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ICH-GCP Addendum

Since the adoption of the ICH E6 guideline on Good Clinical Practice (GCP) in 1996, there have been important developments in the clinical trial landscape. All parties involved realize a globalization of clinical research activities in combination with a fragmentation of roles, more sophisticated study designs with an increased volume of collected data and growing use of information technology and electronic media.
At the same time, regulators observe the failure of the involved parties to adapt quality management strategies to the rapidly changing environment, including failure to prospectively identify critical data and processes within single clinical trials or clinical development projects that may impact trial subjects' rights and safety as well as the reliability of the trial results.
Therefore, it was decided in 2013 to modernize the ICH E6 guideline by supplementing it with additional standards which will better facilitate broad and consistent international implementation of new approaches and methodologies. The guideline has been amended to encourage implementation of improved and more efficient approaches to clinical trial design, conduct, oversight, recording and reporting while continuing to ensure human subject protection and reliability of trial results. For example, centralized monitoring can now offer a greater advantage, to a broader range of trials than is suggested in the original text.
Standards regarding electronic records and essential documents intended to increase clinical trial quality and efficiency have also been updated.
The presentation gives an overview about the ICH process and the topics addressed by the pending ICH E6 Addendum.