

## What is Quality Assurance in Clinical Trials?



There are plenty of factors which affect the clinical trial landscape. Sometimes it could be due to unpredicted patients' behavior or reactions, while performing a study. Newly introduced guidelines which require immediate action different from pre-set processes are able to alter how Pharma is unfolding as well. Technological advancements can also dictate major changes. Developments and tech-driven practices, tools, methods and trends such as implementing [electronic data capture](#), m-health or [cloud computing](#) are all forces which impact the research industry in one way or another. And yet, something that never really changes in terms of how important it is, is the maintenance of quality in clinical studies, the Pharmaceutical and Medical sector as a whole. It shouldn't come as a surprise to anyone that there is an increasing focus on Quality Assurance (QA). Especially if we are to take into account the shifting landscape of clinical trials which at any point can shake the levels of quality that previously appeared to be extremely stable. To prevent drastic outcomes and guarantee excellent Quality Assurance, then, serious measures should be taken and appropriate Quality Assurance systems should be put into place.

To start with, let's have a closer look at Quality Assurance and its meaning. In essence, QA along with Quality Control are part of quality management in clinical trials. These include all of those well-organized procedures which guarantee high quality standards in end products and services provided by research companies. But this is not all. Quality, above all, relates to how such organizations operate; how they conduct their work processes (including documentation, testing, data management etc.); how they support project lifecycles and what tools/systems they adopt along the way.

In this sense, according to the ICH E6 document, Quality Assurance represents “planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented (recorded), and reported in compliance with Good Clinical Practice and the applicable requirements.” The [MHRA](#) defines it as “the sum total of the organised arrangements made with the object of ensuring that medicinal products or services are of the quality required for their intended purpose.”



Consequently, any work-related procedure that takes place, any file, document or data that is being preserved is required to be as efficient as possible. To ensure high levels of quality, no matter what the personnel involved is doing, there is a need of maintaining quality documents and implementing quality systems. Quality documents usually include but are not limited to the following:

- SOPs

- Guidelines
- Quality management plans
- Forms and templates
- Relevant company policies
- Working instructions

In terms of quality assurance systems, the responsibility of maintaining such falls mainly on sponsors and the assigned quality assurance department. Therefore, in order to guarantee that studies are adequately performed and all the necessary data is collected, delivered to the right subjects, documented, reported and protected in accordance with Good Clinical Practice, protocols and regulations, the QA staff is supposed to incorporate the most appropriate QA and QC systems.

Nevertheless, to achieve all of this, anyone involved in the QA process should be experienced enough and able to demonstrate sufficient knowledge. Apart from organizing appropriate training courses, team leaders and project managers should also ensure suitable and motivational working environment. Because one part of QA is adhering to Good Clinical Practice, we at Astra Nova can provide you with well-organized and relevant [online training on GCP](#). More information about the course agenda, corporate discounts and other details is available here.

References:

EFGCP *“The Role of the Quality Assurance Unit”*

<http://www.efgcp.eu/downloads/The%20Role%20of%20the%20Quality%20Assurance%20Unit-website.pdf> [accessed: 24.11.2016]

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