eCOA CHALLENGES OF LONG TERM STUDIES

How to anticipate eCOA complexities in multi-year studies & develop best practice to support sites?

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kayentis

Dedicated to eCOA & Patient Engagement

THANKS

Using eCOA solutions can bring its own set of challenges. This workshop held by Kayentis in 2020 aimed at discussing the hurdles that arise when using eCOA solutions in long lasting clinical trials, essentially from the sites' perspective. What are the main issues encountered on a day-to-day basis? And how can industry stakeholders better understand issues faced by site staff and offer solutions to keep them engaged?

This session was hosted by Louis Chapu, Product Manager at Kayentis.

We warmly thank all the participants for their active contribution to this session.

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DEVICE OR SOFTWARE USABILITY IS THE MAIN ISSUE FOR SITES

As end-users, site personnel can be affected by software or devices issue, whilst their area of focus should remain patient management and safety monitoring. Not all site staff are technologically minded, and their working days are often very busy.

"Whether the hospital staff are conducting clinical trials or working in routine practice, they are more concerned about caring for the patients than handling technology" acknowledged a Global Trial Director from a large pharma company.

In certain studies, patient visits are few and far between, which means that both sites and patients can forget how to use a device. Despite reminders, support, and a helpdesk, difficulties around the use of technology can lead to frustration and compliance issues.

> ***"Whether the hospital staff are conducting clinical trials or working in routine practice, they are more concerned about caring for the patients than handling technology"***

The same happens when it comes to sites starting a study long after the investigators' meeting or in the event of staff turnover: users don't switch on the tablets regularly enough. An important challenge for the industry is to find a way to make sure patients and sites use the system more regularly!

The systems and digital tools should be as user-friendly as possible, so that both patients and site staff understand what to do in a few clicks. The industry must think through the development of their software and devices, always keeping in mind that not all end-users are tech-savvy, and that frustration with technology is common.

LEVEL OF CLINICAL STAFF TRAINING CAN INTRODUCE ADDITIONAL CHALLENGES

What about training and re-training?

"Training and re-training is essential!" claimed the Head of PRO Strategy from a large pharma organization.

Investigator meetings are the main opportunity for training, but what happens afterwards? With potential delays to study starts in some

> *"Training and re-training is essential!"*

countries or sites, or when the visit schedule is such that patients will not come to sites for long periods, site staff tend to forget what they learned during their initial training. If, on top of this, they have limited experience with eCOA, it can be very hard to for them to use the solution easily and efficiently.

Software updates can create issues: when an additional PRO is added, or software improvements are uploaded, a reboot may be necessary, or the update can take some time to upload. If sites are not warned in advance, this can create problems and frustration.

> ***"During the COVID crisis, we only heard when there were technical issues, but sites did not inform us that they needed re-training because of lack of patients visits for weeks"***

In some specific circumstances, such as the COVID-19 pandemic, studies have been put on hold for several weeks if not months, and training could have been performed a long time before study start. By the time of site initiation or re-initiation, the team may have forgotten what was learnt at the training. However, sites rarely ask for a refresher course, and the sponsor should proactively propose refresher sessions and supportive material.

"During the COVID crisis, we only heard when there were technical issues, but sites did not inform us that they needed re-training because of lack of patients visits for weeks" recognized a Global Trial Director from a large pharma company.

In some circumstances, the eCOA vendor can also propose re-training or refresher courses: clinical sites technical issues may be escalated by the helpdesk directly to the eCOA vendor, which should prompt the eCOA representative in the project team to propose refreshers or even to prepare customized material.

Real-time information, reminders, and alerts are key to avoid questions from sites and patients

At trial set-up, the standard training package includes how to switch on the device, launch a session, and how to complete and submit a questionnaire. However, how to handle common issues and simple troubleshooting basics need to be added to this standard training package. A quick reference guide that covers the most common issues is key. A Frequently Asked Questions document (FAQ) or troubleshooting guidelines can also be helpful, but only if they are updated frequently and easily accessible to end-users. Additional training tips were discussed in the eCOA training dedicated workshop in this series of workshops.

"Training plays a big role here; however, despite training, and especially with long-lasting studies, there will still be sites or patients who are not compliant with the system" acknowledged the Head of PRO Strategy from a large pharma organization.

So, to help sites and patients in long-term studies, it is not only training but real-time information, reminders, alerts and training refreshers that will make the difference. Users need to be informed when updates

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are about to happen, how long a software update will take, if and when restart is required, or if a visit has an additional questionnaire. Adding in simple messages such as "Updating the system – this will take a few minutes, please be patient" can reassure the end-user.

