IHE® EUROPE EXPERIENCE DAYS

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Opportunities of EHDS for Research Activities on European Level

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SIEMENS Healthineers AGFA HealthCare ENT Enlightening New Technologies ViCo Dedalus IHE CATALYST

Disclosures

- Speaker Fees: Bayer, Bracco, Astra Zeneca
- Advisory Board: cook medical
- Author Fees: Amboss

Research – from ideas to solutions?

- **Hypothetical scenario 2035:**
  - How was the incidence of rectal cancer across Europe in 2031?
  - How many patients had MRI before surgery?
  - What was the field strength of the MRI scanners?
  - Does field strength have an impact on patient outcome?

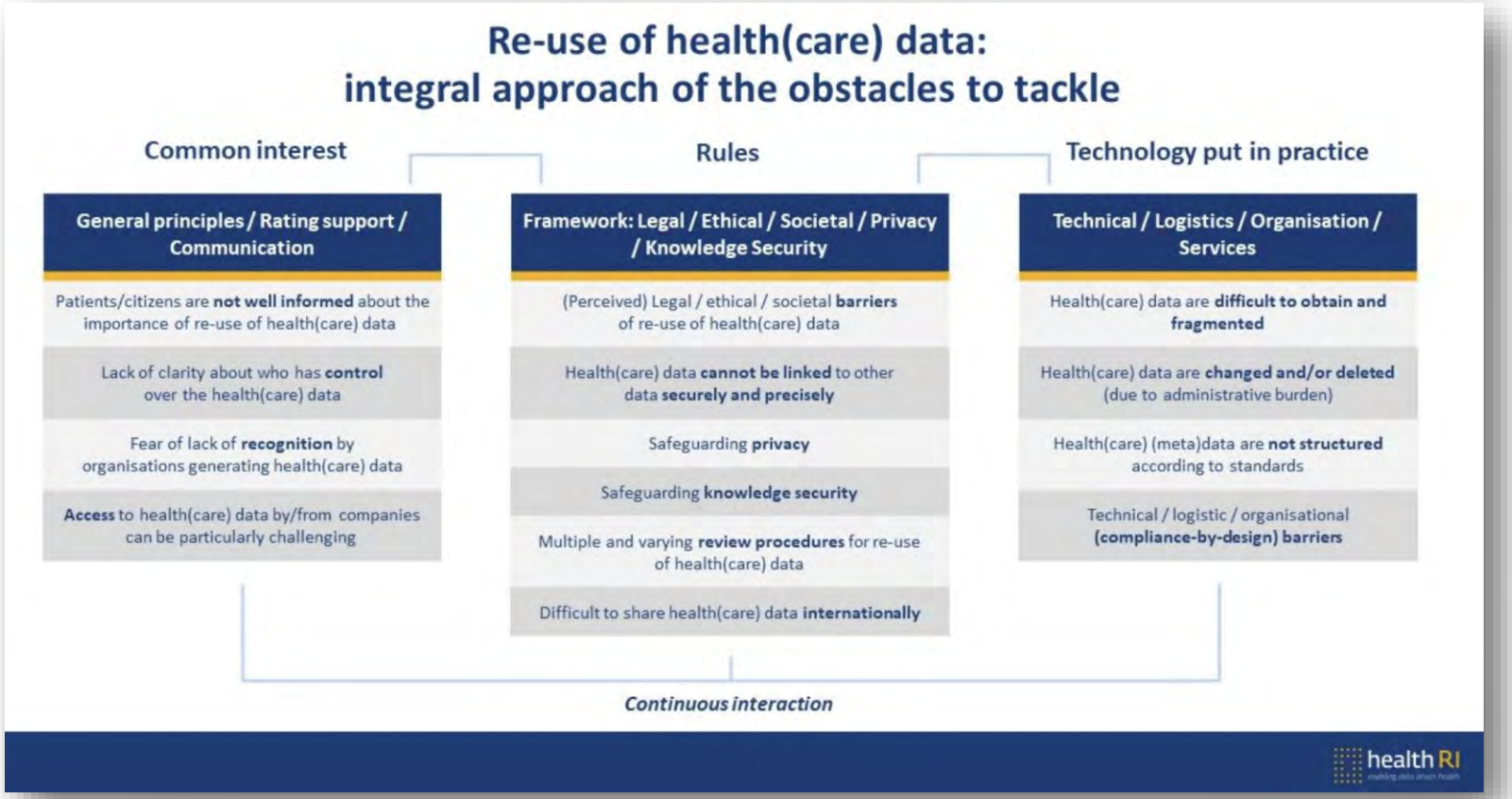
Should be easy, right?

