Coordinating Efforts to address RWD Challenges Lianna Ishihara, Senior Director Real World Data Strategy & Partnerships 24 April 2024



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



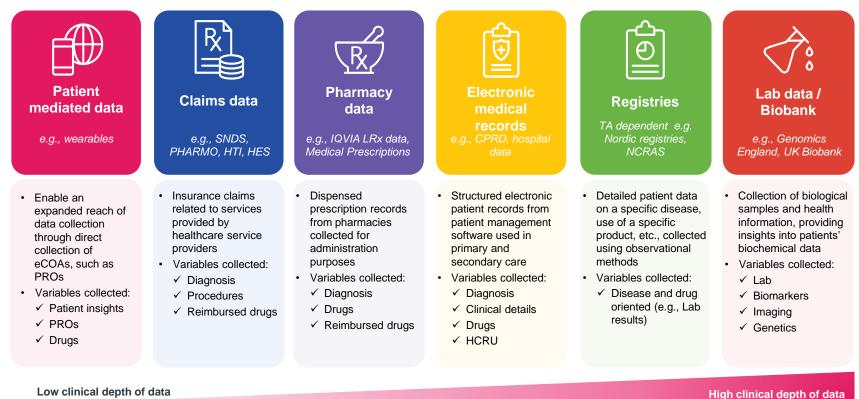
1. Brief intro to RWD

- 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





Areas that require coordinated efforts to address RWD Challenges

Areas that require coordinated efforts to address RWD Challenges For Research Purposes



Networks



Coordinating Efforts within the FAIR Principles

• Coordinating Efforts within the FAIR Principles



Identification of RWD sources

Wider access to RWD sources

Standards, Data Quality Frameworks, fit for purpose

Potential linkage between data sources, Networks



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



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 <u>FDA</u>, <u>EMA</u>, <u>ISPOR</u>, etc

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



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



- 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

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Thank you!

