



EHDS Draft Implementing Regulation on Dataset Descriptions (Art.77) Stakeholder consultation

By UNCAN-Connect and CANDLE
30 April 2026
11:00-12:30 CEST

**Curated Slide deck for
sharing**

Time	Agenda Point
11:00-11:10	Welcome and introduction to the EU “Have your say” public consultation - Carola Schulz (CANDLE)
11:10-11:25	Importance of dataset descriptions to National Cancer Data Nodes and UNCAN.eu - Jan-Willem Boiten (CANDLE), Jayden Khakurel (UNCAN-Connect)
11:25-11:32	Why this consultation – Maria Rujano (CANDLE), Summary of Article 77 EHDS
11:32-11:40	Feedback to the Implementing Regulation Draft – Carola Schulz (CANDLE), - Recitals, Subject matter and Scope
11:40-11:50	Coffee break
11:50-12:25	Feedback to the Implementing Regulation Draft – Eva Garcia Alvarez (UNCAN-Connect) - Metadata elements (Annex C) - Missing metadata elements
12:25-12:30	Closure and next steps



Importance of dataset descriptions to National Cancer Data Nodes and UNCAN.eu

- Jan-Willem Boiten (CANDLE), Jayden Khakurel (UNCAN-Connect)

Introducing the EU “Have your say” public consultation context



- European Commission feedback mechanism for public input on upcoming regulation
- In this case: feedback on Draft Implementing Regulations of the European Health Data Space Regulation, providing more details on Art. 77 on dataset descriptions
- The relevant committee considers this feedback before voting for the final Implementing Regulation
- Relation to TEHDAS2 Public Consultation: TEHDAS2 consults public on deliverables that provide guidance to EHDS stakeholders and input for the Implementing Regulations -> Art. 77 Draft Implementing Regulation already considers TEHDAS2's [D5.1 Guideline for data holders on data description](#) and the respective stakeholder feedback TEHDAS received

Law

European Health Data Space – dataset descriptions

[Have your say - Public Consultations and Feedback](#) > [Published initiatives](#) > European Health Data Space – dataset descriptions

In preparation

Draft act

Feedback period
14 April 2026 - 12 May 2026

Feedback: Open

Upcoming

Commission adoption

Planned for
Third quarter 2026

About this initiative

Summary

As part of the European Health Data Space, health data holders will have to provide descriptions of their datasets to the health data access bodies so they can be included in the dataset catalogues.

This initiative sets out the basic information that these data holders must provide for each dataset, along with the details of those requirements.

Topic

Public health

Type of act

Implementing regulation

Committee

[C131500](#)

Draft act

Feedback: Open

Feedback period

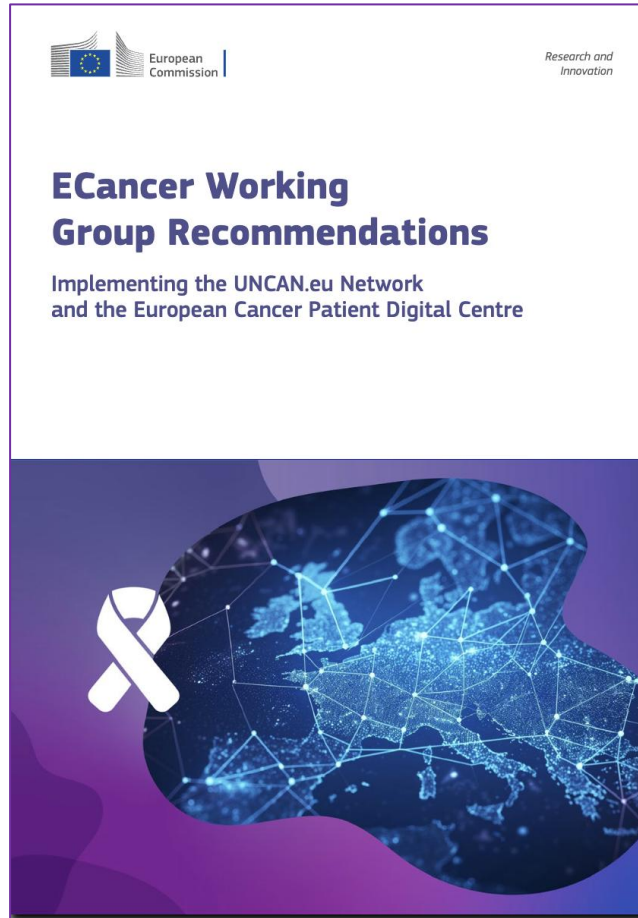
14 April 2026 - 12 May 2026 (midnight Brussels time)