- GET all new C20 (ICD10) diagnoses (Malignant neoplasm of rectum)
  - GET all 395136002 (SNOMEDCT) procedures (Total mesorectal excision)
  - GET all 241629006 (SNOMEDCT) procedures (MRI Pelvis rectum)
  - GET DICOM tag 0018,0087 (MagneticFieldStrength)
  - Etc…

- EHDS2 (HealthData@EU Pilot):
  - Use for research, innovation, policy making and regulatory purposes
  - Opt-out system
  - Privacy and Security aspects under GDPR

Obstacles to the re-use of health(care) data

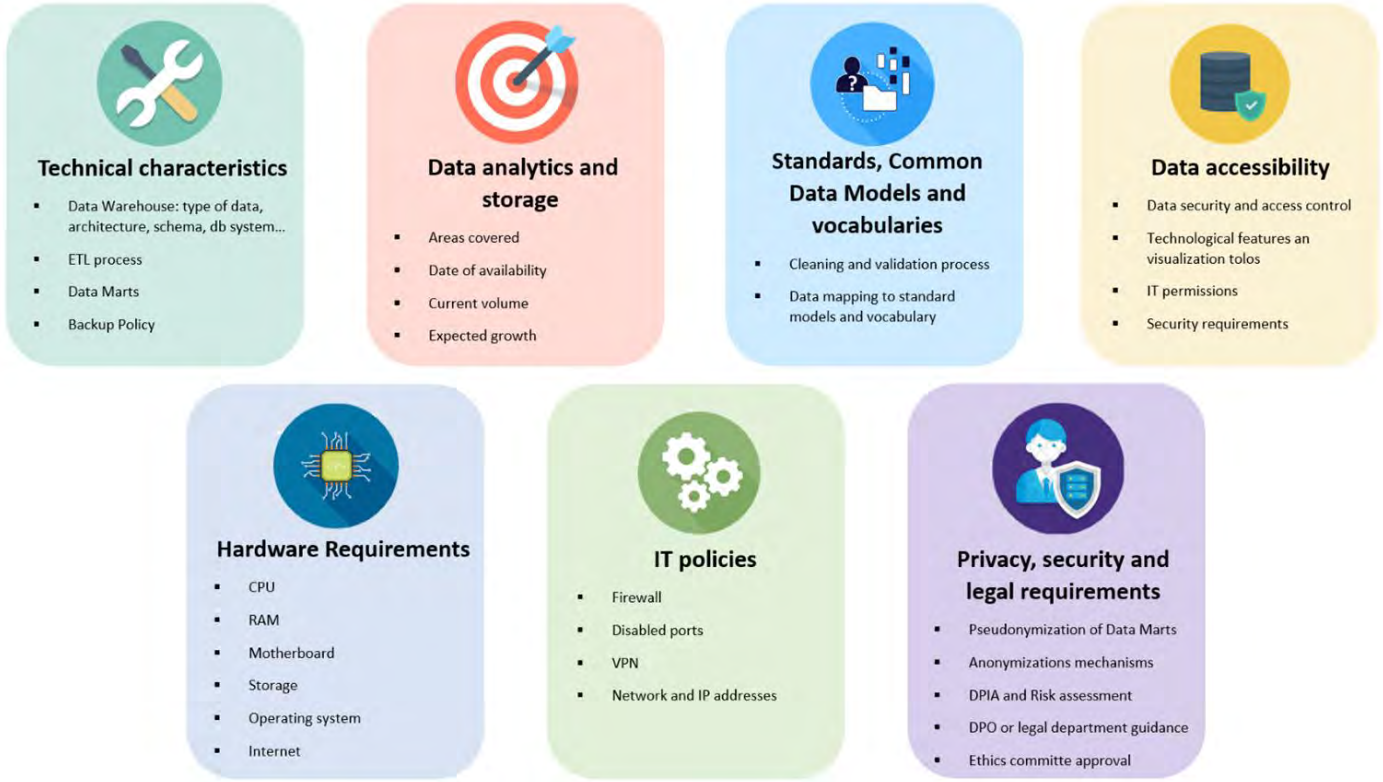
- Fragmented data
- Lack of structure
- Lack of interoperability



Current state of health(care) data re-use.

