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

Organisation	Gemeinsamer Bundesausschuss
Country	Germany
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Health System Organisation	National
Health System Funding	Social insurance
1. Does each patient in your health system have a unique patient id that enables data linkage?	No Are methods used to link patient data across datasets, such as algorithms? No
2. Can the prescribing record be linked with the indication?	Partly: Insurance companies have records of the indication and prescriptions. However these routine data are not accessible for HTA purposes are of insufficient quality. Therefore, they cannot be used for evidence generation for HTA purposes.
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)?	
High quality registries/ registry based studies. There is no conditional reimbursement in Germany. However, decisions can be time - limited and re-evaluated. The Federal Joint Committee (G-BA) can require the collection of routine practice data from pharmaceutical companies to inform benefit assessments of new drugs. These data are usually collected in registries. The G-BA requires registry based clinical studies.	
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?	
In 2020, the Institute for Quality and Efficiency in Health Care (IQWiG) published criteria for the usability of routine practice data in the benefit assessment of drugs. https://www.iqwig.de/download/a19-43_versorgungsnahe-daten-zum-zwecke-der-nutzenbewertung_rapid-report_v1-1.pdf In this concept paper manufacturers and registry operators find recommendations for the collection and analysis of routine practice data and hence for structure and content requirements for the data sources.	

For each requirement of the collection of routine practice data from pharmaceutical companies the G-BA defines core data that have to be collected for benefit assessment purposes.
5. Are there any standards or systems in place to judge data quality?
In 2020, the Institute for Quality and Efficiency in Health Care (IQWiG) published criteria for the usability of routine practice data in the benefit assessment of drugs. High level criteria for data quality are defined in this paper. On a case by case basis, the G-BA commissions IQWiG to assess the data quality of the data, collected in routine practice.
6. Are there any tools or processes to appraise data suitability for OBMEA/conditional reimbursement purposes, such as the EUnetHTA REQueST Tool for registries?
EUnetHTA REQueST Tool is one of the Tools comprising different quality criteria that are also contained in the above-mentioned paper(https://www.iqwig.de/download/a19-43_versorgungsnahe-daten-zum-zwecke-der-nutzenbewertung_rapid-report_v1-1.pdf). These criteria apply to appraise data quality.
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.
not yet applicable. There are different data sources for other purposes: e.g. Under a new legal framework, clinical and epidemiological data from the cancer registries of the German federal states are to be merged at the Centre for Cancer Registry Data (ZfKD) at the Robert Koch Institute. A two-stage process is planned: In the first step - at the beginning of 2023 - the data set currently transmitted annually by the cancer registries to the ZfKD will be supplemented with various clinical data. In particular, the most important information on therapy and the course of the disease will be added. or: The Research Data Centre Health (FDZ Gesundheit) https://www.forschungsdatenzentrum-gesundheit.de/ makes it possible to access the health insurance data of all people with statutory health insurance in Germany. In future, researchers from authorised institutions will be able to analyse data in a controlled analysis environment of the FDZ Gesundheit. Authorised users include important federal organisations that represent the interests of patients and self-help groups for chronically ill people and people with disabilities. The Data Centre is currently under construction. The development will take place in phases. Unfortunately, no applications can be submitted at the moment, as the legal, technical personnel and organisational measures of the new research data centre are currently being defined and implemented The extent to which these data are suitable for the early benefit assessment cannot be assessed at present.

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?
not yet applicable
9. What other information do we need to know about data governance and accessibility in your health system?
n.a.
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, The variety of different data collections for different purposes and the poor quality of the data sources, especially in terms of completeness but also in terms of missing information (e.g. safety data, dosages, etc.).
11. Describe any collaboration your country/region is undertaking to enable health data access across borders?
not known
12. Any other comments?
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13. Outline any major initiatives planned or underway to improve data infrastructure or accessibility in your country.
See 7. The German Law for More Safety in the Supply of Medicines (GSAV) includes that, for certain drugs, the Federal Joint Committee (G-BA) can require the collection of routine practice data from pharmaceutical companies to inform benefit assessments of new drugs. If this data collection leads to a reassessment of the drug, the collected data and the analysis thereof have to be submitted to the G-BA and will be published on the website of the G-BA. However this improves transparency of routine data collection for the public for specific products but does not guarantee accessibility for all kinds of collected data.