

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

Author : Mary Shefoli **PRECISION**
for medicine

01 Implement Design Governance

- Create a CRF Design Checklist:
 - Visit structure mirrors protocol schedule.
 - Dynamic handling for unscheduled/early termination visits.
 - No redundant or ambiguous fields.
- Review CRF with cross-functional stakeholders (Biostats, Programming, Regulatory) before finalization.



02 Minimize Free-Text and Promote Standardization

- Replace free-text with dropdowns or code lists wherever possible.
- Use CDISC-controlled terminology for consistency.
- Allow “Other, specify” only when absolutely necessary.



03 Avoid Storing Derived Values

- Capture raw data only (e.g., height, weight).
- Document derivation logic for analysis stage.
- This prevents traceability issues and audit findings.



04 Right-Size Edit Checks

- Focus on critical checks (subject safety, data integrity).
- Avoid excessive non-critical checks that create query noise.
- Implement tiered severity and context-aware triggers.



05 Harmonize Labels and Logic

- Standardize field names and terminology across all forms.
- Document complex logic transparently in a Design Specification.
- Maintain version control for all rules and functions.



06 Maintain a Design-to-Submission Traceability Matrix

- Link each CRF field to:
 - SDTM variable
 - Analysis dataset
 - Regulatory requirement
- This ensures clarity and reduces surprises later.

