

# Challenges of back-up solutions in eCOA studies



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# Why is there a need for a back-up solution?



In some cases, the eCOA user (investigator/site staff, patient, or observer) may not be able to use the usual eCOA device for questionnaire completion.

## Some possible causes of not being able to enter data into the eCOA device are



- Device is broken or not usable due to hardware problems.
- Device is not operating correctly due to software or study programming problems.
- A network connection is not available but necessary for electronic data entry\*see note below comparison table.
- Device is not available, e.g. lost or currently in use by another person.
- Device is out of charge and the user does not have time to recharge.

The problem could be temporary (e.g. a network issue or if the device is already in use by another user) or permanent (e.g. if the device is physically broken). This does not change the immediate need for a back-up solution, but could reduce or remove resolution efforts.

## Risk assessment



Clearly, an eCOA user should be able to perform the required actions as needed. However, the reality can be more complex. While the unavailability of a device is problematic, the consequences do vary. Planning for back-up options requires a consideration of the complete system, including risk assessment.

### Key elements to consider are:

- Criticality of eCOA data for the study (e.g. primary/secondary *versus* exploratory endpoints, inclusion criteria related to eCOA data).
- Risks around the study power being too low.
- Actions that can be delayed (e.g. waiting for eDevice availability) and actions that should take place regardless.
- Factors external to the eDevice itself (e.g. score calculation, direct communication with IRT for randomization purposes).

Finally, it is key to bear in mind that the user will be inconvenienced by device unavailability. Having planned for a back-up solution and trained users will not only help patients for the collection of diary data but will also help sites manage such unplanned but predictable events.

# What is a back-up solution?



When a user needs a back-up solution, he/she is in a situation where a planned task cannot be performed. Most frequently, but not exclusively, this relates to the completion of questionnaires.

**The back-up solution provides another method for completion of a task, however, the following aspects should be considered:**

- The task may not be completed in the way that was originally planned. The back-up method could be via a different process.
- The back-up solution could result in subsequent additional tasks.
- The back-up solution could result in downstream consequences that should be considered.
- The back-up solution should include instructions regarding how and when to return to the original process.



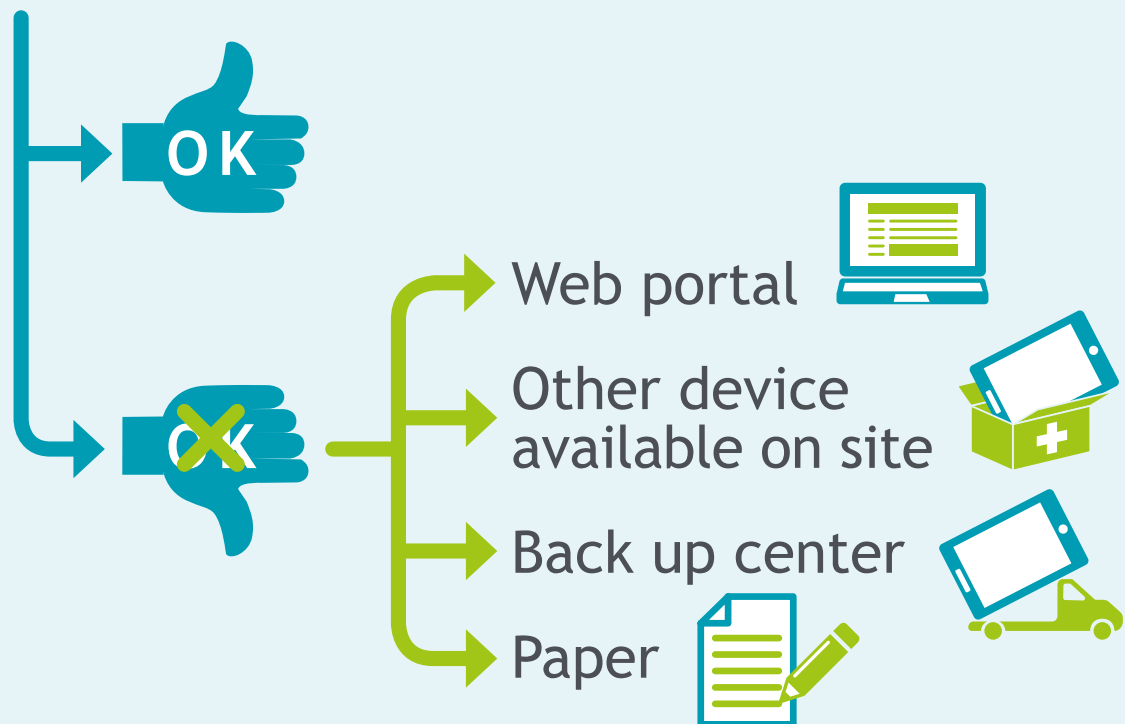
# Which back-up solutions can be introduced?

