eCOA TRAINING

How can we improve the sites' and patients' experience?

October 2020

Kayentis

Dedicated to eCOA & Patient Engagement

THANKS

Focused on eCOA training, this white paper transcribes the discussion from one in a series of 4 workshops about eCOA complexities held by Kayentis in 2020.

Clinical trials and eCOA experts from the pharmaceutical industry shared their experience and suggested best practice during a one-hour session that took place virtually.

This session was hosted by Pascaline Richardot, Kayentis Portfolio Manager.

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

CONTENTS

eCOA TRAINING

How can we improve the sites' and patients' experience?

Training programs for sites and patients are stuck in the past, isn't it time to revisit the training approach?

Is the training for sites and patients adapted or efficient enough, and does it correspond to their exact needs? To answer these questions, a group of experts was gathered together for a workshop, which focused on understanding the reasons why training may not always be adapted to the end users and providing solutions to better support sites and patients and to keep them engaged throughout the study.

SITE TRAINING

How can we develop training opportunities to better support site personnel?

Standard training sounds straightforward. But there are situations where sites may lose track of the training material when updates are issued for the eCOA solution, or following staff turnover. Isn't there anything we can do?

Site staff and principal investigators have the opportunity to be properly trained both during the investigator meeting (IM) and Site Initiation Visits (SIV). Afterwards, the training material (including slide decks, videos, recordings…) is made available for quick and easily accessible

> *"Communication and training should be facilitated and more systematic"*

future reference. This sounds like a sufficient solution in terms of training, as expressed by the workshop group who mostly said that site staff are trained well enough when it comes to using eCOA solutions.

However, there is certainly room for improvement on many levels, starting with communication that could be more systematic, such as sending newsletters to share updates rather than relying on CRAs to convey the information. "*Communication and training should be facilitated and more systematic*" said a pharma company Global Trial Director.

During investigator meetings, an opportunity to show the eCOA solution is provided at the eCOA vendor's booth, which allows investigators to practice using the device and how to navigate through the questionnaires and menus. This is in addition to the formal meeting slide presentation.

> *"The positive effect of training does not last"*

However, not all the sites actually come to the demonstration/practice desk, which is a shame as it provides a real opportunity to learn how to use the system. And even when site staff attended the IM, they tend to forget the training, especially if they don't practice using the eCOA solution soon after the training session.

"*The positive effect of training does not last*" recognized the Head of PRO Strategy from a large pharma company.

What are eCOA vendors and sponsors responsibilities to improve the situation?

At the start of any project, eCOA vendors should plan for proper communication with sponsors for inevitable changes or updates, so that sponsors and sites do not get caught off guard. Although this might sound like an obvious point to be addressed in the project plan, it is worth stating clearly as so much relies on robust and anticipated communication.

When it comes to the training itself: both the sponsor and the eCOA vendor should collaboratively create the training material, propose adapted (potentially shortened/focused) slide decks or any other type of straightforward support material that can be created and included on the Investigator Interface of the web portal. In terms of the practice opportunity during IMs, it is the responsibility of the CRAs to bring their site personnel attending the meeting to the eCOA desk and make sure they make the most of this practice opportunity. As IMs are likely to be switching more and more to digital, eCOA vendors and sponsors will have to be creative and anticipate practice sessions to be organized on site, on top of videos and other digital material they will provide.

It is also important to remember where the responsibilities sit in terms of training content.
The content of the eCOA training provided by the eCOA vendor should focus on the technology and the specifics of use for the eCOA solution: how to use the device, how to change passwords, how to log into a web portal… The training can also touch on specifics around visit scheduling, enabling diary capture, or what to do in case a backup solution is needed. "*However, it should not describe in detail the content of the questionnaires themselves or the reasons why these questionnaires were selected by the sponsor*", confirmed the Kayentis Portfolio manager.

Ultimately, it is very important to discuss upfront with sponsors and sites and get their recommendations to improve the content of the training. This should then be customized and adjusted it to the goals of the study to improve the experience of the various users.

