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Opportunities of EHDS for Research Activities on European Level



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Disclosures

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

Research – from ideas to solutions?



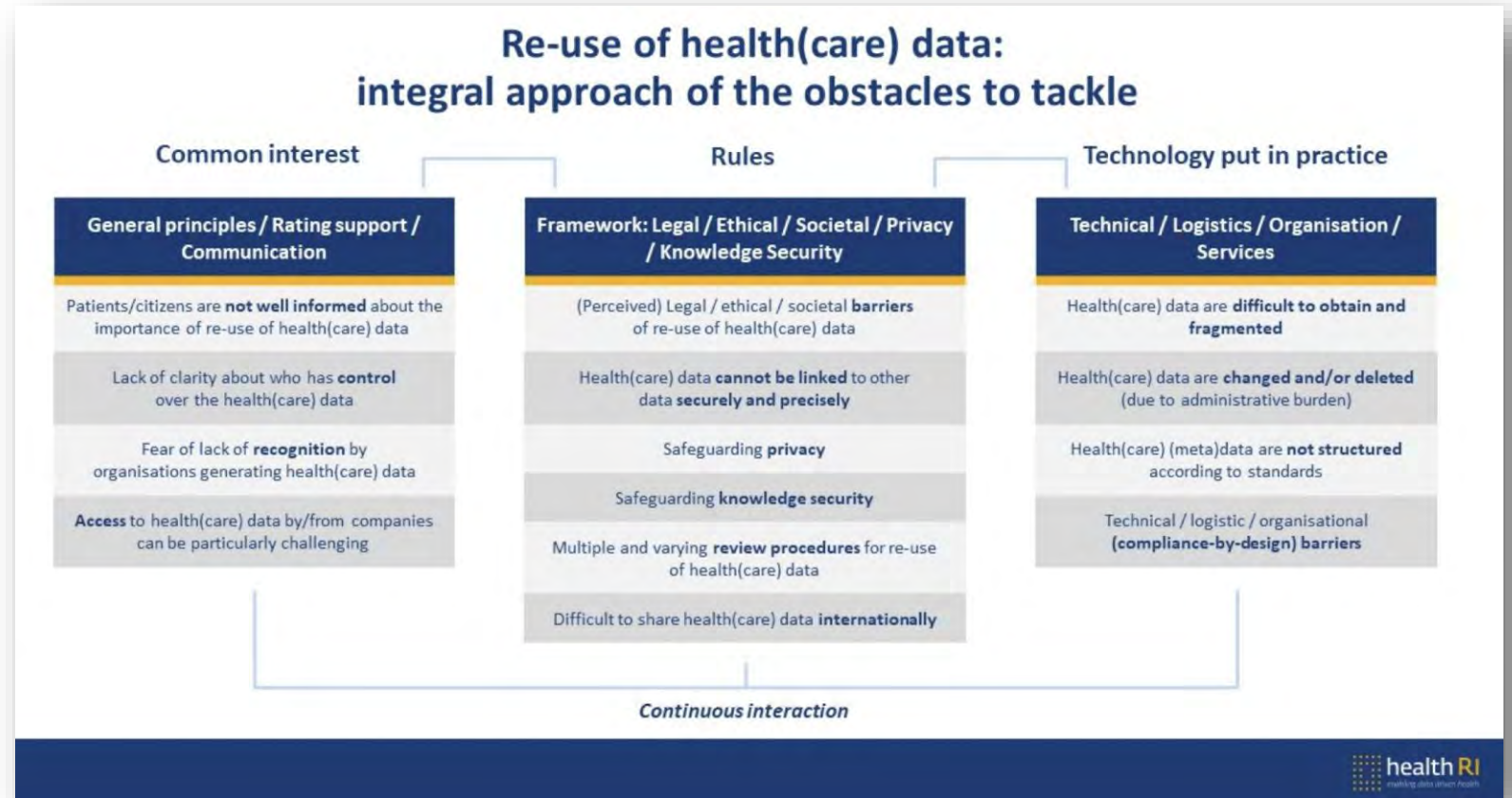
- **Hypothetical scenario 2035:**
 - How was the incidence of rectal cancer across Europe in 2031?
 - How many patients had MRI before surgery?
 - What was the field strength of the MRI scanners?
 - Does field strength have an impact on patient outcome?

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.



