eSource on FHIR

Food and Drug Administration CDER Health IT Board
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Background: Moving away from the “swivel chair” method in clinical research.

Manual abstraction of EHR data for use in clinical research

Costly  Error-Prone  Slow
**Background:** Traditional workflow labor-intensive, relies on two data-related FTEs.

Source: Nordo AH 2017

Slide credit to Ben Parker MD/ MBA Candidate Duke University
**Background:** eSource-based data transfer simplifies workflow, reduces error potential.

- **Clinician:** Identifies patient as appropriate for study → Gets pink folder from clinic work room → Complete Informed Consent → Return pink folder to clinic work room

- **Patient:**
  - Tues and Thurs pick up pink folders from clinic work room
  - Enroll patient in study in MC
  - Add patient to "Patient lists" in MC when mother admitted for delivery

- **CRC:**
  - RF D
  - RF D Auto-populates demographic data

- **Data Entry:**
  - Complete form within MC
  - Saves form
  - Notate on front of pink folder completed
  - Files pink folder

Source: Nordo AH 2017
Slide credit to Ben Parker MD/ MBA Candidate Duke University
Proof of concept: Implementation of informatics has a profound impact.

1.7% Fraction of data captured electronically

- 1 Fewer FTE Needed
- 37% Time Reduction
- 65% Keystroke Reduction
- 30% Scrolling Reduction
- 100% Data Quality Rate

Source: Nordo AH 2017; icon source: various artists at flaticon.com
Slide credit to Ben Parker MD/ MBA Candidate Duke University
Importance / potential: Biopharma industry is enthusiastic and invested in moving forward.

The eSource Initiative supports TransCelerate Member Companies in accelerating the uptake of eSource for clinical trials. Although regulatory enthusiasm increased use of eSource for several years, application of the use of electronic sources of data for clinical trials has been slow to adopt across the industry, particularly for registration trials, due in part to difficulties in commercialization. Research indicates there are numerous obstacles and challenges behind this delay, some real and some perceived. The eSource initiative seeks to assist member companies, and ultimately other trial sponsors in overcoming these real and perceived challenges to influence more efficient data gathering practices to benefit patients, sites, and sponsors.

As the data for clinical trials becomes less about collecting protocol-defined data points, and more about using data from patient records and other electronic sources such as devices/ apps, electronic interoperability and consistent use of data standards become paramount. The 4 eSource categories defined by the TransCelerate eSource initiative are:

- **Devices & Apps**: Covers collection and management of clinical data from non-site personnel (e.g., subjects, participants, and caregivers) using mobile devices including smartphone or tablet applications (e.g., electronic clinical outcome assessment), wearables, and sensors (e.g., glucose monitor, smart pill, remote chemistry, ambient sensors).
- **Non-CRFs**: Includes collection and transfer of data in electronic format from internal sponsor sources (e.g., specialty laboratories) or external vendors (e.g., laboratory results, imaging, ECG, randomization, drug accountability) into clinical research data repositories/warehouses without entering the data onto a Case Report Form (CRF).
- **Direct Data Capture**: Includes direct entry of clinical data by site staff into a mobile application or EDC system.

Benefits:

- Potential to eliminate duplicate data entry, reduce transcription errors
- More informed vendors
- More engaged patients
- Greater efficiency for sites and monitors (potential for full RIM)
- Potential for improved Health Authority review/approval process
- Greater traceability for end to end data flow

Slide credit to Ben Parker MD/ MBA Candidate Duke University
Importance / potential: Food and Drug Administration is enthusiastic and invested in moving forward.
Importance / potential: Fast Healthcare Interoperability Standard (FHIR) provides necessary technical interoperability
Duke’s Solution
Get Patient Data From EPIC

Check List

Study: FHIR Demo Study
Patient: Asap, Shelley

REDCap API Token:
DA0673C2839100F1F96A674DE5404 A1
Fhir record was successfully created.

Check List
Study: FHIR Demo Study
Patient: Asap, Shelley
REDCap API Token: DA0673C2653100F1F98A674DE5404 A1

Demographics
- Patient ID: D1457649
- First Name: Shelley
- Last Name: Asap
- Date of Birth (DOB): 1968-01-01

Observations
- Respiratory Rate (bpm): 
- Heart Rate (bpm): 
- Body Temperature (°C): 

Refresh Data From EPIC
Fhir record was successfully created.

Check List

Study: FHIR Demo Study
Patient: Asap, Shelley

REDCap API Token: DA80673C26391010F1F98A674DE5404 A1

Refresh Data From EPIC

Demographics

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient ID</td>
<td>D1457649</td>
</tr>
<tr>
<td>First Name</td>
<td>Shelley</td>
</tr>
<tr>
<td>Last Name</td>
<td>Asap</td>
</tr>
<tr>
<td>Date of Birth</td>
<td>1968-01-01</td>
</tr>
</tbody>
</table>

Observations

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory Rate (breaths/min)</td>
<td></td>
</tr>
<tr>
<td>Heart Rate (beats/min)</td>
<td></td>
</tr>
<tr>
<td>Body Temperature (°C)</td>
<td></td>
</tr>
</tbody>
</table>
Hold this slide for video
Cross Collaboration: Key solution relies on understanding of multiple stakeholders perspectives.

Develop a **Single solution** based on **Standards**; (leveraging existing standards) that meets the requirements of all stakeholders.
Economic value of eSource in Clinical Trial Data Capture Practicum: Key question relies on understanding of multiple sub-elements.

Given infrastructure expense and adoption challenges...

Under what **specific circumstances** does investment in eSource “make sense?”

- Economics
- Implementation logistics
- Partner trial sites & CROs
- Clinical trial characteristics