TransCelerate BIOPHARMA INC.

TransCelerate Overview

Updated 6 March 2017

TransCelerate Background

TransCelerate is a not for profit entity created to drive collaboration

Our vision

To improve the health of people around the world by **accelerating and simplifying** the research and development of innovative new therapies.

Our mission

To collaborate across the global research and development community to identify, prioritize, design and facilitate implementation of solutions designed to drive the efficient, effective and high quality delivery of new medicines.

Founded in 2012 by 10 Members

abbvie
AstraZeneca
Boehringer Ingelheim
Bristol-Myers Squibb
gsk GlaxoSmithKline
SANOFI
Lilly
Pfizer
Roche
Johnson & Johnson

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Significant Growth Over the Past 4+ Years

2014

2016

Today

TransCelerate Founded

2012

10 Founding Members
5 Active Initiatives

17 Member Companies
12 Active Initiatives
1 Exploratory Initiative

BioCelerate

Launch of BioCelerate

18 Member Companies
11 Active Initiatives
6 Realized Initiatives

Growth of Global Impact:

- Country Network of 22 Countries
- Engagement with 11+ Global Regulatory Authorities

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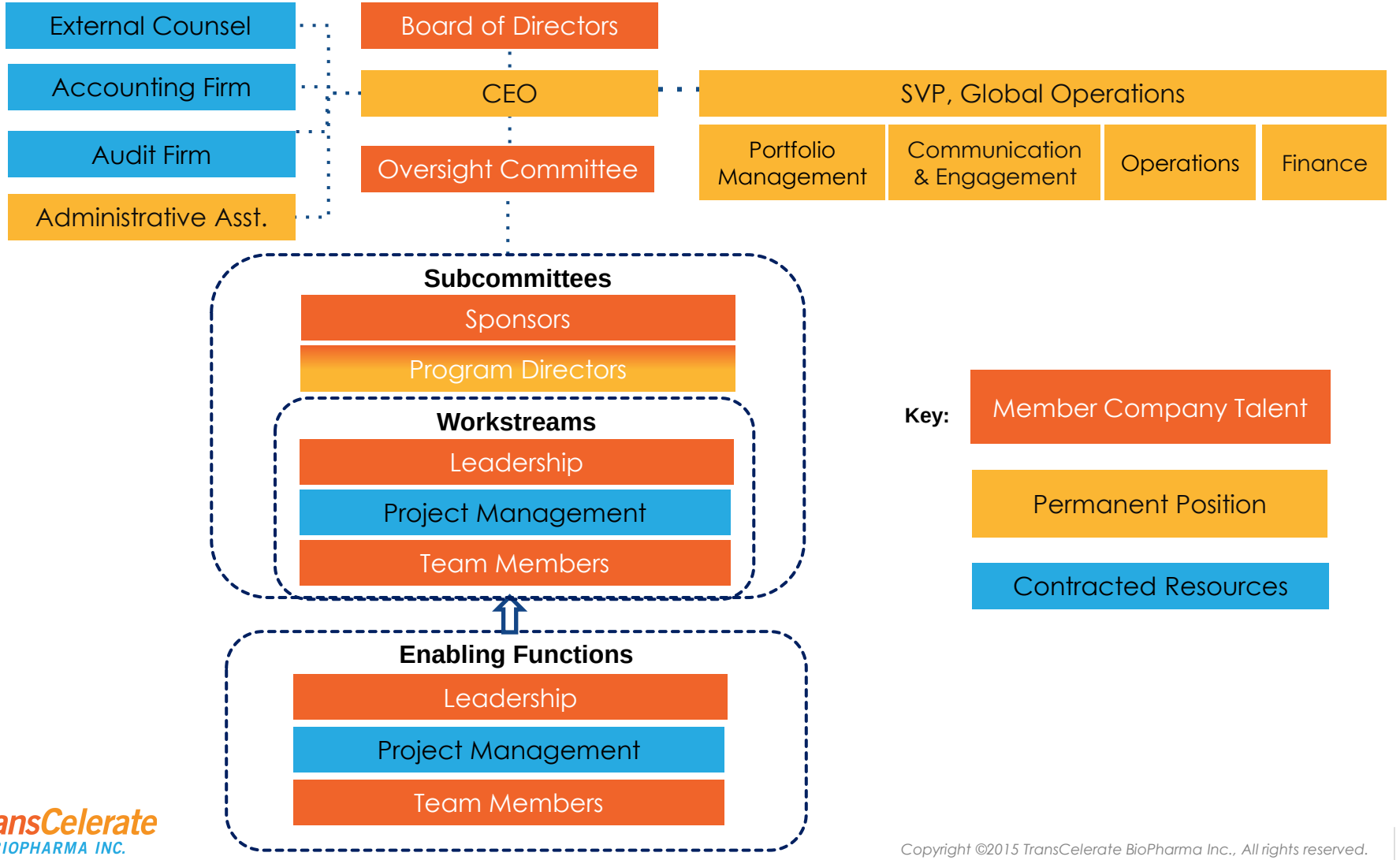
Engage with Key Stakeholders

We continue to reach out to **key industry stakeholders** for engagement opportunities at both a leadership and initiative level.