WHAT ABOUT CONNECTIVITY ISSUES?

With the option to answer questionnaires offline, connectivity can be less of a problem; however, it becomes a significant issue when the data are needed in a timely manner, such as for a randomization score calculation.

Connectivity can also become a significant problem with software updates. Connectivity issues have an impact on the upload of new versions, which can prevent a patient or clinician being able to

> ***"The patients are more than willing to complete the questionnaire. But what can they do if the connectivity is bad and prevents them sending their answers during the visit window?"***

complete a questionnaire during the visit. Not only does this have a significant impact on data collection, but it also affects sites and patients determination to be compliant.

"The patients are more than willing to complete the questionnaire. But what can they do if the connectivity is bad and prevents them sending their answers during the visit window?" confirmed a global pharma organization Global Trial Director.

The solution here comes certainly with communication and planning. If qualification visits for sites are performed well and all the rooms used for questionnaire completion are checked, the risks of connectivity issues could be mitigated. Problems with software updates are minimized

when they are properly planned, with the sites well informed of when they are happening.

Planning a robust back-up strategy is key here. If well prepared and deployed, a robust eCOA back-up plan should allow any patient and site willing to be compliant to actually be compliant.

WHAT ABOUT ISSUES WITH THE HELPDESK SUPPORT?

Again, the struggle is usually on the technical side. It may be difficult to handle patients' frustration and keep them engaged when they cannot use the solution due to technical problems or do not know what is wrong. When the support from the helpdesk and site staff is efficient, most issues will be resolved quickly, but this is not always the case. Additionally it may be difficult for patients who are stuck with an issue to communicate with the helpdesk or to have access to an informed and available resource at the study site.

But even if a helpdesk is always necessary, it's rarely sufficient. A robust eCOA back-up solution such as WebCOA is the solution if the device is not working and/or if communication with the helpdesk or the site is not possible for whatever reason.

And patients' support may sometimes be as simple as guaranteeing that the patient leaves the site with everything that they will need: *"Sometimes the site may forget to provide chargers, or the charger at home doesn't work with the phone"* noticed a Clinical Operations Director from a large pharma group.

> ***"Sometimes the site may forget to provide chargers, or the charger at home doesn't work with the phone"***

Something as simple as lack of oversight can have detrimental consequences on collecting eCOA data.

OTHER ISSUES MAY ALSO OCCUR BECAUSE OF THE SITE STAFF WORKLOAD

It is likely that numerous issues will be driven by the intensity of the workload of site staff, as well as their experience with technology.

A site having a few patients per month may have time to spare for each individual patient, but on the other hand may lack familiarity with the technology from not using it regularly. On the other hand, very busy sites (often having several patients on a given day) will be familiar with

the eCOA solution, but will they have enough time to fully show and explain the solution, to properly train patients, and to make sure the patients go back home fully ready to use the eCOA solution?

The notion of site engagement is also critical. “How to engage the site staff in a better manner?” is a question that all the industry stakeholders should be asking. We always speak of patient engagement, but we should also talk more about site engagement. If a site is well engaged, it is likely that the patients will be as well.

And this goes beyond the monitoring visits and phone calls. Reminding sites of the importance of the study endpoints, providing reports and dashboards, making sure site staff receive an email on their mobile phones mentioning “Your patient hasn’t filled out their diary today,” are simple things that need to be put in place to keep the sites motivated and engaged.

The data we are collecting from patients are precious, and collecting them requires a high level of engagement of the site staff. Keeping site staff engaged in a long-lasting study, with the volume of work that increasingly complex protocols require, is a significant challenge. Developing well thought out training strategies and providing the right level of support – from the perspective of the sponsor, vendor and helpdesk – is required to ensure that sites engagement remains intact during the course of the study. But above all, doesn’t the golden rule remain to design simple and user-friendly systems?

Focused on eCOA complexities in multi-year studies, this white paper transcribes the discussion that was held during one in a series of 4 workshops about eCOA complexities held by Kayentis in 2020.

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eCOA COMPLEXITIES WHITE PAPERS

#1 eCOA training: How can we improve the sites' and patients' experience?

#2 How to anticipate eCOA complexities in multi-year studies & develop best practice to support sites?

#3 No longer the "what if" situation: today's reality and eCOA back-up strategies: how to make sure they are adapted?

#4 eCOA setup: how to anticipate eCOA complexities and ensure a successful launch

Panacee - October 2020

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