



1+Million Genomes Initiative / Beyond 1 Million Genomes CSA Update

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February 2021

ICPerMed Executive Committee Meeting

Declaration for delivering cross-border access to **genomic databases**



1 million **genomes accessible** in the EU by 2022



Linking access to existing and future genomic databases across the EU



Providing **proper scale** for research with clinical impact

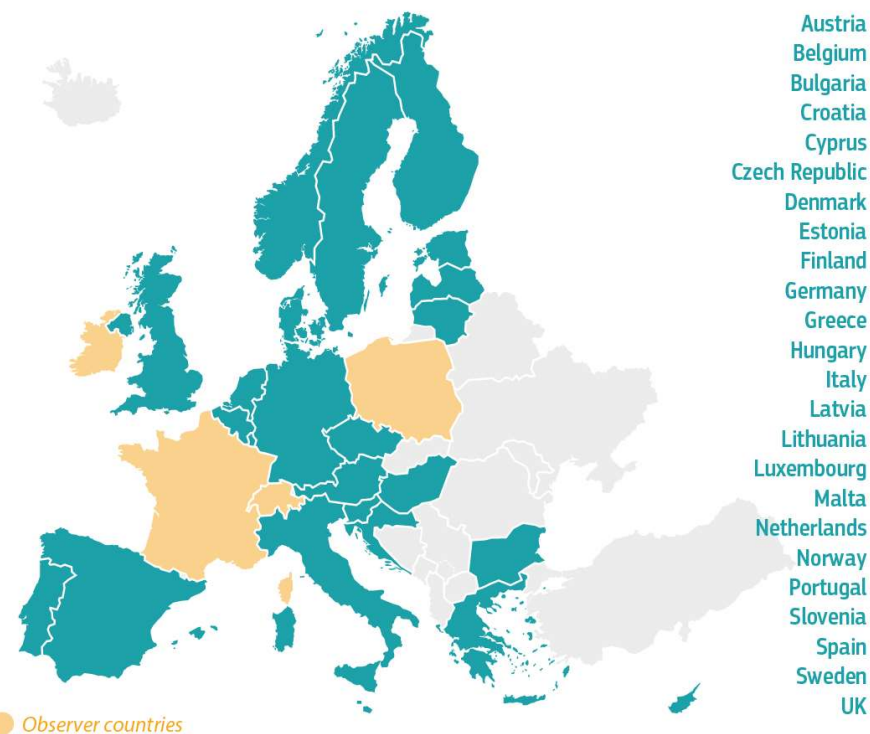


1+MG Declaration of cooperation

24 countries and 5 observers



Countries that have signed the 1+MG Declaration since 2018



● Observer countries

updated on 2 February 2021

The B1MG project

Started 1 June 2020

Coordination and support action of the 1+MG

29

Partners

25

EU countries

€4M

Budget

3

Years



1+MG Working Groups

WG1. Organisation and governance

Coordination

WP6. Coordination and NMGs

WG2. ELSI aspects

WG3. Clinical data

WG4. Genomic Quality

WG5. Infrastructure

WG6. Health economics

WG7. Industry interactions

Technical Working Groups

WP2. ELSI aspects

WP3. Standards and guidelines

WP4. Infrastructure

WP5. Personalised Medicine adoption

WP1. Stakeholders

WG8. Rare diseases

WG9. Cancer

WG10. Common Complex diseases

WG11. Host susceptibility to
Infectious diseases (COVID-19)

Use cases Working Groups

1+MG Roadmap/B1MG objectives



2020

Engaging local, regional, national and European stakeholders

... to define requirements for accessing genomics and clinical data.

2021

Translating requirements for data quality, standards, technical infrastructure, and ELSI

... into technical specifications and implementation guidelines.

2022

Driving adoption and supporting long-term operations

... via the B1MG maturity level model and a methodology for economic evaluation.

