Insight Brief

Accelerating CSR Timelines: Applying Real-Time Data, Governed Standards and Expert Oversight

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Meeting market needs in clinical development

The pharmaceutical industry continues to face mounting pressure to reduce costs and accelerate the delivery of innovative therapies to patients. Achieving these objectives requires not only operational efficiency but also unwavering commitment to safety and efficacy. At IQVIA, we recognize that our customers must make timely, informed decisions about their compounds. When a drug demonstrates positive results, it is imperative to expedite the analysis and submission of the Clinical Study Report (CSR) to regulatory agencies. Conversely, when a compound does not meet expectations, rapid pivoting is essential.

To address these market-driven needs, IQVIA has adopted a staged approach to compress the timeline from last patient, last visit (LPLV) to final CSR. This approach is designed to enable pharmaceutical companies to reach the market faster or make critical decisions earlier in the development process.

IQVIA's staged approach to CSR acceleration

Our strategy is structured into three distinct stages:

- **Stage one:** The Data Management (DM) team employs real-time data cleaning to reduce the interval from LPLV to database lock. Through process optimization, this period has been shortened from 60 days to just 28 days.
- **Stage two:** The analysis team implements real-time data analysis strategies to minimize the time between database lock, top-line results, and the generation of final Tables, Listings, and Figures (TLFs). The goal is to reduce this phase from weeks to days.
- **Stage three:** The medical writing team focuses on expediting the transition from receipt of TLFs to final CSR completion. This stage is the subject of ongoing development and will be addressed in future communications.

This brief focuses on Stage Two, where IQVIA's innovative solutions are driving measurable improvements in CSR timelines.

Real-time data analysis: strategy and early successes

IQVIA's real-time data analysis strategy is underpinned by two core initiatives: the deployment of Standards Engineers and the Study Startup program. These components work in unison to ensure that data flows seamlessly from collection to submission, adhering to industry standards and regulatory requirements.

The role of Standards Engineers

Standards Engineers are pivotal to IQVIA's approach. These professionals possess deep expertise in CDISC standards, including CDASH, SDTM, ADaM, Results Metadata, and DEFINE. Their responsibilities extend beyond technical implementation; they provide strategic, consultative guidance to both internal teams and clients.

Standards Engineers are engaged throughout the lifecycle of a clinical trial, from protocol design and data collection to analysis and regulatory submission. Their holistic perspective enables them to identify the most efficient pathways for data standardization, resolve complex challenges, and ensure that deliverables meet the expectations of regulatory agencies such as the FDA, PMDA, and EMA.

Unlike traditional subject matter experts (SMEs), Standards Engineers are not limited to a single domain. Their comprehensive understanding of data standards allows them to recommend solutions that span data collection, tabulation, analysis, and submission. This end-to-end governance is essential for navigating the diverse interpretations of CDISC standards that exist across sponsors and studies.

Navigating the complexity of CDISC standards

While CDISC provides robust implementation guides, sponsors often introduce their own unique interpretations or adaptations of these standards. This variability can create complex pathways from data collection to submission. Standards Engineers leverage their industry and regulatory experience to advise on best practices, sometimes recommending more efficient approaches than those initially proposed by sponsors.

The continuous learning ethos at IQVIA ensures that insights gained from each project are applied to future studies, driving ongoing improvement in standards governance.

Transforming study startup and delivery

IQVIA's latest study start-up program comprises two key initiatives: Accelerated Startup and Delivery. These initiatives are designed to reduce both the startup time of projects and the interval from LPLV to final delivery.

Accelerate Startup: standard safety package

The ACCELERATE Startup initiative aims to reduce the development time for BIOS deliveries by 50–60% when IQVIA standards are utilized. Central to this effort is the standard safety package, which includes:

- A pre-populated Statistical Analysis Plan (SAP) encompassing all safety components
- Accompanying shells, specifications and programs for SDTM and ADaM datasets
- A comprehensive set of pre-programmed TLFs
- Integration of programming automation and process-related tools

By standardizing common safety elements such as adverse events, concomitant medications, medical history, and vital signs, teams can focus on therapeutic area or project-specific requirements. This approach streamlines the study startup process, enabling teams to be data-ready earlier and better prepared for delivery at study completion.

"Near real-time insights, automated standards, and multidisciplinary collaboration — accelerating CSR timelines while strengthening quality and compliance."

Cross-functional collaboration

The success of ACCELERATE Startup is rooted in cross-functional collaboration. IQVIA brings together BIOS teams, Standards Engineers, data management, and medical writing experts to develop and implement end-to-end solutions. Starting with standardized eCRF and database structures, the programmer ensures that TLFs meet the expectations of medical writing teams for CSR creation. This integrated approach minimizes surprises and missed expectations, reducing the likelihood of changes and delays.

Overcoming challenges

Implementing ACCELERATE Startup has not been without challenges. The lack of consistent EDC data standards historically made it difficult to establish true end-to-end solutions. IQVIA addressed this by working closely with data management and Standards Engineers to build on a solid foundation of data standards from CRF design through database structure.

Updates to standards and tools also present ongoing challenges. IQVIA maintains alignment with the latest requirements and anticipates future releases by collaborating with process owners and innovation teams. This proactive approach ensures that standard packages remain current and effective.

High-quality, fit-for-purpose test data is essential for validating standard packages. IQVIA has initiated longer-term projects to explore generative AI-based solutions for test data generation, further accelerating programming activities before live study data becomes available.

