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

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Background

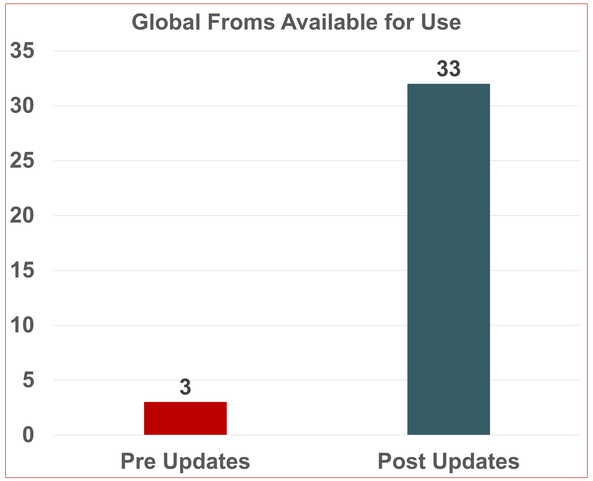
In the dynamic environment of The Ohio State University Comprehensive Cancer Center – James Cancer Hospital and Solove Research Institute, the Clinical Trials Office has historically developed Case Report Forms (CRFs) in OnCore and Advarra EDC, with development being fragmented, inconsistent, and dependent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EDC), aligning roles and expectations between the build team and study teams, and intentionally moving away from outdated workflows.

Goals

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

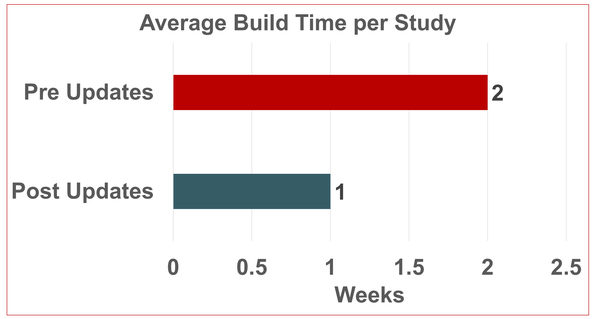
Solutions and Methods

The existing process was overly complex, inconsistent across study teams, and ultimately unsustainable. Implementing a 21 CFR Part 11 validated electronic data capture system using outdated workflows led to significant delays and frustration in CRF development and trial startup. Rather than incremental mapping of legacy processes, a leadership-driven redesign was required to clarify roles and responsibilities across study teams and clinical research informatics. This included standardizing CRFs, preferably through global forms, to reduce variability, form volume, and startup time. Supporting measures included defined roles, SOPs, and service-level expectations to ensure compliance with 21 CFR Part 11 testing and validation requirements. This collaborative model leveraged informatics' technical and regulatory expertise alongside the study team's clinical and protocol knowledge, resulting in improved communication and more efficient use of meeting time.



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.
- Reduced the requirement for a wet-ink signature for validation via the use of a compliant eRegulatory application.
- Standardized form enabled EMR-to-EDC auto-population of labs (FHIR Interface).
- 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 it was established in March 2025.



Lessons Learned and Future Directions

Lessons Learned

- Legacy processes cannot be overlaid onto new technology.
- Simple, well-defined workflows with clear roles, responsibilities, and timelines are essential.
- Understanding prior workflows has limited value; starting fresh saves time.
- Change is challenging but achievable when patient care and study success are the focus.
- Maintaining 21 CFR Part 11 compliance is resource-intensive and adds complexity.
- Full standardization is not always feasible (e.g., study-specific adverse event forms).

Future Directions

- Continue reducing variability through annual review and refinement of global forms.
- Explore feasible internal standardization within disease teams.
- Improve alignment between protocol requirements and requested data prior to form build.
- Expand EMR-to-EDC automation beyond laboratory data where possible.
- Develop meaningful metrics to identify opportunities for improvement.