



European
Genomic Data
Infrastructure

e-IRG Workshop under
Spanish EU
Presidency.

1+MG/GDI - European Genomic Data Infrastructure

Salvador Capella-Gutierrez (BSC) / Juan Arenas Márquez (ELIXIR Hub)

29th November 2023

Valencia



GDI project receives funding from the European Union's Digital Europe Programme under grant agreement number 101081813.



gdi.onemilliongenomes.eu/



[@GDI_EUproject](https://twitter.com/GDI_EUproject)



[/company/gdi-euproject](https://www.linkedin.com/company/gdi-euproject/)

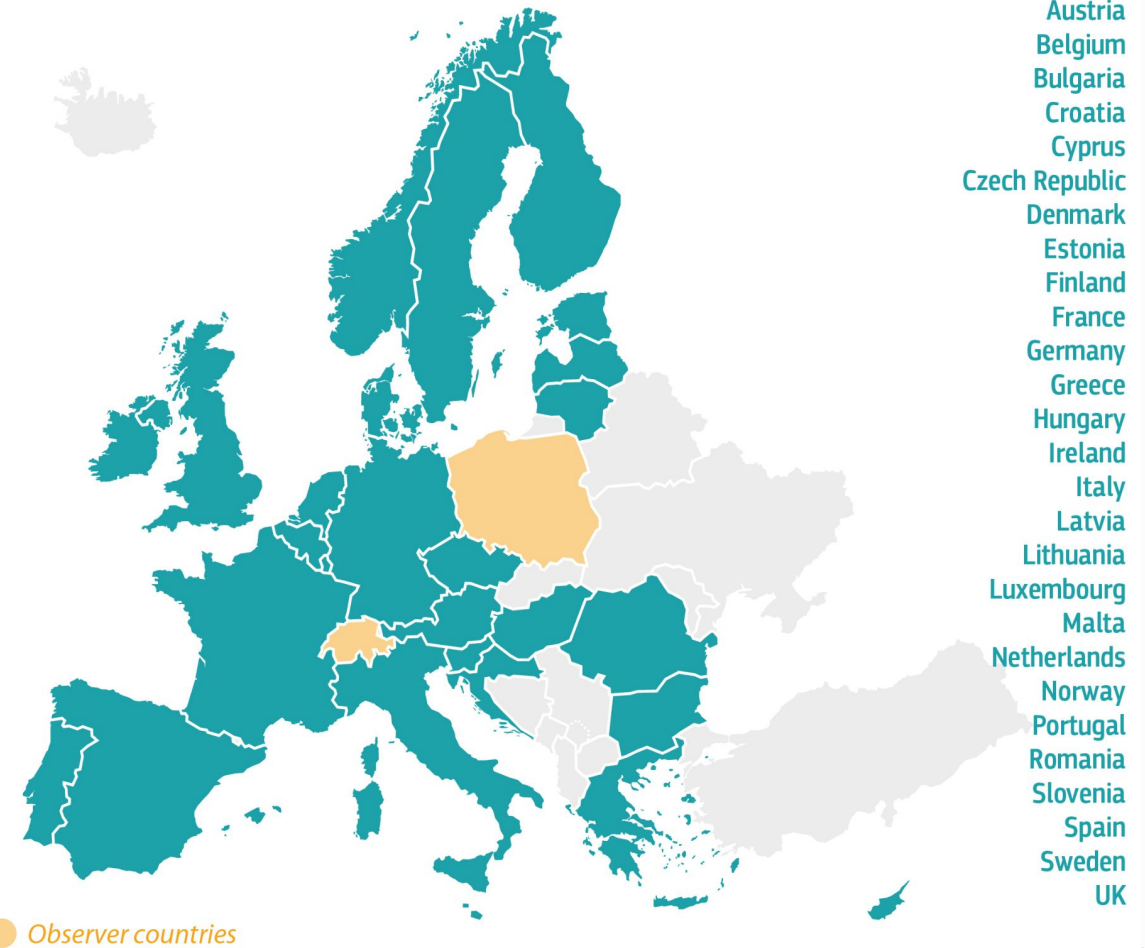


1+MG initiative

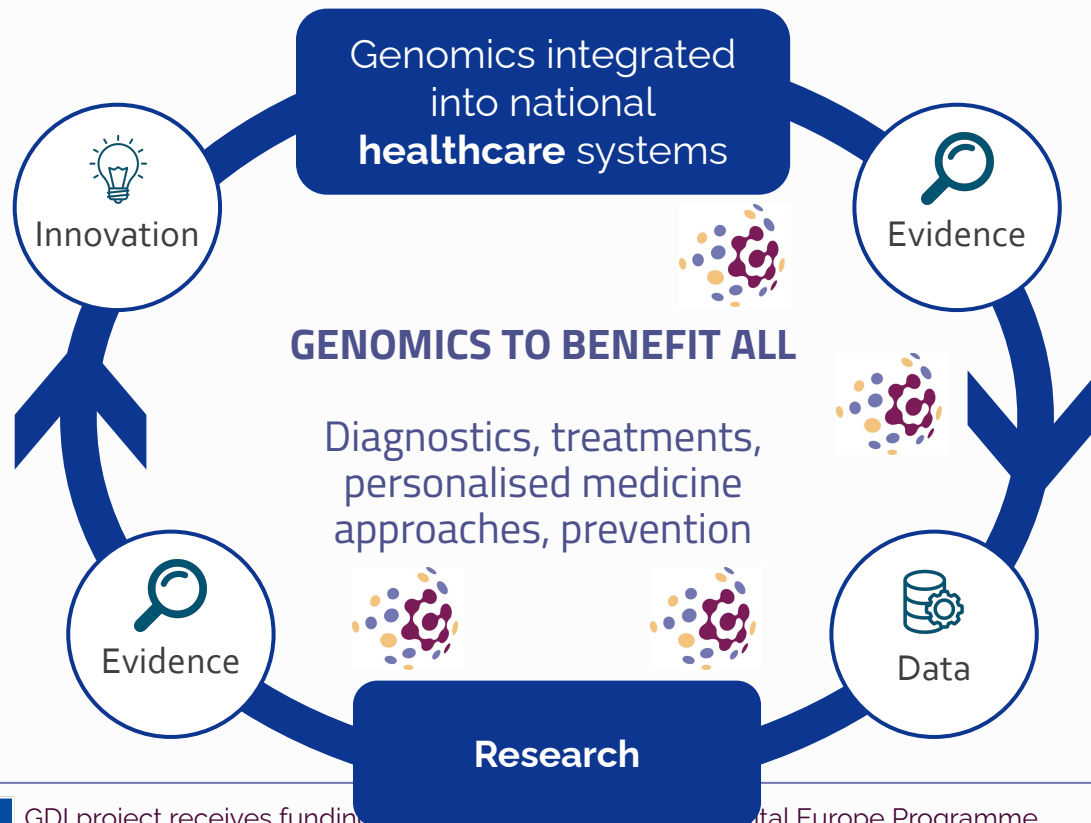


Cross-border access to genomic data, implementation of genomics-based health. Supported by 27 countries to date

Ambition: Enable secure access to high-quality genomics and the corresponding clinical data across Europe for **better research, personalised healthcare and health policy making**



Realising the promise of genomics



Data infrastructure is required

- Data will soon be generated more frequently in healthcare.
- Solutions are required to ensure research findings (if appropriate) can be incorporated into healthcare
- Make a reality of **personalised prevention, diagnostic and treatments**





1+MG Implementation projects



Cross-border access to genomic data, implementation of genomics-based health. Supported by 27 countries to date

2018

2020

2022

2023

2026

2027

Design & Testing

Scale-up & Sustainability



European Genomic Data Infrastructure



Population Genomics

Genome of Europe



GDI project receives funding from the European Union's Digital Europe Programme under grant agreement number 101081813.



