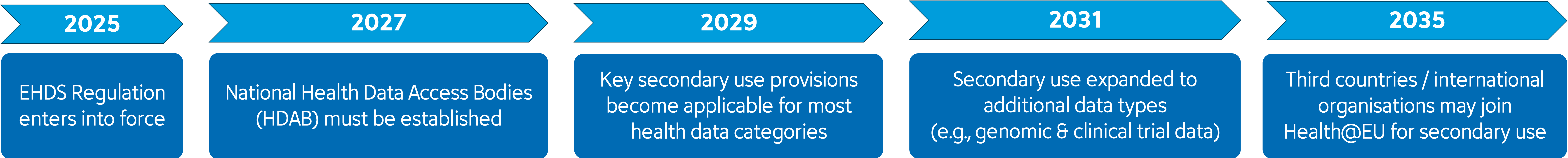


The European Health Data Space (EHDS) is coming

Is Your Data EHDS-Ready?

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EHDS Timeline



What is EHDS?

The European Health Data Space (EHDS) is an EU Regulation establishing a harmonised legal framework for:

- Access to electronic health data
- Cross-border data sharing
- Secondary use of health data for:
 - Scientific research
 - Innovation & AI development
 - Public health
 - Regulatory and policy purposes

DKFZ is a Health Data Holder (HDH) under the EHDS but can also become a Health Data User (HDU).

EHDS Access Procedure

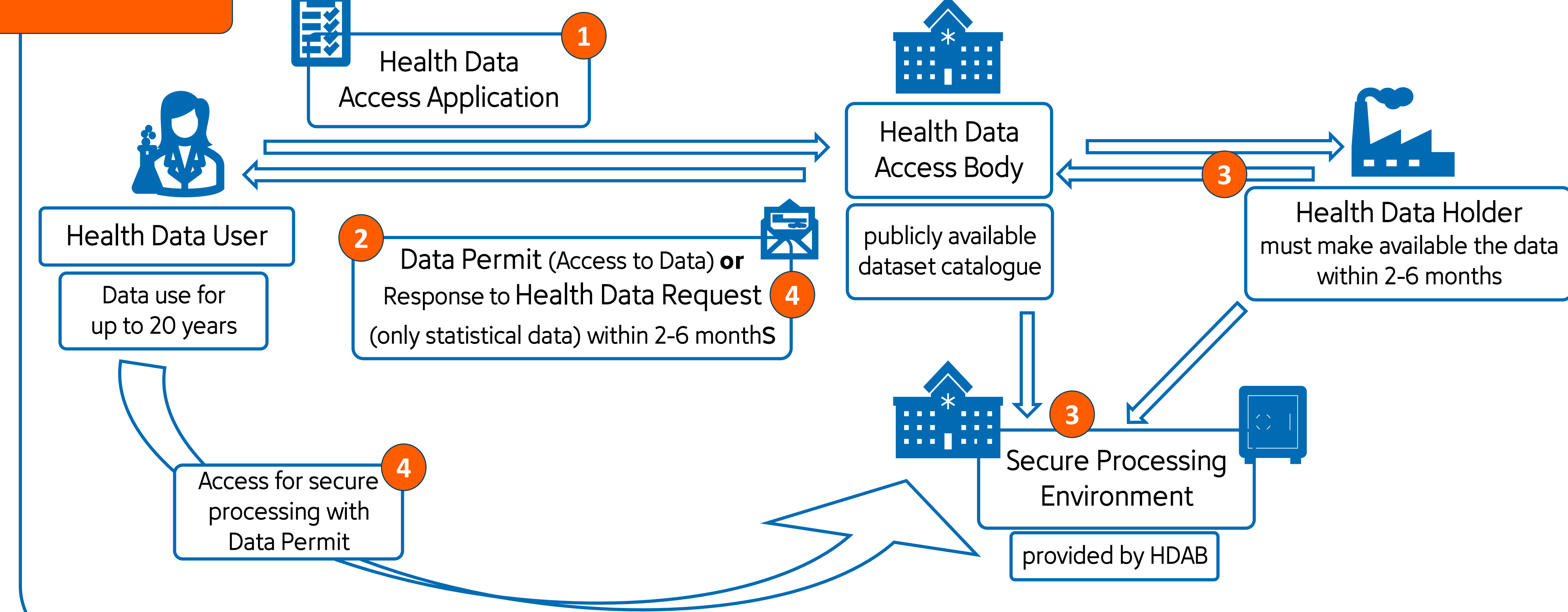


Figure legend: Simplified process for data access under EHDS

Data Categories to be made available by HDHs under EHDS for Secondary Use (i.a.):

- Data on factors impacting on health
- human genetic, epigenomic and genomic data
- other human molecular data such as proteomic, transcriptomic, metabolomic, lipidomic and other omic data
- data from medical registries and mortality registries
- data from clinical trials, clinical studies, clinical investigations
- data from research cohorts, questionnaires and surveys related to health, after the first publication of the related results
- health data from biobanks and associated databases

Institutional Challenges – Data Management Challenges:

- Our data must be findable, describable and made (even more) accessible
- We need a comprehensive data inventory, a clear mapping of datasets relevant for secondary use
- EHDS relies heavily on standardised metadata, so we have to increase efforts to label datasets and enrich metadata
- We will have to align with EHDS interoperability standards
- We need to provide requested data to EHDS-compliant secure processing environments

Regulatory Challenges:

- EHDS → does not eliminate or amend **GDPR**
- Ethical approvals → still required
- Infrastructure → readiness is critical

More information about EHDS:
https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space-regulation-ehds_en



DKFZ needs a holistic governance framework

All relevant stakeholders — researchers, data stewards, IT, legal, compliance, administration, and infrastructure — must be involved from the outset.