

Conference Series LLC Joint International Event on

7th Pharmacovigilance & Pharmaceutical Industry

August 22-24, 2016 Vienna, Austria

Overcoming challenges in conducting clinical trials in Egypt- 10 years experience

Nihal El Habachi

Alexandria University School of Medicine, Egypt

Alexandria CRC is the first center for clinical trials in Egypt. It was established in July 2006 with the assistance of the University of Maryland, USA, under the twinning agreement between the cities of Alexandria and Baltimore. Trials are conducted according to ICH-GCP guidelines after approval of Research Ethics Committee (REC) of Alexandria Faculty of Medicine & Egyptian Ministry of Health (MOH).

The center provides a full range of resources and services directly or in coordination with the institutional resources of Alexandria University Hospital: research patient care, trained research personnel, lab facilities, statistical consultation, computer and data management support.

Our mission is to enhance and expand the magnitude of high-quality & ethical clinical research and avoid exploitation of research subjects. Our vision is upgrading Alex CRC to be a Center of Excellence in Clinical Research. Our objectives are to foster more innovative, high-impact clinical trials and to streamline drug development activities enabling Egyptian patients to access the best medical care, to train local/regional researchers to conduct multinational trials and other health research projects and assume leadership within the MENA region. Also, to integrate all parties involved such as MOH, WHO, academia, pharmaceuticals, CROs and RECs in Egypt into one extensive network for clinical trials. Our research activities are investigator-initiated & industry-sponsored phase II, III&IV multicenter trials. Educational activities include training courses on GCP & research ethics for investigators, research coordinators and REC members, in English and French. Our future plans include obtaining CAP accreditation to the CRC laboratory, establishing a clean area for the optimum preparation of cytotoxic drugs, setting up database registry for clinical trials in Egypt, designing clinical research programs that meet the international standards, granting certified degrees in clinical research and assisting the establishment of other local and regional clinical research centers.

Challenges regarding research subjects, investigators, REC, regulatory authorities, sponsors and local facilities as well as our ways to overcome them will be discussed.

Biography

ElHabachi is a Professor in the Department of Physiology and the Academic Director of the Alexandria Clinical Research Centre in the Faculty of Medicine, Alexandria University, Egypt. She is a multilingual Professor with a track record of establishing multinational partnerships, and teaches in both English and French. She has been pivotal in establishing the University Clinical Research Centre. Part of her pre-doctoral training was conducted in the Heart Science Centre, Imperial College, UK. In May 2006 she studied clinical research and GCP, University of Maryland USA. She has a broad research experience in national and international projects.

nihaelhabachi@yahoo.com

Notes: