CLINICAL EXCELLENCE CONSULTING

How to Read a Protocol

5W+H Framework • Protocol Structure • Inclusion/Exclusion • Investigational Product • AEs/SAEs • Regulatory & Ethical Issues • Protocol Amendments

WHO
Study Population

Patients, investigators, site staff, and sponsors.

WHAT
Objectives & Design

Intervention, endpoints, and study methodology.

WHEN
Timeline & Visits

Phases, visit windows, FPFV to LPLV milestones.

HOW
Data & Compliance

GCP, IRB, informed consent, statistical analysis.

Research Protocol — '5W+H' Framework

WHO	Patient population (I/E criteria) + investigators, coordinators & sponsors.
WHAT	Study objective, intervention, treatment details, and measurable endpoints.
WHEN	Screening, enrollment, treatment, follow-up; visit windows & FPFV–LPLV.
WHERE	Site locations — clinics, hospitals, research centers; inpatient/outpatient.
WHY	Scientific rationale, background evidence, and ethical risk-benefit balance.
HOW	Study design (Phase, randomized, blind), data collection, GCP & IRB compliance.

Protocol Breakdown — Key Sections (Slide 17)

- Title, Synopsis, Objectives/Endpoints, Overview of Study Design.
- Schedule of Events, Inclusion & Exclusion Criteria.
- Investigational Product, Prior/Concomitant & Prohibited Medications.
- Safety (AEs/SAEs), Questionnaires/Procedures, Stopping Criteria.
- Regulatory/Ethical Issues, Risk-Benefit Assessment.

Inclusion & Exclusion Criteria

- Define who can/cannot participate — integral to trial design and scientific validity.
- Protect high-risk individuals and support ethical conduct of the trial.
- Maintain data integrity — prevent bias and control participant characteristics.
- Streamline recruitment by targeting the right population demographics.

Investigational Product (IP) & Medications

- Know dosage, formulation/MOA, route of administration, storage temperature.
- IP compliance: 80–120%; deviations below/above must be reported to IRB per protocol.
- Maintain IP accountability logs — master log and individual subject log.
- Know drug classification of prohibited/concomitant meds before scheduling visits.

Efficacy, Safety & Adverse Event Reporting

- Efficacy: desired therapeutic effect under controlled trial conditions
- AE: any unintended medical occurrence, regardless of causality — recorded by severity
- SAE: severe subset (death, hospitalization, anaphylaxis) — requires immediate reporting

Regulatory, Ethical Issues & Protocol Amendments

- Ethical: informed consent, vulnerable populations, placebo use & conflict of interest
- Regulatory: avoid incomplete protocols, late submissions, delayed SAE reporting
- Amendment: Major = IRB re-approval required; Minor = typically not required