THINKING BIGGER, **ACTING BOLDER**

TRANSCELERATE'S 2024 ANNUAL REPORT

TransCelerate BIOPHARMA INC.

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For a shorter, interactive version of this report, view the **2024 Annual Report Story Stream.**

A MESSAGE FROM

CEO Janice Chang

As I reflect on another transformative year at TransCelerate, I'm filled with immense pride in our collective achievements and a deep sense of purpose for the work ahead.

Our journey in 2024 was defined by our efforts to turn bold visions into tangible actions, deliver solutions to reshape the R&D ecosystem and, most importantly, improve patients' lives. But as I share our progress, I can't help but think of why this mission is so personal to me—and likely to many of you.

Years ago, I lost my father far too early. I often wonder if a clinical trial or new medication had been available, and accessible to him as a non-English speaking immigrant, could he still be with us today? This thought fuels my passion for our work at TransCelerate, and I know my story isn't unique. Most of us can imagine a "what if" scenario for a loved one, and that shared experience is why we do what we do as an organization.

It's with this personal understanding of the urgency of our mission that I look at what we accomplished this year. We made our first strides toward an important objective: **the convergence of clinical research and clinical care.** To move us closer to our goal, we realigned our portfolio to focus on:

1. **Transforming Connectivity**
2. **Information Sharing & Reuse**
3. **Innovative Trial Design**

These aren't just strategic targets—they are our commitment to every patient waiting for a breakthrough, to every family hoping for more time with their loved ones.

As we look to the future, I'm filled with both courage and optimism. The challenges ahead are significant, but so is our resolve. We've made tough calls on where to focus and which new paths to forge, and these decisions have only sharpened our impact.

As always, thank you for your continued support and partnership. Together, we're building a better future for clinical research.

Sincerely,

Janice Chang

EXECUTIVE SUMMARY

Thinking Bigger to Address Systemic Challenges

Bringing new medicines to market is a long and rigorous journey for pharmaceutical companies, requiring an average of **12 years** of research and development. Misalignment between clinical trials and care delivery reduces patient access, while the complexity of the trial process, though essential, can slow progress.

*At TransCelerate, we believe that to truly accelerate innovation, we need to **think bigger.***

We envision a future where clinical research and patient care are seamlessly connected—where participating in research becomes a natural part of the healthcare journey for patients and practitioners alike. A future where vital information about clinical trials is easily accessible to those who need it most. And where life-saving medicines reach patients faster, safer and more effectively than ever before.

Thinking bigger means tackling systemic challenges head-on, but it also entails delivering pragmatic solutions that address the immediate needs of the R&D ecosystem. This balance allows us to pursue long-term transformation while ensuring we continue to solve critical issues that make a difference today.

Our Path Forward: Three Key Focus Areas

One year ago, we identified three key focus areas that have since gained even more momentum—and will continue to serve as our North Star as we push forward:

TRANSFORMING CONNECTIVITY

We're redefining how the various components of clinical research interact. By breaking down silos and facilitating seamless communication, we're creating a more integrated and efficient ecosystem that benefits everyone involved, from researchers to clinicians to patients.

INFORMATION SHARING & REUSE

We're unlocking the potential of essential data. By collecting data with greater focus on patient needs and developing new ways to share and repurpose it, we're accelerating discoveries and reducing redundancy in research efforts, all while maintaining strong data security standards.

INNOVATIVE TRIAL DESIGN

We're working to put patients at the heart of clinical trials. By redesigning studies to better align with real-world patient experiences, we're making participation more accessible and meaningful, ultimately leading to more relevant and impactful research outcomes.

Tackling Ecosystem-Wide Challenges

These focus areas aren't just about fixing problems — they're about thinking bigger to break down systemic barriers in clinical research by:

- Simplifying the clinical development process
- Expanding patient access to trials
- Boosting data quality and usability throughout drug development
- Accelerating study startups and improving overall efficiency

TRANSCELERATE

Catalyst for Clinical Research Progress

When TransCelerate BioPharma Inc. was founded in 2012, we set out with a bold ambition: to create a new model of collaboration focused on transforming drug development to accelerate answers for patients. Drawing inspiration from successful consortia in aviation, banking and semiconductors, we crafted a unique model designed to transform the clinical research ecosystem.

From our early efforts, TransCelerate has experienced exceptional growth.