The Commission would like to hear your views.

This draft act is open for feedback for **4 weeks**. Feedback will be taken into account for finalising this initiative. Feedback received will be published on this site and therefore must adhere to the [feedback rules](#).

[More about draft acts](#)

In order to contribute you'll need to register or login using your existing social media account.

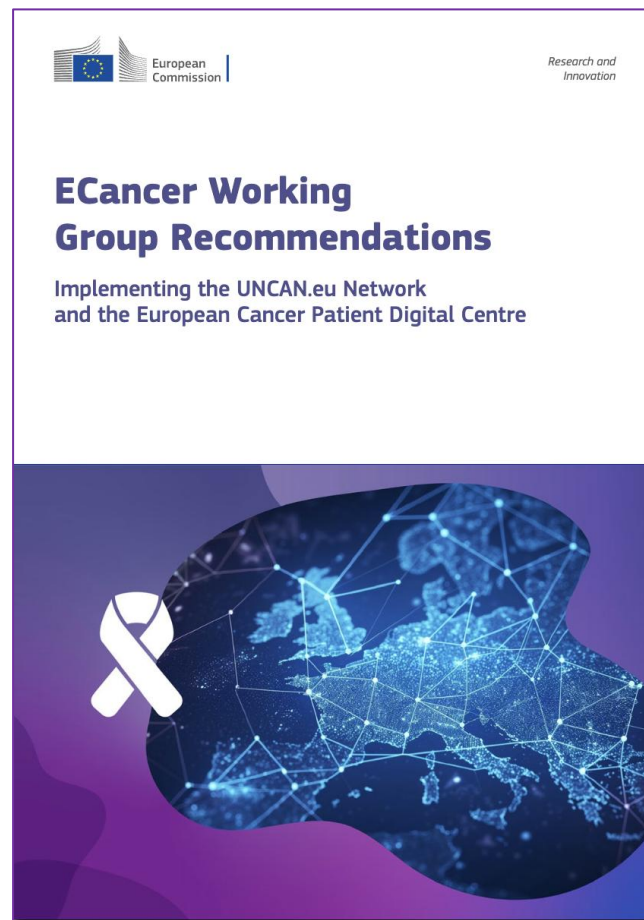


1. Provide tools to improve data quality of cancer data at source
2. Provide tools for cancer data analysis to be used in secure processing environments (SPEs)
3. Ensure all cancer datasets have a metadata record in the EU dataset catalogue
4. Provide advice on common variables for cancer datasets
5. Capacity building at national level

