EHR Integration

Increasing Data Efficiencies

CDISC DC User Group
March 31, 2016
Data Inefficiencies are Impediment to Research

• $2.56 billion to develop new drug – up from $1.04 billion in 2003 – *Tufts Center for the Study of Drug Development, 2014*

• Inefficient data activities include:
  – Recording of data at sites
  – Data collection by sponsor
  – Data cleaning
  – Source data verification
  – Safety Reporting
EHRs Can Increase Data Efficiencies

- Sites can efficiently re-purpose EHR data for clinical research
- Sponsors can accelerate data collection
- With EHR as the eSource:
  - Data is cleaner
  - Source data verification is reduced
FDA eSource Guidance

• CDER Contributors
  – Jonathan Helfgott, Ronald Fitzmartin, Leonard Sacks, Sean Kassim

• Key Points

  “…this guidance *promotes* capturing source data in electronic form…”

  “FDA does *not* intend to assess compliance of EHRs with part 11.”
“Flavors” of eSource

• Direct entry into eCRF
  – eCRF is the source

• Direct from devices
  – eCRF is the source

• Direct from ePRO
  – eCRF is source

• Direct from EHR system
  – EHR is source
  – EHRs can use intervening processes (e.g., algorithms to select data)
Benefits of eSource

• Eliminate unnecessary duplication of data
• Reduce the possibility for transcription errors
• Encourage entering source data during a subject’s visit, where appropriate
• Eliminate transcription of source data prior to entry into an eCRF
• Facilitate remote monitoring of data
• Promote real-time data access for review
• Facilitate the collection of accurate and complete data
Benefits of eSource

Source: Guidance for Industry – Electronic Source
Data in Clinical Investigations, September 2013
Problem – *Burden on Sites*

- Data collection is tedious and time consuming
- EDC shifted data entry to the sites
- Data entry into EDC is often delayed
- Training on multiple EDC systems
- 20-50% of investigators only do one trial
Opportunity – *Burden on Sites*

- Data from EHR better matches site workflow
- Data entry is more timely
- Training is reduced
- Reduced workload encourages more trials
Problem – *Data Quality*

- Duplicate data entry between EHR & EDC
- 92% of sites report >80% of trial data is entered in both EHR and EDC
- Error rate between source and EDC >4%
Opportunity – *Data Quality*

- Research data already collected in EHR
- 92% of sites report >80% of trial data in EHR
- 70% of sites report 100% of trial data in EHR
- Direct import into EDC eliminates errors
Problem – SDV Costs & Data Delays

• Source Data Verification (SDV) is expensive
  – 25-35% of Phase III budget
• Site monitor’s time spent is inefficient
  – Wasted time on data review
  – Time better spent reviewing study conduct
• Delays in data cause delays in decisions
Opportunity – SDV Costs & Data Delays

• Source Data Verification reduced
  – Direct from EHR: no SDV
  – Remote access to EHR
  – Incorporated in Risk Based Monitoring plan

• Data collection that mirrors site workflow accelerates data entry
EHR - Misconceptions

“Most sites still use paper charts.”

“EHRs are only used for billing.”

“Data in EHR systems are unstructured and unusable.”

“There are too many different types of EHR systems”
EHR – State of the Industry

- 70-80% of family physicians have EHR
- >90% will have EHR by 2019
- US adoption driven by ARRA
  - $11B incentives
  - Medicare penalties started January 2015
  - Meaningful Use Stage 3 will require interoperability
EHR Integration Standards

- CDISC – life sciences standards group
- IHE – healthcare standards group
- FDA represented
- Many-to-many standard
  - Multiple EHR systems
  - Potentially multiple EDC vendors (only Nextrials to date)
- EHR standard: CCD
- Integration standard: RFD, RPE
Implementation

• Designed to give most work to EDC vendor

• Minimal site responsibilities
  – Enable communication with EDC system
  – Identify study in EHR

• EDC Vendor responsibilities
  – Map fields in database definition
  – Validate
Compatible EHR Systems

- ~60% of Hospital Market
  - Epic
  - Allscripts
  - Cerner
  - Greenway
  - Tiani Spirit / Cisco
  - eMDs
  - GE
Extensions: “Never Leave the EHR”

- Patient enrollment from EHR system
- Data quality checks run in EHR
- Handle query resolution
- Ability to filter and select from multiple data points
- Visual cues for EHR data
- Flags for EDC/EHR data mismatch
Data Collection - NextGreen Study

