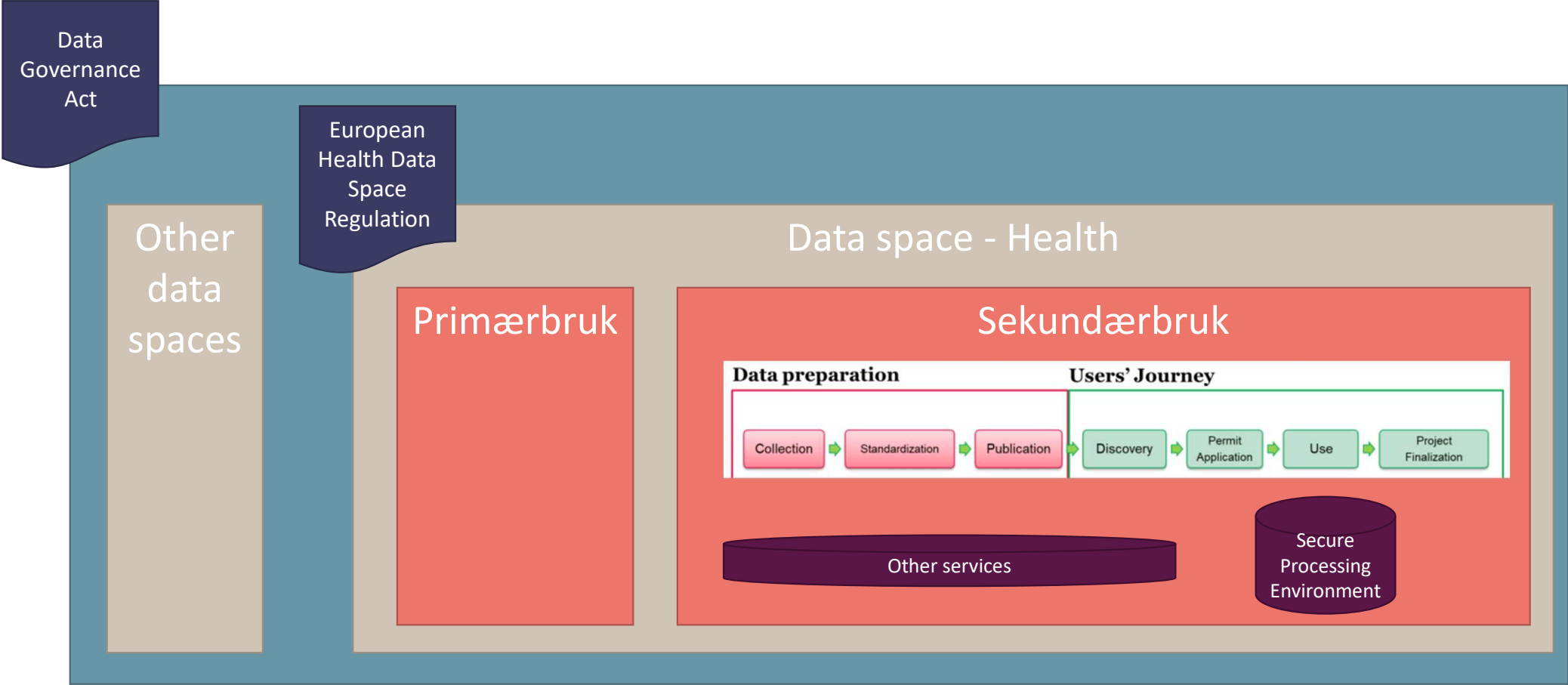


European Health Data Space (EHDS)

Secure Processing Environments (SPE)

