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Clinical Research and FHIR: TransCelerate eSource

Presented by Jesper Kjær, 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.

Current TransCelerate Members

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Significant Growth Over the Past 4+ Years

TransCelerate Founded

2012

10 Founding Members

5 Active Initiatives

2014

17 Member Companies

12 Active Initiatives

1 Exploratory Initiative

2016

BioCelerate Launch

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

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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

5. eLabels
6. eConsent

4. Comparator Network

3. Site Qualification & Training

3. Clinical Data Transparency
4. Risk Based Monitoring

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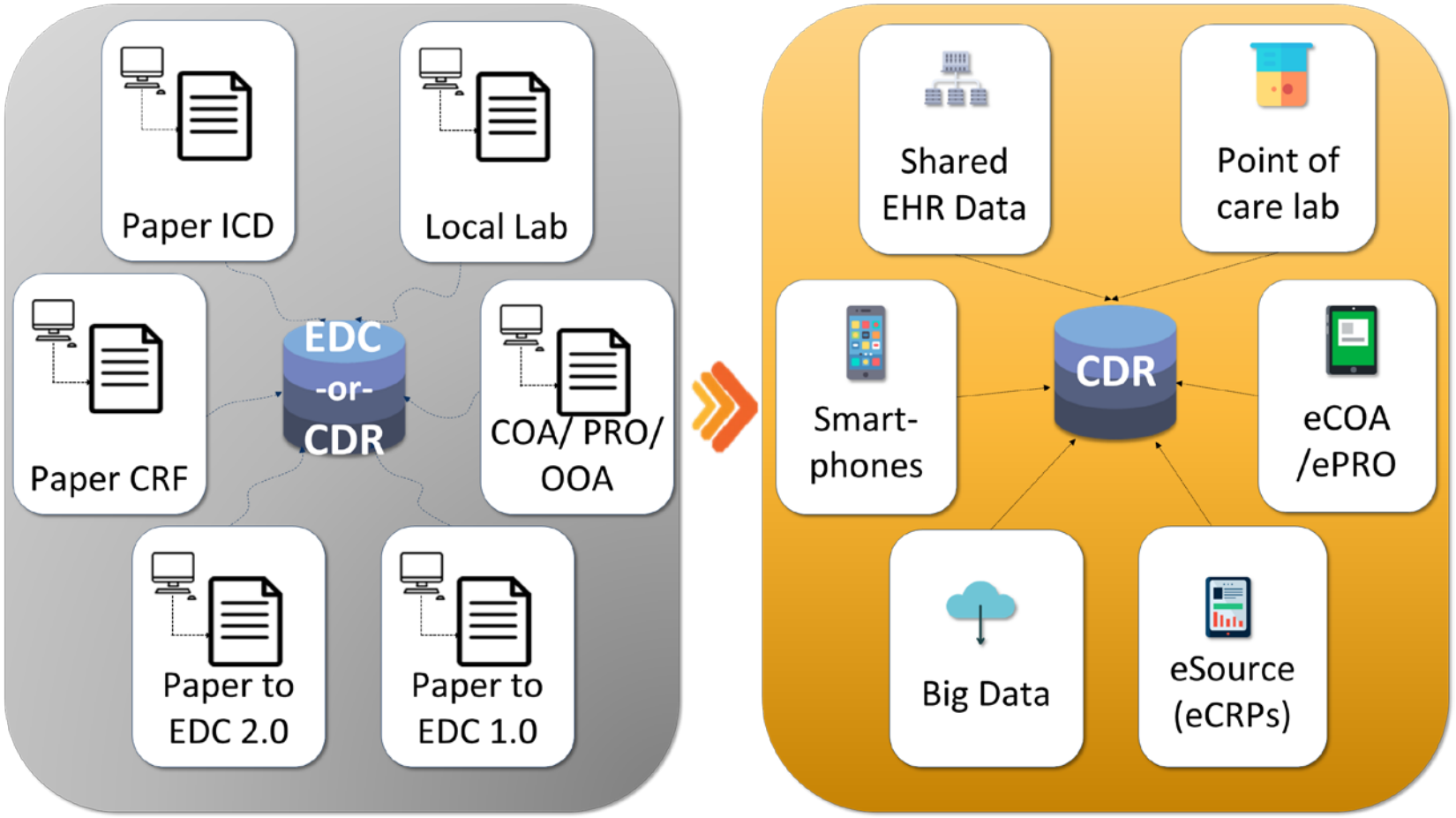
eSource Clinical Data Capture
Current vs Future State



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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.

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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.

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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

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eSource Working Groups

We have divided eSource technologies into four categories for working purposes.*

Non-Case Report Form Data	Direct Data Capture	Devices and Apps	Electronic Health Records
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	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.	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).	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.*

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Completed eSource Deliverables

Published in DIA TIRS

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

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

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 and discussion with technology companies.*

Surveys conducted and results shared on a blinded basis only

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Point of View Paper
For publication in 2018

Targeting DIA TIRS

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

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Point of View Paper Highlight
For publication in 2018

Targeting DIA TIRS

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 inter-operability
- 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

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Demonstration Projects

In-Progress

eSource
A case for Demonstration Projects: FDA & CDISC

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

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eSource
Demonstration Project: HL7 FHIR Connectathon

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) a not-for-profit, ANSI-accredited standards developing organization 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.**

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Clinical Research Track – Proposed Use Cases
FHIR Connectathon – January 27 & 28

Scenarios		*Value*
Extract relevant EHR data for a patient and import into Study Database		Automatically populate eMR information in EDC & Identify changed data in the EHR
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		Scalable and automated indication of EHR data from Sites where patients participating in a Study receive care
Extract lab data from Site EHR to Study database		Available data is made accessible for a Study

WEBINAR

Tuesday, December 12th
10:00 a.m. – 11:00 a.m. EST

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eSource Advancement Roundtables

In-Progress

eSource Advancement Roundtables
On-going stakeholder engagement

KEY
- Confirmed
- Targeted

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**

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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.

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