TransCelerate BIOPHARMA INC.

TransCelerate Overview

Updated: 1 July, 2019

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TransCelerate:

A Not-for-Profit Entity Created to Foster Collaboration

Our Shared Vision:

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

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Current state of organization

2012
TransCelerate Founded

10 MEMBER COMPANIES

5 INITIAL INITIATIVES

2016
BioCelerate Founded

BioCelerate
focus on preclinical research

Today

20 MEMBER COMPANIES
Regeneron most recent member

25+ INITIATIVES
including 4 pharmacovigilance initiatives

BREADTH & DEPTH
Over 30 solutions being delivered across 25+ initiatives, across 3 strategic priorities

ENHANCING INDUSTRY COLLABORATION
With an effective and proven governance structure have increased the ease and desire to collaborate

FACILITATING FUTURE PLATFORM TRIALS
12+ initiatives deliver solutions that facilitate future platform trials

DataCelerate
platform to enable data sharing

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The Reach of our Global Membership is Expanding

Membership is available to biopharmaceutical research and development organizations that engage in innovative discovery, development and manufacturing of new medicines*.

abbvie · Allergan · AMGEN · astellas · AstraZeneca
Boehringer Ingelheim · Bristol-Myers Squibb · Merck KGaA Darmstadt, Germany · gsk GlaxoSmithKline · Johnson & Johnson
Lilly · MERCK & CO., INC. Kenilworth, N.J., U.S.A. · novo nordisk · NOVARTIS · Pfizer
REGENERON SCIENCE TO MEDICINE · Roche · SANOFI · SHIONOGI · ucb

There are over **1,000** people from Member Companies that design and develop TransCelerate solutions.

* to be eligible for membership, companies must meet specified eligibility criteria.

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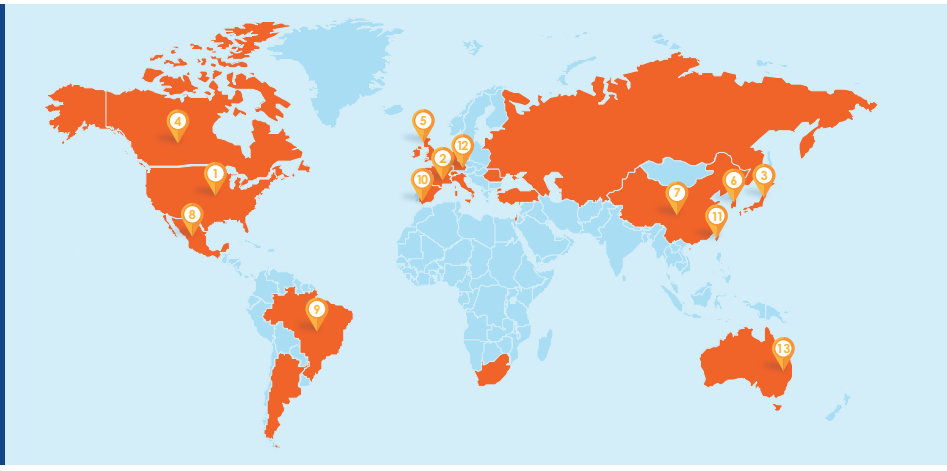
Our Presence, Impact and Engagement is Worldwide

Our Country Network spans

30 COUNTRIES, and

13 GLOBAL REGULATORY AUTHORITIES

have engaged with TransCelerate.



1 FDA 2 EMA 3 PMDA 4 Health Canada 5 MHRA 6 MFDS 7 CFDA 8 COFEPRIS 9 ANVISA 10 AEMPS 11 TFDA 12 BfArM 13 TGA

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External Collaboration will continue to play a critical role in achieving our future state

TransCelerate BioPharma and FDA/NIH
COLLABORATE on Aligned Common Protocol Template

Society for Clinical Research Sites Announces TransCelerate BioPharma's Ongoing
FOCUS ON SITES by launching SCRS Site Advocacy Groups

CDISC and TransCelerate Announce New Standard for Breast Cancer to
SUPPORT DATA SHARING for Oncology Research

As a single stakeholder organization, we understand the value of robust collaboration with key stakeholders* across the R&D ecosystem which provide unique and important insights and perspectives.

