

CLIENT DIAGNOSTIC

Pivotal Architecture Decision Grid

A board-level comparison of pivotal evidence architectures before a preferred design becomes organizationally irreversible.

Board kill-questions

- ☐ What comparator would an external reviewer consider credible today?
- ☐ What is the causal question the pivotal programme must answer?
- ☐ Is confirmatory evidence embedded now, or deferred until after a fragile filing strategy?
- ☐ What happens to label, price, timeline and financing if the selected design underperforms?
- ☐ Which design assumption creates the largest asymmetric downside?
- ☐ What evidence would make the board change architecture before FPI?

Quick score

Domain	Green	Amber	Red
Regulatory comfort	☐	☐	☐
HTA / price protection	☐	☐	☐
Causal strength	☐	☐	☐
Timeline resilience	☐	☐	☐
Patient efficiency	☐	☐	☐
Operational complexity	☐	☐	☐
Capital efficiency	☐	☐	☐

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: a single-arm, hybrid or external-control strategy is being selected mainly because it appears faster, without quantifying the downstream cost of a narrow label, confirmatory delay, payer uncertainty or rework.