2ᵉᵐᵉ édition des rencontres SHS et médecine génomique

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FRANCE MÉDECINE GÉNOMIQUE 2025
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aviesan | CEA ◯ CHRU ◯ CNRS ◯ CPU ◯ INRA ◯ INRIA ◯ INSERM ◯ INSTITUT PASTEUR ◯ IRD
ARIIS ◯ CDEFI ◯ CIRAD ◯ EFS ◯ FONDATION MERIEUX ◯ INERIS ◯ INSTITUT CURIE ◯ INSTITUT MINES-TELECOM ◯ IRBA ◯ IRSN ◯ UNICANCER

1+MG facilitates countries to **realise a practice of personalised medicine and health**, based upon a shared 'trust framework' and the infrastructure to safely access and integrate high quality genomic data and other health data across borders

Countries that have signed the 1+MG Declaration since 2018

Austria
Belgium
Bulgaria
Croatia
Cyprus
Czech Republic
Denmark
Estonia
Finland
France
Germany
Greece
Hungary
Ireland
Italy
Latvia
Lithuania
Luxembourg
Malta
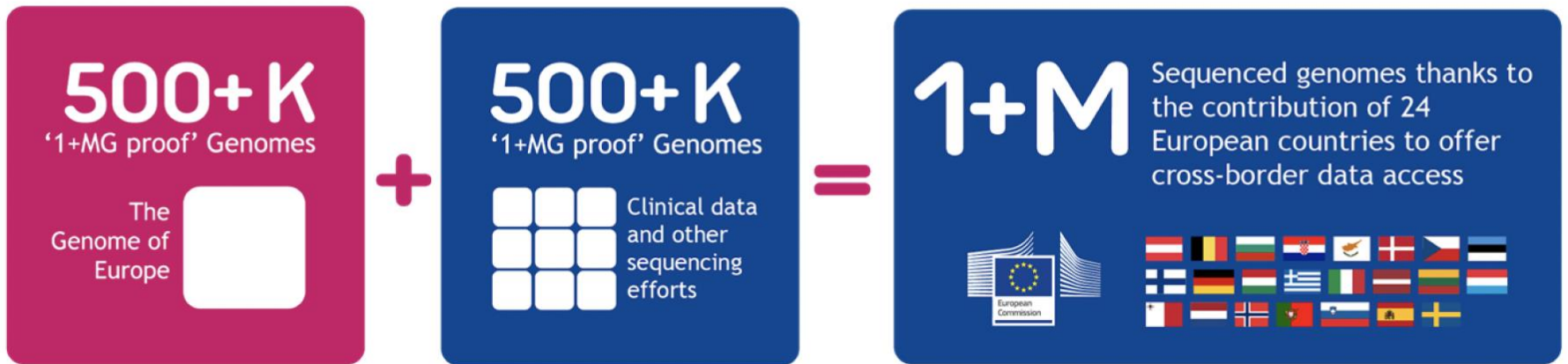Netherlands
Norway
Portugal
Slovenia
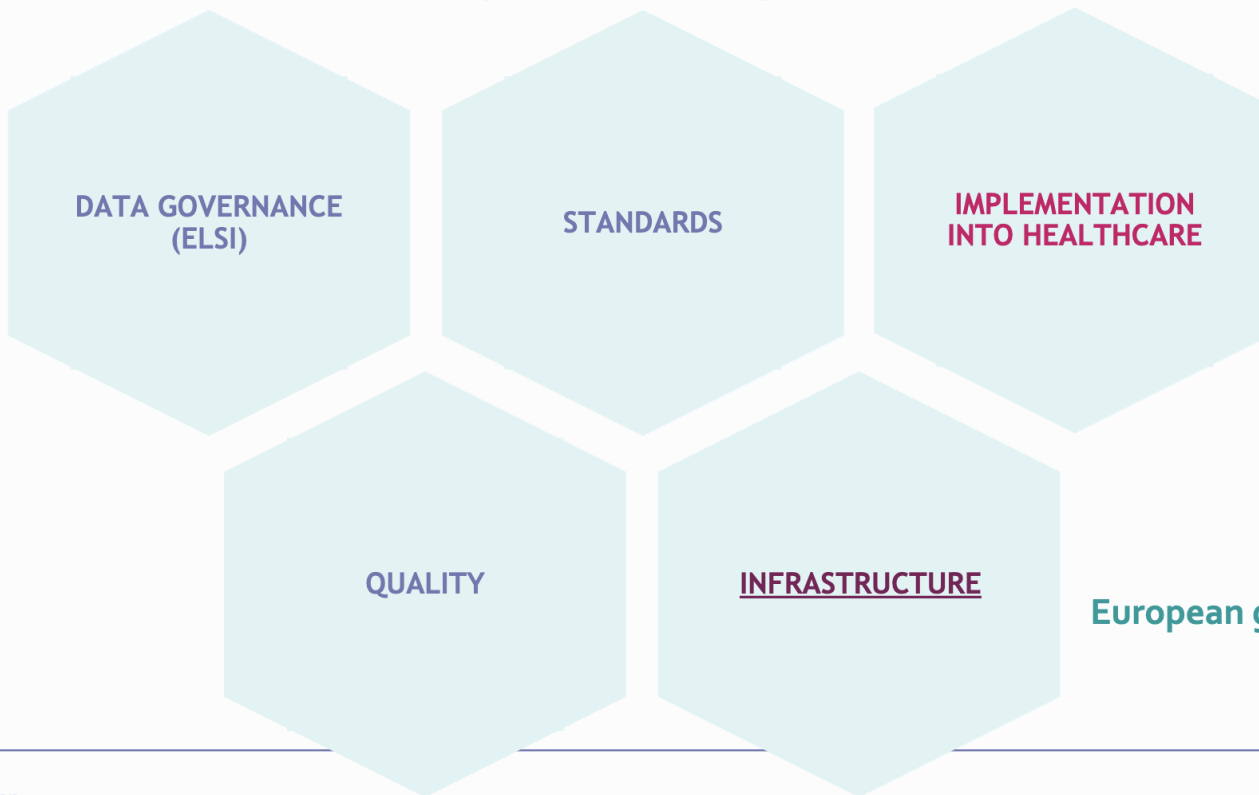Spain
Sweden
UK

