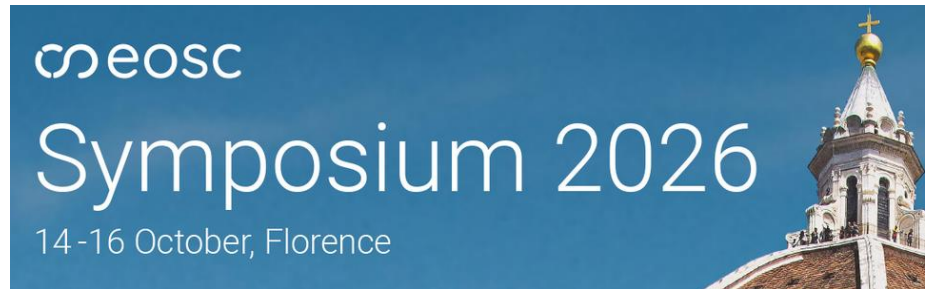


# **EHDS: Bringing the legal framework to life - what are the key challenges for the future?**

EOSC Symposium | 15.10.2026  
Florence

**Irene Schlünder**  
TMF e.V., Berlin



## RECAP: Why EHDS?

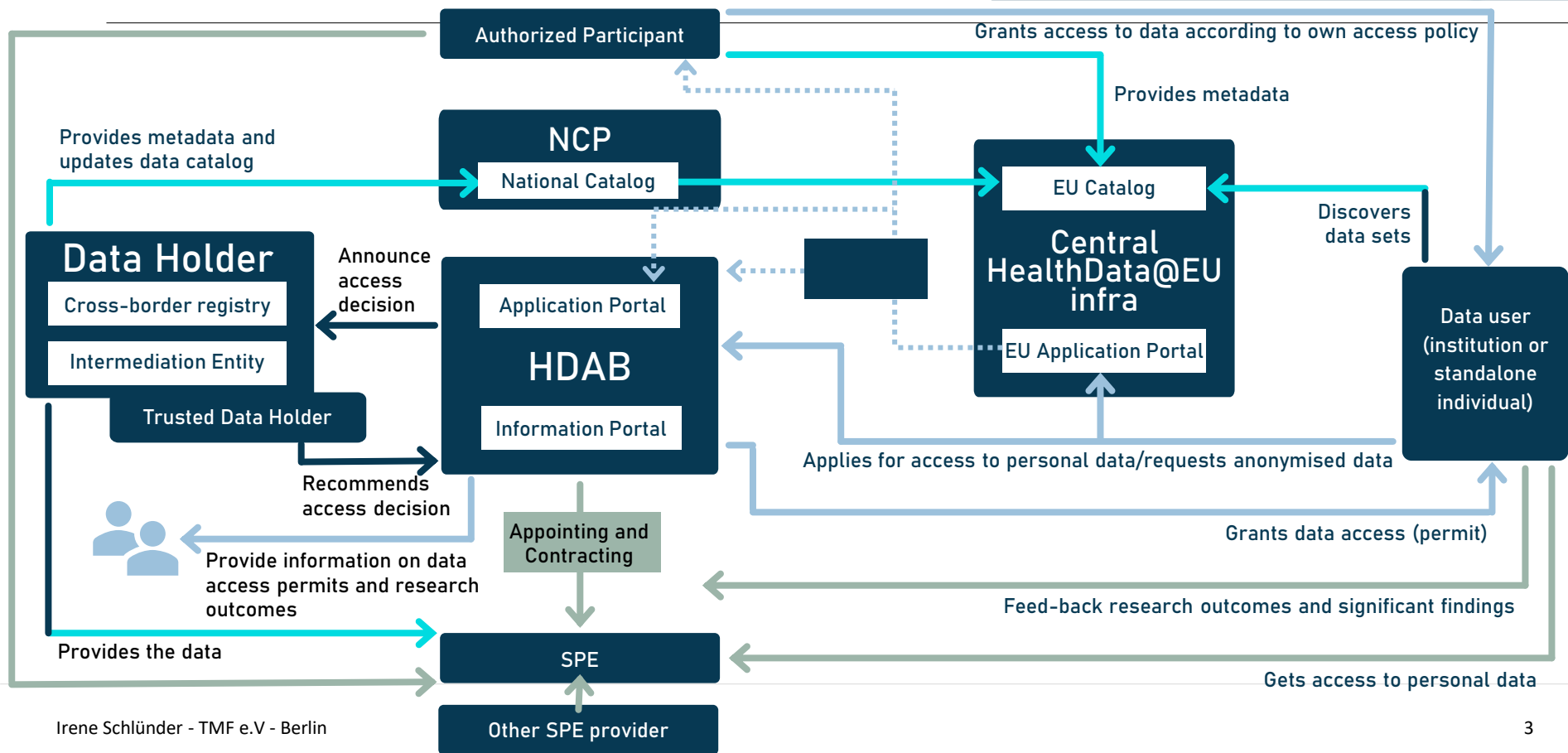
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- Sole gateway to health data on a large scale, such as RWD (routine healthcare data, wearable data, claim data, etc.) in many Member States
- EU-wide harmonized enforceable system (Regulation)
- EU-wide metadata catalogue (HealthDCat)
- One stop agency (applications can all go through HealthData@EU central platform)
- Many others

but that comes at a price...

