Clinical Research and FHIR: TransCelerate eSource

Presented by Jesper Kjr, eSource track member from Novo Nordisk
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.
**Significant Growth Over the Past 4+ Years**

- **2012**
  - TransCelerate Founded
  - **10** Founding Members
  - **5** Active Initiatives

- **2014**
  - **17** Member Companies
  - **12** Active Initiatives
  - **1** Exploratory Initiative

- **2016**
  - **BioCelerate Launch**
  - **19** Member Companies
  - **13** Active Initiatives
  - **6** Realized Initiatives
  - **2** Pharmacovigilance Initiatives

- **Today**
  - **19** Member Companies
  - **13** Active Clinical Initiatives
  - **6** Realized Initiatives
  - **2** Pharmacovigilance Initiatives

**Growth of Global Impact:**
- Country Network of 22 Countries
- Engagement with 11+ Global Regulatory Authorities
TransCelerate has 13 active initiatives in the Clinical Portfolio and 6 in Realization

**Active initiatives** focused on **innovative solution** delivery

1. Clinical Research Awareness
2. Clinical Research Access & Info Exchange
3. Patient Experience
4. Patient Technology

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

1. Investigator Registry
2. Shared Investigator Platform

1. eSource
2. Quality Management System

**Realized initiatives** focused on **enabling adoption**

1. Investigator Registry
2. Shared Investigator Platform
3. Site Qualification & Training
4. Risk Based Monitoring

1. eLabels
2. eConsent
eSource Clinical Data Capture
Current vs Future State

Current State:
- Paper ICD
- Local Lab
- Paper CRF
- COA/PRO/OOA
- Paper to EDC 2.0
- Paper to EDC 1.0

Future State:
- Shared EHR Data
- Point of care lab
- Smartphones
- eCOA/ePRO
- Big Data
- eSource (eCRPs)
The TransCelerate eSource Initiative

**UNMET NEED**

Although regulators have urged increased use of eSource for several years, application of the use of electronic sources of data for clinical trials has been slow to be adopted across the industry, particularly for registration trials, due in part to difficulties in operationalization.

Research indicates there are numerous obstacles and challenges behind this delay; some real and some perceived.

**OBJECTIVE**

Move the industry to optimize the use of electronic data sources, to influence more efficient data gathering practices to benefit patients, sites and sponsors.

**BENEFIT**

Improved global clinical science and global clinical trial execution for patients, sites, and sponsors.
eSource Vision

Helping the industry to optimize the use of electronic data sources to improve global clinical science and global clinical trial execution for patients, sites, and sponsors.

Through execution of:

- Sponsor & Technology Landscape Assessments
- Point of View to identify eSource capabilities to enable uptake of eSource
- Demonstration Projects (Study-Level Data Collection)
- Change Management Approach
- Stakeholder Engagement Approach
- Metrics/KPIs

- We will provide a framework to help solve the challenges.
- We will NOT develop standards or eSource technologies.
Stakeholder Impact

Aligned approach/framework for Health Authorities, Patients, Sites, and Sponsors

**SITES**
- Improved patient engagement
- Greater efficiency for sites and monitors
- Potential to eliminate duplicative data entry & reduce transcription errors

**PATIENTS**
- Improved patient engagement
- Potential for reduced patient burden for research participation (e.g. fewer visits, remote trials)

**SPONSORS**
- Guidance on eSource processes, procedural documents, technology
- Common understanding of Health Authority expectations

**REGULATORS**
- Greater traceability for end-to-end data flow
- Improved Health Authority review & approval process

Potential to eliminate duplicative data entry & reduce transcription errors
We have divided eSource technologies into four categories for working purposes.*

**Non-Case Report Form Data**
- Includes collection and transfer of data in electronic format from internal Sponsor sources or external vendors into clinical research repositories. Efforts to increase operational excellence would have a positive impact on clinical research.

**Direct Data Capture**
- Focuses on direct entry of clinical data by site staff without a source document into a mobile application or EDC system and discusses how DDC methods will impact processes throughout the clinical research ecosystem.

**Devices and Apps**
- Collects and manages clinical data from non-site personnel (subjects, participants, and caregivers) using mobile devices including smartphone or tablet applications, wearables, and sensors (e.g. glucose monitor, smart pill, ambient sensors).

**Electronic Health Records**
- Gathers information on EHR systems and how they are being utilized, the advantages and obstacles to realizing this potential and how ready our industry, the EHR vendors and the regulatory authorities are to make this potential new paradigm happen.

*We recognize that some technologies cross these boundaries and that these categories will likely evolve over time due to technological advances.*
Completed eSource Deliverables

Published papers focused on survey results:

**Sponsor Landscape** *
[Link](Published November 2016)
- eSource Experience
- eSource Potential Future Usage
  - Indications/Therapeutic Areas
  - Study Phases
  - Technologies Used/Planned
  - Member Company Priorities
  - Lessons Learned
  - Utilization Challenges

**Technology Landscape** **
[Link](Published July 2017)
- eSource Experience
- eSource Potential Future Plans
  - Technologies Used/Planned
  - Technology Company Priorities
  - Lessons Learned
  - Utilization Challenges
  - Planned Development

* Data collected via anonymous survey. Results include responses from 13 (out of 17) member companies.

