Taghrid Obied, Pharmaceut Reg Affairs 2014, 3:3
http://dx.doi.org/10.4172/2167-7689.S1.016

OMICS Group Conferences
Accelerating Scientific Discovery

4th International Conference on
Pharmaceutical Regulatory Affairs
September 08-10, 2014 DoubleTree by Hilton Hotel Raleigh-Brownstone-University, USA

Oversight of clinical investigations- A risk based approach to monitoring

Taghrid Obied
Princess Nora Bint Abdul Rahman University, King Saudi Arabia

A recently published FDA guidance "Oversight of clinical investigations- A risk-based approach to monitoring"has been developed to describe the current thinking of the FDA regarding good clinical practice and the conduct of clinical trials. While these documents are nonbinding, most of investigators refer to them to gain a benefit of the cumulative expertise of the FDA teams. Approaches to clinical trials monitoring varies between companies, government organization, and academic institutions including on-site monitoring, centralized monitoring, and other alternative monitoring techniques. Considering this variability, the fore-mentioned guidance discuss a risk-based strategy for monitoringthat start with identifying critical data and processes to be monitored followed by risk assessment and finally preparing the monitoring plan. Critical data and process take account of appropriate informed consent, confinement to the eligibility criteria, and proper documentation. After the assessment of risks, they need to be prioritized according to the probability of error, detectability, and its influence on the integrity of the study andhuman subject. The main purpose of that is to minimize errors while conducting, collecting, and reporting the results of a clinical trial. The monitoring plan should containa description of monitoring approaches, communication of results, management of noncompliance, and plan amendments. Based on this methodology, different monitoring plans are produced as a consequence of the complexity of the study design andendpoints, study population, geography, experience of the involved personnel, use of electronic data capture systems, safety of the investigational product, phase of the study, and the amount of data.

Biography

Taghrid Obied has worked as a regulatory affairs officer for two yearsunder Europe & USA Divisions at Hikma Pharmaceuticals in Amman, Jordan. In 2005, he was awarded a Fulbright scholarship for studying MS degree in the field of Pharmacokinetics/Pharmacodynamics at Virginia Commonwealth University, Richmond, VA, USA. In 2007, she was granted an assistantship for pursuing a PhD degree at the same school, which she completed in 2010. She has been working as an Assistant Professorsince 2011 at Princess Nora Bint Abdul Rahman University, Riyadh, KSA.

taghrid.obied@fulbrightmail.org