

The Power of
Forward

ANNUAL REPORT 2025

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For a shorter, interactive version of this report, view the [2025 Annual Report Story Stream](#).

A Message from CEO Janice Chang

What stood out to me most about 2025 was how quickly the right kind of work can show results—while also laying the foundations that compound over time. We delivered progress that was both immediate and enduring, turning complex ideas into practical tools.

We are not only imagining a bold new future for patients—we are actively building that future together as TransCelerate.

This is what we call “The Power of *Forward*.” Forward is not only about near-term outcomes, but also about creating the conditions for future breakthroughs. It is the steady, collective work of developing frameworks, processes and practices that will open doors to a new era of clinical research and, ultimately, better outcomes for patients.

Over the past year, I’ve seen this power in action. We **strengthened dialogue with global health authorities**, finding common ground on some of the toughest challenges in the development of new medicines. We **deepened our commitment to patient-focused research** with tools that help reduce burdens and open up access to trials. And we worked to **broaden adoption of solutions that strengthen data flow** and use across the ecosystem, supporting smarter, simpler study design.

Each of these steps matters on its own, and together, they create momentum that shortens the time from scientific insight to patient access. Looking ahead, TransCelerate will continue to serve as a trusted catalyst, doing the hard work to support stakeholders, spark innovation and prepare the ecosystem for the next wave of change.

Together, we carry forward the progress of 2025 into the future we are building—one where clinical research and patient care are seamlessly connected, and where solutions reach the communities and individuals whose health depends on them.

Sincerely,



Janice Chang



The Power of *Forward*: Our Vision and How We Delivered in 2025

In 2025, the pressures on pharmaceutical R&D intensified. The cost and complexity of clinical trials continued to rise. Regulators emphasized design quality and diversity, while patients expected faster, more inclusive access and transparency. Yet instead of slowing progress, these challenges lit a spark. The experience made clear that overcoming challenges in drug development cannot be carried by any one company or entity. It demands agility in how we connect, boldness in what we pursue and trust in how we work together.

The Power of *Forward* is about progress on two fronts: delivering real, near-term results while steadily reshaping the ecosystem for lasting change. Our vision is bold but clear: a future where research and care move as one, where taking part in a study feels like a natural part of healthcare processes and where medicines reach people faster.

Momentum Markers

Here are just a few of the ways progress moved forward in 2025:

Digital Data Flow (DDF)

By September, **a majority of our member companies had shared that they were making progress in their DDF** implementation efforts, signifying a major turning point.

ICH E6(R3)

TransCelerate released **15 practical tools** to support adoption of the long-anticipated Good Clinical Practice revisions. Interest was strong, with nearly **2,000 registrants** for our flagship webinar, and multiple publications—from *Citeline* to *Medicine Maker*—covering the launch.

Clinical Data Sharing

Usage of our DataCelerate platform **more than doubled** from the previous year. **Peer-reviewed journals published additional member-authored articles** in 2025, with **more than 10** further manuscripts in review, highlighting growing scientific value from shared datasets.

Patient Safety Reporting

Seven health authorities across three continents actively engaged in dialogue with us on modernizing individual case safety reporting. A *Drug Safety* manuscript on the topic ranked among the journal's top five most-read pieces in 2025, reinforcing global resonance.

Embedded Pragmatic Trials

With the FDA's Center for Drug Evaluation and Research (CDER) Complex Clinical Trials Initiative (C3TI), TransCelerate **released a public summary of a joint tabletop exercise** to explore how pragmatic elements can be applied in practice. Separately, TransCelerate published a resource guide to help sponsors consider and scale embedded pragmatic elements.

TransCelerate Today: Groundwork for Global Progress

The strides we made in 2025 didn't happen by chance. They happened because TransCelerate provides a place where biopharma organizations can work side by side, share resources and tackle common problems.

Our reach today reflects more than a decade of sustained commitment and tremendous effort:

18

global member companies
shaping our work

500k+

solution downloads across
100+ countries

200+

health authority
engagements worldwide

50+

collaborations across four
continents

The power of TransCelerate lies in who's at the table. We combine member company knowledge with regulatory guidance, technology innovation, site experience and patient perspectives to take on the real problems: stretched resources, increasing therapeutic and scientific complexity, changing regulations and the urgent need for streamlined trial design.