2024.01.10

Fra topp til bunn



Regulering



EHDS Article 50: Secure processing environment

1. The health data access bodies shall provide access to electronic health data only through a secure processing environment, with technical and organisational measures and security and interoperability requirements. In particular, they shall take the following security measures:
 - (a) restrict access to the secure processing environment to authorised persons listed in the respective data permit;
 - (b) minimise the risk of the unauthorised reading, copying, modification or removal of electronic health data hosted in the secure processing environment through state-of-the-art technological means;
 - (c) limit the input of electronic health data and the inspection, modification or deletion of electronic health data hosted in the secure processing environment to a limited number of authorised identifiable individuals;
 - (d) ensure that data users have access only to the electronic health data covered by their data permit, by means of individual and unique user identities and confidential access modes only;
 - (e) keep identifiable logs of access to the secure processing environment for the period of time necessary to verify and audit all processing operations in that environment;
 - (f) ensure compliance and monitor the security measures referred to in this Article to mitigate potential security threats.
2. The health data access bodies shall ensure that electronic health data can be uploaded by data holders and can be accessed by the data user in a secure processing environment. The data users shall only be able to download non-personal electronic health data from the secure processing environment.
3. The health data access bodies shall ensure regular audits of the secure processing environments.
4. The Commission shall, by means of implementing acts, provide for the technical, information security and interoperability requirements for the secure processing environments. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).



Forskrift om nasjonal løsning for tilgjengeliggjøring av helsedata

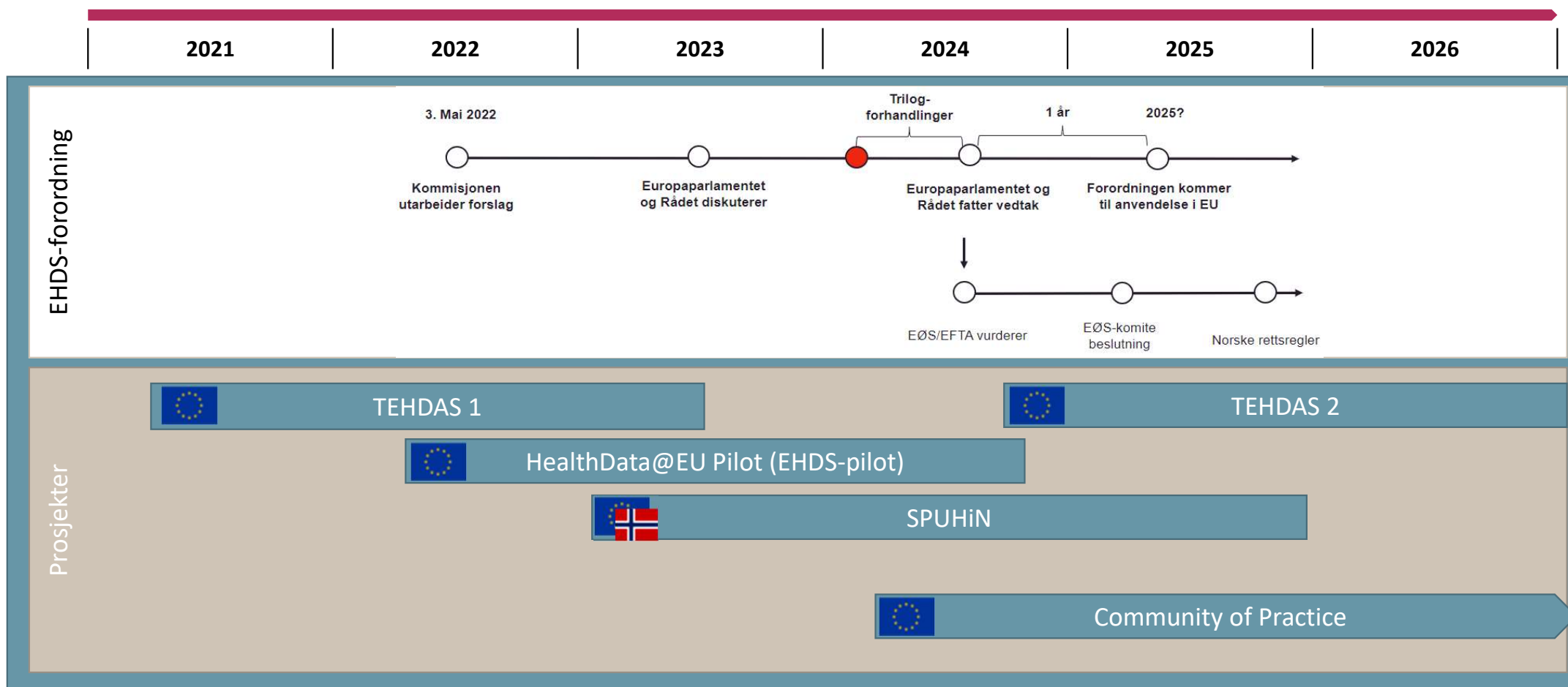
§ 4. Avgjørelser om tilgjengeliggjøring

...

