Coordinating Efforts to address RWD Challenges

Lianna Ishihara, Senior Director Real World Data Strategy & Partnerships

24 April 2024

Disclaimer

I am a full-time employee at GlaxoSmithKline (GSK). Opinions expressed in this presentation are my own and not representative of GSK.

Agenda

1. Brief intro to RWD
2. Areas that require coordinated efforts to address RWD Challenges across: Pharma, biotech, vendors, data partners, regulatory authorities, etc
3. Coordinating Efforts within the FAIR Principles: Findability, accessibility, interoperability, and reusability

Brief intro to RWD

Types of RWD Sources

Patient mediated data

e.g., wearables

- Enable an expanded reach of data collection through direct collection of eCOAs, such as PROs
- Variables collected:
  - ✓ Patient insights
  - ✓ PROs
  - ✓ Drugs

Claims data

e.g., SNDS, PHARMO, HTI, HES

- Insurance claims related to services provided by healthcare service providers
- Variables collected:
  - ✓ Diagnosis
  - ✓ Procedures
  - ✓ Reimbursed drugs

Pharmacy data

e.g., IQVIA LRx data, Medical Prescriptions

- Dispensed prescription records from pharmacies collected for administration purposes
- Variables collected:
  - ✓ Diagnosis
  - ✓ Drugs
  - ✓ Reimbursed drugs

Electronic medical records

e.g., CPRD, hospital data

- Structured electronic patient records from patient management software used in primary and secondary care
- Variables collected:
  - ✓ Diagnosis
  - ✓ Clinical details
  - ✓ Drugs
  - ✓ HCRU

Registries

TA dependent e.g. Nordic registries, NCRAS

- Detailed patient data on a specific disease, use of a specific product, etc., collected using observational methods
- Variables collected:
  - ✓ Disease and drug oriented (e.g., Lab results)

Lab data / Biobank

e.g., Genomics England, UK Biobank

- Collection of biological samples and health information, providing insights into patients' biochemical data
- Variables collected:
  - ✓ Lab
  - ✓ Biomarkers
  - ✓ Imaging
  - ✓ Genetics

Low clinical depth of data → **High clinical depth of data**

eCOA: Electronic clinical outcome assessment; PRO: Patient reported outcomes; HCRU: Healthcare resource utilisation;

Areas that require coordinated efforts to address RWD Challenges

Areas that require coordinated efforts to address RWD Challenges

For Research Purposes

Identification of RWD sources

Wider access to RWD sources

Use of Standards, Data Quality Frameworks and fit for purpose

Potential linkage between data sources, Support of Data Networks

Coordinating Efforts within the FAIR Principles

Coordinating Efforts within the FAIR Principles

Findability	Identification of RWD sources
Accessibility	Wider access to RWD sources
Interoperability	Standards, Data Quality Frameworks, fit for purpose
Reusability	Potential linkage between data sources, Networks

Findability

Identification of RWD sources

- Comprehensive
- International
- Key metadata elements, general and disease area specific
- Continuous updating

Examples:

HMA EMA Catalogue

IQVIA Health Data Catalog

Bridge to Data

Accessibility

What: Wider access to quality RWD for research
Why: Consistency, reproducibility, generalisability…

Possible modes of access:

- Direct licensing or purchase
- Partnerships with indirect or direct access
- Secure data environments / Trusted research environments
- Federated data networks

Interoperability

Data standardisation

- e.g. FHIR- Fast Healthcare Interoperability Resources standard is a set of rules and specifications for exchanging electronic health care data

Common Data model examples for research

- OMOP/OHDSI
- Sentinel
- SIGMA Consortium

Data Quality and Fit for purpose

- Frameworks have been proposed from FDA, EMA, ISPOR, etc

Key Question: How do we ensure that these standards and guidance are adhered to?

Reusability

Collective efforts could focus on improving Linkage between data sources that could be available to multiple stakeholders. Also support to ensure data networks are sustainable over time

Examples:

- UK Health Security Agency National data, laboratory data, regional primary care EHR via Secure Data Environments
- European Health Data and Evidence Network (EHDEN)

Out of scope: Reusability within a company as this is often proprietary

Summary

- RWD is expanding and being used more widely to generate insights and evidence to inform pharmaceutical development
- All of the FAIR principles have areas that could be addressed collectively for improvement over time
- A key question is how do we raise the bar for adhering to the standards and guidance that already exist for RWD

gsk.com

Thank you!