Rising to the Challenges of R&D in 2025

The reality of biopharma R&D today is a system stretched between scientific potential and operational friction, with complexity mounting faster than organizations can adapt. In 2025, we saw clear signs that these challenges, while significant, can be reimagined, reshaped and steadily overcome.

CHALLENGE

Complex and Inefficient Protocol Design

Clinical trial protocols remain one of the most persistent pressure points in drug development. They often grow in scope and complexity, which can add stress for sites and make participation harder for patients. In 2025, there was broad acknowledgment among sponsors and regulators that protocol complexity had become unsustainable—along with a clear movement toward action, exemplified by ICH E6(R3) and practical tools supporting simpler, risk-proportionate approaches.

The release of [15 new resources to support adoption of ICH E6\(R3\)](#) was a major step in that direction. These tools, including implementation guides, case studies and templates, help teams translate ICH E6(R3) into practice; not just to navigate a regulatory update, but to enable more streamlined, proportionate trial conduct that preserves rigor while reducing burden.

At the same time, the [Optimizing Data Collection](#) initiative—in collaboration with the Tufts Center for the Study of Drug Development (CSDD)—[published a benchmarking study](#) spanning more than 100 protocols from 14 member companies.

The study offered one of the clearest pictures yet of data collection, revealing opportunities to reduce participant and site burden in clinical trials through smarter, more efficient data collection. The findings set the stage for practical tools in 2026.

CHALLENGE

Inefficient Information Flow and Data Management

Clinical research generates enormous volumes of data, yet much of it remains siloed or underused. This slows progress, limits the ability to make confident decisions and misses opportunities to maximize the value of existing data. In 2025, we saw growing momentum toward digitized, automated approaches that not only reduce redundancy, but also make information more reusable, interoperable and impactful across the ecosystem.

A centerpiece of this progress was the continued advancement of **DDF**. Digitizing protocols are enabling interoperability and automation. By September, a majority of our member companies had shared that they were making progress in their DDF implementation efforts, a key indicator of momentum.

Beyond membership, positive ecosystem signals were apparent: Our **Mission Possible** event reached capacity with waitlists in the U.S. and Europe, and vendors continued building to CDISC's Unified Study Definition Model (USDM). Together, these are strong indicators that progress is accelerating across the ecosystem.

This work is tightly linked to the development of digital protocol standards. Through collaborations around ICH M11 and FDA's PRISM initiative, TransCelerate and its members contributed expertise that is shaping how digitized protocols will be structured, shared and ultimately submitted to regulators. These efforts are positioning the industry for an era when protocol information can flow cleanly between research and care systems, accelerating both study start-up and regulatory review.

At the same time, our **Clinical Data Sharing** platform saw reported usage more than double compared to 2024, with member-authored publications demonstrating how responsible reuse of patient-level data can improve study design while honoring patient contributions by using data to its fullest potential.

High failure rates in clinical development highlighted an opportunity to discover concerns earlier in the lifecycle. Our **Enabling Translational Safety** initiative advanced an important public-private partnership with FDA, making strides toward developing a terminology translation tool to enable linking of preclinical and clinical data. This work is intended to maximize the value of data that already exists, connecting preclinical and clinical insights in ways that improve translational safety and strengthen confidence in early decision-making.

CHALLENGE

Complexity in Assessing Patient Safety Reporting

Managing safety data is among the most resource-intensive aspects of drug development—essential for protecting patients, yet often slowed by redundant processes and fragmented global requirements. Over the past year, TransCelerate and its members set out to change that story, working directly with regulators to explore options to simplify while keeping the spotlight where it belongs: on protecting patients.

A major focus was **Modernizing ICSR Management**. Seven health authorities across three continents actively engaged in dialogue on what a simplified, modernized model could look like for managing individual case safety reports (ICSRs).

These discussions reflected a shared recognition that today's processes often make it harder, not easier, to detect safety signals. By exploring opportunities for a more efficient model, a determined cohort is working towards a future where safety data are more timely, consistent and actionable.

Alongside this, TransCelerate advanced the **Interpretation of Pharmacovigilance Guidances and Regulations** effort with two new publications—one focused on maternal health, the other on digital health. Both highlighted how safety monitoring must evolve to reflect the realities of modern medicine and diverse patient populations.

