

5 Tips to Keep in Mind in Your European Clinical Study

Daniela Karrer
Director, Clinical Affairs
Donawa Consulting

1. Mind Your Paper Work

As the sponsor of a clinical study, you may be planning to rely on your investigator's team to prepare the submission package for the local ethics committee. While this may be tempting, it may not be wise. Investigators are focused on medicine and science and often are not aware of important regulatory issues. As a result, the ethics committee may not approve the study, or the approval may be delayed because a basic requirement is lacking, such as a date and version on the informed consent form. Without ethics committee approval, most Competent Authorities will not review or approve the study. So the lesson here is to leave the paper work to the experts. Your regulatory expert or CRO should always be involved in preparing the ethics committee submission package.

2. Mind Your P's & Q's

When you submit documents for your clinical study to ethics committees and Competent Authorities, don't forget to include a list of all your attachments in the cover letter, noting the version and date. Not only will you know exactly what was submitted, but this will reduce the risk of errors or omissions in the approval letter issued by the ethics committees and regulatory authorities. Another way to avoid complications and delays is to be sure that you do not submit any documents meant only for your internal use. By following these practices, you can help ensure that the regulatory approval letter will be complete and accurate and you will avoid lengthy delays that can occur when approval letters need to be corrected and reissued.

3. Mind Your Budget

If you plan to ask your investigator to review a study protocol before it is final, make sure you budget for his or her time. Although some investigators work only for the glory, opinion leaders may in fact ask to be paid.

4. Mind Your Indication

If you are planning to conduct a clinical study on a CE-marked device, be sure you understand how the product will be used during the study, and whether this use is within or beyond the scope of the CE-mark. If the use is beyond the scope of the CE mark, it will be considered a study on a non-CE marked device from the regulatory perspective. That is, in addition to notifying ethics committees, Competent Authorities will also need to be notified. It is not necessary to notify Competent Authorities if the device is being used within the scope of its CE mark.

5. Mind Your Language

Clinical studies should be conducted under normal conditions of use. Many European countries require that medical device labels and Instructions for Use (IFUs) be provided in the local language. IFUs used in clinical studies need to be in the same language as those that will be sold with the CE-marked device. This means that labels and IFUs may need to be translated into the local language(s) for the study.