Paper PD10

Disruption in Clinical Trials: How Conventional Roles Are Set to Change

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ABSTRACT

Emerging technologies—AI, real-world data, decentralized models—are rapidly reshaping clinical trial execution. Yet the deeper disruption lies in how conventional roles are evolving. Functional silos are breaking down, and roles once focused on execution are shifting toward digital fluency, data literacy, and systems thinking.

This session explores how clinical operations, data management, statistical programming, and regulatory functions are being redefined. Statisticians now help shape protocols. Trial monitors interpret real-time data remotely. Medical writers adapt to AI-assisted content generation. We'll examine these shifts through real-world examples, highlighting what's already changing and what's next.

Attendees will learn which competencies are gaining priority—automation, interoperability, metadata strategy—and how organizations can foster agility through cross-functional training and flexible team models. The future of trials depends not just on new tools but on how well people adapt to new roles. This session offers a practical lens on how to prepare.

INTRODUCTION: THE TRANSFORMATION OF CLINICAL R&D

The changes brought about post COVID-19, coupled with advancements in AI, are fundamentally changing the nature of tools, applications, processes, and even the regulations set for clinical trials. With that context in mind, the human being on whom clinical trials are conducted, and the one supporting and driving the clinical trial ecosystem, is also undergoing a paradigm shift.

In this paper, we will focus on the changing nature of tasks performed by individuals owing to the changes in the clinical trial landscape. We will explore how individuals and organizations can adapt to and thrive in this new age. Specifically, for individuals, we will see what skill sets are needed; while for organizations, we will see how partnering with the right technology partner can make all the difference by implementing a robust integrated data flow management platform strategy.

Historically, clinical trial execution was characterized by rigid, sequential, and siloed hand-offs between specialized teams. This model, while compliant, lacked the agility needed for modern, data-intensive research. The pharmaceutical industry, operating under rigorous regulatory oversight (e.g., FDA, EMA), now requires a new approach where speed and compliance are achieved simultaneously.

DRIVING FORCES BEHIND THE EVOLUTION OF ROLES

In summary, today's clinical trial model is characterized by functional silos, sequential handoffs, and heavy reliance on manual processes. While this structure has historically provided clarity and regulatory confidence, it has also introduced inefficiencies, redundancies, and delays. This baseline sets the stage for examining the critical forces that are fundamentally altering how these teams will function in the future.

The paradigm shift in roles is driven by three main factors:

- **Artificial Intelligence (AI):** Automation of complex tasks (code review, report drafting) and advanced analytical capabilities (predictive modeling, safety signal detection).
- **Digital Data Standards (e.g., USDM):** The push for universal, machine-readable data formats to ensure interoperability and seamless data flow from source to submission.
- **Decentralized Trial Models:** The shift from centralized site visits to remote patient monitoring using wearables, ePROs, and Real-World Data (RWD), dramatically increasing data volume and requiring new data governance models.

REDEFINING CONVENTIONAL ROLES IN THE DIGITAL AGE 💡

The introduction of AI, automation, and continuous data streams necessitates an evolution in job functions. Roles are becoming less about process execution and more about governance, strategy, and interpretation.

CLINICAL OPERATIONS (CLINOPS)

From: Trial monitors and site managers focused on paper-based source data verification (SDV) and site visits.

To: Real-Time Data Interpreters and **System Governors**. Trial monitors now interpret *real-time data remotely*, focusing on risk-based quality management (RBQM) signaled by centralized data review tools. The new focus is on system interoperability, managing data ingestion from decentralized sources (wearables, home health), and acting as the interface between technology and patient care.

Data Management (DM)

From: Primary focus on manually cleaning data collected in the Electronic Data Capture (EDC) system.

To: Metadata Strategists and **Data Scientists**. DM teams now take on responsibility for **end-to-end data pipelines**. Their new priority is designing the **metadata strategy**—ensuring data standards (like CDISC) are applied at the source, managing data governance for RWD ingestion, and overseeing automated cleaning routines.