General Developments

WG1 - Coordination Group

- Alliance of 1+MG signatory countries grows
 - Denmark and Belgium recently signed the declaration



1+MG Roadmap summary publication

- Translated the 1+MG Roadmap adopted February 2020 into a public brochure for the (educated) general public
- Editorial team with input from EC, 1+MG CG and WG/WP leads
- Supported through a Digital Health Europe Grant
- Published late Sept 2020

<https://ec.europa.eu/digital-single-market/en/news/roadmap-1-million-genomes-initiative-now-clearly-illustrated-new-brochure>



Survey on accessible genomes



https://ec.europa.eu/eusurvey/runner/1plusMG_Survey2020

EUSurvey

Login | Help

Save a backup on your local computer (disable if you are using a public/shared computer)

1+MG - Survey on accessible genomes - July 2020

Fields marked with * are mandatory.

You are invited to participate in this survey because according to our information or your indication of interest, your dataset may be eligible for participation in the European 1+ Million Genomes initiative (1+MG).



Views

Standard [Accessibility Mode](#)

B1. SPECIFICALLY REGARDING RARE DISEASES

on Member States and Norway to establish a cross-border

C1. CLINICAL AND PHENOTYPIC DATA (Rare diseases)

- * 1. What was the main purpose for data collection?
 - Clinical
 - Research
 - Another purpose (e.g. biobanking, epidemiology, surveillance)
- * 2. What type of genetic data was collected?
 - (Please select all that apply.)
 - Whole Genome Sequencing (WGS)
 - Whole Exome Sequencing (WES)
 - Clinical exome
 - Arrays
- * 3. What phenotypic/clinical data is available?
 - (Please select all that apply.)
 - Clinical information
 - Treatment
 - Treatment response
 - Lifestyle (questionnaires)
 - Social-economic status information
 - None of the above
- * Clinical information:
 - (Please describe key content)

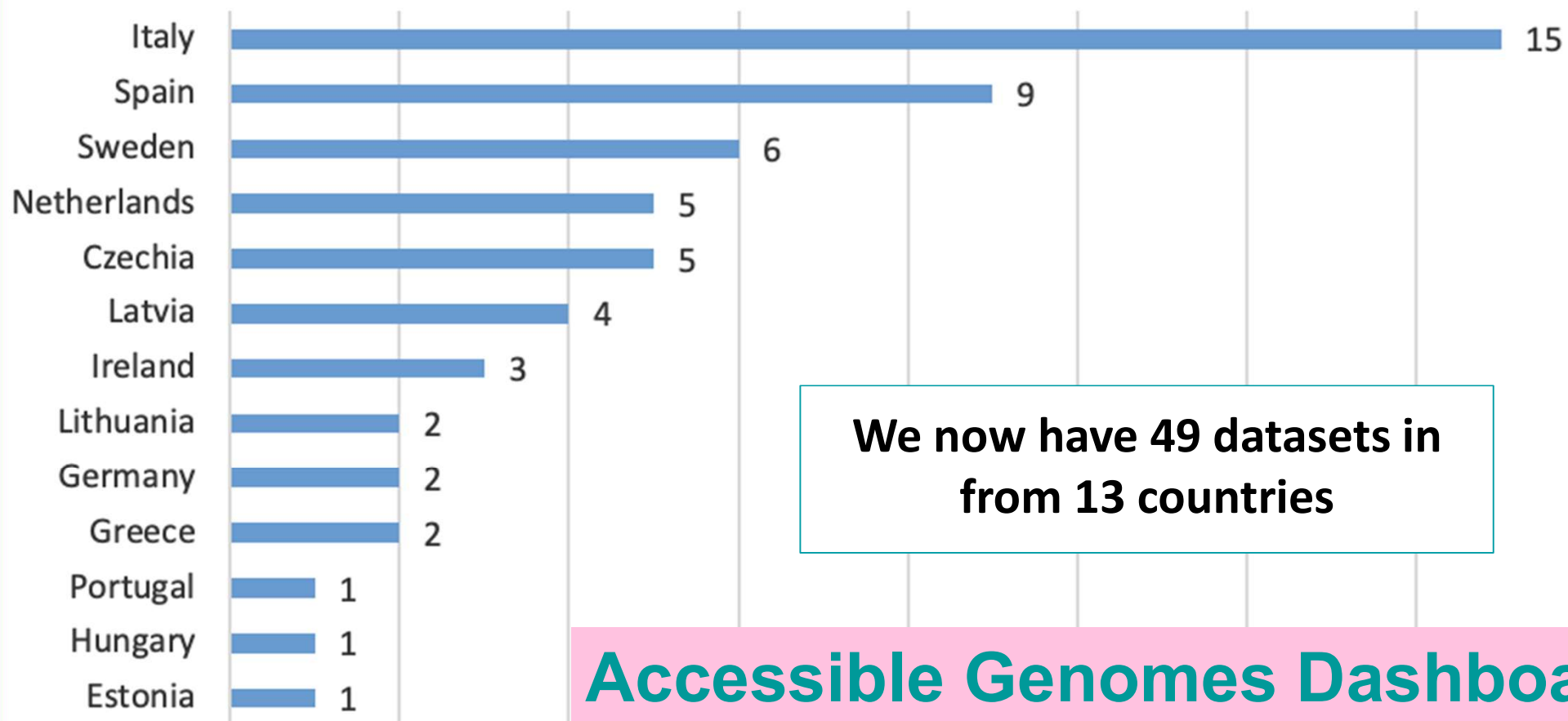
- * 1. Is the clinical/phenotypic data:
 - Centralised (collected and stored at a central location)
 - Federated in local systems like Electronic Health Record systems
- * 2. Please specify how each subject or participant in the project is identified?
 - (Please select all that apply.)
 - (include the variable(s) or methods used to uniquely identify each subject/participant)
- * 3. Is the phenotypic data linked to:
 - (Please select all that apply.)
 - WGS data
 - WES data
 - Clinical exome data
 - Array data
 - Other
- * 4. Data structure and format:
 - (Please select all that apply.)
 - Free text
 - Structured data
 - Date fields

