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

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Role	Oncologist
Country	Scotland
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Health System Organisation	National
Health System Funding	National Health Service from general taxation
1. Does each patient in your health system have a unique patient id that enables data linkage?	Yes CHI – Health and Social Care
2. Can the prescribing record be linked with the indication?	Yes For certain diseases only.

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)?

Hospital diagnostic and procedures, community prescribing, hospital prescribing, cancer prescribing, disease-specific registries death registration, laboratory values and some coded outcomes that may provide a basis for Outcomes-Based Pricing (OBP).

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?

Yes – mainly available via Public Health Scotland

5. Are there any standards or systems in place to judge data quality?

Yes – reporting by Public Health Scotland

6. Are there any tools or processes to appraise data suitability for OBMEA/conditional reimbursement purposes, such as the EUnetHTA REQueST Tool for registries?

No, other than submitting a feasibility request to Public Health Scotland

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.

Scottish Safe Haven Network is available for non-commercial use.

Commissioned analysis service available in South East Scotland (DataLoch) for payers

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?

National access governed by the Scottish Public Benefits and Privacy Panel

Regional Access governed by local Caldicott Guardians (South East Scotland delegates this to the DataLoch Governance process).

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

Data quality is good and governance processes are robust – the limiting factor is data scientist manpower (and clinical oversight) within NHS Scotland.

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.

Public Health Scotland and National Services Scotland are undertaking proof of concept studies to test the feasibility of complex patient access schemes – this focuses on indication specific pricing in cancer initially rather than OBP.

11. Describe any collaboration your country/region is undertaking to enable health data access across borders?
Innovative Licensing and Access Pathway (ILAP) represents an active collaboration between the Scottish Medicines Consortium (SMC), the National Institute for Health and Care Excellence (NICE) and the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK looking at accelerated adoption with a prospect of evidence development.
12. Any other comments?
13. Outline any major initiatives planned or underway to improve data infrastructure or accessibility in your country.
Research Data Scotland is working to make public sector data more available for research in Scotland.