Category: Clinical Trial Operations (Trial Start-up, Regulatory, Finance, Data Management, IITs) - Work in progress

Standardizing EDC Case Report Form Development in a 21CFR P.11 Compliant EDC

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1. Background

In the dynamic environment of The Ohio State University, the James Comprehensive Cancer Center Clinical Trials Office has historically developed Case Report Forms (CRFs) in OnCore and Advarra Electronic Data Capture (EDC), with development being fragmented, inconsistent, and dependent on legacy practices. This abstract examines the transformative process of implementing a standardized CRF development process within Advarra EDC, aligning roles and expectations between the build team and study teams, and intentionally moving away from outdated workflows.

2. Goals

1. Understand the rational and regulatory requirements for standardizing CRF development within a 21 CFR Part 11 validated system (Advarra EDC)
    a. Learn how systematization improves compliance, audit readiness, and data quality
2. Identify key strategies for aligning expectations between build teams and study teams to ensure successful CRF implementation
    a. Explore communication frameworks, documentation standards, and clarify roles
3. Recognize the significance of change management in moving away from legacy practices
    a. Learn strategies to overcome resistance, build consensus, and maintain adoption

3. Solutions and Methods

The established process was overly complicated, lacked standardization, varied greatly among study teams, and ultimately proved unsustainable. Implementing a 21 CFR Part 11 validated EDC system cannot rely on outdated procedures when adopting new technologies. Our experience shows that this approach caused significant delays and frustration in creating compliant CRFs and initiating trials. Instead of attempting to map and outline outdated workflows, a redesign, led by senior leaders, was necessary to improve how roles and responsibilities are assigned to each study team member and to clinical research informatics. It also involved reducing variability and standardizing CRF forms—preferably global forms—to decrease the volume of data collection forms needed and the time required for study startup. Methods to support this included clarifying roles and responsibilities, documenting procedures through Standard Operating Procedures (SOPs), and establishing service-level agreements (expectations) for all teams involved in developing case report forms, while ensuring compliance with 21 CFR Part 11 regulatory requirements for testing and validation. This collaborative approach leverages the strengths of clinical research informatics staff and their technical knowledge of application functionality and regulation, along with the clinical expertise of the study team, including protocol knowledge and

data requirements. Increased collaboration and well-defined roles facilitated better communication and more efficient use of meeting time.

4. Outcomes

- Requests for "unique" form builds decreased from an estimated 900 (225 per year) across 42 studies since December 2021 to fewer than 100 after the redesign in March 2025
- 30 Global forms created and tested, eliminating the need to further test and validate if used for a study, saving significant time and resources
- Established an annual review of global forms (no new forms required as of February 2026)
- Reduced the requirement for wet ink signature for validation via the use of a compliant eRegulatory application
- Standardized form allowed for the use of Electronic Medical Record (EMR) to EDC auto-population of labs
- Reduced friction and increased collaboration between teams
- Minimal variation in workflow across 17 disease teams
- Minimal pushback from investigators
- No changes to the workflow since established in March 2025

5. Lessons Learned and Future Directions

- Lessons learned:
    - The old process cannot be overlaid on new technology
    - It is critical to establish clear, uncomplicated workflows with clear expectations of roles, responsibilities, and timelines
    - Understanding the past workflows does not always help with new ones. Helps to start fresh and saves time
    - Change is hard, but possible when the patient and the study are the goal
    - Adhering to and maintaining 21CFR.P11 adds significant challenges, and resources are slim
    - It is not reasonable or possible to standardize everything, e.g., study-specific adverse event forms
- Future directions:
    - Continued focus on reducing variability where possible through an annual review of global forms for changes or additions. Assessing the potential for each disease team to internally standardize, where feasible
    - Evaluating ways to improve discrepancies between the protocol and the data requested by the investigator before form building
    - Increasing automation with EMR to EDC functionality, which may include more than just lab values
    - Determining methodology to gather meaningful metrics to better understand where improvements may be necessary.