

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!



When do we need a back-up system?

90% of Kayentis' clients have never required equipment replacement. The technology we use to collect data was designed to circumvent any problems that may arise during clinical trials, including those to do with network connectivity. Data is collected in real-time offline and sent to our servers immediately upon connection. However, sometimes things happen that are beyond our control, such as power-outs or maintenance work that impacts connectivity. This is why back-up systems are crucial in case of any unforeseeable events.

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.

What are the main drawbacks of a paper back-up system for eCOA?

- ✓ **No control over the assessment date** nor the identity of the person entering the information (lack of compliance with 21 CFR Part 11).
- ✓ **Less prevention of data entry errors:** lack of automated control measures and reduced query resolution.
- ✓ **Reduced conformity of data**, e.g. due to more data entry errors, multiple responses to a single question, and excess information on the form.
- ✓ **Inconsistency of data with other study data**, leading to a comparison of error-prone data (paper back-up) with 100% reliable data (eCOA).
- ✓ **More 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 two systems.
 - ! 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 can lead to their misuse when not required, which can result in a worsening of the negative effects of paper back-up.



The use of a paper back-up system is less beneficial than an electronic back-up system; furthermore, the latter is neither more complicated nor more expensive to set up. Additionally, the FDA does not encourage the use of paper as a means of record-keeping.

Please contact us to find out more about back-up solutions developed to ensure data reliability.

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