Tools

Data &
users

Community



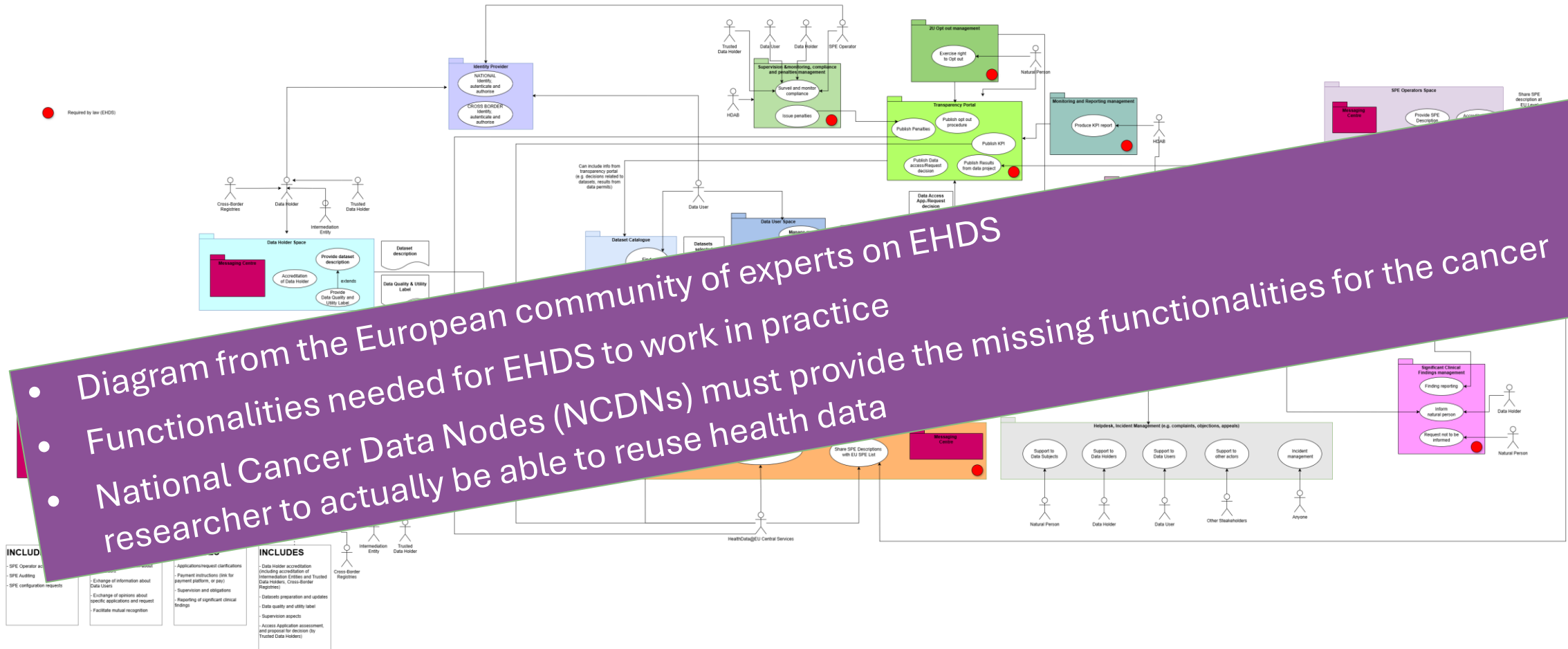
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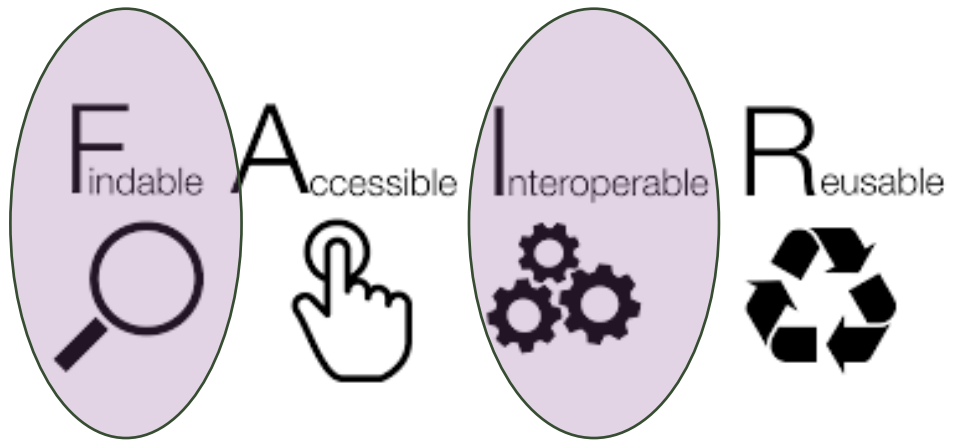
Data &
users