20+

Expanded to 20+ member companies, representing the vanguard of global biopharmaceutical innovation. We're pleased to welcome Gilead, who joined our consortium in early 2024, further strengthening our collaborative efforts.

15

Led 15 active initiatives in 2024, a testament to our early success, allowing us to take on increasingly complex challenges.

570+

Delivered over 570 tools and solutions in the past 12 years, each designed to drive efficiency, effectiveness and quality in new medicine development.

Our proven success in delivering and implementing high-impact solutions has built a foundation for growth, empowering us to tackle increasingly ambitious challenges across the R&D spectrum while creating measurable value for stakeholders.

Board Commitment to Our Mission

Our board of directors, composed of senior leaders from member companies, demonstrates unshakable commitment to our mission. These leaders dedicate significant time and resources to TransCelerate, balancing their responsibilities with demanding roles in their respective organizations. This level of engagement reflects the importance they place on our mission and the potential they see in our collaborative approach.

"The mission of TransCelerate and the role we can collectively play in advancing positive change has never been more important. With the strategic direction that we have set and our track record of delivering tangible, meaningful solutions, I am extremely confident about what we can accomplish next."

Robert Metcalf
Group Vice President, CDDA,
China & Japan Medical, Eli Lilly & Co.

"We look forward to continuing to reduce unnecessary barriers to the conduct of clinical trials and the implementation of the innovations that our patients desperately need. TransCelerate has facilitated tremendous progress in clinical research and we are eager to continue on this journey."

Eliav Barr
Senior Vice President, Head of
Global Clinical Development and
Chief Medical Officer, MSD

"I echo the many voices from the board in full support of TransCelerate going forward: Our vision and strategy and the related implementation efforts will continue to deeply impact the future of clinical development, pharmacovigilance and all areas touched by the TransCelerate teams."

Iris Loew-Friedrich
Executive Vice President
and Chief Medical Officer, UCB S.A.

Transforming Member Companies from Within

At the heart of TransCelerate's success are our member companies, collectively investing over **$125 billion annually** in R&D to bring new medicines to market. Our impact resonates deeply within these organizations, with **more than 700 benefits** reported across categories including efficiency, quality and speed.

The widespread adoption of our solutions shows their value. Both mature and newer initiatives have achieved **75% or higher adoption rates** among our member base in recent years, demonstrating the enduring relevance of our efforts.

Thomas Senderovitz, Senior Vice President at Novo Nordisk, articulates the value of our collective work:

"As part of TransCelerate, Novo Nordisk benefits from a collaborative network of industry leaders, committed to knowledge sharing and innovation, which significantly enhances our ability to efficiently respond to challenges."

This commitment is reflected across our membership through their active participation in initiative teams, conference presentations and collaborative summits.

Tackling Key R&D Ecosystem Challenges

From streamlining complex processes and leveraging untapped data resources to enhancing patient safety reporting and advancing patient-centered trial designs, each of our initiatives represents a step toward a more efficient, effective and patient-focused R&D ecosystem.

CHALLENGE

Inefficient Information Flow and Data Management

The journey of new treatments to patients is frequently delayed by clinical trial bottlenecks, stemming from fragmented information systems and complex data management challenges. Through the **Clinical Content & Reuse (CC&R)** initiative, we aim to harmonize protocol structure and provide model content, enabling seamless reuse and traceability throughout the trial lifecycle. This work is being amplified by the **Digital Data Flow (DDF)** initiative, which is working to enable a data-centric approach that moves beyond traditional and error-prone document-based processes.

While CC&R's 2024 release further advances content reusability to improve document creation and interpretation, DDF leverages this foundation to advance protocol digitalization. Together, these initiatives create a more efficient clinical trial ecosystem, promising improved cycle times, better data quality and enhanced information accessibility — from sponsors and sites to regulators and patients.

CHALLENGE

Unrealized Value of Existing Data

The biopharmaceutical sector faces an ongoing challenge: Valuable data remains trapped in silos, hindering scientific decision-making and therapeutic advances. To address this, we have focused several efforts on improving the utility of critical data.

At the preclinical stage, the **BioCelerate Toxicology Data Sharing** initiative leverages the DataCelerate platform to create a shared repository of toxicology data, while the **Enabling Translational Safety (ETS)** initiative, in partnership

with health authorities, establishes crucial feedback loops between preclinical and clinical data to improve trial success rates. In addition to these efforts, the **Privacy Methodology for Data Sharing** initiative helps companies develop their own approaches to data anonymization while preserving data quality, and the **Historical Trial Data (HTD) Sharing** program enables secure data reuse for several use cases, including to improve study design and reduce placebo use. The combined impact is transforming how stakeholders use essential data to accelerate drug development, enhance patient experiences and advance scientific understanding.