D1. ETHICAL AND LEGAL ISSUES (Rare diseases)

For your data collection, we need to know for how many subjects you observe the following:

- * 1. General Data Protection Regulation (GDPR) Authorisation: Under the GDPR, does the data collection have a consensual basis (i.e. specific consent following Art. 6(1)a with 9(2)a) or non-consensual basis (e.g. statutory basis such as public interest based on Art. 6(1)e with Art. 9(2)g,h,i or j), as implemented in your country, that would allow to contribute this data in a cross-border genome initiative like the 1+MG?
 - No
 - No, but re-consenting is possible
 - Yes
 - Don't know
- 2. Ethical and legal legitimacy. Can the data be used for the following purposes? (Please note that, typically, ethical clearance comprises either informed consent or a waiver of informed consent and approval by an ethics committee.)
 - * a) The use in future (not yet defined) research projects?
 - (Please select all that apply.)
 - No
 - Yes
 - Don't know
 - * b) The use in healthcare for the benefit of other patients?
 - (Please select all that apply.)
 - (e.g. the data would be used by doctors of independent hospitals to find the most appropriate therapy for their patients)
 - Yes
 - No
 - Don't know

Dataset count by country



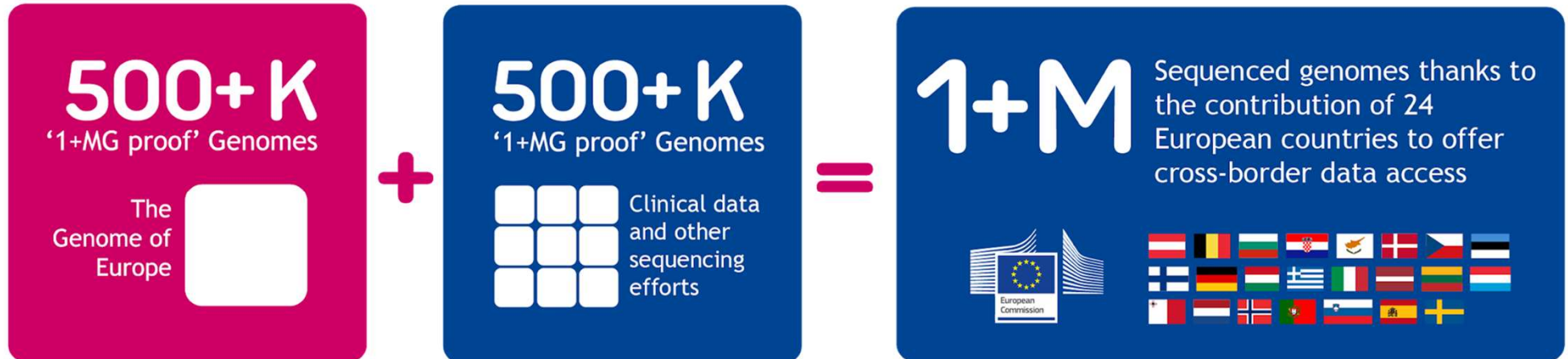
**We now have 49 datasets in
from 13 countries**