Observer countries

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

500+K
'1+MG proof' Genomes

The Genome of Europe

+

500+K
'1+MG proof' Genomes

Clinical data and other sequencing efforts

=

1+M

Sequenced genomes thanks to the contribution of 24 European countries to offer cross-border data access

1+MG Trust Framework

Technical recommendations and guidelines for **genomics data**

DATA GOVERNANCE (ELSI)

STANDARDS

IMPLEMENTATION INTO HEALTHCARE

QUALITY

INFRASTRUCTURE

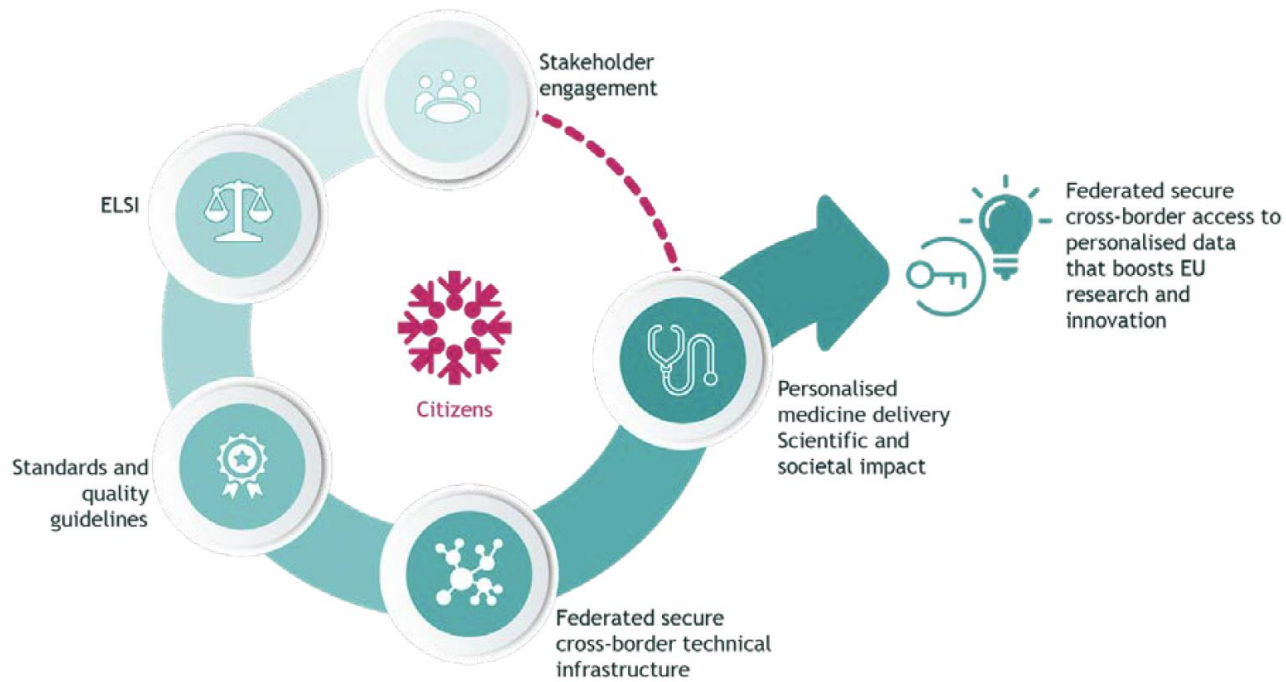**European genomics dashboard**

Iterative process

- An iterative approach for the implementation of the 1+MG programme is being followed, involving key stakeholders at national and international level.

Implementation projects

Cross-border access to genomic data, implementation of genomics-based health
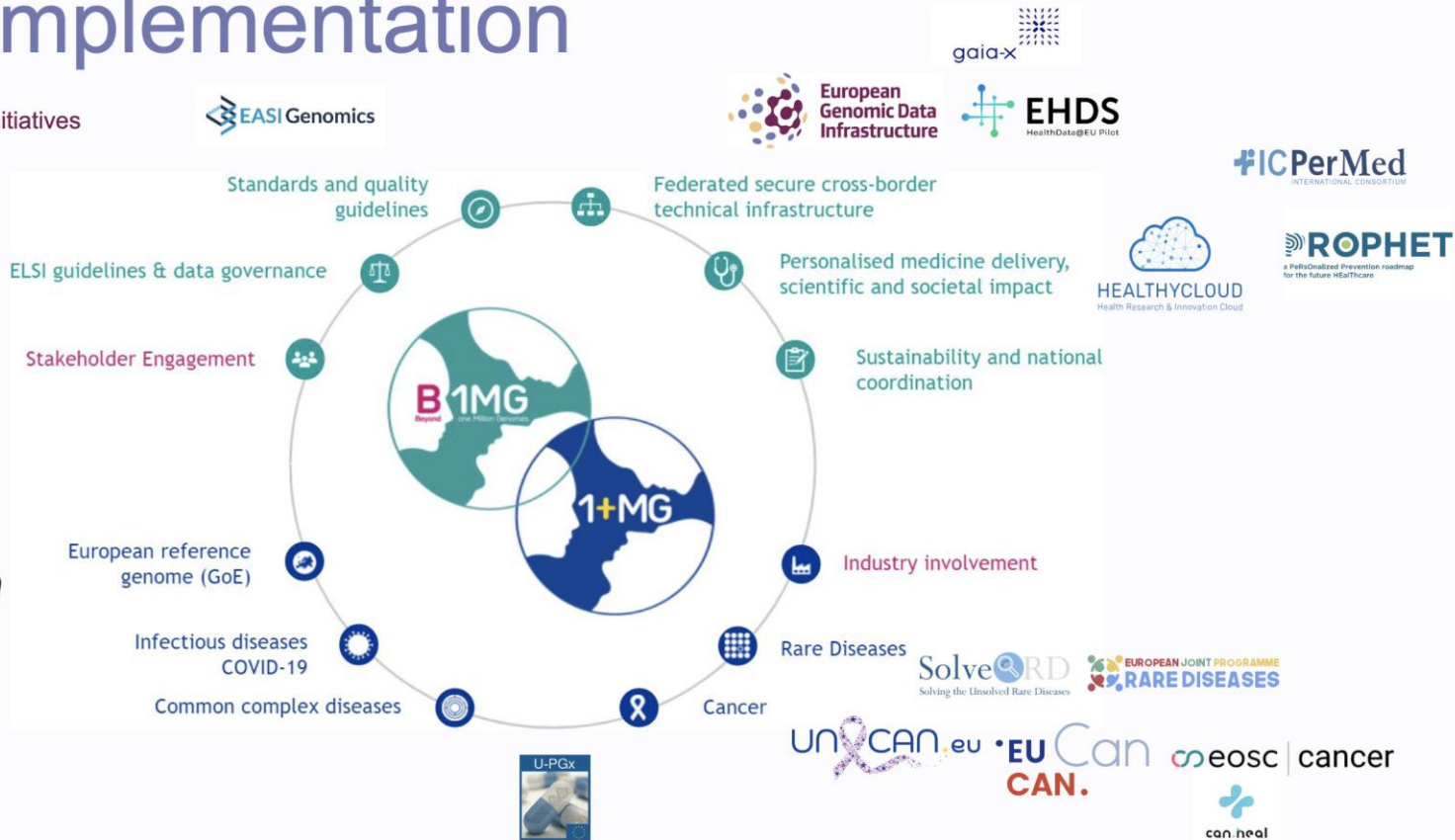

