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Global challenges in conducting clinical trials

Clinical trials using human subjects are an integral part of the approval of new drugs and biologics. About 40% of clinical trials out of total trials registered in USA took place in emerging nations of Asia, Latin America and Africa. At the same time, clinical trials have become increasingly costly ventures apart from its complex conduction, adding to the overall cost of developing a drug and, ultimately, the price that patients pay for drugs. The requirement of large sample sizes and the potential for fast recruitment leading to a speedy completion of clinical studies are probably the most important factors that have fueled globalization of studies. While an enlarged clinical trial universe certainly benefits patient recruitment and diversity, it also multiplies the operational and strategic obstacles that clinical trial professionals must circumvent. In addition to inexperience in conducting trials and differing quality standards, there are wide spread differences from country to country in customs knowledge, experience and laws. Other challenges include the need to manage logistics complicated by countries with limited infrastructure as well temperature sensitive biologics, especially outside major cities. There are regional idiosyncrasies -- differences of language, both spoken and unspoken, working patterns, culture and religion -- that add another layer of complexity. Above all, a high level of co-ordination between participating centers across the globe is a different level of challenge one has to handle. Big pharmas and small biotechs alike are looking for innovative ways to improve trial outcomes and, in turn, lower trial costs--this means increasing the efficiency in which they recruit patients, monitoring more closely how drugs are supplied and being more flexible about trial design. Pharmaceutical companies and some academic cooperative groups have been conducting challenging, large pivotal registration studies with multinational participation. Most importantly, the process of expanding the network of clinical research sites also fosters the integration and the development of closer relationships among investigators at a global level. Reduced operational costs and the ability to expedite the regulatory approval of drugs in various countries or regions are also important drivers. Some of the tools that are optimizing clinical trials today and help in overcoming current challenges will be discussed.

Biography

Milan C Satia is a PhD student of Pharmacology with more than 22 years of experience working across the local pharma majors and CRO industry, playing key leadership roles. He has led operations at R&D for a pharma major and CROs, setting up of a Pharmacokinetic cell within technology center, managed client relationship, and has led teams of expert and played important role in contributing to strategies, developing new business opportunities and to provide scientific knowledge base. He is having a wide knowledge base and experience of varied facets of pharmaceutical research including pharmacology, toxicology, bioavailability and bioequivalence studies, clinical trials, medical writing and exposure to various international audits. He is also a conversant with regulatory framework globally and a crucial member for setting up of CROs in India. Currently, he is a CEO of Ethicare Clinical Trial Services since 2009 and located at Ahmedabad, India. He is providing services from Phase I to Phase IV clinical trials along with data management services.

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