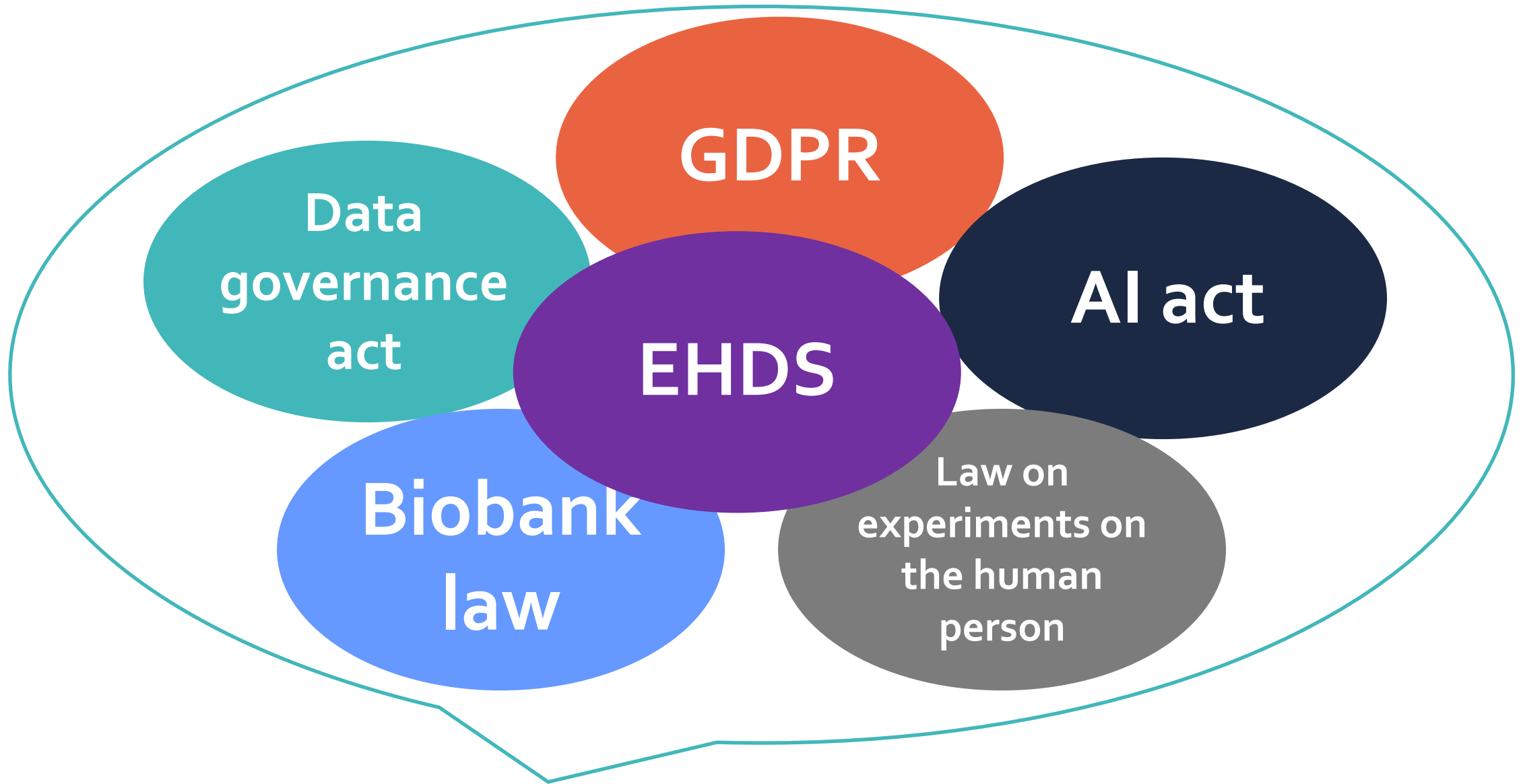


Health data and basic and translational research

Current practices and consequences of the EHDS

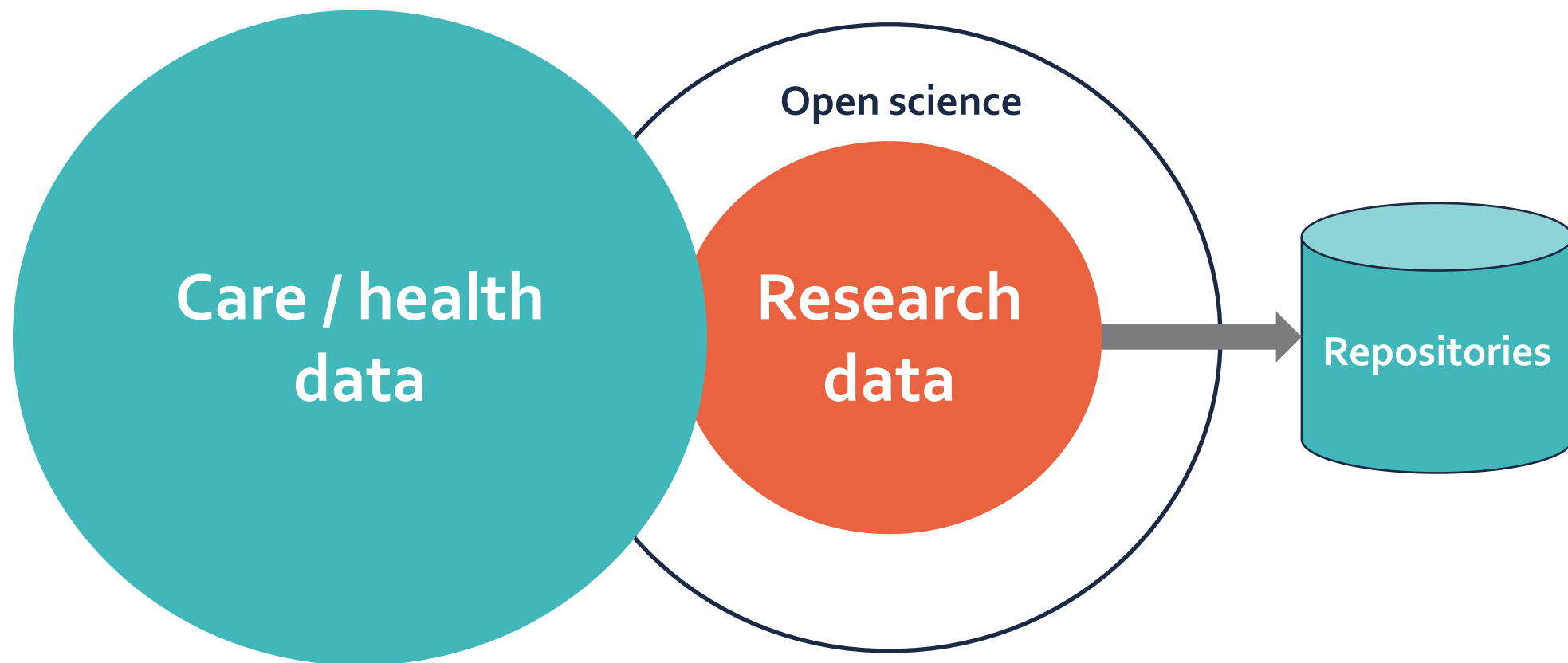


Intentions of the EHDS

1. Give data subjects more control over their care/health data
2. Facilitate the harmonization and cross-border exchange of primary care/health data
3. Facilitate the secondary use of care/health data

