How to Accelerate Clinical Data Analysis and Reporting

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An efficient process from data analysis and reporting to regulatory submission is critical. Here's how to streamline A&R for faster time to submission.

The Last Mile: How to open the Data Pipeline for Faster Clinical Data Analysis and Reporting

In shipping, last-mile delivery is the final and arguably most important step of the journey. Drug development has a last mile of its own: the journey from data analysis and reporting (A&R) to regulatory submission.

Both scenarios demand an efficient process to ensure on-time delivery. However, just like shippers get bogged down by traffic and disorganized delivery routes, drug developers get bogged down by data and incompatible systems.

The 2020 Tufts CSDD–IBM Watson Health benchmarking study found the average cycle time to convert raw data to analysis-ready data was 15.5 days for larger companies and 21.4 days for smaller companies.[1] That's reasonable. But what about the analysis itself? If manual workarounds and IT issues are holding you back, consider a new approach.

Accurate clinical data A&R and on-time regulatory submission require a centralized, cloud-based statistical computing environment. In this environment, biostatisticians, clinical programmers, and other analysts can travel the last mile faster and with fewer complications.

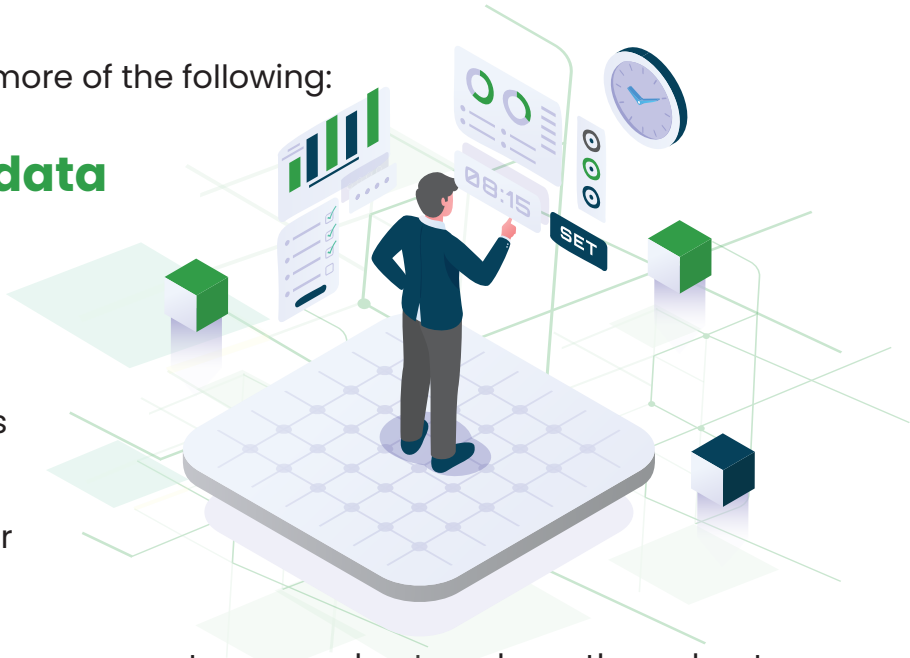
1. https://www.appliedclinicaltrialsonline.com/view/characterizing-clinical-data-management-challenges-and-their-impact

Challenges that Impact Clinical Data Management and A&R

The factors that hold back clinical trial data operations and management impact A&R even more acutely. Because the end goal of clinical trials is to obtain regulatory approval, improvements in A&R cycle times impact the timing of regulatory submission and, ultimately, revenue.

Last mile roadblocks include one or more of the following:

More and more diverse data



It's well reported that the average protocol collections have million of data points from a wide variety of sources. The average clinical trial may use data collected at the site as well as data collected from apps, medical images, electronic health records, and lab results, among other sources.[2]

A higher volume and variety of data may generate more robust analyses throughout the study, but it also makes data integration, quality management, aggregation, standardization, and review more time-consuming.[3] Data from images, apps, and EHRs don't follow the same standards as EDC data, creating compatibility issues. Using data from three or more sources also raises the risk of data quality due to duplication or missing information, as it is observed when patient-reported data gets reconciled in EDC.

The resources needed to resolve these issues kicks A&R farther down the road. When data is ready for analysis, manual processes simply take too long, are too cumbersome, and raise the risk of error. Deadlines get missed; regulatory submissions get delayed.

2. https://www.appliedclinicaltrialsonline.com/view/enabling-digital-transformation-managing-external-clinical-data-sources-to-advance-drug-development

3. https://www.contractpharma.com/contents/view_online-exclusives/2017-11-21/volume-and-diversity-of-clinical-trial-data-sources-expected-to-soar

Planned and/or unplanned midstudy changes

Planned and unplanned midstudy changes and their associated delays also impact A&R. Protocol amendments can delay a trial for months. Study data base updates add more time to the project.

Modern EDCs with cloud-based infrastructures enable study teams to implement midstudy changes themselves, which mitigates some of the technical delays. However, amendments may still affect A&R.

Siloed systems

Clinical trial sponsors and CROs use an average of five different applications to manage clinical trials. About a third use six or more, according to a survey of clinical operations leaders. No surprise, most (70%) list integrating these applications as their Number One challenge.[4]

All these applications—combined with spreadsheets, which are still commonly used—lead to data and process silos. These silos hinder clinical trial operations and data management. Using disconnected legacy applications and spreadsheets for complex clinical trials negatively impacts visibility between stakeholders and slows the process from study launch to A&R.

