CLIENT DIAGNOSTIC

Trial Autopsy — Failure Signal Check

A board-level diagnostic to distinguish a disappointing result from an uninterpretable test of the asset.

Use this before committing more capital
A negative or ambiguous trial result does not automatically mean the biology failed. The first task is to test whether the study generated a controlled, biologically plausible and decision-relevant experiment.

Eight questions that should be answerable

☐ Was exposure or target engagement sufficient in the relevant tissue, dose and duration?
☐ Did the enrolled population match the biology the intervention was intended to affect?
☐ Did the primary endpoint measure the expected effect at the expected time horizon?
☐ Were discontinuation, rescue, switching, death or other intercurrent events handled consistently with the clinical question?
☐ Did recruitment, eligibility control, site/rater performance or vendor execution materially distort the experiment?
☐ Did missingness, variance, event rate or model assumptions differ materially from planning assumptions?
☐ Do region/site or subgroup patterns have a biologically credible explanation rather than post-hoc convenience?
☐ Can the present evidence support the next board, regulatory, partnering or financing decision?

Quick score

Domain	Green	Amber	Red
Biological test integrity	☐	☐	☐
Population / phenotype	☐	☐	☐
Endpoint / estimand	☐	☐	☐
Execution / data	☐	☐	☐
Statistical interpretability	☐	☐	☐
Regulatory relevance	☐	☐	☐
Capital decision value	☐	☐	☐

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 team cannot clearly separate biology, exposure, design and execution failure, or the next study would repeat the same architecture without resolving the dominant uncertainty.