# EHDS gateway to health data

Legend



# **EHDS is based on national nodes**

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## **EHDS roles on national level**

- National Contact Point (NCP)
- HDAB
- Intermediation Entity
- Data Holder
- Trusted Data Holder
- Cross-border registry

HDABs funded and organised in the Community of Practice

## **EHDS roles on EU & international level**

- Data User from EU
- Data User from third countries or international organisations (starting 2036)
- Authorised participant (ERICs & EDICs)

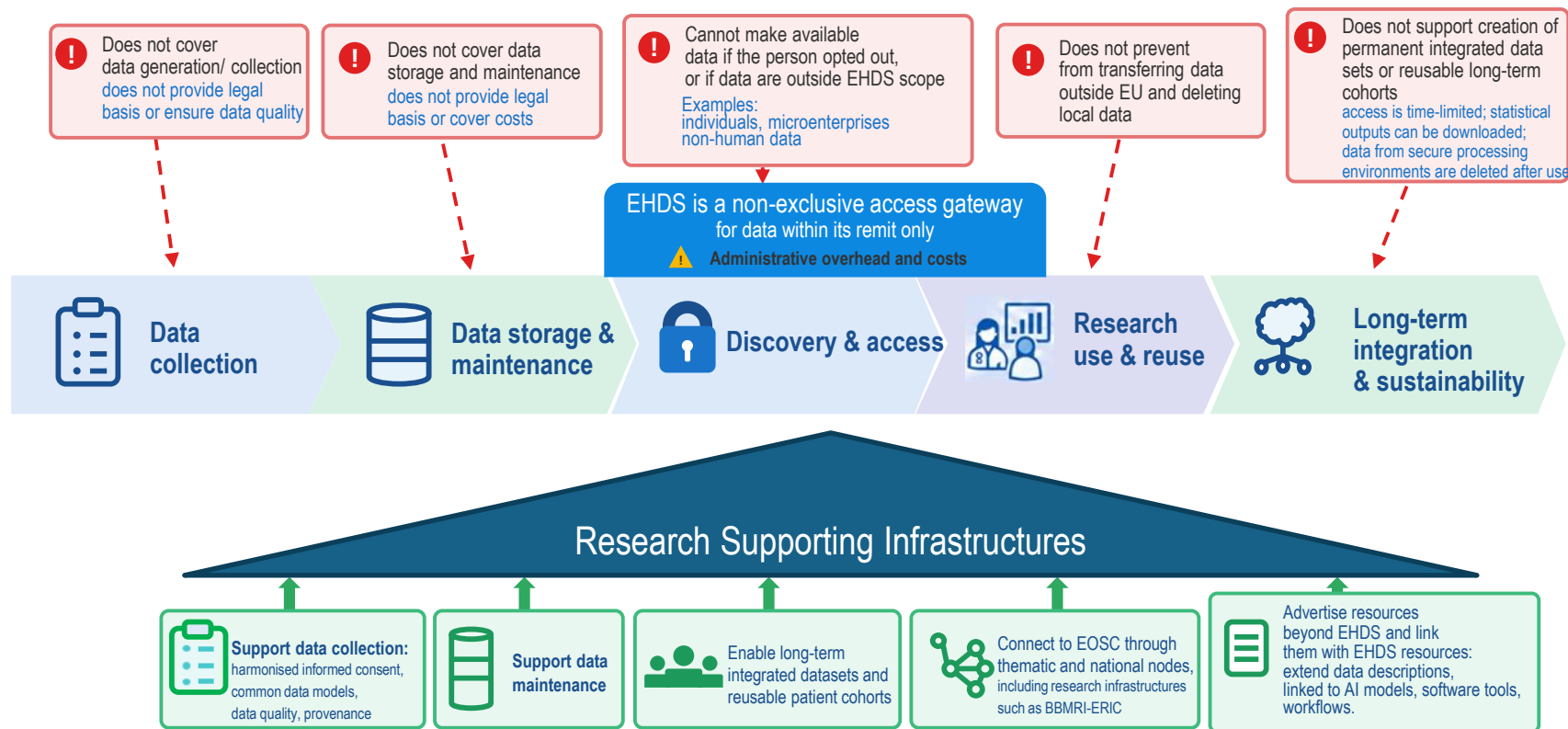
EU-wide initiatives at loss, trying to find roles that aren't suited to them

# Some misconceptions about EHDS

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- Does EHDS provide the legal basis for generating, capturing, storing, curating personal health data? **NO**
- Could organisations freely choose to become an intermediation entity to support its members being data holders? **NO, national law needed**
- Would it be a good idea for organisations to become an HDAB to share data more easily?
  - a lot of red tape
  - resources and expertise in administrative law needed
  - possible conflict with other roles and its own members
- Is it feasible to fulfil various roles under EHDS at the same time?
  - still unclear

# How can existing (EU) initiatives support EHDS?



# Challenges

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- Misconceptions what EHDS provides about what „official“ role to take in order to be part of EHDS
- Organisation around national nodes runs counter to EU-wide initiatives
- More detailed meta data and quality ensurance mechanisms needed
- Layered access for feasibility studies needed
- Data linkage on individual level across borders seems to be an unresolved issue
- Research integrity and good clinical practice requires long term storage of data, SPE approach is costly and limited in time
- How to integrate AI agents supporting research activities & AI factories

# Challenges are there to be addressed...



Europe: Towards a global leading AI continent powered by EHDS, AI factories, and European research infrastructures

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SCALE-UP BIOTECH AI INNOVATION UNDER  
THE EUROPEAN HEALTH DATA SPACE



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Just started: October 1st, coordinated by LNDS

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