INVESTIGATOR SITES*

RESEARCH AND CRO COMMUNITY*

PATIENT ADVOCACY GROUPS*

OTHER ASSOCIATIONS*

HEALTH AUTHORITIES*

* Representative organizations, not exhaustive

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TransCelerate's Initiatives deliver practical solutions to overcome inefficiencies in research & development

OUR MISSION:

Collaborate across the global biopharmaceutical R&D community to identify, prioritize, design and facilitate implementation of solutions designed to drive the efficient, effective and high-quality delivery of new medicines

HARMONIZE PROCESS AND SHARE INFORMATION

- Clinical Data Standards
- Common Protocol Template
- Comparator Network
- DataCelerate®
- eSource
- Digital Data Flow
- Placebo Standard of Care
- Toxicology Data Sharing
- Common Clinical SAE

IMPROVE THE PATIENT AND SITE EXPERIENCE

- Clinical Research Access and Information Exchange
- Clinical Research Awareness
- eConsent
- eLabels
- Investigator Registry
- Patient Experience
- Patient Technology
- Site Qualification and Training
- Shared Investigator Platform

ENHANCE SPONSOR EFFICIENCIES & DRUG SAFETY

- Advancing Safety Analytics
- Clinical Data Transparency
- Data Monitoring Committee
- Intelligent Automation Opportunities in Pharmacovigilance
- Interpretation of Guidance and Regulations
- Modernization of Statistical Analysis
- Protocol Deviations
- Quality Management System
- Risk-Based Monitoring
- Value of Safety Information Data Sources

Our Work in Preclinical Development: BioCelerate

BioCelerate, a subsidiary of TransCelerate BioPharma, focuses on the identification and development of pragmatic and tangible solutions to improve efficiencies in preclinical research.

Leadership and Governance Structure: BioCelerate has been established as a separate legal subsidiary of TransCelerate with separate funding and support.

Toxicology and Background Control Data Sharing Initiative

The first Initiative, **Toxicology Data Sharing**, is working to help close critical gaps between patient response and preclinical toxicology findings.

Nonclinical Study Optimization

The initiative is focused on working with key stakeholders to implement common best practices such as harmonization of SEND data sets and authoring of protocols and reports.

Membership in TransCelerate is a prerequisite for BioCelerate membership.

Our Work in Data Sharing: DataCelerate

DataCelerate will be used to aggregate and analyze preclinical and clinical information* to improve drug development efficiency and bring new medicines to patients faster.

Toxicology & Background Control Data
May, 2018

Enables participating companies to make data-driven decisions on compound progression based on an increased understanding of on-target and off-target toxicity.

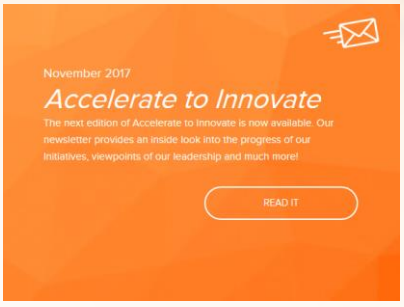
Placebo Standard of Care Data
2019

Enables participating TransCelerate members to collect and share anonymized clinical data historically gathered in the placebo and standard-of-care arms of clinical trials among participating member companies.

Additional data types currently under assessment

Our Solutions provide transformational value and impact

SPEED	COST	QUALITY	EXPERIENCE	MINDSET
"Implementation of the GCP mutual recognition was an important win for us Now it is one less training that the PIs have to complete, **which speeds up our startup process**…"	"Given the intense price pressure pharma is under, **we need to get inefficiency out of trials** to make them economical. Ultimately that is how the market will grow"	"We're seeing improvement in quality…[Risk Based Monitoring] **allowed us to improve patient safety and data integrity.**"	"Stability data information helps support temperature excursions that may occur during shipping or storage… [allowing] **use of product** that would've normally been discarded."	"Harmonizing our templates worked out well for both sides. Developing a template with FDA & NIH alone, **there is no way that we would have found traction with industry**."
- Sponsor Company on Site Qualification & Training	*- CRO on TransCelerate's industry impact*	*– Sponsor Company on Risk Based Monitoring*	*– Sponsor Company on how the Comparator Network reduces study delays*	*– Health Authority on the Common Protocol Template*



Visit us, for more information:
www.TransCelerateBioPharmaInc.com

Watch our "About Us" Video

Sign up for our Newsletter,
Accelerate to Innovate

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TransCelerate BioPharma Inc.