Dataene skal tilgjengeliggjøres for databrukeren som anonyme opplysninger eller i en **lukket og sikker analyseinfrastruktur**.

Direkte og indirekte personidentifiserbare helseopplysninger kan likevel tilgjengeliggjøres på andre måter dersom det er nødvendig for å oppnå formålet databrukeren har oppgitt i søknaden til direktoratet.

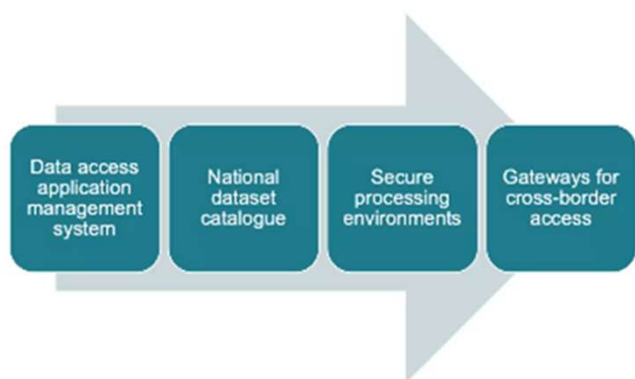
Overordnet tidsplan EHDS



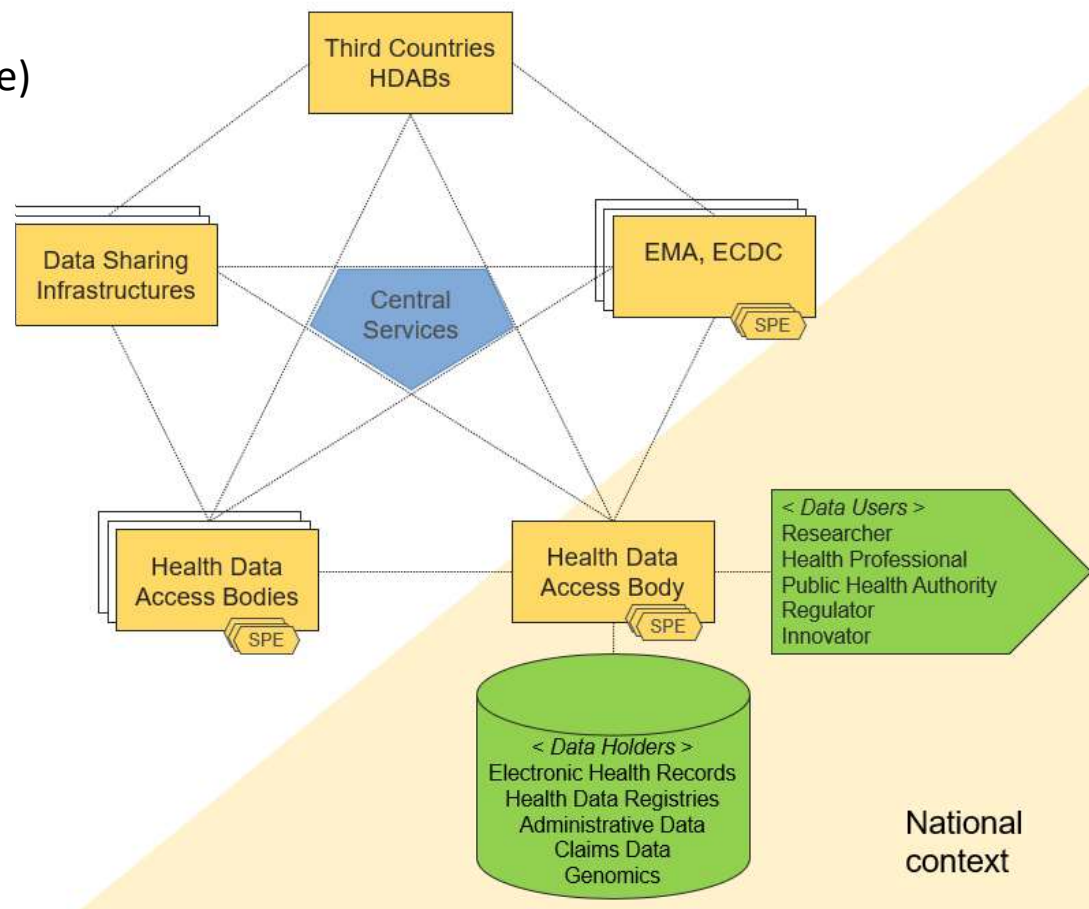
Sekundærbruk av helsedata – HealthData@EU