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

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Technical characteristics

- Data Warehouse: type of data, architecture, schema, db system...
- ETL process
- Data Marts
- Backup Policy

Data analytics and storage

- Areas covered
- Date of availability
- Current volume
- Expected growth

Standards, Common Data Models and vocabularies

- Cleaning and validation process
- Data mapping to standard models and vocabulary

Data accessibility

- Data security and access control
- Technological features an visualization tolos
- IT permissions
- Security requirements

Hardware Requirements

- CPU
- RAM
- Motherboard
- Storage
- Operating system
- Internet

IT policies

- Firewall
- Disabled ports
- VPN
- Network and IP addresses

Privacy, security and legal requirements

- Pseudonymization of Data Marts
- Anonymizations mechanisms
- DPIA and Risk assessment
- DPO or legal department guidance
- Ethics committe approval

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

Dataset

Open Challenge Prostate Cancer V1

Description: Clinical and Image data from Prostate Cancer datasets for the open challenge. Add
Data available at July 23

Id: 472faf77-863b-4f97-81c7-7060efdd1446

Number of subjects: 429

Number of studies: 429

Number of series: 10166

Body part: [Head](#)
[Abdomen](#)
[Pelvis](#)

Condition: [93974005 - Primary malignant neoplasm of prostate](#)

Topography: [C61 - Prostate gland](#)

Imaging modality: [Computed Tomography](#)
[Digital Radiography](#)
[Positron emission tomography \(PET\)](#)

Image year range: 2015-2022

Image size (GB): 118

Sex: [Male](#)

Age: 37-86 years (Median: 65 years)

Dataset series

CHAIMELEON – Prostate Cases Imaging and clinical Data unknown

[View CHAIMELEON – Prostate Cases Imaging and clinical Data](#)

[Website](#)

[Email](#)

Dataset series id: CHAI-5

Providers

Name: ChAlmeleon

[View provider ChAlmeleon](#)

[COVID-19 PATIENT GROUPING](#) [COVID-19 PHASE](#) [HEALTH CARE PHASE](#) [HOSPITAL CARE](#) [HUMAN DISEASE](#) [NURSING HOME CARE](#)

[REGIONAL](#) [REHABILITATION](#) [TRANSMURAL](#)

COVID-19 Follow-up care paths and Long-term Outcomes Within the Dutch health care system: a combined rehabilitation, pulmonary, and intensive care perspective

COVID-19 Follow-up care paths and Long-term Outcomes Within the Dutch health care system: a combined rehabilitation, pulmonary, and intensive care perspective...

Unique individuals:

Temporal coverage: September 1, 2020 - September 1, 2024

Dataset holder: Majanka Heijenbrok

Last updated: October 31, 2023

[Request dataset](#) [Add to dataset basket](#) →

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

The screenshot shows the EUCAIM Federated Data Explorer interface. The search bar contains 'MRI'. The filter sidebar on the left includes categories like Patient, Clinical Parameters, Image Parameters (with 'Magnetic Resonance Imaging' selected), Body Part, and Manufacturer. The 'Results' section shows 12 collections and 17338 patients. A pie chart titled 'Studies per collection' shows the distribution of studies across different providers. A table lists the following collections:

Collections	Provider	Studies	Subjects
UC1	ProCancer1	8848	8826
UC2	ProCancer1	5434	5432
Breast cancer MRI Only championship phase	CHAIMELEON	116	112
Rectum cancer championship phase	CHAIMELEON	475	313
Prostate cancer championship phase	CHAIMELEON	681	677
Prostate cancer classification phase	CHAIMELEON	433	431
Prostate Cases MRI Only (July 23)	CHAIMELEON	306	298
Rectum Cancer MRI Only (July 23)	CHAIMELEON	583	429

