Kayentis

Global provider of eCOA and patient-centric solutions

Switching from COA to eCOA – 6 points checklist

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Benefits generated by a switch from COA to eCOA have already been clearly demonstrated by many: it allows instant access to data, collection of a greater quantity, much higher quality and reliable data, and to flag data that has not been filled in compliance with the protocol.
In many cases this move generates cost cuts for the sponsor as well, by reducing drastically spendings on monitoring, data management, logistics and non-quality impacts; if the instruments chosen bear study endpoints, the increase of data quantity and quality would in itself justify the switch to eCOA.

For a successful switch from paper to electronic, consider these 6 elements early enough:

1. Choose the device that matches your study subject

- The device should be carefully chosen to match the specificities of the study: age of the subjects, instruments chosen, therapeutic area, duration of the study, online/offline capacity …
- For instance: a handheld will be perfect for an NRS but not a VAS, an ePEN might be perfectly suitable for some CNS indications, and Web a smart alternative for some real life studies, for instance.

2. Adapt your device to your targeted patients

How easy are the devices to be used by the targeted population subjects?

- Some subjects have never used a smartphone and may not feel at ease using them, especially the most senior subjects and/or those in countries where smartphones are not yet as popular as in USA and Europe.
- For this reason, and for the general ease of use of subjects, layout and intuitiveness of the solutions should be carefully looked at, as well as all supportive documentation (online training and help, supporting documentation).

3. Manage the transition from paper to electronic versions

Ensure an appropriate transition of the instruments from paper to electronic versions.

- Early work between the eCOA vendor, the translation company, authors and the sponsor is important so that all constraints are taken into consideration: study specificities, copyright, keeping or not open question, running eventual equivalence studies and/or usability testing.

- Also, most of the ethics committees will request copies of the texts patients will face in local languages and in the exact final display of screens, quite early in the course of setup.

4. Adapt processes to secure source data

- While paper PRO constitutes the source data today, eCOA will drastically change the paradigm; the primary data base will consist in source data
- The study team should evaluate if the vendor's solution is fully validated to capture / host / secure source data and has full audit trail
- Also end of study processes need to be cautiously evaluated (copy of the source for the sites, and legal archiving of the source).

5. Define the backup

- Paper COA is always available and does not need a backup
- eCOA is populated via an electronic device that can potentially break, run out of battery, be lost or stolen.
- The study team should carefully evaluate backup options depending on study context; the choice can vary from no backup at all to one backup device per country or even per site.
- Whatever backup option is chosen should be based if possible on the same device for the sake of consistency.

6. Think beyond eCOA

- Once the decision is made to go for eCOA and budgeted to pay for the solution, one may find useful to think beyond eCOA and take advantage of the device at site to implement other solutions on the same device.

Several vendors now propose eICF on top of eCOA on the same device for instance, generating savings for the sponsor while making it very simple for the sites and really informative for the subjects.

Moving forward towards eCOA is undoubtedly beneficial to the quality of the data and the trial, and implementation of eCOA solutions is expected to grow quickly in the next few years. In order to smoothly manage this transition, sponsors should strongly consider early work with translation companies and eCOA vendors to cope with the aforementioned challenges.

Guillaume JUGE, CEO – Kayentis – June 20, 2016

// Check here the infography about switching from COA to eCOA //

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