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Improving Data Management with Systems Integration and Next Generation Data Flow

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Safe Harbor Statement

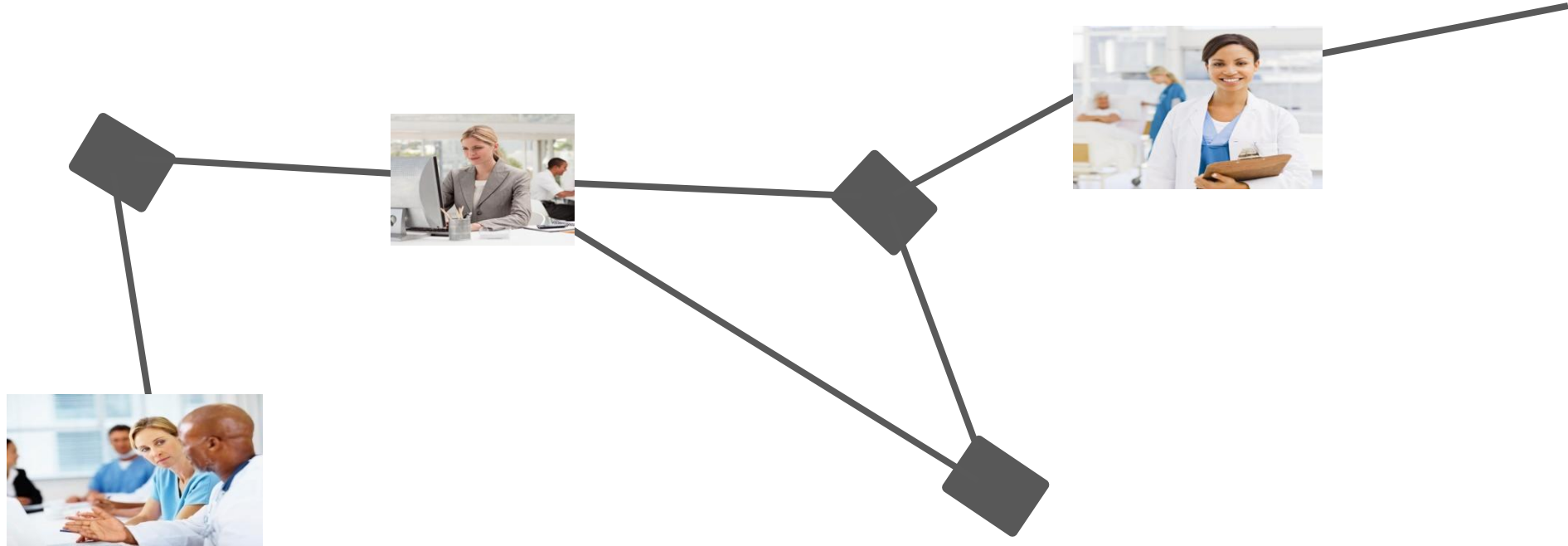
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Program Agenda

- DATA SOURCES AND OUR TECHNOLOGY FOOTPRINT
- A PRACTICAL EXAMPLE
- OPERATING IN ISOLATION
- INTEGRATION
- EXTENDED INTEGRATION
- HOW CAN TECHNOLOGY HELP
- BACKEND INTEGRATION
- SUMMARY