Health Data Access Body (Helsedataservice i Norge)

Four Digital Business Capabilities to be deployed:



-  Central support services provided by EC
-  National data management services provided by authorised participants
-  Secure Processing Environments
-  Local services provided by/to local partners

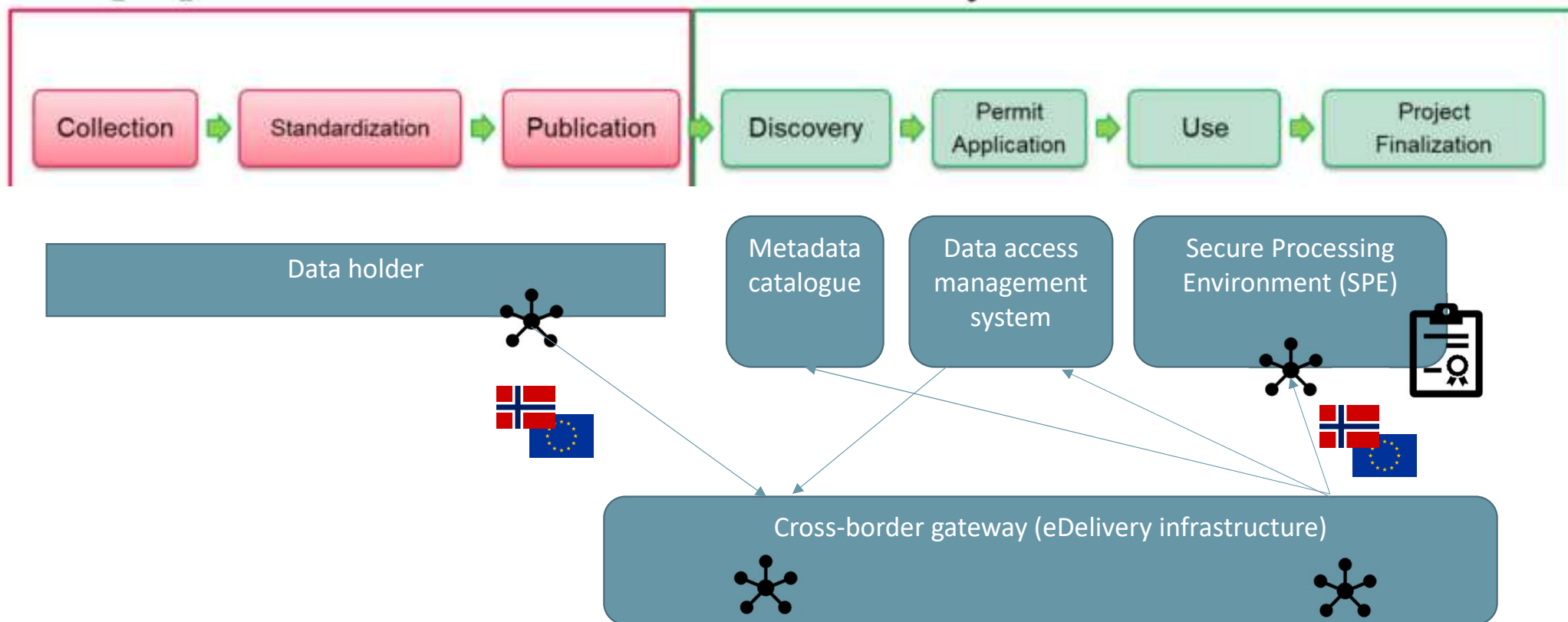


Kilde: [European Health Data Space \(europa.eu\)](http://European Health Data Space (europa.eu))

