Paper SI04

How A Clinical Metadata Repository Facilitates Compliance With Industry Standards & Expedites Metadata Storage, Sharing, Analysis & Submission Times

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ABSTRACT

Compliance with CDISC and other industry standards is mandatory for clinical trial submissions to the FDA, PMDA and MHRA. However, standards compliance is often still viewed as a road block, or considered an after-thought in the clinical trials process.

This presentation explores the benefits of implementing industry standards from the start of a trial. And how designing a compliant clinical trial upfront leads to faster delivery of submission deliverables, ultimately avoiding submission delays. We explore how a Clinical Metadata Repository (CMDR) facilitates the implementation of industry standards, including how it handles new versions and changes to standards. This includes how a CMDR can be used to design studies in previous and current versions of standards, and how such a platform stays aligned with evolving standards.

INTRODUCTION

We explore the challenges faced by the industry regarding compliance, metadata management and analysis. We look at the impact this can have for sponsors, as well as the knock-on effect for clinical trial submissions. This paper sets out the core features of a Clinical Metadata Repository (CMDR), and how it addresses these challenges. We go a step further to consider the benefits of a CMDR, and how it can help optimize the clinical trial process from setup to submission.

CHALLENGES

We examine the typical challenges faced by the industry in relation to:

- Visibility and control
- Compliance
- Reuse
- EDC build
- Submission deliverables
- SDTM datasets

SOLUTION

In this presentation we discuss how a holistic approach to the end-to-end clinical trial process can alleviate issues and expedite trials. This includes the adoption of a CMDR platform, and the need for this to go hand in hand with the correct approach to SDTM dataset design and mapping.

CLINICAL METADATA REPOSITORY (CMDR)

What is a Clinical MDR? What does it do? We examine the key top-level functionality provided by typical MDR platforms, including:

- CRF design and visualization
- Standardization and reuse
- CDISC compliance – building compliant studies from approved standards
- EDC build
- SDTM mapping and conversion

We discuss the key benefits that can be leveraged from each area of functionality when implementing a CMDR.

RETURN ON INVESTMENT (ROI)

What sort of ROI can you expect when implementing a CMDR? With the help of a customer use case, we explore the impact a Clinical MDR can have on the effort required to set up a trial.

BEST PRACTICE - SDTM DATASET DESIGN

We discuss our best practice approach to designing SDTM datasets. If aligning with SDTM is left until after data collection, greater time and resources are required downstream. There's also a high risk of poor quality, incomplete data that doesn't comply with CDISC data standards. This can lead to delays in submission, and at worst, could jeopardize a drug successfully getting to market.

To avoid this, the best practice approach is to design SDTM datasets and mappings from the start of a trial. That way, datasets are aligned to SDTM before any patient data has been collected. We discuss how with this approach, SDTM conversions can be done far earlier, and can be run in real-time. This enables Clinicians to analyze patient data immediately, and to make timely safety and efficacy decisions.

AUTOMATION

We consider how automation can drive further benefits, from trial setup to submission. This includes the following areas:

- Specifications
- Approvals
- EDC build
- Compliance - rules
- Impact analysis
- CRF annotations
- Quality and compliance
- SDTM dataset conversions

API INTEGRATIONS

Taking things a step further, we show how advanced automation can 'close the loop' for end-to-end trials. Integration with 3rd party technologies enables data to automatically be pushed and pulled between different software platforms, resulting in even greater efficiencies.

COVID-19 USE CASE

The benefits of standardization became even more apparent for COVID-19 trials. The ability to standardize and automate data collection existed before the COVID-19 pandemic, however the need to develop therapies at an unprecedented speed brought its importance into the spotlight.

We explain how cloud-based CMDR technologies were used in several high-profile COVID-19 studies.
As a result, it became apparent that vaccines and new treatments could be brought through clinical trials much faster than anyone thought possible before.

CONCLUSION

To conclude, we summarize the key benefits of adopting a CMDR, and how adoption of such technology improves compliance with data standards and accelerates clinical trials. As such, audiences can see how standardization and automation are shaping the future of our industry.

CONTACT INFORMATION

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