Assessment of Real-World Data Sources and A Hybrid Approach in Real-World Evidence Generation Using Unharmonized Data Sources

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Background

- Real-world evidence is increasingly used for regulatory, reimbursement, and patient access decisions in APAC.
- RWE can capture large and diverse patient populations in a cost and time efficient manner and can help bridge evidence gaps from randomized clinical trials to support products across their lifecycle.[1-2]
- However, differences in data maturity of data sources in APAC poses a challenge for multi-country research.[3-4]
- We propose the use of an innovative method that standardizes diagnoses, drugs, and variables of interest across different data sources to allow for a consistent analysis and interpretation of data.

Methods

Assessment of Real-World Data Sources

- We developed a research-specific evaluation matrix with technical and operational dimensions **(Table 1)** to assess the variable coverage and operational accessibility of candidate data sources for a multi-country study.

Table 1. Examples of dimensions for evaluating data sources

Technical	Availability	Completeness	Data Format	Patient Counts	Data Period
Operational	Data Access	Research Capacity	Linkage Capability	Collaboration Potential	Data Enhancement Potential

- Data sources were evaluated to determine the best combination of fit-for-purpose data sources to address the research questions. Suitable data sources were identified in some APAC countries but lacking in others.
- To ensure a standardized research conduct across all APAC countries of interest, we adopted a hybrid (Mosaic) approach to utilize data sources of varying levels of data maturity

Results

What is the Mosaic Approach?

- The Mosaic approach harmonizes data collected using different data collection methods (secondary data extraction, site-based chart review, survey) when a single method is not feasible across all data sources of interest.
- The Mosaic approach adopts a common data model to harmonize data for analysis and overcomes the challenges faced with unharmonized data sources and concerns about data privacy, while ensuring consistency and validity of the research under a single protocol, analysis, and timeline.
- Adaptations of data collection methods for specific data sources may be required to ensure that data collected is fit-for-purpose while overcoming the limitations of each data source.
- A step-by-step framework to illustrate the Mosaic approach using two different data collection methods is described in **Figure 1**.

Benefits of a Mosaic Approach

- **Bespoke yet efficient solution to data collection in a heterogenous landscape**
- Provides a flexible data collection methodology to create a bespoke yet efficient solution from heterogeneous landscape. By relying on a single methodology, we risk excluding certain sites or countries of interest due to differences in data source maturity.
- **Sufficient breadth and depth of final dataset**
- Analysis from a Mosaic approach address sufficient breadth and depth which represents a middle ground approach in compared to a single data collection methodology and reflects a pragmatic balance between representativeness and richness.
- **Cater to multiple research needs, can be used for multiple stakeholders**
- Data collection methods can be tailored by sites and country to be fit-for-purpose for multiple stakeholders like regulators, HTA bodies, Payers etc.

Figure 1. Mosaic Approach using two data collection methods

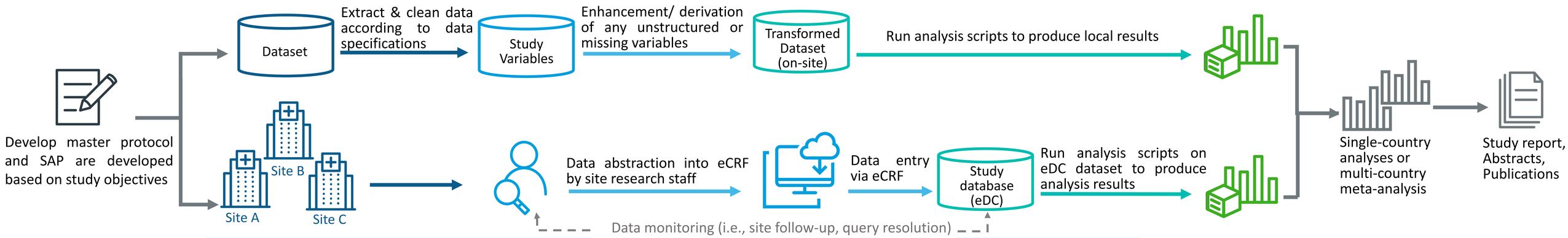
Step 1. Study design

A master study protocol and SAP are developed based on study objectives.

Step 2. Data collection

Step 2a. Data collection for electronically structured data sources (e.g., electronic medical records, registries)
- Data specifications are developed according to the master study protocol and SAP and standardized to a common data model.
- Data enhancement by free-text mining, manual chart review, or image review may require for unstructured or missing variables.

Step 3. Analysis and reporting
- Data analysis can be conducted using the established common data model.
- Single-country analyses or multi-country meta-analysis can be conducted based on study objectives.



Step 2b. Data collection for paper-based or electronically unstructured data sources (e.g., medical records)
- An electronic case report form (eCRF) is developed and aligned with the database specifications.
- Data entered into the study database (eDC) are standardized to a common data model.
- Routine data monitoring is required to ensure data completeness and quality.

Conclusion

- This Mosaic approach has been implemented in research studies in APAC, overcoming the challenges of data sources with varying robustness and formats, and enabling data variables captured across different data sources to be standardized for analysis.
- When considering a Mosaic approach, it is essential to take into account the similarities or differences in local treatment practices.

Abbreviations: APAC, Asia-Pacific; eCRF, electronic case report form; eDC, electronic data capture; HTA, health technology assessment; RWE, real-world evidence; SAP, statistical analysis plan

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