Current state of organization

2012
TransCelerate Founded

2016
BioCelerate Founded

Today

MEMBER COMPANIES
20

INITIATIVES
30+

BAYER MOST RECENT MEMBER

Enabling 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

BREADTH & DEPTH

Over 60 solutions being delivered across 25+ initiatives, across 3 strategic priorities

Our Country
Network spans
30 COUNTRIES,
and
14 GLOBAL REGULATORY AUTHORITIES
have engaged with TransCelerate

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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*.

Thousands of people have contributed to the design, development and deployment of TransCelerate solutions

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

* Representative organizations, not exhaustive
How TransCelerate is working to make the vision a reality
Change how information is captured, structured and moves through its lifecycle

**eSource**
- Moving point of data digitization closer to the point of collection
- Enable capture of electronic source data to sponsor’s database
- To get standards to start working across healthcare and clinical research
- HL7 Accelerator : Project Vulcan founded

**Clinical Content and Reuse (CC&R)**
- Encourages automated content reuse throughout the project lifecycle
- Transform document content into data

**Digital Data Flow (DDF)**
- Automating configuration and enabling flow of information
- Automate how systems are prepared and how information is moved
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 clinical research data repositories/warehouses without entering the data 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.*
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

2017
Focus and Initiate

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
Awareness and Action

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
Proposed 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

2020
Focus on Sites and Regulatory

Engage with Site Advocacy Groups
Collaborate with Standards Setting Organizations e.g. HL7

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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

Fast Healthcare Interoperability Resources
An HL7 data standard for exchanging healthcare information electronically amongst hospitals, caregivers, patients, etc. FHIR aims to simplify implementation without sacrificing information integrity
TransCelerate 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 *(published)*
- Technology Considerations for the Future State *(published)*

**Knowledge Insights**

- eSource Site Capability Questionnaire
- CDISC Lab Semantics in FHIR Implementation Guide
- eSource Site Maturity Curve *(published)*
- Regulatory Landscape Assessment *(pending)*

**Tools & Solutions**

- Engage with Site Advocacy Groups
- Collaborate with Standards Setting Organizations (e.g. HL7)
- Complete regulatory analysis, confirm findings
- Share and align information at industry events and conferences
TransCelerate eSource Regulatory Landscape Assessment

Why?

• eSource has a huge potential for transforming clinical trials, with new ways of capturing data and improving on quality.

• New opportunities also come with new challenges

• We wanted to understand what expectations regulatory agencies and industry bodies have expressed in their ‘guidance’ documents on the use of new eSource technologies.

• How aligned are the guidelines for the purpose of doing global trials?
What we did

• The team was expanded with operational data management experts to define key topics of relevance to eSource. The list is shown to the right

• The regulatory expert team identified the relevant sections in the guidelines covering the topics

• This was summarised and line referenced in a common spreadsheet

• Topics were assigned two reviewers each to review the summaries and amend as needed.

• Reviewers independently evaluated each topic, and highlighted where the available guidelines are:
  • In consensus
  • Have differences
  • Have gaps (topic was not covered or topic could benefit from more guidance)

• During a team meeting we conducted a deep-dive discussion and concluded on a final review summary for each topic
## Preliminary Results by Topic

**Archiving**
- **Global State**: Gap
- **Note**: EDC centric Consensus, Technology gap for eSource

**Audit Trail**
- **Global State**: Differences
- **Note**: EDC centric guidance, ambiguity for eSource

**Control (i.e. Access and Security)**
- **Global State**: Consensus
- **Note**: Clear ICH defined expectations

**Data Integrity**
- **Global State**: Consensus
- **Note**: Differences in level of details

**Data Privacy**
- **Global State**: Gap
- **Note**: Governed by local laws

**Data Standards**
- **Global State**: Gap
- **Note**: No guidance

**Fraud Detection**
- **Global State**: Differences
- **Note**: EHR and eSource Integration - No common guidance around integration

**Interim state, paper copies during transition to full future state, source/original documents**

**Interoperability**
- **Global State**: Consensus
- **Note**: Interoperability is encouraged yet no guidance on expectations

**Lineage/Traceability**
- **Global State**: Consensus
- **Note**: Sufficient guidance exists

**Monitoring expectations**

**Ownership (i.e. where data is stored, who owns & manages it)**
- **Global State**: Consensus
- **Note**: PI oversight

**Source definition/modality source**

**Sponsor oversight**

**Validation**
- **Global State**: Differences
- **Note**: Specific for EHR
Preliminary Results – Examples

CONSENSUS

Topic: Control (access and security)
Observations:
• In general, all regions in alignment with ICH

DIFFERENCES

Topic: Validation
Observations:
• General consensus that validation of eSource systems is needed, and validation of data transfers is needed.
• There is distinct difference with FDA having ONC certification defined in: “FDA Use of Electronic Health Records Data in Clinical Investigations”
• Other regions do not have an equivalent.

GAP (TECHNOLOGY)

Topic: Archiving
Observations:
• Consensus across regions around archiving in general but there is a technology gap around archiving eSource data and subsequent retrieval of the data.
• This gap impacts both sponsor and sites to be inspection ready. Data is not suitable for PDF files as archive format.
eSource Logical Architecture