Scope EHDS extends beyond care/health data

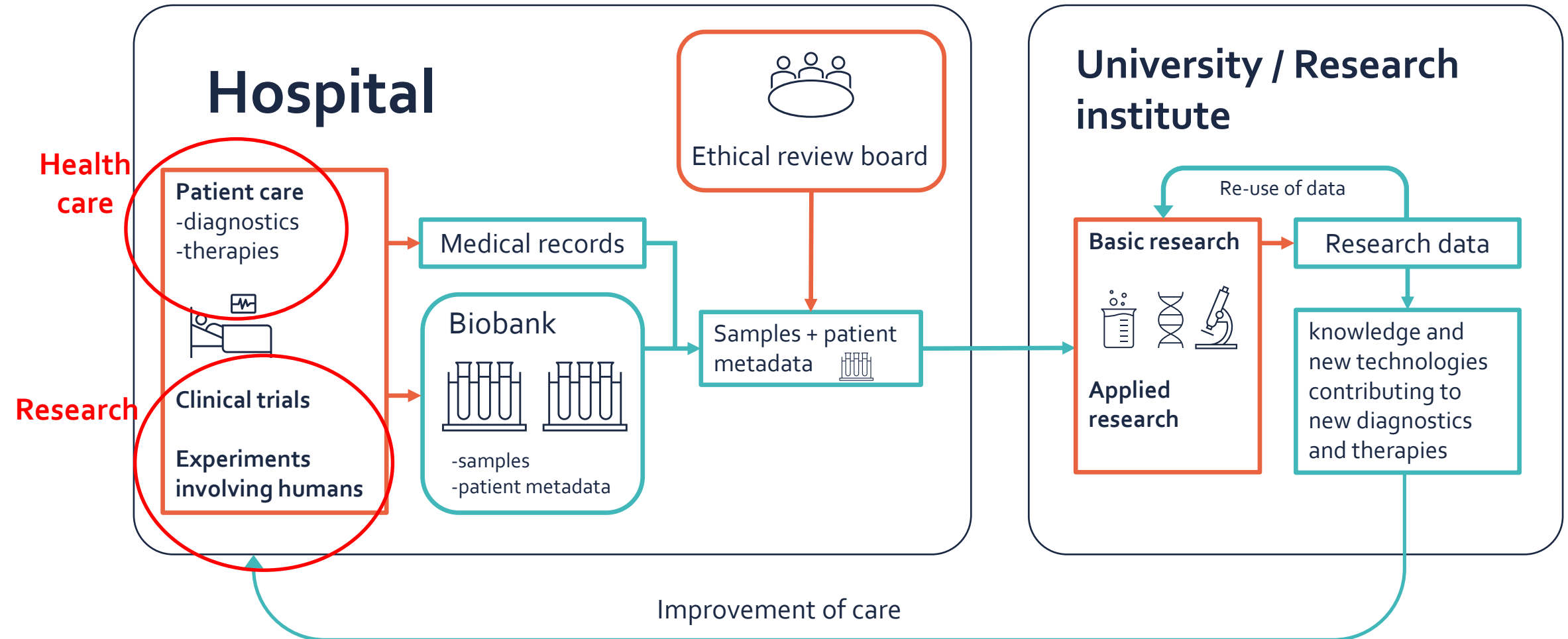
- **'Data holder'** includes research institutions
- **'Electronic data for secondary use'** include:
 - ▶ 'relevant' pathogen genomic data
 - ▶ Human genetic, genomic and proteomic data
 - ▶ Electronic health data from biobanks and dedicated databases



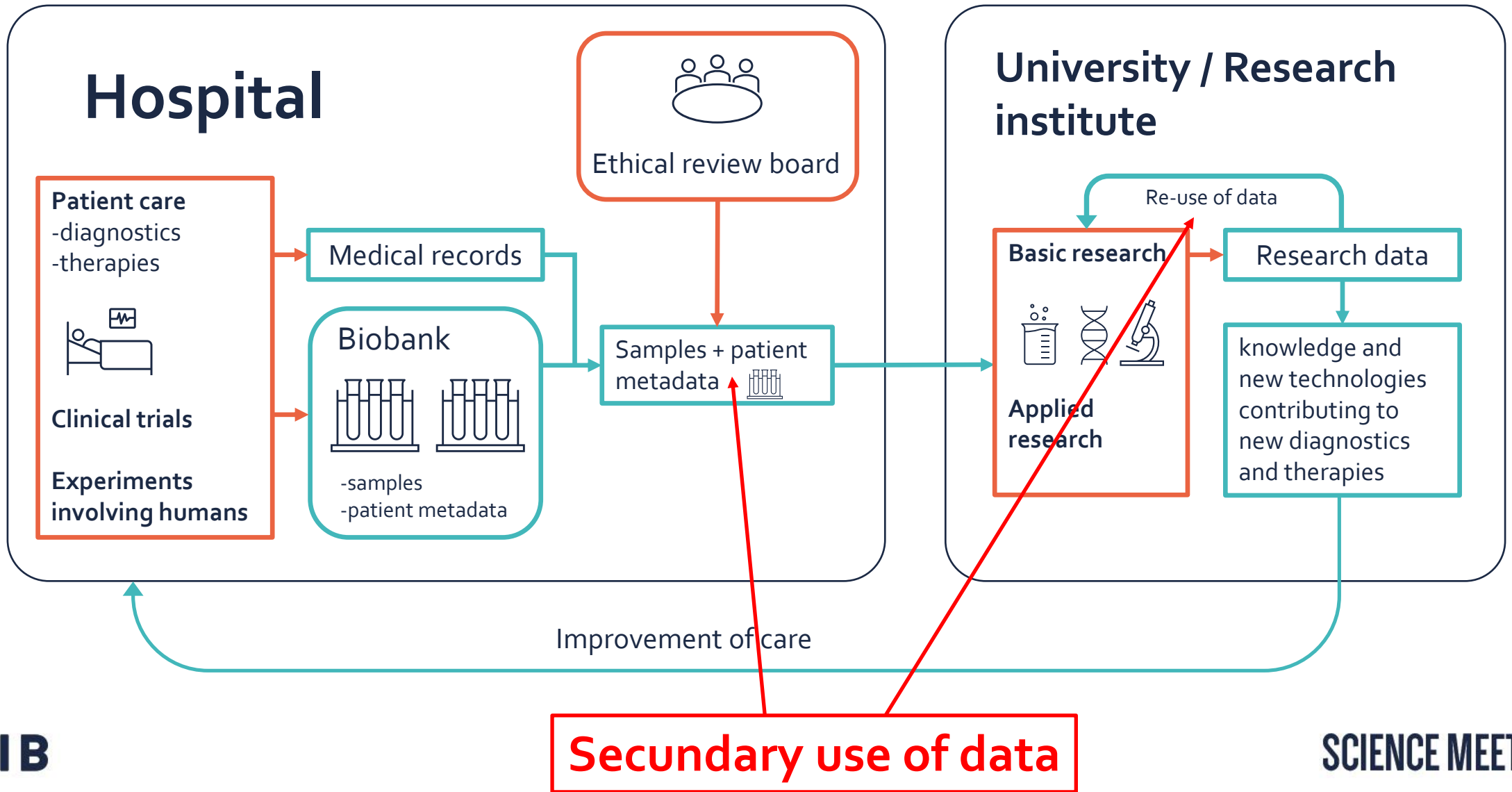
Hospitals, care
institutions, health fund

