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EHDS
HealthData@EU Pilot

HealthData@EU: Update on EHDS pilot

ENCePP Plenary, 1 December 2023

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An agency of the European Union

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European Health Data Space - User perspectives

MyHealth@EU

Empower citizens to have control over their health data

Better diagnosis and treatment, improved patient safety, continuity of care
and improved healthcare efficiency

Enable healthcare professionals to have access to relevant health data

Health data from apps and medical devices

Health data in registries

Electronic health records

HealthData@EU pilot

Assist policy makers and regulators in accessing relevant health data

Facilitate access to health data for innovators in industry

Grant access to health data for researchers

Better health policy, greater opportunities for research and innovation

Slide extracted from the EHDS Pilot GA Oct 2023, Courtesy of M. Berneaux, EC Policy Officer

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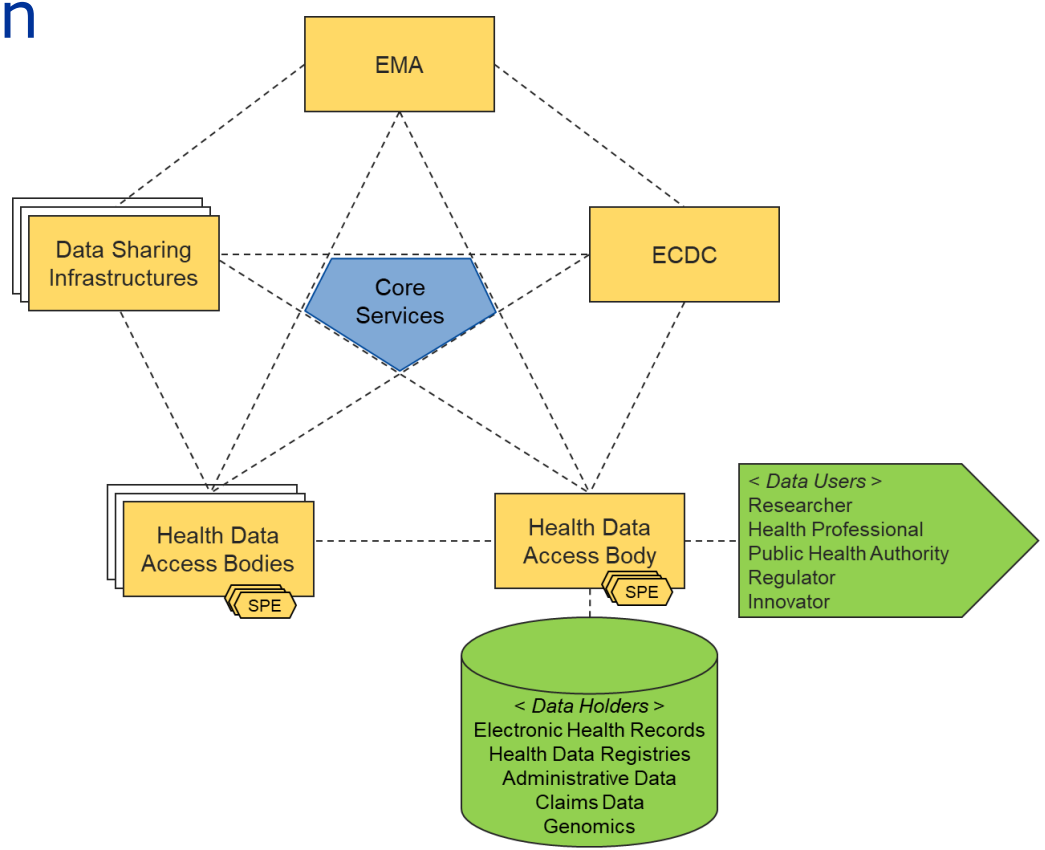
HealthData@EU – a vision

- **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 authorized participants

SPE Secure Processing Environments

LOCAL Services provided by/to local partners

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The User Journey

Data user

Data discovery

What health data exists to support my project (research, public policy, innovation)?
What supplementary data (e.g., demographic) exists and how can it be linked?

Permit application

Can I use this data for my project?

Data preparation

Issue permit and make data ready for use, ensuring data quality, privacy and linkability.

Health Data Holders

Health Data Access Body

Data provision

Give access to Secure Processing Environment.

Data use

Link, analyse and process data.

Data user

Results output

Publish results, ensuring privacy and verifiability, transparency.

