

THE PROACTIVE FEASIBILITY ADVANTAGE:

DESIGNING CLINICAL TRIALS WITH PRECISION FROM DAY ZERO

Dr Jelena Curtius (Barjaktarovic)
Executive Director Feasibility, Patient and Site Engagement

First patient in, last patient out, database lock, and regulatory submission. Clinical research success is often measured in milestones, but the real determinant of success happens long before any of these markers. For sponsors, the answer lies in a single, often overlooked principle: **proactive feasibility**.

Why Traditional Feasibility Falls Short

More than 55% of clinical trials are terminated due to recruitment failures. This is a signal that feasibility is being treated as a checkpoint rather than a strategic foundation. Despite widespread agreement on the importance of feasibility, the industry too often defaults to reactive assessments that confirm what we already suspect: that the protocol may not fit the patient population or site realities.

Reactive feasibility, typically conducted after protocol finalization, places sponsors in a defensive position, reacting to issues as they arise. By contrast, proactive feasibility is a forward-aligned methodology. It anticipates challenges, engages stakeholders early, and integrates data-driven analysis to inform everything from protocol design to site strategy. In essence, it moves feasibility from a report to a roadmap.

The Financial Stakes of Poor Planning

Clinical trials are expensive undertakings, accounting for nearly 40% of the pharmaceutical R&D budget. Oncology trials, in particular, can cost upwards of \$2.6 billion per approved drug, according to the Tufts Center for the Study of Drug Development. Yet many trials still launch without a full understanding of feasibility risks, skipping feasibility to gain time often causes avoidable delays (1).

Consider that 76% of clinical trials undergo at least one protocol amendment (2), with each amendment costing between \$141,000 and \$535,000. Tufts research estimates that nearly a quarter of these changes are preventable. The indirect costs—lost recruitment momentum, resubmissions, reconsenting—are harder to quantify but no less damaging. Sponsors who invest four to six weeks in upfront feasibility routinely avoid these issues.

What Proactive Feasibility Really Means

True proactive feasibility is a multi-dimensional process that begins well before protocol lock. When sponsors involve stakeholders early—investigators, research coordinators, patient advocates, regulatory consultants—they gain insights that are both tactical and transformational. Each voice adds a layer of operational reality to the blueprint.

Advanced modeling can simulate how even modest protocol adjustments might impact recruitment or site participation. One small tweak to an exclusion criterion, identified during early modeling, can dramatically expand

the eligible patient pool without compromising endpoint integrity.

Designing Trials That Work in the Real World

This type of foresight changes how protocols are optimized. Instead of designing in a vacuum, sponsors assess procedure complexity, visit schedules, diagnostic access, and the competitive trial landscape before committing to assumptions. The result is a protocol that's not only scientifically defensible but also executable.

In 2023, the FDA's Center for Drug Evaluation and Research (CDER) emphasized in their guidance on decentralized trials the importance of operational feasibility and patient-centric design—particularly in studies where patient burden and procedural complexity directly impact retention (3).

Smarter Site Selection

Site selection also benefits from this approach. Rather than relying on legacy relationships or prestige site lists, proactive feasibility encourages a match between a site's real-world capabilities and the protocol's specific demands. This minimizes the all-too-common outcome of activating sites that never enroll a patient—still a reality in 11% of U.S.-based clinical sites, according to a 2022 NIH-sponsored analysis (4).

It also respects the site's time and resources, building stronger sponsor-site trust in the process. That trust is not cosmetic—it directly impacts data quality, timeline adherence, and site willingness to prioritize one sponsor's trial over others.

Recruitment Begins Long Before Activation

And perhaps most important of all, recruitment isn't left to chance. Mapping the patient journey, identifying referral barriers, understanding regional access issues—these insights should shape your recruitment plan before your first site goes live. In rare and high-precision indications, such customization can mean the difference between meeting timelines or entering rescue.

Pre-screening patient recruitment vendors, validating site outreach strategies, and exploring novel digital pathways can amplify access to underrepresented populations—an increasingly urgent mandate for many sponsors as they seek to mirror the patient population in clinical trials (5).

The Precision for Medicine Model

At Precision for Medicine, we treat feasibility as a living, breathing element of trial design. From Pre-IND discussions to commercial strategy, our teams use cross-functional data to inform protocol development, select the right countries and sites, and guide recruitment planning. We don't simply ask whether a trial can be done—we define how to do it right.

One sponsor recently approached us after struggling to recruit for a Phase 3 oncology study. The science was strong, but feasibility challenges had been overlooked. Our team identified that the imaging requirements limited site participation. Rather than modifying the protocol in a way that weakened its rigor, we developed a mobile imaging platform that allowed under-resourced but qualified sites to contribute. Recruitment accelerated, and the trial stayed on track.

Prevention Is the Best Strategy

Every protocol amendment, recruitment delay, and underperforming site is an opportunity lost—not just financially, but in time patients can't afford to lose. Proactive feasibility is how we change that. It's how we bring wisdom to the table to position you for success.

The investment you make in thoughtful planning today becomes the foundation that supports your entire team when challenges arise. And they will arise—that's simply the nature of clinical research. The question is whether you'll face them with a solid plan or find yourself building the plane while flying it.

Ready to build a trial strategy that anticipates success from the start?

Let's start the conversation.

Frequently Asked Questions

- 1. How early should proactive feasibility begin?** Ideally, feasibility should begin during protocol concept development—well before finalization. Early insights shape smarter assumptions and avoid mid-trial corrections.
- 2. Does proactive feasibility slow down startup?** Not at all. It may add a few weeks upfront but typically prevents months of downstream delays caused by avoidable amendments or recruitment challenges.
- 3. What stakeholders should be included in feasibility assessments?** Think broadly: investigators, research coordinators, patient advocates, regulatory experts, even payers. Each perspective can flag risks and offer opportunities for better alignment.
- 4. Can this approach work for small biotech with limited budgets?** Yes. In fact, smaller sponsors often benefit most by avoiding expensive missteps. Proactive feasibility is a form of cost avoidance and risk mitigation.
- 5. What makes Precision for Medicine's approach unique?** We integrate feasibility across the full trial lifecycle, combining scientific expertise, lab capabilities, and operational data to shape protocols, sites, and strategies from the outset.

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