Community

Another angle - EHDS business capabilities are leading for CANDLE

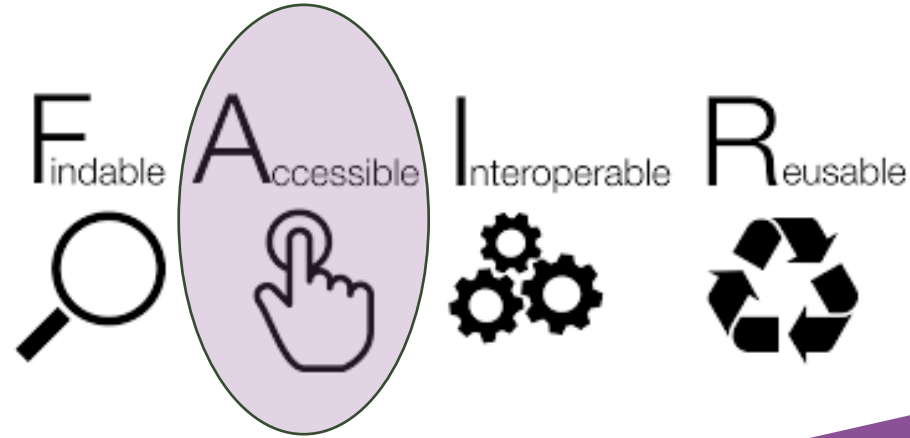


Primary focus for tool development has been in the areas of findability and interoperability

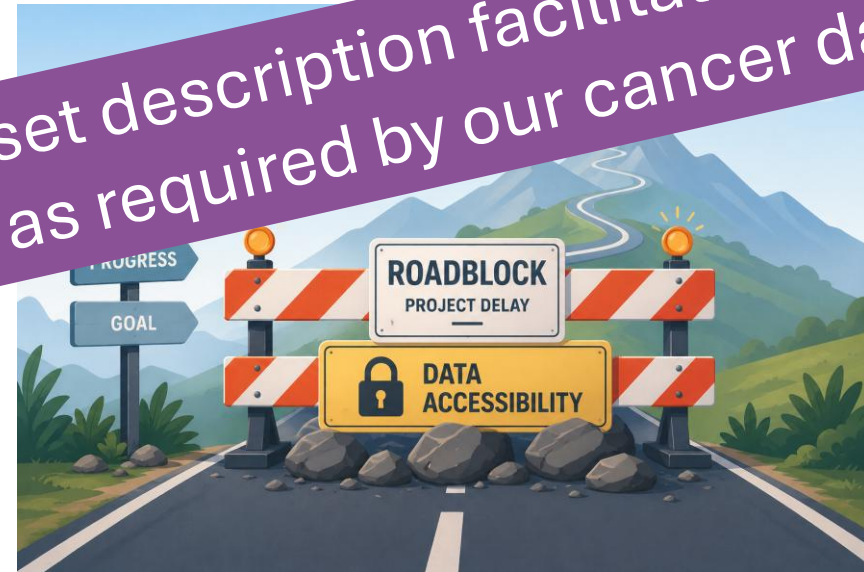


EHDS offers a once-in-a-lifetime opportunity for data access

Primary focus for tool development has been in the areas of findability and interoperability



We should make sure the EHDS dataset description facilitates all data access capabilities (the “webshop”) as required by our cancer data users



UNCAN.eu act as the main coordination, navigation and capacity-building hub of the UNCAN-Connect infrastructure. The platform will help researchers find relevant datasets and digital research assets, while allowing data to remain with the institutions that generate and manage them. It will also improve discoverability and clarify access and use conditions, thereby supporting collaboration across research groups, research infrastructures, and national initiatives.

