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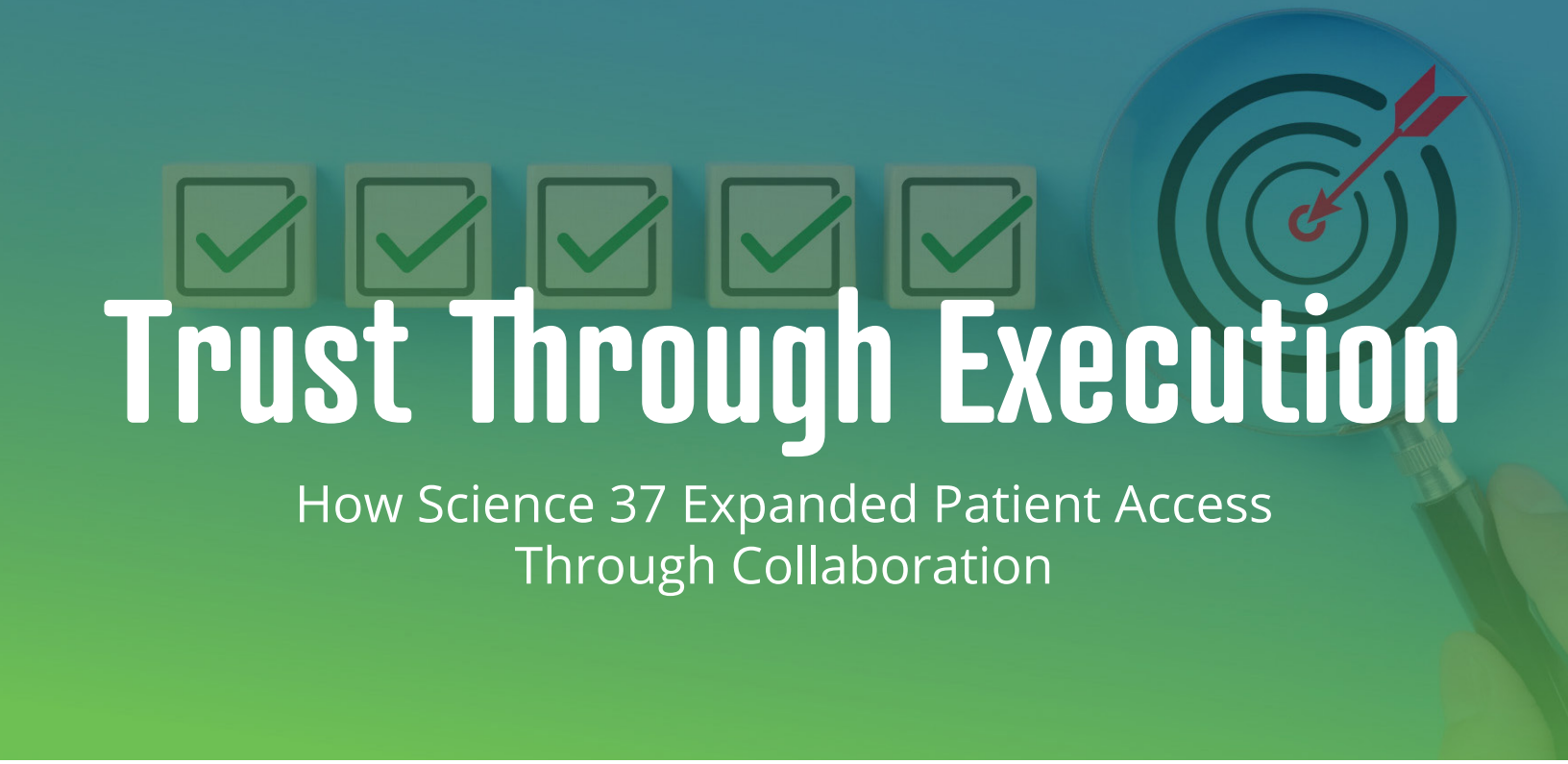

Trust Through Execution

How Science 37 Expanded Patient Access Through Collaboration

For patients participating in rare disease and pediatric studies, clinical trial participation often extends far beyond the clinic visit itself. Travel, caregiving responsibilities, scheduling challenges, and years-long commitments can create significant burdens for patients and their families.

In many pediatric trials, the parent or guardian effectively becomes a "secondary patient," shouldering the intense logistical and financial strain of participation. Additionally, conventional clinical settings can be overstimulating or distressing for children with neurodevelopmental conditions, leading to early dropout or missed data.