GDI in numbers

€40M (50% co-funded)

45 Project Beneficiaries

6 Affiliated Entities

7 Associated Partners

58 Total Project Partners

20 European countries

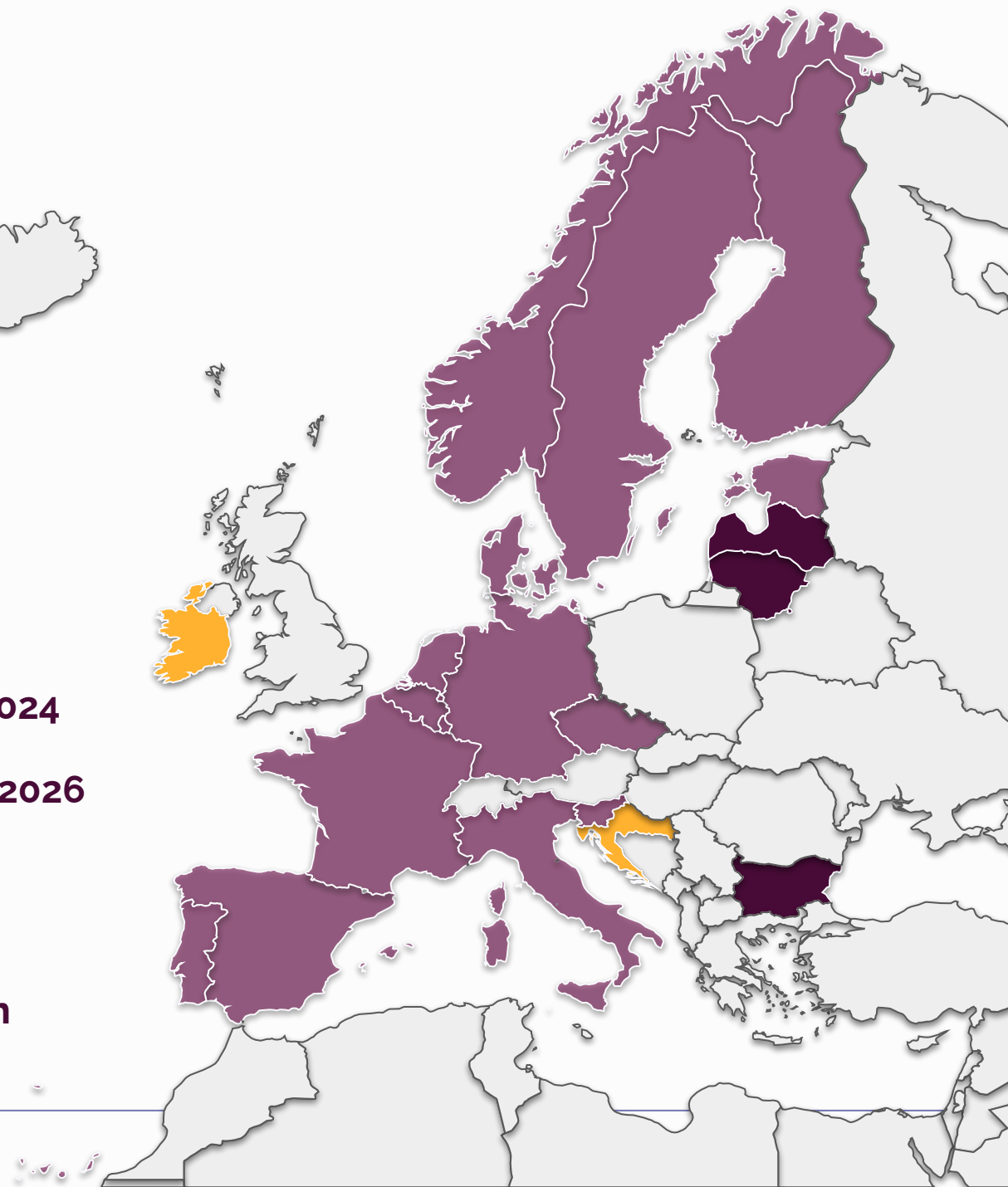
At least **6** countries technically operational by **2024**

