

What is the Importance of Clinical Trial Progress Reports?



One of the very critical aspects in clinical research is monitoring. Overseeing the progress of any phase, step, procedure, and process in real time is crucial to the accurate completion of any clinical trial project. Regular monitoring activities are necessary to ensure [quality](#), efficacy, compliance with regulations and predefined principles, as well as comprehensiveness, and precision in clinical research. Such activities also guarantee that the trial is not only conducted in accordance with Standard Operating Procedures (SOPs) but they also serve to confirm that it is properly recorded and reported. However, there is something else that has a major role in the proper implementation of trials. And that thing is called trial progress reports.

The purpose of progress reports is to collect and outline updates, key aspects, and summaries of an on-going trial. These written documents identify how exactly the study is unfolding and what results it has achieved until the moment of [reporting](#). It is important to note that progress reports are to be submitted to institutional review board/independent ethics committee (IRB/IEC), after a trial has received favorable opinion.

Who Is Responsible For The Submission Of Progress Reports In Clinical Trials?



In essence, the person who is expected to present the relevant ethics committee (or institutional review board) with specific updates regarding the status of a given clinical research project is the chief investigator. The time period through which a progress report should be submitted is at least once in a year. Nevertheless, depending on the case and the RECs' requirements, such reports may be handed in more frequently, while the study is still going and until its official completion date.

Apart from the ethics committee, investigators may be also required to present annual progress reports of a trial (including any relevant amendments or risks) to sponsors, supporting institutions, and/or organizations, and other interested parties if necessary.

What Information Should Be Included In An Annual Progress Report?



Any such report should be carefully prepared and it should outline the ways in which a research is performed. It should also point out recruitment progress and processes; should highlight and explain changes to the study, and should point safety issues in case there are any.

Another important thing to mention is that there are several separate forms when it comes to submitting progress reports which investigators should take into account before proceeding. Precisely, those forms are:

- **Annual progress report form for clinical trials of investigational medicinal products (CTIMPs)**
- **Annual progress report form for all other types of research**
- **Annual Report form for Research Databases**
- **Annual Report form for Research Tissue Banks**

After filling in the forms, they should be signed by the Chief Investigator. Print name and date of submission should be written as well. An electronic copy is also required to be sent to the interested sites and committees within a 30-day period after the reporting process has been completed.

In conclusion, [monitoring](#) and reporting procedures have a very important role in clinical trials. The appropriate conduct of such processes not only ensures compliance with laws, regulations, and predetermined requirements, but it also makes sure that the study does not pose any risks to patients and their health. Progress reports, then, enable practitioners, experts, researchers, ethics committees, and other people involved to keep track of the trial and its progress. They can indicate any amendments or risks and can, therefore, respond to them accordingly, timely, accurately, and effectively.

If you are interested in acquiring relevant skills on GCP or you want to update your know-how, sign up for our comprehensive Good Clinical Practice course [here](#).

References:

ICH Guidelines for Good Clinical Practice

HRA <http://www.hra.nhs.uk/resources/during-and-after-your-study/nhs-rec-annual-progress-report-forms/> [accessed: 17.11.2017]

You can find the online version of this article here: <https://crotraining.co.uk/what-is-the-importance-of-clinical-trial-progress-reports/>