

EHDS -- Country Responses Questionnaire

HTA/Payer Real-World Data Context to Support Outcomes-Based Managed Entry Agreements (OBMEA) / Conditional Reimbursement with Data Collection

Step 1

1. Contact Information *

Mandatory fields

Full Name:

***Organisation:**

***Email:**

***Country:**

Step 2

2. National Healthcare System Context In

this section, please provide information about:

1. Your national healthcare system organisation:

Upload any supporting materials
Upload file(s) / links

2. Your national healthcare system funding:

Upload any supporting materials
Upload file(s) / links

Step 3

3. National Health Data Landscape

Please answer the questions below and provide resources or references wherever possible.

1. Does each patient in your health system have a unique patient ID that enables data linkage?

Upload file(s) / links

2. What sources and types of data could be used in your health system for conditional reimbursement purposes or OBMEA (e.g. to determine clinical outcomes of care or inform economic evaluations)?

Upload file(s) / links

3. Do dataset catalogues* exist that include descriptions of the content (meta- data) of distributed data sources, which could support discoverability of data for HTA/Payer purposes?

** Dataset catalogue means a collection of dataset descriptions, arranged in a systematic manner and including a user-oriented public part, in which information concerning individual dataset parameters is accessible by electronic means through an online portal.*

Upload file(s) / links

4. How are data accessed? What processes are in place to improve the quality* of the dataset?

**Data quality means the degree to which the elements of electronic health data are suitable for their intended primary use and secondary use*

Upload file(s) / links

5. Is there a service available to help data users identify suitable datasets or data sources for secondary use, such as feasibility assessments for a specific OBMEA/conditional reimbursement purpose?

Upload file(s) / links

6. Can prescribing records be linked with the indication? Please answer separately for:

a. Medicines dispensed from community pharmacies (e.g., outpatient prescriptions, electronic prescriptions):

Upload file(s) / links

b. Medicines administered in hospital settings (e.g., inpatient treatments, ward-based medication records):

Upload file(s) / links

c. If yes, how is the linkage made (e.g., via diagnosis codes, structured fields, free text)?

Upload file(s) / links

d. If no, what are the main barriers (e.g., technical, legal, organisational)?

Upload file(s) / links

Step 4

4. Data Access and Use

Please answer the questions below and provide resources or references wherever possible.

1. Are there secure processing environments in your country that enable access to health data for approved secondary uses, such as HTA or payer evaluations? If yes, please list the environments or provide a link to more information

Upload file(s) / links

2. How is access to data governed (e.g. legislation, data permits, register of uses)? Are there differences in governance between national and regional datasets?

Upload file(s) / links

3. What other information do we need to know about data governance and accessibility in your health system?

Upload file(s) / links

4. Is there a centralised source or service where information is available about the use of health system data in OBMEA or conditional reimbursement? If yes, please list the source or provide a link.

Upload file(s) / links

5. Describe any collaboration your country/region is undertaking to enable HTA/Payer health data access across borders?

Upload file(s) / links

Step 5

5. Additional Information

1. Outline any major initiatives planned or underway to improve data infrastructure or accessibility in your country.

Upload file(s) / links

2. Any other comments?

Upload file(s) / links