Accessible Genomes Dashboard



European commitment to achieve access to at least 1 million sequenced genomes by 2022

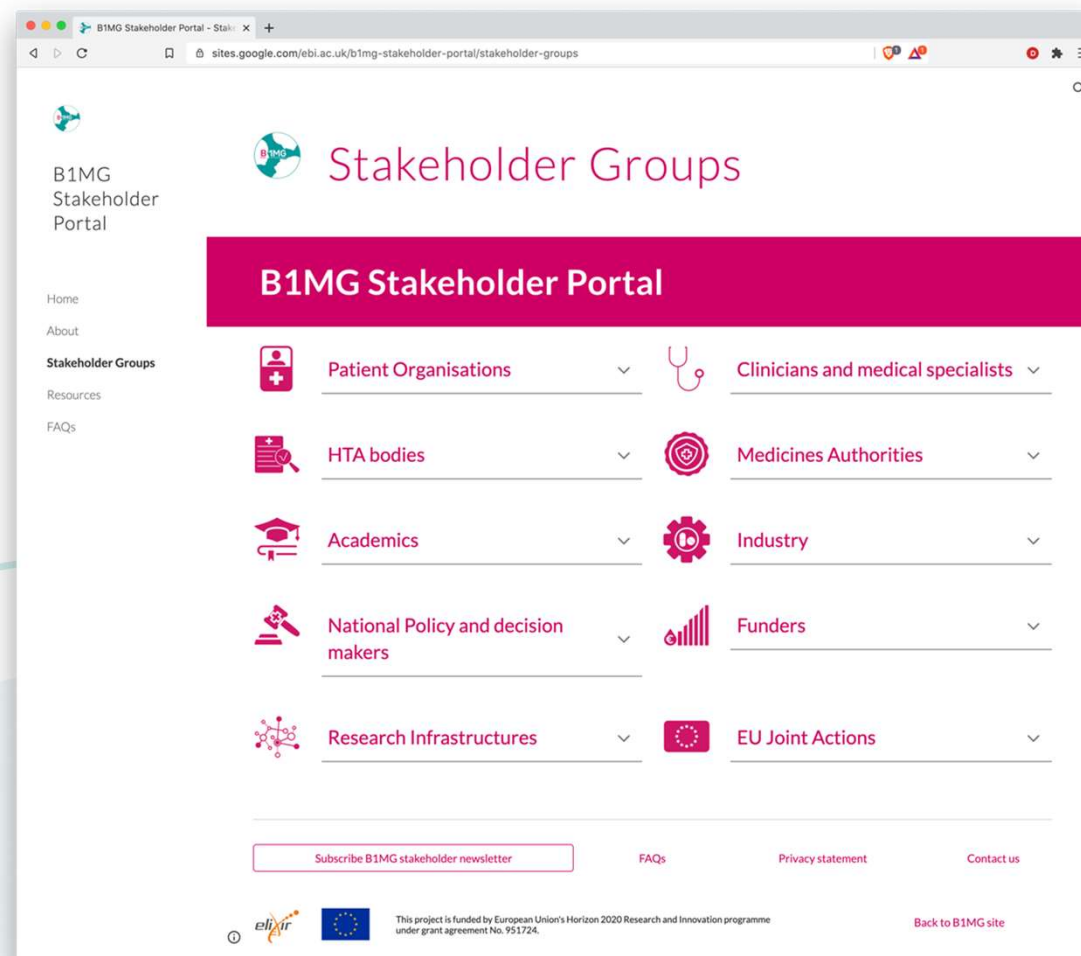
B1MG is creating legal guidance, best practices, recommendations and an infrastructure to achieve the goal



