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A Diagnostic Framework to Evaluate Real-World Data Sources for Real-World Evidence Generation

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INTRODUCTION

- Pharmaceutical companies use many real-world data (RWD) sources to generate real-world evidence (RWE) but struggle with understanding whether these RWD sources are capable of generating evidence suitable for their research goals, including reliability for regulatory submissions and market access purposes
- We created a diagnostic framework to have a structured, streamlined approach to generate RWE, emphasizing a comprehensive portfolio review to realize value from RWD source investment

METHODS

- We developed a framework to assess RWD sources, consisting of 13 questions regarding data access (privacy and use of data), data quality (structure, linkage, and coverage of data), and data relevance to research questions at hand
- The diagnostic framework was tested on four representative longitudinal US RWD sources, with the aim of developing a similar framework for a global audience following initial framework testing
- Data sources were evaluated based on goodness of fit to industry standards for each individual data source and together as a portfolio of RWD sources

DATA SOURCES

PRESCRIPTION RECORDS

- **Collection Method:** Computerized dispensed prescription records at the anonymized patient level collected from retail, LTC, specialty and mail order pharmacies
- **Coverage:** 43,300 outlets across channels (92% national retail coverage); total mail (65% coverage – varies by TA); LTC (~50% coverage across all TAs)
- **History:** 2003 – Present

HOSPITAL RECORDS

- **Collection Method:** Anonymized patient level data are sourced from hospital charge detail masters (CDM) and collected from resource management software within short-term, acute-care and non-federal hospitals
- **Coverage:** 8% of all non-federal hospitals in the US; 350+ acute care, non-federal hospitals
- **History:** 2001 – Present

ADMINISTRATIVE CLAIMS

- **Collection Method:** Fully adjudicated prescription, hospital and medical claims at the anonymized patient level sourced from commercial payers
- **Coverage:** 130M+ enrollees (medical and pharmacy benefit)
- **History:** 2007 – Present

ELECTRONIC HEALTH RECORDS

- **Collection Method:** Anonymized patient records collected from Patient Management software used by GPs and specialists are sent to a central location, then processed and aggregated by Ambulatory EMR vendor
- **Coverage:** 33M patients; 345M medication records (Rx & OTC); 40K+ Providers; 315 PC/Specialist/GP
- **History:** 2006 – Present

DATA RELEVANCE

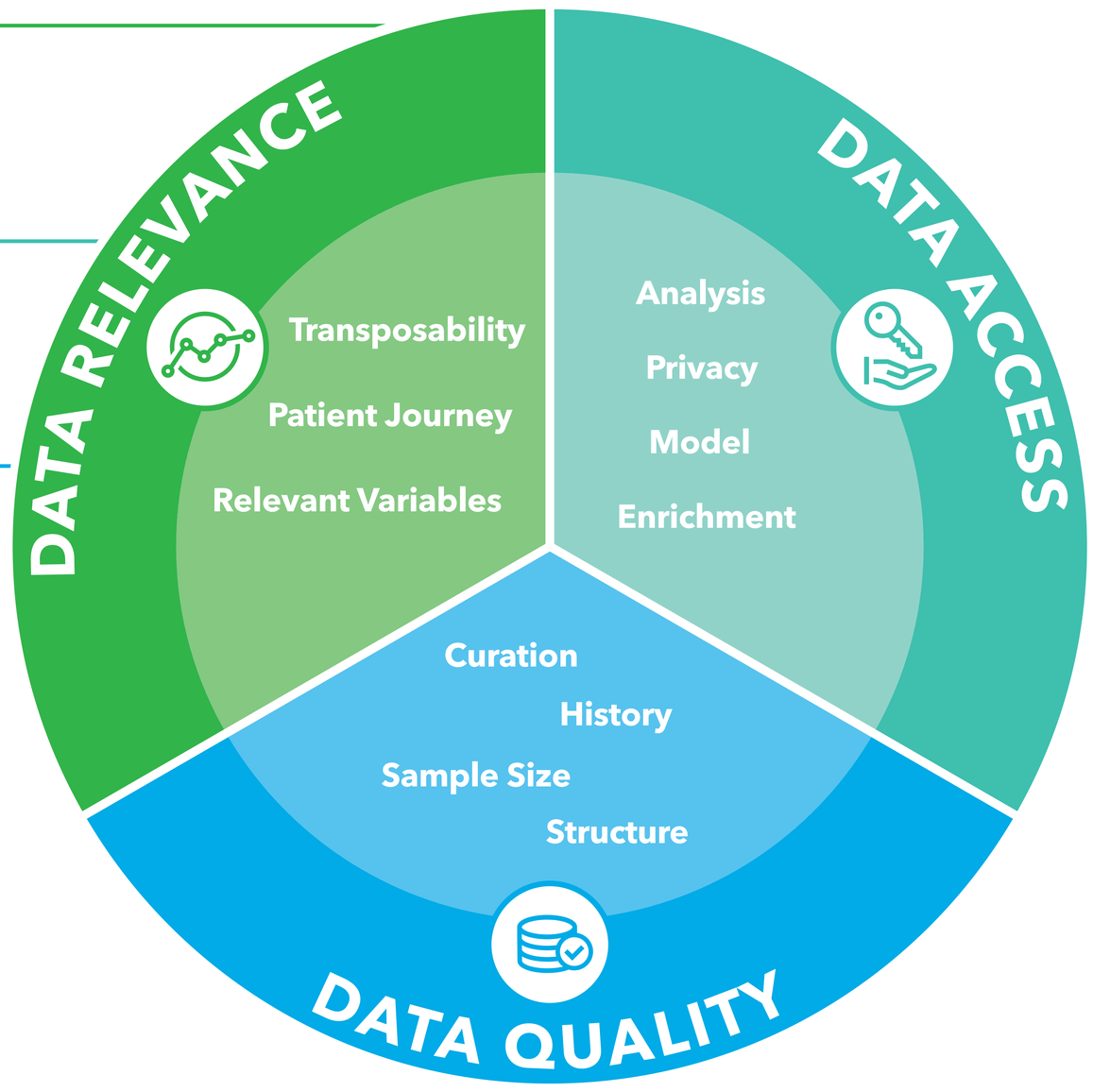
1. Is the data source applicable to the current indications of interest?
2. Does the time frame of data collection capture the relevant patient journey for indications of interest?
3. Does the data source contain relevant variables for the specific therapy-areas of interest?
4. Does the data source adequately capture patient medical history and pre-existing conditions to the agreed upon threshold?

