Selected Case Snapshots

Representative examples. Client identifiers removed.

CLINICAL DEVELOPMENT STRATEGY | TRIAL RESCUE | PIVOTAL DESIGN

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Consolidated medical, regulatory, HTA/HEOR, commercial, and operational development strategy. Governed through execution.

Chief Medical Officer | CNS | Sleep Medicine | Rare Disease | Oncology | FDA/EMA

> Most clinical programs do not fail because one function failed. They fail because medical rationale, regulatory strategy, payer logic, commercial positioning, and operational execution were never integrated into one decision-grade development architecture.

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CASE SNAPSHOT 01

Neurodegeneration / Early Development Readiness

Early neurodegeneration programs must generate more than safety data. They must preserve Phase II/III decision value.

CONTEXT

Early neurodegeneration programs require more than a safe Phase I protocol. They need a development architecture that translates safety, biomarker, pharmacodynamic, and clinical signals into a credible Phase II/III path.

CONSTRAINTS

- High biological uncertainty
- Limited early efficacy signal detectability
- Complex endpoint selection
- Need to align biomarkers, population, safety monitoring, and registrational feasibility

INTERVENTIONS

- Built integrated clinical development logic from early safety to pivotal readiness
- Defined endpoint, biomarker, and population strategy
- Developed risk map and decision gates across clinical, regulatory, payer/HEOR, commercial, and operational domains

OUTCOMES

- Decision-grade development path from early data to Phase II/III planning
- Stronger alignment between science, regulation, execution, and future value narrative

Strategic implication: early-phase studies must be designed to create downstream decision value, not only early safety data.

CASE SNAPSHOT 02

Pivotal Design / Rare Disease & Complex CNS

Pivotal trials must do more than test a hypothesis. They must create evidence that can survive regulatory review, HTA scrutiny, payer assessment, and operational reality.

CONTEXT

A rare disease / complex CNS program required a pivotal architecture that could satisfy regulators while remaining credible for HTA, payer, investor, and launch-year decision-making.

CONSTRAINTS

- Endpoint and estimand choices exposed the program to interpretability risk
- HTA/HEOR evidence needs were not sufficiently reflected in early design choices
- Operational noise risk from baseline instability, rater variability, and read strategy
- Competitive positioning required a defensible value narrative beyond statistical significance

INTERVENTIONS

- Aligned endpoint and estimand strategy with FDA/EMA expectations and HTA/HEOR logic
- Built operational guardrails around baseline control, rater strategy, and reading approach
- Developed decision gates linking clinical signal, regulatory feasibility, payer relevance, and launch differentiation
- Strengthened the evidence narrative for internal governance, investors, and external stakeholders

OUTCOMES

- Submission-ready protocol package
- Payer-credible evidence narrative
- Clearer differentiation logic for launch and partnering discussions
- Reduced risk of a statistically positive but commercially weak trial

Strategic implication: pivotal design must integrate regulatory, payer, commercial, and operational logic before the protocol is locked.

CASE SNAPSHOT 03

Phase II/III Rescue / CNS Multi-Country

Trial rescue is not cosmetic project management. It is the restoration of signal integrity, feasibility realism, and execution control before the dataset loses decision value.

CONTEXT

A late-phase CNS program was at risk due to feasibility drift, unstable enrollment, delayed activation, and vendor underperformance.

CONSTRAINTS

- Over-optimistic feasibility assumptions
- Misaligned country and site mix
- Startup and recruitment cadence failing against plan
- RBQM and escalation logic not tuned to endpoint and data-quality risk

INTERVENTIONS

- Re-forecasted feasibility using operational reality rather than legacy assumptions
- Rebuilt country/site strategy and activation cadence
- Reset vendor oversight, delivery metrics, and escalation rules
- Aligned RBQM with endpoint risk, recruitment variance, and database-lock interpretability.

OUTCOMES

- Enrollment stabilized
- Forecast accuracy improved through rolling forecasts and activation cadence
- Measurement and data-quality controls restored interpretability at DBL
- Governance became more predictable and decision-oriented

Strategic implication: a rescue plan must protect the future evidence package, not only accelerate recruitment.

CASE SNAPSHOT 04

RBQM Reset / Complex Endpoints

RBQM only creates value when it detects threats to interpretability early enough to change execution.

CONTEXT

A global program with complex endpoints faced late operational surprises, query burden, deviation risk, and uncertainty around database-lock interpretability.

CONSTRAINTS

- Central monitoring KPIs were visible but not actionable
- Site triage was inconsistent across countries and vendors
- Rater drift and endpoint variance were insufficiently controlled
- Governance cadence lacked clear decision rights and escalation thresholds

INTERVENTIONS

- Implemented actionable centralized monitoring KPIs
- Defined site triage rules and escalation pathways
- Enforced rater QC, drift control, and endpoint-protection cadence
- Clarified governance roles, decision rights, and sponsor/vendor accountability

OUTCOMES

- Improved interpretability at database lock
- Reduced query aging and rework burden
- Fewer late surprises from sites, raters, and vendors
- Stronger inspection readiness and audit trail discipline

Strategic implication: RBQM is not a dashboard. It is a governance system for protecting evidence quality.

