TransCelerate BioPharma Inc. is a non-profit organization with a mission to collaborate across the biopharmaceutical research and development community to identify, design and facilitate the implementation of solutions to drive efficient, effective and high-quality delivery of new medicines, improving the health of people around the world.
Letter from the CEO

Accelerating the Development of Medicines

TransCelerate BioPharma brings together Research & Development leaders from biopharmaceutical companies, research sites, clinical research organizations, regulatory authorities and patient-focused organizations to help to identify solutions to common drug development issues and drive efficiencies into the Research & Development process.

TransCelerate is proud to lead a progressive agenda that advances innovation in R&D. In the coming years, we will continue to challenge ourselves and take on new Initiatives that we believe will improve the investigator and patient experience, encourage data sharing as appropriate, reduce cost and process inefficiencies, and improve quality.

Most importantly, we will maintain an unwavering commitment to meaningful collaboration, so that together, we can ensure drugs are delivered to patients across the globe safely and efficiently.

"This is a collaboration of unprecedented pharmaceutical acumen. We have the world’s most successful biopharmaceutical companies working in the spirit of collaboration to truly change and improve upon drug development as we have historically known it. TransCelerate represents the future of how clinical trials will be designed and how drugs will be delivered to patients."

Prof. Dr. Iris Loew-Friedrich,
Chair of the TransCelerate Board of Directors, Executive Vice-President and Chief Medical Officer, UCB

"TransCelerate is delivering broad change on a global scale that better engages and connects teams across country borders. With a focus on improving quality in clinical trials, simplifying conduct of studies while enhancing the experience of clinical investigators, their staff and most importantly, the patients who volunteer to work with us, TransCelerate has real impact, and lasting reach."

Paul Stoffels, MD,
TransCelerate Board Member & Chief Scientific Officer,
Worldwide Chairman of Pharmaceuticals,
Johnson & Johnson
Our Initiatives

TransCelerate's diverse portfolio of initiatives focuses on the shared vision of accelerating and enhancing the research and development of innovative new therapies. Drawn from the combined expertise of our members and industry collaborators, our initiatives develop practical solutions to overcome inefficiencies in clinical trials. Many of our initiatives seek to reduce the administrative burden placed on investigator sites, so clinical researchers have more time to focus on patients.

Patients

eConsent
The eConsent Initiative will facilitate broad, voluntary adoption of eConsent by describing a framework/guidance for eConsent digital components and a toolkit to aid sponsor implementation. Successful industry adoption of eConsent will empower patients, caregivers and the providers that care for them, while increasing regulatory compliance and reducing quality risks.

eLabels
The eLabels Initiative will help the industry progress on the journey to digitally-supported, patient-centric clinical supply chains. eLabels are expected to enhance patient and site utility, promote consistent, up-to-date information and be a catalyst for future digital clinical supply transformation.

Clinical Research Awareness and Access
Clinical Research Awareness and Access seeks to increase awareness of and education about clinical research and its impact, improve potential participants’ access to clinical study opportunities and information on available studies, and enable more meaningful sharing of information with study participants.

Patient Experience and Technology
The Patient Experience and Technology (PE&T) Initiative will help the industry understand (and measure) the patient’s clinical trial journey. With this understanding, the initiative can better facilitate the acceleration of technology solutions that specifically target and reduce patient burden and improve the patient experience in clinical trials.

Sites

Investigator Registry
The Investigator Registry Initiative will create a shared repository of investigator contact details and some site-related data from consenting investigators and sites, accelerating the identification and recruitment of qualified investigators and reducing cost and trial length by avoiding duplication of common study start-up processes.

Shared Investigator Platform
The Shared Investigator Platform (SIP) will reduce the burden on sites by providing them with a central point of access, harmonized content and services, and streamlined interaction with participating clinical trial sponsors.

Site Qualification and Training
The goal of the Site Qualification and Training Initiative is to enhance and simplify the clinical trial site qualification and training process by creating programs, tools and resources that reduce time spent on non-study specific tasks, allowing more time to focus on patients.

“I believe the work TransCelerate has undertaken will have direct benefit to helping drive improved efficiency and effectiveness into the clinical development process. The increased collaboration across all stakeholder groups will bring further benefit in the future to R&D, the broader healthcare industry and most importantly, patients.”

Jamie MacDonald, Previous ACRO Chair and Chief Executive Officer, INC Research
Joining TransCelerate was an important decision for us. We recognized that we needed to continue to transform how we develop drugs - and we recognized that we couldn’t do it alone. Being part of TransCelerate is enabling us to work towards a common goal of improving efficiency in non-competitive operational aspects of R&D on an industry-wide scale, while also allowing us to advance some of our own Merck innovations. We get the best of both worlds.”

Andy Lee,
TransCelerate Corporate Treasurer, SVP,
Head of Global Clinical Trial Operations,
Merck

“Working with TransCelerate on the
Shared Investigator Platform is truly a
momentous endeavor and everyone stands to benefit:
sponsors, sites, and trial participants. I’m proud to
be a part of this movement.”

Matthew D. Wenker, MD,
Medical Director & Investigator,
Sterling Research Group
Our Values & Strategic Priorities

The formula driving TransCelerate forward is that we are comprised of some of the most passionate, innovative thinkers in R&D, from some of the world’s most successful biopharmaceutical organizations, who have fundamentally recognized that, in certain areas, working together can be more productive and efficient than working apart. However, our mission would prove unsuccessful if it were not for our partnerships with a large array of external stakeholders that enable us to create benefits for the biopharmaceutical industry.

We benefit from robust partnerships with industry organizations such as a CRO forum, under the leadership of ACRO (Association of Clinical Research Organizations), CFAST (Coalition For Accelerating Standards and Therapies), CTTI (Clinical Trials Transformation Initiative) and SCRS (Society for Clinical Research Sites), as well as collaboration and insight from more than 12 Regulatory Agencies around the world — that enable us to create global value for the industry.

Our values are harnessed through our strategic priorities:

**Improve the Site Investigator Experience**
Improve the site investigator experience as they work with Sponsors to execute clinical trials.

**Facilitate Information Sharing**
Facilitate the sharing of clinical trial related information as appropriate amongst industry stakeholders, focused on exchanges of information that would enable the industry to capture efficiencies.

**Enable Harmonization of Clinical Trial Processes**
Enable the industry to move toward greater harmonization of clinical trial processes to facilitate the advancement of technologies and processes within the broader clinical ecosystem.

**Enhance Sponsor Efficiencies**
Through collaboration, streamline redundant sponsor activities to reduce investigator and patient burden, while refocusing resources to drive and deliver innovative drugs to patients faster and safely.

**Improve the Patient Experience**
Improve the patient experience by decreasing patient burden, enabling a better informed patient and improving clinical research awareness, study participation and engagement.

"The value of our two organizations working together can't be overstated. Integrating the perspectives of clinical sites and investigators with those of the industry elevates what we're all able to accomplish as individual forces. It's a landmark collaboration."

Christine Pierre, President, Society for Clinical Research Sites
"What’s particularly powerful about TransCelerate is the spirit of partnership. Leading a team of accomplished professionals from across many global biopharmaceutical companies - all bringing their passions and perspectives together to create positive change in the conduct of clinical trials is truly inspiring. They are proof that the power of collaboration to make an impact, can be enormous."

Lynn Marks, MD,
TransCelerate Secretary & Chair of the Oversight Committee,
Senior Vice President, Projects, Clinical Platforms & Sciences,
GlaxoSmithKline