EUCAIM CANCER IMAGE EUROPE

Questionnaire for evaluating the status of the existing health information systems for secondary use of data (secure processing environment)



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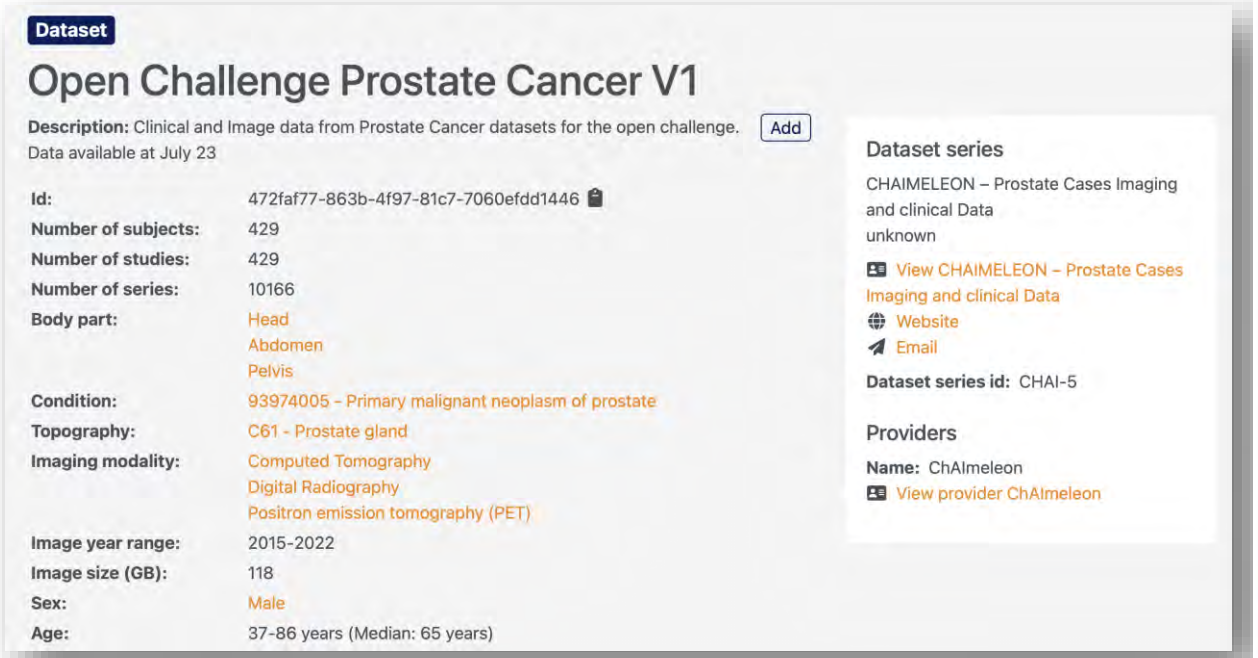
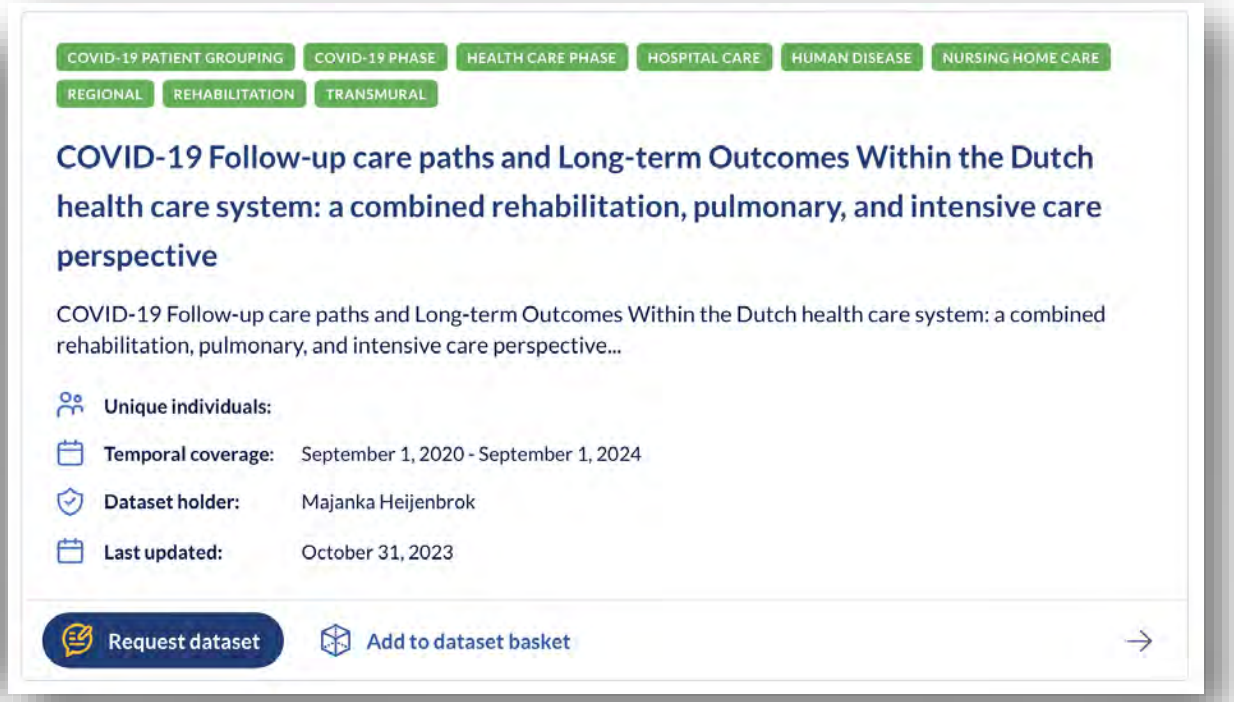