2018   2020   2022   **2023**   2026   2027

European
Genomic Data
Infrastructure

Horizon 2020
European Union funding
for Research & Innovation

1+MG implementation

WGs 1+MG

- **WG1 Gouvernance / National Mirror Groups – Fernando Martin-Sanchez, Angela Ponce** => Frédérique Nowak (coordinatrice scientifique), Inês Amado (Point de contact national) & MESR

- **WG2 ELSI - Regina Becker**

- **WG3 Data standards – Jeroen Belien**

- **WG4 Quality metrics for sequencing – Ivo Gut**

- **WG5 Technical infrastructure – Tommi Nyronen**

- **WG6 Health Economics – Ilse Custers**

- **WG7 Private sector – Sandra Liede**

- **WG8 Rare Diseases – Bruno Dallapiccola**

- **WG9 Cancer – Giovanni Tonon**

- **WG10 Common & Complex Diseases - Andres Metspalu**

- **WG11 Infectious disease use case - Katja Kivinen**

- **WG12 Genome of Europe – André Uitterlinden**

Mise en place du Groupe Miroir National demandée par 1+MG

1+MG NATIONAL MIRROR GROUPS
NMGs at glance

COMPOSITION & PROFILE

5-12 members

1 Scientific Coordinator

1 National Contact Point (NCP)
Nominated by each NMG, they work as interlocutors between the EC and their group.

The 1+MG National Mirror Groups (NMGs) feed their national experience into the 1+ Million Genomes Initiative.

These national instances will ensure the effective implementation of the roadmap at a national and local level by 2022.

MISSION

Improve quality of life

> To improve EU citizens quality of life by enabling transnational access to genomics data

Facilitate access to the initiative's information
For national experts and policymakers to ensure the alignment of Member States with the initiative's objectives.

Promote national adoption and sustainability
To ensure synergistic implementation in each National Health System and provide recommendations to local and European funders.

