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.
Current state of organization

**2012**
TransCelerate Founded

- **10** MEMBER COMPANIES
- **5** INITIAL INITIATIVES

**2016**
BioCelerate Founded

- **20** MEMBER COMPANIES

**Today**

- **20** MEMBER COMPANIES
- **25+** INITIATIVES
  - including 4 pharmacovigilance initiatives

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

**CULTURE OF COLLABORATION**
With an effective and proven governance structure have increased the ease and desire to collaborate

**ENABLING PLATFORM TRIALS**
12+ initiatives deliver solutions that enable future platform trials

Regeneron most recent member

*Confidential - NOT FOR DISTRIBUTION*
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*.

* to be eligible for membership, companies must meet specified eligibility criteria.
Our Country Network spans 22 COUNTRIES, and 13 GLOBAL REGULATORY AUTHORITIES have engaged with TransCelerate.

Our Presence, Impact and Engagement is Worldwide
External Collaboration will continue to play a critical role in achieving our future state

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.

<table>
<thead>
<tr>
<th>INVESTIGATOR SITES*</th>
<th>RESEARCH AND CRO COMMUNITY*</th>
<th>PATIENT ADVOCACY GROUPS*</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACRP</td>
<td>JCRoa</td>
<td>Ciscrp</td>
</tr>
<tr>
<td>Aaci</td>
<td>National Institutes of Health</td>
<td>International Alliance of Patients’ Organizations</td>
</tr>
<tr>
<td>Scrs</td>
<td>CROForum</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>OTHER ASSOCIATIONS*</th>
<th>HEALTH AUTHORITIES*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bio</td>
<td>FDA</td>
</tr>
<tr>
<td>Dia</td>
<td>Efpia</td>
</tr>
<tr>
<td>Efpi</td>
<td>Phrma</td>
</tr>
<tr>
<td>intervals</td>
<td>Euromedica</td>
</tr>
</tbody>
</table>

* Representative organizations, not exhaustive
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
- Common Statistical Analysis Plan Template*
- Comparator Network
- DataCelerate™
- eSource
- Digital Data Flow*
- Investigator Registry
- Placebo Standard of Care
- Toxicology Data Sharing

**ENHANCE SPONSOR EFFICIENCIES & DRUG SAFETY**

- Advancing Safety Analytics*
- Clinical Data Transparency
- Data Monitoring Committee*
- Intelligent Automation Opportunities in Pharmacovigilance*

- Interpretation of Pharmacovigilance Regulations
- Protocol Deviations*
- Quality Management System
- Risk-Based Monitoring
- Value of Safety Information Data Sources

---

**IMPROVE THE PATIENT AND SITE EXPERIENCE**

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

---

* New Initiative launched in 2018

---

* Confidential - NOT FOR DISTRIBUTION *
eSource
Overview
What is eSource?

Currently, there is no standard industry definition of eSource

Per FDA, data initially recorded in electronic format

FDA also notes that eSource data “can include information in original records and certified copies of original records of clinical findings, observations, or other activities captured prior to or during a clinical investigation used for reconstructing and evaluating the investigation”
TransCelerate describes eSource and its four different modalities as...

“Electronic source data are data initially recorded in electronic format…”

Non-CRF
The collection and transfer of electronic data from internal sponsor sources or external vendors into data repositories/warehouses without into a Case Report Form (CRF).

Devices and Apps
The collection and management of clinical data from non-site personnel, wearables, and sensors.

DDC
The direct entry of clinical data by site staff into a mobile application or EDC system.

EHR
The collection and reuse of data for use in clinical research from site/patient electronic health record systems.

*The eSource team recognizes that some technologies cross these boundaries and that these categories will likely evolve over time due to technological advances*
eSource adoption faces multiple challenges

Lack of change management
Acceptance of novel technology solutions that enable eSource
Unknown quality and regulatory clarity on the data in these solutions

Lack of system interoperability
Interoperability is referred to by the Institute of Electrical and Electronics Engineers (IEEE) in basic terms as “the ability of a system or a product to work with other systems or products without special effort on the part of the customer. Interoperability is made possible by the implementation of standards.”

