Data Integrity When Using Disparate Systems – Challenges and Solutions

A CRO Case Study

Sina Adibi, CEO, Adaptive Clinical Systems

State of Clinical Research Technologies

- The growing number of potential data sources and analytics tools to mine them now offer an unmissable opportunity to glean useful clinical information for sponsors and CROs*

- But data sources like CTMS, EDC, eSource, and others are disparate, difficult and expensive to connect.

- So what's the missing link?
New technology that connects both old and new – and yet to come – data sources for ultimate interoperability and insights into the data seamlessly.

*PharmaTimes September 2019

Challenges Facing Research Organizations

Today every company is a **digital company** trying to keep up

- Every day **new tools** and solutions become available
- Increasingly **complex** study protocols
  - ePRO & **Wearables** adding to the **data deluge**
- Increasing **sponsor involvement**
- More stringent **privacy** demands from regulators and patients
- Too many **unconnected solutions**
  - High error rate
  - Inconsistent Audit logs
- Need to reduce time and labor – **More with less**

Category Solutions
E-Clinical Platform Integration – A Key Differentiator
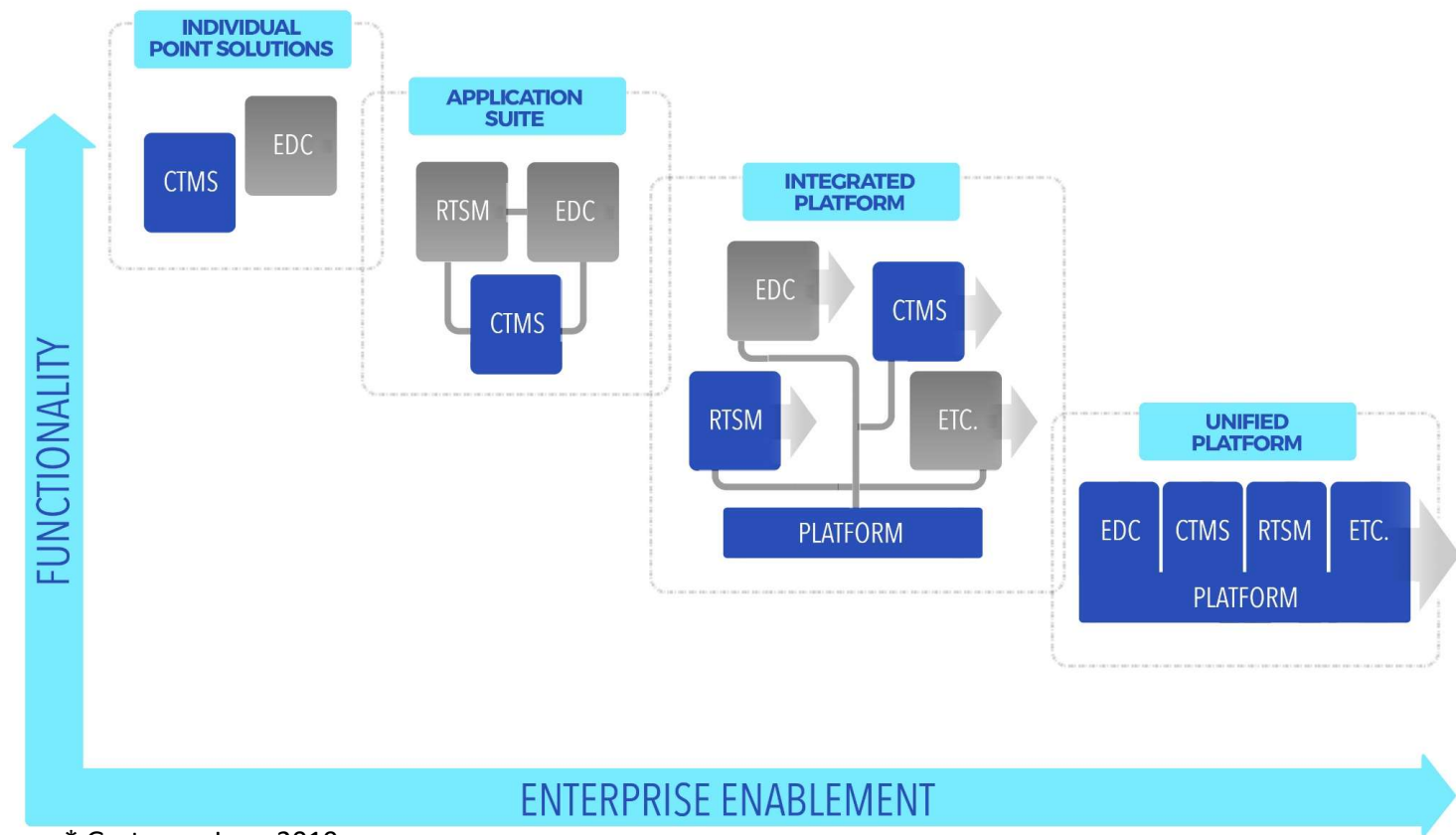
* Gartner – June 2019

