

DECLARATION OF COOPERATION

Towards access to at least 1 million sequenced genomes in the European Union by 2022

Česká republika

and

Eesti Vabariik

and

Reino de España

and

Repubblica italiana

and

Κυπριακή Δημοκρατία

and

Lietuvos Respublika

and

Grand-Duché de Luxembourg

and

Repubblika ta' Malta

and

República Portuguesa

and

Republika Slovenija

and

Suomen tasavalta

and

Konungariket Sverige

and

United Kingdom of Great Britain and Northern Ireland

Having regard, among other initiatives, to:

- The Digital Single Market strategy midterm review¹ and notably its priorities on health and care announcing the intention of the European Commission to adopt a Communication including inter alia "supporting data infrastructure to advance research, diseases prevention and personalised health and care in key areas including rare, infectious and complex diseases";
- The Council conclusions on "Health in the digital society – making progress in data-driven innovation in the field of health"², adopted on 8 December 2017, emphasising that " without prejudice to national legislation and legal grounds for health data processing, flexible systems and tools are needed enabling citizens to access their own data and information on the use of their data, as well as to manage their consent to processing and sharing their health data, including for "secondary use" and inviting the Member States and the Commission to "work together with the aim of improving access to larger European datasets, longitudinal data and world-class high performance computing infrastructure for health research and innovation purposes, while ensuring a high level of data protection", building thereby on existing initiatives such as the European Cloud Initiative, encompassing EuroHPC and the European Open Science Cloud;

¹ COM/2017/0228 final

² <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2017:440:0003:0009:EN:PDF>

- The Council Conclusions on "Encouraging Member States driven Voluntary Cooperation between Health Systems"³ adopted on 16 June 2017, inviting Member States to "explore areas in which voluntary cross-border collation of data and the development of common principles on data collection in compliance with data protection legislation, may provide added value, while fully respecting Member States' competences";
- The Council conclusions on "Personalised medicine for patients", adopted on 7 December 2015, inviting the European Commission to pursue a "dialogue with Member States' authorities and stakeholders to facilitate step-by-step implementation of the public health genomics approach both at European Union and national level on the basis of past European Union initiatives";
- The Council conclusions on "Safe and efficient healthcare through eHealth" adopted on 1 December 2009, calling upon the Member States to conceive and implement initiatives aimed at enabling the deployment and use of eHealth services;
- The Recommendation of the Council of Europe on Research on Biological Materials of Human Origin⁴ and other relevant recommendations adopted by the OECD⁵
- Different national and regional initiatives on genomic medicine that are being developed across the Union, and based on which cooperation can be further enhanced to deliver added value for European research and clinical practice;
- Existing European and global initiatives and public-private partnerships aiming to foster data-driven research and innovation in health.⁶

The signatories of this declaration recognise that:

³ <http://data.consilium.europa.eu/doc/document/ST-10381-2017-INIT/en/pdf>

⁴ Recommendation CM / REC (2016) 6 of the Council of Europe

⁵ C (2009) 119 - Recommendation of the Council on Human Biobanks and Genetic Research Databases, C (2007) 48 - Recommendation of the Council on Quality Assurance in Molecular Genetic Testing, C (2005) 149 / Rev1 - Recommendation on the licensing of genetic inventions, Recommendation of the OECD Council on Health Data Governance

⁶ Such as G4GH, IC Per Med, ERAPerMed, BBMRI-ERIC, ELIXIRn IRDiRC, ERACAN, IMI and others