TASKS

NMGs, alongside stakeholders, will create a space for dialogue to:

Build a decision-making framework
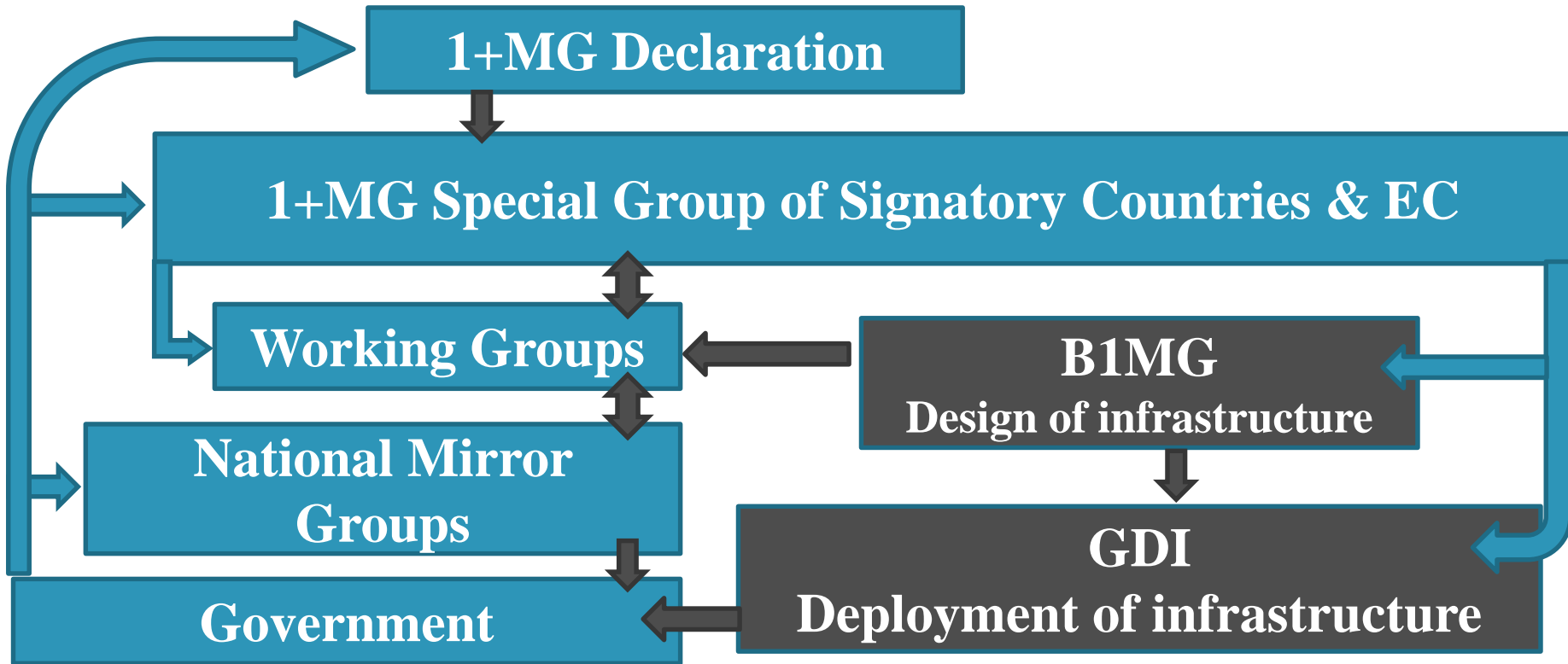For public-private participation and increased health literacy among stakeholders.

