Event Code: ECI/TG072017/802

Presented by:

exalt
Communication Infomedia

Venue : Mumbai

Date : 04th August 2017.

CLINICAL TRIALS 2017.

REGULATORY ASPECTS OF DRUG DEVELOPMENT IN INDIA

Theme

A Clinical trial is the most important and the last requirement in development of new drugs or medical devices. This is the only way of establishing the efficacy and safety of newer medical technologies in human population. India is emerging as the most favoured destination for clinical trials for many reasons. It has a vast therapy-naïve patient pool with considerable genetic variability, a large number of English speaking highly trained medical and para-medical professionals, adequate infrastructure and very favourable regulatory restrictions. The poverty-laden Indian patients are easily agreeable to be included in clinical trials as they would have never been otherwise able to receive that quality of health care.

This favours faster completion of the study unlike in other countries where patient availability is limited. In addition, per subject cost of clinical research in India is just about 10-15 % of the cost in the Western countries. Consequently, the current clinical trial business of US$500 millions in India is estimated to touch $1 billion mark before 2016 with the key players from Americas and Europe. However, in recent times India has realized that the Indian patients particularly from the lower strata of society are too prone to allurement and susceptible to exploitation by the multi-national drug manufacturers. They give their consent for inclusion in clinical trails often without properly understanding the implications. The Supreme Court of India in a Public Interest Litigation WP(C) No. 33 of 2012 has directed that the clinical trials of new chemical entity shall be conducted strictly in accordance with the procedure prescribed in Schedule 'Y' of Drugs & Cosmetics Act, 1940 and that too under the supervision of the Secretary, Health & Family Welfare. It has recently further commented that "India is a heaven for clinical research but clinical trials are hell for India". The Indian regulatory authority, the DCG(I) has therefore started tightening its belt and new stricter regulations are being notified regularly. These encompass establishing the scientific rationale based on in vitro and in vivo experimentations with regard to efficacy and safety followed by strict ethical considerations as provided primarily under the ICMR Guidelines with due cognizance of recommendations of ICH, GCP and international bodies like CIOMS and IEGBR. Often complications arise on IPR ownerships, costs & compensations and on other issues in patients' ICF, CRAs and MTAs.

Professional Training

CLINICAL TRIALS 2017.

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Regulatory Aspects Of Drug Development In India

Programme

Registration will begin at 8:30 am with tea & Snacks. The course will commence from 9:00 am to 17:30 pm the days. Two Refreshments & Lunch will be served on both the days

- Establishment of sound scientific rationales
- Development of Ethical Requirements with examples
- ICMR and other Guidelines and role of IRB/IEC
- Schedule Y of the Drugs and Cosmetics Act 1940 and notifications relevant to clinical trials e.g. Rules 122DA, 122DAA, 122DAB, 122DAC, 122DD and 122E.
- Special features in ICFs, CRAs, MTAs relating to IPRs.

Course Faculty

Dr.B.B.Singh is a practicing lawyer for the last 16 years. He holds a masters degree in Law from Mumbai University specializing in the field of IPR relating to Biomedical Technologies. He has been regularly writing research papers and general articles in the print media on subjects like ethics and law of clinical trials and on implications of India's international cooperation in nuclear industry. He is a member of Ethics Committees of several hospitals and research institutes in Maharashtra. He also has to his credit over 170 research papers in the field of biosciences relevant to cancer treatment and prevention. He holds a doctorate degree from London University and is a widely traveled scientist. He has worked in several prestigious institutions in India and abroad and for several years with the United Nations.

He is a member of Editorial Boards of International journals in these fields of science and law. He is a popular and sought-after speaker and is an active member of numerous scientific and social organizations like Rotary Club and Masonic Lodge and many swadeshi movements.

Professional Training

We realise that the Participants would be investing their time and money to attend this program. We therefore assume that the participants would be committed to actively participating and benefiting from the program. We urge all participants to completely switch off their cell phones and use them during the breaks.

Business Opportunities

A limited amount of sponsorship opportunities are available for this Programme. These include, but are not limited to opportunity to present case studies, exhibit, host networking functions, and benefit from the extensive branding and marketing exposure generated throughout the life cycle of the event.

For further information

Please contact on **+9122 65612818 / 98206 23016**

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We at **Exalt Communication Infomedia** would like to thank everyone who has helped with the research and organisation of this Course, particularly the trainer for his support and commitment.

For Registration Details:
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