- The digital transformation of health and care and, in particular, the use of genomic medicine, will help health systems to meet the challenges they face and become more sustainable, thereby improving the provision of high quality health services for citizens and the effectiveness of treatments for patients;
- There is a need to ensure that the Union remains competitive in the global race to advance personalised medicine, and that its citizens benefit from the latest innovation in this field.
- Scaling up digital health and connected care and unlocking progress in implementing data-driven digital solutions requires a concerted effort to overcome data silos, lack of interoperability and fragmentation of initiatives across the EU;
- Secure and authorised cross-border access to genomic and other health data in the Union will support innovation leading to more cost effective use of health care resources in the Union and new approaches to care delivery that better address the needs of individual patients;
- Secure and authorised cross-border access to genomic and other health data in the Union will enable targeted research and innovation as well as efficient translation of that research into clinical settings and public health work, which can lead to more effective therapies for individual patients and improved preventive measures. It will enable researchers to define subsets of patients who are not benefiting from standard treatments;
- Coordinating secure access to data from >1M genomes that are linked to health data, as well as pooling analytical capabilities, in compliance with the General Data Protection Regulation, is crucial to advance the understanding of genetic associations that cause or predispose diseases;
- Efforts to allow cross-border access to genomic and other health data must be implemented in a lawful, secure, appropriate and specific way;
- Strengthening cooperation between Member States in the field of genomic and related health data will translate into improved health outcomes and will also contribute to investments, economic growth and jobs. Benefits of coordination across national initiatives and biobanks include accessing data from different phenotypes at scale

and enhancing technology and infrastructure capacity. This will avoid silos that could hamper the advancement of personalised medicine, including genomic medicine, in the future.

The signatories of this declaration share the same resolve in ensuring that in the future:

- Citizens' needs are at the centre of data-driven healthcare innovation as active agents in their own health journey and can benefit from more precise and personalised treatments as well as a more participatory healthcare experience;
- Citizens better understand the benefits of sharing genomic and other related health data;
- Citizens, researchers and health systems in the Union can benefit from the full potential of genomics to advance targeted health care interventions leading to better prevention, early diagnosis and treatment of diseases;
- The Union stays at the forefront of genomic and personalised medicine globally, and improves its scientific capabilities and industrial competitiveness for the benefit of patients and the economy.

In order to realise this shared vision, the signatories of this declaration agree to work together to provide cross-border, data-driven health and care solutions to benefit citizens of the Union. As part of this goal the signatories will work towards building a research cohort of at least 1 million sequenced genomes accessible⁷ in the EU by 2022. This cooperation, which will build upon existing initiatives in genomics and personalised medicine, will inter alia aim to:

- Define a voluntary coordination mechanism of national, regional and local public authorities to link ongoing genomic medicine initiatives and to steer the activities stemming from this declaration;
- Ensure distributed, authorised and secure access to national and regional banks of genetic and other relevant data for the advancement of science and innovation, while taking appropriate measures to protect the privacy of individual data donors;

⁷ Access provided in a federated (not centralised) network to genomics data-sets at national / regional level.

- Define a governance model of cooperation, particularly concerning the terms and conditions for distributed access to genomic data across borders, usage of the data and other aspects deemed necessary by the signatories;
- Support the development of technical specifications for secure access and cross-border exchange of genomic datasets and facilitate interoperability of relevant registries and databases to support research;
- Develop a secure infrastructure and tools to enable cross-border sharing or analysis of genetic and other data-sets, anonymised as appropriate, from multiple Member States, building upon existing infrastructure;
- Develop a coordinated data governance framework necessary to facilitate Europe-wide large-scale processing of health and related data in compliance with the applicable data protection legal framework, in order to support shared health policy goals; notably to achieve better health for citizens, future sustainability of health systems, and to boost large-scale data-driven biomedical and clinical R&D in Europe;
- Promote the use of open standards and data management systems to ensure interoperability of genomic and other health data with a view to enhance research on personalised medicine and genetic diseases;
- Strengthen cooperation on the implementation of the General Data Protection Regulation particularly as concerns the further processing of personal data concerning health.

The signatories of this declaration invite the European Commission to:

- Consider the shared vision enshrined in this declaration and endorsed by the signatories as it implements measures to support the digital transformation of health and care further to the Digital Single Market mid-term review, notably aiming at "supporting data infrastructure to advance research, diseases prevention and personalised health and care";
- Support and facilitate Member States cooperation set out in this declaration;
- Mobilise funds from the Horizon 2020 and Connecting Europe Facility programmes to support pilot actions, pooling data and resources across the Union, and demonstrate the benefits in advancing genomic medicine. Consider further support from future programmes;
- Regularly report on progress achieved regarding the implementation of the commitments outlined above, including updates on global developments concerning genomic medicine.

The signatories of this declaration invite all Member States of the European Union, the European Economic Area (EEA) and the European Free Trade Association (EFTA) to join this cooperation, while stressing that this declaration does not entail any financial commitment by the signatories.

For the

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