

Global provider of eCOA and patient-centric solutions

eCOA study: Paper back-up and data reliability

kayentis · Monday, September 16th, 2019

eCOA study: the impact of a paper back-up system on data reliability

In any eCOA study, a data back-up solution is needed in case of any issues that may arise with the electronic equipment, such as a tablet, used to collect data.

Although the use of back-up systems is seldom necessary, their availability is crucial for when something goes wrong. And it's important to choose the right back-up system because it may have a huge impact on data reliability, and therefore on your clinical trials.

Main drawbacks of a paper back-up system:

- No control over the assessment date
- Less prevention of data entry errors
- Reduced conformity of data
- Inconsistency of data with other study data
- More expensive and difficult to set-up
- Loss of the benefits of eCOA
- Improper use

Download our infography: "eCOA STUDY: THE IMPACT OF A PAPER BACK-UP SUSTEM ON DATA RELIABILITY"



eCOA study: the impact of a paper back-up system on data reliability

In any eCOA study, a data back-up solution is needed in case of any issues that may arise with the electronic equipment (such as a tablet) used to collect data.

Although a paper back-up solution can seem like an attractive option due to its apparent ease of use and cost-effectiveness, such an approach can have an adverse impact on data quality and reliability. Electronic back-up systems, such as second tablets or web interfaces, assure a much stronger data reliability than paper back-up systems; some of the most common problems of the latter include incorrect or missing data, lack of traceability of data entry (which makes it impossible to confirm identities and other important details), and missing time/date stamps.

Using a paper back-up system: a negative impact on data reliability!



90% of Kayentis' clients have never

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drawbacks of a paper

🎸 No control over the assessm ent date no of the person entering the infor pliance with 21 CFR Part 11). Less prevention of data entry errors: of automated control measures and reduced

duced conformity of data, e.g. due to entry errors, multiple responses to a single and excess information on the form.

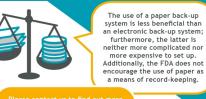
. mconsistency of data with other study leading to a comparison of error-prone data pack-up) with 100% reliable data (eCOA).

expensive and difficult to set up: re expensive and difficult to set up: Translation problems, particularly with alphabets going from right to left. Potential study design modifications. Time loss and extra costs incurred due to implementation of

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Potential extra copyright costs for use of multiple media Loss of the benefits of eCOA regarding patient involvement.

Improper use: studies have shown that paper back-up systems lead to their misuse when not required, which can result in a worsening he negative effects of paper back-up.



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Learn more and compare the main back-up solutions in our white paper "CHALLENGES OF BACK-UP SOLUTIONS IN eCOA STUDIES"

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