At least **15** countries technically operational by **2026**

2 International Organisations*

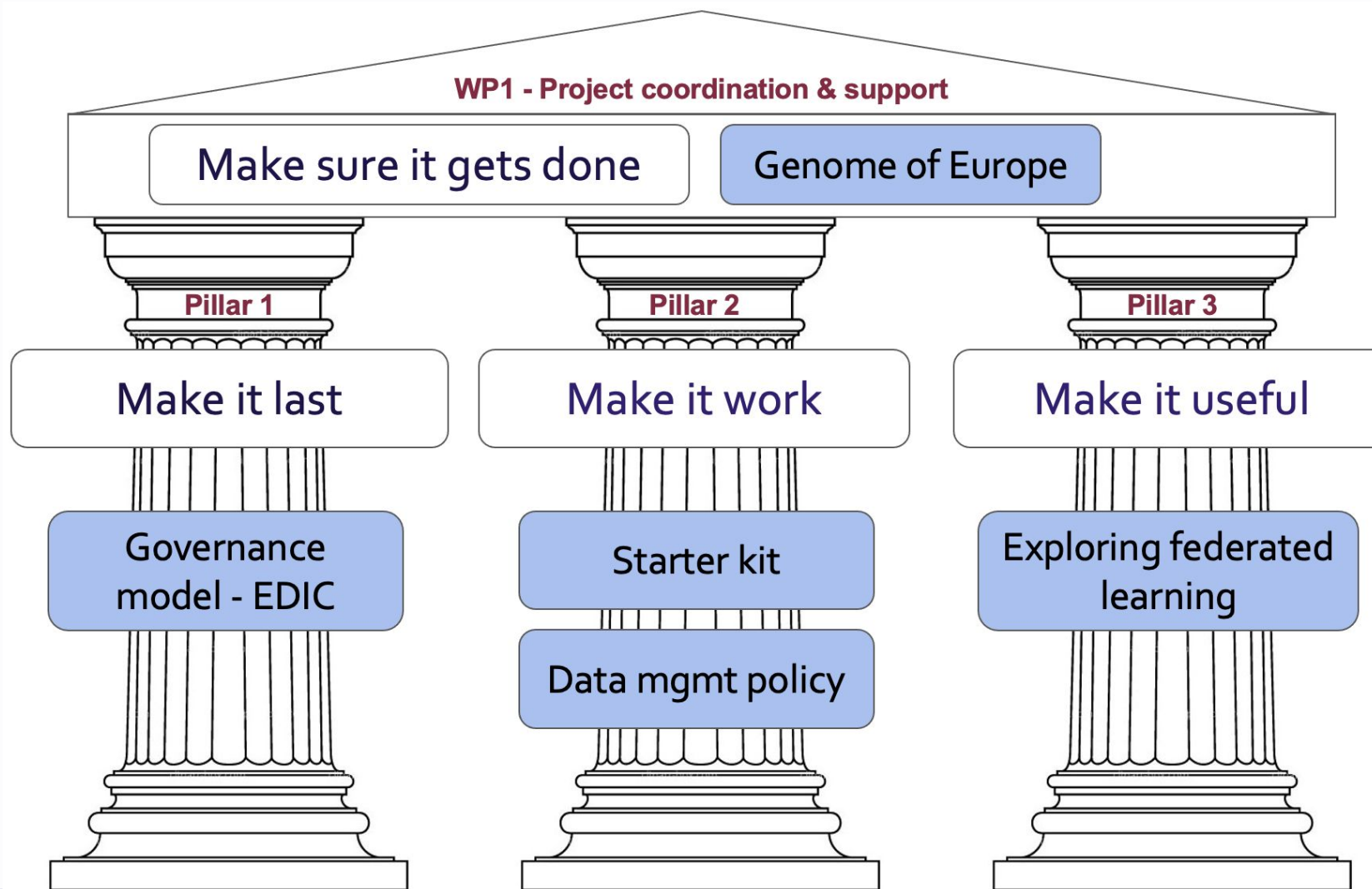
*ELIXIR & BBMRI-ERIC

Cyprus, Hungary, Malta and Romania joining GDI soon





GDI Project overview





Why an EDIC for 1+MG

- **Beyond research**
 - 1+MG will be a data infrastructure for **secondary use** beyond research (ERIC instruments) as it includes also reuse in **healthcare** and **policy development**
- **Governance of a genome data space**
 - The 1+MG Declaration aims at a **joint harmonised governance**
 - Enable participation of EU member states, EC, private sector and other institutions as agreed by EDIC members: ESFRIs, eInfras, EOSC,...
 - By definition members are expected to contribute in-kind or in cash
- **Legal framework for a genomic data space**
 - Systematic data sharing for secondary use needs **(new) legislation**
 - **EDIC** as a **new legal instrument** may have **weaknesses** for 1 +MG purpose→ **exploration** needed





Legal framework – potential instruments

- Evaluation of potential legal instruments

- **Identification** of main **criteria**, e.g. possibility to allow a **mission beyond research; liability**; ease to set up etc.
- Evaluation identified “**European Digital Infrastructure Consortium**” (**EDIC**) as most promising

- EDIC characteristics

- **Modelled on ERIC** of research infrastructures
- **Any mission** to support digital agenda
- **Differences** with respect to **members** and **role as international organisation**

✓: YES (✓): depends on choices made ~: not entirely X: NO

	Consortium agreement	Corporate entity on national law	EEIG	Intergov. Organisation	Joint Undertaking	ERIC	EDIC
