

A 10-point operational framework from HYGEIA Group. Most Venture Capital investors check the Science and IP. This checklist vets the *execution plan* and uncovers the risks that they miss.

1. The "Hockey Stick" Runway Model

- ✓ **RED FLAG:** The runway model (e.g., 24-36 months) is based on best-case scenarios and doesn't account for enrollment delays or vendor cost overruns.
- ✓ **DILIGENCE CHECK:** Has a credible, conservative financial model been built, stress-testing the key operational assumptions (e.g., cost/patient, vendor fees)?

2. The "Founder's Pet Project"

- ✓ **RED FLAG:** Capital is allocated across multiple programs based on founder sentiment, not on a rigorous analysis of expected enterprise value (EV) contribution.
- ✓ **DILIGENCE CHECK:** Has the lead asset been validated as the highest-value program, and is capital being decisively focused on it?

3. Flawed Clinical Trial Design

- ✓ **RED FLAG:** The trial design has unclear endpoints, inadequate statistical power, or weak controls (poor blinding/randomization), making the resulting data unconvincing to regulators or acquirers.
- ✓ **DILIGENCE CHECK:** Has the protocol been audited by an independent, unconflicted expert for operational and statistical rigor *before* the first patient is enrolled?

4. Unvetted Data Integrity

- ✓ **RED FLAG:** Relying solely on the company's "clean" data package without reviewing raw data or statistical methods. This risks "*p-hacking*" or selective reporting.
- ✓ **DILIGENCE CHECK:** Is the raw data available for independent review, and has a plan for third-party validation been established?

5. The "Portfolio Black Box"

- ✓ **RED FLAG:** The founder reports on "progress" with vague summaries, lacking hard, real-time data on trial performance.
- ✓ **DILIGENCE CHECK:** Is there an operational dashboard with real-time KPIs (e.g., enrollment velocity vs. target, site activation lag, monthly burn vs. milestones)?

6. Weak CRO & Vendor Contracts

- ✓ **RED FLAG:** The Master Service Agreement (MSA) with the CRO is a standard "pay-as-you-go" contract with no financial penalties for poor performance.
- ✓ **DILIGENCE CHECK:** Are vendor contracts structured to tie payments to specific, measurable performance triggers, KPIs and milestones? Are there clawback provisions?

7. The "Founder-Operator" Gap

- ✓ **RED FLAG:** A brilliant scientific founder with no prior experience in global trial operations or C-suite management is tasked with scaling the company.
- ✓ **DILIGENCE CHECK:** Is there a plan to surround the founder with senior, experienced operational leadership (e.g., an embedded Interim C-Suite Exec or specialist advisor)?

8. No "Buyer-Ready" Blueprint

- ✓ **RED FLAG:** The development plan is focused only on the next data readout, with no clear strategy for reimbursement or what a Big Pharma acquirer will demand to see.
- ✓ **DILIGENCE CHECK:** Has an end-to-end "*Regulatory-to-Reimbursement*" blueprint been mapped to align clinical milestones with a successful commercial exit?

9. Vague Contingency Planning

- ✓ **RED FLAG:** The only plan is "success." There are no pre-defined scenarios for asset sale/licensing, milestone-based syndication or non-dilutive bridge financing if necessary.
- ✓ **DILIGENCE CHECK:** Are there clear, pre-planned "Plan B" and "Plan C" financing and strategic contingency plans? Ensure transparency in communication with shareholders.

10. Governance Gaps

- ✓ **RED FLAG:** The board lacks a true operational or clinical trial expert, preventing it from effectively challenging the C-suite's plans and data.
- ✓ **DILIGENCE CHECK:** Is there a mechanism for a rapid-response, independent operational team to be deployed for intervention when KPIs flash red?



Stop Guessing. Start De-Risking.

HYGEIA Group provides the director-level CRO expertise to run this playbook for you. We deploy in 4-week "**Due-Diligence Sprints**" to give you a clear "Go/No-Go" report *before* you invest and provide "**Interim Clinical Leadership**" to rescue portfolio assets *after*.

Schedule a 30-minute, confidential briefing to discuss your deal flow or a specific portfolio challenge. Contact us at info@hygeiagroupinc.com or scan QR code for more details.

