From: OC GCP Questions
To: [redacted]
[redacted]
Subject: Can sponsor provide worksheets to a site in clinical trials ?
Date: Wednesday, August 01, 2018 11:18:00 AM
Attachments: [redacted]

Good morning –

FDA's regulations do not address how initial study data, that is, source data, are collected. Sponsors are not prohibited from providing a specialized form (worksheets) for use in the study on which information is directly entered. If worksheets are created by the sponsor, providing version control would probably be a good idea. Have standard operating procedures and training related to how the worksheets should be completed would be advisable too.

There may be some pros and cons to the use of sponsor provided worksheets. Most sites have their own documents they routinely use to capture medical information regarding patients treated there. The site personnel are familiar with these forms and are more likely to capture pertinent data in an effective, efficient manner using their own forms. However, in studies where specialized testing or questionnaires are employed, there may be a benefit to using specific forms to capture this information. When sponsor worksheets are used, training of site personnel in the use of the worksheets may be necessary. SOPs may also be needed to ensure that the subject's case histories and medical records are accurate and complete (for example, by ensuring a copy of the worksheet in included in the subject's medical records).

For CRFs, when the regulations were written, capture of information regarding study subjects was expected to mimic how physicians record patient information during routine medical visits. That is, it was expected that notes would be entered into a subject's chart, with information specific to CRF data transcribed to the CRF at a later time. Since some information and a number of testing procedures (e.g., quality of life surveys, pain scale determinations) may be study-specific information, many sponsors/clinical sites choose to enter such information directly on a CRF. An obvious advantage is that it eliminates transcription errors, which can be numerous for studies that collect a large amount of data. While this means there is no other source that can be used to verify information captured only on the CRF, FDA has not forbidden this practice. If a sponsor chooses to do this, the study protocol should specifically spell out which data are directly entered onto CRFs and therefore have no corroborating documentation. This will allow for consistency across study sites and inform FDA bioresearch monitoring (BIMO) investigators of this fact, should a BIMO inspection occur.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

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From: [redacted]
Sent: Tuesday, July 31, 2018 10:45 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Can sponsor provide worksheets to a site in clinical trials ?

Dear FDA

During the clinical trials, EMR is considered as a source document. However, in many clinical trials, specific measurements and observations, which are not considered “standard of care” and not be part of the routine assessment, are necessary for the trial. It is in these instances that a worksheet may be utilized as the source documentation and many sponsor companies provide source document worksheets to sites to ensure complete documentation.

MY first question is "Can sponsor provide source document worksheets to sites in clinical trials ?"
If yes, my second question is "Can sponsor cotrol the worksheets (e.g. version control, which not allow the site to modify the worksheets without sponsor's confirmation)?

As recording data on the source document is full responsibility of the site, I would like to hear what is FDA's expectation on using worksheet, which is provided by a sponsor, as a source document.

Thank you.
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