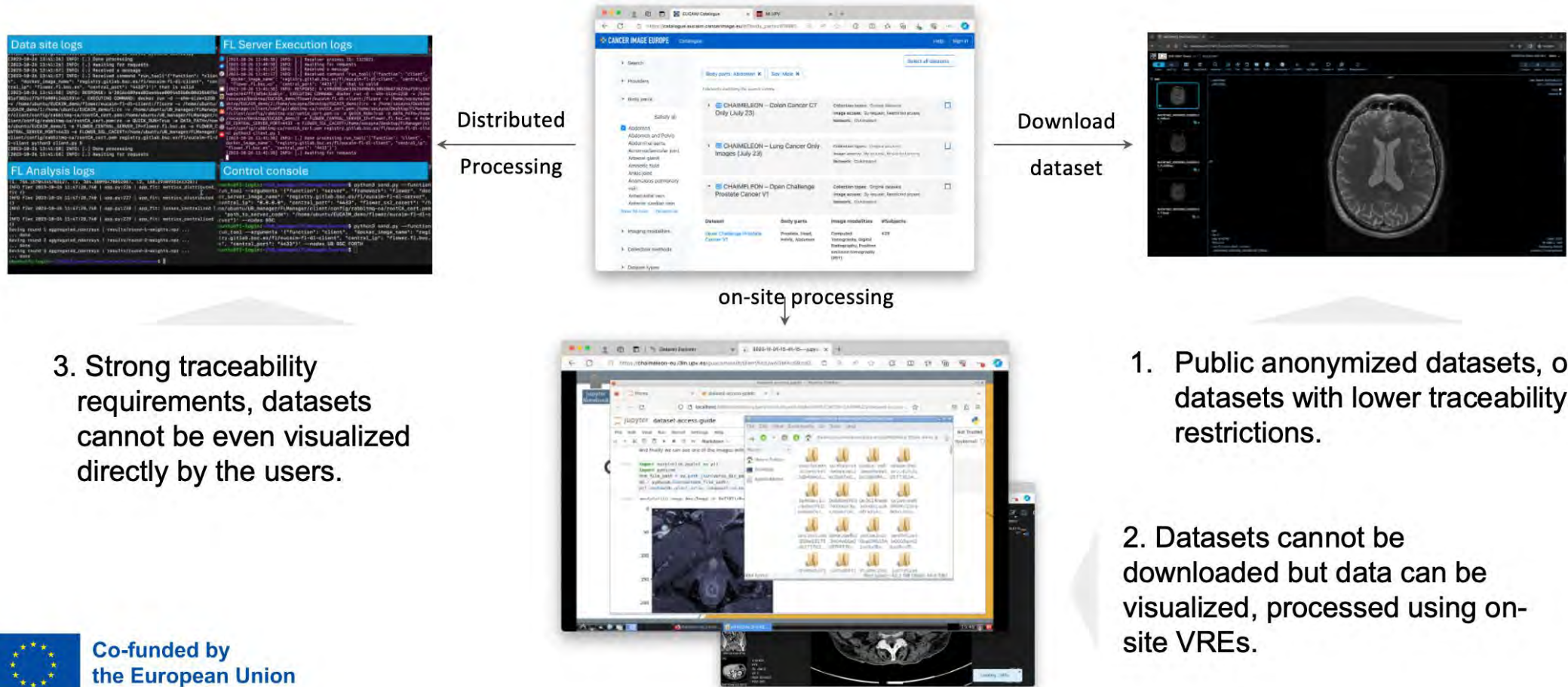
An inset window shows the detailed view for 'Prostate Cases MRI Only (July 23)', including a description, subject count (298), and contact information for Paul Jiménez Gómez. A code editor in the bottom right shows a JSON snippet:

```

{
  "operand": "AND",
  "children": [
    {
      "key": "RID10311",
      "type": "IN",
      "system": "urn:oid:2.16.840.1.113883.6.756",
      "value": [
        "RID10312"
      ],
      "display_short": ""
    },
    {
      "key": "main",
      "de": "haupt",
      "en": "main",
      "display_short": ""
    }
  ]
},
{
  "key": "collections",
  "value": 12,
  "stratifier": [
    {
      "key": "studies",
      "stratum": [

```

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



EHDS – a dream come true?


Secondary Use (Ch... For data holders

31. Who is a data holder...
The definition of who qual...
includes several elements:

'any natural or legal person...
including reimbursement s...
products or services inten...
wellness applications, perf...
mortality registry, as well a

- (i) the right o...
capacity as...
the provisio...
research, in...
purposes; c
- (ii) the ability...
the technic...
restricting

i Test environment of the HealthData@EU Central Platform
This platform is the gateway to the HealthData@EU Infrastructure and (once fully developed) will provide relevant information and the key services required by the European Health Data Space Regulation (such as Dataset Catalogue, Data Application Forms).



HealthData@EU Central Platform

Home | EU Dataset Catalogue | Registry | Reports and Monitoring | My Applicant space | Glossary | Documentation | Implementation Support

Dataset Records

Home > Dataset Records

Access Level [?]

Dataset Records | Dataset Catalogues | Sort by: Name ascending

Formats [?] 13 dataset records found

gories listed in Article 51 available

will apply in a staggered way. While...
ed with an asterisk (*) will have to be

Examples for what is out of scope

HR kept by a healthcare provider...
that qualifies as a micro-enterprise...
unless that Member State extended...
the duty to make available data also...
to such entities, see Article 50(2)).

detailed socioeconomic data...
collected outside healthcare settings...
or purely environmental data not...
linked to health.