Workstreams

WP1 - Stakeholder

Stakeholder portal - creates an interface to facilitate community participation and engagement, communication and collaboration



WP1 – Stakeholder Engagement



Workstreams

WG2 & WP2 - ELSI



Provide ELSI Toolkit to:

- Consolidate national requirements, policies and recommendations
- Provide practical advice and Model Documentation on ELSI compliance over the data life cycle in 1+MG

Workstreams

WG3, WG4, WP3- Clinical & Data Quality

WP3 – Standards and
Quality Guidelines

WP2

WP1

WP4

WP6

Provide standards and quality guidelines:

Minimal requirements for:

- Sample source
- Bioinformatics analysis
- The description of patient-specific phenotype and clinical data - considering national particularities, such as clinical systems and languages

Workstreams

WG5/WP4 - Infrastructure

Technical roadmap document about components and infrastructure requirements for:

- Security and privacy
- Interoperability standards

Map member state readiness for adopting solutions, including gap analysis

Test cross-border interoperability

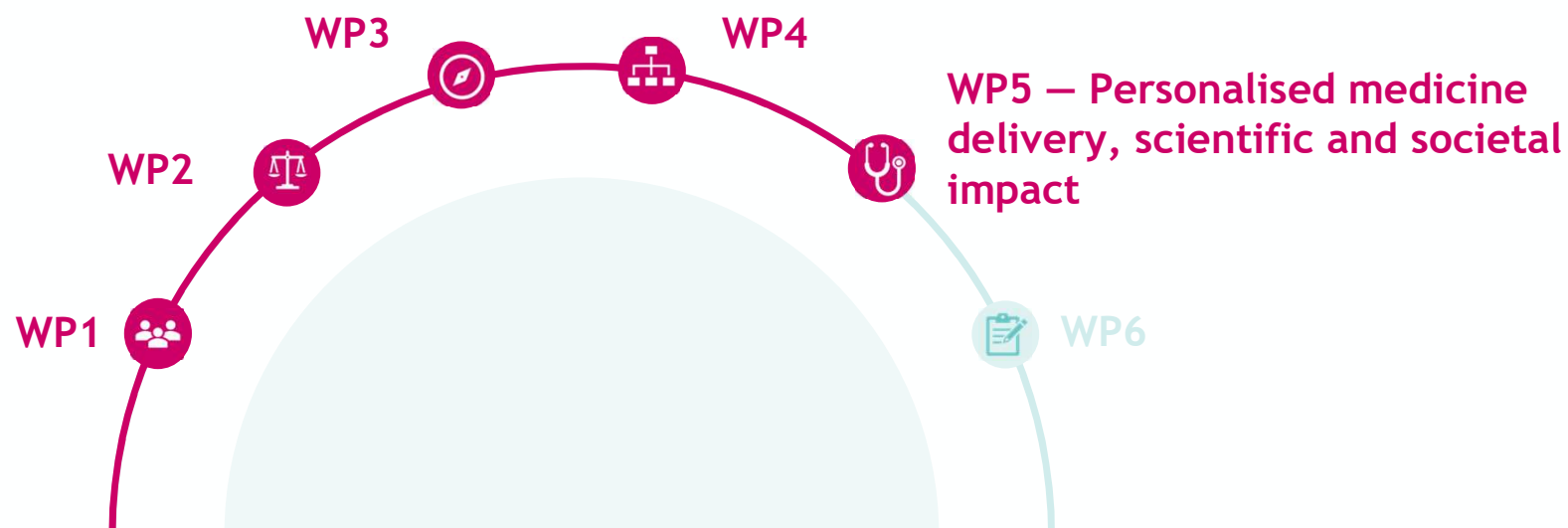
WP4 – Federated secure cross-border technical infrastructure



