ENHANCING DATA QUALITY

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INTRODUCTION

Data quality is a key success criteria in a regulated environment to see how best data suits to serve its purpose. Accuracy & completeness of data plays a vital role in clinical trials as it pertains with safety of subjects, decision making, and aids expediting existing processes & learnings to enable faster drug delivery of unmet medical needs of society.

AIM

To reduce manual intervention by adapting newer technologies in clinical trials which are both robust and regulated by,

1. Endorsing on Standard processes & methods
2. Risk based quality monitoring (RBQM)
3. Identification of critical data & gaps by Periodic qualitative analysis
4. Manual & automated tools for review process
5. Diverse source of data collection for analysing & Visualizing e.g. Power BI, Python, R

METHODS

- Interoperability
- Predictive & Prescriptive Data Collection
- Compatible interconnected systems
- Single interface web
- BPA (Business Process Automation)
- Standard Quality governance
- Reinventing data review

RESULTS

1. Integration of different systems in eDC tool can reduce significant reconciliation efforts with data quality, consistency across different clinical trials.
2. Cost effectiveness in utilizing single tool serving many purpose.
4. Providing customer support experience to site 24/7 with greater quality.
5. Reduction in timelines at critical milestones with enhanced quality.

CONCLUSION

Data quality is a key success criteria in a regulated environment to see how best data suits to serve its purpose. Accuracy & completeness of data plays a vital role in clinical trials as it pertains with safety of subjects, decision making, and aids expediting existing processes & learnings to enable faster drug delivery of unmet medical needs of society.

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