HealthData@EU pilot

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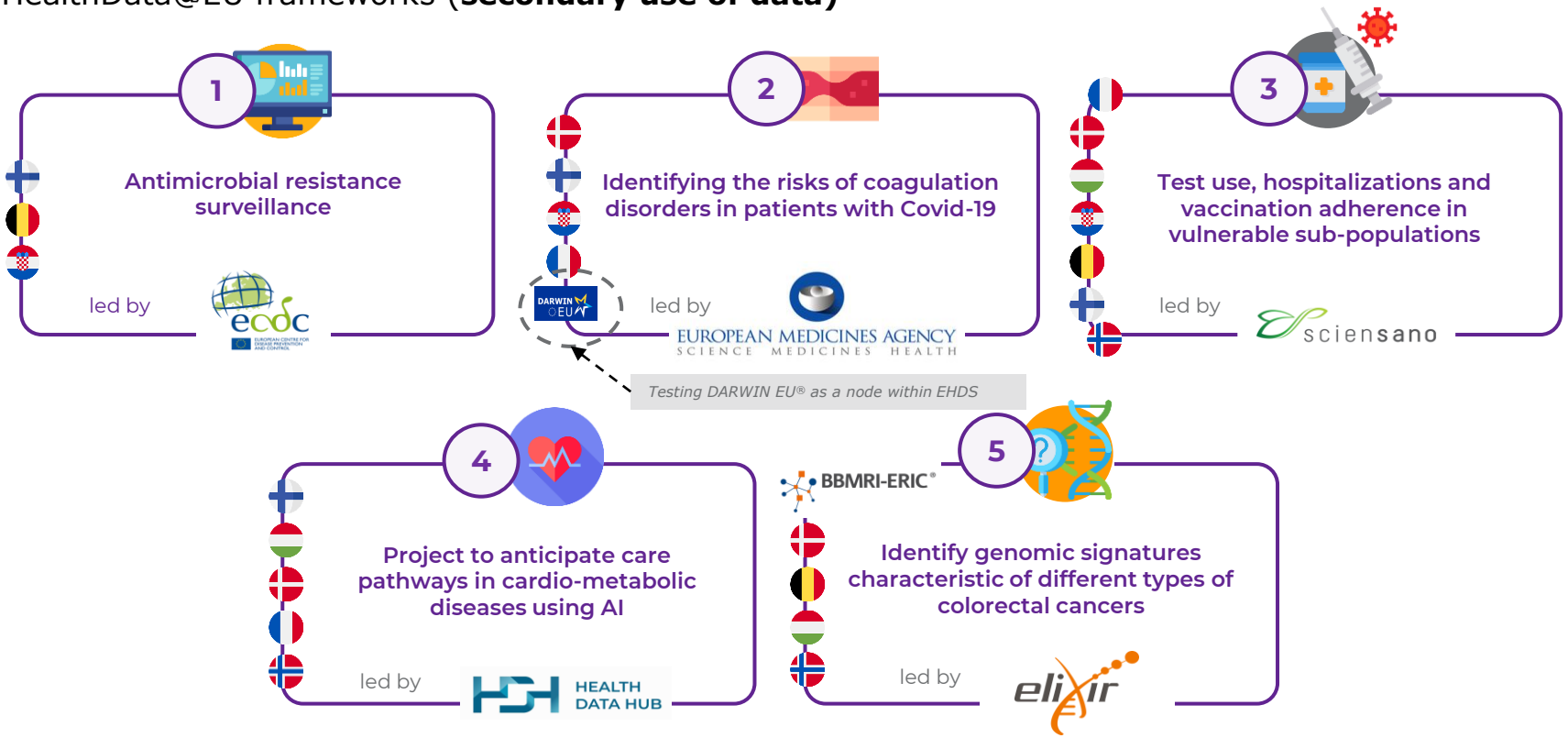
A 2-year pilot kicked off in Oct 22 - **Five use cases** to inform design, development, and deployment of HealthData@EU frameworks (**secondary use of data)**