Statistical Programming & Biostatistics

From: Executing analysis plans (SAP) and writing SAS code to generate tables, figures, and listings (TFLs).

To: Protocol Influencers and **Polyglot Architects**. Statisticians now actively help **shape protocols** and trial design, using simulation and RWD to optimize endpoints. Programmers must be **Polyglot** (fluent in SAS, R, Python) and are responsible for deploying and governing **Agentic AI** applications for intelligent tasks like code review and dataset validation within the GxP environment.

Regulatory Functions

From: Reviewing final documents and submitting dossiers.

To: AI-Assisted Content Governors and **Digital Traceability Auditors**. Regulatory teams are adopting **AI-assisted content generation** for medical writing, shifting their focus from manual authoring to auditing the AI-generated content. Their primary concern becomes verifying the **lineage of every decision and output** to satisfy regulatory bodies (e.g., demonstrating 21 CFR Part 11 and ICH E6 compliance).

Medical Writer

From: Manually compiling and writing Clinical Study Reports (CSRs), protocols, and Investigator's Brochures (IBs).

To: AI-Assisted Content Governors and **Digital Content Validators**. Shifting focus to using generative AI for rapid draft creation and ensuring that every claim and data point in the final document is traceable to the validated TFLs and source data within the clinical trial ecosystem.

Pharmacovigilance (PV)

From: Manual collection, triage, and reconciliation of Adverse Events (AEs) and Serious Adverse Events (SAEs) against the clinical database.

To: Real-Time Safety Signal Analysts and **Automated Reconciliation Experts**. Leveraging RWD and AI for faster safety signal detection to automate GxP-compliant reconciliation and tracking of safety data lineage.

Technical Support

From: Reactive ticket-based troubleshooting, manual remediation, and basic user access management.

To: Decentralized Infrastructure Managers and **System Health Auditors**. Focus shifts to managing the compliance and connectivity of **Decentralized Clinical Trial (DCT) devices** (e.g., wearables, ePRO hardware). Responsible for monitoring device connectivity, anticipating and preventing compute/performance bottlenecks, and ensuring that the **mitigation path and RCA** for all issues are clearly documented and confirmed by the customer before ticket closure.

IMPORTANCE OF DATA FLOW MANAGEMENT

Successful navigation of these evolving roles requires a managed, integrated flow of data—a concept realized through an **integrated data flow management platform**. The integrated platform framework, underpinned by the right technology partner, provides the single, compliant ecosystem where all these roles can operate, collaborate, and ensure traceability.

These integrated platforms serve as the orchestration layer, providing a validated environment built around three core principles:

1. **Polyglot Programming:** Allowing programmers to utilize modern languages (R, Python) alongside legacy systems (SAS) within a single, GxP-validated environment.
2. **Automated Governance:** Ensuring continuous, native adherence to standards like **21 CFR Part 11, GxP, and EU Annex 11** without manual intervention.
3. **End-to-End Traceability:** Creating an immutable record of every action, ensuring that all programming outputs, QC reports, and final datasets are tied to the specific version of the source data and program code that generated them.

CHALLENGES AND MITIGATION IDENTIFIED

While the shift to integrated platforms offers significant benefits, the transition within a regulated environment presents specific challenges related to skills, processes, and technology. Identifying these challenges and proactively implementing mitigation strategies is crucial for successful digital transformation.

