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Giuseppe Assogna, J Forensic Toxicol Pharmacol 2018, Volume 7
DOI: 10.4172/2325-9841-C4-016

World Congress on
Toxicology & Applied Pharmacology
October 15-16, 2018 Rome, Italy

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Clinical trials in pharmacotherapeutics

Clinical trials are research studies involving patients in order to evaluate how different treatments are safe and work. Similarly clinical trials are carried out to try to answer specific questions on health and illness and are the best way to compare different approaches to preventing and treating illness and health problems. Clinical trial methodology as well as rules governing this important area of research is actually regulated in EU countries, by the Directive 2001/20/EC, to be replaced by the clinical trials - Regulation EU No 536/214, which will come into force, most likely, in October 2019. The new regulation has many positive aspects, such as authorization timing, monitoring for all studies (profit and no profit), transparency of results, etc., while some aspects may raise criticalities, like low intervention clinical trials and insurance indemnities. As for budget impact of clinical trials, according to a 2014 study by the Tufts Center for the Study of Drug Development (TCSDD), the cost of developing a new drug, from Research and Development (R&D) to marketing approval, is approximately $2.9 billion and although clinical trials evaluate pharmacotherapeutic intervention under highly controlled conditions, remains a need to evaluate medication use in real clinical practice. In this high cost scenario is there a concrete possibility to try to reduce (part of) the cost of drug development? Probably yes, according to the Avicenna - A Strategy for in Silico clinical trial – document, published in 2015. The document focuses on "how biomedical products are developed today, where in silico clinical trials technologies are already used and where else they could be used. From the identification of the barriers that prevent wider adoption, we derived a detailed list of research and technological challenges that require pre-competitive funding to be overcome".

Biography

Giuseppe Assogna has completed his graduation in Medicine and specialized in Liver Diseases and Metabolism at the University La Sapienza of Rome. After a short period of medical activities, he gained extensive experience in multinational pharmaceutical companies (Janssen, Organon, Speciality European Pharma, The Medicines Company) as Director of Clinical Research, Medical, Market Access and Regulatory Affairs. He also carried out important educational projects, launch, support and defense of numerous products, including crisis management. He is the author of numerous publications and scientific communications, President at SIFEIT-Italian Society of Economics and Ethics on Drug Studies and Therapeutic Interventions and Member of associations and scientific societies. He has held teaching positions and currently teaches in master and postgraduate courses at the Faculty of Medicine in La Sapienza and Catholic University in Rome.

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