Suitable for research, healthcare and policy development purposes	✓	✓	✓	✓	X	✓ ⁺ /X ⁺	✓ ⁺
Possibility to create lawfulness under Art. 6.1.e/9.2 including professional secrecy	X	X	X	n/a**	✓/X ⁺	✓/X ⁺	✓
Open for non-EU countries as members	✓	✓	~	✓	✓	✓	✓
Open for other stakeholders as members	✓	✓	✓	X	✓	X	✓
Clearly defined management and accountability	(✓)	✓	✓	✓	✓	✓	✓
Operating inside GDPR	(✓)	(✓)	✓	X	~/✓	✓	✓ ⁺
Controllership with 1+MG infrastructure	X	✓	✓	✓	✓	✓	✓
Limited liability	X	(✓)	X	✓	X	✓	✓
Sustainability	(✓)	(✓)	(✓)	✓	✓	✓	✓
Possibility to receive community funds	(✓)	✓	✓	✓	✓	✓	✓
Possibility to receive user funds	✓	✓	✓	✓	✓	✓	✓
VAT exemption	(✓)	~	X	✓	✓	✓	(✓)
Reasonably easy and fast to establish	(✓)	✓	✓	X	~	✓	✓

*: research only; ⁺: healthcare and policy development; **: operates outside GDPR; ⁺ subject to Commission Implementing Decision





Journey so far

- **Pursuit on an EDIC**
 - **EDIC selected as most promising solution** to be pursued by the **1+MG initiative**
- **Subsequent activities around the EDIC**
 - Submission of “**Expression of Interest**” on creating an EDIC for the genomic infrastructure to the Digital Decade Board by **19 countries**
 - **Pre-notification of willingness** to create an EDIC with indication of **first financial contributions (9 countries + ELIXIR)**
 - Included recommendation to maximise utilisation of current EU capacity as well as EC and MS investment when applicable (ESFRIs, EuroHPC, EOSC, eInfras,... could be invited to participate by the MS forming the EDIC)
- **Impact of EDIC EoI / pre-notification**
 - Creation of the **1+MG EDIC Working Group** supported by GDI pillar I and MCP Accelerator