Universities, research
institutes

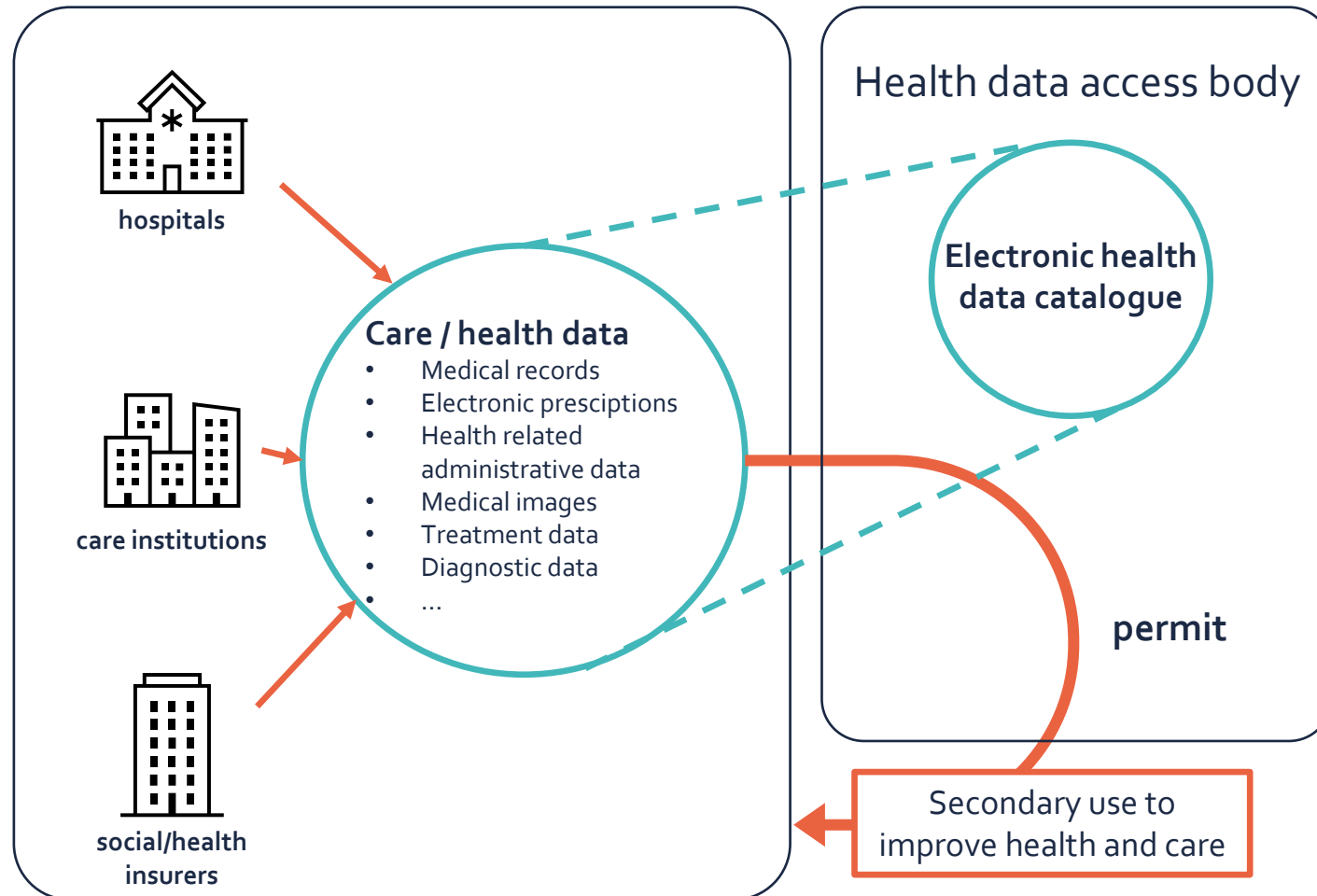
Biomedical research: the interplay between hospitals and research