From EHDS requirement to UNCAN functionality

- EHDS requires datasets to be described using standardised metadata (HealthDCAT-AP)

These metadata descriptions are the primary input used by UNCAN.eu

NCDN supports this process



What UNCAN.eu uses metadata for

- Identify and index datasets across countries
 - Understand
 - dataset content (e.g. cancer type, stage, treatments)
- variables and coding systems
- Assess whether datasets **can be linked and compared**

What breaks without proper metadata

- cancer cohorts cannot be compared across countries
- differences in coding systems prevent linking
- datasets cannot be selected for specific research questions

Why this matters for this consultation **This directly affects their usability in UNCAN.eu**

The metadata elements defined in Annex C determine whether cancer datasets (e.g. tumour type, stage, treatment) are

- interpretable
- comparable
- reusable across countries



Why this consultation

Summary of Article 77 EHDS

– Maria Rujano (CANDLE)

Scope and actors:

- Provides details for implementation for Article 77 EHDS Regulation
- Applies to: health data holders, health data access bodies, authorised participants in HealthData@EU
- Covers both personal and non-personal electronic health data

Core obligations → article 3 of Draft Implementing Regulation + annex

- Mandatory provision of a defined set of minimum metadata elements
- Metadata must follow:
 - HealthDCAT-AP structure
 - Defined cardinalities
 - Controlled vocabularies
- Annual verification requirement

Technical framework:

- HealthDCAT-AP is the required metadata profile
- Built on DCAT-AP, tailored for health datasets
- Enables semantic & technical interoperability across Member States

Timeline

- Regulation applies from **26 March 2029** → long lead time, but:
 - system changes
 - metadata mapping
 - governance arrangements
 - need early planning

- **Core Framework:** The mandatory use of **HealthDCAT-AP** (Part A of the Annex)
Discussion Point: Is the current/upcoming infrastructure compatible? Do we need new tools?
- **Minimum Metadata Elements:** The specific list in Part B of the Annex (see next slide)
Discussion Point: Are the required fields feasible to extract from legacy systems? Are any definitions ambiguous?
- **Operational Requirements:**
Discussion Points:
 - Annual Verification: The requirement to verify dataset accuracy at least annually (Recital 3).
 - Timeline: Application starts March 2029 – Is this realistic for our roadmap?
- **Strategic Questions for Partners:**
 - What are the potential burdens of compliance?
 - Are there gaps in the metadata that could hinder data discovery?
 - How should we frame our position on voluntary additional metadata (Article 1.3)?



Feedback to the Implementing Regulation Draft - Recitals, Subject matter and Scope

– Carola Schulz

- Recitals: summarise EHDS Article 77: see previous slides
- Article 1 – Subject matter and scope
 - Sets minimum metadata elements and their characteristics for dataset descriptions
 - Applies to health data holders providing descriptions to HDABs for secondary use of electronic health data
 - Also applies to authorised participants in HealthData@EU
 - Allows voluntary additional metadata elements if the same metadata framework is used
- Article 2 – Definitions
 - Uses the definitions set out in HealthDCAT-AP, as referred to in Annex Part A.
- Article 3 – Requirements for minimum metadata elements
 - Requires health data holders to provide the minimum metadata elements listed in Annex Part B.
 - Requires these elements to follow HealthDCAT-AP definitions, structure, cardinalities and controlled vocabularies.
- Article 4 – Entry into force and application
 - Applies from 26 March 2029.



Feedback to the Implementing Regulation Draft

- Metadata elements (Annex C)
 - Missing metadata elements
- Eva Garcia Alvarez (UNCAN-Connect)

Proposed order of the properties for the discussion:

1. Description
2. Health category
3. Health theme
4. Variables
5. Coding system
6. Code values
7. Provenance
8. Conforms to
9. Access rights
10. Has personal data
11. Custodian
12. Health Data Access Body
13. Publisher
14. Geographical coverage
15. Temporal coverage
16. Type
17. Identifier
18. Keyword
19. Distribution
20. Is structured
21. Number of records
22. Number of unique individuals
23. Contact point
24. Language
25. Applicable legislation
26. Was generated by
27. Title

[MetadataElementsPriorities](#)

- Slides will be published on zenodo and shared via email with you
- Your feedback will feed into UNCAN-Connect's and CANDLE's joint response to the public consultation, we will submit 12 May 2026 on the Have Your Say Page

One form to engage with
UNCAN-Connect, CANDLE,
EU-CiP!



[Sign up for the group here](#)