Hope Is Not a Strategy

Clinical development strategy that delivers regulator- and payer-credible outcomes

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Where Clinical Development Programs Fail

Non-decision-grade endpoints

Selected for feasibility or precedent, not regulatory or payer credibility.

Unrealistic feasibility assumptions

Enrollment and operational plans that fail in execution.

Three-way misalignment

Clinical, regulatory, and payer requirements addressed in silos.

Governance that delays decisions

Structures that dilute accountability and slow convergence.

The result: Trials that complete—but cannot support approval, reimbursement, or investment decisions.

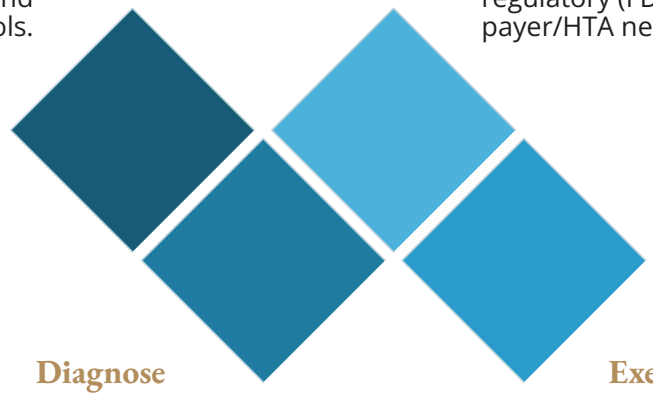
What I Do

Redesign

Develop fit-for-purpose pivotal strategies and protocols.

Align

Integrate medical, regulatory (FDA/EMA), and payer/HTA needs.



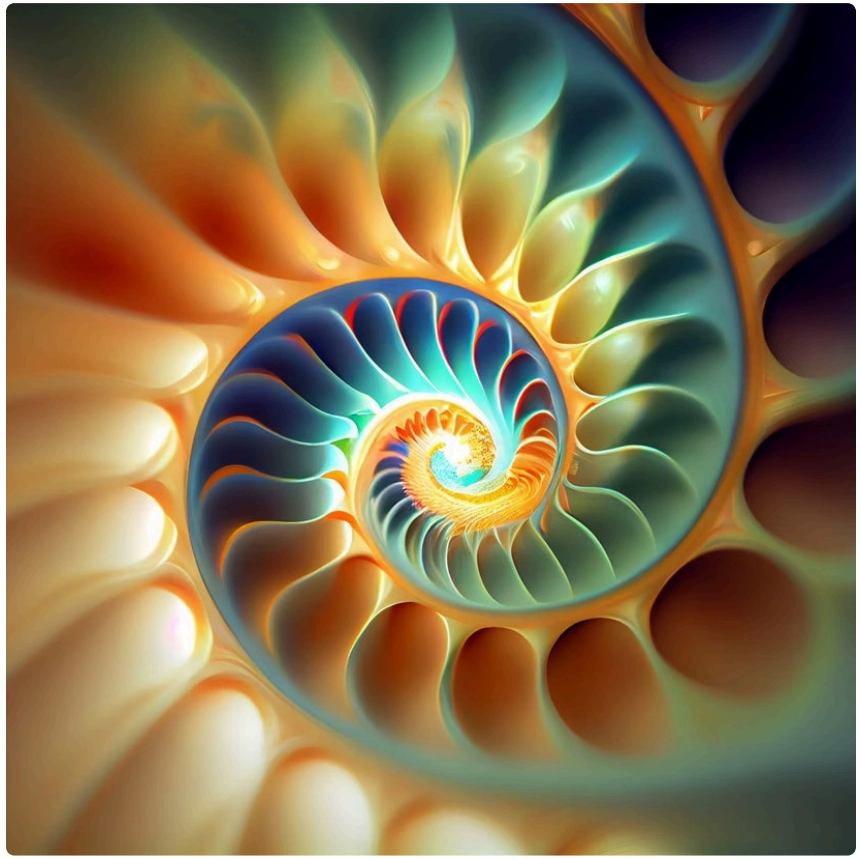
Diagnose

Rapid risk mapping of design, feasibility, endpoints, governance.

Execute

Establish governance for decision-grade data at database lock.

Every engagement moves through a disciplined sequence—from rapid risk identification to the governance structures that protect data interpretability all the way to database lock.



Core Expertise

Pivotal Trial Design & Rescue

Phase II/III strategy, protocol redesign, and high-risk program recovery.

Advanced Trial Architectures

Adaptive, platform, and basket designs calibrated to evidentiary objectives.

Neurology & Rare Diseases

Deep therapeutic expertise including migraine, stroke, and rare CNS conditions.

Global Regulatory Strategy

FDA, EMA, and multi-region alignment built into the development plan from day one.

Medical-Commercial Integration

Payer/HEOR and commercial strategy embedded alongside regulatory and clinical planning.

Selected Impact

100+

Clinical Trials

Phase I–IV across CNS, rare diseases, oncology, and HE&OR

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Global Agencies

Repeated FDA and EMA interactions on complex endpoints and regulatory pathways

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Payer-Ready Packages

Submission-ready evidence aligned with payer and HTA expectations

Program Rescue

Strategic redesign of high-risk programs to restore interpretability and decision value

Global Submissions

Aligned multi-region strategies enabling coordinated regulatory submissions across geographies

Current Roles

AgoneX Biopharmaceuticals — CMO

Clinical development strategy for AGX-201 in chronic migraine; IND preparation and FDA engagement; platform strategy extending into neurodegeneration and oncology.

AND Biotech — CMO

Clinical and regulatory strategy across infectious disease, oncology, and immunology portfolios.

Verum (CRO) — CMO

Medical oversight and optimization of global clinical trial execution across therapeutic areas.

Fewer assumptions.
Cleaner designs.
Decisions that hold.

How I Add Value

Less Time Lost

Reduce time lost in design iterations and internal misalignment.

Higher Acceptance Probability

Increase probability of regulatory and payer acceptance.

Interpretable Outcomes

Ensure trials generate interpretable, decision-grade outcomes.

Independent Senior Judgment

Provide independent senior judgment in high-stakes situations.

When to Involve Me

High-Stakes Trial Design

A pivotal trial must be designed under time pressure, investor scrutiny, or both.

At-Risk Programs

A study is underperforming or trending toward non-interpretable outcomes at lock.

Strategic Misalignment

Clinical, regulatory, and commercial perspectives are not converging on a shared plan.

Pre-Investment Assessment

A program needs independent, credible review before a major capital or partnership decision.

Let's Talk

If your program is navigating a critical design decision, a regulatory inflection point, or an investment milestone—bring in independent, senior-level judgment before the window closes.

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