Kayentis

Global provider of eCOA and patient-centric solutions

Advantages of direct review of patient-recorded data by clinicians

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In ePRO clinical trials, patients may use tablets to record their data. What if the clinician uses the same device when reviewing ePRO data? Are there real benefits for the clinician and the clinical trial?

Why is it so important to facilitate the review of patient questionnaires using tablets in ePRO clinical trials?

- It is essential that clinicians review PRO data to be fully informed regarding patients' health status, to track potential adverse events and to check the completeness of the data. The main challenges to ensure an effective review using electronic devices are to provide smooth, user-friendly navigation and a quick route to the patients' answers.
- In ePRO trials, when patients complete questionnaires using a tablet, clinicians appreciate the ease of reviewing their patients' data directly on the same device. Using another device, and another interface, increases the complexity for the clinician and can lead to delays in the review or even increase the incidence of missing reviews.

Although some clinicians consider that a paper review is simpler (by having all the responses together), having user-friendly navigation on the device is beneficial for reviewing ePRO data. A particular advantage for the clinician is being able to flag questionnaires that require review, and, for the Sponsor, the ability to trace the review.

How to handle ePRO review on a tablet?

When collecting PROs, the review of patient data by the clinician may require reading the complete questionnaire filled out by the patient. This review is often documented in another system such as an eCRF.

This adds significant complexity for the investigator, including:

- The need to log-in to another system
- The possibility of a delay, increasing the risk of a review being missed
- The possibility of delays by not being guided through the review

- The need to find a way to document that the review has been performed.

New review process in ePRO with Kayentis' eCOA version 1.4

Kayentis has launched a new version of its eCOA solution to simplify tablet-based data review in ePRO trials.

- The process

As soon a patient's questionnaire is completed and the data are captured using an eCOA device, the data are available for review but with no alert. At the next login, the clinician will receive an alert and can either proceed with or delay the review. By default, the clinician is invited to look at unreviewed PRO data but can also display all PROs if needed. Each question and answer is displayed on a scrollable screen in the site's preferred language. Clinicians can efficiently review all the questionnaires and confirm the review. The tablet can also alert when the clinician initiates a new visit without having reviewed the previous one.

The eCOA provides real help not only to the clinicians but also to other study stakeholders by ensuring a timely and full review of patient questionnaires.

- Report a complete review status centrally

In the new eCOA release it is not only possible to see patient data but also to notify whether the data have been reviewed or not. The completion of a review is clearly indicated in an audit trail in the tablet, including a full timestamp and reviewer information. To learn more about clinical review of data, click here.

> "*I found the new review section in the recent update version very good, it's more clear and easier to use/view. As always you guys do a great job*", Logistic Manager – Top 5 pharma company

To meet challenges in data review and to further ePRO and eCOA innovation, Kayentis introduces a new eCOA version (Version 1.4) with an enhanced interface for reviewing patient questionnaires on a tablet device. A clear overview is provided on the tablet, and the review process is more efficient for clinicians and includes a complete audit trail that is recorded centrally in Kayentis' Clin'Form application.

For more details of the potential of Kayentis' eCOA webportal, please visit our website.

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