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

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Date of completion	17/05/22
Health System Organisation	National
Health System Funding	National Health Service
1. Does each patient in your health system have a unique patient id that enables data linkage?	Yes relates only to health data on Valtermed (Data Collection System) but this id number is linked with the number of the Health Card so all health records could be linked
2. Can the prescribing record be linked with the indication?	Yes, see above
3. What sources and types of data could be used in your health system for conditional reimbursement purposes or OBMEA (e.g. to determine clinical effectiveness or inform economic evaluations)?	
Each OBMEA is linked to a clinical protocol and data supporting the OBMEA are collected for that purpose.	
4. Do data catalogues exist that include descriptions of the content (meta-data) of distributed data sources, which could support discoverability of data for HTA/Payer purposes?	
No, specific pharmacoclinical protocols are designed to collect data	

5. Are there any standards or systems in place to judge data quality?
Not yet, we are working currently on data governance
6. Are there any tools or processes to appraise data suitability for OBMEA/conditional reimbursement purposes, such as the EUnetHTA REQueST Tool for registries?
Data are collected for the primary purpose of supporting a specific MEA, so the process is: decision on use of RWE to support decision>>design of a protocol of data collection>>data collection
7. Describe "Secure Operating Environments" or "Trusted Research Environments" that exist within clear governance processes to enable access for approved purposes to one or more data sources that could potentially be used for HTA/Payer purposes.
There is no Secure Operating Environment or Trusted Research Environment but restricted access to the information.
8. How is access to data governed (e.g. legislation, data permits, register of uses)? Are there differences in governance between national and regional datasets?
There is only a national registry with the access to the information divided in 3 levels: - Clinician: only can access to the data of his/her patients - Regional authorities: only can access to anonymized data of the region - National managers: access to all to anonymized data From April onwards Clinicians and Regional authorities can compare their data against the rest of the Country Data aggregated.
9. What other information do we need to know about data governance and accessibility in your health system?
We are able to check completeness of the registries crossing purchasing data with clinical data by region/hospital
10. Is there a precedent for national health system data to be used in OBMEA/conditional reimbursement? If yes, describe any supporting legislation or processes. If no, identify key challenges.
No nationally, some regions have used data collection systems for some risk sharing agreements

11. Describe any collaboration your country/region is undertaking to enable health data access across borders?
We do not have any plan of this as we have just reached 2 years of data collection
12. Any other comments?
13. Outline any major initiatives planned or underway to improve data infrastructure or accessibility in your country.
We expect to address this in the following evolutionary developments: • Web services to send large amounts of data (currently testing) • Application programming interfaces linked to electronic medical records • Quick data visualization: each user (clinician, hospital, region) can see its data against the rest of the country as a whole without any comparison between clinician, hospital or regions.