** Data collected via anonymous survey and discussion with technology companies.

Surveys conducted and results shared on a blinded basis only.
Point of View Paper
For publication in 2018

Why
Define an optimal state and call to action

What
Drive the eSource data collection strategy with Use Cases

How
Create a short & long term roadmap
i.e. which eSource projects and modalities to achieve the ‘what’

The PoV Paper will deliver a call to action in pursuit of the following:

- Influence practice
- Create framework
- Cultivate environment
- Collaborate with Standards Development Organizations
- Share Knowledge
The eSource Capability Maturity Model is featured in the paper to demonstrate progression points towards a desired future state.

**Current State**
- Fragmented approaches
- POCs: limited scale
- Limited semantic interoperability
- Limited BYOD
- Labs mature
- Uncertain regulatory environment
- Limited workflows

**Early Emerging State**
- eCOA mature
- Exchange & query standards established
- Increased # medical grade devices; pilots
- Coordinated technology at sites, incr BYOD
- Single site POC EHR-EDC
- Sponsor incr informatics acumen
- Site workflow and adoption engagement

**Interim State**
- Use of exchange standards for multi-site pilots of EHR-EDC
- Site/patients are eSource change agents
- eSource factored into trial design & site workflow
- BYOD at scale; multi-collection devices
- Patient portals for access to data
- Device/apps are commonplace; show important outcomes

**Maturing State**
- Data broker model established; data exchange: at scale
- Critical data rec’d in real-time to facilitate decision making
- Barriers addressed for remote visits
- Incr application predictive & prescriptive analytics for design, data review
- Incr pragmatic trials and new trial designs
- Patients engaged in trial design
- Site and sponsor workflow aligned
- Incr clarity- regulatory environment

**Desired Future State**
- Clinical data are eSource and rec’d near real-time
- End-to-end digitized dataflow
- Metadata driven processes are automated
- Data collection redundancy eliminated
- Data broker model at scale
- Workflow at site/ sponsor coordinated and optimized
- Seamless connection of healthcare and research via single ID number, trial design, interoperability
- Regulatory certainty

**Behavioral Paradigm Shift**

Achieving the Desired Future State will involve collaboration with additional TransCelerate Initiatives.
Demonstration Projects
In-Progress
US FDA issued a call in June 2015 for Demonstration Projects to:
“...test the capability and evaluate performance of using an end-to-end eHR-to-EDC single-point data capture approach, using established data and implementation standards in a regulated clinical research environment.”

Responses were published - Federal Register (December 2015).

CDISC has also issued a call for demonstration projects.

Links provided for reference
What is a Connectathon?
A Connectathon is an event where innovative, boundary-breaking expertise from business, academia, and technology come together to solve critical challenges and test solutions in a safe environment.

The HL7 FHIR Connectathon aims to progress the Clinical Trial research community towards utilizing complete and interoperable electronic health data sources in clinical trials.

What is HL7 and why does FHIR matter?
As healthcare records have been increasingly digitized, sources of electronic health data need to be structured and standardized. HL7 (Health Level Seven International) is a not-for-profit, ANSI-accredited standards developing organization that has developed the FHIR (Fast Health Interoperability Resources) specification, which serves as a standard for the electronic exchange of healthcare information.

What is a FHIR Connectathon?
A FHIR Connectathon gives participants the chance to work with the FHIR specification outside a production environment. This feedback improves FHIR and ultimately advances the industry.

When are HL7 FHIR Connectathons?
Connectathons take place 3 times a year. The next session is January 27 & 28 in New Orleans.
# Clinical Research Track - Proposed Use Cases

**FHIR Connectathon - January 27 & 28**

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<tr>
<th>Scenarios</th>
<th>Value</th>
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<tbody>
<tr>
<td>Extract relevant EHR data for a patient and import into Study Database</td>
<td>Automatically populate eMR information in EDC &amp; Identify changed data in the EHR</td>
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<tr>
<td>Receive and apply Real World Evidence updates to the study database as new or changed data is recorded in the EHR or received from patients</td>
<td>Scalable and automated indication of EHR data from Sites where patients participating in a Study receive care</td>
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<tr>
<td>Extract lab data from Site EHR to Study database</td>
<td>Available data is made accessible for a Study</td>
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**WEBINAR**

Tuesday, December 12th  
10:00 a.m. - 11:00 a.m. EST
eSource Advancement Roundtables In-Progress
**eSource Advancement Roundtables**

On-going stakeholder engagement

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<tr>
<th>eSource Advancement Roundtables</th>
<th>2017</th>
<th>2018</th>
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<td><strong>SEP</strong></td>
<td><strong>OCT</strong></td>
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<td>JAN 26 New Orleans, LA*</td>
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**1st Roundtable**

**Sunday, September 10th**
San Diego, CA
Complimentary to HL7 Meeting

32 attendees: Academic Sites, Health Authorities, Sponsors, Standard Setting Bodies, Technologists (EHR, EDC & Integrators)

**2nd Roundtable**

**Thursday, October 26th**
Copenhagen, Denmark

22 attendees: Academic Sites, Sponsors, Standard Setting Bodies, Technologists (EHR, EDC & Integrators)

*Roundtables will occur in conjunction with other events such as HL7 FHIR Connectathons & CDISC interchanges*
eSource Advancement Roundtable
Actionable Insights

The barrier to eSource advancement is not perceived as a technology issue, rather it is a people/process issue to be solved through change management solutions.

Data collection for the study protocol should happen in conjunction with patient care activities to eliminate duplicative data entry efforts.

The advancement of eSource will not be solely dependent on a single solution nor a single stakeholder.