Zelta

How a Unified Data Management and Acquisition Platform Bolsters Adaptive Clinical Trials

By Merative and MMS Holdings

MMS The difference is in the data.®

merative™

Adaptive clinical trial designs can maximize a trial's potential and utility based on data accumulated throughout the study. They add a review-adapt loop to traditionally linear trial design analyses, allowing for near-real-time betterment of trials ranging from to early-phase and exploratory studies to trials conducted to satisfy post-marketing commitments.

In a recent webinar, Achieving Adaptive Trial Success with a Unified Data Management and Acquisition Platform, Danya Potgieter and Lizette Kilian of MMS Holdings, alongside Walker Bradham of Merative, discussed both adaptive clinical trial design challenges and the benefits of using a unified data management and acquisition platform. Following the webinar, the trio responded to audience questions about adaptive trial design in general, challenges encountered and overcome during the ongoing TOGETHER trial, and the capabilities of Merative's Zelta clinical trials platform:

What types of study adaptations and mid-study changes (aka, post-go-live changes) have been required throughout the TOGETHER trial? Also, were these always associated with a protocol amendment?

Changes were not always associated with a protocol amendment. In addition to amending or adding protocols, we also continuously updated the study design as the study progressed. This allowed for continuous collection of data based on study requirements at any given point. For example, when the sponsor noticed data could be collected more effectively by combining specific fields from two separate case report form (CRF) pages onto one page, we added new/additional visits with their own CRF pages into the study design. We also improved users' ability to update or replace existing CRF pages (e.g., eligibility), as well as updated rules and system query conditions.

How is the team able to validate database changes and any impacts on the data quickly?

Using the Zelta platform (formerly Merative Clinical Development), we do not need to submit a ticket to start a patient priorities check (PPC). We are able to manage everything internally and the program is updated as it would be with any other amendment (i.e., in a short timeframe). Not only is the Zelta user interface (UI) user-friendly, we also have a dedicated user acceptance testing (UAT) team and apply test scripts where possible, which makes the study-specific modification process proceed quickly. Further, we can make cosmetic changes and update/inactivate edit checks without doing a PPC. Small things have a huge impact when making updates.

Zelta differs from other EDC or CDM systems in that it is a single-instance solution. Thus, even development or UAT

versions of the study are in the same environment, so when promoting or deploying changes, the environmental issues that can plague other technologies are a non-factor, greatly improving efficiency. Users also are able to see the differences between the versions so the concept of revisions to study design can be compared and the implications they may have on study data and metadata can be better understood.

MMS Holdings is running other adaptable trials using interactive response technology (IRT; also called randomization and trial supply management, or RTSM). How do you deal with the impact of mid-study changes in your system integrations?

We really can integrate anything into the system or add additional systems since Merative already has the randomization and IRT modules. When we made updates to the database, for example, to the randomization plan, we handled it like any other programming update. Those features are built directly into the product's code base.

Does MMS Holdings specialize in data management of platform trials? What other services do you offer?

Specific to drug manufacturing, we provide services for all phases and therapeutic areas, adhering to Clinical Data Interchange Standards Consortium (CDISC) standards. We also work on traditional trials (not just adaptive), so we can meet the needs of a diverse client base.

The Zelta platform can generate data sets for each protocol despite all data being collected in one database. Does that require a custom database query (i.e., that must be validated through a manual effort)?

Prior to releasing any updates in the live study database, Merative's validation team performs UAT of those updates within the study's UAT environment. This is conducted according to the UAT plan, which is created according to required mid-study changes. This practice allows us to confirm the updates function as expected.

Moreover, the systems' revision jump capability allows users to confirm update details relevant to a specific revision, as well as test the export of those separate revisions (initially added into the UAT environment). This validated product feature preempts the need for any special script or processing of the data to split it out. As noted previously, the TOGETHER trial was composed of a single study running multiple protocols, but the Zelta platform allows users to specify when they are running an ad hoc export or scheduling an export (e.g., for the entirety of the trial with all data, or extracting data sets for specific arms or protocols).

What key considerations guide database design for an adaptive study?

Careful planning is crucial, because you are utilizing accumulated data to modify the operating characteristics of an active trial. Adaptive design approaches introduce real-time flexibility while a trial is underway (e.g., allowing dynamic adjustment of dose schedules, treatment arms, study size, etc.).

Which Zelta platform features stand out in adaptive studies?

First is flexibility: the Zelta platform is so versatile. Then, the ability to choose only what you need from the fully integrated modules based on your unique study requirements, as well as the ability to control your study independently through self-service, are invaluable. Finally, the validation tools available within the system are outstanding. The combination of all these tools and resources makes conducting a trial so much easier.

About the Contributors

Walker Bradham is the Product Management Lead for Zelta, Merative's clinical trials solutions business. He brings 20 years of experience defining, designing, and deploying web applications to the marketplace, and leads the product roadmap for all EDC/CDMS and eCOA offerings. A champion of user empowerment through SaaS principles and AI, he works to provide intuitive tools to solve complex problems in health IT and clinical research. He holds a BS in business management from North Carolina State University.

Lizette Kilian is a Data Team Lead at MMS Holdings with years of experience in data management, quality, and validation across various studies. She completed a Certified Management Development Certificate with distinction from Milpark Business School and has completed multiple courses and certificates related to performance management, leadership, business, and accounting.

Danya Potgieter is a Data Team Lead at MMS Holdings. She has extensive lead experience in data management and database validation across various therapeutic areas. Danya holds a BA in integrated marketing communication.

About Merative

Our goal is to help employers, governments, providers, health plans, and life sciences companies unlock the full value of their health data. First, we take the sting out of data management by cleaning and organizing your data. Next, we apply advanced analytics and AI to that data — generating actionable insights that you can use to inform clinical, operational, and financial decisions. Finally, we offer open-source capabilities that provide new opportunities for collaborating with stakeholders. The result is meaningful change — for members, patients, citizens, employees, and everyone else across the system of care.

About MMS Holdings

Our mission is to deliver high-quality service and technology solutions — rooted in strong science and decades of regulatory experience — that will assist our clients in developing and marketing life-changing therapies to positively improve lives worldwide. MMS emphasizes and values strong internal processes through defining, following, and improving upon the steps that lead to high-quality deliverables.

Produced in the United States of America
March 2023

MCD-4099164780 Rev 1.0