A range of back-up solutions need to be available to cover different scenarios, as is the case at Kayentis.

The study protocol and associated processes are key elements for the back-up assessment and the accurate evaluation and mitigation of risks to provide the best back-up solution for a specific study.

## Main eCOA back up solutions

### eCOA device





# 1 Use an alternate electronic data entry solution: data entry using a web portal

- **FOR CLIN'ROS**, for example with Kayentis' solution, investigators perform Data Entry directly via the Clin'Form Portal using their own login/password.
- **FOR ON-SITE PRO DATA ENTRY**, the investigator (or study nurse) logs in and prepares the patient data entry, as for the eCOA mobile application. Then the patient performs the data entry.
- **AT HOME**, the user logs in and is automatically routed to the relevant questionnaire, without any choice by the end user.

The layout of questionnaires is usually simple and can be displayed in a generic way, or could be also more specific (e.g. EQ5D, PASI questionnaires, body maps).

## **Additional work might be required in planning for this back-up method, e.g.:**

- Languages used in the web display may need to be considered.
- Necessity for an equivalence study for eCOA and back-up data capture methods.

This solution will not work in the event of local wider network outage, or at the provider's data center.

Offering data entry using a web portal is a solid back-up option for on-site or home usage. It offers a complete audit trail, and is fully compatible with workflows in place for normal eCOA device usage. In some countries or specific populations, this solution may not be an option at home.

## 2 Set up a stock of spare devices



Another solution would be to have some spare devices on-site (for on-site use or diary replacement).

- Requires accurate estimates regarding quantity, and has a cost impact.
- Minimal delay for making the spare device “operational”, but support or travel may be needed for home usage.
- Using a spare device is not a foolproof solution (some causes of device failure may also affect the spare).

Note that spare devices can be also used to manage periods of high demand (e.g. if many patients attend a visit on the same day), although this would not be considered to be “back-up” use of the spare device per se.

## 3 Set up an efficient device replacement process



A quick device replacement process can be set up. Another device can often be provided quickly, either by eCOA provider support or by another local site that has spare devices (e.g. at a country level).

This solution is similar to having spare devices but requires preparation and shipment delays. Although it may be a cheaper back-up option, it incurs a delays and, if the only back-up solution, it will not eliminate some data loss.



# 4 Guarantee data capture with paper and perform data entry later



For this solution, users complete a paper version of the questionnaire. The paper questionnaire will usually be printed and provided by the site, but the user could obtain the paper version by other means if more suitable to a particular situation. Subsequently, the user a study nurse, investigator, or the provider enters the data from the paper version into an electronic system (e.g. a web portal or via the eCOA device once available).

**A paper back-up solution requires good anticipation and planning as it can have a significant impact on processes, costs and timelines.**

**Some requirements for a paper back-up solution are listed below:**

- The production of paper templates and printing guidelines, training, paper archiving by the study site, and data entry process with Source Data Verification (SDV).
- Using paper may also incur additional costs (e.g. translation and licensing). Some copyright holders may require licensing for each mode of use (e.g. paper, web-based, tablets).
- In some instances, paper back-up may not be possible, e.g. if the questionnaire has been entirely designed for electronic use and a paper version does not exist.

**We also have to keep in mind that a paper back-up system may have a negative impact on data reliability.**



**Below are some of the 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 with other study data.
- More expensive and difficult to set-up.
- Loss of the benefits of eCOA.
- Improper use.



**Learn more about "Paper back-up and data reliability"**



**While paper is not considered a good option for backing up an electronic device this approach has one key benefit:  
IT WILL ALWAYS WORK AND ENSURES DATA ENTRY!**

This can be an appropriate solution on-site, despite the significant drawbacks. It is important that the use of a paper back-up solution is limited to situations where there is a real need, and to ensure that the filing and subsequent data entry are as error-free as possible. A paper back-up solution could be used only for critical visits.