CASE SNAPSHOT 05

Long-Term Follow-Up, Safety Governance & HEOR

Complex therapies need a safety and value strategy that extends beyond the first clinical readout.

CONTEXT

A complex therapy program required credible long-term safety, durability, and outcomes evidence beyond the initial study endpoint.

CONSTRAINTS

- Long-term safety and durability uncertainty
- Need to align regulatory commitments with payer evidence expectations
- Risk of overburdening sites and patients with impractical follow-up demands
- Limited resources requiring pragmatic evidence generation and governance

INTERVENTIONS

- Designed post-treatment safety and outcomes evidence logic
- Integrated HEOR, real-world evidence, and patient-relevant outcomes into the evidence plan
- Defined governance to manage vendor/site burden, data quality, and follow-up discipline
- Connected long-term evidence generation with access, lifecycle, and value narrative

OUTCOMES

- Clear post-treatment evidence roadmap
- Better alignment between safety, access, and operational feasibility
- Reduced rework risk by integrating evidence expectations early
- Stronger basis for payer, regulator, and partner discussions

Strategic implication: long-term follow-up must be designed as evidence strategy, not as a regulatory afterthought.

CASE SNAPSHOT 06

Capital & Partnering Readiness

Investors and partners do not buy a protocol. They buy a credible risk-adjusted path to decision-grade evidence and future value.

CONTEXT

Capital raise and partnering discussions required a coherent, diligence-ready clinical development, evidence, and risk narrative.

CONSTRAINTS

- Regulatory path, pivotal evidence, and payer logic were not fully integrated
- Competitive landscape at launch was not reflected in the differentiation strategy
- Communications and publication planning were not aligned with value inflection points
- Board and investor materials needed sharper risk logic and mitigation structure

INTERVENTIONS

- Built evidence architecture with clinical, regulatory, HTA/HEOR, commercial, and operational decision gates
- Produced risk map and mitigation plan aligned to investor and partner diligence questions
- Integrated competitive, payer, and regulatory logic into the development narrative
- Aligned publications and communications with key data milestones

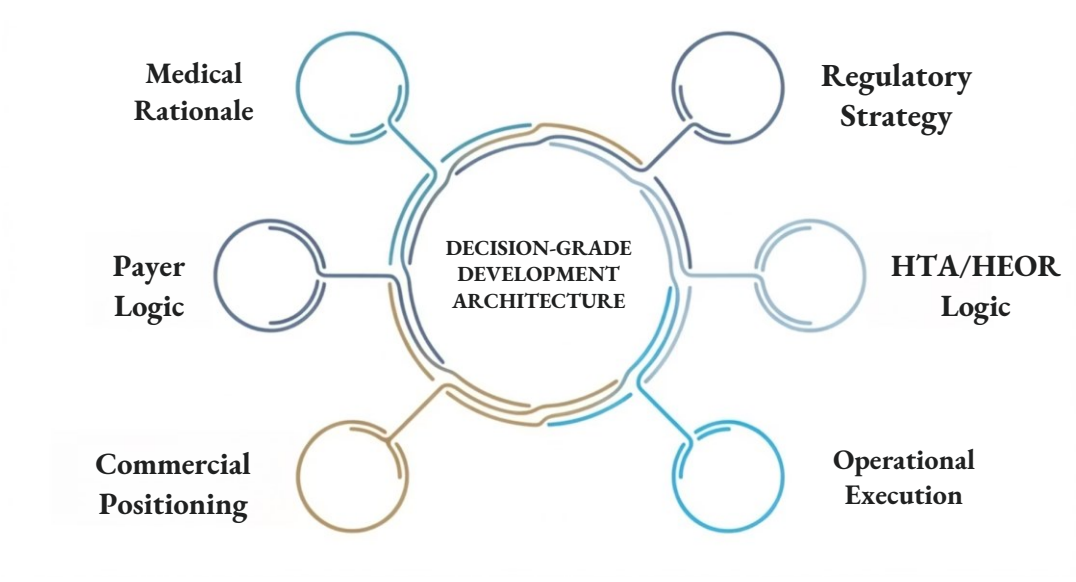
OUTCOMES

- Improved diligence readiness
- Stronger credibility at financing and partnering inflection points
- Clearer explanation of risk, value, and development optionality
- Contributed to >$50M in financing and value-inflection discussions across engagements

Strategic implication: capital readiness depends on evidence architecture, not optimistic storytelling.

The Pattern Across All Cases

> A protocol exists. A CRO is selected. Sites are activated. Money is spent. But the evidence architecture is incomplete.



My work is to connect what must be true **medically**, **regulatorily**, **payer-side**, **commercially**, **operationally and from a safety-governance** perspective before capital is committed at scale.

The same failure mode appears repeatedly across programs, therapeutic areas, and development stages: activity is mistaken for strategy.

Integration is not an aesthetic layer added after protocol design. It is the operating logic that determines whether the study produces decision-grade evidence.