Article Lindus internal analysis · Prepared for sponsors

Enrollment timeline performance

A data-driven analysis of trial enrollment delivery

Lindus[#]

[#] Lindus Health, London, United Kingdom and New York, NY, USA. ✉ Correspondence: rob@lindushealth.com

82%

of Lindus-executed trials completed enrollment on or ahead of the timeline presented at proposal.

23/28
Trials meeting all three inclusion criteria

70–92%
Sensitivity range across 10 alternative filter scenarios

88.5%
On-time rate when targets set outside the feasibility process are removed

< 20–400+
Range of target enrollments across the cohort

1 Overview

Returns on biopharma R&D have fallen below the cost of capital[1]. Clinical trial complexity has grown[2]. Competition has intensified, both within indications as sponsors crowd around the same molecular targets[3] and across geographies as China has become the second-largest contributor to the global pipeline[4]. The regulatory environment has been increasingly uncertain.

Drug development programs can no longer absorb delays, and the bar for sponsors keeps rising. Timeline variance lives in the gaps between fragmented vendors and contracts that reward activity over outcomes. The cost is concrete: the Tufts Center for the Study of Drug Development estimates direct daily trial costs at $23,737 for Phase II and $55,716 for Phase III, plus an additional $800,000 per day in lost or delayed prescription sales once a drug reaches market[5]. A peer-reviewed analysis of 2,542 randomized clinical trials registered on ClinicalTrials.gov found that only 1 in 5 trials completed on their originally planned timeline[6].

The Lindus next-generation CRO model engineers clinical study execution as an accountable system: real-time visibility, milestone-based payment terms, and an integrated operating system. Whether that model works comes down to a single operational question: do trials hit the timelines committed at proposal?

This paper documents Lindus's performance against that metric. The methodology is transparent, the exclusions are documented, and the result is verifiable from source data. A companion document provides the full methodology, sensitivity analyses, exclusion criteria, and decision log for independent review[7].

2 The 82% result

23 of 28 Lindus-executed trials (82.1%) completed enrollment on or ahead of the enrollment time presented at proposal[8] (Fig. 1).