Workstreams

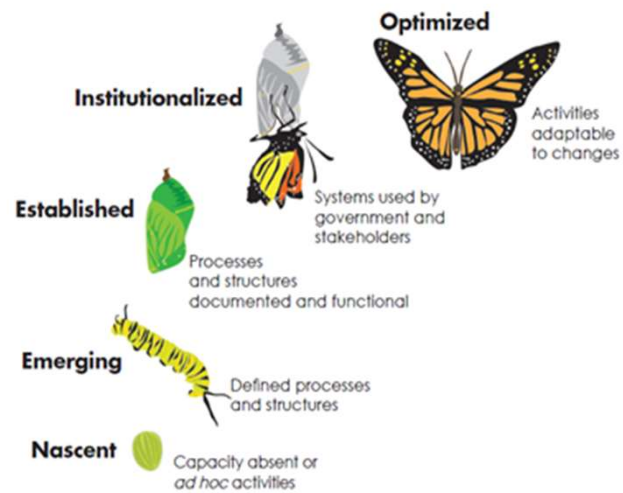
Tools to facilitate implementation:

- Maturity Level Model
- Country visits for knowledge exchange - UK, Estonia, Finland
- Economic model for evaluating personalised medicine approaches

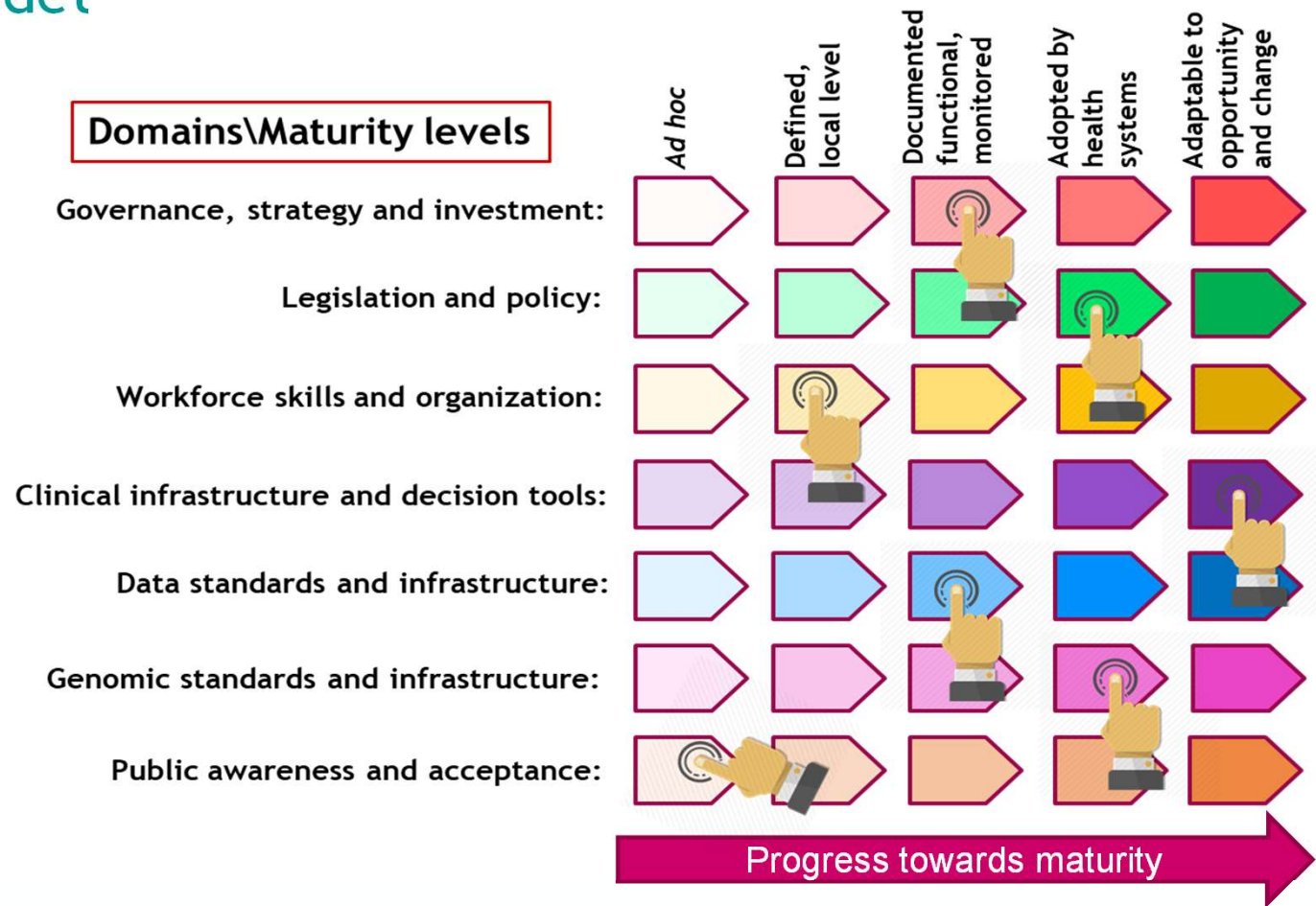


Tools

- B1MG Maturity Level Model

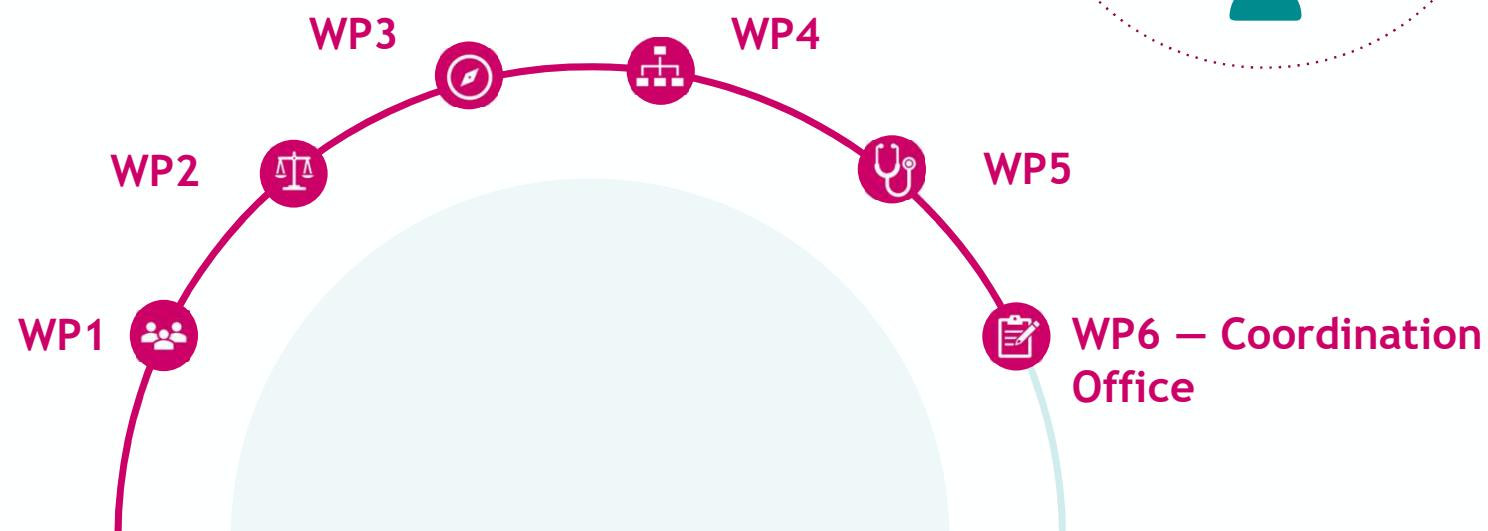


from: <https://www.measureevaluation.org/resources/tools/health-information-systems-interoperability-toolkit>



