

# Kayentis

Global provider of eCOA and patient-centric solutions

## Patient Reported Outcomes: don't skip that question!

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**When setting up Patient Reported Outcomes (PRO) for Clinical Trials, at some point you will inevitably consider the option of whether to skip questions or not. Should you force patients to provide information for greater data completeness? Or give them the possibility to skip a specific question? What is a right balance for your trial to maintain patient engagement without decreasing data quality?**

This is a brief overview of what you should take into consideration.

### Skip a question

- When allowing patients to skip a question on devices, you introduce the risk of skipping a question in error. For example, when confirming an answer, the patient could accidentally double-click and so unintentionally skip the following question.
- To avoid this scenario, you might ask patients to confirm when skipping a question. Although this might be a bit more time-consuming for the patient, you would be sure not to lose data in error.
- But for important patient reported outcomes (PRO)-related data (e.g. eligibility, primary or secondary endpoints) an incomplete dataset caused by skipped questions might cause serious problems in data analysis. An intuitive application with clear answer options could contribute to more complete dataset and reduce the skipping of questions even if patients have this option.

### Don't skip a question

- To get the most complete PRO data possible, you might therefore decide not to allow patients to skip any question.
- However, if opting for this approach you will want to make sure that patients in your trial do not feel forced to provide information they don't want to share (e.g. questions about their sexual or alcohol habits). Think about adding the expectations to provide answers in the informed consent form.
- Forcing patients to answer such questions may adversely affect patient engagement.

PROs that are developed to be completed entirely would require that no question can be skipped to allow approval by the PRO authors.

### Mix it up

When you have multiple PROs in your protocol, you might want to consider the possibility of

having a mix of the two options. You could block the skipping of questions for important PROs or allow only other questions to be skipped.

Although a mixed option can be more complex during the set-up it might be worth considering.

**The issue of whether or not to allow questions to be skipped may seem straightforward, but you have to take into consideration a range of aspects to find the best solution. An experienced eCOA provider is able to correctly analyze your protocol and to discuss the above options with you to develop the best solution for your trial.**

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