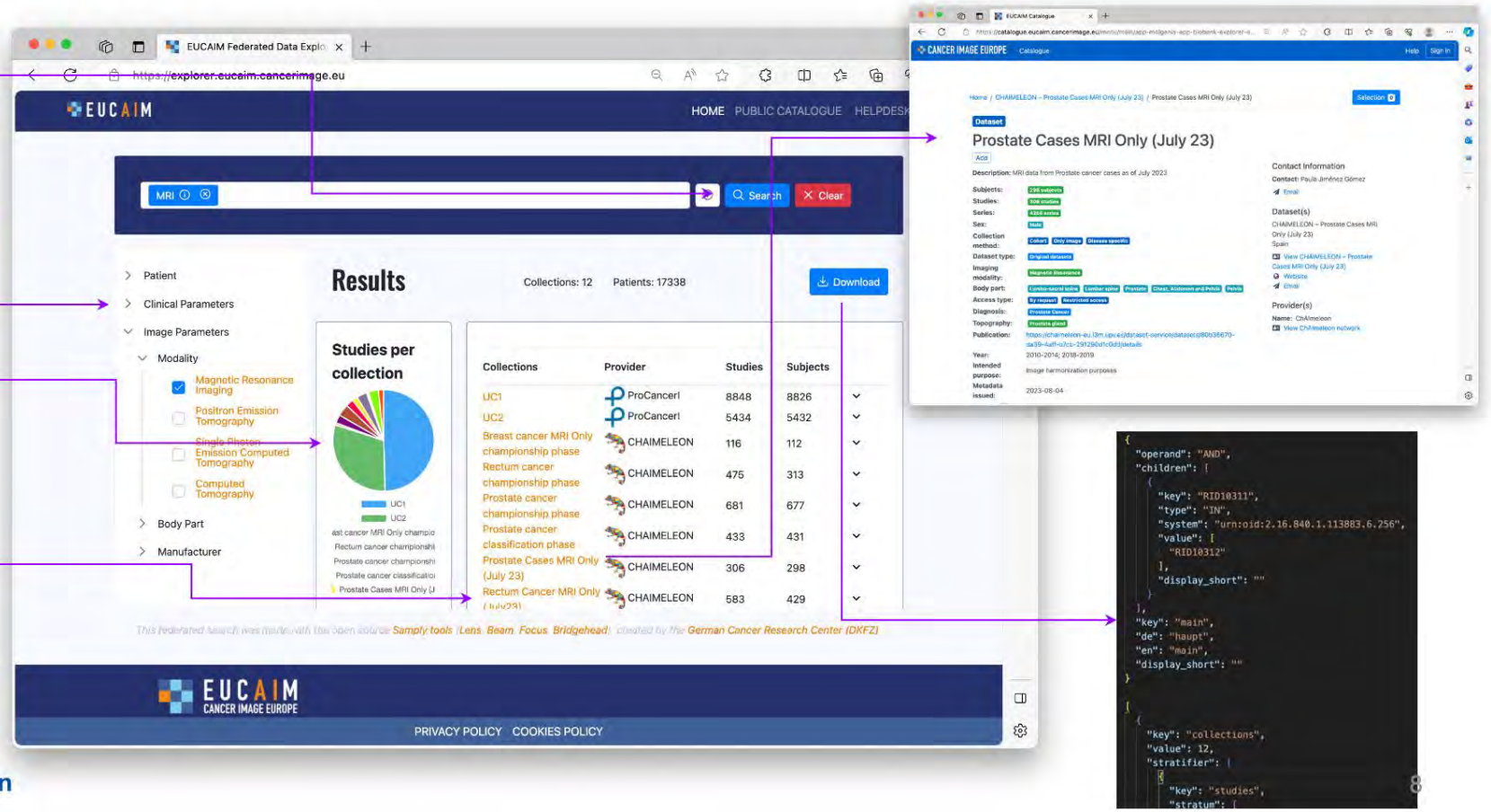
Current state of health(care) data re-use.

