

4th International Summit on

GMP, GCP & Quality Control

October 26-28, 2015 Hyderabad, India

Virtual clinical trials in Asia: A new study paradigm for the future?

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The conventional conduct of clinical trials can be inefficient, time consuming, very resource intensive and often inconvenient for trial subjects. Trial participation is often limited to people living in close proximity to study centers and multiple study visits can be inconvenient, leading to subjects dropping out from the study, slow recruitment and may compromise data quality. The session will describe a novel, innovative Participatory Patient-Centered (PPC) study concept in which an investigator interacts with participants directly, mainly via internet and telephone, and participants are not required to be physically present for clinical study site visits. Participants, who can be recruited without geographic limitations, undergo a newly designed remote electronic informed consent process and are followed up with eDiaries and web-based questionnaires. An investigator is available by phone or email at any time during the study. The PPC model can potentially benefit the patient, physician, and investigator in a number of ways. In order to demonstrate the flexibility of the PPC model, it can be used in combination with conventional trial elements and primary care physicians may be included in the management of engaged patients participating in the study. This concept can be applied to local and global clinical trials. The session will discuss the learning from the trial design, illustrate differences between the PPC model and conventional trials, demonstrate the benefits for patients, primary health care providers, investigators and regulators, highlight special considerations for implementation, and look at the necessary enabling changes in the trial environment to make this exciting new model most efficient.

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Bioactive compounds from natural product to pharmaceutical industry: GMP via GLP

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For herbal, Ayurvedic and different traditional medicines system in which direct plant materials or its extracts, after standardization, may be used as medicinal agent as such in the form of tinctures or fluid extracts or further processed to be incorporated in definite dosage form such as tablets and capsules, contain complex mixture of many medicinal plant metabolites, such as alkaloids, glycosides, terpenoids, flavonoids and lignans lead to good products. Even in these medicine formulations Good Manufacture Practices (GMP) via Good Laboratory Practice (GLP) leads in quality product. In natural product chemistry, an extract are further processed through various techniques of fractionation to isolate individual chemical compounds from natural products. In any natural product isolation program in which the end product is to be a drug or a lead compound, some type of bioassay screening or pharmacological evaluation must necessarily be used to guide the isolation process towards the pure bioactive component. For example, one successful story of taxol production by Hauser chemical research for National Cancer Institute (NCI) 1989 via CRADA which was awarded to BMS via GMP for clinical uses. The BMS became source of bulk taxol for clinical and commercial, have reported commercial scale 16000 lb to 13000 lb of bark of *Taxus brevifolia* to produced 1 kg taxol and 3.2 million have collected for 200-246 kg taxol in 1992. BMS have delivered 16 kg taxol to formulate in vials for human use for 8000-10000 people affected by Cancer. FDA, USA approved that bark of Pacific yew, *T. brevifolia* use for taxol production under Act, 16, U.S.C.4801-4807(1992), later New Drug Application (NDA) also approved it. Nowadays, hot sale GMP certified 100% pure natural taxol US \$ 1-1200/Kg. Similarly, vincristine and vinblastine from the Madagascar periwinkle, *Catharanthus roseus* G. Don, introduced a new era of the use of plant material as anticancer agents. They were the first agents to advance into clinical use for the treatment of cancer. Vinblastine and vincristine are primarily used in combination with other cancer chemotherapeutic drugs for the treatment of a variety of cancers, including leukemias, lymphomas, advanced testicular cancer, breast and lung cancers, and Kaposi's sarcoma. These successful stories happen possible due to GMP via GLP from Natural Product Chemistry Laboratory to Pharmaceutical Industry. Integrated Natural Product Chemistry Laboratory and Pharmaceutical Industry Laboratory with GLP for GMP lead to quality product. Based on GLP manufacturing will lead to be GMP for active drugs in Pharmaceutical Industry result in quality products.

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