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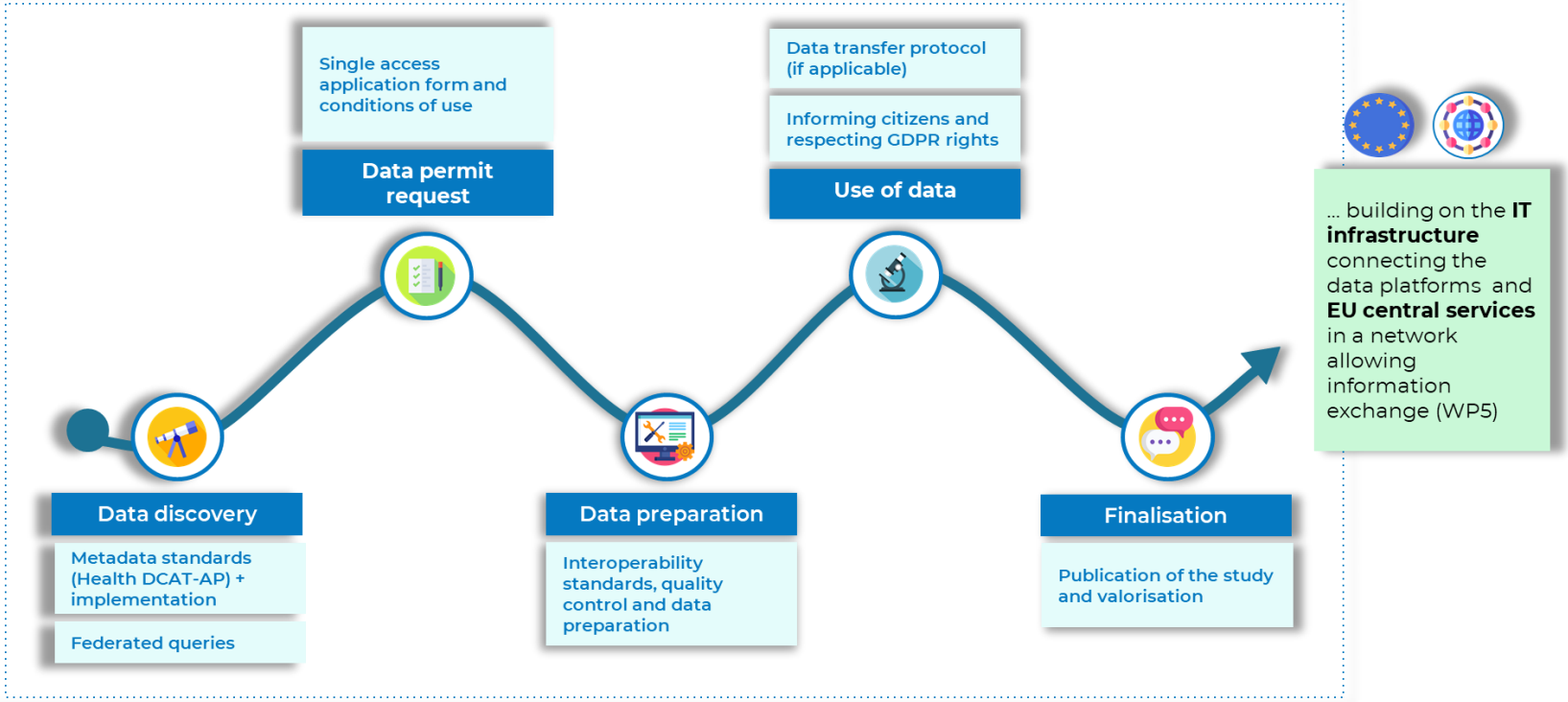
Expected results



Slide extracted from the EHDS Pilot GA Oct 2023, Courtesy of M. Jendrossek, European Projects Lead, HDH

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Connection with ENCePP Guide on Methodological Standards