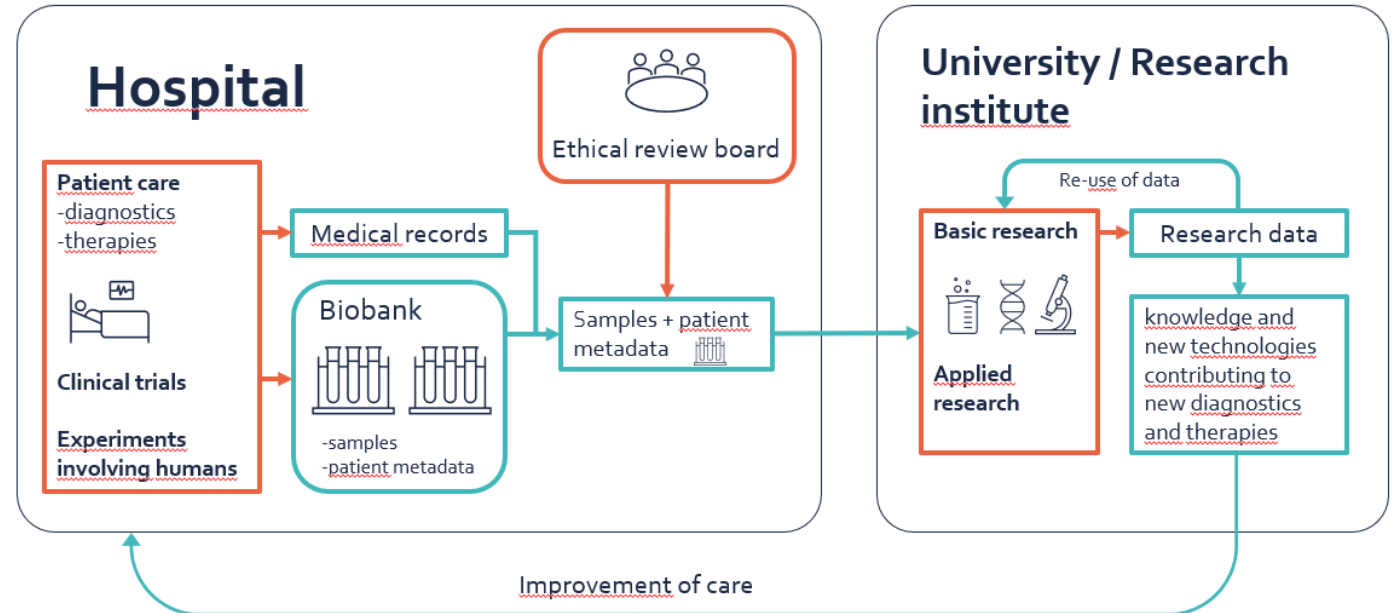
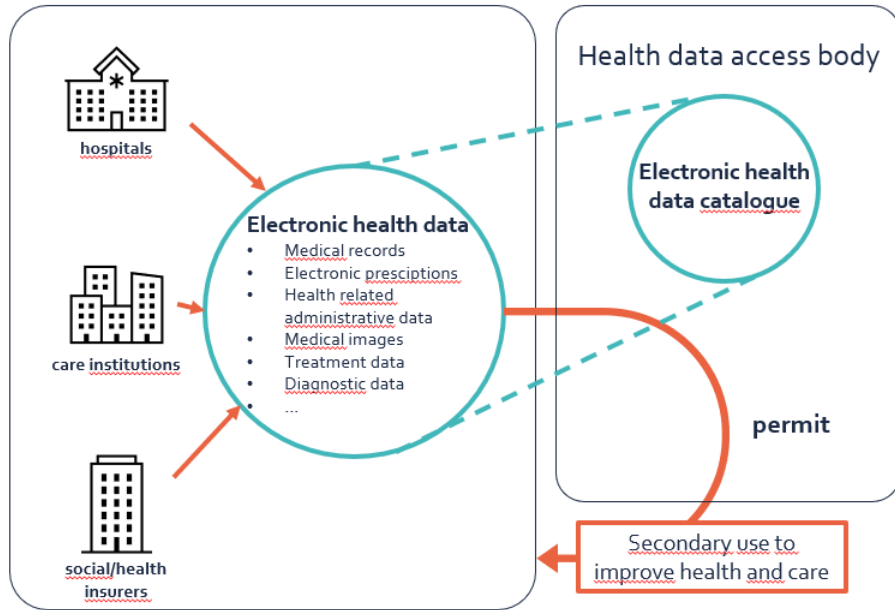
Biomedical research: the interplay between hospitals and research



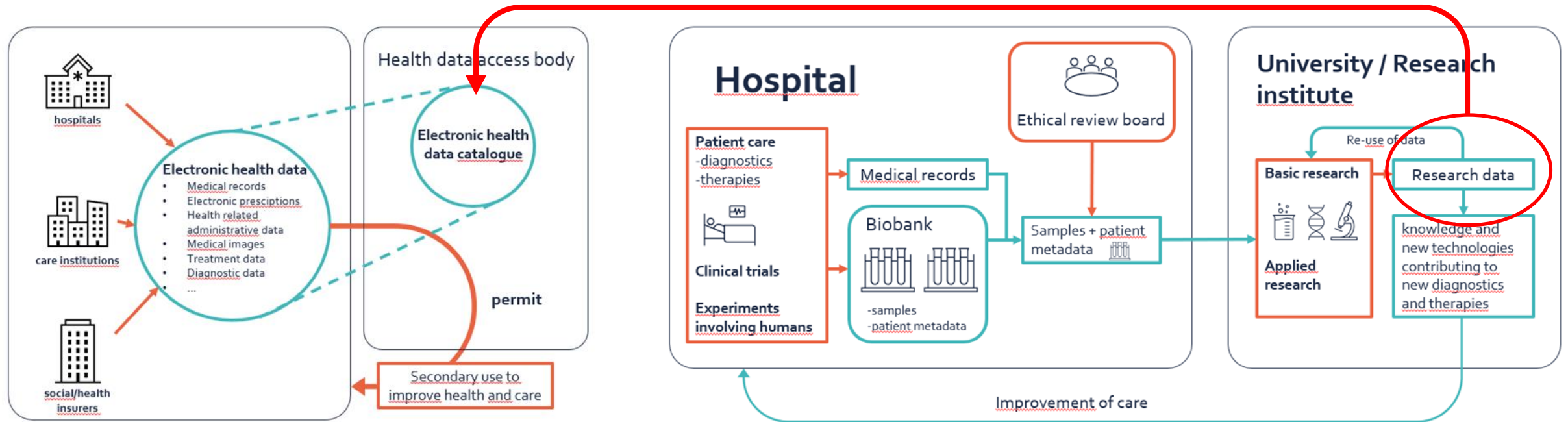
Introducing the Electronic Health Data Space



