# A NEW APPROACH TO CLINICAL TRIAL PLANNING: How Mid-Market and Emerging Pharma Can Take Greater Control of Patient Enrollment

A growing share of the industry's R&D pipeline now comes from mid-size and emerging companies. For mid-size and emerging pharma, earning the right to compete starts with a planning model that converts limited resources into clearer site choices, defensible forecasts, and faster course correction.



**HARINI LAKSHMINARAYANAN**
Director, Products
ZS Associates



**JENNIFER BALTZELL**
Principal
ZS Associates



**MARIA KLIATCHKO**
GM, ZAIDYN® Clinical
ZS Associates

*Sponsored by*

ZS

Applied CLINICAL TRIALS®

## INTRODUCTION

**A GROWING SHARE** of the industry's R&D pipeline now comes from mid-size and emerging pharma companies, making these organizations an important source of innovation. But the planning environment they operate in looks very different from that of a large sponsor. The stakes for enrollment are just as high, yet these organizations typically have fewer dedicated feasibility resources, less internal trial history to draw on, and less capacity to connect planning and execution across tools and contract research organization (CRO) partners. The question is no longer whether lean teams can match the scale of large pharma; it is how they can retain greater control of the decisions that shape enrollment performance.

Four realities consistently shape this environment: limited historical data to guide country, site, and investigator decisions; planning and execution resting on a small team with limited bandwidth; experience alone rarely providing a complete picture of enrollment risk; and delays carrying outsized business consequences for a lean organization.

Teams often have less historical data to guide country, site, or investigator decisions, increasing the value of external evidence such as claims data, trial intelligence, real-world data, and industry benchmarks. At the same time, planning and execution responsibilities often fall to a small group, leaving scenario planning and time-intensive analysis to compete with everything else on their plates. The constraint is capacity, not expertise, and newer technology and automation are beginning to expand what lean teams can accomplish with the capacity they have.

Planning and execution responsibilities often fall to a small group, leaving scenario planning and time-intensive analysis to compete with everything else on their plates.

Experience alone also rarely provides a complete picture of enrollment risk. Stronger decisions combine that experience with independent benchmarks, protocol-specific evidence, and transparent assumptions that the entire team can evaluate consistently. Finally, enrollment delays can have outsized business consequences for a lean organization. A delayed readout can affect a financing event, partnership discussion, or launch plan, with fewer parallel assets or financial buffers available to absorb the impact.

That shift matters most in the sponsor-CRO relationship. Mid-market sponsors do not need to insource every activity or duplicate a CRO's operational infrastructure. They do need enough evidence, transparency, and analytical control to challenge assumptions, align on trade-offs, and make planning decisions jointly rather than accepting recommendations primarily because internal resources are limited. Technology-enabled feasibility, automated comparator-trial analysis, and dynamic forecasting give lean teams a stronger basis for partnership: CROs can contribute operational reach and site relationships, while sponsors retain clearer ownership of the strategic decisions that determine enrollment success.

Enrollment control ultimately comes down to three connected decisions: which countries, sites, and investigators to select; how to forecast a defensible timeline; and how to oversee and adapt performance when a study does not unfold as planned. Treating these decisions as one connected process, built on a shared data foundation that brings together registries, real-world data, trial intelligence, site performance, and a sponsor's own study data, can help lean teams participate more directly in feasibility and site selection, pressure-test forecasts with CRO partners, and maintain greater control over enrollment rather than managing each task in isolation.

This article examines how the ZAIDYN® clinical platform from ZS Associates supports lean teams across these trial workflows, connecting selection, forecasting, and adaptation into an evidence-based process. The approach is demonstrated through an illustrative Phase 3 *ALK*-positive non–small cell lung cancer (NSCLC) trial and further explored through examples of how the same principles can be applied across a broader portfolio.

## THE ILLUSTRATIVE TRIAL: SELECTING THE RIGHT SITES

Selection is the highest-leverage decision in the process because it can set the ceiling for how quickly a trial can recruit. The cost of getting it wrong is real: a meaningful share of activated sites never enroll a single patient, while many more fall well short of enrollment expectations.
ZAIDYN® replaces guesswork with a benchmark-first process built around three steps. First, an agent reads an uploaded protocol, extracts eligibility criteria and other key parameters, and matches them against a connected data foundation to identify comparator trials. This creates a protocol-specific evidence base rather than requiring a team to assemble comparable studies from memory.

Second, the platform scores and ranks countries, sites, and investigators against that evidence base, incorporating factors such as site experience, historical performance, and current operational workload. It also surfaces the other trials a site is already involved, helping teams see where they may be competing for the same patients before committing to a site.

Third, stakeholders and CRO partners review the resulting shortlist together, creating a shared basis for final selection rather than relying on assumptions held by one part of the team.
In the illustrative trial, uploading the protocol allowed the platform to automatically assemble a comparator-trial list and show how each comparator matched the protocol based on factors such as eligibility criteria, phase, patient population, and molecular profile. It also produced a preliminary enrollment timeline before a single site had been chosen.

From there, a broad universe of roughly 1,200 candidate sites was narrowed to a focused shortlist of 120 sites across eight countries, with each site's experience, performance, current workload, and competitive trial involvement surfaced for review. Work that would typically span weeks of benchmarking and list review was compressed into a fraction of that time, while helping the team avoid the activation and site-management costs associated with a non-enrolling site and giving stakeholders a shared, evidence-grounded shortlist to align around.