Kapabiliteter i brukerreisen for databruk

Data preparation

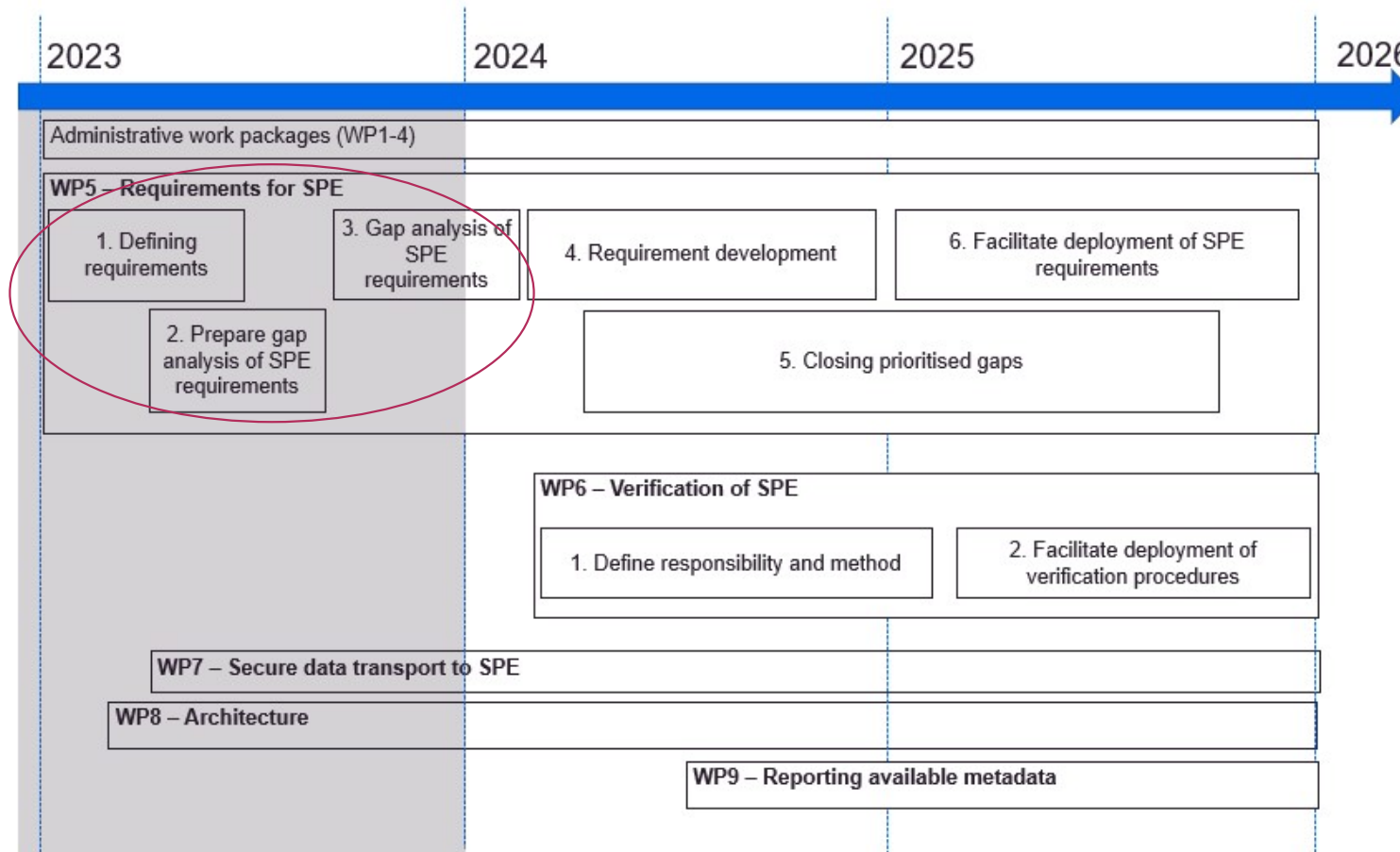
Users' Journey





Co-funded by the European Union

SPUHiN project plan



TEHDAS – options for SPE (selection)