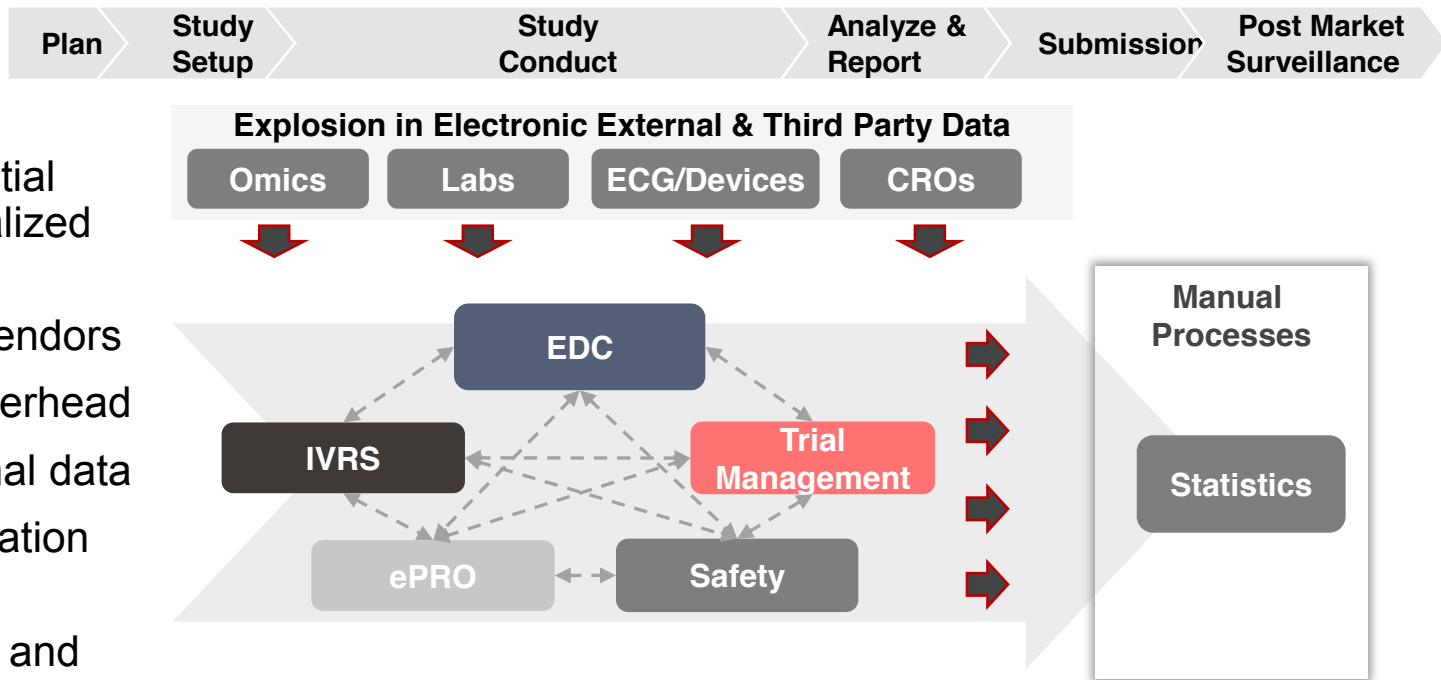
DATA SOURCES AND OUR TECHNOLOGY FOOTPRINT

R&D is becoming more Virtualized and Networked



The Technology Challenge Has Changed

Broader Focus on Optimizing the End-to-End Process



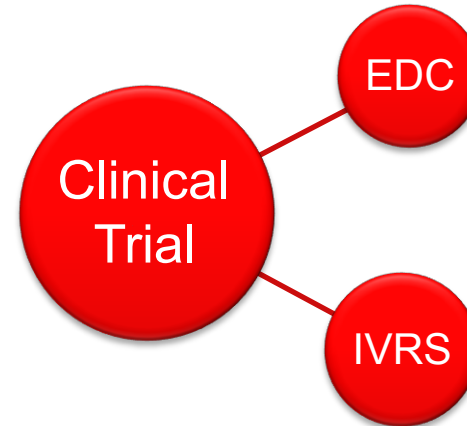
- Historically sequential with compartmentalized stakeholders
- Multiple systems/vendors
- High integration overhead
- Explosion in external data
- Manual data integration processes
- Lack of traceability and control

