Using A Centralized Platform to Integrate Retrospective and Prospective Data – Lessons Learned

RWD 111

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OBJECTIVES

In recent years there has been an increasing focus on real-world data (RWD), in part due to regulatory interest. RWD is usually pieced together from retrospective data sources. While this approach enables researchers to collect data more efficiently, there are limitations: missing key health subject data, inconsistent standardization of health measures, and minimal availability of patient-reported outcome (PRO) data, to name a few.

A more targeted approach to RWD involves conducting prospective studies to supplement retrospective data. For increased certainty, a centralized and standardized platform is a must.

> By combining prospective and retrospective data sources through a centralized platform, life sciences companies can increase efficiencies by leveraging one platform through all phases of the drug development lifecycle including post-approval follow-up.

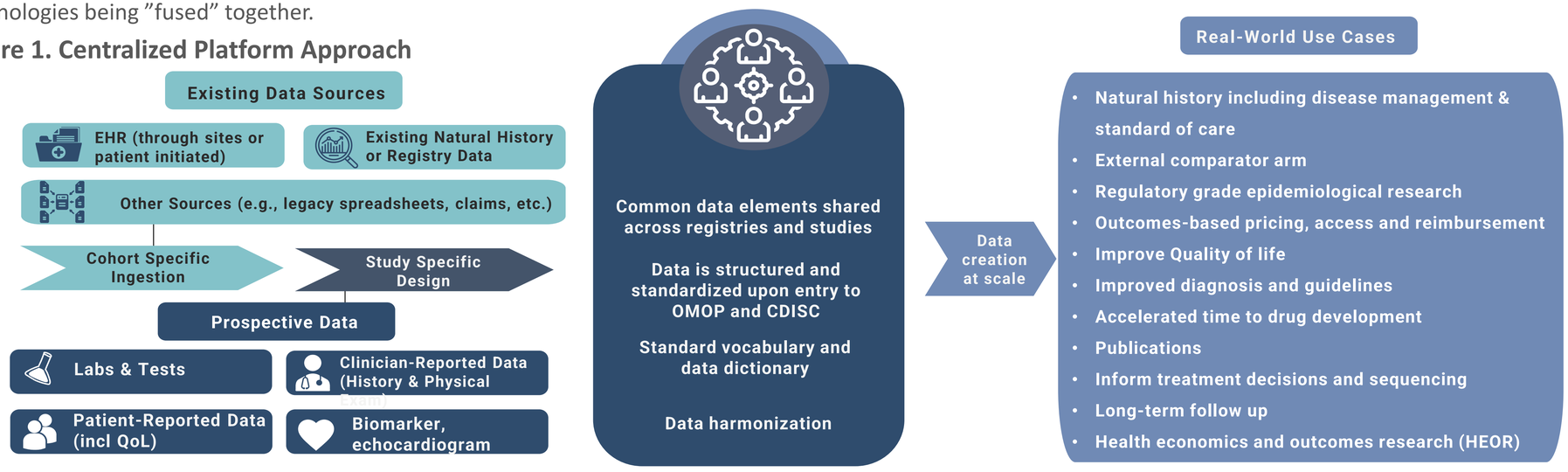
METHODS

We considered the various uses of RWD and the flexibility required to accommodate ambispective studies while designing the platform. We used a standardized vocabulary to curate and harmonize different data sources, data mapping to an ontology was a pre-requisite as well as standardized vocabularies to collect data consistently. Defining common data elements for diseases and subsequently disease specific variables form an underlying foundation to cross interrogate data, especially where data are sparse, such as in rare diseases where existing RWD often collect different data & inconsistently.

RESULTS

Data within a centralized platform, are structured and standardized within the platform so the data are of high quality allowing the data that are prepared for analysis to be of high-fidelity study, reliable and consistently interpretable. The reliability and availability of data make it more facile to collaborate and share de-identified data, and support studies that are retrospective, hybrid (with decentralization) allowing patients to directly enter data and sites to provide clinical and biomarker data. This holistic approach to evidence generation within a single environment reduces the risk of erroneous results due to data from multiple technologies being ”fused” together.

Figure 1. Centralized Platform Approach



CONCLUSION

Through prospective studies, life sciences companies can target what RWD needs to be produced to address unmet evidence generation needs in specific populations. This may include natural history data, supplemental health measures or outcomes found in clinical trials to build comparisons between trial populations and usual care, supportive pricing reimbursement studies and post-marketing safety information, etc. By combining them with retrospective data through a centralized platform, life sciences companies can increase efficiencies by leveraging one platform through all phases of the drug development lifecycle including post-approval follow-up.

REAL-WORLD Publications and Use Cases

Below are conclusions from real-world studies published from the evidence generated from a centralized platform.

1. **Melanoma** - A study that used data from the melanoma registry found that when these drugs, called immune checkpoint inhibitors, were given as the first drug in advanced melanoma with a mutation of the BRAF gene, survival rates improved compared to patients who were given drugs that targeted the melanoma directly, as shown through real-world data.[1]
2. **Uveal Melanoma** - Patients with high-risk uveal melanoma were given crizotinib, a drug usually used as an additional treatment, not a main one. Researchers did not notice an overall reduction in cancer relapse.[2]
3. **Lung Cancer-** Researchers studied patients with non-small cell lung cancer caused by a mutation of the EGFR gene in a specific stage of the disease. When given a drug usually administered as an additional therapy instead of a main therapy, patients surprisingly did not do any better than if they had not been given the drug at all.[3]

1. Kartolo A, Deluce J, Hopman WM, Liu L, Baetz T, Ernst S, Lenehan JG. Real-World Evidence of Systemic Therapy Sequencing on Overall Survival for Patients with Metastatic BRAF-Mutated Cutaneous Melanoma. Curr Oncol. 2022 Mar; 29(3): 1501–1513. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8947206
2. Sacco, J. J., Orloff, M. M., Pradyuman Patel, S., Conway, M., Lim, L.-A., Fog, L. S., Sia, D., McKenzie, J., McKay, D., Isaacs, T., Noor Shoushtari, A., Sullivan, R. J., Kin, S., Hussein Gwadry-Sridhar, F., Joshua, A. M., & Carvajal, R. D. (2022). TPS9610 Poster Session: Capturing uveal melanoma (UM) global practice patterns and clinical outcomes in the collaborative ocular melanoma natural history (OMNi) study (NCT04588662).
3. Kuruvilla MS, Syed I, Gwadry-Sridhar F, Sachdeva R, Pencz A, et al. Real-world outcomes in resected stage IB-IIIA EGFR mutated NSCLC in Canada: Analysis from the POTENT study. Annals of Oncology. 2021; 32(5): S931-S932