Case Study

Present a real life scenario that mirrors many scenarios in the industry – achieving data integrity when there are disparate and disorganized systems in the data stack:

- One CRO's goals to achieve seamless interoperability
- Requisite capabilities for interoperability
- The challenges that they faced when it was time to step up in terms of transparent connectivity – full data visibility and support.
- The solution to their problem, results, and a solution to the industry in terms of best-in-class data integration.

Situation

Organization with limited staff wanted to expand CRO service in new therapeutic areas to increase revenues and better serve its customers.

- The organization had already developed **a proprietary** medical imaging system (PACS)

- Pre-existing **off-the-shelf technology** for CTMS, EDC and medical imaging analytics

- Multitude of Radiology Sites **(onsite and remote)**

- Sought to use **best-in-breed** tools to provide competitive service both in terms of speed and quality

Challenges

- EDC Study data was being manually collected, collated, and entered into multiple systems

- Remote Site Image Data was often late, missing, or inaccurate demographic data that resulted in post transfer queries

- Sponsors had to wait for project status data to be gathered, entered into Excel forms, and checked for quality before they could see reports

- Data transcription errors were causing significant project and reporting delays

- Certain derivations such as "best overall response" were manually determined wasting valuable staff time

Project Goal

Formulate technology framework to achieve seamless interoperability while using disparate systems:

- Review and identify best-in-breed tools that fit the required feature set and above all fit budget

- Design data flow and implement data controls to reduce error and minimize workload

- Identify interoperability features so that:
    - They are reusable across all future studies
    - Must be extendable to new and emerging technologies
    - Option to introduce new tools or replace old ones

Mandatory capabilities for Interoperability

Flexible middleware architecture is key

- Modular "Connectors"
  - Enable Real-time interoperability with ANY third-party tool through "Connector" suite

- Configurable "Clinical Rules Engine"
  - Eliminate duplication of data by capturing and transmitting eSource data
  - Auto-populate electronic study forms directly from appropriate eSource (e.g. Electronic Medical Record entries)
  - Reduce transcription errors and improve the quality of data
  - Encourage entering source data at the point of care
  - Facilitate remote monitoring of data to reduce the number of onsite visits

- Data Warehouse
  - Serves to harmonize and standard disparate data
  - Scalable & validated
  - Must be secure and easily manage GDPR requirements and obligation

Challenges

In short, using its pre-existing tools to provide the new service turned out to be cumber-some, costly, inefficient, and error-prone.
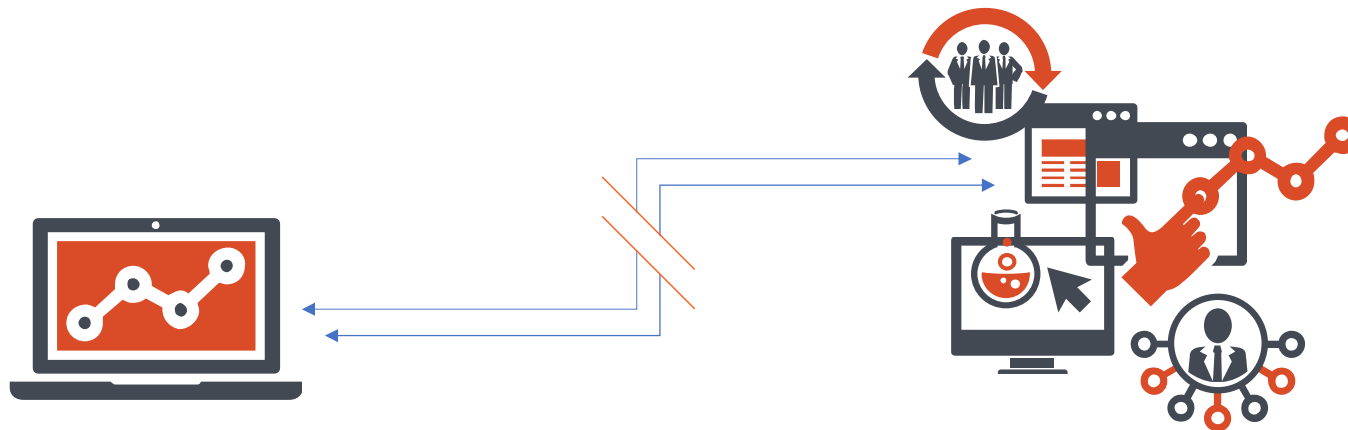
The Solution