Finally, the role of **Real World Data (RWD)** in pharmacovigilance came into sharper focus. A survey of more than 30 organizations published last year identified persistent barriers to RWD access and use for safety purposes.

CHALLENGE

Limited Real-World Applicability of Traditional Trials

In 2025, the focus shifted from an “all-pragmatic” mindset—which often felt overwhelming and difficult to implement in full—to a more modular approach focused on incorporating pragmatic elements more selectively. The objective remained the same: to simplify trials, broaden access and accelerate enrollment. With the **Embedded Pragmatic Clinical Trials initiative**, TransCelerate is equipping the ecosystem to make further progress—clarifying what’s feasible now and how to scale what works.

One example was the **tabletop exercise with FDA/CDER**, where TransCelerate and regulators worked through scenarios to test how pragmatic trial elements could be applied in practice. The dialogue reinforced that pragmatic approaches can be both rigorous and feasible, while helping sponsors address long-standing barriers in recruitment and design.

Separately, TransCelerate published a **resource guide** to support companies considering pragmatic trial elements. This guide offers practical direction for teams seeking to integrate real-world practices into traditional studies, which is a critical step toward building broader confidence in these approaches.

The forward motion was evident in pharmacovigilance, too. New templates for **Rapid Signal Assessment using RWD** were introduced to streamline safety signal detection. These resources demonstrate how existing healthcare data can be applied to safeguard patients and inform regulatory decisions more quickly.

TransCelerate is equipping the ecosystem to make further progress—clarifying what’s feasible now and how to scale what works.

CHALLENGE

Advancing Human-Centered Clinical Trials

Every initiative at TransCelerate ultimately exists to benefit patients, but some efforts bring that impact closer to the surface. The focus on human-centered trial design took a step in the right direction with new resources aimed squarely at reducing burden and expanding equity.

The **Modernizing Clinical Trial Conduct** initiative delivered four new outputs in 2025, each designed to bring the perspectives of patients and sites more directly into the research process. Among the updates were enhancements to the **Patient Protocol Engagement Toolkit**, giving study teams resources to obtain patient input earlier in design. Complementary feedback surveys offered opportunities for real-world insights into participant and site experiences, helping sponsors understand where protocols create friction and where they might be simplified.



TransCelerate ultimately exists to benefit patients, but some efforts bring that impact closer to the surface.

Working Together for Impact

Our impact is magnified when we move forward together—with members, partners, regulators and thought leaders across the globe. In 2025, that collective spirit ignited new collaborations, deepened health authority engagement and drove bold leadership.

Tackling Complex Questions with Tufts

Our partnership with Tufts CSDD stands as a proof point of how collaboration can identify practical opportunities to simplify. Together, we benchmarked study data collection across the industry, generating evidence that is informing the development of resources to support more efficient and patient-friendly trials.

“TransCelerate has built an outstanding reputation for focusing on big, highly relevant challenges and opportunities in drug development. Through its collaboration with Tufts CSDD, TransCelerate and its member companies made it possible to conduct a robust, empirical study that not only quantifies the magnitude of the problem but also establishes clear and practical opportunities to optimize clinical trial data collection and reduce participant and investigative site burden. A passion to go all in on tackling difficult, industry-wide issues lies at the heart of TransCelerate and contributes greatly to global advances and improvements in drug development.”



Ken Getz
Executive Director, Tufts Center
for the Study of Drug Development



Global Dialogue with Health Authorities

In 2025, TransCelerate sustained broad engagement with regulators worldwide:

More than 15 active discussions with health authorities across three continents on topics of shared interest

Supported implementation of two ICH new guidances critical to the future of clinical trials

FDA's PRISM M-11 pilot showcased how digital protocol data standards, developed with our thought leadership and financial support, are being applied in regulatory practice

Years of consistent dialogue are yielding results—reducing burden and strengthening the global R&D community.

“TransCelerate’s work in harmonising standards and improving data exchange has strengthened collaboration between regulators and industry. At BfArM, we value these efforts and share the goal of advancing a more connected, efficient, and patient-centered clinical research environment across Europe.”



Prof. Dr. Karl Broich
President, Federal Institute
for Drugs and Medical Devices
BfArM



Reflecting on the Journey, Shaping the Future

Last year’s founders’ gathering reunited senior R&D leaders who launched TransCelerate more than a decade ago. Their reflections reinforce our determination to tackle what’s next. Watch the [video](#) to hear how early bets became today’s building blocks, and why the next wave of hard work matters now more than ever.

