Holger Maria Rohde

Transparency in Clinical Research of Medicinal Products: Pre and Post Marketing Authorisation

Clinical trial transparency has become a centre of attention over the last decade. What is the history behind this and what are the current rules? The EU-CTR provides us also with new transparency provisions that pose additional requirements to any clinical trial sponsors, may they be commercial or academic. In order to be able to cope with the new regulatory requirements, sponsor structures and processes in their organisations will be heavily impacted from planning of the trials until the reporting of results. Guidance for company positioning and necessary strategic activities will be outlined by the speaker. Finally, the presentation will focus on patient lay summaries which will introduce a new era of patient information and communication.