The Impact of Novel Data Sources on Clinical Data Management

Alex Blanchard, September 27, 2019
Introduction

25th DFUG

25th Anniversary of SCDM
The Evolution of Clinical Data Management to Clinical Data Science

A Reflection Paper on the impact of the Clinical Research industry trends on Clinical Data Management

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The foreword states:

“...the SCDM Innovation Committee seeks to raise awareness on the upcoming industry trends affecting Clinical Data Management and prepare for its evolution toward Clinical Data Science.”
Introduction

• **More complexity**: Increasing use of a wider variety of data sources
• **More workload**: New data sources will produce bigger data sets in less time
• Could Robotic Process Automation help manage the increased workload?
eClinical Landscape Study

• Conducted online between May – July 2017
• 257 companies responded
• Mean of 16.5 years CDM experience
• 87.9% of respondents located in US
• Sponsors (N=193) & CROs (N=56)
eClinical Landscape Study

- 97% of companies increasing use of any data sources
- 70% increasing number of data sources used
eClinical Landscape Study
Data Sources Used Currently and Projected Use in 3 Years

<table>
<thead>
<tr>
<th></th>
<th>Data Used Currently</th>
<th>Projected Data Usage in 3 Years</th>
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<tbody>
<tr>
<td>EDC</td>
<td>100.0%</td>
<td>100.0%</td>
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<tr>
<td>eInformed Consent</td>
<td>30.8%</td>
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<tr>
<td>eCOA / ePRO</td>
<td>92.7%</td>
<td></td>
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<tr>
<td>Smart Phone</td>
<td>92.6%</td>
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<tr>
<td>eSource</td>
<td>44.8%</td>
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<tr>
<td>Custom Apps</td>
<td>84.1%</td>
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<tr>
<td>mHealth</td>
<td>82.7%</td>
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<tr>
<td>Personal Cardiac Monitoring</td>
<td>76.3%</td>
<td></td>
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<tr>
<td>Blood Glucose Monitoring</td>
<td>61.8%</td>
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Percent of companies
FDA Quotes

• “Advancing [Real World Data] into regulatory quality real world evidence is a key strategic priority for the FDA. ”

• “develop a framework on how digital systems can be used to enhance the efficient oversight of clinical trials.”

• “great potential in using digital technologies to bring clinical trials to the patient.... This is an FDA priority. ”
Current Status of Data Sources

SCDM: 70% of data volume is not coming from EDC sources.

ClinicalTrials.gov: “wearable” search yields 406 active studies (9/22/19)
My Data Sources

• eCOA via cell phone app
• Physiological measures – digital and paper outputs
• Paper questionnaires
• Computerized behavioral tasks
• Lab data
Data Sources You Use?

• What types of data sources do you use?
• Any new eSources that you weren’t using a few years ago?
• Or that you aren’t using yet but are planning to?
More Data!

Even more data will be coming from a wider variety of sources.
More Data! Can RPA help?

• Many other industries use Robotic Process Automation (RPA) to streamline their workload, maximize efficiency, and reduce costs in the process.

• Can Data Management utilize RPA?
First Off….What is RPA?

• Robotic process automation (RPA) refers to software that can be easily programmed to do basic tasks across applications just as human workers do.

• Like Siri? Or Alexa? Not quite…
Robotic Desktop Automation
with manual intervention

Robotic Process Automation
with digital triggers or self service

Machine Learning
with prescriptive analytics & decision engines

Artificial Intelligence
with deductive analytics

Increasing complexities & costs

Straight Through Processing

Data-driven

Doing

Thinking

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Examples of RPA Tools

- Blue Prism
- UiPath
- winautomation
Transform Healthcare with RPA
RPA Advantages

• RPA software doesn’t require programming knowledge
• Use existing infrastructure – great for multiple data sources
• Reduce errors
• Reduce cost
RPA Advantages

• Improve productivity
• DM manage more studies, handle more data, provide more site interaction/help
• RPA can mimic most human user actions on computer
Any current RPA users?

• Does anyone use RPA software currently either in a research context or organization context?
How could RPA help manage all the data?

- RPA can talk to various software applications from various eSource data to merge into EDC
- RPA could run batch edit checks after uploads and apply queries
- RPA could validate clean records to a certain level
Other Repetitive Tasks for RPA

• Create basic study setup
  – Common CRFs: data fields, global edit checks, field properties
  – Global settings
  – Page map
  – Etc.
Other tasks for RPA?

• Paperwork for database changes
• RPA could assist with executing Acceptance Test Kit
• What other processes would be well suited for RPA?