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Why we can and should change eCOA data

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Changing – or rather not changing - eCOA data is a topic that frequently pops up during discussions about eCOA/ePRO set-up with clients and colleagues. When getting to the point of review, cleaning and DCFs (or whichever terms you want to use), I often get the push back "It is eCOA data. We must never change it, that's the rules". Or "It's the source and truth, so why should we clean it?". Or "We don't need any DCFs, in fact, we don't even need to look at it".

I disagree fundamentally with these categorical statements, both from a regulatory and quality perspective. And for electronic as well as paper solutions. We can and should change eCOA/ePRO data from time to time. But to do this, we need to add a bit of nuance to the discussion.

Of course, we should never challenge a patient's subjective assessment, score or experience. And we should also put measures in place to ensure that investigators don't either (it does happen, believe me).

However, there are several scenarios where the "administrative" or "related" data (things like patient ID, visit ID, dates) and sometimes *even the patient reported data*, can and should be corrected. The key thing is to differentiate subjective, personal assessments from objective facts where something has gone wrong and there is actual evidence, or if it is fully clear that the data should be something else.

These things happen on a regular basis, either due to technical issues, human mistakes or misunderstandings. Let's look at some examples:

- Site selecting the wrong visit for an on-site ePRO instrument (not all trials are "linear" and can be fully controlled by set-up). Evidence? Yes, we know which visit it truly was.
- Patient mixing up IMP and rescue medication (RM), and registering intake of IMP as RM (real case). Evidence? Yes, all dispensed RM was returned at the subsequent visit.
- Device time was not changed when the patient travelled across time-zones. Evidence? Yes, documentation of travel times.
- Site incorrectly selecting female instead of male in device set-up, resulting in male patient completing questions that are not applicable for male.

So, as these things do happen (even if we should of course do our best to minimize the risk by proper set-up, training etc.), we need to discuss it up-front and put guidance and methods in place for how to handle them. There must be a process for how to review the data, identify issues, raise DCFs, ensure clarification, suggest, approve and implement changes. All of this should be supported by processes and technology and it should be adequately documented.

Therefore, we can and should review and clean (e)COA data. Sometimes we should change it, sometimes we should not. When? - as usual, it depends.

More reading and information on this topic

TriTiCon White paper: "Data Handling and Change of eCOA data" – www.triticon.com/resources
TriTiCon Trainings: "Introduction to eCOA/ePRO " - www.triticon.com/training
TriTiCon eClinical Articles: – www.triticon.com/resources

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