The Clinical Data Landscape Has Changed

Clinical trial data volume has increased seven-fold in the last 20 years to 3.6 million data points in a typical Phase III study. Only approximately 30% of clinical trial data is entered through eCRFs in EDC systems. More data is being captured directly from patients and from outside the clinical trial site, driven by the growth in decentralized trials.

But Clinical Data Management Technologies and Processes Have Not Kept Pace

Aggregating and reconciling data from multiple sources takes huge effort. Integrating different data capture systems and their data is challenging. An exhaustive point-by-point review of data cannot scale. Query-based data cleaning doesn’t contribute proportionally to improving data quality.

Database lock and data transformation into submission-ready outputs are too manual and take too long.

Transforming Clinical Data Management Technology to Tackle the Evolving Data Landscape

So how do we modernize clinical data management technologies to manage the new and rapidly evolving data landscape?

New cloud-based platforms and intelligent data analytics will transform clinical data management processes.

Comparing Traditional and Next-Generation Clinical Data Management Approaches

Here is a visual comparison between traditional and next-generation clinical data management approaches.

Results Achieved by Medidata Customers

- Conduct studies 2 months faster
- Reach database lock 9 days sooner
- Reduce On-site Monitoring by 4 days per site on each study using Rave EDC + TSDV (Targeted Source Data Verification)
- Conduct <50% SDV (Source Data Verification) and maintain the same data quality with Rave EDC + TSDV
- Analysis of difference in median FPI to LPLV time for Rave EDC + at least one additional Medidata product vs. Rave EDC only studies (p<0.05) 2017 to 2021; Reduction of 59 Days.
- Analysis of difference in median LPLV to DBL time for EDC + at least one additional product vs EDC only studies from 2017 to 2021.
- Includes 241 studies per cohort. Statistically significant at *p<0.05 for comparison of means. Monitoring On-Site Rate defined as rate of on-site monitoring days per year across studies and sites for a study active period.
- 12% lower average total query rate* in group using TSDV. Total Query Rate: # of Queries per 1000 datapoints. n=254 per group *p<0.05.

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