Data appears by clicking on the search button

Select and fill-in the searching criteria

Accumulated results are shown in a pie chart

Datasets appear with the number of cases matching the filter criteria



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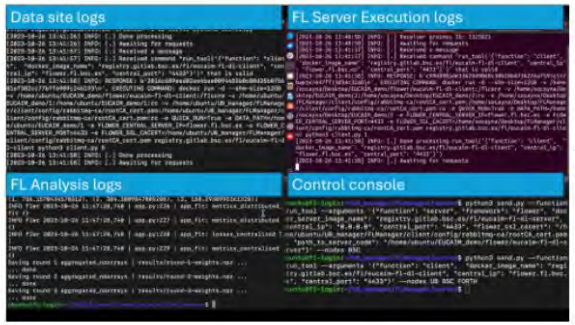
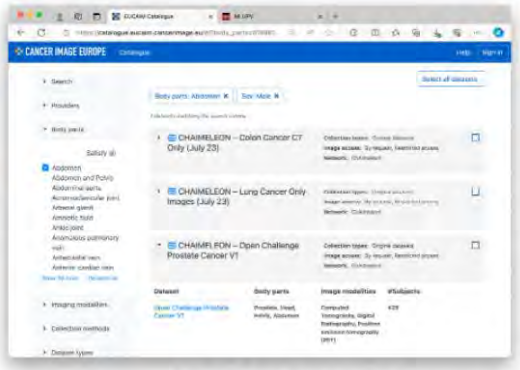
Current state of health(care) data re-use.