**It is essential not to lose any data, and it is equally important to ensure that the data are good quality, even when a back-up is used.**

**The use of paper questionnaires at home is discouraged due to the potential for poor quality data and the limited possibility for quality control.**

# 5

## Other back-up solutions



- **Back-up data capture with IVRS (for Diaries only)**

This solution currently has several drawbacks, including the complexity of the set-up and the possibility of inconsistencies between IVRS and the usual eDevice due to the differences in the method of data capture. Accordingly, Kayentis does not consider this to be a good back-up solution in most cases.

- **BYOD**

BYOD is a promising option for the future, and once in place will be particularly useful for Diary back-up.

# Deep dive into numbers



Kayentis has used real world experience to extract and analyze data from tens of studies from various therapeutic areas, and of various duration and complexity, with different eCOA device models (mostly on-site but also at home) to assess the different back-up solutions quantitatively.

## eDevices are rarely broken or stolen

The first finding is that eDevices are rarely broken or stolen.

- Definitive replacement of the site device during a study is **<2%**
- **>90%** of sites never need a replacement eDevice.

In most cases, the back-up solution is only needed temporarily, with the original eDevice fully operational later on without needing to be permanently replaced.

Note that some devices might be replaced for other reasons, which are generally study-specific (e.g. to limit the burden at sites) but without any impact on data capture.

## The main consequences of the lack of device availability are related to the availability of a back-up solution, and the complexity or delay to put one in place

Whether an immediate back-up solution is in place or not has an impact on the incidence of missing study visits:

- When an immediate back-up solution is in place (i.e. a spare device is available on-site) eCOA missing visits will be almost **0%**; in this situation there are likely to be only a small number of missing visits, mainly due to external events (e.g. the patient didn't attend a visit or the site didn't capture the eCOA data for a visit).

- When an immediate back-up solution is not in place, eCOA missing visits will be **1-2%** for most studies (this may be higher for larger, more complex studies).

**There is no difference in the incidence of missing visits between the different types of immediate back-up solutions:**

- There is no significant difference between the incidence of missing visits when spare devices are available on-site or when a paper back-up is in place.
- There are insufficient data to compare the incidence of missing visits when a web data entry back-up solution is in place, although an incidence similar to that for the other back-up solutions, i.e. close to 0% missing visits, would be expected.

**At home**, the incidence of missing data due to device-related issues is **<1%**

**For studies with a spare eDevice on-site**, two eDevices are often used in parallel. The spare device is often used not only as a back-up but also to help to handle the workload (in approximately **10-20%** of cases). Also, the spare device is sometimes used instead of the initial device after a while.



# Conclusion

Defining a back-up plan must be considered as part of normal project management. This does not reflect the quality of the solution but acknowledges the existence of the possibility of equipment failure and the need for a risk analysis and mitigation plan.

Any eCOA vendor should integrate an analysis of back-up options as part of the study set-up. Factors such as the study design, size, duration, and criticality of COA data should be taken into account to assess the risks and impact of eDevice unavailability.

Sponsor and eCOA vendor study teams should jointly investigate and select an appropriate back-up plan. The eCOA vendor will then be able to deliver all the relevant components, such as specific devices, instructions, training material, or additional processes.

# Comparison of the main back-up solutions

	Web data entry	Spare @site	Paper back-up	Express shipment
Solves hardware issue	✓✓✓	✓✓✓	✓✓✓	✓✓✓
Solves software issue	✓✓✓	✓✓✓	✓✓✓	✓✓✓
Solves network issue*	✓✓✓	✓✓✓	✓✓✓	n/a
Works fine at site	✓✓✓	✓✓✓	✓✓✓	✓✓✓
Works fine at home	✓✓✓	✓✓✓	✓✓✓	✓✓✓
Data quality	✓✓✓	✓✓✓	✓✓✓	✓✓✓
Critical visit needs	✓✓✓	✓✓✓	✓✓✓	n/a
Reduced missing visits	✓✓✓	✓✓✓	✓✓✓	✓✓✓
Compatible with score calculation	✓✓✓	✓✓✓	✓✓✓	n/a
Low back-up cost	✓✓✓	✓✓✓	✓✓✓	✓✓✓
Limited burden from back-up use	✓✓✓	✓✓✓	✓✓✓	✓✓✓

*\*In case of network outage (local or external to site or home), this might be difficult or may require support assistance. In most cases, the Kayentis eCOA device can work without network connectivity but some processes such as score calculation or IRT might require immediate network access.*

*To reduce this risk, Kayentis eCOA devices are equipped with dual network options (Wifi and GSM). Additional options such as MiFi could also be considered.*

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