Security standards requirements

	Requirements for SPEs point directly and solely to requirement sets in existing standards, frameworks or schemes. E.g. one or several ISO-standards.	Requirements for SPEs point to existing standards, frameworks or schemes and are complemented with EHDS-specific requirements.	A new set of requirements for SPEs is developed based on existing standards.
Average	2.429	4.500	2.643
Stdev	0.938	0.650	1.499

Level of verification compliance

	SPE providers can verify compliance through self-assessment. Voluntary compliance testing is also available. (e.g., similar to CISPE Data Protection Code of Conduct)	SPE providers can verify compliance through self-assessment. External audits are performed (e.g., similar to the Data protection agencies audit procedures today).	An external party performs testing against requirements to verify compliance and provide certification. (e.g., similar to the certification process in Finland)	
Average	2.000	2.500	3.643	4.000
Stdev	0.555	1.019	1.082	0.784

TEHDAS – options for SPE (selection)

Data extraction harmonisation

	How to control extraction of data from the SPE (including for federated analysis) should be determined by each SPE.	How to control extraction of data from the SPE (including for federated analysis) should be determined by each country.	How to control extraction of data from the SPE (including for federated analysis) should be harmonised within the EU.
Average	2.143	2.929	3.643
Stdev	0.864	0.917	1.151

Functional capabilities

	Functional capabilities for SPEs are solely controlled by market needs.	A set of minimum functional capabilities for SPEs are defined in each country.	A set of minimum functional capabilities for SPEs are defined on an EU-level.
Average	2.214	3.429	4.214
Stdev	0.893	0.938	1.051

Utvalg av kontroller

1. **Styringsystem for informasjonssikkerhet (ISMS)**
2. **Tilgangsstyring**
3. Innlesing av helsedata
4. **Nedlastingskontroll**
5. Kryptering
6. Logging og overvåking
7. Backup
8. Beskyttelse ved lagring
9. Hendelseshåndtering
10. **Sikkerhetsarkitektur**
11. Sikker drift
12. **Analysekapasitet**
13. Support, vedlikehold og utvikling av SPE-tjenester
14. Arkivering
15. Interaksjon med SPE-tjenesten



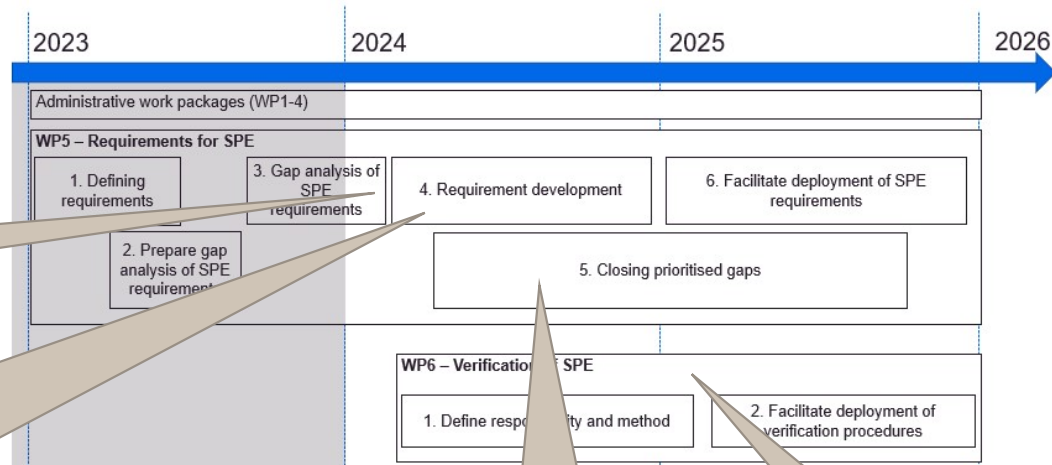
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Veien videre

Rapport
gap-
analyse
SPE



Veiledninger

Gir råd innen spesifikke områder basert på beste praksis fra flere virksomheter



Retningslinjer

Beskriver nasjonale myndigheters oppfatning av hva som er god praksis innenfor et område



Anbefalte standarder

Standarder anbefalt av offentlig myndighet, med intensjon om at de skal bli obligatoriske



Obligatoriske standarder

Standarder som er hjemlet i forskrift
Dette er bindende normer

Normerende dokumenter



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Spørsmål, kommentarer, innspill?

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