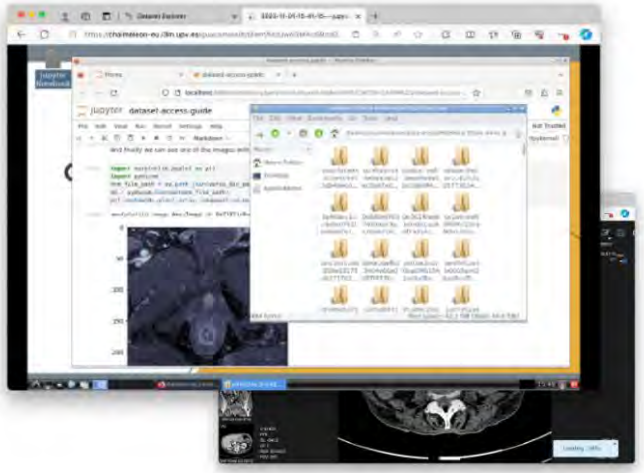


Distributed Processing



Download dataset

on-site processing



3. Strong traceability requirements, datasets cannot be even visualized directly by the users.

1. Public anonymized datasets, or datasets with lower traceability restrictions.

2. Datasets cannot be downloaded but data can be visualized, processed using on-site VREs.

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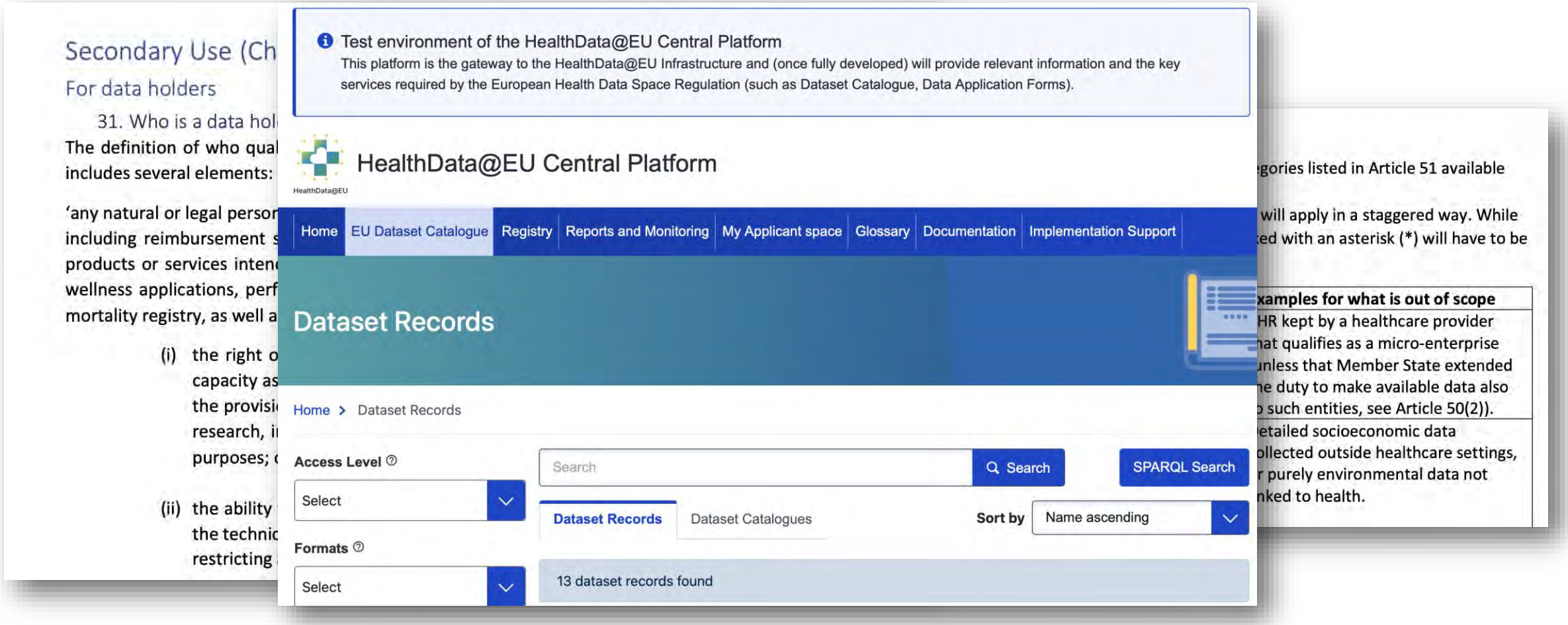
EHDS – a dream come true?