DATA ACCESS

5. Can the data be analyzed internally by the relevant stakeholders?
6. Are the data limitations clearly and transparently communicated?
7. Is there verification that due diligence has been conducted to ensure the data source abides by relevant privacy regulations?
8. Is there direct access to the data, with or without limited use restrictions?
9. Can the data source be augmented/linked to include missing variables of interest?

DATA QUALITY

10. Is there verification that a curation and QC process have been used to ensure the quality of the data?
11. Is the sample size of the target population large enough to uncover meaningful differences?
12. Is the data available in a structured format, or able to be converted to a structured format?
13. How frequently is the data source refreshed / updated?



RESULTS

Data Source	Score: Access	Quality	Relevance	Framework Output
Hospital	3	3	1	Source does not capture deep clinical data, specifically regarding the patient journey, TA-specific variables, and adequate patient medical history
	Source total: 7 / 13			
Prescription	5	4	3	Source has comprehensive data access and quality, but is unable to fully capture patient medical history and pre-existing conditions
	Source total: 12 / 13			
Claims	5	4	3	Source has comprehensive data access and quality, but it unable to fully capture patient medical history and pre-existing conditions
	Source total: 12 / 13			
EHR	5	4	4	Source effectively captures all variables necessary for a reliable data source
	Source total: 13 / 13			

11/13 OVERALL PORTFOLIO SCORE

This portfolio exhibits many hallmarks of reliable data sources, however, has room to improve through the addition of other sources, such as registries, to provide a comprehensive approach to real-world evidence generation

- Scores were generated across all three dimensions (access, quality, relevance), showing variability both across and within those dimensions
- This tool considers the strengths and limitations of each source, highlighting how the sources can be used to complement each other as part of a robust portfolio to support a given research agenda

CONCLUSIONS

- Use of a diagnostic framework to evaluate RWD sources within a pharmaceutical company's portfolio allows for greater understanding of gaps and enrichment opportunities aligned with local and global evidence goals
- Output from this assessment will help frame a strategic vision of how RWE can be used to help pharmaceutical companies achieve short and long-term goals, allowing for RWD sources to be used to their full potential
- A limitation of this diagnostic framework is that it does not guarantee that a RWD source will meet regulatory requirements and payer thresholds for data quality, but can provide a starting point to objectively review data sources when designing a RWE strategy across the product lifecycle

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