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/>)

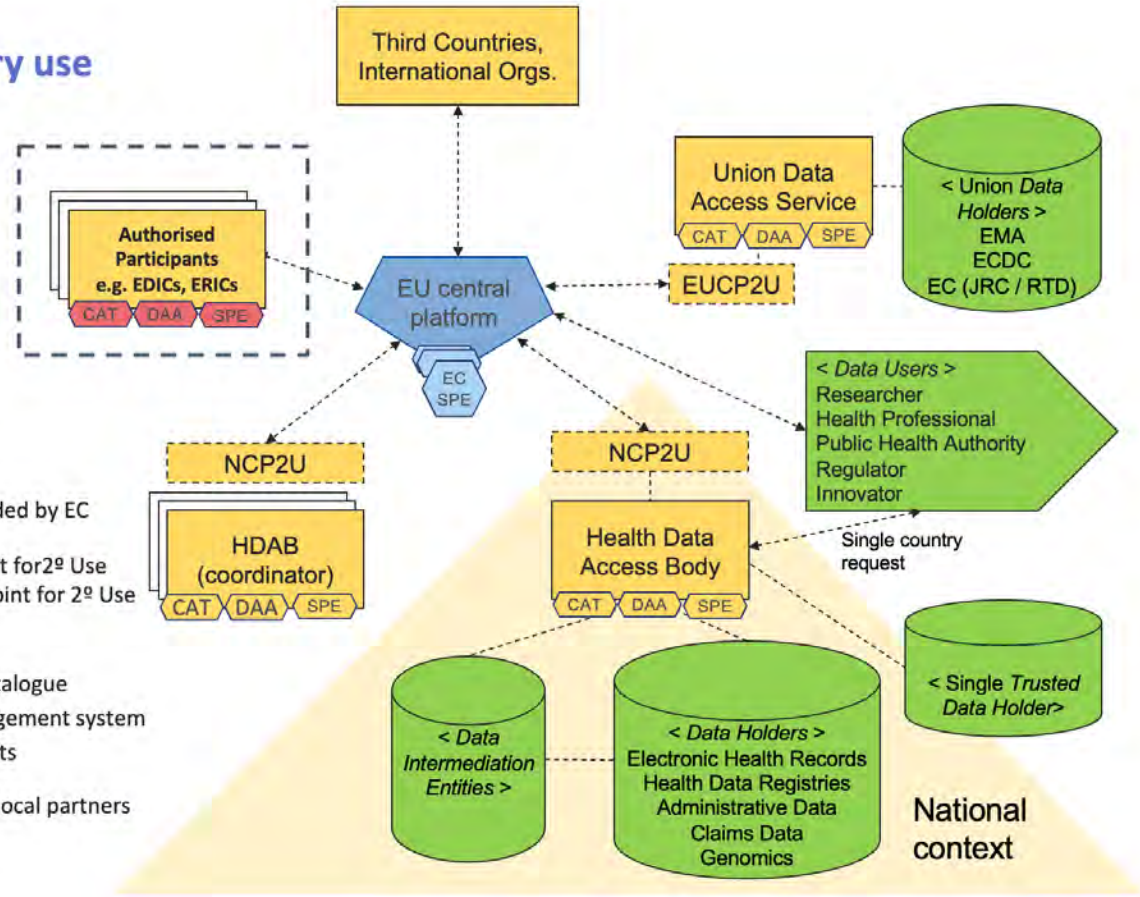
EUCAIM – a step in the right direction

- Less fragmented
- More structure
- Better interoperability



Cross-border secondary use infrastructure

HealthData@EU



- Central support services provided by EC
- NCP2U - National Contact Point for 2nd Use
EUCP2U - European Contact Point for 2nd Use
- Data access services
- CAT National dataset/metadata catalogue
- DAA Data Access Application Management system
- SPE Secure Processing Environments
- Local services provided by/to local partners

EHDS – a dream come true?

28. Will health data already dep

The requirement for question 16 above). They could for exam 'translates' between health authorities to

The rules in Chapter will can import and e

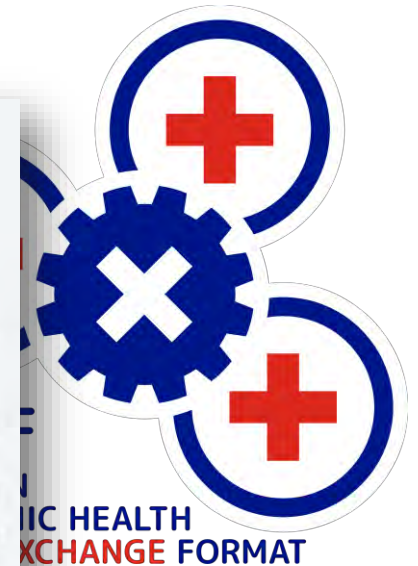
European Electronic Health Record exchange Format (EHRxF)

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

- 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!