Challenge Area	Description	Mitigation Strategy (Technology Partner Focus)
People & Skills	Talent Gap and Resistance to Change: Existing staff lack necessary skills in Python, AI orchestration, and cloud computing, leading to friction with new tools.	Cross-Functional Upskilling: Mandate and provide training focused on digital fluency, data literacy, and polyglot programming. Redefine job descriptions to incentivize systems thinking and collaboration over siloed execution.
Process & Compliance	Maintaining GxP Auditability Across New Sources: Ensuring data integrity, security, and traceability when integrating data from wearables, APIs, and external RWD feeds.	Automated Governance and Single Source of Truth: Mandate an integrated platform with Automated Governance capabilities (21 CFR Part 11) that treats all data sources equally and enforces version control and blinding/unblinding rules centrally.
Technology & Integration	Interoperability and Legacy System Lock-in: Difficulty integrating modern AI/Polyglot environments with existing SAS servers, EDC systems, and proprietary formats.	Polyglot Architecture and Standard Enforcement: Utilize a platform built with Polyglot capability to bridge modern (Python/R) and legacy systems. Enforce digital standards (USDM) at the data ingestion point to reduce transformation friction.

CASE STUDY

CASE STUDY: EXPEDITING DATABASE LOCK (DB LOCK) THROUGH INTEGRATED PLATFORM 🚀

The Database Lock (DB Lock) is the final, irreversible action that concludes the data collection phase of a trial. Delays here are costly. This case study demonstrates how a data flow integrated environment ensures the DB Lock process, incorporating the detailed requirements for pre-lock review, is completed efficiently and compliantly by clearly defining the roles responsible for each step and maintaining decision lineage.

PHASE 1: PRE-LOCK REVIEW AND DATA FREEZE

This phase focuses on cross-functional quality assurance, leveraging the platform's **end-to-end traceability** to confirm data integrity.

Step	Role(s) Responsible	Platform Benefit & Action
Final Data Review (Completeness, Accuracy)	**Clinical Data Management (CDM), Clinical Operations (ClinOps), Biostatistics**	At the starting point a **visual tracking** of all data points is needed. CDM runs automated consistency checks; ClinOps confirms source verification is complete; Biostatistics reviews preliminary TFLs against raw data for consistency.
Checklist Item 1: Subject Data Presence	**CDM**	Automated alerts flag missing subjects or expected visit data. The **data lineage** verifies every subject's record is closed.
Checklist Item 2: Data Review Listings Actioned	**CDM, Biostatistics**	**Integrated Audit Trails** confirm that every system-generated data listing query has an associated, time-stamped resolution or justification documented by CDM.
Checklist Item 3: Queries Answered & Resolved	**CDM, ClinOps**	The system automatically checks the status of all queries across the EDC. **Tickets cannot be closed** until ClinOps (Monitor) provides explicit confirmation that the source document supports the resolution.
Checklist Item 4: Medical Coding (AEs)	**CDM (Coder)**	The platform tracks the status of coding (e.g., MedDRA) in real-time. **Automated governance** ensures the final coded data is approved before moving forward.

Checklist Item 5: Vendor/External Data Reconciliation	**CDM**	The **interoperability layer** performs automated reconciliation against vendor data (e.g., lab, imaging) and flags any discrepancy logs for final sign-off.
Checklist Item 6: SAE Reconciliation	**Pharmacovigilance (PV), CDM**	**Automated audit trails** link the final serious adverse event (SAE) log to the corresponding database record. PV provides the final sign-off on the completed discrepancy log, which is permanently secured.
Checklist Item 7: Final SDTM Package Approved	**Statistical Programmer, Biostatistics**	**Agentic AI** assists the programmer with final dataset validation. Biostatistics approves the **SDTM package** version, linking the approved metadata to the final analysis environment.
Soft Lock (Data Freeze)	**CDM**	The EDC system is put into a "read-only" state. The data flow system captures a **version-controlled snapshot** of the database at this exact moment, preventing further changes while final quality checks run.
Test Lock	**CDM, IT/System Admin**	A simulated hard lock is performed within a test environment to confirm all technical settings, roles, and security protocols function correctly, ensuring the final lock is flawless.

PHASE 2: SECURING FINAL STAKEHOLDER SIGN-OFF (REGULATORY COMPLIANCE)

The final step is securing formal approval, where the integrated data flow platform provides the necessary **proof of compliance** and **decision lineage** for auditability.