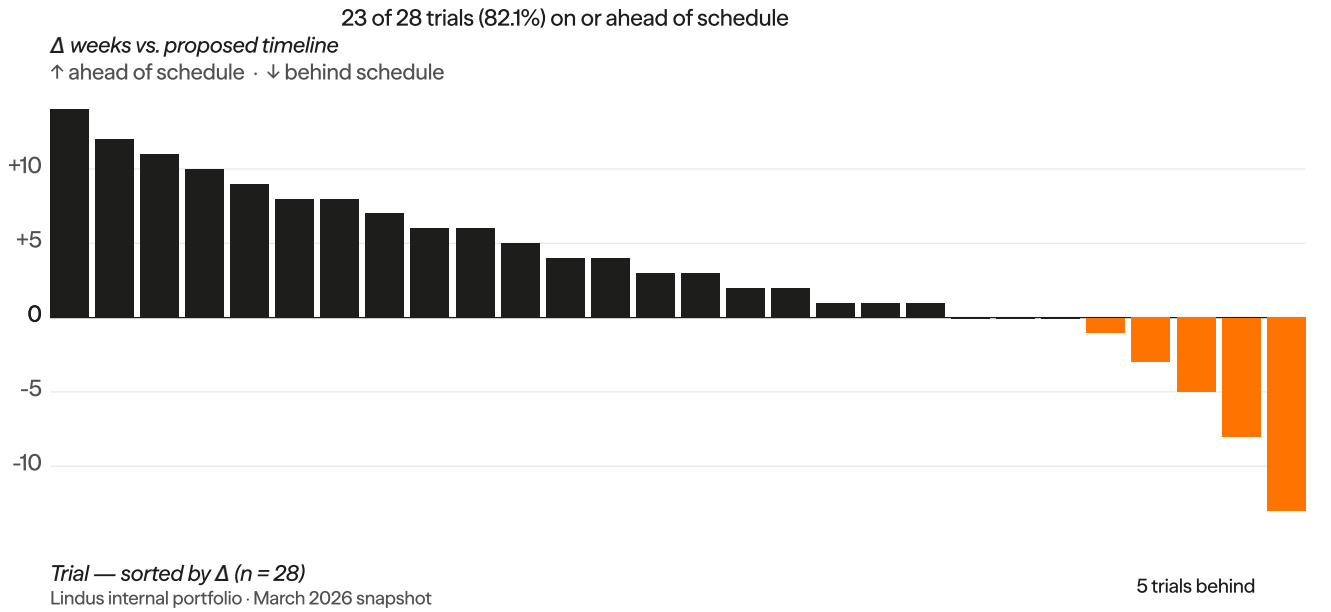

Fig. 1 | Enrollment timeline performance across the 28-trial cohort. Each bar represents one trial, sorted by Δ weeks (actual enrollment duration minus the timeline presented at proposal). Negative deltas indicate enrollment finished ahead of schedule; positive deltas indicate enrollment finished behind. Trials are anonymized by therapeutic area grouping to preserve sponsor confidentiality. 23 of 28 trials (82.1%) completed enrollment on or ahead of the timeline presented at proposal.

The result reflects the complete population of trials meeting the following inclusion criteria:

- A sponsor target was defined at proposal
- Actual enrollment duration is recorded and measurable
- Lindus had operational responsibility for enrollment delivery

The cohort spans multiple therapeutic areas, with target enrollments ranging from under 20 participants to over 400.

The 82.1% figure holds under sensitivity testing across 10 alternative scenarios, with on-time rates ranging from 70.0% to 92.0% depending on filter criteria. The full sensitivity analysis is provided in the companion methodology document.

3 What we measured

The on-time threshold is Δ ≤ 0 weeks, where Δ is calculated as actual enrollment duration minus the sponsor's target enrollment duration as stated at proposal. A negative Δ means enrollment finished ahead of schedule; a Δ of zero means enrollment finished on the committed timeline. No tolerance band is applied.

The 28-trial denominator is the complete set of trials that meet all three inclusion criteria. Two trials with computable deltas were excluded for principled reasons: one withdrawn trial and another where Lindus did not own enrollment.

This metric measures performance against the timeline Lindus committed to in the proposal, not against retrospectively revised targets. A second internal dataset contains revised targets for five of the 28 trials. In all five cases, the sponsor target was increased while the enrollment timeline remained unchanged. Using revised targets would produce a higher on-time rate (approximately 90%) but would measure performance against retrospectively adjusted expectations. The 82.1% figure uses the original proposal targets.

4 The operational model behind the result

The 82% on-time rate is enabled by an integrated model spanning feasibility, central enrollment infrastructure, and flexible site models. Trials run on Citrus, an AI-assisted trial operating system with clinical, medical, and regulatory oversight at every decision point, and payments are tied to milestone completion.

Proprietary feasibility-anchored targeting reduces unrealistic commitments. Lindus participates in setting enrollment targets during the proposal stage, combining therapeutic area domain expertise with three feasibility inputs: site-level enrollment data from a network of approximately 1,000 preferred sites, indication-specific benchmark enrollment rates by site and geography, and eligibility prevalence data drawn from approximately 40 million electronic health records across the US and UK. The combination produces scenario-modeled enrollment predictions before commitments are made, reducing the gap between what is committed and what is operationally achievable. Among the five behind-schedule trials in the cohort, two had targets later identified internally as having been set outside the standard feasibility process. When these are removed, the on-time rate rises to 88.5%. This is not an excuse for the misses; it is evidence that the feasibility mechanism works when it is applied.

Integrated execution eliminates handoff delays. In fragmented operating models, enrollment is typically managed by one organization while protocol design, site activation, and data collection are handled by others. Each handoff introduces delay, information loss, and diffused accountability. The Lindus operational model consolidates these functions within a single integrated team, with shared operational visibility across protocol, sites, recruitment, and data. When a site activation delay threatens enrollment timing, the team adjusting the enrollment forecast is the same team that activated the site. The feedback loop is immediate. In a fragmented model, that signal travels through contract boundaries and reporting layers before it reaches the team that can act on it.

The on-time rate holds steady across subgroups: 82.4% for fully completed trials and 81.8% for active trials where enrollment is complete but other phases (follow-up, analysis) are ongoing. Consistency across completed and active trials, across therapeutic areas, and across trial sizes from under 20 to over 400 participants indicates the result is not driven by a single trial profile.