1+MG & EHDS

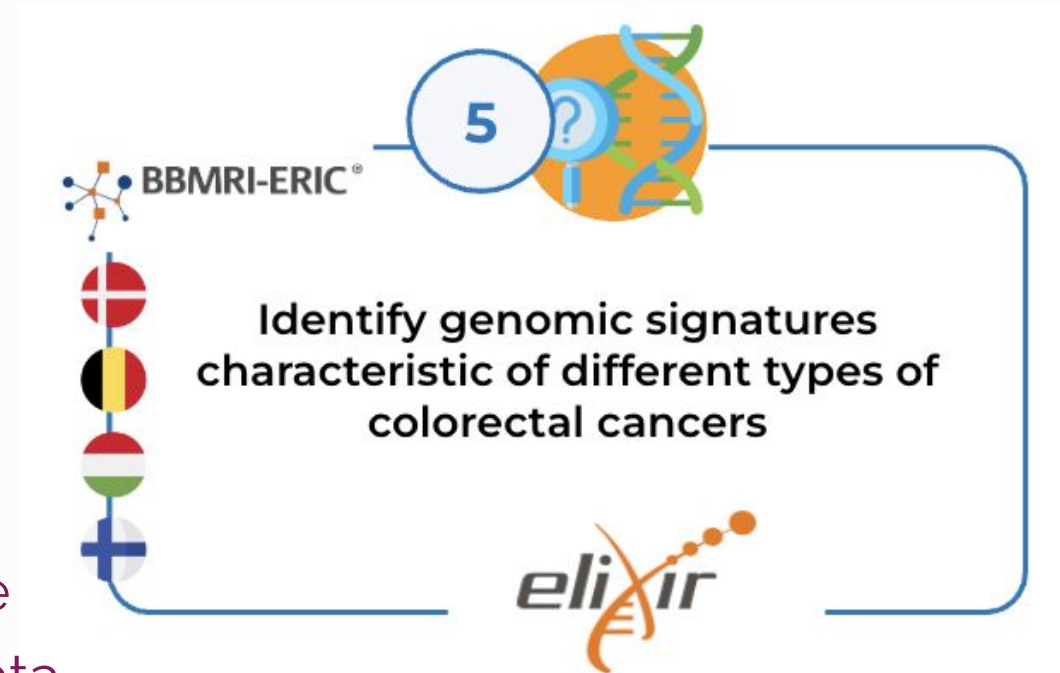
*a path for EDICs participation in
EU Data Spaces?*





