

## **Year-In-Review: Clinical Research Today And Tomorrow**

### **Looking back at 2025 and what the Industry needs in 2026**

The clinical trial landscape of 2025 will likely be remembered as a year defined by a paradox: biotech venture funding rose in total capital<sup>1</sup>, yet fewer companies actually secured financing. This disconnect shaped strategic decision-making throughout the sector, from early discovery all the way through translational and clinical development.

#### **2025's central challenge: risk aversion amid uncertain markets**

Despite an overall increase in biotech Venture Capital (VC) investment volume, 2025 saw investors concentrate funding into a smaller number of companies and assets. Geopolitical instability, inflationary pressures, and increasingly cautious Limited Partners (LP) expectations pushed VCs toward “safer bets”, typically programs with validated mechanisms, known pharmacology, or pre-existing clinical signals.

For many emerging and early-stage biotechs, this environment created a frustrating bottleneck:

- More money existed, but
- it was harder than ever to secure, and
- competition was now not just scientific, but psychological, fighting against investors' risk sensitivity.

The result was an industry in which smaller or leanly funded companies often adopted short-term survival strategies such as minimalistic first-in-human (FIH) programs focused on safety, tolerability, and pharmacokinetics (“feed & bleed”). These early studies are expected to allow companies to advance to Phase 2 quickly in hopes of attracting the next funding milestone, but they often do so without generating the deeper mechanistic insights needed to truly de-risk a novel drug.

#### **The missed opportunity: early Proof of Pharmacology and Proof of Mechanism**

By focusing narrowly on the least expensive, fastest path to early clinical milestones, many innovative companies unintentionally increase downstream risk. Without proof of pharmacology (PoP) in healthy volunteers and proof-of-mechanism (PoM) or mechanistic proof-of-concept (PoC) in patients, companies enter Phase 2 with limited understanding of target engagement, biological effect, or dose–response relationships.

In 2025, CHDR highlighted this issue across multiple publications in our portfolio<sup>2,3</sup>, emphasizing that FIH success is not binary. True de-risking requires understanding how and why a drug works, not simply whether it is safe.

#### **A better path forward: investing in insight, not just progression**

If 2025 was dominated by risk aversion, 2026 must be the year when biotech and investors reclaim scientific rigor as a risk mitigation strategy, not a luxury.

This is precisely where CHDR sees its responsibility. Each year, we invest 10% of our turnover into the development and validation of biomarkers, models, and clinical methods that help companies generate meaningful PoP and PoM/PoC data early in development. These tools empower biotechs to demonstrate mechanistic validity even with limited patient populations; crucial evidence when competing for selective VC attention.

In a funding climate where every investment must be justified, evidence-rich early studies offer a competitive advantage. They transform a program from “promising but unproven” to “mechanistically validated and strategically lower-risk.”

### **Looking ahead to 2026: what the Industry needs**

To overcome 2025’s bottlenecks and accelerate innovation in 2026, the sector must prioritize:

#### **1. Evidence-driven early development**

PoP and PoM/PoC must become the norm, not the exception, in FIH and early patient studies.

#### **2. Strategic use of validated biomarkers and physiological models**

Industry should leverage proven tools rather than improvising under pressure.

#### **3. Collaborative risk-sharing**

Clinical research partners should invest alongside their clients, as CHDR does, to strengthen the translational ecosystem for everyone.

#### **4. A shift from speed-at-all-costs to smart acceleration**

Deeper insight early on ultimately enables faster, more successful progression later.

If 2025 taught us anything, it is that uncertainty amplifies the value of knowledge. In 2026, the companies that thrive will be those that generate meaningfully de-risking data early and the partners who support them in doing so.

### **References**

1. GlobalData. M&A trends in pharma – Q3 2025. GlobalData Pharma Intelligence Center. <https://pharma.globaldata.com> (2025).
2. Ruijs, T. Q., de Cuba, C. M. K. E., Heuberger, J. A. A. C., Hutchison, J., Bold, J., Grønnebæk, T. S., Jensen, K. G., Chin, E., Quiroz, J. A., Petersen, T. K., Flagstad, P., de Kam, M. L., van Esdonk, M. J., Klaassen, E., Doll, R. J., Koopmans, I. W., de Goede, A. A., Aulin, L. B. S., Pedersen, T. H., & Groeneveld, G. J. (2025). Safety, Pharmacokinetics, and Pharmacodynamics of a First-in-Class CIC-1 Inhibitor to Enhance Muscle Excitability: Phase I Randomized Controlled Trial. *Clinical pharmacology and therapeutics*, 117(3), 768–778. <https://doi.org/10.1002/cpt.3516>
3. Grievink, H. W., Breedveld, C., Öhd, J., Schoonderwoerd, M., Permentier, H. P., Foks, A. C., Bot, I., Neubert, E., & Moerland, M. (2025). In vitro and in vivo lipopolysaccharide-driven activation of human neutrophils in healthy volunteers as a tool for clinical drug development. *Journal of immunological methods*, 544, 113968. <https://doi.org/10.1016/j.jim.2025.113968>