CRF/EDC Design & Data Dictionary — Service Segment

NTHRYS »
Services »
Academic Services »
PhD Assistance »
Study Design & Protocols »
CRF/EDC Design & Data Dictionary
← Back to Section

Help Desk · WhatsApp

Service Segment · CRF/EDC Design & Data Dictionary Charge: Rs 13800

We convert your variables, endpoints, and visit schedule into structured CRF or EDC pages plus a clear data dictionary. The goal is to make data collection simple for the team, minimise errors at source, and give you an analysis ready dataset with predictable variable names, codes, and formats.

- CRF or EDC shell organised by visit, module, or form, aligned with your schedule of assessments
- Field level specifications including labels, allowed responses, and basic instructions
- Data dictionary listing variable names, types, codes, ranges, and missing value rules
- Draft edit checks and validation notes for key fields and calculated items
- Mapping of CRF or EDC fields back to endpoints, hypotheses, and planned analyses

Text blocks that describe CRF or EDC structure and data handling for use in protocols and SOPs

Workflow — How CRF/EDC Design & Data Dictionary Runs

1. **Review of variables, endpoints, and schedule**
   We start with your variables and endpoints pack plus visit or contact schedule, so that every field we design supports a clear purpose.
2. **Clustering into forms or modules**
   Related variables are grouped into logical forms or modules, such as demographics, baseline assessments, lab results, interventions, follow up visits, or outcomes.
3. **CRF or EDC shell drafting**
   A shell is drafted that lays out each page or screen, the fields on it, and the visit or timepoint where it is used.
4. **Field level specification**
   For each field we specify label, response options, field type, units, simple help text, and whether the field is required or conditional.
5. **Data dictionary construction**
   Variable names, descriptions, data types, codes for categorical variables, valid ranges, and missing value conventions are compiled into a single dictionary.
6. **Edit checks and validation notes**
   Simple edit checks and validation rules are drafted for critical data points, such as range checks, cross field consistency, and basic derivations.
7. **Alignment with statistical plan**
   We check that the CRF or EDC captures what is needed for the planned analysis shell, and flag any missing fields or coding risks.
8. **Compatibility with paper or electronic capture**
   Layout and terminology are designed so they can work for either paper CRFs or commonly used EDC or spreadsheet based capture.
9. **Protocol and SOP wording**
   Short descriptions of the data capture approach, CRF or EDC structure, and data management basics are assembled for your

protocol and SOPs.

10. **Delivery and refinement cycle**
    You receive the CRF or EDC shell and dictionary. After guide or team feedback, one refinement cycle is included to adjust structure or fields.

What You Get in Your CRF/EDC & Data Dictionary Pack

- **CRF or EDC shell document** listing forms or pages, with fields organised by visit or module.
- **Field specification list** that captures labels, response options, data types, and required status for each field.
- **Data dictionary** with variable names, short and long descriptions, codes, ranges, and missing value handling rules.
- **Basic edit check notes** for key variables, including obvious range and cross check suggestions.
- **Mapping sheet** linking fields to endpoints, hypotheses, and analysis variables, useful for later analysis and reporting.
- **Protocol ready text** for sections that describe data capture tools, CRFs, and basic data management approach.

The aim is that anyone joining your project can understand what needs to be captured, where to capture it, and how it will be interpreted at analysis time.

Detailed Deliverables, Formats, and Service Boundaries

Deliverables and formats

- One **CRF or EDC shell** in DOCX or spreadsheet format, with form or page level breakdown.
- One **field specification list** covering labels, response categories, and field types.
- One **data dictionary file** suitable for sharing with analysts and data

managers.
- **Short protocol text** describing CRF/EDC design and data capture methods.

What is included

- Structuring of variables into practical forms or screens.
- Definition of field properties such as type, options, and basic constraints.
- Construction of a clear data dictionary for your study dataset.
- Simple edit check and validation suggestions for critical variables.
- One round of refinement after guide or reviewer feedback.

What is not included

- Full build and hosting of an electronic data capture platform or database.
- Complex regulatory level electronic validation and audit trail configuration.
- Ongoing data entry, coding, cleaning, or discrepancy management during the live study.
- Advanced encryption or security architecture design; we focus on structure and content.

When to Use This Service and What You Should Have Ready

Best time to book

- After variables, endpoints, and case definitions have been outlined and agreed in principle.
- Before you begin live data collection, so that CRFs or EDC screens are stable.
- When ethics or institutional reviewers ask for clear CRF examples or data collection tools.
- When you want to avoid messy spreadsheets or ad hoc data

capture that is hard to analyse later.

Helpful inputs from your side

- Your latest variables and endpoints tables and visit schedule.
- Any sample CRFs, EDC layouts, or institutional templates your department prefers.
- Information on whether you plan paper, spreadsheet based, or electronic capture.
- Notes from your statistician or guide on key derived variables or planned analyses.
- Any local IT or data management constraints that may affect layout or field design.

FAQs — CRF/EDC Design & Data Dictionary

1. Do I need an electronic data capture system for this to work?
No. The same design principles apply whether you use paper CRFs, spreadsheets, or a formal EDC platform. We structure content so it can be implemented in any of these.

2. What is the difference between a CRF shell and a data dictionary?
The CRF shell shows what the forms and fields look like during data entry, while the data dictionary describes how the resulting variables are stored and coded in your dataset.

3. Can you work with simple Excel based capture?
Yes. Many PhD projects use spreadsheets. We design sheets and dictionaries so that data can still be analysed cleanly and with fewer errors.

4. Will this cover all possible edit checks?
We focus on the most important checks that protect data quality at PhD scale. Very complex automated edit checking frameworks fall outside the scope.

5. How does this link to my statistical analysis plan?

Variables are named and coded with the planned analyses in mind, so that later you or your analyst can quickly understand which fields feed which models and summaries.

6. Can this be used for lab only or bench projects?
Yes. The same logic works for lab registers, experiment logs, and instrument readout tables, with wording tuned for those contexts.

7. What if I already started collecting data?
We can still create or refine a dictionary around existing structures, but more changes may need negotiation with your team and guide.

8. Does this include anonymisation or de identification planning?
We can note which fields are identifying and suggest simple anonymisation approaches, but full privacy and legal reviews are handled by your institution.

9. Will you install or configure any software?
We provide structured documents and specifications. Installation, configuration, and maintenance of any software remain with your local IT or research team.

10. Is this useful if my project has a small sample size?
Yes. Clear CRFs and dictionaries help even small projects, reducing confusion, missing data, and rework at the time of analysis and viva.