> ***"However, it should not describe in detail the content of the questionnaires themselves…"***

This leads to the next logical question: Who is then responsible for making sure the site staff and patients understand why it is critical to fill out the questionnaires and the importance of their role in collecting this information?

When new sites are initiated, everything starts with the SIV. The CRA in charge is usually well trained and informed and knows that they should go through every single aspect of the protocol during the SIV, to explain the entire protocol and all its requirements. This is the appropriate point to cover specifics of why the COAs included are important, what they are supposed to measure, what will happen with the data collected, the consequences of not collecting the data, and the role of the data in the context of the protocol. This is planned and helpful for the sites. However, once patients start their visits and start using the eCOA solution, this is when additional support is needed – due to the lag between the SIV and First Patient In (FPI).

"*It happens that the first patient comes long time after the SIV, who is making sure, at that very timepoint, that the site staff in charge of the visit is the one who actually received the training, and that the training happened recently enough so that no refresher or no additional information is required?*" commented a Global Trial Director from a large pharma organization.

> ***"Short, focused demos are perfect"***

The investigators' meeting and SIV remain the main opportunities for sharing information and relevant training. However, multiplying the opportunities to share information is a golden rule: webcasts of IMs, additional webcast training, short videos or recordings organized in a way that they bring focus on specific aspects of the eCOA set up process could all represent helpful site-centric solutions in the new normal that we face.

"*Short, focused demos are perfect*" said a Clinical Project Manager from a pharma organization.

Offering refresher sessions, recordings of complete training sessions or short, focused, easily accessible material can allow specific questions

> ***"More room for questions and answers should be created…"***

to be covered, and can offer an opportunity to provide a quick refresher for sites, eg due to staff turnover. Also, FAQ documents create easy opportunities to support sites and patients in their day-to day use of an eCOA solution, which can be particularly useful at the start of a study.

"*More room for questions and answers should be created: building a dynamic form of usual Q&A and making it available in a way that sounds most appropriate according to the specifics of the study can be very supportive!*" added a Global Trial Director from a large pharma organization.

PATIENT TRAINING

Are patients sufficiently supported through the understanding of the purpose of ePRO completion and the value of the data that they provide?

Patients receive a lot of information in many ways, but is all this information always relevant and transmitted at the right time?

Patients first receive their training and general information including at the study site, including the overall perspective of the study and the full understanding of the ins and outs of the clinical trial. All this happens at a time when the site staff is tasked with creating a trusting relationship with each patient.

> ***"Unless it is clearly reported by the sites, we stay quite blind on this matter"***

Site interactions with each patient lead sponsors to believe that the training is done well, however receiving qualitative feedback on the level of understanding the patients have when it comes to eCOA remains limited. "*Unless it is clearly reported by the sites, we stay quite blind on this matter, we have to assume that if nothing has been reported to us via the CRA, this means there is no issue*" acknowledged a large pharma Senior Global Development Director.

Guaranteeing this level of under-standing should be a key pre-requisite to patients' compliance.

"*When the patient understands the why behind providing data, this works well, but if they are not convinced enough of the value of the data they provide, this is less likely that the patients will be filling correctly their questionnaires*" recognized an external Development Operations Supplier Lead of a large pharma company.

When it comes to interacting with the device and questionnaires, patients generally understand and adapt well. They have patient user

> ***"Everything happens when people actually have the tablets in their hands and experience the study…"***

guides they can refer to as well as training material they can come back to at their own time. Despite this, there will be a time when they will face technical issues, and resolving them is where patients need the most support.

"*Everything happens when people actually have the tablets in their hands and experience the study, this is when the questions will start to come!*" reminded a large pharma company Clinical Trial Director.

Patients receive part of this technical support from the local helpdesk, which should be able to help as a first line of support in many situations. The simple support of plugging the device in, turning it on or off, and resetting the password are usually managed by the helpdesk, but other issues linked to software updates are not supported by the helpdesk. This is where patients can get confused and lose track of who to contact in each situation.

"*The expectations regarding the level of the helpdesk support, including 24/7 and timezone coverage, should be clearly set early on*" confirmed Kayentis Portfolio Manager.