Biomedical research <-> EHDS

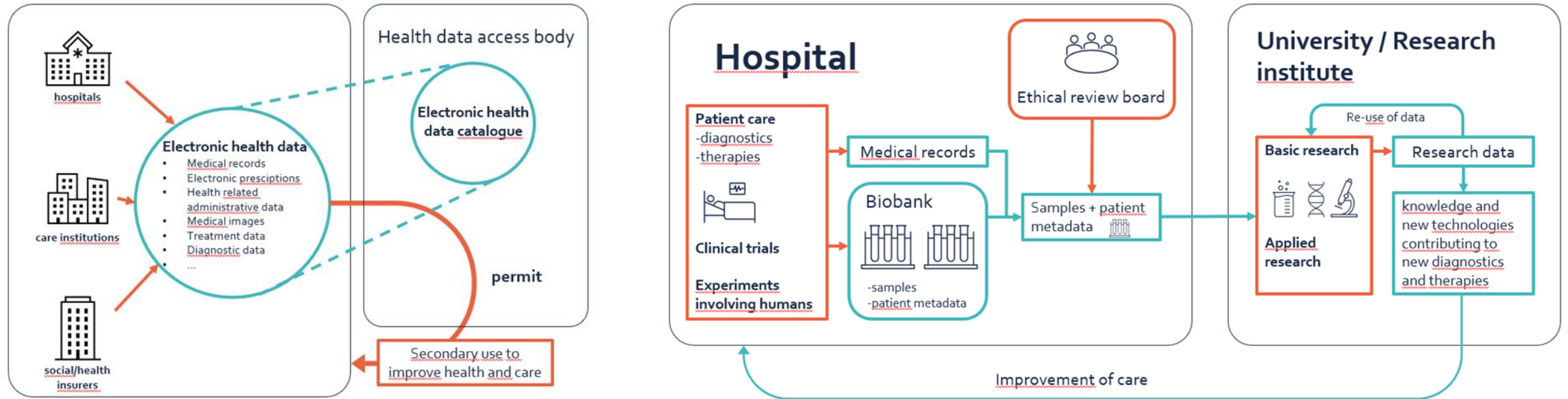


Biomedical research is drawn into the EHDS

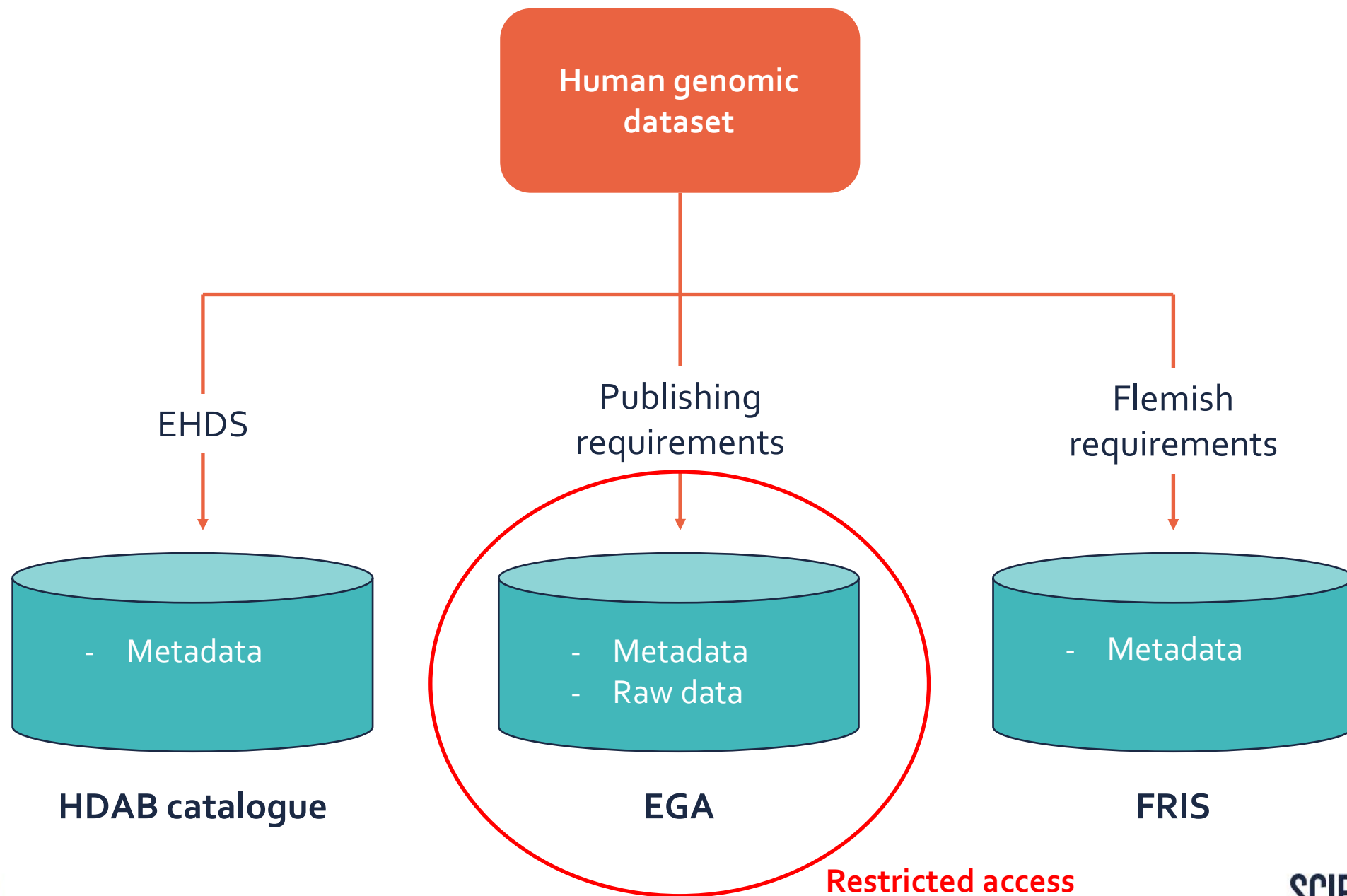


- Research data also have to appear in the health data catalogue

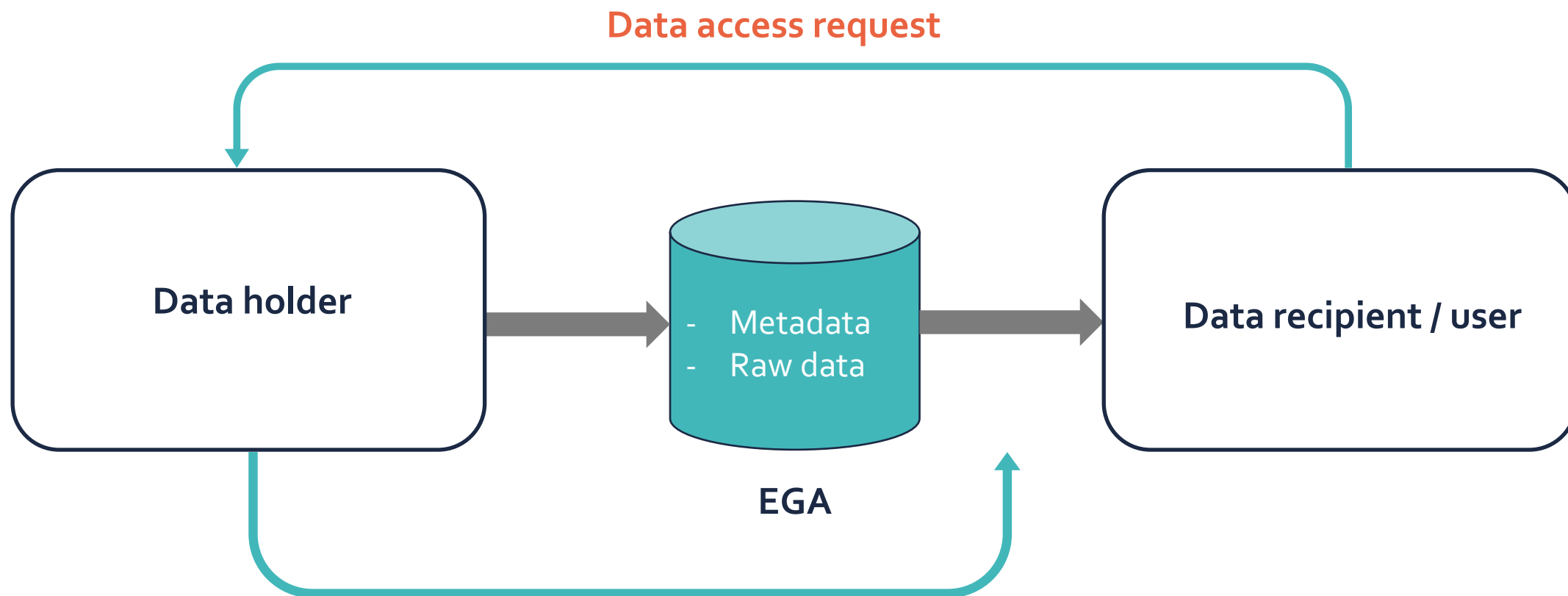
The EHDS does not replace current biomedical research practices



- Open science requirements remain to exist
- Publisher requirements on accessibility of data remain to exist
- Law on experiments involving humans remains to exist
- Biobank law remains to exist

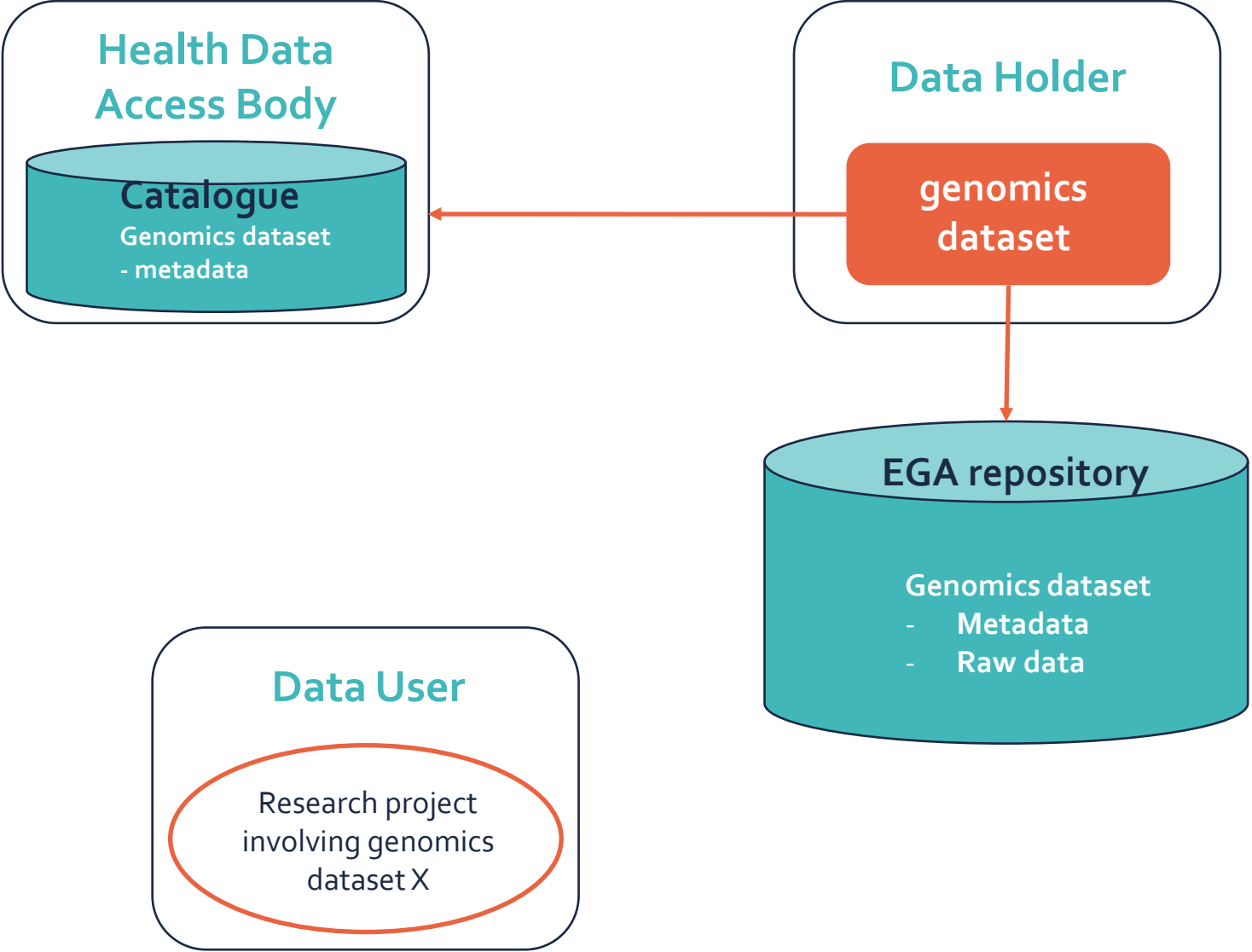


Sharing of data for secondary use of **human genomic data** in current biomedical research

