SD06: Master Data Management and Possible Applications for Clinical Trial Data

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Abstract

What is Master Data Management (MDM)? General purpose tools exist to categorize the variables in tabular and relational data. Are these tools suitable for data collected during clinical trials? Can MDM concepts, processes, and tools be used to better organize and aggregate data collected during clinical trials? The answer is yes, but with some caveats. This presentation will define MDM, what it means to clinical programming, and how and when to apply (or not!) MDM tools on both legacy and current trial data.

Master Data Management – A Definition

Master data management is a way to intelligently consolidate and manage data and deliver a more unified view of the enterprise across applications and platforms. MDM integrates the subject's identity from existing data sources, consolidating these sources into a master reference file, which then can feed information back to the sources, creating accurate and consistent data across the enterprise. MDM allows for consistent, reliable identity to feed every operational and analytical application that needs to contribute, helping end users access the right data about individuals, results, contractors, and finances at the right time.

MDM and Clinical Development

MDM can manage the common data attributes represented in clinical trials including participants, investigators, and their different representations in the collected data. The goal is to achieve a unified view of participants (and other entities) across projects and investigators across the different operational data collection systems and contract research organizations.

This unified view provides the basis for adverse event reconciliation and incorporating laboratory results. Adverse events are typically captured in at least two disparate systems: Electronic Data Capture (EDC) and Serious Adverse Event (SAE) – many of which do not communicate with each other and have independent identifier lists. Using Master Data Management, these multiple sources are easily joined by way of a master entity hub, removing duplicate records and merging updated results. MDM is used to help standardize, cleanse, and harmonize clinical trial data to achieve a single unique identifier for each participant, investigator, and study without having to maintain manually developed tables joining identifiers across the clinical trial operational systems.

These same single study techniques can be employed across studies to provide the foundation for loftier goals like connecting all individuals across clinical development and commercial areas of a company.