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Accelerating Trial Startup: Automated Central Monitoring Visualizations and Safety Package Management

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ABSTRACT

This paper introduces a streamlined approach to accelerate the setup of clinical trials, utilizing test data that seamlessly transitions into real data upon the first patient visit. Emphasizing the automation of central monitoring and safety packages, we showcase crucial information such as enrolment rates, patient demographics, adverse events, and lab results for efficient trial oversight. We simplify the process by defining a minimal set of key data elements applicable across trials. Test ADaMs, containing these key data elements, serve as the foundation for trial startup visualizations and tables for central monitoring and safety packages. When the first patient visit occurs, the Test ADaMs easily transition into ADaMs with real data. This basic Trial startup package facilitates seamless integration of automated visualizations into trial workflows, ensuring smooth operations from setup to patient visit.

INTRODUCTION

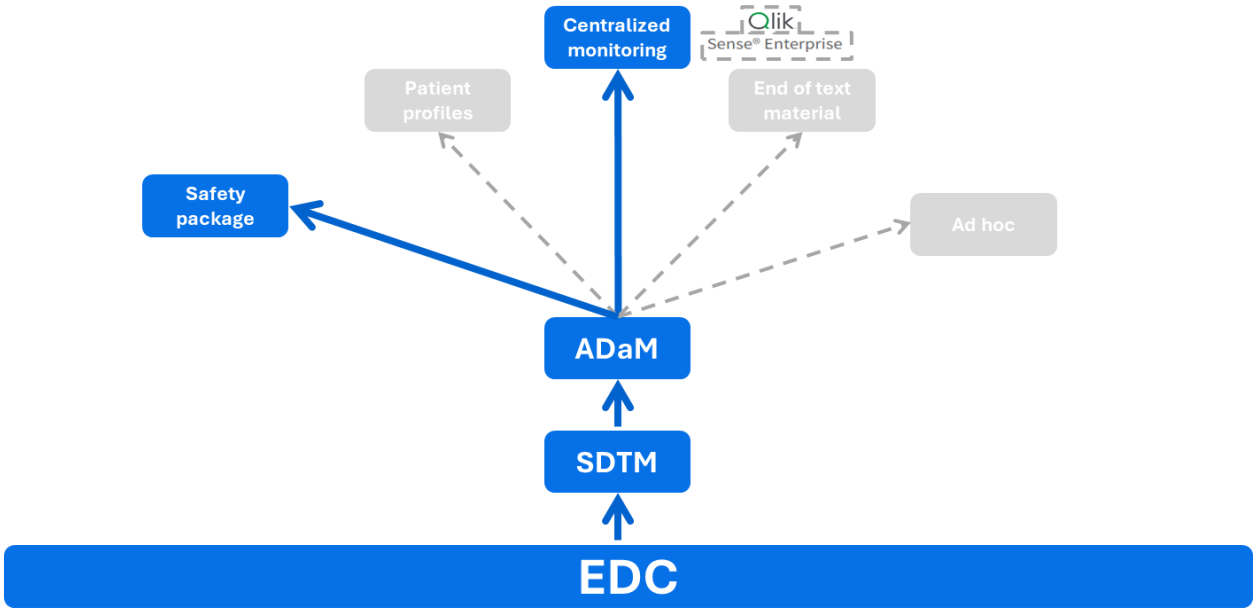
In clinical trials, a streamlined and efficient startup process is essential to minimize delays, maintain regulatory compliance, and ensure successful trial execution. A well-coordinated startup phase allows for better oversight, patient safety, and resource allocation. Traditional methods often involve manual processes that can introduce inefficiencies. At Ferring, our objective is to have systems prepared for central monitoring and safety packages before first patient first visit (FPFV). Consequently, there is a need to front-load components. This paper proposes an innovative approach that leverages automation in central monitoring visualizations and safety package management to enhance the trial startup process, using test data that seamlessly transitions into real data with the first patient visit.

THE ROLE OF AUTOMATION IN TRIAL START-UP

Automation plays a pivotal role in improving the efficiency of trial startup activities. The approach described in this paper centers around the automation of key trial components, such as ADaM (Analysis datasets), central monitoring visualizations and safety package management. Central monitoring typically involves real-time visualizations for tracking of various trial metrics like patient enrollment, demographics, adverse events, and lab results, as defined in the central monitoring plan for each trial. These metrics are essential for making informed decisions and ensuring patient safety during the trial's duration. Automating the setup allows for rapid, accurate data analysis and visualization, thereby reducing manual workload and minimizing errors shortly after first patient first visit (FPFV).

Safety package management, on the other hand, involves the systematic oversight of data related to patient safety, such as adverse event reports and lab results. In a typical trial setup, this information is compiled from manually created programs, which can be time-consuming to set up and increase the risk of inconsistencies. By incorporating automation, the process becomes more reliable, reducing the potential for errors and ensuring timely and accurate reporting.