Concerns over eSource acceptability as endpoints; lack of clarity from key study stakeholders

Low risk tolerance in Pharma industry
However, the benefits of an eSource Investment impacts all stakeholders

<table>
<thead>
<tr>
<th>Value Drivers</th>
<th>Time</th>
<th>Cost</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Value</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>For <strong>SPONSORS</strong>, harmonized clinical data collections standards resulting in easy of data exchange between different sources and reduced clinical development timelines</td>
<td>⏰</td>
<td>$</td>
<td>✅</td>
</tr>
<tr>
<td>For <strong>SITES</strong>, reduces the manual transcription of data, related errors, and completeness of data through the utilization of existing data thus free up site to focus on the patient</td>
<td>⏰</td>
<td>$</td>
<td>✅</td>
</tr>
<tr>
<td>For <strong>PATIENTS</strong>, potential reduction in site visits due to continuous data collection through eSource modalities</td>
<td>⏰</td>
<td>$</td>
<td>✅</td>
</tr>
<tr>
<td>For <strong>REGULATORS</strong>, greater traceability for end-to-end data flow for improved Health Authority review &amp; approval</td>
<td>⏰</td>
<td>$</td>
<td>✅</td>
</tr>
</tbody>
</table>
TransCelerate eSource Workstream
The eSource Initiative works towards the advancement of the digitalization of clinical development for patients, sites, and sponsors

2015
Workstream founded

2016
Understand and Align

Uncovered the common aspirations to modernize the data collection

Identified Member Company priorities in adoption of eSource Modalities

2017
Revealed technology vendor willingness to engage with pharma
Exposed primary barrier to eSource advancement as a people and process issue
Prompted CDISC mapping to FHIR and EDC
Vendors to participate in HL7 FHIR connectathon work

2018
Initiated TransCelerate directed mapping to FHIR
Connected Duke with Member Companies for EHR to EDC Pilot
Identified need of site training and understanding of eSource capabilities
Recommended pharma as a trusted entity in the exchange framework to enable scalable EHR

2019
Engage and Accelerate

Engage with global regulatory agencies
Accelerate the maturity of EHR as an eSource for Clinical Research to create a scalable solution

Publish Sponsor call to action for change
Describe pharma needs to vendors through Logical Architecture and Data flow Diagram in collaboration with Tech council
Future State Interoperability: Explosion of FHIR
Pharma companies have yet to invest significant resources to solve the EHR interoperability issue

Changes in policy, emerging technologies, and advances in EHR data are transforming healthcare

These advances have the potential to provide great value to both patient care and Clinical Research

Amazon, Google, IBM, Microsoft, Oracle and Salesforce pledge to remove interoperability barriers

At the White House, technology heavyweights work together improving data exchange, the Argonaut Project and more.

A FHIR Future Burns Brightly for Population Health Management

As the healthcare industry warms up to FHIR, population health management and health data interoperability may be in for some significant improvements.

SMART on FHIR app uses machine learning to help dermatologists make diagnoses

Physicians at one Missouri health system are using the app to quickly reach conclusions and move forward with the best care options, its CMIO says.

Apple announces effortless solution bringing health records to iPhone

Health records bring together hospitals, clinicians and the existing Health app to give a fuller snapshot of health.

Copyright ©2017 TransCelerate BioPharma Inc., All rights reserved.
eSource Initiative, to date and beyond

Various eSource Assets and Industry Resources can be found at the eSource Website (Link to eSource Assets Page)

- eSource Sponsor Landscape *(published)*
- eSource Technical Landscape *(published)*
- Best Practices for non-CRF Data
- Roadmap to eSource Adoption: A TransCelerate Perspective *(pending publication)*
- Technology Considerations for the Future State *(pending publication)*
- eSource Site Capability Questionnaire
- CDISC Lab Semantics in FHIR Implementation Guide
- eSource Site Maturity Curve *(pending)*
- Method to calculate value & cost on eSource adoption *(pending)*
- Regulatory Landscape Assessment *(pending)*

- Engage with Site Advocacy Groups
- Collaborate with Standards Setting Organizations (e.g. HL7)
- Share and align information at industry events and conferences