Getting ready for using the European health data space

ISPOR Fast Facts session

FTI Consulting – Petra Wilson & Adam Day

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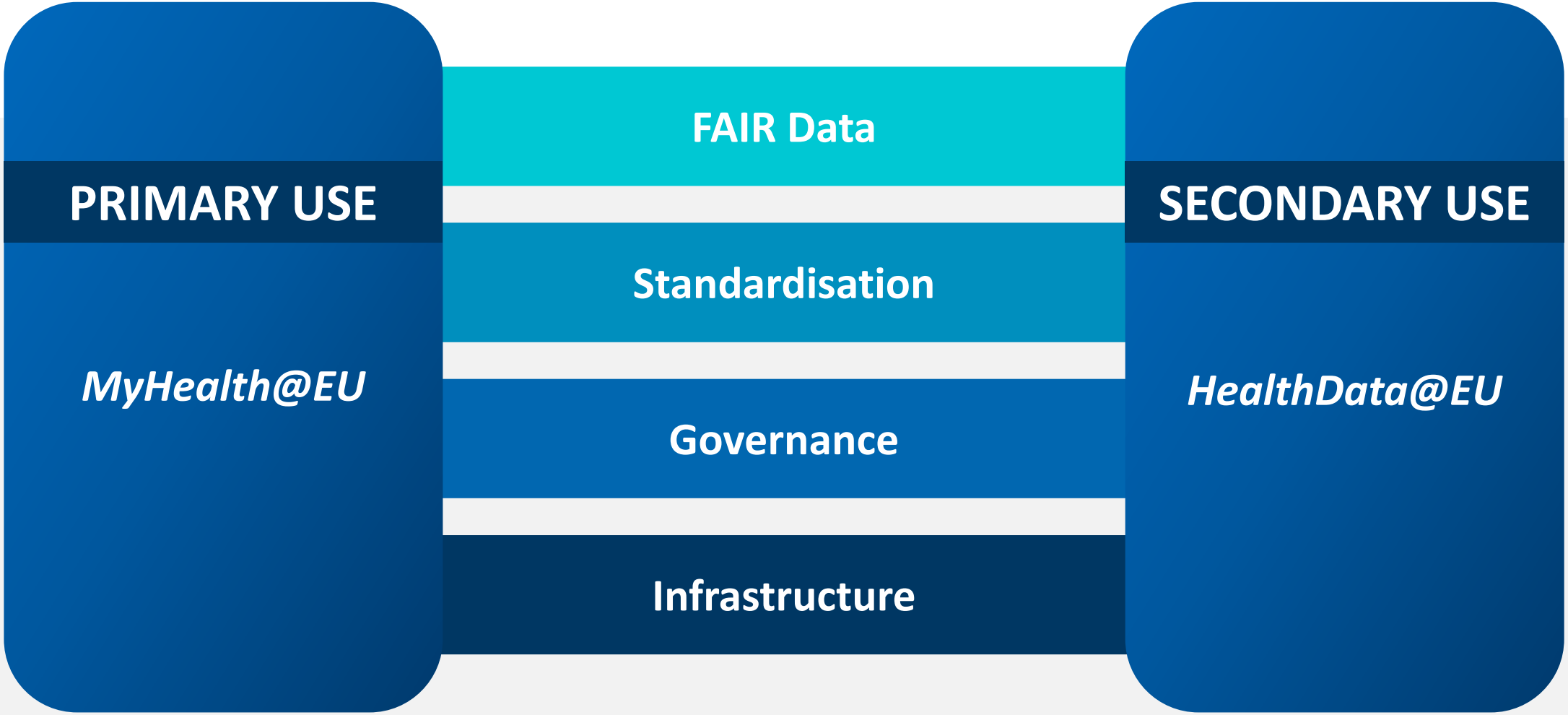
Key provisions of the EHDS



SECONDARY USE

HealthData@EU

Purposes

Public interest
Regulation
Policy making
Scientific research
Education
AI development

Data categories

EHR data
Pathogen data
Genetic/genomic data
Public health registries
Clinical trial data
Research cohort data

Process

Health Data Access Bodies
Data cataloguing
Data access application or data request
Secure Processing Environment
Trusted health data holder