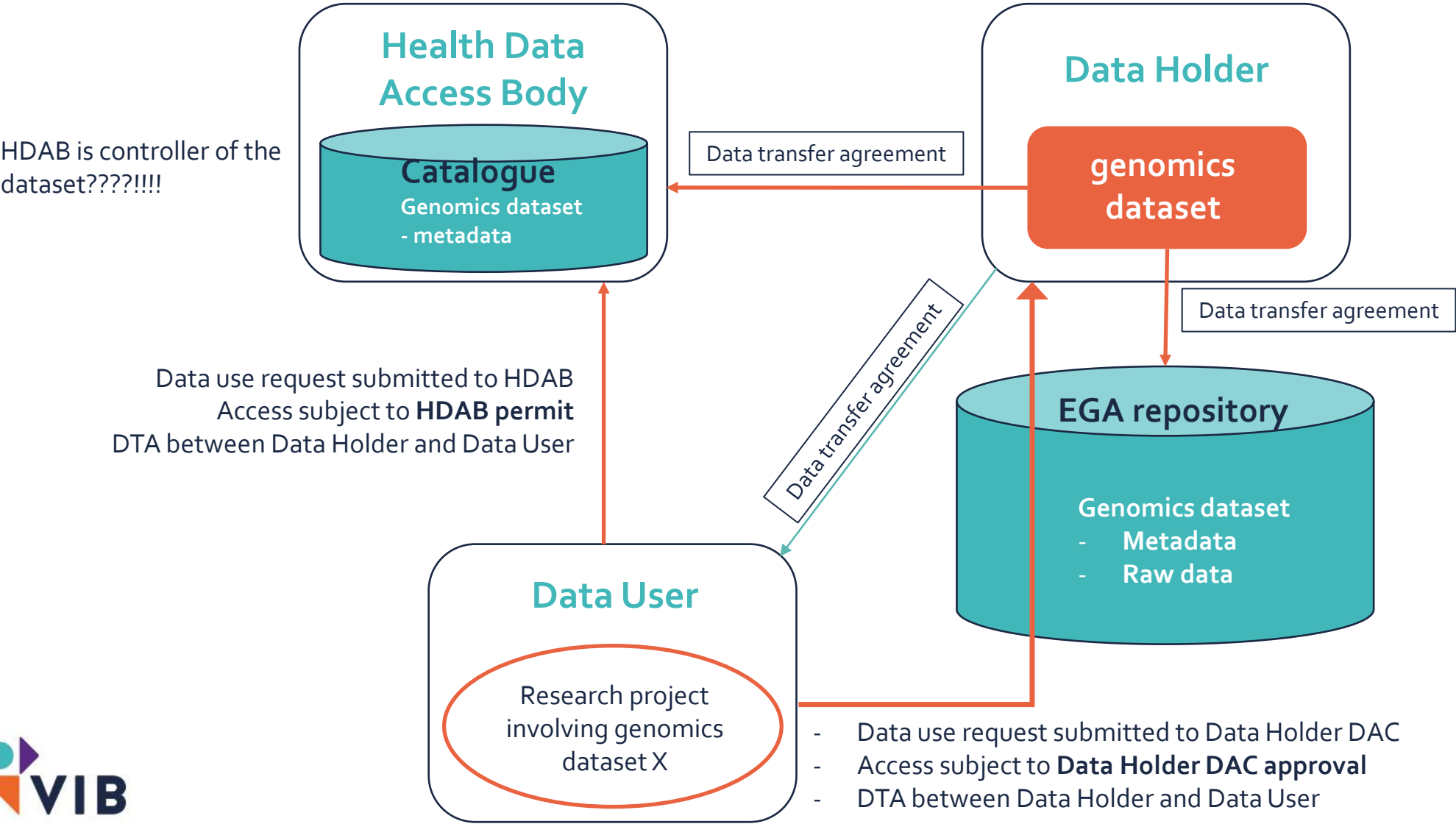


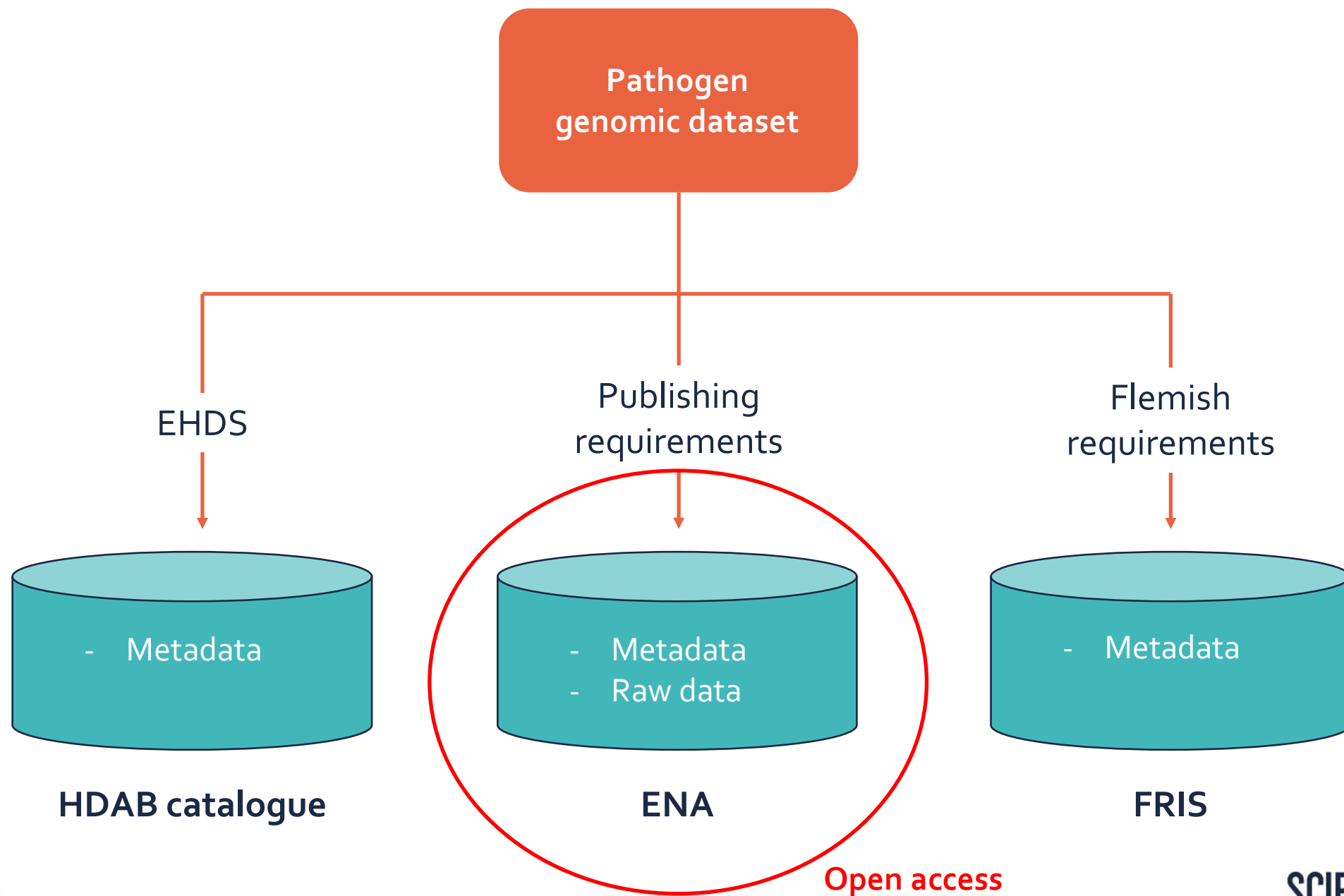
- Data access committee procedure
- Data access agreement