CHALLENGE

Complexity in Monitoring and Assessing Patient Safety

The global nature of drug development, with its diverse international regulations and region-specific guidance, creates significant challenges in patient safety monitoring. TransCelerate is modernizing these complexities through strategic efforts such as the **Interpretation of Pharmacovigilance Guidances & Regulations** initiative, which focuses on developing resources for emerging areas like digital health technologies and maternal health trials.

This work is enhanced by the **Pharmacovigilance Agreements Optimization** initiative, which provides a suite of customizable solutions to help organizations streamline their end-to-end pharmacovigilance agreement processes. Meanwhile, the **Intelligent Automation Opportunities in Pharmacovigilance** initiative harnesses automation to help transform safety data handling. Rounding out these projects, the **Modernizing ICSR Management** initiative is reimagining how Individual Case Safety Reports are processed. These programs collectively help to advance global patient safety monitoring while improving operational efficiency and regulatory compliance across the ecosystem.

CHALLENGE

Limited Real-World Applicability of Traditional Trials

The controlled nature of traditional clinical trials, coupled with the complex regulatory environment surrounding the use of real-world evidence, limits the translation of research findings into practical, patient-centered healthcare solutions. TransCelerate is bridging this gap through initiatives that evolve trial design and data utilization.

The **Electronic Health Record (EHR) Connectivity** initiative aims to seamlessly integrate clinical research with patient care systems, while the **Real World Data (RWD) Audit Readiness** initiative developed tools and methodologies to strengthen the credibility of real-world data in regulatory submissions. These foundational efforts are complemented by the **Rapid Signal Assessment Using RWD** initiative, which is working to accelerate safety signal assessments through real-world data analysis, and the **Embedded Pragmatic Clinical Trials** initiative, which focuses on creating resources and best practices to better integrate research into routine care settings. Through this multi-faceted approach, TransCelerate is helping to transform clinical research into a more practical, patient-centered pursuit.

CHALLENGE

Advancing Patient-Centered Clinical Trials

Clinical trials often face challenges in prioritizing patient needs, with complex protocols and burdensome requirements creating barriers to diverse participation and meaningful engagement. TransCelerate addresses this through initiatives that re-envision the trial experience from multiple angles.

The **Diversity of Participants in Clinical Trials** initiative, established in 2014 and revitalized in 2020, has laid crucial groundwork through recruitment best practices and community engagement tools, with diversity remaining a central priority that will shape future TransCelerate work. This commitment to accessibility is strengthened by the **Optimizing Data Collection** initiative, which is benchmarking current data collection practices to identify opportunities and approaches to reduce patient burden and protocol complexity.

The **Participant Data Return** initiative is intent on further enhancing engagement by equipping sponsors with resources to share individual results with trial participants, while the **Modernizing Clinical Trial Conduct** initiative is focused on enabling uptake of patient-friendly technologies like telemedicine to increase flexibility while maintaining safety and data integrity. Together, these efforts are reshaping clinical trials to be more accessible, efficient and genuinely patient-centered.

The work is important, filled with victories and setbacks, but our resilience and belief keep us moving forward.

Fostering Collaboration Across the R&D Ecosystem

This year, we reinforced our collaborative efforts, and took on challenges that no single organization could address alone. By thinking bigger and fostering partnerships beyond traditional boundaries, we're creating a more interconnected and efficient R&D ecosystem.

Key Collaborations in Action

Association of Clinical Research Organizations (ACRO)

We jointly developed tools to support the implementation of new Good Clinical Practice guidelines.

EU-PEARL

We partnered with the Innovative Medicine Institute to advance the future of master protocol template design and platform trial research.

CDISC and HL7 Vulcan

CDISC, with our support, is developing standards for clinical data, while our collaboration with HL7 Vulcan focuses on healthcare data standardization. These efforts are fundamental to our Digital Data Flow initiative, striving to connect the dots between research and care.

Engaging Health Authorities

TransCelerate's mission often intersects with the goals of global health authorities, creating natural opportunities for productive collaboration.

