

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
- Differences in data maturity of data sources in APAC pose 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 elements (**Table 1**) to assess variables coverage and operational accessibility of candidate data sources for a multi-country study.

Table 1. Key elements 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

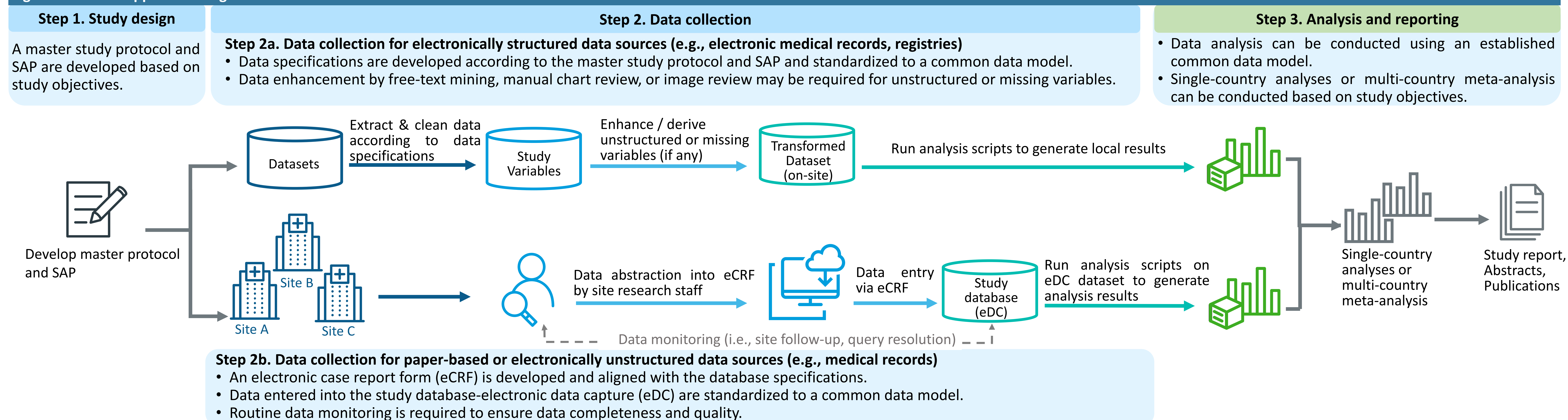
What is the Mosaic Approach?

- 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

- Efficient solution to conduct research across different types of data sources**
 - Research conduct under a single study and protocol improves efficiency
 - Broader inclusion of sites in study, better representativeness
- Sufficient breadth and depth of combined dataset**
 - Breadth and depth of combined dataset which represents a middle ground compared to a single data collection method
 - Pragmatic balance between representativeness and richness of data
- Fulfilling multiple research needs**
 - Data collection methods can be tailored by sites/country to be fit-for-purpose based on research needs

Figure 1. Mosaic Approach using two data collection methods



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.
- Similarities or differences in local clinical treatment practices should be taken into account when considering a Mosaic approach.

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
References: 1. Hiramatsu K, Barrett A, Miyata Y, PHRMA Japan Medical Affairs Committee Working Group 1. Current Status, Challenges, and Future Perspectives of Real-World Data and Real-World Evidence in Japan. *Drugs Real World Outcomes*. 2021;8(4):459-480. doi:10.1007/s40801-021-00266-3. 2. Crane G, Lim JCW, Gau CS, Xie J, Chu L. The challenges and opportunities in using real-world data to drive advances in healthcare in East Asia: expert panel recommendations. *Curr Med Res Opin*. 2022;38(9):1543-1551. doi:10.1080/03007995.2022.2096354. 3. Duszynski KM, Stark JH, Cohet C, et al. Suitability of databases in the Asia-Pacific for collaborative monitoring of vaccine safety. *Pharmacoepidemiol Drug Saf*. 2021;30(7):843-857. doi:10.1002/pds.5214. 4. Lai EC, Man KK, Chaiyakunapruk N, et al. Brief Report: Databases in the Asia-Pacific Region: The Potential for a Distributed Network Approach. *Epidemiology*. 2015;26(6):815-820. doi:10.1097/EDE.0000000000000325

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