Envision a future framework
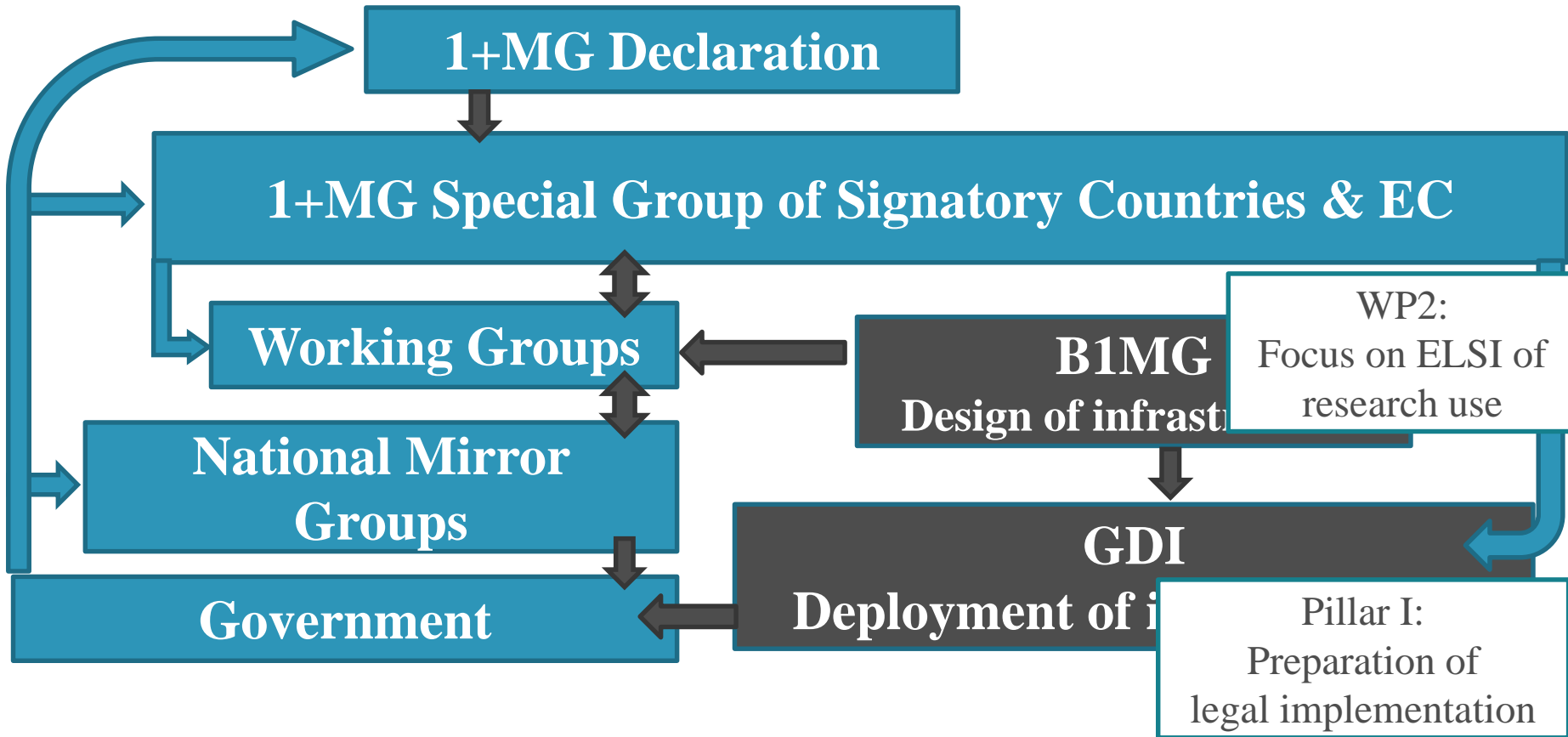For integrating emerging health technologies into health systems.

Identify prospective mechanisms
For stakeholder cooperation — inside and outside the EU.

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Relationships & roles in 1+MG

Relationships & roles in 1+MG

Background: Scope of 1+MG

- Scope of 1+MG: the what and the who
- Membership
  - EEA countries
  - Openness of other country of similar ethical values
- Activities
  - Scientific research
    - ✓ Open for users worldwide
    - ✓ Potentially more safeguards / limitation of IP for non-EEA countries
  - Healthcare reuse
    - ✓ Member countries only
  - Policy development
    - ✓ Member countries only unless policies of general interest

