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New version of ICH-GCP - R2 - what does it really mean

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and wellbeing of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible. Since the development of the ICH GCP Guideline, the scale, complexity and cost of clinical trials have increased. Evolutions in technology and risk management processes offer new opportunities to increase efficiency and focus on relevant activities. When the original ICH E6 R1 text was prepared, clinical trials were performed in a largely paper-based process. Advances in use of electronic data recording and reporting facilitate implementation of other approaches. ICH GCP R2 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. ICH GCP R2 was published 30.11.2016.

There are few new changes changes from previous version – R1. They were caused due to several reasons:

1. Common development of clinical trials
2. New technologies
3. More complex design of clinical trials

We will have made brief review of these changes, affect on all participants of clinical research – IRB/IEC, Investigator and Sponsor.

Biography

Vladimir Andrianov has 10+ years of experience in the field of organization and conduct of clinical research. Before joining the Institute, he worked in the largest international CRO and pharmaceutical companies. Comprehensive experience of the monitor and manager in 30+ clinical trials - management of clinical centers, monitoring, budget, selection, qualification and closure of clinical centers, preparation and conduct of audits of clinical centers and central file, preparation for regulatory inspections, pharmacovigilance. He has experience in various therapeutic fields (oncology, cardiology, dermatology, neurology, rheumatology, endocrinology, psychiatry, radiology) and various phases of clinical research. Authorized for conduction of all types of site visits: PSVs, SIVs, IMVs, COVs, motivational visits. Authorized for conduction of Training Visits and Authorization Visits for inexperienced employees. Worked with IXRS, EDC Oracle, Medidata Rave. He has excellent knowledge of ICH-GCP, Russian, EEU, CIS and international legislation in the field of clinical research. He studied in Russia, England, Switzerland, the Netherlands, Germany, Denmark and Spain in organizing and conducting of clinical trials. At present work as Chief Research Officer/Head of Scientific studies department with main responsibilities: business development (local & international) of Department, line management for 18 employees (managers and specialists), oversee on ongoing clinical trials and PV projects, performance to plan & budget, conduction of trainings for company and customers, vendors' selection & negotiation, search for research grants. Speaker at the regional & international conferences, round-tables and etc.

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