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Conducting a clinical trial in Mauritius: Legal, regulatory and ethical frameworks

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Since 1980's, clinical research in Mauritius has been limited to small observational and population-based studies, often with a strictly national relevance. However, the establishment of a legal framework for clinical trials in 2011 boosted the interest of sponsors to conduct interventional trials. Since 2011, Mauritius has seen a major development in its life sciences and research sector with the development of clinical research organizations, set-up of clinical research units in hospitals, and the growing training given to local investigators and clinical staffs. Indeed, the Clinical Trials Act provides for the setting up of a Clinical Research Regulatory Council (CRRC) responsible for the regulation and control of trial licenses being issued, an Ethics Committee (EC) to advise the CRRC regarding welfare, safety, health and protection of human subjects participating in clinical trials, and a Pharmacovigilance Committee (PC) to monitor all clinical trials being performed and ensure Good Clinical Practice (GCP). We propose to describe in this poster the legal framework for clinical research, and the regulatory process for conducting a clinical study in Mauritius. The objective of this presentation is to confront international guidelines and regulations for conducting a clinical trial (Good Clinical Practices, FDA Guidelines) to the Mauritian dispositions and laws. A second objective is to question the ethics of research in Mauritius, in the lights of concerns raised by recent publications about clinical research in developing countries.

Biography

Mona Dawood is Head of the Pharmaceutical Operations & Regulatory Affairs for CIDP group. She completed BSc (Hons) in Biomedical Chemistry from University of Warwick (UK) and a Diploma in CRA from Sup-Santé, Paris, France. She joined CIDP seven years ago and has acquired a significant expertise in specific monitoring in various therapeutic areas (oncology, diabetes and pediatrics). She has also an excellent knowledge of the European & Asian regulations, regulatory aspects, claims validations, pharmacovigilance.

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