Pilot study: epidemic response vaccine

The Startup package was piloted on an epidemic response vaccine study, characterized by compressed timelines and protocol instability. Multiple protocol versions necessitated pauses to avoid rework, but once a stable protocol was established, SDTMs were finalized within one week of receiving patient data.

The pilot demonstrated that adherence to standards and cross-functional collaboration enabled successful, timely delivery. The standard package allowed teams to shift focus from routine safety components to analysis specifics and management of study-specific challenges. The absence of client-requested changes post-delivery underscored the quality and efficiency of the approach.

Continuous improvement

IQVIA is committed to continuous improvement. Lessons learned from pilot studies are incorporated into program guidance and package updates. As the ACCELERATE program is rolled out to additional studies, a feedback loop ensures that insights from each project drive further enhancements. Ongoing maintenance accommodates changes in technology, processes, and regulatory requirements, such as the transition from CDISC version 3.4 to 4.

Technology and process innovations

IQVIA is advancing several technologies and process innovations to further accelerate CSR timelines:

- **Direct data repository connections:** Programs are being connected directly to clinical data repositories, which will enable nightly runs of SDTM and ADaM programs. This will provide teams with near real-time views of cleaned data.
- **Core data review tool:** A unified issue tracking tool is being released to connect all functions, replacing multiple siloed trackers. This integration ties data management and BIOS teams closer together, reducing redundant activities and allowing programmers and statisticians to focus on data insights.
- **Metadata repository solution:** The upcoming metadata repository will enhance governance of standards across studies, tracking compliance with CDISC and customer standards. This will facilitate future improvements in dataset generation.

The ACCELERATE Delivery initiative is piloting changes to pre- and post-lock processes, aiming to move activities earlier in the study lifecycle and achieve additional reductions in post-lock delivery times. The standard safety package enables teams to concentrate on efficacy and complex endpoints, ensuring that resources are available to manage updates as study lock approaches.

Conclusion: partnering for success

IQVIA's commitment to accelerating CSR timelines is reflected in our staged approach, deployment of Standards Engineers, and the ACCELERATE program. By integrating real-time data analysis, governed standards, and expert oversight, we deliver measurable improvements in efficiency, quality, and regulatory compliance.
Our solutions are designed to be scalable and adaptable, meeting the needs of both large sponsors and budget-constrained clinical groups. Whether you are seeking to define safety standards for a single study or implement end-to-end governance across your portfolio, IQVIA offers the expertise and technology to support your objectives.

To learn more about how IQVIA can help you accelerate your clinical study report timelines and optimize your data processes, we invite you to contact our team for a customized consultation. Together, we can drive innovation and deliver better outcomes for patients worldwide.

Contact IQVIA today to explore how we can support your next study. Together, we can transform clinical research into a more efficient, inclusive, and patient-focused experience.

About the authors

EMMA BICKFORD
Senior Director Biostatistics, IQVIA

Emma Bickford is a Senior Director of Biostatistics at IQVIA with 29 years of industry experience. As Chief of Staff, she is an active member of the Global Biostatistics senior leadership team and has a proven track record in setting and delivering on strategy, including leading process improvement initiatives and driving innovation adoption to support Real Time Data Analysis (RTDA). Before her current role, Emma line-managed a large team of statistical team leads. Her expertise also extends to a two-year period serving on the Biostatistics SOP team, during which she led a groundbreaking and highly successful Lean Sigma project. This initiative resulted in the development of a new SAP template and year-on-year improvement in the quality of SAPs produced. Emma's dedication to continuous improvement and innovation ensures that the Biostatistics department remains at the forefront of excellence.

KAREN ZIEKER
Vice President of Biostatistics, IQVIA

Karen Zieker brings more than two decades of experience in the clinical development industry to her role as IQVIA's Vice President, Global Head of Biostatistics and Programming. Her team utilizes their therapeutic, statistical and programming expertise to ensure high-quality and timely delivery of statistical analysis deliverables for Phase I- Phase III trials. Karen is trained in quality improvement methodologies and brings that knowledge and experience to her role to improve quality and make processes more efficient. Her prior experiences include leading statistical programming study teams, and pharma partnership management.

DRIES BECKER
Director Statistical Programming, IQVIA

Dries has 18 years of experience in the clinical research industry. He leads biostatistics and cross-functional optimization initiatives within the Business Solutions group and manages a team of programmers and statisticians across regions and client portfolios.

Dries has held key leadership roles, including head of the European programming group and also headed up the biostatistics data visualization group for a decade. In this role, he delivered tailored medical data review solutions to medical teams across multiple client partnerships. His earlier experience includes leading statistical programming project teams across multiple indications and study phases in complex, multi-national environments.

PAUL SLAGLE
Senior Director, Data Standards, IQVIA

Paul Slagle has led multiple teams in the implementation and use of CDISC and other standards over the last 10 years. Paul is also an active member of the CDISC Standards team in leading the development of the ADaM Oncology Examples Document and multiple CDISC Therapeutic User Guides. He has also contributed to the SDTM Standards development. Before working and leading the development of standards teams, Paul led the Statistical Programming team at a few CRO's and built the Statistical Programming team at a remote site for one CRO. Paul has been working in the pharmaceutical industry for over 20 years and, prior to that, worked in the R&D department for food manufacturing for almost 20 years. Paul is a member of the PharmaSUG Executive Committee and the 2023 Chair for the PharmaSUG Annual Conference in San Francisco.

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