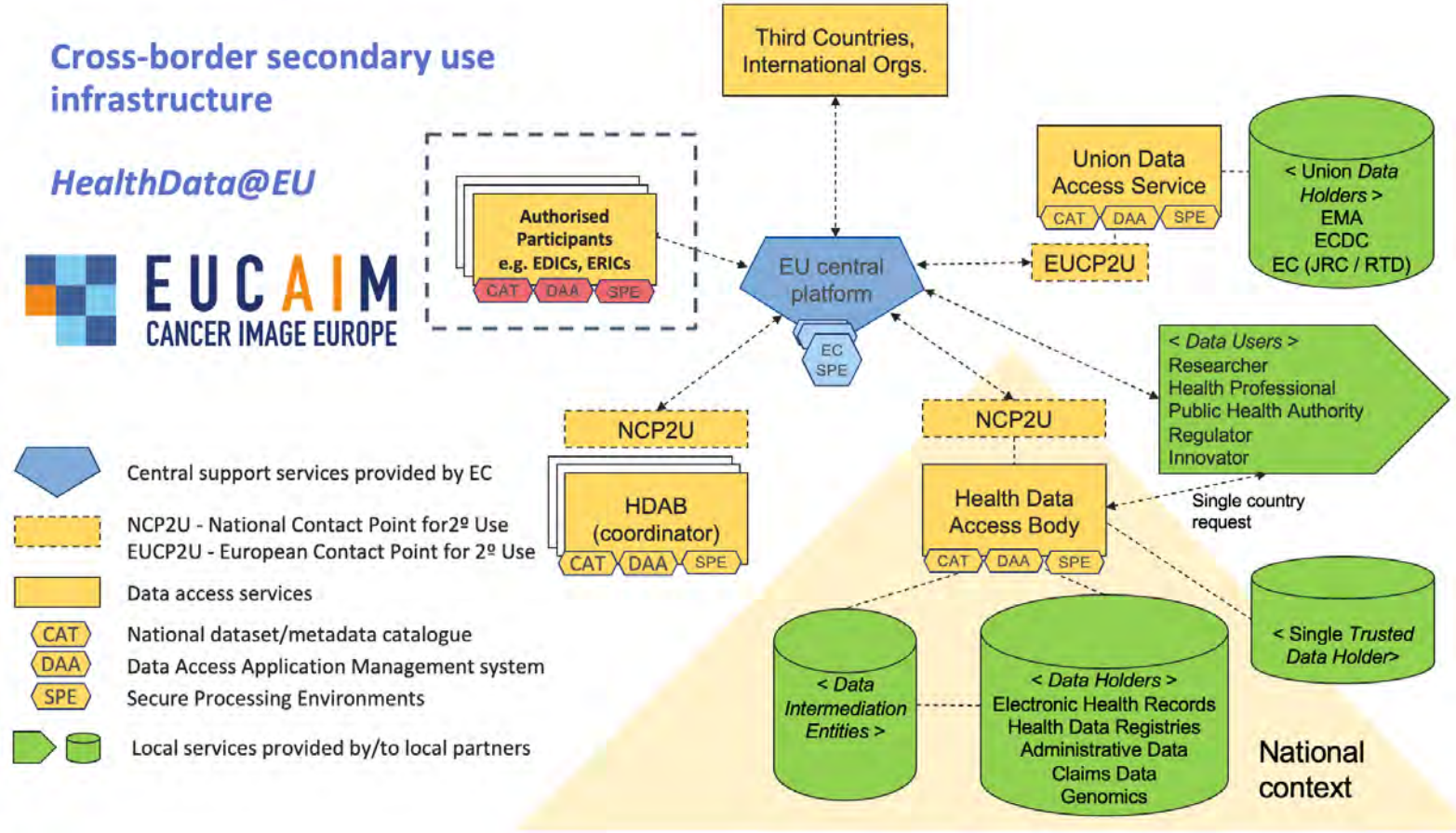


EHDS – a dream come true?

- openly accessible metadata catalogues according to HealthData@EU infrastructure, accessible through Health Data Access Bodies (HDABs; intermediaries, e.g. UK biobank), full dataset access via data permits (like human genotype project)
- Second Joint Action Towards the European Health Data Space (TEHDAS2) consultation
  - focuses on developing common guidelines and technical specifications to facilitate access to health data for secondary purposes (https://ehdis.nilin.org.pl/en/)
- SHAIPED project (Nov 2024)
  - aims to leverage artificial intelligence (AI) to enhance medical devices by improving accessibility to health data while prioritizing robust data governance. In alignment with the European Health Data Space (EHDS) regulation, SHAIPED represents a collective ambition to create a secure and innovative health ecosystem for European citizens (https://eithealth.eu/news-article/shaiped-and-the-european-health-data-space-ehds/)

EUCAIM – a step in the right direction

- Less fragmented
- More structure
- Better interoperability



EHDS – a dream come true?

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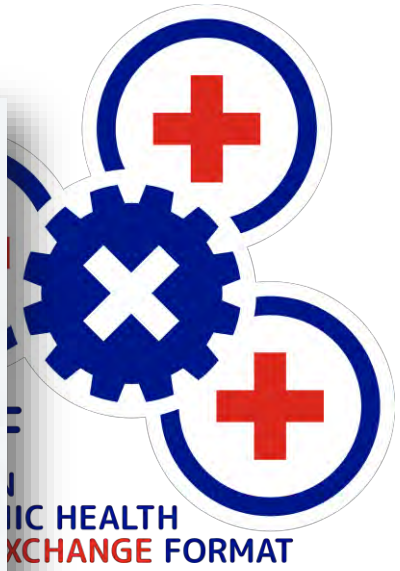
European Electronic Health Record exchange Format (EHRxF)

The European Electronic Health Record exchange Format (EHRxF) will enable the secure and seamless sharing of personal health data among trusted partners. Patients and healthcare professionals (doctors, nurses, etc.) are the key trusted partners in the exchange of health data.

The EHRxF will empower patients to access their health data from any healthcare professional, whether in a hospital, private practice, or home care setting. More importantly, every patient will be able to share personal health data with whomever they wish, in a common format that is understood by everyone, even across borders. In addition, healthcare professionals across Europe will be able to access all relevant personal health data of their patients available anywhere (across their country or elsewhere in Europe), under the condition that they are actually entitled to access the electronic health record of that individual patient.

