TransCelerate BioPharma

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Research Areas

⚙️ **Tool Development**
Clinical Trial

⚙️ **Data-Sharing Enabler**

At a Glance

- Status: **Active Consortium**
- Year Launched: **2012**
- Initiating Organization: **TransCelerate Biopharma**
- Initiator Type: **Industry**
- Location: **North America**

Abstract

TransCelerate BioPharma Inc. is a non-profit organization with a mission to collaborate across the global biopharmaceutical research and development community to identify, prioritize, design and facilitate the implementation of solutions to drive efficient, effective and high-quality delivery of new medicines.

Mission

TransCelerate aspires for a future state where research and development is faster, more efficient, and harnesses all the available information. We envision this happening in 3 ways:

1. **Participation** – Full participation across all stakeholders – clinical trial sponsors, sites, investigators and patients and their healthcare providers
2. **Informed Design** – Information is fully used to improve the design of clinical research
3. **Execution** – Improving the execution of clinical research through harmonization and

consistency with the potential to conduct collaborative trials

Current Initiatives:

Clinical Data Standards

- The Clinical Data Standards Initiative develops industry-wide Data Standards in priority Therapeutic Areas to support the exchange and submission of clinical research and meta-data, while improving patient safety and outcomes.

Clinical Data Transparency

- The Clinical Data Transparency Initiative was formed with a mission of developing a model approach for redacting privacy information found in clinical study reports and a model approach for the anonymization of patient-level data shared with the broader healthcare community.

Clinical Research Access and Information Exchange

- Clinical Research Access and Information Exchange seeks to provide a better window into information about clinical research and trial options while also contribute to a more rewarding clinical trial experience via better exchange of information with trial participants.

Clinical Research Awareness

- Clinical Research Awareness seeks to educate the public about clinical research and encourage conversations about clinical trials between patients and their health care providers

Clinical Trial Diversification

- TransCelerate's Clinical Trial Diversification Initiative has achieved its goal of developing better practice materials for Site and Sponsors to improve engagement and recruitment of minority patient populations.

Common Protocol Template

- The Common Protocol Template Initiative works with industry stakeholders and regulators to

create a model clinical trial protocol template containing a common structure and model language to improve accuracy in data recordation and speed study start up.

Comparator Network

- The Comparator Network Initiative establishes a reliable, rapid sourcing of quality products for use in clinical trials for participating Member Companies to avoid counterfeiting and avoid delays in study start-up.

eConsent

- The eConsent Initiative will create a common approach for the electronic consenting of patients using an array of digital elements and process efficiencies to increase insight into patients' understanding, increase regulatory compliance, and reduce quality risks.

eLabels

- The eLabels Initiative will establish an innovative information channel in clinical trials: electronic labels. The initiative will help the industry progress on the journey to digitally supported, patient-centric clinical supply chains.

eSource

- The eSource Initiative seeks to assist TransCelerate Member Companies, and ultimately other trial sponsors, in overcoming real and perceived challenges to influence more efficient data gathering practices to benefit patients, sites and sponsors.

Interpretation of Pharmacovigilance

- The Interpretation of Pharmacovigilance Regulations Initiatives will share expertise to more efficiently and effectively meet the intent of pharmacovigilance requirements that seem ambiguous.

Investigator Registry

- The Investigator Registry Initiative enhances TransCelerate's Shared Investigator Platform,

and accelerates identification and recruitment of qualified investigators, which will avoid duplication of standard site qualification and the creation of investigator documentation, and thereby reducing cost and trial length.

Patient Experience and Technology

- The Patient Experience & Technology (PE&T) Initiative seeks to facilitate and accelerate the industry's progression towards a future where patients have access to innovative technologies that enhance the patient experience and reduce patient burden in clinical trials.

Pediatric Trial Efficiencies

- This Initiative thoroughly assessed potential solutions that would lead to faster access to new drugs for pediatric patients. Rather than continue as a standalone initiative, a decision was made to transition the focal points of pediatric populations across the broader TransCelerate portfolio, where appropriate.

Placebo and Standard of Care Data Sharing

- The Placebo and Standard of Care Initiative was established to enable the sharing of data to maximize the value of clinical data collected historically in the placebo and standard of care control arms of a clinical trial. The goal is to enhance clinical trial designs, develop disease models and improve patient recruitment.

Quality Management System

- Through partnerships with Health Authorities and other industry stakeholders, the Quality Management System (QMS) Initiative aims to explore ways to improve quality across the industry.

Risk Based Monitoring

- TransCelerate's Risk-Based Monitoring initiative seeks to develop a model approach for risk-based monitoring of clinical trials, with the goal to both enhance patient safety and ensure the quality of clinical data.

Shared Investigator Platform

- TransCelerate's Shared Investigator Platform (SIP) will facilitate interaction between investigators and multiple clinical trial sponsors, enabling study planning, study start-up and study conduct activities while reducing the administrative burden on site staff.

Site Qualification and Training

- The Site Qualification and Training (SQT) Initiative collaborates with TransCelerate Member Companies, investigator sites, CROs and health authorities to achieve the goal of enhancing and simplifying clinical trial SQT processes and to reduce administrative burden on sites.

Value of Safety Information Data Sources

- The Value of Safety Information Data Sources Initiative will seek to identify sources of safety information for a single high value valid case and develop a proposed method for aggregate reporting of lower value cases.

