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From:	General Secretariat of the Council
To:	Council
Subject:	State of play of 1+Million Genomes (1+MG) Initiative and the implementation of the 1+MG Roadmap 2023-2027 *- Information from the Estonian delegation, supported by the Finnish delegation*

Delegations will find in Annex an information note from the Estonian delegation on the above mentioned subject to be raised under "Any other business" at the meeting of the EPSCO Council (Health) on 30 November 2023.

ANNEX

State of play of 1+Million Genomes (1+MG) Initiative and the implementation of the 1+MG Roadmap 2023-2027

In 2018, the 1+Million Genomes (1+MG) Initiative[1] started with the signature of a Ministerial declaration of cooperation[2], to date signed by 25 Member States, the UK and Norway. The declaration set forth a vision to build a research cohort of at least 1 million sequenced genomes and to create a European data infrastructure for genomic data by enabling federated data access. At the end of 2020, the Commission created a special expert group, the 1+MG Group[3], with a view to facilitate the cooperation and coordination at the level of national representatives of the signatory countries.

Genomics has the potential to revolutionise healthcare in many ways. It could lead to the development of more targeted personalised medicines, therapies and interventions. Currently, more than 30 million Europeans are affected by rare diseases of which over 80% have genetic origin. Further, recent data demonstrate that approximately 1 in every 80 individuals has more than one monogenic disease. Integration of large-scale mutation and clinical information for rare disease patients will clearly aid early diagnosis and improve outcomes. New insights how genes affect predictive risk to disease or a person's response to a drug will stimulate innovation and new products across the healthcare industry. Equally important, genomics has the potential to improve the effectiveness, accessibility, sustainability, and resilience of health systems in the European Union.

The 1+MG initiative will give a boost to digital innovation of healthcare and aligns with countries' preparations for the European Health Data Space. The goal of the 1+MG initiative is to make the personal genomic datasets accessible in a secure manner for collective diagnostic purposes and prevention, and for research and innovation. To this end, a 1+MG data infrastructure will enable the effective and secure cross-border access to repositories of personal genomic datasets among participating countries. This infrastructure will be supported by a trust framework covering collective agreements on ethical, legal and social implications aspects such as GDPR-compliance.

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1 https://digital-strategy.ec.europa.eu/en/policies/1-million-genomes

2 https://digital-strategy.ec.europa.eu/en/news/eu-countries-will-cooperate-linking-genomic-databases-across-borders

3 https://digital-strategy.ec.europa.eu/en/policies/1mg-group

The implementation of this framework will take until 2027 along a two-staged roadmap[4], detailing activities across four dimensions: governance, trust framework, infrastructure, and data.

In the first phase, the Horizon 2020 project 'Beyond 1 Million Genomes' (B1MG) supported and coordinated on the operational level the implementation of the roadmap, by leading up to an agreement on the infrastructure set-up, legal and technical guidance, data standards, and requirements, and best practices to enable data access. This project ended in October 2023.

In November 2022, the project Genomic Data Infrastructure (GDI), co-funded under the Digital Europe programme, was launched marking the start of the scale-up and sustainability phase of the 1+MG initiative (a 40 million euros four-year project with 54 project partners and 24 European countries). It will establish a federated data infrastructure for genomic and linked health data across Europe enabling distributed learning for various use cases, provide a data access governance and a sustainable coordination mechanism, and contribute to improving the inter-operability of genomic and clinical data made available for access. Of the countries engaged, 15 have committed to deploying it fully by 2026 (Belgium, Czechia, Denmark, Estonia, Finland, France, Germany, Italy, Luxembourg, Portugal, Slovenia, Spain, Sweden, The Netherlands, Norway). Six of them will have achieved this target by 2024.

Furthermore, as part of the 1+MG Initiative, the Genome of Europe (GoE)[5] 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 represent the European population. All countries involved in GoE will generate a national genomic reference dataset via Whole Genome Sequencing and establish their own national population genomic reference cohort, all according to jointly established '1+MG-proof' guidelines. Each national dataset will form a unique national reference collection that will benefit national personalised healthcare and prevention strategies. Collectively, cross-linked via the 1+MG initiative and GDI, the national collections will establish a world-class European reference data resource (The Genome of Europe) for research and innovation of healthcare.

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4 The first 1+MG Roadmap 2020-2022 was adopted in February 2020 and the second Roadmap 2023-2027 in November 2023.

5 https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/digital-2023-cloud-ai-04-genome

For the implementation of the 1+MG Roadmap 2023-2027 it is important to stay focused on:

- planning the resources for the implementation and co-financing;
- ensuring that appropriate technical infrastructure is available across the EU, allowing for secure, federated access to genomic data;
- making sure that ethical and legal implications of genomics are clear and taken into account;
- ensuring that the general public and policy makers in Member States and signatory countries are well informed about genomics, in order to ensure its uptake by healthcare systems and integration into personalised healthcare.

The initiative has reached important milestones with significant accomplishments and has further potential to improve disease prevention, allow for more personalised treatments and support groundbreaking research. Therefore, it is a good opportunity for Ministers to take stock on the achievements, raise awareness in the Member States, and plan further support to reach the goals of this ambitious initiative and to ensure the pan-European implementation.