Captivate™ EDC vs. Paper Data Collection

Time, Efficiency, and Cost | Is Paper Less Expensive than EDC?

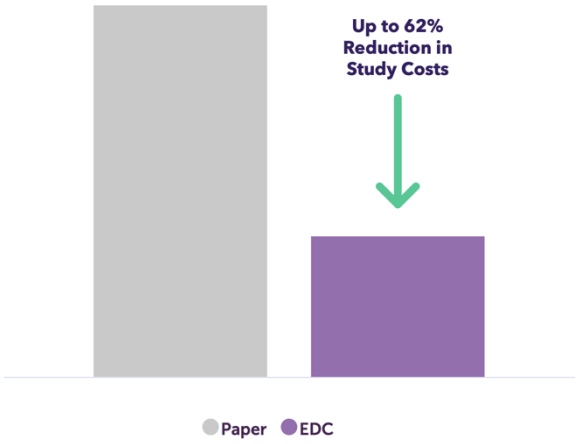
Historically, a common barrier to entry for implementing Electronic Data Capture (EDC) systems for small studies is the upfront costs, a large part of which, comes from professional services fees. Luckily, as technology has evolved, there has been an industry-wide shift away from legacy EDC systems, which require programming, to easy-to-use systems with drag-and-drop design interfaces. The shift toward do-it-yourself systems has decreased study build time and eliminated professional services costs. This white paper is written, alongside supporting industry research, to debunk the myth that paper is more cost effective than EDC, even for small studies.

Supporting Data

In a 2009 study conducted by Pavlovic, Kern, Miklavcic, it was found using EDC saved overall study costs by 49-62% compared to paper data collection.

EDC technology has greatly improved in recent years, making it even more cost-effective for studies. The key areas where EDC can reduce costs are: during study build, data review, data cleaning, monitoring, statistical analysis, and quality review. EDC functionality greatly reduces the amount of time clinical researchers need to spend in these areas, which saves money in the long-term.

The remainder of this white paper will discuss how EDC functionality saves time and costs in more detail.



Shorten Timelines and Reduce Errors

Both EDC and paper studies require generation of case report forms (CRFs). However, unlike with EDC, paper CRFs may incur significant printing, shipping, and physical storage costs throughout the lifetime of the study. These costs can be substantial, especially if there are multiple groups who need to review the CRFs. Each time a CRF needs review, shipping costs are incurred or study personnel, such as Data Managers, may need to travel to and from sites to retrieve the CRFs which introduces travel accommodation costs to the study. This method also increases the risk for mishandling or losing CRFs with crucial study data.

Data Accessibility

Building electronic CRFs (eCRFs) in modern EDC systems, should not take longer than designing a paper CRF. Performing data capture directly in the EDC removes the need for double data entry. Additionally, the ability to easily configure data validations will reduce the number of potential errors during data entry. For any queries that do arise, the data is available to be reviewed in real-time. Remote monitoring capabilities including source data verification with electronic signatures and automated audit trails can drastically reduce time and decrease your study costs.

EDC systems also provide insight into real-time study data. In-application reports allow users to easily visualize data and complete tasks based on their user role. Customizable data exports in Excel, SAS, SPSS, and SDTM reduces costs for statistical analysis.

Data Security and Compliance

Paper studies require data to be securely transferred and safely stored in a physical vault. Each time the data on paper is physically moved, a potential security risk may be introduced. With EDC, data is securely stored in the cloud which includes backups and SSL encryption during transfers. Additionally, EDC systems contain audit trails which allow customers to meet all FDA 21 CFR Part 11, HIPAA, EU GDPR, and EU Annex 11 requirements and enable customers to meet Good Clinical Practice (GCP) compliance requirements, saving on quality costs.

In Conclusion

It is widely accepted that collecting study data using EDC is more efficient. However, comparing EDC subscription software cost vs. the costs incurred throughout a study using paper data collection models, shows that EDC is also more efficient financially. The benefits of error reduction, time-savings, and quality and compliance assurance makes using an EDC for any sized study a no-brainer.