TransCelerate's Organizational Structure

High engagement from member talent is a key attribute in our success.



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TransCelerate Project Portfolio Overview

TransCelerate Strategic Priorities

TransCelerate assesses industry challenges and selects initiatives aligned with our five 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.

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Portfolio Overview

Active Portfolio
Design, Develop, & Deploy Phase

Patients

1. Clinical Research Awareness
2. Clinical Research Access & Info Exchange
3. eConsent
4. eLabels
5. Patient Experience
6. Patient Technology

Sites

1. Investigator Registry
2. Shared Investigator Platform

Sponsors

1. eSource
2. Quality Management System

Info Sharing Harmonization

1. Common Protocol Template
2. Data Standards
3. Placebo / Standard of Care

Realization & Governance

1. Clinical Data Transparency
2. Clinical Trial Diversification
3. Comparator Network
4. Pediatric Trial Efficiencies
5. Risk Based Monitoring
6. Site Qualification & Training

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*Note: Adoption of TransCelerate solutions are voluntary

Significant Accomplishments To Date

- ✓ Designed a model **Risk Based Monitoring Methodology** for use by industry.
- ✓ Operationalized a program for **mutually recognizing Good Clinical Practice (GCP) training** across sponsors to eliminate sites taking duplicative training.
- ✓ Developed a series of **templates/forms for Sites** to create value and streamline processes
- ✓ Launched the **Shared Investigator Platform & Investigator Registry** for use by Member Companies to improve and streamline interactions with Investigator Sites.
- ✓ Operationalized a **network** of TransCelerate Member Companies to **secure Comparator Drugs** for studies from each other.
- ✓ Collaborated through CFAST to **publish 22 Therapeutic Area Data Standard User Guides**.
- ✓ Developed and published a **Common Protocol Template** and made publicly available on the TransCelerate website.
- ✓ Published a model approach for **Data De-identification and Anonymization of Individual Patient Data** in Clinical Studies.
- ✓ Published **Clinical Quality Management System** Concept, Issue Management and Knowledge Management papers in DIA's Journal (TIRS).
- ✓ **Launched BioCelerate** - A subsidiary of TransCelerate focused on preclinical collaboration.

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Watch our "About Us" Video

Visit us, for more information:

www.TransCelerateBioPharmaInc.com

Appendix

Active Initiatives with the Shared Goal of Innovative Operational Approaches to Speed Progress on Patient-Centered Clinical Trials

Workstream	Objective
Clinical Research Access & Awareness	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.
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.
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.
Patient Experience & 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.

Active Initiatives with the Shared Goal of Decreasing the Burden on Investigator Sites

Workstream	Objective
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.

Active Initiatives with the Shared Goal of Streamlining redundant sponsor activities, while refocusing resources to drive and deliver innovative drugs

Workstream	Objective
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. This initiative will help sponsors more efficiently meet regulatory requirements regarding data transparency and enhance transparency and facilitate future research preserving the privacy of patients, investigators and clinical trial staff for operational transparency issues related to privacy.
eSource	The eSource Initiative will help accelerate the uptake of eSource for clinical trials, assisting trial sponsors in overcoming real and perceived challenges to influence more efficient data gathering practices, which will benefit patients, sites and sponsors.
Quality Management System	The Quality Management System Initiative aims to explore ways to improve quality across the industry through partnerships with health authorities and other industry stakeholders - which can enhance patient safety by improving quality, assuring data integrity, minimizing delays in clinical trials and bringing drugs to market faster.

Active Initiatives with the Shared Goal of facilitating the sharing of clinical trial related information as appropriate amongst industry stakeholders

Workstream	Objective
Clinical Data Standards	The Clinical Data Standards Initiative, in collaboration with CDISC (Clinical Data Interchange Standards Consortium), C-Path (Critical Path Institute), NCI-EVS (National Cancer Institute—Enterprise Vocabulary Service) and FDA as part of the CFAST (Coalition For Accelerating Standards and Therapies), aims to establish therapy area (efficacy) data standards to support the exchange and submission of clinical research and meta-data, while improving patient safety and outcomes.
Common Protocol Template	The Common Protocol Template Initiative works with industry stakeholders to create a model clinical trial protocol template containing a common structure and language, to reduce protocol development time, regulatory review, and improve end to end data flow, while making protocols more user-friendly for investigators and patients.
Placebo / 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. Our goal is to enhance clinical trial designs, develop disease models and improve patient recruitment.

Realized Initiatives

Workstream	Objective
Clinical Trial Diversification	This Initiative has achieved its goal of developing better practice materials for Site and Sponsors to improve engagement and recruitment of minority patient populations. To learn more about this Initiative's mission and accomplishments please continuing reading below.
Comparator Network	The Comparator Network Initiative established a reliable, rapid sourcing of quality comparator drug products for use in clinical trials through a Comparator Supply Network, which enables accelerated trial timelines and enhanced patient safety.
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, we will transition the focal points of pediatric populations across the broader TransCelerate portfolio, where appropriate.
Risk Based Monitoring	By developing a scalable model approach for risk-based monitoring of clinical trials, TransCelerate's objective is to both enhance patient safety and ensure the quality of clinical trial data.
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.