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TransCelerate Tools and Resources

VIDEOS

- About Us
- Patients
- Sponsors
- Sites
- Info Sharing & Harmonization
- eConsent
- eLabels
- Common Protocol Template

INITIATIVE ASSETS

- Clinical Trial Registry of the Future eBook
- RBM Interactive Guide
- Common Protocol Template Assets
- eConsent Implementation Guidance
- eLabels Design & Delivery Toolkit

ABOUT TRANSCELERATE

- Brochure
- Accelerate to Innovate
- The Pulse on Progress

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Initiatives with the Shared Goal of

Improving the Patient and Site Experience

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

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Initiatives with the Shared Goal of

Improving the Patient and Site Experience

INITIATIVE	OBJECTIVE
Patient Experience	The Patient Experience Initiative seeks to facilitate and accelerate the industry's progression towards a future where the patient experience is enhanced in clinical trials and the patient burden is reduced.
Patient Technology	The Patient Technology Initiative strives to enable and accelerate patient-facing technology in support of an improved patient experience and richer data collection in clinical trials.
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.
Shared Investigator Platform	The Shared Investigator Platform 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.

Initiatives with the Shared Goal of

Harmonizing Processes and Sharing Information

INITIATIVE	OBJECTIVE
Clinical Data Standards	The Clinical Data Standards Initiative, in collaboration with Clinical Data Interchange Standards Consortium (CDISC), Critical Path Institute (C-Path), National Cancer Institute—Enterprise Vocabulary Service (NCI-EVS) and FDA, as part of the Coalition For Accelerating Standards and Therapies(CFAST), 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.
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.
Common Statistical Analysis Plan Template	The Common SAP Template initiative will develop a Common SAP Template, which aims to provide a common layout and model content for SAP documentation, and will link directly to TransCelerate's Common Protocol Template (CPT).
Digital Data Flow	Th Digital Data Flow initiative aims to move the drug development process from a current state of manual, study start-up asset creation to a future state of fully-automated, dynamic, study start-up readiness via an open-sourced, vendor-agnostic technical solution that will reduce cycle times and improve data quality for sponsors, third-party providers, sites and regulators.

Initiatives with the Shared Goal of

Harmonizing Processes and Sharing Information

INITIATIVE	OBJECTIVE
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.
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.

Initiatives with the Shared Goal of

Enhancing Sponsor Efficiencies and Drug Safety

INITIATIVE	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 facilitate future research preserving the privacy of patients, investigators and clinical trial staff for operational transparency issues.
Protocol Deviations	The Protocol Deviations Initiative is striving for an improved protocol deviation processes that should ultimately lead to improved patient safety, reliability of study data, human subject's protections and data quality.
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 markets faster.
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.

Initiatives with the Shared Goal of

Enhancing Sponsor Efficiencies and Drug Safety

INITIATIVE	OBJECTIVE
Advancing Safety Analytics	This initiative aims to develop best practices and guidance around the application of interrogative methods towards various safety data sources.
Intelligent Automation Opportunities in Pharmacovigi-lance	This initiative focuses on identifying how intelligent automation technologies can be used to better support execution of Pharmacovigilance activities/processes.
Interpretation of PV Regulations	This Initiative will share expertise to more efficiently and effectively meet the intent of pharmacovigilance requirements that seem ambiguous to improve patient safety and reduce sponsor compliance risks due to a better understanding and more reliable interpretation of regulations.
Value of Safety Information Data Sources	This Initiative seeks 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. This hierarchy of values will be based on the evidence derived from the collective experience of drug companies and other stakeholders.