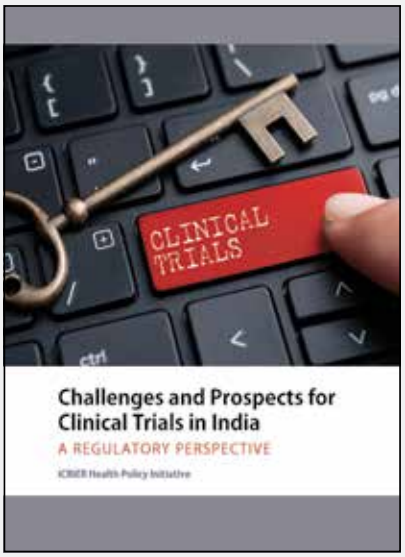

Challenges and Prospects for Clinical Trials in India

A Regulatory Perspective

ALI MEHDI, RAHUL MONGIA, DEEPMALA POKHRIYAL, SEEMA RAO

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ABOUT THE BOOK:

Clinical trials are integral to drug discovery and bringing out newer and better medicines. With the evolution of India's disease burden as well as its pharmaceutical industry, the need for clinical trials has increased manifold. This report analyses prospects and challenges of clinical trials in India, focusing on New Chemical Entities and new drugs, and likewise proposes actionable policy recommendations for the Indian drug regulatory landscape so that the country can realise its untapped potential, while addressing concerns raised regarding the conduct and quality of clinical trials. The Government of India needs to develop a promotive ecosystem around clinical trials—now more than ever, sooner rather than later. A clear set of policy, rules and guidelines around clinical trials would be a central component in the larger strategy to address India's public health challenges and incentivise the country's pharmaceutical industry to mature to the next level.

PRAISE FOR THE BOOK:

"This report provides a helpful overview of the clinical trials regulatory framework in various countries, with a particular emphasis on the dynamic regulatory landscape in India, which has been dramatically altered by new and in some cases controversial regulations, beginning in 2013. The report includes helpful suggestions on how Indian national policy can be revised to re-invigorate the clinical trials enterprise in this most promising country."

— Mark Barnes, J.D., LL.M
Barbara Bierer, M.D.,
Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard University

"Regulation of clinical trials in India is of crucial importance to patients and public health. This report, from a group of recognized experts, will be of great assistance to the Indian authorities as they consider possible reforms to the existing regulatory systems."

— Richard Kingham
Senior Counsel of Covington & Burling LLP in Washington, DC, and London and Adjunct Professor at the Georgetown University Law Centre

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