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

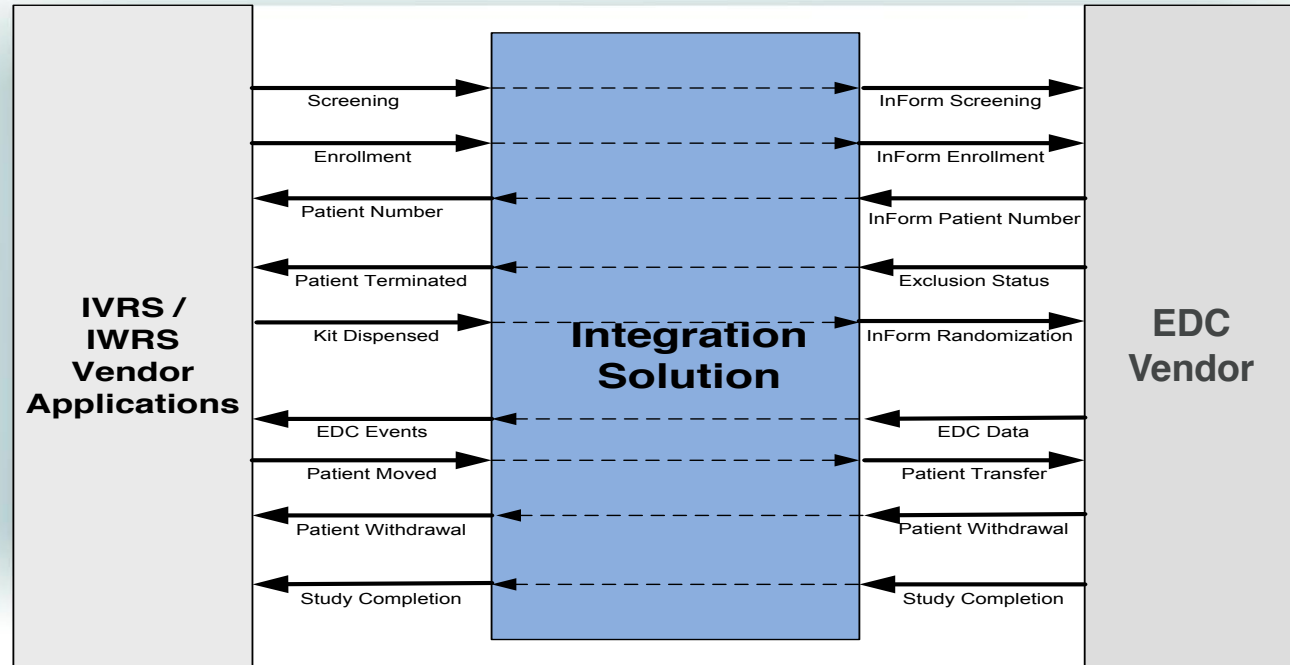
- Systems from different vendors ?
 - Multiple contracts
 - Multiple helpdesks
- Multiple interfaces/credentials ?
 - Frustrating for site users
- Data duplication ?
 - Enrol/Randomization/Visit/Patient Data ?
 - Sites enter data twice
- Custom integration ?
 - Low tech & costly
 - Supports poor processes
- Reconciliation
 - Technically complex and not real time ?

Integration

What could integration support ?

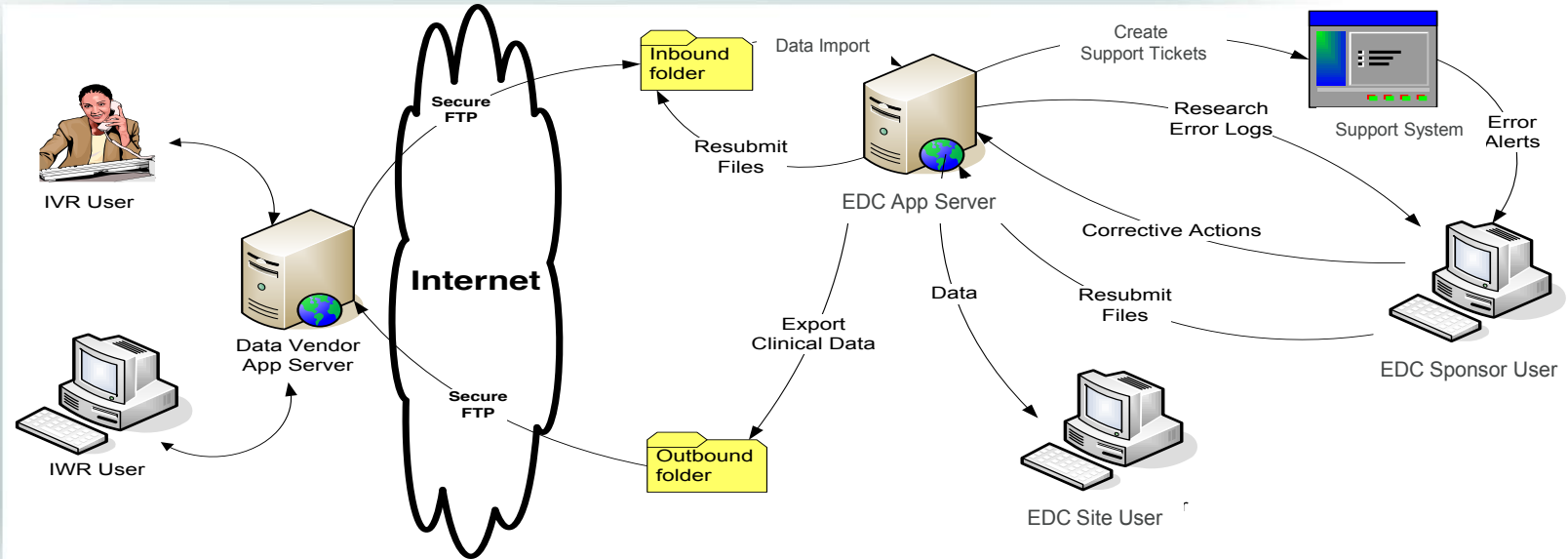
- Screening
- Enrollment
- Inserting new data
- Updating existing data
- Deleting existing ?data
- Clearing eCRF
- Transferring Patient