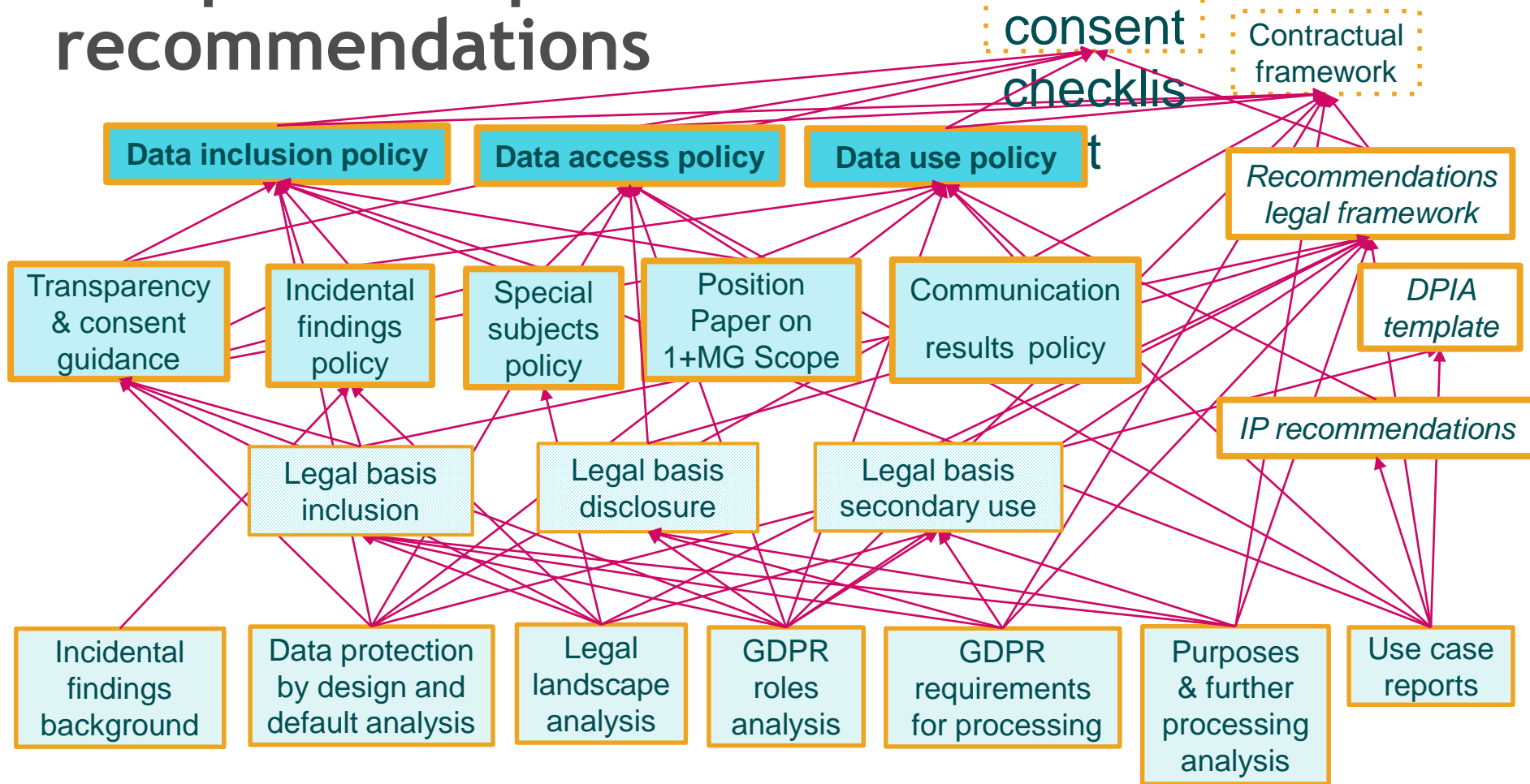# Overview compilation of legal landscape workshops

