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

Overview

Access to compelling and relevant evidence is crucial to drug development, safety monitoring and better patient outcomes. However, gaps between clinical trial and real world data (RWD) make it hard to fully draw the insights necessary to understand long term outcomes and therapeutic efficacy - resulting in suboptimal data, costly delays or additional follow-up visits which increase the burden to sites, patients and sponsors alike.

ADDRESSING INDUSTRY CHALLENGES

Medidata Link allows sponsors to collect clinical trial data and link it at the patient level to multiple RWD sources without adding additional burden to sites and patients — bridging evidence gaps to save time and feel more confident in their decision making.

- **Gain a headstart in evidence generation:** Begin collecting real world patient level data within the trial and jump-start evidence generation and patient insights. And, for completed trials, use RWD sets to bolster patient-level data about your specific participants, rather than waiting for general RWD to accumulate after launch.
- **Enhance data collection beyond a single trial:** Track longer-term patient outcomes, insights and health resource utilization variables not captured within the finite period of the clinical trial, to generate evidence to support payor and provider discussions.
- **Enable efficient safety-tracking:** Enhance safety monitoring using RWD, allowing sponsors to reduce burdensome follow-up visits, lowering costs and patient attrition rates. And, use RWD to fill gaps and understand outcomes for patients lost to follow-up.

A Better Approach

Medidata Link offers the only centralized, CRO-agnostic solution to connect patient-level clinical trial data and RWD, powered by and fully integrated with Medidata Clinical Cloud. The solution supports multiple de-identification token vendors and is integrated with a broad ecosystem of RWD. Medidata Link includes:

- **Scalable PII ingestion:** Support current and completed trials and centrally process personally identifiable information (PII) via one-time site-based collection, patient entry and file transfer, eliminating the need for site-based token creation or multiple PII-entry, then generate multiple token schemas with the PII.
- **A secure, compliant environment:** Tie patient-level data from your clinical trials to a massive RWD ecosystem within a secure, compliant environment. Reduce the risk of unblinding and re-identifying patients by protecting sponsors from directly holding PII, while still allowing teams to access data and collaborate for internal and independent analyses.
- **Analysis plus expertise:.** The Medidata Acorn AI team offers deep industry expertise, powered by AI and machine learning capabilities, to generate evidence and insights that can be applied across your organization.

Solutions

Connecting clinical trial data and RWD through Medidata Link solves challenges across your product development lifecycle:

Use Cases	Pre-Trial	In-Trial	Post-Trial
	Patient insights for marketing and precision recruitment	Paint a fuller picture of the patient journey across the health ecosystem	Better differentiate the therapy against other treatments on the market
	Retrospective patient data for enhanced screening or baselining	Enhance safety and efficacy monitoring	Long term tracking of safety and outcomes

Case Study

A Top Pharmaco leveraged longitudinal patient data to monitor the long-term safety of its investigational COVID-19 therapy by gaining patient consent to link their clinical trial data with RWD at the patient level. Medidata Link ingested PII and applied de-identification technology from multiple tokenization vendors within its secure, compliant environment.

Medidata Link provided the sponsor with the ability to perform long-term safety surveillance after the trial, circumventing traditional clinical approaches that are slow and costly with high rates of patient attrition. This decreased investigator, site and patient burden by reducing the need for follow-up visits while simultaneously enhancing evidence generation activities.

The Medidata Acorn AI Advantage

From planning to launch, we are your collaborative partner -- pushing innovation through unparalleled technology, expertise, advanced analytics and predictive modeling. Acorn AI is dedicated to ensuring that new possibilities are always on the horizon for you, the patients we ultimately serve, and life sciences as a whole.

Acorn AI, by Medidata, a Dassault Systèmes company, combines data, technology, and deep expertise to help life sciences companies deliver actionable insights.
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