Consequences of the EHDS:

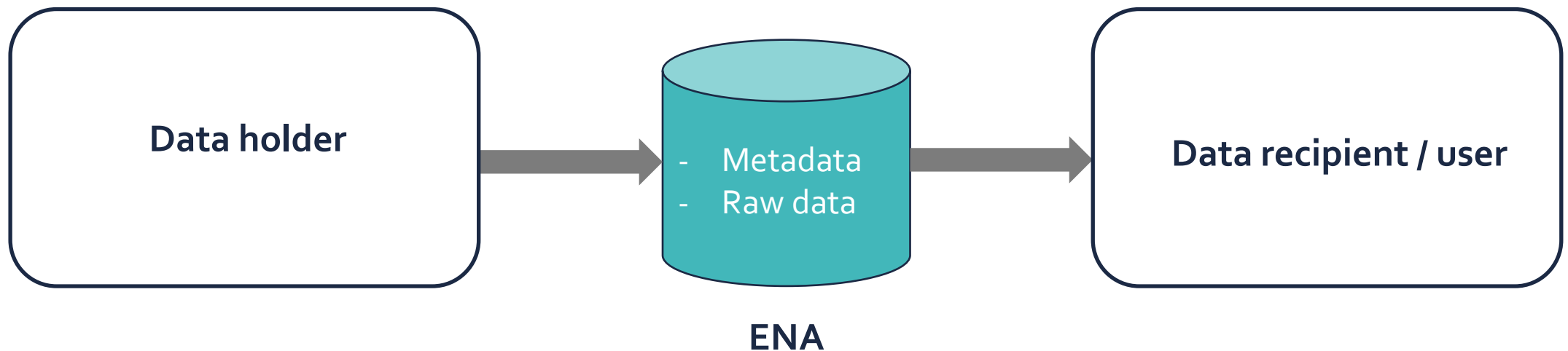


- Consequences of the EHDS:**
- 1. Same dataset can be accessed via two different routes where two different entities decide on access
 - 2. EHDS requires additional agreements for the Data Holder





Sharing of data for secondary use of **pathogen genomic data** in current biomedical research

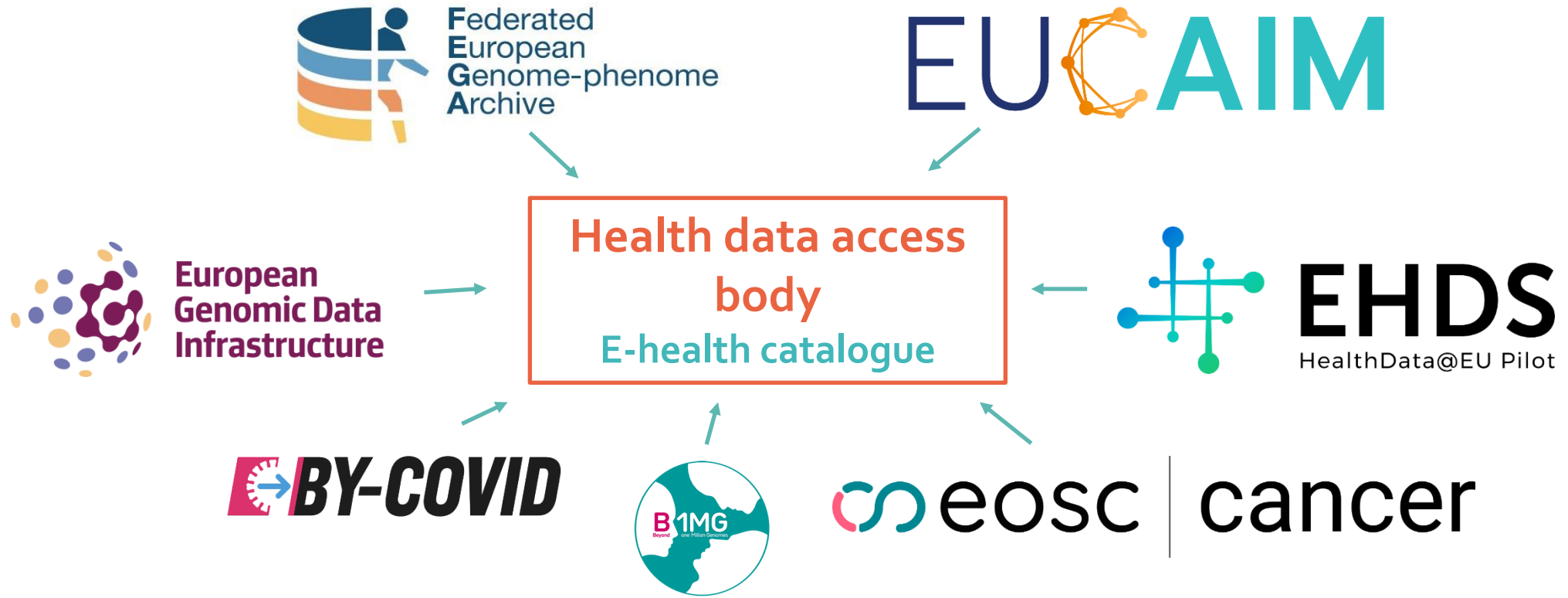


- Open access!!
- But access via HDAB catalogue requires a permit!

In current biomedical research

1. Approvals for (secondary) use of data are given by ethical committees
2. Data are being shared in a GDPR compliant manner
3. Contracts are in place between hospitals – biobanks – research institutes, dealing with:
 - a. Ownership of data
 - b. Use scope allowed
 - c. Privacy – GDPR
 - d. Intellectual property
 - e. Publications, and sharing of data
4. Data access committee procedures exist
5. Data access / transfer agreements for secondary use are in place

How many infrastructures do we need?



Should the HDAB be determining for which research the data in all these infrastructures can be used?

Questions from a research organisation's perspective

- Is there a need for the EHDS in order to facilitate secondary use of biomedical research data?
- Does the EHDS truly facilitate the secondary use of biomedical research data, or do things become more complex?