## THE ILLUSTRATIVE TRIAL: BUILDING A DEFENSIBLE FORECAST

A majority of trials take longer to recruit than planned, and that baseline timeline often underlies a sponsor's financing, partnering, and launch decisions. A defensible forecast follows the shortlist through additional steps: pressure-testing assumptions, validating projected enrollment rates with stakeholders, and building best- and worst-case scenarios around factors such as activation strategy and screen-failure risk.

ZAIDYN® helps teams review enrollment patterns and target dates at the individual-country level and adjust country-specific targets directly within the forecast. Rerunning the forecast under new assumptions—a process that previously took days—can now be completed in minutes. This allows teams to pressure-test scenarios and update their view before a stakeholder meeting rather than after it.

That speed carries a cost benefit of its own. Keeping a trial in flight comes with a substantial daily operational cost, so a forecast that teams can trust and rerun quickly, rather than one that takes days to revisit, gives lean organizations a real opportunity to reduce enrollment inefficiencies

and the operational spend that comes with them. The result is a forecast grounded in visible assumptions that stakeholders can review and evaluate, rather than a single number that one person needs to defend.

In the illustrative trial, the platform's initial forecast, based on the benchmarks described above, estimated that the study would take roughly 16 to 17 months to enroll its target of 440 patients. Once the shortlist was finalized, the team was able to build a more detailed forecast using actual site-level data.

That analysis replaced the early single-number estimate with a full enrollment curve, projecting a timeline of about 19 to 20 months at an 85% probability of success, with defined confidence bands around the projection. The timeline changed not because the study necessarily became more difficult, but because the assumptions became more specific once real site data was incorporated.

## THE ILLUSTRATIVE TRIAL: ADAPTING AS ENROLLMENT UNFOLDS

Plans can drift once a study is enrolling, so the same connected foundation needs to keep tracking performance against the baseline forecast. Leading indicators such as activation pace, screening rates, and competing trials in the same geography can surface deviations early enough for teams to act, whether the issue is localized to a site or country or the overall timeline is at risk. The earlier enrollment risk is identified, the more options teams have to respond before timelines, budgets, and milestones are affected.

ZAIDYN® monitors enrollment performance, activation status, and projected completion against the plan in real time, drawing on those same leading indicators to identify emerging risks. Teams can then reforecast under updated assumptions and take corrective action before a deviation affects the projected completion date.

The timeline changed not because the study necessarily became more difficult, but because the assumptions became more specific once real site data was incorporated.

The value of identifying that drift early is significant. Even a short delay can carry substantial commercial consequences. Earlier visibility into a slipping timeline gives teams more options for intervention, whether that means adding sites or countries or addressing a screening or activation issue directly, rather than discovering the risk after those options have narrowed.

In the NSCLC trial, ZAIDYN® helped the team track live recruitment against its baseline forecast from early in the study. Enrollment was tracking slightly above the expected pace globally, and the platform allowed the team to break that view down by country, showing which countries were driving faster early enrollment and which were lagging.

This gave the team a basis for targeting corrective action where it was needed rather than across the study as a whole. As actual enrollment data came in, the platform continuously updated the projected completion date to slightly under 20 months, improving on the original forecast.

## BEYOND THE SINGLE TRIAL:

### THE PORTFOLIO IMPACT

The trial shows how selection, forecasting, and adaptation can work together for a single study run through ZAIDYN®. But the value of connecting these decisions extends beyond a single trial. When the same approach is applied across a portfolio, small improvements at each stage can compound into meaningful gains.

In a representative portfolio of five studies—two Phase 1, two Phase 2, and one Phase 3—with roughly 110 active sites and about 1,200 patients enrolled across them, better selection alone, by avoiding roughly eight of the 110 sites that would never have enrolled a patient, translated into an estimated $300,000 in avoided operational spend.

Better forecasting added an estimated $900,000 in operational cost savings and roughly 30 days saved across the portfolio. Earlier adaptation avoided an estimated $500,000 tied to roughly two substantial protocol amendments. Combined, these improvements represent an estimated $2 million in direct operational savings across the portfolio.

The larger opportunity, though, sits beyond that operational savings figure. In this same representative portfolio, helping the portfolio reach a key readout roughly one month earlier translated into an estimated $18 million in protected timeline value, on top of the $2 million in direct operational savings, for a total estimated portfolio impact of approximately $20 million.

That value does not come from any single decision done well. It comes from consistently selecting better, forecasting more realistically, and adapting sooner across a study's full life cycle, where even modest improvements can compound into meaningful impact at the portfolio level.

### CONCLUSION

Mid-size and emerging pharma companies now drive a significant share of the industry's R&D pipeline. A connected, data-driven planning process can help lean pharma companies evaluate evidence alongside experience, engage CRO partners with clearer assumptions and stronger oversight, select sites with greater confidence, forecast timelines they can defend, and adapt quickly when a study does not go according to plan. The ZAIDYN® clinical platform from ZS Associates supports lean teams across trial workflows, helping connect selection, forecasting, and adaptation into an evidence-based process rather than a series of one-off tasks.

Watch the full on-demand webcast:
**A New Approach to Clinical Trial Planning:**
How Mid and Emerging Pharma Can Take Greater Control of Patient Enrollment
CLICK HERE