Over the years, we have engaged with more than 18 health authorities worldwide. Our ongoing interactions with health authorities focus on areas of mutual concern, such as enhancing patient safety, improving clinical trial efficiency and promoting data quality. The impact of these collaborations is evident in the words of Dr. Janet Woodcock, former Deputy FDA Commissioner:

"TransCelerate has led the way in showing the tremendous benefits of collaboration, solving both enduring problems and stepping up in emergencies."

In 2024, we made significant strides in enhancing our engagement with health authorities in support of meaningful outcomes. Some highlights:

- **Active participation alongside health authorities at conferences and public events.** This included robust discussion with representatives from MHRA and the Netherlands Pharmacovigilance Center on case reporting transmission, the impact of replication, and the potential to improve drug safety assessment by modernizing ICSR management.
- **Development of thought leadership on topics of shared interest.** We published a paper on sponsor experiences implementing decentralized clinical trial elements and were able to provide health authorities with additional insights and answer questions related to this work.
- **Assembling and sharing data, metrics and real-world use cases.** Our neutral platform has repeatedly enabled us to collect and share evidence in support of enhanced decision-making and better outcomes.

By facilitating communication between sponsor leaders and regulatory bodies worldwide, TransCelerate continues to play a pivotal role in shaping the future of clinical trials on a global scale.

Solutions and Tools: Driving Innovation in 2024

2024 was a year of strategic innovation for TransCelerate, with our initiative teams delivering a powerful array of solutions and tools designed to resolve the most pressing challenges in the R&D ecosystem. Each launch represented a carefully crafted response to industry needs, embodying our commitment to driving meaningful change through targeted, high-impact solutions.

Key initiatives that launched impactful solutions this year include:

- Rapid Signal Assessment Using Real World Data
- Clinical Content & Reuse
- Intelligent Automation Opportunities in Pharmacovigilance
- Digital Data Flow

Of particular note, our Digital Data Flow initiative gained significant momentum, with **30% of our members** already sharing use case studies and remarkable ecosystem uptake by **over 30 technology providers.**

Sharing Knowledge and Insights

We're not just building solutions. We're sparking ecosystem-wide transformation through various channels:

White Papers: We released comprehensive analyses on crucial topics ranging from decentralized clinical trials to the use of real-world data in regulatory decision-making.

Peer-Reviewed Publications: Our teams contributed significant research to leading journals, including Therapeutic Innovation & Regulatory Science (TIRS) and Toxicological Sciences, addressing key issues in clinical research and patient safety.

Media Engagement: TransCelerate's thought leadership was featured in prominent industry publications, from Global Forum (DIA) and Applied Clinical Trials to Nordic Life Science and Clinical Leader, discussing important topics such as clinical protocol digitization, enhancing trial diversity and the impact of ICH E6(R3) on Good Clinical Practice.

