Medidata Link: Linking Clinical Trials to Real World Data

Medidata Link enables linkage between clinical trial data (CTD) to real-world data (RWD) at the participant level to enhance evidence generation beyond what is possible in traditional clinical trials. By creating an enriched view of the patient journey before, during, and after trial completion, Medidata Link generates insights that support the acceleration of clinical development and commercialization.

To break down data silos and connect trials to the largest US-based RWD ecosystems, Medidata Link seamlessly integrates into existing workflows to manage the process for obtaining consent and personally-identifying information – all while minimizing site burden and costs.

Industry Focus on Real-World Data

Clinical trials are becoming increasingly challenging – as sponsors target more complex diseases and treatments, regulators are requiring more evidence for approvals. To generate the evidence required by regulators and payors, sponsors need complex studies that are larger and longer than ever before - increasing their own costs while adding burden onto participants.

By linking clinical trials to participants' RWD, sponsors can tap into ubiquitous data sources that are collected as part of routine care to fill in key evidence gaps, without burdening participants or adding significant cost to their trials.

BETTER TOGETHER: BENEFITS OF LINKING CTD WITH RWD

Utilizing participants' RWD in your trial, you can:

Reduce risk of costly trial delays caused by lost to follow-up by monitoring participants' treatment journey and outcomes outside of the confines of your clinical trial.

Capture evidence that can enable label expansion by enhancing your clinical trial data with additional measurements and outcomes from RWD sources.

Improve RWD-based external control arms and pragmatic trials by passively capturing patient data for standard of care control arm populations.

Provide evidence for regulatory approval on long-term safety and effectiveness by investigating participant outcomes after trial completion without adding burden to participants or sites.

Demonstrate economic value in payor and provider discussions by measuring the cost of care and healthcare resource utilization for trial participants before, during, and after the trial.

A FRESH APPROACH: MEDIDATA LINK

Future proof your planned and ongoing trials with Medidata Link. Unsure of which data or token vendors, CROs, and consent options you would like to leverage for various trials across your portfolio? Powered by the Medidata Clinical Cloud, Medidata Link offers an unrivaled, seamless solution to linking clinical trials to RWD while providing you the flexibility to work with partners of your choosing and minimizing burden to your sites and trial participants.

How Medidata Link Supports Clinical Trial Data Linkage:

Simplify Implementation for You and Your Sites
Seamlessly collect and ingest PII via paper, eConsent, or Registry routes with frictionless patient or site-facing data collection tools.

Set Up Data Linkage Workflows and Create Tokens On-Demand
Centrally manage PII and the end-to-end data linkage process so that you don't need to determine your downstream analytics or required RWD datasets upfront, and can support scaling across your portfolio.

Ensure Your Data Set is Up-To-Date and Compliant
Robustly manage consent status and streamline the ability to withdraw consent even after the trial concludes and sites become inaccessible.

Maximize RWD Coverage With Your Choice in Tokenization Technology
Implement or pivot to your choice of tokenization technology to connect your trials to the broadest array of RWD ecosystems.

Set Your Sites Up for Success
Support trial sites with comprehensive training materials and enable seamless implementation within their existing workflows for an out-of-the-box launch.

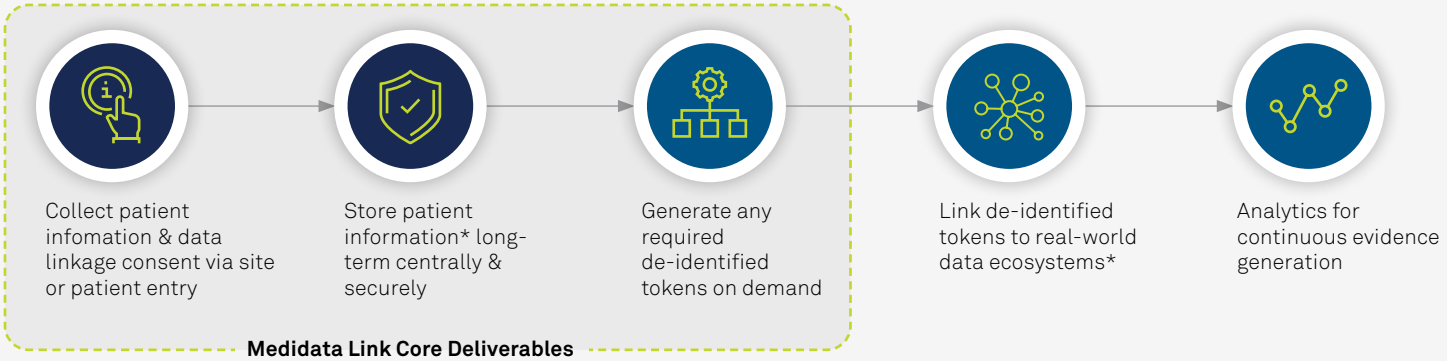
REAGAN-UDALL FOUNDATION
for the Food and Drug Administration

Medidata Link has been awarded the 2022 Innovation Award from Reagan-Udall Foundation for the U.S. Food and Drug Administration.

The Innovation Award recognizes individuals or organizations that have made particularly groundbreaking contributions to regulatory science or policy to improve public health.

HOW DATA LINKAGE WORKS

Activities that must be completed during the trial — **Activities that can be performed post-trial completion**



***US Based RWD ecosystem as standard |** Medidata keeps all PII separately partitioned from case report forms, eliminating any risk of exposing sponsors to identifying information on participants. Medidata also obtains external certifications and assessments performed by 3rd-party independent auditors for the security controls that protect the Confidentiality, Integrity, and Availability (C-I-A) of Customer Data, including ISO 27001, 27017, 27018, 27701 certifications as well as SOC-II Type 2 audits with additional control enhancements.

Medidata, a Dassault Systèmes company, is leading the digital transformation of life sciences.
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