Extending Our Reach

From Basel to Buenos Aires, Zurich to Tokyo, TransCelerate's presence across international forums continued to expand:

HIGH ENGAGEMENT

Our 2025 webinars drew more than **7,000 registrants**, reflecting strong demand for practical guidance.

AMPLIFIED VOICE

Featured in **50+ publications and media stories** throughout 2025:

- *Fierce Biotech* coverage of the [Tufts CSDD collaboration](#) to benchmark data collection practices
- *MedCity News* and *PharmaTimes* on advancing [women's health](#) and the need for [inclusive research](#)
- [Applied Clinical Trials](#) coverage of SCOPE 2025, featuring CEO Janice Chang on the future of converging research and care
- *Clinical Leader* features and bylines on [bridging research and care](#), [ICH E6\(R3\)](#) and [pragmatic trials](#)

GLOBAL FOOTPRINT

Shared insights at **20+** key conferences, including **The State of Clinical Trials: Charting the Path to 2030 (Washington, DC)**, **SCOPE Europe (Barcelona)**, **DIA Japan (Tokyo)** and **Society of Clinical Data Management EMEA25 (Brussels)**, alongside events in Singapore, Canada and Latin America.



Scale That Enables Impact

Every year, TransCelerate’s member companies invest more than \$130 billion in R&D.

That scale of commitment underpins everything we do, and highlights the importance of our work to resolve common problems that slow the delivery of new medicines to patients.



“ In 2025, TransCelerate once again demonstrated the power of collaboration to accelerate simplification in clinical research. The body of work advanced last year delivered swift support on near-term needs while still building momentum on longer-term transformative opportunities. No single company could achieve alone what we are accomplishing together, and I am proud to guide the effort.”



Dr. Eliav Barr

Senior Vice President, Head of Global Clinical Development and Chief Medical Officer, MSD; Chair, TransCelerate Board of Directors



“ *Innovation in pharmaceutical development must address today’s needs and tomorrow’s patient care. By forging meaningful collaborations, we can enable patient-centric and faster clinical development for better long-term outcomes. My vision for TransCelerate is to continue building a focused framework that drives our ambition forward within an ever-evolving environment.*”



Lykke Hinsch Gylvin
Chief Medical Officer, Head of Global Medicine,
Boehringer Ingelheim; TransCelerate Board Director



Our publicly available tools often create second-order benefits. In some regions, NGOs have adapted them to help establish clinical sites where research access has historically been limited, showing the broader ripple effect of shared solutions.

“ *TransCelerate’s site education toolkits have revolutionized research in the Middle East and across the African continent. We are thrilled to be using these same materials to help improve healthcare through our partnership with the Pan African Parliament and engagement with payers, physicians and patients.*”



Mimi Choon-Quñones
Founder & Board Chair, Partners for Patients NGO;
Pan African Parliament Honorary Ambassador for
Public Health and Global Health



What's Next: The Power of *Forward*

2025 was a year of proof and progress. TransCelerate demonstrated that even entrenched challenges can be translated into solutions the industry can use today. That validation creates the momentum to aim higher, building on these foundations to deliver even greater impact in the years ahead.

The next chapter is already unfolding, and TransCelerate is poised to:

➤ **HELP ENABLE DIGITAL PROTOCOLS FOR REGULATORY USE**

With the DDF initiative and CDISC's USDM standard aligned to ICH M11, sponsors and regulators can move from document-based to fully digital protocols, streamlining everything from authoring to submission.

➤ **LEVERAGE EHRs TO BENEFIT PATIENTS**

The next horizon includes linking digital protocols with EHRs to make trial participation a more natural extension of care—improving feasibility, representativeness and patient experience.

➤ **DRIVE MORE PROGRESS THROUGH SHARED LEARNING**

New collaborative forums to build on learnings and foster a culture of experimentation, knowing not every attempt will succeed. The courage to test, adapt and keep pushing is how lasting change is made.

The Power of *Forward* is the courage to imagine better, the will to act together and the persistence to keep going. With that spirit, TransCelerate and its partners will continue to transform challenges into progress, and progress into impact.

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