Countries	Secondary use for public interest	Act on secondary use	Consent for health data to research	RECs for health data to research	Consent for research data to healthcare	RECs for research data to healthcare	Specific safeguards on DPA	Anonymization or pseudonymization	Attention to subjects' rights	Need of DPIA
Denmark				✓	✓	✓	✓	✓		
Finland	✓	✓					✓	✓	✓	✓
Norway		✓	✓	✓	✓	✓	✓		✓	
Sweden	✓		✓	✓	✓				✓	
Greece			✓	✓	✓	✓	✓	✓	✓	✓
Italy			✓	✓	✓	✓	✓	✓	✓	✓
Malta	✓			✓	✓			✓		
Portugal			✓	✓	✓	✓	✓	✓	✓	✓
Spain	✓		✓	✓	✓		✓	✓	✓	✓
Netherlands			✓	✓	✓			✓	✓	✓
Belgium	✓		✓	✓	✓		✓	✓	✓	✓
France	✓			✓	✓	✓	✓	✓	✓	✓
Germany	✓		✓		✓				✓	
Poland			✓		✓				✓	✓
Czech Republic	✓		✓	✓			✓	✓	✓	✓
Latvia	✓		✓		✓					
Estonia	✓									

Slide: Olga Tzortzatou, Marina Makri, Alexandra Ziaka

Topics broached

- Legal base (for analysis, core processing...)
- Definition of roles under the GDPR
- Legal framework applicable
  - GDPR
  - "European Digital Infrastructure Consortium" (EDIC)
- Transparency and consent guidance
- Inclusion of special (vulnerable) subjects
- Incidental findings (IFs)
- Communication general research results
- Data protection assessment

Complex setup of ELSI recommendations

Transparency & consent checklist

Contractual framework

Data inclusion policy

Data access policy

Data use policy

Recommendations legal framework

Transparency & consent guidance

Incidental findings policy

Special subjects policy

Position Paper on 1+MG Scope

Communication results policy

DPIA template

IP recommendations

Legal basis inclusion

Legal basis disclosure

Legal basis secondary use

Incidental findings background

Data protection by design and default analysis

Legal landscape analysis

GDPR roles analysis

GDPR requirements for processing

Purposes & further processing analysis

Use case reports

Missing elements and next steps

- **Obvious gaps**
  - Data governance for **healthcare reuse**, **policy development** *[not part of B1MG]*
  - **Contractual** relations *[only possible if overall setup is agreed]*
  - **Content suggestion** for information and consent forms *[only possible if overall setup is agreed; not part of B1MG]*

- **Other elements**
  - International transfer
  - Sometimes **no detailed report** compiled E.g. recommendations integrated into data governance without producing individual report (IP, data subjects' rights)
  - ...

Merci pour votre attention !

Mise en place du Groupe Miroir National demandée par 1+MG

Composition des Groupes miroir nationaux :

- Groupe de travail de l'initiative à laquelle il appartient.

- Rôle : coordinateur/expert.

- Type d'acteur (partie prenante) :

  o Ministère/Agence/Administration/Décideur politique.

  o Recherche/Université.

  o Communautés cliniques.

  o Communautés informatiques/données.

  o Communautés scientifiques.

  o Groupes consultatifs en matière de politiques.

  o Industrie/Secteur privé.

  o ELSI (Éthique, aspects sociaux et juridiques de la recherche scientifique et technologique).

  o Agences de financement.

  o Organisations de patients.

Review gaps for current roadmap objectives

Gap themes:
- Health
- Data
- Sustainability

Topic	Coverage			Gaps 2023-2027
	1+MG	B1MG	GDI	
Governance	WG1, WG2	WP2	WP2	Implementation in healthcare & public health
Trust framework	WG2, WG3, WG4, WG5	WP2, WP3, WP4	WP2, WP4, WP6, WP8	Health policy scenario; sustainability
Infrastructure	WG5	WP4	WP3, WP4, WP8	Data stewardship and technical capacity building; actions for healthcare professionals
Data	WG3, WG4, WG12	WP3	WP1 ,WP4, WP6	Sequencing; data curation and integration, storage costs and sustainability
Use cases	WG8, WG9, WG10, WG11	WP7	WP7	
National efforts	WG1, WG6	WP5, WP6	WP1, WP5	
Stakeholders	(WG7)	WP1, WP6	(WP1), WP5, WP8	
Other initiatives	(CG)	WP1, WP6	WP5	
Societal impact	(WG6)	WP4	WP3, WP4, WP8	Funding for capacity building, networking