Stakeholder Role	Sign-Off Focus	Platform Benefit
Principal Investigator (PI)	Clinical integrity and completeness of data.	PI approves the final data status via an electronic signature, providing **21 CFR Part 11 compliant non-repudiation**.

Study Monitors (ClinOps)	Confirmation that all site monitoring and query resolution duties are complete.	Monitor confirms that all tickets requiring their attention were resolved and closed **with confirmation**, as verified by the platform's support audit trail.
Clinical Data Manager (CDM)	Data quality, consistency, and adherence to the Data Management Plan.	CDM approves the final **metadata package** and all reconciliation logs, confirming all data cleaning steps are complete.
Biostatistician	Readiness of the data for final analysis (SDTM/ADaM package approved).	Biostatisticians confirm the analytical datasets are **reproducible** and accurately derived from the frozen source data, using a **one-click validation summary report**.

Any breakdown in the **lineage of these decisions**—from the Protocol to the final data—can stall the DB Lock process as reviewers struggle to reconcile versions and justifications. By managing the entire process within an integrated environment, the trial ensures that the DB Lock is not a frantic scramble, but a rapid, auditable final step supported by full **traceability and lineage of decisions** across all roles, thereby significantly **expediting the clinical trial process.**

SOLUTION FOR EXPEDITING DB LOCK

A managed and data flow integrated environment mandates that all cross-functional activities are linked and traceable:

1. **Start with the Protocol:** The statistician's input on trial design is immediately version-controlled and tied to the final SAP.

2. **Continuous Data Flow:** Data acquisition is linked to the DM's metadata strategy, ensuring data quality checks happen in real-time, drastically reducing the final query resolution burden.

3. **Integrated Decision Lineage:** Every programming output (TFL), every QC report, and every dataset validation is tied to the **specific version of the source data and the program code** that generated it. The platform ensures **end-to-end traceability** across the entire data journey, including **data provenance, blinding/unblinding status, and chain of custody**.

4. **Expedited Review:** When the DB Lock review begins, all stakeholders—DM, Biostatistics, and Regulatory—have **one-click access** to a comprehensive audit trail and validation summary reports. This high level of **reproducibility and transparency** drastically cuts down the time spent on reconciliation, allowing the team to quickly confirm the database integrity and achieve the lock on time, or even ahead of schedule.

CONCLUSION: FOSTERING AGILITY THROUGH COMPETENCY

The future success of clinical trials hinges on organizations fostering agility and adapting the human element to leverage new tools. This requires prioritizing:

- **Competency Development:** Training staff in **automation**, **data literacy**, and **interoperability standards**.
- **Cross-Functional Training:** Breaking down silos by creating **flexible team models** where Statisticians and Data Managers collaborate on metadata strategy, and ClinOps works with Data Management on decentralized data governance.
- **Mandating Digital Management:** Adopting A managed and data flow integrated platforms that provide the technological foundation for **end-to-end traceability** and **integrated compliance**.

By moving beyond siloed functions and fully embracing the **Digital Data Flow Manager** concept, organizations can transform their complex, regulated process into a streamlined, traceable, and accelerated path to critical milestones like the Database Lock.

RECOMMENDED READING

Autonomy in clinical research and CDISC USDM by Dough Bain
https://www.linkedin.com/pulse/autonomy-clinical-research-cdisc-usdm-doug-bain-ykyje/?trackingId=o0B8tv%2FPvZGRIJORIL6Zrw%3D%3D

Diamonds in the Legs by Dave Iberson-Hurst
https://www.linkedin.com/pulse/diamonds-legs-dave-iberson-hurst-partner-at-d4k-qiwnf/?trackingId=YzhzdXb4zfft9oIsNf8cCg%3D%3D

https://scdm.org/wp-content/uploads/2024/03/SCDM-Position-Paper-Evolution-into-Clinical-to-Data-Science-V9.0.pdf

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