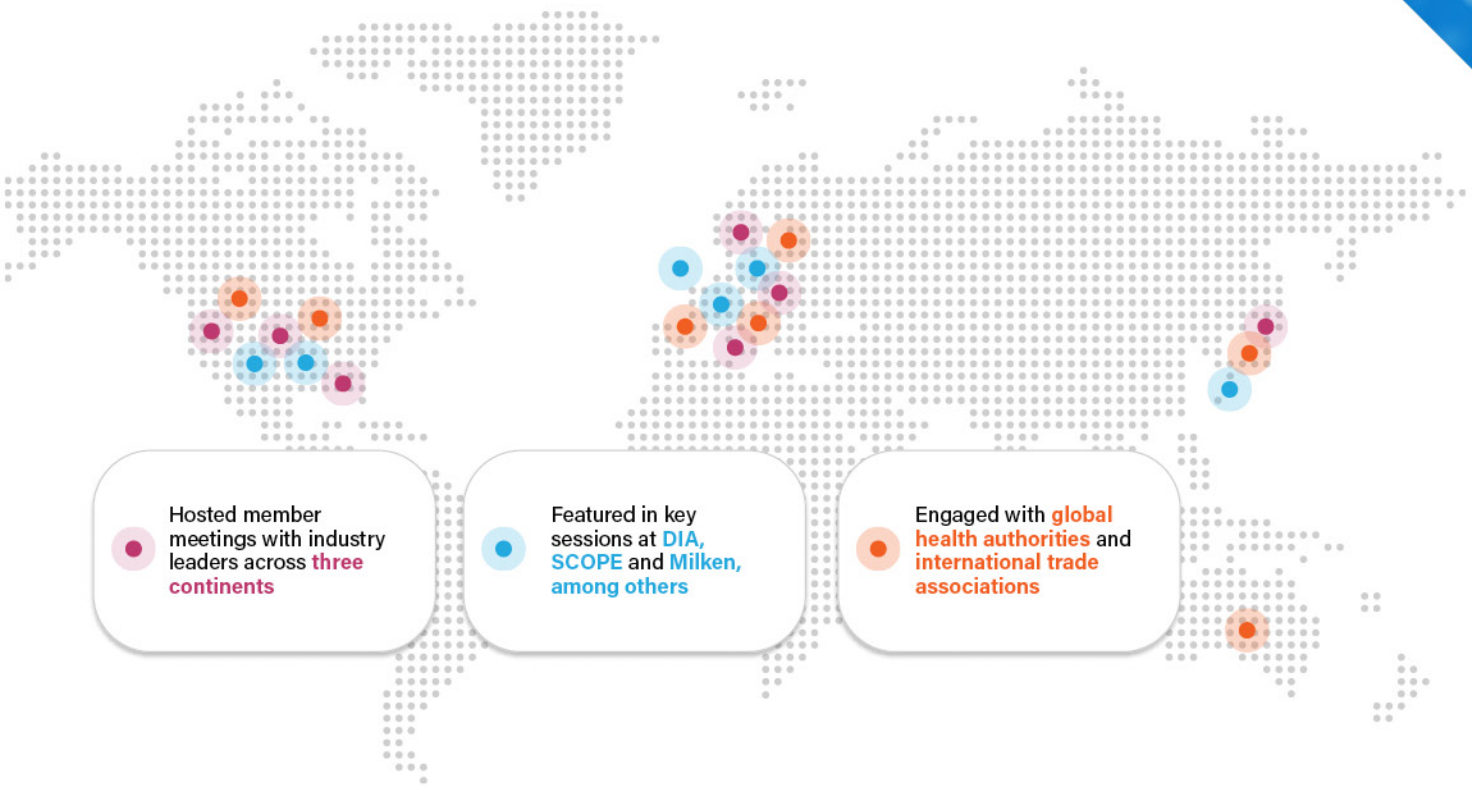
Thought Leadership Blog: Through our website, we shared in-depth insights on pressing industry issues, from fostering inclusion in clinical trials to transforming pharmacovigilance practices.

Webinars and Educational Content: We hosted **10 public webinars** in 2024, reaching more than **4,000 professionals.** These sessions have provided a platform for sharing our tools and building broader industry engagement.

Global Presence and Engagement

In 2024, TransCelerate's reach transcended borders, showcasing our commitment to driving global progress in biopharmaceutical R&D. Our team participated in over **40 key events** across **four continents**, connecting with industry leaders, regulators and innovators worldwide.

Whether presenting at top conferences or convening critical member meetings, our presence spanned from San Diego to Sydney, Brussels to Boston and Tokyo to Berlin. This worldwide presence highlights both the diversity of our membership and our focus on sparking international collaboration and shaping the future of R&D.



LOOKING AHEAD

Future Challenges and Opportunities

As TransCelerate charts its course, we're focusing on the transformative movements that could reshape biopharmaceutical R&D and our role in this constantly evolving space.

Transformative Trends and Opportunities

1. **Data Interoperability**
   As the foundation for future progress, we'll champion the need for comprehensive data standards and collaborate to create seamless systems facilitating sharing.
2. **Artificial Intelligence**
   We're taking a measured approach to understanding AI's potential in clinical research, evaluating where these emerging technologies might improve recruitment efforts and trial design.
3. **Convergence of Clinical Research and Care**
   We're advocating for the integration of research activities into routine healthcare and expanding opportunities for patient participation in trials.

TransCelerate's Evolving Role

- **Expanding Collaborations**
  We'll forge strategic partnerships across the R&D ecosystem, co-creating solutions with diverse stakeholders.
- **Embedding Diversity**
  Moving beyond standalone initiatives, we're integrating diversity considerations into all our projects.
- **Balancing Focus and Flexibility**
  We'll maintain our commitment to high-impact initiatives while remaining agile to address emerging needs.

We're not just observing change — we're convening some of the brightest minds in R&D to architect the future of clinical research. By tapping our members' collective wisdom and determination, championing cutting-edge tech and building strategic partnerships, we're laying the groundwork for a more efficient, patient-focused R&D ecosystem.

TransCelerate BIOPHARMA INC.

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