Variables, Endpoints & Case Definitions — Service Segment

Help Desk · WhatsApp

Service Segment · Variables, Endpoints & Case Definitions

Charge: Rs 12800

We translate your aims and PICO or PECO blueprint into concrete variables, endpoints, and case definitions that can actually be measured. The focus is on operational definitions, timing of assessments, and clear, reproducible wording that flows directly into CRF or EDC design and the statistical plan.

- Primary and secondary endpoints expressed with clear timepoints and units where applicable
- Structured lists of exposure, outcome, confounder, and other covariate variables
- Operational definitions and diagnostic or case definitions aligned with accepted guidelines where possible
- Measurement scales, instruments, and scoring rules mapped to each key variable
- Schedule of assessments table that links visits or timepoints to

the variables measured

Traceability notes that connect endpoints and variables to planned analyses and CRF or EDC fields

Workflow — How Variables, Endpoints & Case Definitions Runs

1. **Review of aims and blueprint**
   We start from your approved or draft aims, PICO or PECO framing, and any existing protocol blueprint to ensure full alignment.
2. **Listing candidate endpoints and variables**
   Together we list candidate primary and secondary endpoints and the variables that might need to be collected to support them.
3. **Prioritisation of what is essential**
   The list is trimmed to what is realistically collectable at PhD scale, while still answering the primary question and key secondary aims.
4. **Drafting operational and case definitions**
   For each important endpoint or status, we create precise definitions, drawing on established criteria or guidelines where available.
5. **Assigning measurement methods**
   Each variable is matched with measurement tools, lab methods, questionnaires, scales, or data sources, along with basic instructions.
6. **Building the schedule of assessments**
   A table is created that sets out when each variable will be measured (by visit, timepoint, or phase), supporting both CRF and logistics.
7. **Consistency and feasibility checks**
   We check for internal consistency, clashes with feasibility constraints, and redundancy across variables and endpoints.
8. **Protocol ready wording**
   Text is assembled for the protocol sections on outcomes, variables, and case definitions, using language acceptable to reviewers.
9. **Alignment with statistics and CRF or EDC**

We flag how the chosen variables and endpoints will later map into your CRF or EDC design and your statistical analysis shell.

10. **Delivery and refinement cycle**
    You receive the definitions, tables, and text blocks. One refinement cycle is included after guide or internal feedback.

What You Get in Your Variables & Endpoints Pack

- **Endpoint definition sheet** listing primary and secondary endpoints with measurement details and timepoints.
- **Variables catalogue** for exposure, outcome, confounder, and key covariates, including type and basic coding hints.
- **Case definition or classification criteria** for conditions, events, or statuses relevant to your study.
- **Schedule of assessments table** that aligns visits or timepoints with what is collected when.
- **Protocol ready text blocks** for Methods sections describing outcomes, variables, and case definitions.
- **Integration notes** indicating how these definitions feed into CRF/EDC design and the analysis plan.

The aim is to remove ambiguity at the level of measurement and classification so that your data can be collected, cleaned, and analysed without confusion later.

Detailed Deliverables, Formats, and Service Boundaries

Deliverables and formats

- One **variables and endpoints table** in DOCX or spreadsheet format with names, types, and descriptions.
- **Case definition sheet** describing inclusion rules for diagnoses, events, or categories where relevant.
- **Schedule of assessments table** mapping timepoints or visits to

measurements.
- **Methods section paragraphs** that explain main outcomes, key variables, and how they are measured.

What is included

- Clarification and structuring of primary and secondary endpoints.
- Definition of variables necessary to support those endpoints and analytic plans.
- Operationalisation of case definitions using standard criteria where appropriate.
- Construction of a practical schedule of assessments.
- One round of refinement after feedback from your guide or internal team.

What is not included

- Full CRF/EDC page layout design (covered under CRF/EDC Design & Data Dictionary).
- Detailed statistical analysis plan or sample size calculation (covered under Statistical Links segment).
- Creation of highly specialised clinical scoring algorithms beyond standard scales or indices.
- Ongoing data management, cleaning, or coding during live study execution.

When to Use This Service and What You Should Have Ready

Best time to book

- After your protocol blueprint and basic design family are reasonably clear.
- Before you design detailed CRFs/EDC or commit to a statistical analysis plan.
- When guides or ethics committees ask for clearer definitions of

outcomes and key variables.
- When you are concerned that different team members may interpret variables or cases differently.

Helpful inputs from your side

- Your latest aims, hypotheses, and protocol draft if available.
- Any guideline or consensus definitions used in your field for key conditions or outcomes.
- Lists of measurements, tests, or questionnaires you are considering.
- Information on practical constraints such as number of visits, lab access, and typical patient or sample flow.
- Any departmental or sponsor templates that specify how outcomes and variables must be described.

FAQs — Variables, Endpoints & Case Definitions

1. What is the difference between an endpoint and a variable?
Endpoints are key outcomes used to judge the success or effect of an intervention or exposure. Variables are the individual pieces of data you collect; some combine to define endpoints.

2. Why are case definitions so important?
Clear case definitions ensure that everyone uses the same criteria for diagnosing or classifying participants or samples, reducing misclassification bias and reviewer concerns.

3. Can you work with non clinical or lab based projects?
Yes. We adapt language for engineering, management, basic science, or other domains where outcomes may be performance metrics, technical measures, or process indicators.

4. What if I already have a long list of variables?
We help prioritise and simplify the list, focusing on what is essential for your aims and analysis plan so that data collection remains realistic.

5. Do you choose my laboratory tests or clinical scales?
We suggest typical options and help with wording, but final choice depends on your guide, institutional norms, and resource availability.

6. Will this pack also define how data is coded?
We include basic hints on data types and simple codes, especially where these affect the analysis, while detailed coding schemes are refined during CRF or data dictionary design.

7. Is this aligned with reporting guidelines such as CONSORT or STROBE?
We keep major reporting standards in mind so that later, when you write manuscripts, your outcomes and variables already match expected structures.

8. Can I change endpoints later?
Yes. Research often evolves. The advantage of having written definitions is that any changes are easier to document and justify.

9. Does this cover safety endpoints for interventional studies?
Where applicable, we can include basic safety or adverse event endpoints and suggest simple ways of capturing them at PhD scale.

10. Will you also design the CRF/EDC fields?
High level field implications are noted, but full CRF/EDC layout and data dictionary work is handled in the dedicated CRF/EDC Design & Data Dictionary segment.