As illustrated in the figure below, data is captured in the Electronic Data Capture (EDC) system, mapped to SDTM domains, and further to ADaM domains. This paper focuses on the safety package and centralized monitoring. Other areas, such as patient profiles, end of text (EOT) material, and ad hoc requests, are also covered using ADaM domains but are not within the scope of this paper.



DEFINING KEY DATA ELEMENTS FOR TRIAL STARTUP

A critical aspect of this approach is the establishment of a minimal set of key data elements that are commonly used in central monitoring visualizations and safety packages across clinical trials in our company. These elements form the foundation for test data, which are central to the startup phase. Currently, considerable time is spent creating trial-specific test data by combining data from previous trials and simulating trial-specific data. By using test data (SDTM look-alike) to create ADaMs, we can front-load central monitoring visualizations and safety packages. The new approach will continue to use test data; however, instead of generating trial-specific test data for each trial and customized visualizations and safety packages, we will standardize these elements to ensure consistency across trials, facilitating the efficient deployment of trial monitoring tools. Using standardized test data, ADaMs can be designed to contain the key data necessary for generating automated visualizations and tables integrated into trial workflows.

AUTOMATED VISUALIZATIONS AND SAFETY PACKAGES

The central component of this trial startup package is the automated visualization of trial metrics. These visualizations provide trial monitors with real-time updates on patient enrollment, demographic distribution, adverse event reports, and lab results. By automating this process, trial monitors can quickly identify trends and potential issues, ensuring timely interventions. This not only accelerates trial startup but also enhances the overall safety and effectiveness of the trial.

The safety package, which is also part of this automated system, enables the continuous monitoring of adverse events and lab results. As the trial progresses, the system allows for the addition of more complex visualizations and tables, facilitating comprehensive monitoring throughout the trial's lifecycle. This flexibility ensures that the trial remains adaptable to new data and evolving safety concerns, allowing for better decision-making and patient care.

TRANSITIONING FROM TEST DATA TO REAL DATA

One of the most significant advantages of this approach is the seamless transition from test data to real data. Test ADaMs are designed to simulate the trial's actual data structure, enabling early trial setup and the generation of visualizations before the first patient is enrolled. When the first patient visit occurs, these test ADaMs are automatically updated with real patient data, eliminating the need for manual reconfiguration and reducing the risk of errors.

This transition allows the trial team to maintain oversight from the earliest stages of the trial and ensures that all trial components are ready for real-time data collection and analysis. The ability to switch from test to real data without significant delays is crucial for minimizing downtime and ensuring that the trial remains on schedule.

EXPANDING ADAMS FOR COMPREHENSIVE MONITORING

As the trial progresses and more data becomes available, the ADaMs can be expanded to accommodate additional data elements and visualizations. This modular approach allows for the incorporation of new metrics without disrupting the existing trial setup. It ensures that the monitoring system remains robust and comprehensive, adapting to the increasing complexity of the trial as more patients are enrolled and more data is collected.

The flexibility of this system also allows for customization based on the specific needs of the trial. For example, if a particular trial requires enhanced monitoring of adverse events or lab results, additional visualizations can be easily integrated into the existing framework. This adaptability ensures that trial monitoring remains effective and relevant throughout the trial's duration.

CURRENT SOLUTION FOR TRIAL SET-UP

The current solution for the trial set-up involves manual work, requiring programmers to track the availability of new SDTM datasets and update the prepared ADaM programs based on test data. At the start of the trial, extra hours are expected, which could be avoided through a more automized process.

PROCESS OF TRIAL STARTUP ACTIVITY

In scope of automating trial startup activities includes defining selected data points that will be available for nearly all trials. Data is selected from various existing trials and compiled into the new standardized version of the test data.

When FSFV occurs, a macro variable will be adjusted to point to the trial data instead of the test data. For the standard package to be operational from FSFV when trial data collection begins, the ADaM programs are designed to check the existence of the SDTM dataset. If the SDTM dataset does not exist, for example no adverse events are present, an empty ADaM dataset is passed to the visualization tool. Subsequent programs will still be able to execute without manual intervention.

Errors, warnings and notes are predefined and programmed to appear in the log. For instance, if a required variable is missing and the ADaM domain cannot populate any value, an empty ADaM domain containing only metadata will be passed.

CONCLUSION

The proposed approach to automating central monitoring visualizations and safety package management offers a significant advancement in clinical trial startup processes. By utilizing test ADaMs and automating key components of trial oversight, this method ensures a seamless transition from trial setup to real-time patient data collection. The ability to expand ADaMs as the trial progresses ensures that the monitoring system remains flexible and comprehensive, supporting the trial from the initial patient visit to completion. This approach not only accelerates trial startup but also enhances data accuracy, reduces manual workload, and improves patient safety. The automation of these processes represents a forward-thinking solution to the challenges associated with clinical trial startup, offering a blueprint for more efficient and effective trial management in the future.

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