National workshops on good clinical practices and regulatory requirements for clinical trials in India, Training Manual by Dr. Urmila Thatte and Dr. Renuka Kulkarni. Published by Department of Clinical Pharmacology, TN Medical College and BYL Nair Ch. Hospital, Mumbai.

With an increasing number of molecules being released for clinical trials by drug companies, there is a great pressure on investigators in India to participate in such trials for one of two reasons: (a) a perception that in view of prevailing health status, recruitment of sufficient number of patients will not be a problem and can be quickly achieved within the target period and (b) a feeling that regulatory requirements are less stringent in India than in developed countries making possible trials which would have had difficulty in taking off elsewhere.

In this context, there is an urgent need for a training manual for familiarizing investigators and other concerned players on good clinical practice and regulatory requirements for clinical trials in India. Although these guidelines are available as separate publications, it would be useful to have them all accessible for consultation at one site in one volume. Current level of knowledge across the breadth of the profession lacks depth in this area. Many medical institutions do not even have a properly constituted Ethics Committee.

The training manual entitled “National Workshops on Good Clinical Practice and Regulatory Requirements for Clinical Trials in India” prepared by the Central Drugs Standard Control Organization; and co-ordinated by the Department of Clinical Pharmacology, TN Medical College & BYL Nair Ch. Hospital, Mumbai goes a long way in fulfilling this vital need. The authors have focused their attention on all four major players in this field viz. Investigators, ethics committee members, regulators and sponsors. Each section is classified into introduction, specific objectives resource material, group tasks and tests. The material is lucidly presented with important concepts being highlighted in boxes. References are provided when required. The manual is supplied along with a CD which contains the full text of the presentation and the current regulatory guidelines. The information provided is systematic and comprehensive and the step by step approach adopted will greatly facilitate organizations of such workshops at other sites. Case studies with common mistakes along with correct responses provided by the authors will facilitate learning.

I found all sections of the manual extremely informative. In fact, I could not find much that is worthy of criticism in the content or presentation. I feel that the Training Manual is a “must have” for all scientific institutions and regulatory agencies besides being a valuable adjunct to all medical institution libraries.

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ICH Good Clinical Practice. Background: The Global Health Clinical Consortium (GHCC) is comprised of clinical operations leaders from 14 Product Development Partners (PDPs). These organisations are conducting ~125 ongoing and planned trials to develop vaccines, microbicides/preventatives, therapeutic products and diagnostics covering more than 20 disease areas at more than 260 clinical research sites in resource-limited settings. The GHCC functions as a platform to share learnings and pool resources to leverage expertise across PDPs. Carmelita Africa - Clinical Project Associate, International Partnership for Microbicides. Web. Liam Boggs - Training Manager, The Global Health Network, Centre for Tropical Medicine & Global Health, University of Oxford. Web. National workshops on good clinical practices and regulatory requirements for clinical trials in India, Training Manual by Dr. Urmila Thatte and Dr. Renuka Kulkarni. Published by Department of Clinical Pharmacology, TN Medical College and BYL Nair Ch. Hospital, Mumbai. With an increasing number of molecules being released for clinical trials by drug companies, there is a great pressure on investigators in India to participate in such trials for one of two reasons: (a) a perception that in view of prevailing health status, recruitment of sufficient number of patients will not be a problem and c