SCDM India Single Day Event

THEME
CDM — Revisiting fundamentals in an evolving clinical research landscape

August 26, 2023, Mumbai
eSource & The World of Unknowns - Know The Basics First
Agenda

- eSource and Sources of Different eSource Data
- Advantages of eSource in Clinical Trials
- Challenges and Mitigations of eSource data from different Sources
- DM Challenges managing eSource data and Mitigations
- New skills to be acquired by DM to manage eSource data
- Case study
- Summary
- Key takeaways
- Q and A

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Sources of Different eSource Data

- EMR/EHR (Electronic Medical Records/Electronic Health Records)
- Devices & Apps
- Direct Data Capture
- Non-eCRF

- Labs
- ECG
- eCOA/ePRO
- Apps
- Smart watch

Advantages of eSource in Clinical Trials

- Real-time data capture
- Data quality and integrity
- Remote monitoring and decentralization
- Efficient source data verification
- Enhanced patient engagement
- Streamlined regulatory compliance
- Faster data analysis and reporting
- Cost savings
- Improved data management and archiving
Challenges and Mitigations

- Data Accessibility
- Data Standardization and Interoperability
- Data Quality and Accuracy
- Data Privacy and Security
- Regulatory Compliance
Data Accessibility

- Easy access of eSource data from various clinical sources with which the data can be obtained, retrieved and utilized for the analysis and decision making

Challenges
- Data Silos
- Heterogeneity
- Compatibility
- Data Sharing Agreements

Mitigation
- Data integration platform
- Standardized Data Models
- Standardized APIs and Data Exchange Protocols
- Collaboration
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Investigation of Serial Studies to Predict Your Therapeutic Response with Imaging And Molecular Analysis 2 (I-SPY 2 TRIAL)

CURRENT STATE

Secondary Systems
- Pathology Reports
- Radiology Reports

UCSF EHR
Provider Notes

Clinical Investigators

I-SPY EDC CRFs

FUTURE STATE

Secondary Systems
- Pathology Reports
- Radiology Reports

UCSF EHR
Provider Notes

Data Standards Mappings
- CDISC – TAGU-BrCa1
- CDISC – Adverse Event (AE) and other Domains
- CTCAE2 for Serious Adverse Event (SAE) data
- MedDRA3

I-SPY EDC CRFs

1: Therapeutic Area Data Standards for Breast Cancer
2: Common Terminology Criteria for Adverse Events (CTCAE)
3: Medical Dictionary for Regulatory Activities

https://www.fda.gov/media/132130/download?attachment
Data Quality and Accuracy

Challenges:
- Data Variability
- Missing Data
- Data Accuracy

Mitigation Methods:
- Standardized Data Models
- Data Validation
- Real-time Monitoring
- Transfer file conformance check to identify the common errors, missing data and duplicates based on the key variables
- Reconciliation by comparing the CRF data.
- Spotfire integration for data visualization.
- Check the quality and accuracy of varieties of eSource data including IXRS/IWRS, ePRO, wearable device, Lab/Biomarkers etc.
Data Privacy and Security

• Data privacy and security of clinical data refer to the comprehensive measures implemented to protect the confidentiality, integrity and sensitive patient information that are during the clinical trials.

Challenges
• Data Sharing
• Secure Data Transfer
• Patient Consent

Mitigation
• Data Sharing Protocols
• Encryption and Access Control
• Anonymization
Regulatory Compliance

- Refers to the adherence of processes, practices and data management in clinical trials as per the applicable laws, regulations and guidelines as set forth by the regulatory authorities, ensuring the ethical conduct of research, data integrity and patient safety.

**Challenges**
- Regulatory Variability
- Data Privacy
- Diverse Data Sources
- Data Consistency

**Mitigation**
- SOPs
- Regulatory Training
- Encryption
- Anonymization
- Standard Data Models
- Data Mapping
- Cross-Functional Collaboration
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CDM to monitor the data flow efficiently to rapidly identify safety data signals & define up-front escalation paths and alert levels when managing fast paced/high data volume.