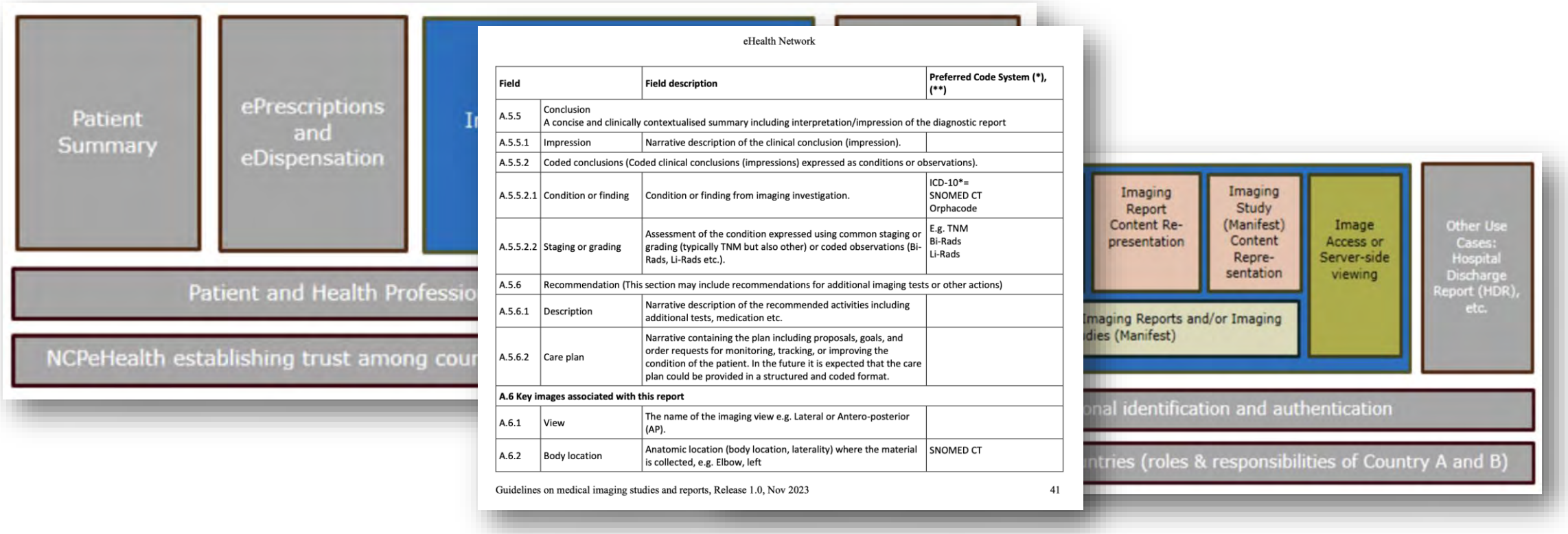
The European Electronic Health Record eXchange Format (EEHRxF) is the subject of the European Health Data Space regulation (article 15) and will become formally established by March 2027 at the latest. This means the European EHRxF is still under collaborative development. Certainty about its specifications cannot be provided before the formal publication of the Implementing Acts by the European Commission.

The contents of this website and the artefacts relating to the European EHRxF provide our best guess, based on a long history of projects and policy engagement. The website will be updated regularly in alignment with the European Commission and with the support of all our stakeholders including ESHIA and related projects.



eHealthNetwork Guidelines

- eHN Guidelines on Medical imaging studies and reports



eHealth Network

Field		Field description	Preferred Code System (*), (**)
A.5.5	Conclusion A concise and clinically contextualised summary including interpretation/impression of the diagnostic report		
A.5.5.1	Impression	Narrative description of the clinical conclusion (impression).	
A.5.5.2	Coded conclusions (Coded clinical conclusions (impressions) expressed as conditions or observations).		
A.5.5.2.1	Condition or finding	Condition or finding from imaging investigation.	ICD-10*= SNOMED CT Orphacode
A.5.5.2.2	Staging or grading	Assessment of the condition expressed using common staging or grading (typically TNM but also other) or coded observations (Bi-Rads, Li-Rads etc.).	E.g. TNM Bi-Rads Li-Rads
A.5.6	Recommendation (This section may include recommendations for additional imaging tests or other actions)		
A.5.6.1	Description	Narrative description of the recommended activities including additional tests, medication etc.	
A.5.6.2	Care plan	Narrative containing the plan including proposals, goals, and order requests for monitoring, tracking, or improving the condition of the patient. In the future it is expected that the care plan could be provided in a structured and coded format.	
A.6 Key images associated with this report			
A.6.1	View	The name of the imaging view e.g. Lateral or Antero-posterior (AP).	
A.6.2	Body location	Anatomic location (body location, laterality) where the material is collected, e.g. Elbow, left	SNOMED CT

Guidelines on medical imaging studies and reports, Release 1.0, Nov 2023 41

EHDS for research activities

- The true potential is real-world data!
- Still unclear if EHDS is intended for all data to be available for secondary use.
- Interoperability will be key!