Recognizing these challenges, Science 37 set out to explore a different approach.

Operating as a modern direct-to-patient clinical trial site, the organization sought to create a complementary model that expands access to patients traditionally unreachable by brick-and-mortar sites. Through collaboration with patients, caregivers, advocacy organizations, sponsors, CROs, and other research sites, Science 37 has helped demonstrate how patient-centered operational design can improve both the participant experience and study performance.

Executive Leadership Support for a Direct-to-Patient Model

Building a new operational model requires more than technology or process changes. It requires a willingness to challenge assumptions about how clinical research is conducted.

Science 37's leadership recognized that many participation barriers stemmed from the way research had historically been delivered. Rather than expecting every patient to adapt to the demands of a study, the organization explored ways to bring elements of the study experience directly to patients' homes—transforming stressful clinical procedures into manageable tasks within spaces where patients already feel safe and trust.

"Our model can really supplement traditional research sites," said Dr. Debra Weinstein, Chief Medical Officer at Science 37. "We are focused on expanding access, increasing participation, and meeting patients where they are."

This strategic commitment helped guide investments in direct-to-patient and in-home research capabilities while creating alignment across the organization around a shared goal: *reducing patient burden without compromising quality.*

The approach has proven particularly valuable for rare disease and pediatric studies, where participation may span two years or longer. During that time, families may experience changes in employment, insurance coverage, caregiving responsibilities, or living situations. Repeated travel to research sites can create additional stress for patients and caregivers alike.

By focusing on the realities patients face outside the clinic, Science 37's leadership helped establish a model that reaches patients living far outside the geographic catchment areas of traditional sites, offering equitable access to populations who might otherwise be excluded from research opportunities.

Designing Around Patient Needs Through Collaboration

Science 37 knew it could not design its direct-to-patient model without hearing directly from patients, caregivers, and advocacy organizations.

The organization worked closely with patient advocacy organizations, caregivers, patients, sponsors, and operational teams to better understand where traditional participation models created friction. These conversations provided valuable insights into the challenges patients face and helped identify opportunities to reduce burden while maintaining the rigor required for clinical research.

For pediatric patients, repeated site visits can be disruptive and stressful. For rare disease communities, travel to specialized research centers may require significant time and financial resources. Caregivers often shoulder additional responsibilities, balancing work, family obligations, and study participation.

"Patients are experts in their own experience," said Mindy Cameron, Patient Advocacy Lead. "When we listen to patients and caregivers, we learn how to design studies that are more practical and sustainable."

Through its collaboration, Science 37 was able to fully understand these realities and design programs better. This led to programs that aligned more closely with how patients live their daily lives—such as utilizing a "play-first" protocol to build trust with pediatric patients in their own homes, or sending dual-nurse teams to support families with multiple children enrolled in the same rare disease study.

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Building Sponsor Trust Through Information Governance

While patients and caregivers quickly understood the potential benefits of in-home participation, sponsors understandably sought to better understand how a direct-to-patient approach would maintain oversight, data quality, and operational consistency.

Science 37 found that building confidence required transparency, discipline, and a commitment to setting realistic expectations.

Rather than positioning its direct-to-patient site as a solution for every study, the organization focused on helping sponsors understand where the model could provide value and how it fit within the broader clinical trial ecosystem. Teams worked to establish clear operational processes, engage quality stakeholders early, and demonstrate consistency through execution.

"Trust is built through success," said Weinstein. "The more we demonstrate strong outcomes, quality data, and positive patient experiences, the more confidence sponsors have in the model."

Trust was built gradually through successful study delivery, consistent inspection outcomes, and demonstrated operational performance across more than 200 clinical trials. To date, Science 37 has successfully completed multiple FDA inspections with No Action Indicated (NAI) classifications and zero Form 483 observations.

Importantly, sponsors increasingly recognize that direct-to-patient approaches are not about replacing traditional site relationships. Rather, they can provide additional pathways to reach and retain patients who may otherwise face barriers to participation.

The Operational Impact of Collaboration

As sponsors, patients, advocacy organizations, and operational partners became more familiar with the model, measurable outcomes began to emerge.

Science 37 reported success in enrolling patients more quickly, retaining participants through lengthy studies, and expanding access to individuals who may not otherwise have had the opportunity to participate in research.

