Basic Principles of Clinical Research and Methodology

Institute of Clinical Research (India)
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Basic Principles of Clinical Research and Methodology

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Requirements and guidelines to Undertake Clinical Trials In India Schedule Y (Amended Version)

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FOREWORD

India is increasingly being recognized as a quality player and a preferred partner for global clinical trials. India has several prized attributes for clinical trial development making it the "Hub for Global Clinical Research". It is certain that as Clinical Research is growing in India, the demand for Clinical Research professionals is increasing. According to McKinsey Report, the global clinical trial outsourcing to India in the pharmaceutical industry is estimated to reach around Rs. 5,000 crores by the year 2010, and there will be requirement of approximately 50,000 Clinical Research Professionals.

Clinical Research requires specific cognitive and communication skills to handle complex issue. Such know-how resides with specialists, such as clinical research associate, clinical team leader, project manager, clinical supply manager, quality assurance manager, medical and regulatory affairs manager, data manager and head of clinical operations. Training of these professionals in GCP standards would go a long way to strengthen the CR industry. Specialized training requirements may include, training on clinical trial processes, development of standard operating procedures and GCP and applicable regulatory guidelines.

India has already demonstrated its capabilities to undertake contract research for compound discovery and development. There is a phenomenal increase in screening capacity of pharma companies and the Process Development and Synthesis. India's expertise in chemical synthesis can be utilized for development of cost-effective processes for new drugs and intermediates. At this stage the operational deficiencies should be defined and appropriate Regulations/Guidelines developed.

Education in Clinical Research Methodology requires the most up-to-date information to achieve the Global Standards. The book on "Basic Principles of Clinical Research and Methodology" contributed by the eminent professionals from Academia and Industry will fulfill the long felt need for such a publication in the country. I congratulate Institute of Clinical Research (India) and Professor S.K. Gupta for bringing out this excellent publication.

N.K.Ganguly
Director General

PREFACE

In the last decade, there has been a paradigm shift in drug discovery from the days of lab chemistry, isolation of actives and synthesis to clinical research. Clinical trials represent a bridge from early stage drug development to commercialization. It takes over billion dollars to bring a drug from the lab to the market after a time-span - 9 years on average. Traditionally, high quality clinical research has been branded as a "Western capability" as they possessed excellent infrastructure, standardized research processes, mature Government regulations and healthcare systems and intellectual property protection.

India is fast gearing and rising up to the challenge and catering to the needs of the clinical research industry. It is being recognized as "tomorrow"s market". The fast growing private healthcare sector, lower costs for conduct of trials, rapidly increasing awareness of Good Clinical Practice, vast majority of educated, English conversant population, ethno-socio-cultural diversity, Government commitment and above all wide spectrum of disease-conditions, lure top names in the pharmaceutical world to zero-in on India for their pursuits in clinical research. Global consultancy McKinsey and Co estimates that by 2010, global pharma majors would spend around $1-1.5 billion just for drug trials in the country. Many big global pharma names like Novo Nordisk, Aventis, Novartis, GlaxoSmithKline, Eli Lilly and Pfizer have begun clinical drug trials across various Indian cities. Today, about 80 government and private hospitals in India are engaged in global and local clinical trials. The multinationals in the CRO segment include ICON Clinical Research, Omnicare Clinical Research, Pharmanet global, Pharm-Olam, ClinTec International and Quintiles Spectral have already set their eyes on India.

However, there are some burning issues regarding clinical research that need to be addressed such as amendment of regulations, availability of trained and experienced medical staff, ethical considerations, patient education, pharmacovigilance, intellectual property rights etc. Though a gradual change evident, the area is still in its infancy. WHO and ICMR sponsored survey on the issue had shown that there are no standard, consistent, planned teaching programme on the subject. An academic curriculum needs to develop that can mould and inculcate the essentials of the need and methodology of clinical research right at the undergraduate level. This will equip the students of today to become rational, effective and safe clinical researchers of tomorrow and help to launch India as global leader in the field.

Institute of Clinical Research India has made outstanding contributions in education and training programmes by providing structured course to the postgraduate students. Thus, Clinical Research professionals by providing postgraduate education this fulfilling the need of the country. ICRI is the pioneering institute in India which provides Masters in clinical research and postgraduate courses in clinical research, clinical data management and quality assurance.

This book addresses the broad array of essential topics in clinical research and provides a valuable overview of this rapidly evolving field, not only for professionals from academia but also those in the pharmaceutical industry. All efforts have been made to merge the inputs from the stalwarts in the area, and comprehensively provide information in this area, which appears as a maze, hitherto.

S K Gupta

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I first congratulate all the contributors for being a part of this launch venture and secondly, thank them for their outstanding contributions. Despite their busy schedule and pressing commitments, the authors have put their best effort to give shape to this textbook. The practicalities and nuances that they have gained as experience by way of being in the field for decades, have been succinctly described here. My earnest thanks to them once again, for an excellent job done.

Dr. Laxman Prasad, Advisor and Head, Department of Science and Technology and Dr. G. J. Samathanam, Advisor, Department of Science and Technology (DPRP) Programme of the Government of India, has been constant source of inspiration and help for providing financial support for this publication, which has been the part of proceedings of the national conference.

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