CLINICAL RESEARCH REGULATIONS IN THE FUTURE

As most of the clinical research insiders would agree – the clinical industry is heavily regulated by different governmental and third-party regulations. The first major success in bringing all of them together on the same side – the side of global safety and efficiency – was achieved during the **International Conference of Harmonization (ICH**). With the Declaration of Helsinki of 1977 many countries like the USA, the UK and Japan have adopted the ICH GCP guidelines and then almost every other country in the world started following the requirements set in the **Good Clinical Practice (GCP) regulations**.

This was a real progress for the time being. Even though it is the key to success of the industry, it was the first time to have regulated clinical trials on an international scale and professionals. Nowadays, many experienced clinical research professionals have several trainings on ICH GCP, where in some countries like the UK they need to get recertified every two years. However, in others, like Germany for example, getting an update every single year is not necessary.

If you want to learn more about the different Good Clinical Practice online courses and how to get certified in ICH GCP, please read the article: *Should I choose Good Clinical Practice online training or seminar*.

Even though it is a fact, it has been assumed that Good Clinical Practice guidelines are not enough to ensure safety nowadays. One of the reasons for this is that these are regulations which give you **the workflow of documentation and the structure of clinical trials**, but **the control over how people implement them is way too low**. This was one of the key issues the Alliance for Clinical Research Excellence and Safety (ACRES) has pointed in order to bring a major change into the clinical research area. The respectful allies have suggested creating of standardisation process of the investigator sites and a database of these accredited sites. This standardization is going to cover all aspects of documentation, patient engagement, professional qualification etc. of the organization, where the clinical trials are going to be conducted. Instead of focusing on the way

they follow ICH GCP regulation, ACRES thinks we need to make sure what the efficiency profile of the investigator sites will be.

Whether these standartisation rules will become regulations later on or not is a matter of time probably, because, as in many other areas, the recent laws have been forced by the industries. If this procedure among the investigator sites manage to bring quality, safety and efficiency in the clinical trials, they will be officially adopted.

We are curious to hear your opinion on this matter and of course follow us on LinkedIn or Medium for other interesting articles. Thank you!

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