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.
Central Data Review Tool

Queries can be pushed to EDC Real time

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

**Targeted Data Review**
- Enables in-scope data cleaning
- Projected metrics for upcoming milestones

**Real Time Data Cleaning**
- Generates data discrepancies throughout the lifecycle
- Reduce wait time
- Integrated Query management through EDC

**Analytics**
- More meaningful metrics generation and visualization to understand data trends

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

**Cost Saving**
- Operational efficiencies
- Effective Resource utilization
- Reduced LSLV to DBL TAT

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