Integration of the validated Adaptive eClinical Bus® solution with CTMS, EDC and Image Analysis Tool - delivering Accurate, Real-time, Validated Information

- Integrate EDC, CTMS, and MI systems
  - ➢ mint Lesion™, MI Analytics
  - ➢ Clinical Conductor CTMS
  - ➢ Open Source EDC
  - ➢ Proprietary PACS

- SaaS Interoperability Platform by Adaptive Clinical Systems®

- CDISC native data

The Solution

- No change to the underlying applications and processes

- Scalable and repeatable 'plug-and-play' connectors

- Full data visibility and support

- Minimal training required

- ALCOA
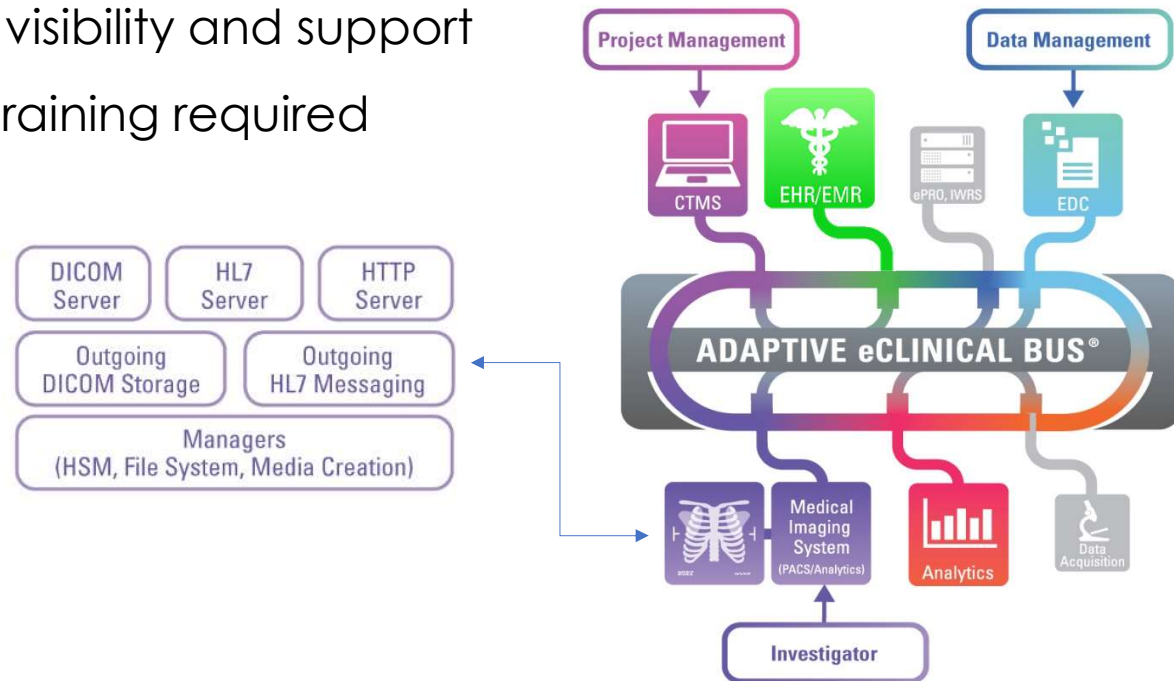
Overall Results

- Seamless data interchange among all system components by study

- Study startup reduced to less than 2 weeks

- Data errors due to reentry were eliminated

- Real-time, on-demand Status reporting

- 100% Audit Success Rate

- New clients were acquired based on the ability to demonstrate integrated, cost-effective, accurate, and validated processes

Quantifiable Improvements

70% Reuse of design content regardless of EDC

68% Reduction in study setup time

55% Reduction in data management, data Reformatting, and aggregation

43% Reduction in time spent verifying source data

27% Reduction in resources

Thank You

Adaptive Clinical Systems
1175 Markress Rd, #2632,
Cherry Hill, NJ
USA, 08034
+1 856 452 0864

E-mail:
Sina.adibi@adaptive-clinical.com
+1 856 473 4370

www.adaptive-clinical.com