**Challenge:**
Unclear data chain of custody

Establishing clear data governance frameworks, including defining data ownership roles and creating robust data sharing agreements with clear RACI

**Challenge:**
Making sense of high volume of data

Switch from Traditional CDM processes to advanced analytics processes to review the data in holistic manner by use of advanced analytical & Visualization methods

**Challenge:**
Identification of change in data pattern

CDM must implement more sophisticated data monitoring tools to identify sudden changes in data patterns generating from such e Source big data. e.g., Comprehensive Patient profiles

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New skills to be acquired by DM to manage e Source data

- **Data integration.** Knowing the integration points of data and end to end data flow
- **Data profiling.** Includes collecting descriptive statistics, discovering metadata, assessing its accuracy, identifying distributions, performing inter table analysis. Understanding completeness, quality, and age of data
- **Analysis.** Using technology to identify and read anomalies and understand their impact on the total study.
- **Entity resolution.** Knowing for certain it is the same user when gathering data from multiple sources.
- **Awareness and curiosity.** With a rapidly changing environment, staying aware of the latest issues, standards, and regulatory requirements.
Case study for e Source data

Clear Roadmap of Requirements Allows Sponsor to Speed Multiple Sclerosis App Development

Challenges

The Sponsor Pharma team was challenged by the fact that the app had been initially developed as a simple proof-of-concept that would not be used to inform any decisions and thus did not require GCP compliance. This Proof-of-Concept app needed to move into the development stage and thus to comply with GCP requirements. The digital health team needed a compelling case to help the software development staff understand what requirements needed to be met and why they were crucial to protecting the patient and data integrity of the tool. Digital health technologies that capture measures for endpoints have special requirements that are not considered in a typical computer system validation, and those needed to bring this app to the forefront.

Solution

Following CTTI's guidance, the Sponsor Pharma team brought together key stakeholders across development, regulatory, statistics and quality functions via a workshop. To show the group in practical terms the necessity of the required adjustments to the app, the statistics group presented use cases of what may happen if these requirements were not implemented. For example, what would happen if a patient's child picked up the phone momentarily? It is important to ensure that the data integrity of the app is not compromised. Following the workshop, the entire group collaborated to prioritize what requirements should be implemented on the very first app release and this was approved by EU MDR (The European Medical Device Regulation) certification.
Data flow between the eSource record (ESR) & electronic data capture (EDC) systems
Summary

Patients
allows for direct data capture outside of the clinic/hospital, reducing patient burden and enhancing their experience.

Data Managers
allows for comprehensive data reviews thereby increasing data availability and enhance data quality, promotes real-time access for data review.

Sponsors
reducing the time it takes to get medicines to patients and reducing trial costs.

Monitors
allows for greater use of risk-based monitoring, as well as remote data reviews. Allow monitors to focus on the most critical issues and reduce time spent on SDV.

Sites
Spend more time with patients by eliminating paper transcription and duplicate data entry errors.

eSource is rapidly changing the clinical research landscape. Adoption of eSource is beneficial to all the stakeholders however, to ultimately reap the downstream benefits of eSource, Sponsors and CROs should consider using a comprehensive unified platform solution that seamlessly unifies multiple eSource data capture sources and its end-to-end processing.
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<tr>
<th>Key Takeaways to manage e Source data</th>
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<tbody>
<tr>
<td>To engage the key stakeholders right from the clinical trial design phase</td>
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<td>Solve interoperability constraints through effective piloting, application of standards, and leveraging innovative technology platforms</td>
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<td>Promoting end-to-end data integrity &amp; secure data collection, aligned with established regulatory expectations for data privacy, validation, &amp; control</td>
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<td>Upskilling of Data Managers towards Data Scientist skills for holistic review of big data with intelligent, automated workflows</td>
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<td>Centralized study design to enhance data utilization with a single source of truth, automate data cleansing &amp; reconciliation processes, offer real-time data transformation to allow for analysis on demand &amp; Standardize submission-ready outputs</td>
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References

2) EMA: Guideline on computerised systems and electronic data in clinical trials
3) The Clinical Trials Transformation Initiative (CTTI) eSource working group is developing resources and tools to help sponsors and investigators use eSource in clinical trials https://ctti-clinicaltrials.org/
4) The TransCelerate BioPharma eSource Solutions website provides information on eSource systems and services
   https://www.transceleratebiopharmainc.com/
5) National Library of Medicine: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9823571/
6) CDISC: https://www.cdisc.org
7) SCDM: https://scdm.org/white-papers/
8) GCDMP: https://scdm.org/gcdmp/
9) GCP: https://ichgcp.net/
10) HL& FHIR: https://fhir.org/
eSource & The World of Unknowns - Know The Basics First

"The sky is not the limit; it's just the beginning. Chandrayaan 3, reaching for the stars."

It’s beginning of revolution in Clinical trial landscape through eSource, so let’s stick to our Basics, adopt to the Changes, learn from our Mistakes/Challenges and explore the Unknowns!
Q & A