Society for Clinical Data Management
DATA DRIVEN

Theme:
Capabilities | Collaboration |
Change on the way to Clinical Data Science

SCDM Live

India conference

2nd - 3rd December 2022
Radisson Blu Hotel, Bengaluru

Industry Context

Full potential of EDC has not been realized and that most implementations ended-up converting existing inefficient paper processes inside an electronic tool.

Overall changes to downstream processes and systems were not transformational enough to take advantage of faster data availability from EDC.

Additionally, despite the faster availability of data from the sites compared to paper-based processes, the cycle time from last patient last visit to database lock has been hardly reduced over the last decade. Decreasing from about nine (9) weeks in 2008 to seven (7) weeks in 2018.

The volume of data collected outside EDC has already surpassed significantly the volume of data collected on eCRF and it is growing at much faster pace every year, driven by the cries for patient centricity leading to the rapid adoption of eCOA, wearables, sensors, TPV data and other eSource solutions.

Additionally, the increasing cost of Clinical Development and the need for greater predictability of outcome requires the use of tool which helps in real time data validation, tracking and reporting of data sources specially for high-volume data collected outside EDC in order to making a positive and meaningful impact on Clinical Development.

Source: SCDM reflection Paper

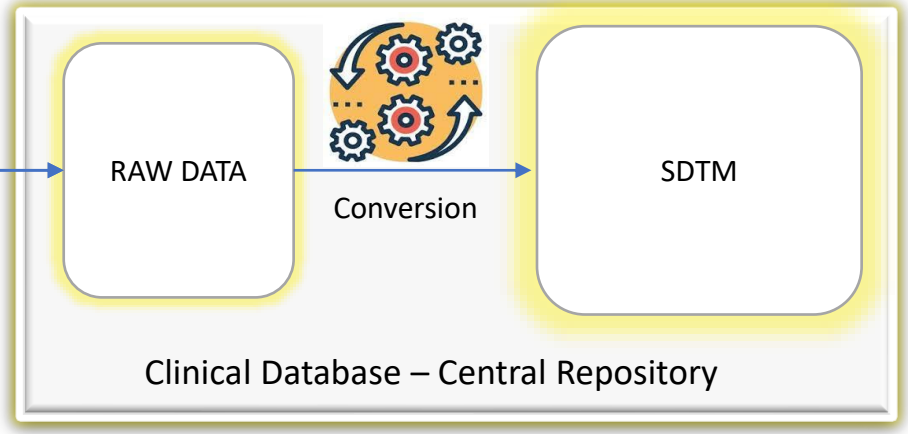
Central Data Review Tool

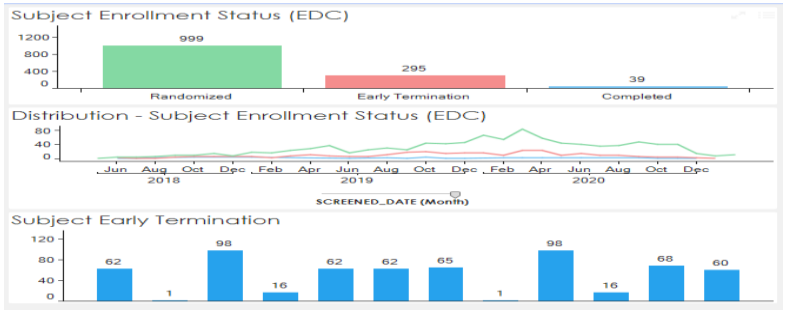
Queries can be pushed to EDC Real time

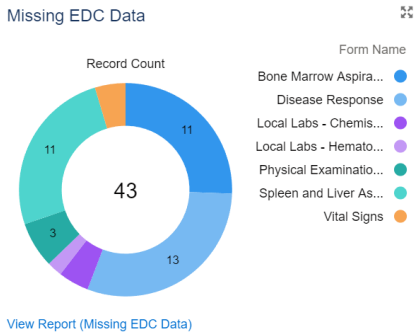
EDC

Third Party Data

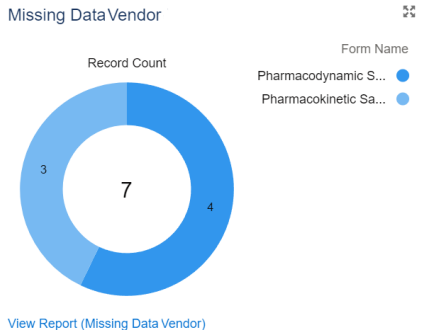
Central Data Review Tool







View Report (Missing EDC Data)



View Report (Missing Data Vendor)

Subject Name	Subject Status	Country	PI/Institution	Open EDC Queries	Answered EDC Queries	Missing Data	Pending CDR Discrepancies	Pending Vendor Queries	Pending Manual Queries	Pending SDV	Pending PI Signature	Pending SDR	Forecasted Data
12345	Early Termination	South Africa	XYZ Institute of Life Science	0	0	0	0	0	0	0	11	0	0
67893	Early Termination	United States of America	ABC Hospital	0	0	0	0	0	0	0	3	0	0
98765	Early Termination	United States of America	ABC Hospital	0	0	0	0	0	0	0	1	0	0
			TOTAL	179	42	399	55	0	9	45217	218880	799	0

Extract, Transform and Load Clinical data from all sources

Generate discrepancies through programmed edit check outside EDC

Generates meaningful Operational Analytics

Outcome and Learning

Effective Data Review

- Increase data review efficiencies
- Enables Cross functional review
- Streamlines data monitoring

Real Time Data Cleaning

- Generates data discrepancies throughout the lifecycle
- Reduce wait time
- Integrated Query management through EDC

Automation

- Semiautomated review involves less manual intervention
- Can be enhanced with AI ML capabilities
- Realtime CPT (Clean patient Tracker)

Targeted Data Review

- Enables in-scope data cleaning
- Projected metrics for upcoming milestones

Analytics

- More meaningful metrics generation and visualization to understand data trends

Cost Saving

- Operational efficiencies
- Effective Resource utilization
- Reduced LSLV to DBL TAT

CDR Tool can be 21CFR Part11 and ICH-E6-R2 compliant