Paper PP30

From Clicks to Compliance: How eCRF Design Decisions Echo Through to Submission

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ABSTRACT

This poster explores how upstream choices made during eCRF development — including field structures, custom functions, and validation logic — directly influence downstream challenges in SDTM mapping, data traceability, and regulatory readiness.

Drawing from real project experiences, the poster highlights how seemingly minor design decisions can result in costly rework, queries, or audit risks. It outlines common pitfalls, lessons learned, and proposes practical, design-stage interventions to strengthen data governance and submission flow.

Rather than presenting a technical deep-dive, this work reflects on the overlooked role of CRF designers in shaping submission outcomes — and invites a shift in mindset from building for compliance to building for clarity and continuity across the data pipeline.

INTRODUCTION

In clinical trials, the journey from data capture to regulatory submission is tightly interconnected—often in ways that are easy to overlook. The design of an electronic Case Report Form (eCRF) is more than a data-collection exercise; it lays out the foundation for how cleanly, consistently, and compliantly study data will flow through downstream processes. From edit checks and metadata standards to alignment with CDASH and SDTM expectations, every design decision has implications that echo across data management, biostatistics, and ultimately the submission package. Understanding these ripple effects helps teams avoid rework, reduce ambiguity, and ensure that the data story regulators see is both accurate and compelling. This session explores how thoughtful eCRF design can streamline the path from first clicks to final compliance.

PROBLEM STATEMENT

Despite its importance, eCRF design remains variable across sponsors, therapeutic areas, and study teams. Design decisions—such as inconsistent variable naming, unnecessary data fields, or poorly structured forms—can introduce ambiguity and require substantial rework during cleaning and mapping. These issues create inefficiencies, inflate query burden, and can ultimately hinder regulatory review. Yet the full extent of these ripple effects is often not recognized during startup.

OBJECTIVES

This paper aims to:

- Examine how eCRF design choices influence downstream data transformation, mapping, and submission outcomes.
- Identify common design issues that result in data inconsistencies or increased programming burden.
- Provide recommendations for optimized, standards-aligned eCRF design to reduce rework and ensure regulatory readiness.

METHODOLOGY

- Implementing Design Governance
- Minimizing Free-Text and Promote Standardization
- Avoid Storing Derived Values
- Right-Size Edit Checks
- Harmonize Labels and Logic
- Maintain a Design-to-Submission Traceability Matrix

CASE STUDIES

CASE STUDY 1: ADVERSE EVENTS(AE) FORM

A poorly designed AE form captured “action taken” as free text instead of standard categories.

Results:

- 30% increase in queries
- manual coding required
- discrepancies in AEACN mapping

CASE STUDY 2: CONCOMITANT MEDICATIONS(CM) FORM

A single field captured both doses and units.

Results:

- complex parsing during SDTM mapping
- increased risk of unit-conversion errors

CASE STUDY 3: MEDICAL HISTORY(MH) FORM

Onset dates were optional and did not allow partial dates.

Results:

- high proportion of missing dates
- unclear temporal relevance in SDTM
- reviewer requests for clarifications

CONCLUSION

eCRF design plays a critical yet frequently underestimated role in ensuring data integrity and submission compliance. Decisions made during form design influence query generation, mapping complexity, and the clarity of regulatory submissions. By adopting standardized, metadata-driven design principles and fostering cross-functional collaboration at study startup, sponsors can reduce downstream inefficiencies and improve the quality and reliability of clinical trial submissions.

REFERENCES

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