- 4 sites / 40 patients retrospective study - 2009
- Integrated with Greenway EHR
- Based on CDISC/IHE standards
- >75% of data was auto-populated from EHR
- Site: “The ease of data capture within our system is amazing!”
Conclusions for EHR Integration

• Faster, Cleaner Data
• Supported by FDA and EMA
• Implemented by Multiple EHRs
• Decreased burden on sites
• Reduced SDV costs
RFD – EHR Integration Standard
Process Description
Future Possibilities

Form Filler (EHR – Cerner, Allscripts, Greenway, Epic, GE, E-MDS, TS)

Form Manager (Nextrials)

Request Form  Submit Form  Archive Form

Form Receiver (Nextrials)

Form Archiver (Nextrials, Abnology, or other 3rd party archive solution)
**Ambulatory Summary**

**Biddle, Linda L**
- Age: 65 years
- DOB: 08/15/1945
- MRN: BWMC 008-775
- FIN: 017258

Visit Reason:

**Problems** (4 Active):
- CLL - Chronic Lymphocytic Leukemia (12/21 13/45/19)
- Headache (11/30/19)
- Hypercholesterolemia (2/23/19)
- Hypertension

**Medications** (4) + Add
- **Aspirin** 325 mg oral enteric coated tablet 325 mg 1 tab(s) PO q4hr PRN 50 tab(s) 0 refills
- **Amitriptyline** 10 mg oral tablet 1 tab(s) PO Once Daily 90 tab(s)
- **Ibuprofen** 400 mg oral tablet 1 tab(s) PO q4hr PRN 50 tab(s)
- **Levothyroxine 20 mg oral tablet 1 tab(s) PO Once Daily**

Routing: None Selected

**Vitals and Measurements** Last 2 years + Add

<table>
<thead>
<tr>
<th>BP</th>
<th>Latest</th>
<th>Previous</th>
<th>Previous</th>
</tr>
</thead>
<tbody>
<tr>
<td>126/86</td>
<td>--</td>
<td>21 mos ago</td>
<td>--</td>
</tr>
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</table>

**Labs Last 2 years**

- No results found

**Health Maintenance** (0 Overdue | 4 Due)

**Diagnostics** (0) Last 6 months

**CDC Growth Chart** Last 2 years + Add

**Immunizations** (0)
- No immunizations recorded

**Visits** (1)
- Previous (1)
- Date: 05/05/09
- Type: Outpatient
- Location: BW Hospital

**Microbiology** (0) Last 6 months

**Pathology** (0) Last 2 years

**Outstanding Orders** (0) Last 2 years
- No outstanding orders

**Notes/Reminders** (0)
- No results found.
- **Aspirin**
- Priority: Subject: Due

**Past Medical** (0)

**Procedures** (0)

**Social** (0)

**Family** (0)

**Pregnancy** (0)
Future Possibilities

Data Repository
Archive System

- Data Repository or Archive System stores each transaction as an entire component in its database.

Patient Care
(EHR) System

- Patient experiences an adverse event.

- Medical professional at site brings up patient record in EHR system.

Clinical Research
System

- EHR system submits pre-pop patient data and a request to Clinical system for specific form(s). A copy is submitted to Archive at the same time.
Future Possibilities

Clinical system collects pre-pop data and pre-fills form with patient data already collected in the EHR system.

Clinical system submits pre-filled form to the EHR system to be displayed within the EHR interface.
### Concomitant Medication

<table>
<thead>
<tr>
<th><strong>Concomitant Medications Exist</strong></th>
<th>No</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medication Name</strong></td>
<td>Lisinopril</td>
<td></td>
</tr>
<tr>
<td><strong>Start Date of Medication</strong></td>
<td>2011-01-17</td>
<td></td>
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<tr>
<td><strong>Stop Date of Medication</strong></td>
<td></td>
<td></td>
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<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td><strong>Indication</strong></td>
<td>20 mg oral tablet</td>
<td></td>
</tr>
</tbody>
</table>

Submit
Future Possibilities

Data Repository Archive System

Data Repository or Archive System stores each transaction as an entire component in its database.

Patient Care (EHR) System

User reviews data and enters additional information as needed into the embedded Clinical form.

When complete the Medical professional at site submits the form which is immediately transmitted to the Clinical system.

Clinical Research System
EHR Integration Standard

Demo