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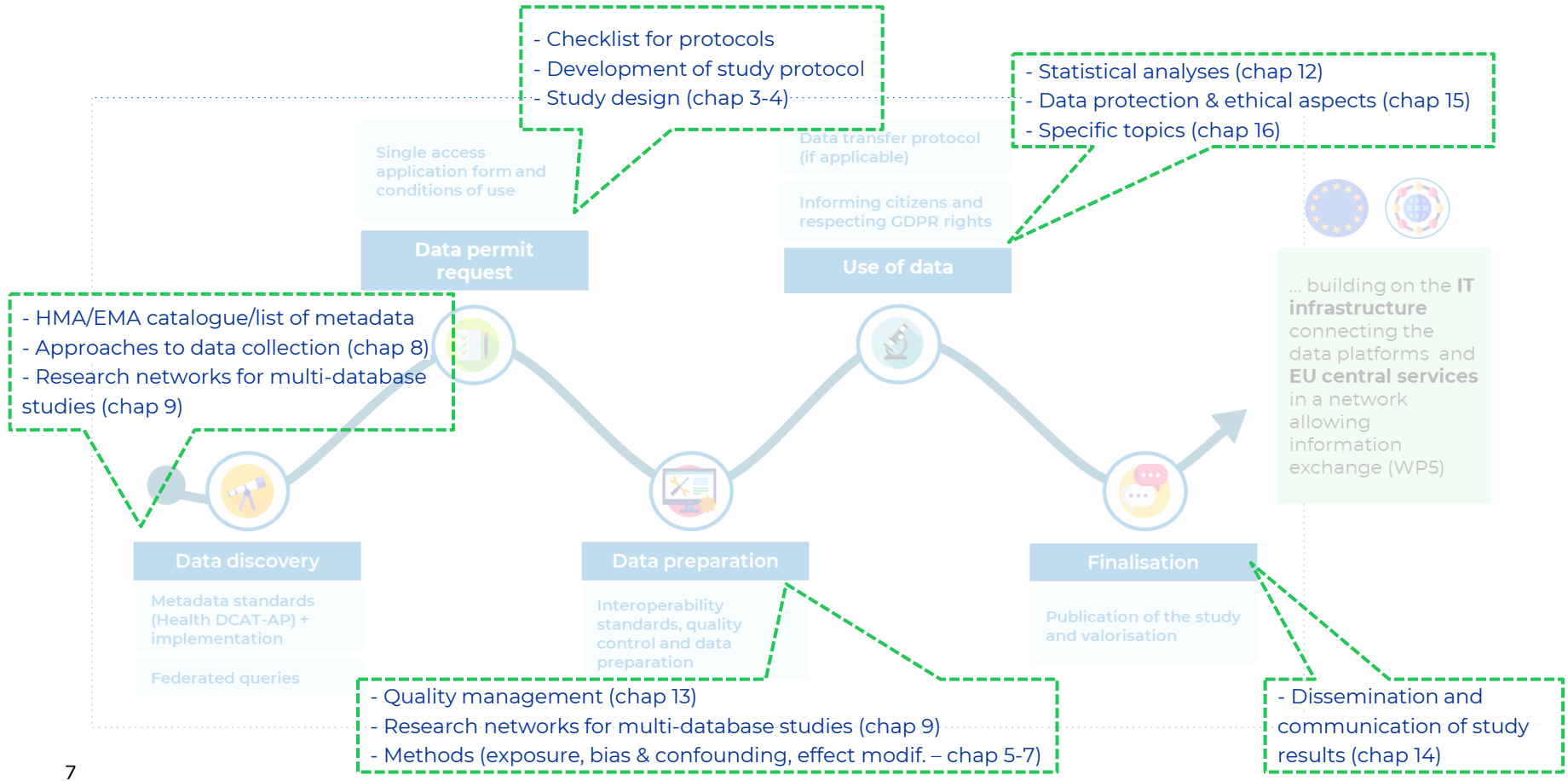
- Checklist for protocols
- Development of study protocol
- Study design (chap 3-4)

- Statistical analyses (chap 12)
- Data protection & ethical aspects (chap 15)
- Specific topics (chap 16)



- HMA/EMA catalogue/list of metadata
- Approaches to data collection (chap 8)
- Research networks for multi-database studies (chap 9)

- Quality management (chap 13)
- Research networks for multi-database studies (chap 9)
- Methods (exposure, bias & confounding, effect modif. – chap 5-7)

- Dissemination and communication of study results (chap 14)

*ENCePP Guide on Methodological Standards

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EHDS & HealthData@EU

Opportunity to enable a Rapid, Wide and Deep access to healthcare data ?

Opportunities

- Increased EU representativeness in studies (geographic coverage, care settings, size of studies…)
- Rapid, Wide, Deep access to healthcare data to support better and faster decision making

Enabled by

- Implementation & readiness - potential tensions between common EU vs each MS interpretation and/or timelines
- Transparency & trust – adopted mechanisms need to remain compatible with the need for rapid, wide and deep secure access
- Data access - smooth governance & interoperable infrastructures
- Data protection & data security – balancing anonymisation and pseudonymisation with possible tensions related data linkage

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Closing

- EHDS has the potential to strengthen observational research and the use of RWD/RWE
  - **R**apid, **W**ide and **D**eep access for secondary use of healthcare data
- Transparency, trust and collaboration are key instruments
- ENCePP work has been paving the way in many areas of the user journey
- Monitor progress and ensure connection and input in the implementation

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Any questions?

Further information

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