Consortium History

TransCelerate BioPharma Inc. was formed in 2012 and evolved from conversations at various forums for executive R&D leadership to discuss current issues facing the industry, and examine solutions for addressing common challenges. The founding member companies are AbbVie, AstraZeneca, Boehringer Ingelheim, Bristol-Myers Squibb, Eli Lilly and Company, GlaxoSmithKline, Johnson & Johnson, Pfizer, the Roche Group, and Sanofi. Additional members that have joined since the inception of TransCelerate include Allergan, Inc., Amgen, Astellas Pharma Inc., EMD Serono, Inc. (a subsidiary of Merck KGaA, Darmstadt, Germany), Merck & Co., Inc., Novo Nordisk, Shionogi & Co., Ltd. and UCB.

Structure & Governance

TransCelerate BioPharma has leadership from major biopharmaceutical companies – who have dedicated their careers to medicine, science and ensuring access to life-saving medicines through efficient and safe drug research and development. TransCelerate leadership has an unwavering dedication to assessing, refining and creating processes to make the drug development environment efficient, safe and innovative.

TransCelerate supports Member Companies in selecting areas of focus and delivering results. Member Companies make all decisions regarding implementation, including if they would like to implement or adopt a TransCelerate solution.

Financing

Membership of TransCelerate is available to pharmaceutical and biopharmaceutical companies with R&D organizations who engage in the innovative discovery, development, and manufacturing of new drugs.

TransCelerate workstreams are led and powered by Member Company resources. This is why TransCelerate membership in comprised of two components; an annual membership fee and a talent contribution commitment. There is a small team of TransCelerate employees and outsourced functions that help operationalize activities across the portfolio – but member company talent is the defining characteristic that has made TransCelerate successful in delivering solutions.

There are three membership tiers that are defined by a company's global R&D spend. Each tier has a different annual membership fee and talent contribution commitment level.

While CROs, Investigator Sites, and other stakeholder groups are not eligible for membership – TransCelerate has other avenues in which they engage.

Intellectual Property

TransCelerate owns the copyright rights in the deliverables that it has developed. TransCelerate posts many of its deliverables on its website and publishes others in journals and other media to enable industry stakeholders to benefit from and use the guidance provided in these deliverables.

Nevertheless, TransCelerate retains the exclusive rights under the copyright laws to reproduce, copy, distribute, and publicly display these works and to make derivative works based on these deliverables.

Patent Engagement

TransCelerate's patient-focused initiatives are centered around improving how patients experience their journey before, during and after a clinical trial, and seeks to better inform patients, their caregivers and healthcare providers by facilitating improved touchpoints with clinical research information. As such, the organization has introduced several Initiatives including:

- Clinical Research Awareness (CRA) and Clinical Research Access and Information Exchange (CRAIE) which are designed to provide a better window into information about clinical research and trial options, encourage conversations between patients and their healthcare providers and contribute to a more rewarding trial experience via better information exchange with trial participants.
- The eConsent Initiative seeks to develop practical guidance on efficient processes and interactive multimedia components to create general awareness and facilitate broad, voluntary adoption of patient eConsent. Successful industry adoption of eConsent will boost patients' understanding of clinical trial study objectives and design and empower them to make better, more informed decisions.
- The eLabels Initiative will help the industry progress on the journey to digitally supported, patient-centric supply chains. The Initiative will increase efficiency in clinical development, boost patient safety, enhance the utility and comprehension of clinical labels and lead to better compliance.

TransCelerate's goal is to not only engage with patients about clinical trials, but also to offer higher value to patients and other healthcare stakeholders through more effective use of trial information. With these initiatives, TransCelerate reduces the challenges and inconsistencies commonly faced by patients throughout the clinical trial process.

Data Sharing

While many of TransCelerate's active initiatives are focused on specific stakeholders involved in clinical trials, our Information Sharing and Harmonization Initiatives support the entire clinical lifecycle by developing innovative solutions that enable and facilitate data sharing and harmonization through enhanced technology and aligned common processes, while also protecting individuals' privacy. This will ultimately help streamline communication and information sharing across the industry.

Impact/Accomplishment

TransCelerate has achieved important milestones in recent years, demonstrating a clear evolution in the way the biopharma industry aims to streamline efficiencies through the sharing of data, and harmonizing on critical challenges. TransCelerate has recorded measurable progress in its mission to help drive efficient, effective and high-quality delivery of new medicines for patients.

For example, on two key Initiatives TransCelerate uncovered results that exemplify significant progress in the journey to improve patient safety and efficiency in clinical trials:

> The Comparator Network executed end-to-end operations on updated technology, enabling access to top global comparator products and eliminating the chance for counterfeit drugs to enter the investigational supply chain. The Network has surpassed transaction volume of $120M and saves members approximately 10 to 12% per transaction.
> The Placebo & Standard of Care Data Sharing Initiative has seen significant progress, with preliminary results indicating that use of such well-defined historical data can reduce study time substantially, and decrease the number of patients in the placebo/standard of care arm.

In years to come, TransCelerate will continue fulfilling its pledge to bring innovation to the drug development process, improve trial awareness, access and experience and deliver meaningful change for patients.

Links/Social Media Feed

Consortium homepage	http://www.transceleratebiopharmainc.com
Twitter	@transcelerate
LinkedIn	https://www.linkedin.com/company/transcelerate-

biopharma-inc-

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