WP1 in this regard).

Connection with the European Health Data Space (and other data sharing initiatives)

In the longer term, it is envisaged that each European country will implement resourced centres to provide a transnational computational data access service, with appropriate regulated approval processes for accessing national linked genomic and phenotypic data and epidemiological data. These centres will constitute a secure and federated cross-border infrastructure, based on common standards, providing transnational access to genomic and health data in compliance with local, regional, national and European regulations. Given the magnitude and complexity of this objective, more concrete work should be done on defining how phenotypic data will be linked to genomic data, and how this secure federated cross-border infrastructure will fit into the future EHDS (also EOSC), as this is not yet clear. Relationships with the EHDS (through the future pilot to be developed by the recently opened EU4Health call[82]) and the other data sharing initiatives, need to be defined and implemented so that the federated secure cross-border infrastructure is compatible and aligned with them.

Cost estimation and partnership models

Work needs to be done on cost estimates of what the infrastructure and its maintenance will cost and to determine where this investment will come from and what long-term financial commitment Member States need to make to make this possible. This also needs to be linked to future Digital Europe Programme calls.

In addition, as it will require a large investment, success will require partnerships, together with governments, health systems, industry and other stakeholders. We must ensure that these partnerships and the 1+MG initiative are surrounded by an innovation-friendly policy, allowing for industry participation, as well as including strong ethical and legal considerations. In addition, countries must have sufficient funding to provide examples of implementation and then make the solutions work.

[82] https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/eu4h-2021-pj-06

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Access and pay-per-use model

There is a need to define what the access and payment model will be, e.g. Will there be a per-access payment for individual accesses? Will there be annual fees per country, per centre? Who will pay these fees? What will these fees be used for? Will these fees be used for the maintenance of the infrastructure? The access model for industry or private health systems is also not defined.

Training model

The training model for capacity building of health professionals has not only not been defined but has not yet been framed within any working group. It is essential that if we want to generalise the use of genomics in health systems and, in the longer term, to implement personalised medicine, professionals are trained and updated in these matters from the beginning of the establishment of the infrastructure.

It is also necessary to determine where the investment needed to carry out this training and education is going to come from.

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8. Next steps

In the first half of 2022, we will develop the **second 'Policy brief' focusing on Governance and Access Data dimension** (according to the infrastructure model chosen).

To work in this second 'Policy brief', we need to **have more information about**:

- The actual **commitments** at national level to the 1+MG Initiative, at governance and financial level.
- The existing **resources** already made available to the initiative by Member States and the EC.
- What the **access model** to the data and infrastructure will look like and whether, for example, there will be pay-per-use/access to them.
- An **estimate** of the **costs** of the infrastructure and its maintenance.

To develop this work we plan to **organize a workshop**(s) with other WPs and external experts to discuss and share knowledge about different dimensions of Sustainability.

Countries will also need to be **consulted** (survey, focus group) on some issues connected to the commitment and funding related to the long-term national sustainability of infrastructure.

For the correct development of these activities we will require the **support from** all WPs and national representatives of Member States.

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