Medidata Link: Combining Patient-Level Clinical Trial & Real World Data

Industry Overview

Due to challenges in obtaining, integrating, and handling sensitive data, clinical trial data (CTD) and real world data (RWD) have mostly existed in disparate silos. These silos leave sponsors without a full view of the patients' journey outside of the confines of their clinical trial, resulting in significant delays in generating data such as safety and effectiveness evidence. The industry has taken notice, and with new legislation and regulatory guidance, sponsors are increasingly realizing the impact that RWD will have in filling key evidence gaps:

- **Sponsors are increasing the use of RWD in submissions:** From 2019 to 2020, the number of FDA-approved NDAs/BLAs that utilized real world evidence (RWE) to evidence safety and/or effectiveness rose from 53% to 78%.[1]
- **Linked data can mitigate the significant impacts of patients being lost to follow-up:** Phase III clinical trials often struggle with high rates of patient dropout (approximately 30%).[2]
- **Post-approval market access depends on RWD, but there is a latency in availability:** It can take years post-trial for RWD to mature enough for sponsors to gain useful insights.

A Fresh Approach

Medidata Link is the only centralized technology solution that works across research sites to connect patient-level CTD and RWD. Powered by the Medidata Clinical Cloud unified platform, Medidata Link offers unrivaled, secure data management and analysis. It is fully integrated with multiple de-identification token vendors to offer the broadest array of RWD for sponsors looking to match patient data. Medidata Link includes:

- **Scalable Personally Identifiable Information (PII) Ingestion:** Centrally process PII through patient entry (via the myMedidata patient portal) or site entry (via the Medidata Link Site-Facing Form) without interrupting existing clinical workflows.
- **Secure, Compliant Data Management:** Tie patient-level data from clinical trials to massive RWD ecosystems within the secure, compliant Medidata environment. Reduce the risk of unblinding and re-identifying patients without directly holding PII, while still allowing teams to access the combined dataset and collaborate for independent analyses.
- **Continuous Evidence Generation:**The Medidata Acorn AI team offers deep industry expertise, powered by AI and machine learning capabilities, to generate evidence across the clinical development continuum that can be applied across your organization.

Process Overview

1 Aetion eBook: The Role of Real-World Evidence in FDA Approvals, 2021.
2 Alexander W. The uphill path to successful clinical trials: keeping patients enrolled. *P T.* 2013;38(4):225-227.

Better Together

Medidata Link powers use cases across the clinical development continuum, future-proofing your clinical trials by allowing you to:

- **Mitigate the risks of patients lost to follow-up:** Continue to collect meaningful data by monitoring patient activity in the real world, providing insights into key clinical endpoints such as overall survival, progression-free survival (PFS), or changes to treatment pathways for their study cohort. This approach can minimize the need to recruit larger cohorts to compensate for lost patients, ultimately improving regulatory evidence generation.
- **Contextualize and complement patient reported outcomes (PROs) with quantitative data:** Measure PROs against RWD over time to track how PROs correlate with other outcomes, such as prescribing patterns or hospitalizations, to create robust quantitative insights
- **Investigate the total healthcare resource utilization (HCRU) for patients during and after a trial:** Enhance insight into health system burden and experimental therapy performance compared to the standard of care. Data linkage ensures that sponsors do not miss key events and provides payors with a longitudinal view of the economic burden of illness.
- **Generate long-term safety and effectiveness evidence:** Medidata Link enables the capture of enhanced safety and efficacy data without adding significant burden. This can augment submissions, improve internal decision-making, and bolster launch-planning activities. Faster and more robust evidence generation is also a key factor for several regulatory scenarios such as Emergency Use Authorizations, Accelerated Approvals, or Breakthrough Therapy Designations.
- **Augment data collection in decentralized clinical trials and reduce patient burden:** Employ more DCT technologies while limiting the risks associated with reduced patient contact. The augmentation of CTD with RWD lessens the need for frequent follow-up visits, decreases study operational costs, and reduces patient burden while limiting costly investigator-led follow-ups.
- **Accelerate evidence generation for label expansion studies:** Medidata Link provides longitudinal patient information that can unveil novel subgroups with a differential effect, improving the selection of high benefit expansions and immediately generating data for regulatory conversations. With data linkage, new insights into potentially-eligible patient groups are brought forward years in advance, reducing sponsors' reliance on label expansion studies for evidence generation.

Unlocking & Accelerating Key Insights with Medidata Link

Linked CT+RW enhances evidence generation capabilities