A simple but key rule to remind patients is that they can contact their study site whenever they need to, especially if they have an issue that cannot be resolved by the helpdesk. They can also refer to the provided material which – as already mentioned – should be easy to use and customized to the specifics of the study.

And what about pediatric patients? Are the material always adapted to them?

"*In pediatric research, we need parents on board!*" claimed a global pharma organization Head of PRO Strategy.

It is well established that information shared with patients, including training material, requires customization for different age groups. This is reinforced by our workshop audience ranking the eCOA resources being adjusted to the target audience as a top priority. When it comes to pediatric populations the key is to be able to adapt the training and

> ***"In pediatric research, we need parents on board!"***

speaking language to the specific pediatric patient populations whilst still engaging the parents who must understand how to use the system too. This is where it might become more complex.

"*We can engage them also through reminding that they not only help their child but also help other families with children suffering from the same condition*" reminded the Head of PRO Strategy from a large pharma company. If parents are engaged, it is likely that the children will be, and vice versa. We should not underestimate the influence that parents and children will have on each-other.

Parents should be reassured during the training that it is ok if they do not understand everything, and that repeat training, refreshers, and Q&A sessions will be provided to help them throughout the clinical trial.

In the new normal of a post-COVID world, virtual interactions take over face to face trainings.

How can we efficiently train sites & patients in a manner that keeps the engagement level the same?

Of course, we all know that face-to-face interactions generate more interactivity than virtual interactions, and may offer wider room for discussion, especially during small breakout sessions where people feel confident and may ask questions more freely. However, we know that today there are far fewer opportunities for face-to-face interactions, at least for the time being.

Is there a risk for virtual training sessions to be less efficient than face-to-face training sessions?

"*It is key to try and maintain face-to-face meetings (Investigator's meetings, SIVs) where more questions are raised and communication is facilitated, especially for non-English speakers; however, we're living times where meetings and communications are more and more digital, and we need to carefully think through clever ways of maintaining adequate support*" commented an external Development Operations Supplier Lead of a large pharma company.

For as long as virtual meetings and training will be necessary, it is important to stay mindful through regular interactions and

> ***"This is very important to have a source of information, people need to know where to go and where to refer to…"***

communication. The CRAs, the eCOA vendor, and the sponsor need to carry on spending the necessary time with the site to efficiently support them. Not only is initial training key, but regular communication and focused checks-ins are also critical.

"*This is very important to have a source of information, people need to know where to go and where to refer to. The online support of the vendors is key as this will be the reference during the study, which can last for years*" reminded a large pharma Senior Global Development Director.

This permanent, reliable, and dynamic source of information is maybe even more important than the initial training.

How do you think eCOA training for sites and patients can be improved in order to keep them engaged during the study?

Please rank from top priority (1) to lowest priority (4):

1. Improve eCOA training content focusing on eCOA technology
2. Improve eCOA training content focusing on eCOA study objectives
3. Adjust eCOA training resources to targeted audience (e.g. face-to-face meeting, paper materials, live demo, webex, e-learning modules)
4. Adapt eCOA training frequency (e.g. adding training reminders/refreshers during the life cycle of the study)

It is not often reported that more frequent training is required, and the audience ranked the item on adapting training frequency last on the list. Instead, regular checks and close communication, that will drive the implementation of refreshers or the provision of supportive material, will keep patients and sites engaged.

Although technology aspects represent a barrier in some patient populations, these are less and less of an issue today, which is supported by the poll. The key is likely to be the identification of populations that need more assistance and to customize the support accordingly.

Despite great progress, the industry still has work to better train and support sites and patients throughout a study. Convincing patients of the value of the data they generously provide and continuously supporting them in their clinical trial journey must be the whole industry's goal in the coming years.

Focused on eCOA training, 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.

WORKSHOP CONTRIBUTORS

- Clinical trials and eCOA experts from the pharmaceutical industry

WORKSHOP MODERATOR

- Pascaline Richardot, Kayentis Portfolio Manager

AUTHORS

- Estelle Haenel, Kayentis Medical Director
- Andrea Murison, Kayentis Business Development Director

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

kayentis

Dedicated to eCOA & Patient Engagement