These observations are supported by broader industry research. **A recent analysis** conducted by Science 37 and the Tufts Center for the Study of Drug Development (Tufts CSDD) found that Science 37's direct-to-patient site achieved an 86.3% participant completion rate compared with a traditional site benchmark of 35.7%. Studies reached database lock an average of 121 days faster and enrolled nearly three times more Black participants than traditional site benchmarks. These findings suggest that reducing patient burden can simultaneously improve retention, accelerate study timelines, and expand representation.

The findings reinforce what Science 37 has seen in practice: when organizations reduce burden for patients, enrollment, retention, and study performance often improve as well.

For sponsors, sites, and CROs, the findings reinforce an important lesson: collaboration can create measurable operational value. Whether through engaging patients earlier, reducing participation burden, or incorporating operational expertise into study design, collaborative approaches can improve both participant experience and study performance.

The future of clinical research is unlikely to be defined by traditional sites or decentralized approaches alone. Instead, organizations across the ecosystem have an opportunity to explore collaborative models that combine the strengths of both, expanding access while maintaining the trusted relationships sites have built within their communities.

Looking Ahead: Bringing Collaboration Earlier into Protocol Design

As direct-to-patient models continue to gain acceptance, Science 37 sees an opportunity to engage even earlier in the clinical development process.

Historically, Principal Investigators (PIs) and operational partners have often been asked to operationalize protocols after key decisions have already been made.

Increasingly, Science 37 is collaborating during protocol development and feasibility planning, helping sponsors evaluate patient burden, operational considerations, and safety oversight before studies begin.

"Many of the barriers that affect enrollment and retention are designed into studies long before the first patient is recruited," said Kelly McKee, VP of Strategy & Transformation. "When operational teams, investigators, and patient representatives are brought into protocol discussions earlier, sponsors have an opportunity to proactively reduce burden rather than trying to solve those challenges after startup."

For sponsors, CROs and operational teams, this shift offers a significant opportunity. Operational flexibility is far easier to build into a study during protocol design than it is to retrofit after startup activities are underway. Early collaboration can help identify potential barriers, reduce the need for protocol amendments, and improve feasibility assessments before studies launch.

The earlier engagement can accelerate startup activities, and create a smoother experience for patients, sites, sponsors, and operational partners alike.

It also reflects a broader shift occurring across the industry. The most successful collaborations are increasingly happening before challenges emerge, not after.

As sponsors become more comfortable with direct-to-patient approaches, Science 37 has found that demonstrated outcomes often lead to deeper engagement. As the clinical research industry continues to evolve, the question is becoming less about whether direct-to-patient approaches can work and more about where they can create the greatest value. Science 37's experience suggests that when patients, investigators, advocacy groups, sponsors, and operational teams collaborate early and execute consistently, expanding access and maintaining quality are not competing goals. They are mutually reinforcing outcomes.

The findings reinforce what Science 37 has seen in practice: when organizations reduce burden for patients, enrollment, retention, and study performance often improve as well.

Collaborate Forward Takeaways

- **Start with the patient:** Effective innovation begins by collaborating with the patients, caregivers, and advocacy groups most affected by the geographic and logistical barriers of traditional research.
- **Embed operational flexibility early:** Bringing PIs and operational partners into study design discussions reduces friction and prevents costly protocol amendments.
- **Trust requires data-backed execution:**Transparency, realistic expectations, and proven compliance build the sponsor confidence needed to adopt new models.
- **Oversight is about governance, not geography:** Strong collaboration requires clear information sharing, governance, and accountability across stakeholders.
- **Adapt through continuous feedback:** Internal and external feedback loops help organizations refine protocols and continuously improve the patient experience.
- **Measure what matters:** Collaboration is most powerful when it translates into measurable improvements for patients, sites, sponsors, and study performance.

Participating from Science 37

- **Mindy Cameron**, Patient Advocacy Lead
- **Kelly McKee**, VP of Strategy & Transformation
- **Dr. Debra Weinstein**, Chief Medical Officer

Additional Resource

Science 37 and the Tufts Center for the Study of Drug Development's analysis, **"Direct-to-Patient Clinical Trial Site Access and Patient Representation,"** was published in *Applied Clinical Trials*.

Science 37®

Disclaimer: The information presented reflects Science 37's experience and observations across studies utilizing its direct-to-patient clinical trial model. Certain performance metrics referenced herein are based on a retrospective analysis conducted jointly by Science 37 and the Tufts Center for the Study of Drug Development (Tufts CSDD) and should not be interpreted as guarantees of future performance or outcomes. Individual study results may vary significantly based on protocol design, therapeutic area, patient population, sponsor requirements, operational considerations, and other factors.

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