EDC/IVRS as a Two-Way Dialogue



IVRS communicates patient information back to Vendor Applications

IVRS – EDC Architecture

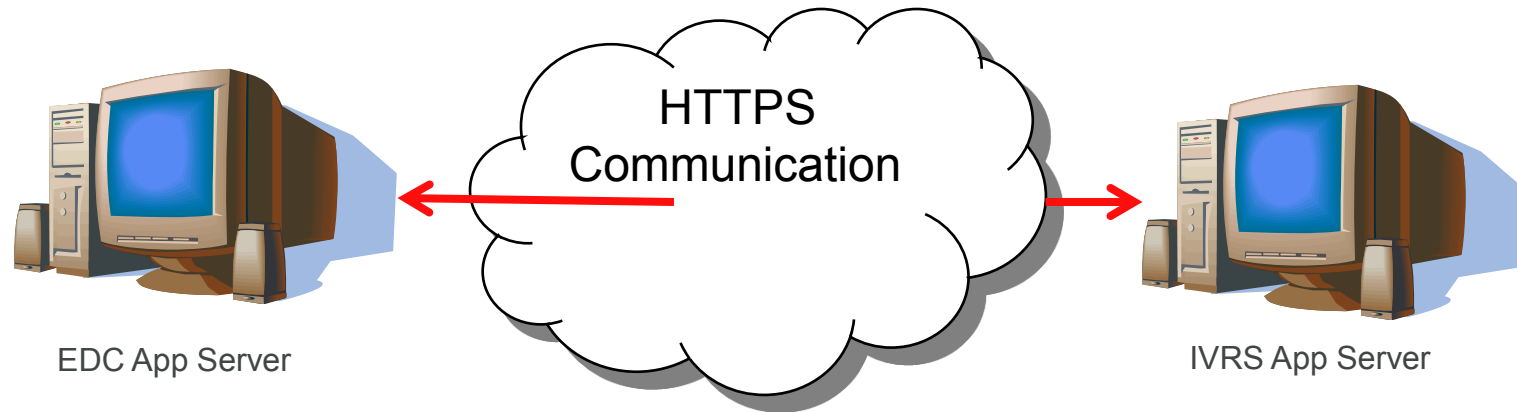


Web Services

- 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

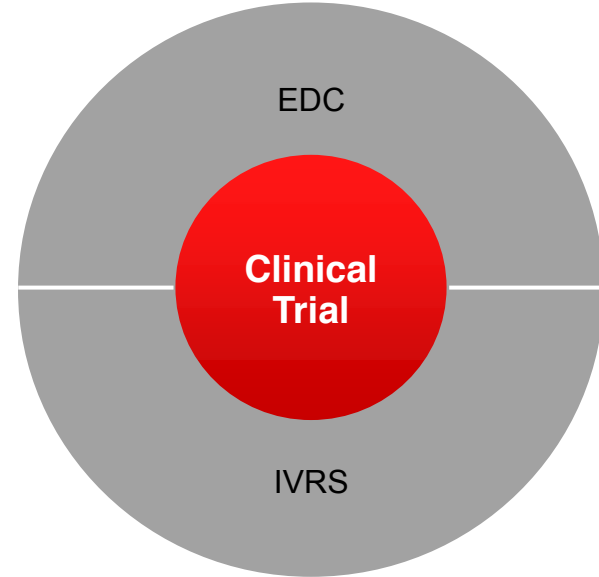


Extended Integration

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

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