5 Conclusion

Across the 28 Lindus-executed trials where a sponsor set an enrollment target at proposal and enrollment progressed far enough to measure, 82% completed on or ahead of the committed timeline. The figure holds under sensitivity testing, is consistent across completed and active subgroups, and is derived from the more conservative of two available target definitions.

Three things make this finding operationally significant for sponsors evaluating risk.

Predictability across the portfolio. The 82% rate is consistent across therapeutic areas, geographies, and trial sizes. For a sponsor building a development timeline around enrollment assumptions, this consistency reduces the need to pad schedules with contingency buffers that delay every downstream milestone.

Operational control. The result traces to specific structural decisions: feasibility-anchored targeting that reduces unrealistic commitments, and integrated execution that eliminates the handoff delays inherent in fragmented operating models. These are architectural features of the operational model, not claims about effort or culture, and they are visible in the data.

Reduced sponsor risk. When enrollment runs to plan, the consequences are concrete: site costs stay within budget, regulatory submissions proceed on schedule, and the program maintains its position within the patent window. An operational model that delivers on-time enrollment in 82% of measured trials measurably reduces enrollment risk.

This paper does not claim that Lindus eliminates enrollment risk. No operational model can guarantee that. The data shows the Lindus model measurably reduces it, and that the evidence is auditable, reproducible, and conservative.

Methodology summary

Parameter	*Specification*
Source	Lindus internal trial portfolio data, March 2026 snapshot
Cohort	28 trials meeting three inclusion criteria
On-time definition	Δ (weeks) ≤ 0, where Δ = actual enrollment duration − sponsor target at proposal
Result	23 of 28 = 82.1%, reported as 82%
Sensitivity range	70.0% to 92.0% across 10 scenarios

Full methodology, sensitivity analyses, exclusion criteria, and decision log are available in the companion document.

References

1. Deloitte. *Measuring the return from pharmaceutical innovation: Be brave, be bold.* 15th edition. Deloitte Centre for Health Solutions; March 2025.
2. Markey, N., Howitt, B., El-Mansouri, I., Schwartzenberg, C., Kotova, O. & Meier, C. Clinical trials are becoming more complex: a machine learning analysis of data from over 16,000 trials. *Sci. Rep.* 14, 3514 (2024).
3. Fougner, C., Cannon, J., The, L., Smith, J. F. & Leclerc, O. Herding in the drug development pipeline. *Nat. Rev. Drug Discov.* 22, 617–619 (2023).
4. Liu, S., Hu, H., Ge, C., Yuan, S., Jiang, J. & Chen, X. The rise of China's pharmaceutical industry from 2015–2024: a decade of innovation. *Nat. Rev. Drug Discov.* Published online 21 July 2025.
5. Smith, Z., DiMasi, J. & Getz, K. *Quantifying the Value of a Day of Delay in Drug Development.* Tufts Center for the Study of Drug Development; August 2024.
6. Shadbolt, C., Naufal, E., Bunzli, S. et al. Analysis of rates of completion, delays, and participant recruitment in randomized clinical trials in surgery. *JAMA Netw. Open* 6, e2250996 (2023).
7. Lindus Health. Enrollment Timeline Performance: Methodology and Decision Log. May 2026. Available on request.
8. Lindus internal analysis, March 2026 portfolio snapshot. Methodology documented in the companion methodology document (reference 7).

Data availability

Trial-level data are confidential under sponsor agreements. Aggregate, de-identified figures and the methodology decision log are available on request from the corresponding author.

Competing interests

The authors are employees of Lindus. The analysis was conducted using Lindus internal portfolio data and has not been peer-reviewed. This paper is prepared for sponsor audiences and is not a published journal article.

Correspondence

Correspondence and requests for materials should be addressed to rob@lindushealth.com.

About Lindus

Lindus is a next-generation CRO, engineered to give biotech and pharma sponsors confidence and control to generate clinical data on time and on budget. Citrus™, an AI-assisted trial operating system with clinical oversight, connects centralized patient identification across 40 million EHRs to full-scope trial execution. Milestone-based payments tie fees to delivery. Backed by investors and advisors including Peter Thiel and Prof. Robert S. Langer.

Talk to our team about your timeline

rob@lindushealth.com