Improving Data Management with Systems Integration and Next Generation Data Flow

Rich Davies
Director, Global Sales Consulting - HSGBU
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Program Agenda

- DATA SOURCES AND OUR TECHNOLOGY FOOTPRINT
- A PRACTICAL EXAMPLE
- OPERATING IN ISOLATION
- INTEGRATION
- EXTENDED INTEGRATION
- HOW CAN TECHNOLOGY HELP
- BACKEND INTEGRATION
- SUMMARY
DATA SOURCES AND OUR TECHNOLOGY FOOTPRINT
R&D is becoming more Virtualized and Networked
The Technology Challenge Has Changed
Broader Focus on Optimizing the End-to-End Process

- Historically sequential with compartmentalized stakeholders
- Multiple systems/vendors
- High integration overhead
- Explosion in external data
- Manual data integration processes
- Lack of traceability and control

Explosion in Electronic External & Third Party Data

- Omics
- Labs
- ECG/Devices
- CROs

EDC

IVRS

Trial Management

ePRO

Safety

Manual Processes

Statistics

Plan | Study Setup | Study Conduct | Analyze & Report | Submission | Post Market Surveillance

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Manual data integration processes
A Practical Example
Next Generation Data Flow?

A Practical Example

- Oncology Clinical Trial that requires EDC and IVRS/Drug Supply Management
- Technology provided by different vendors
- Both Cloud solutions
Operating systems in isolation
Operating in Isolation

Potential Challenges

- Systems from different vendors?
  - Multiple contracts
  - Multiple helpdesks

- Multiple interfaces/credentials?
  - Frustrating for site users

- Data duplication?
  - Enrol/Randomization/Visit/Patient Data?
  - Sites enter data twice

- Custom integration?
  - Low tech & costly
  - Supports poor processes

- Reconciliation
  - Technically complex and not real time?
Integration
What could integration support?

- Screening
- Enrollment
- Inserting new data
- Updating existing data
- Deleting existing data
- Clearing eCRF
- Transferring Patient
EDC/IVRS as a Two-Way Dialogue

IVRS communicates patient information back to Vendor Applications
IVRS – EDC Architecture
Web Services

- Put simply – an adapter
- Programmatic access to an applications data and event information
  - Facilitates internal and external information exchange
  - Shorten the integration cycle and reduces integration costs
- Versioned independently of product
  - More flexible and timely updates
Web Service Integration

HTTPS Communication

EDC App Server

IVRS App Server
Extended Integration
Extended Integration

Solution

- Data duplication
  - Integrate to eliminate
- Integration
  - Technically advanced
  - Process centric
  - Real-Time
- Reconciliation
  - Simpler to achieve
  - Less errors to rectify
- Multiple Systems – Single Interface
  - 1 x User Credentials
Summary
Next Generation Data Flow

- Uses web services technology to
  - Integrate at the process level, not just at the data level
  - Execute the integration as transactions occur
  - Embed logic and feedback into the integration
  - Reduce data inconsistencies
  - Integrate new types of data (i.e. User credentials)
  - Reduce the burden of data reconciliation
Hardware and Software
Engineered to Work Together