Data holder obligations

Input dataset description into catalogue
Make data available for secondary use

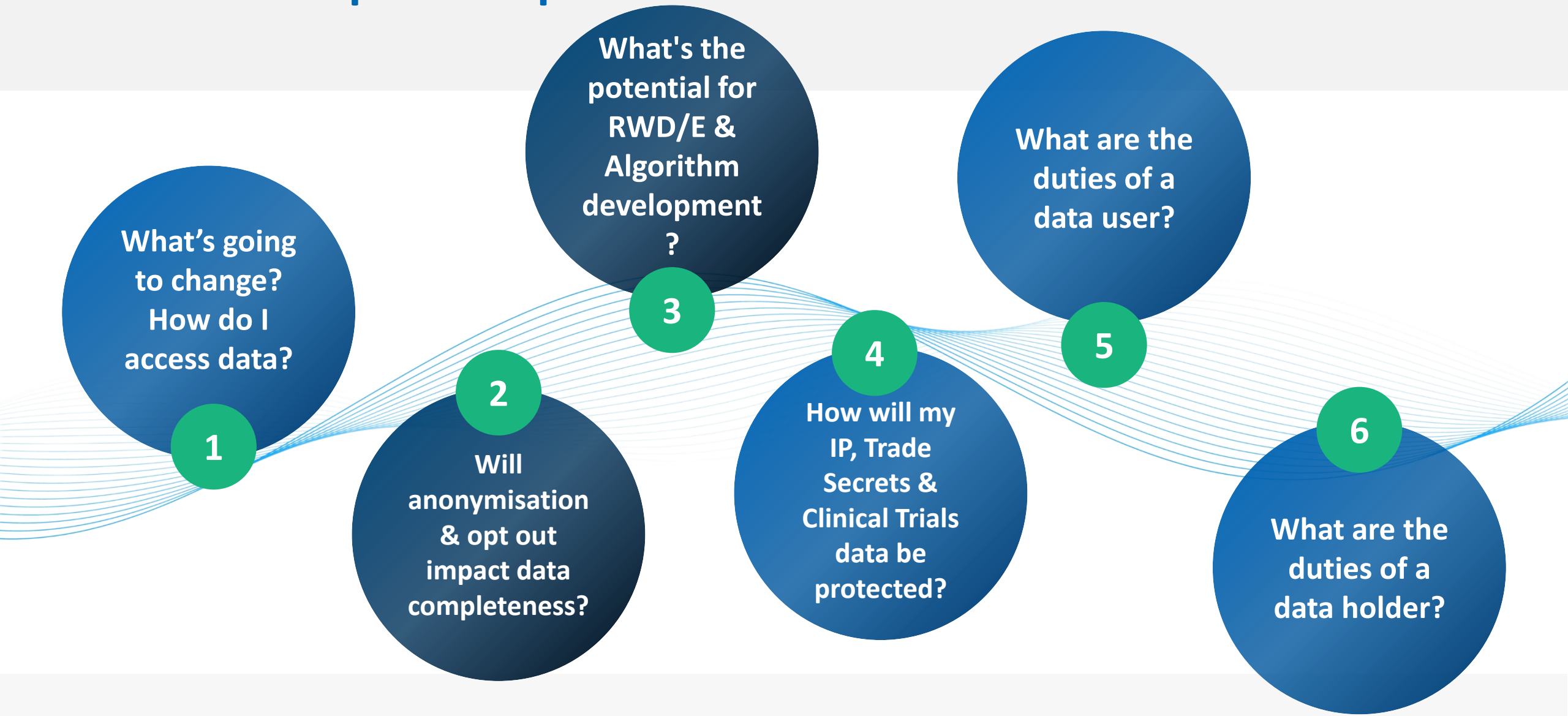
Data user obligations

Enriched data to be made available
Notification of significant findings

HDAB obligations

Data access application or data request
SPE
IP & Trade Secret protection

Potential deep dive topics



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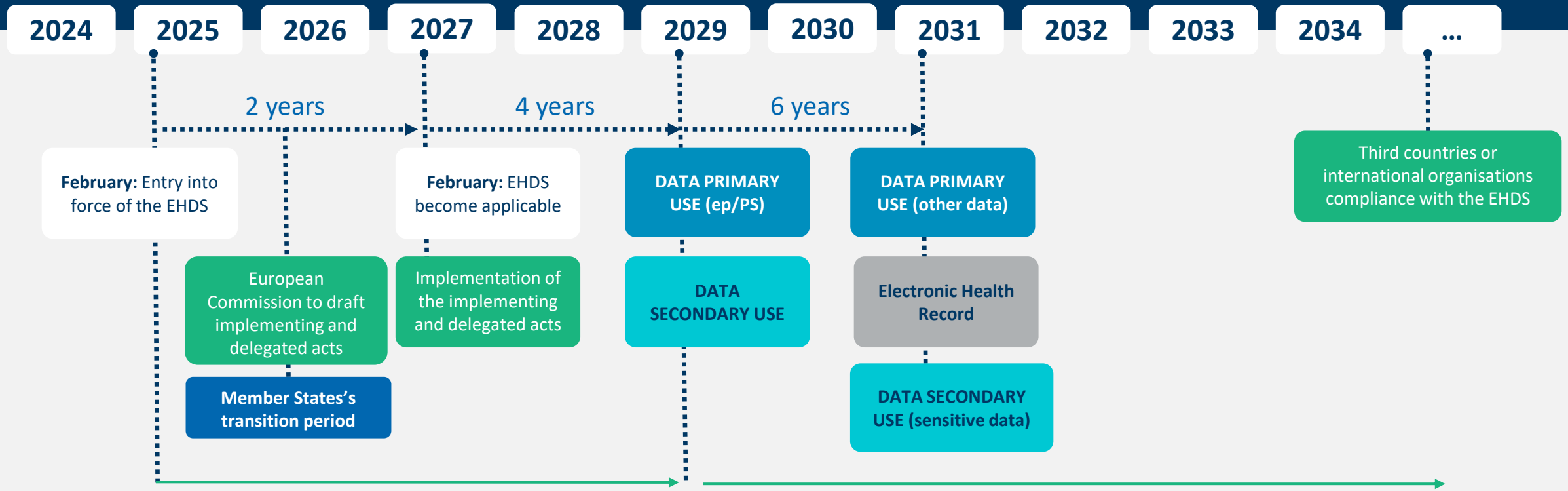
EHDS implementation timeline



PHASE 1:

- Establish digital infrastructure
- Adopt preparatory measures to support MS, health data holders and EHR systems manufacturing in meeting their obligations

This phase includes setting up the foundational systems and ensuring that all parties are ready to effectively comply with the EHDS requirements.

PHASE 2:

- Regular updating of implement acts
- Maintenance and operation of the systems under the EHDS at EU and MS level

This phase ensures the sustained functionality and compliance of the digital health infrastructure.

Thank you!

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