

CLIENT DIAGNOSTIC

Clinical Development Concept Completeness Check

A pre-protocol diagnostic to expose missing decisions before a concept sheet is mistaken for a development plan.

Twelve elements that should exist before protocol drafting accelerates

- ☐ A concise development decision and value hypothesis are explicit.
- ☐ The target population is defined clinically and operationally, not only epidemiologically.
- ☐ Primary objective, endpoint and treatment effect of interest are aligned.
- ☐ Comparator and study architecture answer the intended regulatory and commercial question.
- ☐ Key inclusion/exclusion criteria have been tested against real patient availability.
- ☐ Visit schedule, procedures and patient burden are operationally plausible.
- ☐ Safety monitoring and relevant discontinuation / rescue logic are specified.
- ☐ Statistical decision criteria and major assumptions are visible at concept stage.
- ☐ Clinical development strategy explains what this study unlocks next.
- ☐ Regulatory strategy identifies the decisions or interactions that can change the programme.
- ☐ Country and site strategy reflect patient flow, expertise and execution reality.
- ☐ The concept states what evidence would cause redesign, pause or termination.

Quick score

Domain	Green	Amber	Red
Clinical rationale	☐	☐	☐
Population	☐	☐	☐
Endpoint / estimand	☐	☐	☐
Comparator / design	☐	☐	☐
Operational feasibility	☐	☐	☐
Statistics / decision criteria	☐	☐	☐
Regulatory strategy	☐	☐	☐
Next-value-gate clarity	☐	☐	☐

Interpretation: any Red item, or three or more Amber items, warrants structured review before the next irreversible decision.

What this tool does — and does not do

This diagnostic is designed to expose uncertainty, inconsistency or execution risk. It is intentionally not a substitute for programme-specific medical, statistical, regulatory, operational or legal analysis.

Escalate when: the document contains many protocol details but the team cannot state the development decision, evidence threshold, regulatory purpose or next value gate in one coherent chain.