Workstreams

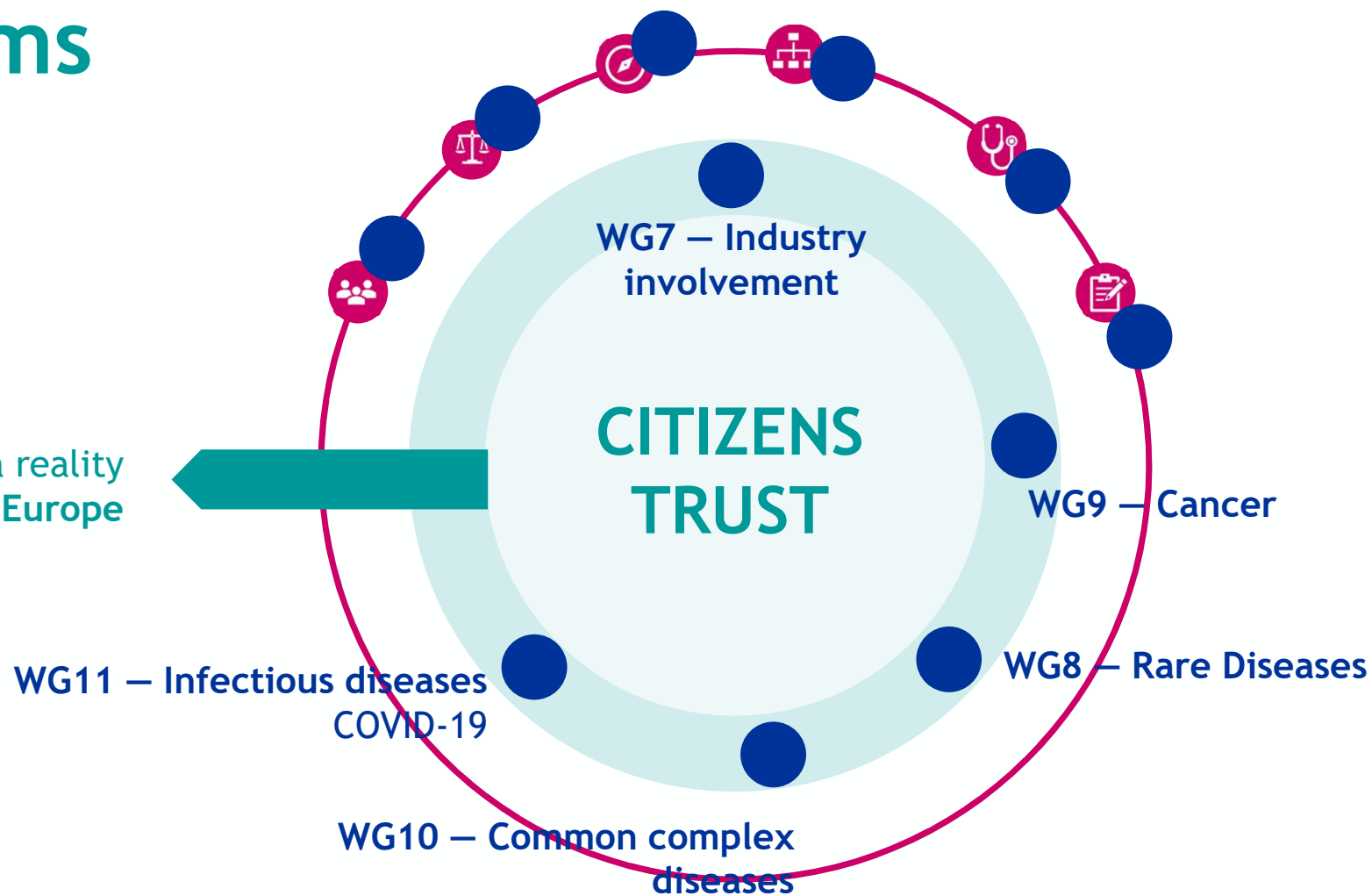
- Project management
- Communication
- Governance
- Sustainability



Workstreams



Personalised medicine a reality across Europe






+ B1MG has received funding from the European Union's Horizon 2020 Research and Innovation programme under grant agreement No 951724





Thank you!

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