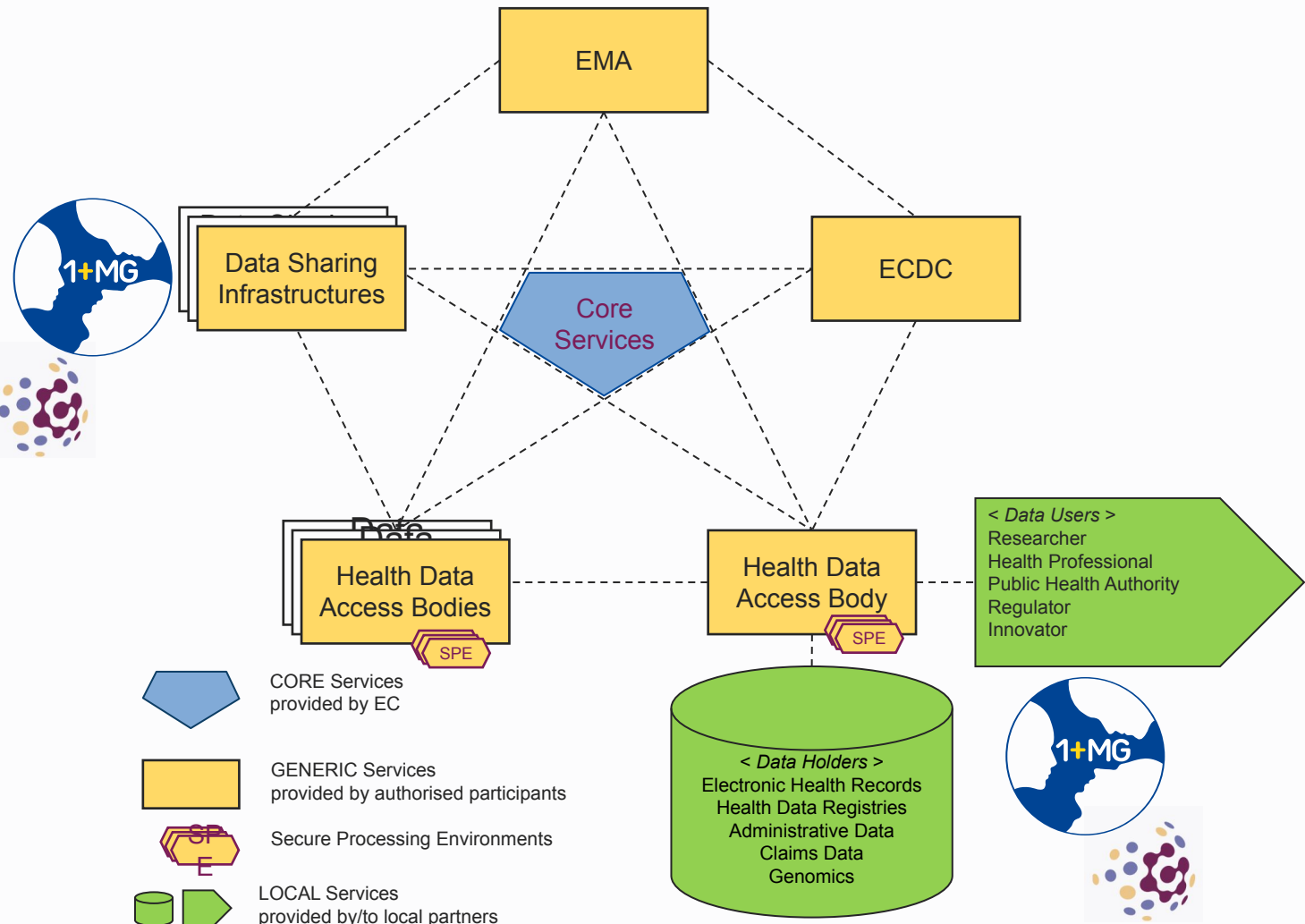
1+MG/GDI and EHDS

- 1+MG CRC use cases included in Healthdata@EU pilot project
 - Accessing EHDS participants data
 - BE, DK, HU, NO Health data body
 - BBMRI-ERIC Data sharing infrastructure
 - WGS, Phenotypic and, socioeconomic data
- Demonstrate use of 1+MG/GDI standard to manage genomic and health data within the Healthdata@EU



HealthData@EU: vision and reference architecture

Slide developed by the European Commission (updated on 01/07/23)



- **New infrastructure for secondary uses of health data**
- Connecting health data access bodies and data sharing infrastructures
- Several health data access bodies are established, or in the process, across Member States

CORE Services provided by EC
 GENERIC Services provided by authorised participants
 Secure Processing Environments
 LOCAL Services provided by/to local partners



EHDS and GDI

- 1+MG use case on colorectal cancer leveraging data infrastructure participation in EHDS (ELIXIR & BBMRI)
- Common interests on crucial issues such as data discovery, data access, etc.
- GDI and Healthdata@EU pilot projects are complementary and synergetic projects for secondary use of health data. Close collaboration a key success factor for both projects.





1+MG/GDI

- By delivering GDI we are also contributing to deliver EHDS
- GDI infrastructure/products can provide services under different governance models:
 - National infrastructures
 - 1+MG
 - EUCAIM
 - EHDS
 - FEGA
 - EOSC
 - Others

It is an implementation decision.





European Genomic Data Infrastructure

salvador.capella@bsc.es / juan.arenas@elixir-europe.org
gdi-coordination@elixir-europe.org



@GDI_EUproject



/company/gdi-euproject



GDI website



GDI project receives funding from the European Union's Digital Europe Programme under grant agreement number 101081813.