Legacy A&R platforms

Legacy A&R platforms, typically known as "statistical computing environments," add to the bottleneck caused by other clinical processes and systems. That's because legacy A&R platforms are often custom-built applications based on old technology. They cannot scale to meet the demands of today's data requirements.[5]

Until recently, statistical operations teams haven't had access to integrated, scalable systems. Lack of communication and collaboration between individuals and tasks, combined with manual processes, have made these functions slow and cumbersome.

Statistical operations require transparency through traceability of the statistical analysis to meet more stringent regulatory requirements.[6] That type of visibility simply is either impossible or difficult to achieve on rigid legacy applications.

4. https://www.veeva.com/resources/clinical-operations-survey-report-2020/
5. PHUSE Clinical Data Scientists Guide to Studies Impacted by COVID-19. July 16, 2020.
6. https://journals.sagepub.com/doi/abs/10.1177/009286151004400104

How to Improve A&R Through a Data Pipeline

Biostat teams need timely data access to develop timely regulatory submissions and other reports. Real or near real-time access to quality data enables them to develop tables, listings, and figures (TLFs) for clinical study reports, and efficacy datasets, without getting bogged down by manual, cumbersome processes to access quality-assured data.

These teams also need technology that automates rote manual tasks, along with processes that facilitate collaboration and transparency. Cloud-based, integrated statistical computing environments (SCE) shift data closer to computing, thereby improving A&R cycle times.

Statistical programming also calls for a defined set of practices. Standardization will help improve the overall cycle time in building and managing regulatory submission-standard data, analytics, and reporting. With compliance standards, instream metadata, and technology that amalgamates for delivering in place and distributed governance, programmers can focus on generating required outputs without having to worry about the compliance aspect of the process.

MaxisIT's SCE is purpose-built for what we call the three Cs: Collaboration, Compliance, and Computing horsepower. As a unified model, SCE harmonizes the delivery of milestone data, analytics, and reports, while offering improved capabilities that empower statistical programmers.

A Few Key Features

Rigorous flexibility

SCE enables language-agnostic statistical programming development environments (DEV) while maintaining compliance. Programmers can employ their personal preferences of code editor and/or programming language of choice (e.g., SAS, R, Python).

Quality data

SCE helps you create high-quality clinical data pipelines that can stream updates to the right data consumers and the right statistical programs/algorithm in near real-time.

Integrations

SCE includes more than 40-plus data source integration connectors, with more on the way. It accommodates a variety of data formats, sizes, and types, as well as point-integration, publish/subscribe mechanism, or push/pull approaches.

Consumer-focused delivery

Data ingestion and pipeline delivery can be synchronized with each new lot of uploaded data delivered as soon as it is validated. Or, source data updates can be allowed to accrue, with delivery on a longer frequency based on calendar or business rules.

Low-code/no-code environment

SCE's no-code/low-code data processing provides a graphical drag & drop user interface that requires no code development for simple to complex mappings from source to target. An intuitive clinically-oriented language expression builder enables complex or conditional derivations.

Agile project management

SCE provides project management tools based on streamlined agile development best-practices for improved traceability and deliverable quality. Dashboard navigation simplifies the handling of change requests and incorporates software quality control tasks based on your organization's validation requirements.

Automation

Each study typically has multiple types and iterations of datasets based on quality management cycles (SDTM/ADaM) and several TLFs. Event-driven, automated refresh across the datasets, ADaMs, and TLFs helps eliminate downtime which can delay submission.

To ensure compliance, integrity of submission-standard deliverables, and to deliver overall optimization across statistical computing cycle times, SCE's event-driven process automation leverages metadata, standards, and computing algorithms. End users can focus on key analysis as opposed to creating datasets and programs or organizing deliverables.

AI and machine learning

Machine learning-based tools boost clinical trial data analysis by way of predictive analytics. Built-in AI-enabled data quality and statistical programs provide traceability. They also flag issues ahead of time, both of which support timely submission.

Exploratory reviews

Embedded R Shiny visualization supports faster safety review and cohort analysis in a more interactive fashion. It also allows biostatisticians and clinicians to review reports without depending on programming changes for each request.

Conclusion

The last mile is arguably the most critical in the journey from drug discovery to regulatory submission. To reach the destination as quickly as possible, while maintaining data quality and compliance, A&R demands a flexible and modern SCE that facilitates compliance, collaboration and computing at scale.

This diagram shows what a scalable, integrated statistical computing environment can do for analysis and reporting and beyond.

About MaxisIT

MaxisIT's purpose-fit and intelligent clinical data analytics platform helps improve clinical trial performance, mitigate risk, and optimize clinical outcomes. We provide a centralized and reliable source of truth for diverse data types from various sources, giving life sciences companies real-time insight to shorten cycle time and increase return on investment.

Incorporating an end-to-end clinical data pipeline from intake to visualization, MaxisIT's solutions are powered by AI/ML and metadata-centric approaches. Our impressive portfolio of over 3,300 clinical trials and an unparalleled 100% customer retention rate affirm the quality and reliability of our services.

Moulik Shah
Founder & CEO, MaxisIT

Moulik Shah is a passionate healthcare technology entrepreneur and the visionary CEO of MaxisIT, where he has been at the forefront of leveraging technology to transform pharmaceutical and life sciences clinical trials.

His dedication to improving patient outcomes and his leadership in directing patient-centricity, patient diversity, interoperability, and real-world-data-led collaborations have been at the core of his vision of an integrated healthcare ecosystem based on effective use of data and analytics platforms.

He has been instrumental in driving innovation and progress in the industry. Under Moulik's leadership, MaxisIT has become a leading provider of clinical data and analytics which is driving real-world impact in the pharmaceutical and life sciences clinical trials.

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