



Challenges and Prospects for Clinical Trials in India

A Regulatory Perspective

ALI MEHDI, RAHUL MONGIA,
DEEPMALA POKHRIYAL,
SEEMA RAO

2017 • PB • 8½ X 11 • 88P
ISBN 13: 9789332704268
Rs. 1295; US\$ 69.95

Published by :



ACADEMIC FOUNDATION

4772 / 23 Bharat Ram Road, (23 Ansari Road),
Darya Ganj, New Delhi - 110 002, India.

Tel: +91-11-23245001 / 02 / 03 / 04.

Fax: +91-11-23245005.

e-mail: booksaf@gmail.com

website: www.academicfoundation.org

and

**INDIAN COUNCIL FOR RESEARCH
ON INTERNATIONAL ECONOMIC
RELATIONS (ICRIER)**

Core 6A, 4th Floor India Habitat Centre,
Lodhi Road, New Delhi 110003

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

CONTENTS

List of Tables, Figures and Appendices

List of Abbreviations

Glossary

Foreword

Acknowledgements

Executive Summary

1. Introduction

- 1.1 Regulating Clinical Research
- 1.2 The Global Clinical Research Landscape
- 1.3 The Indian Clinical Research Growth Story

2. Research Methodology

- 2.1 Country Selection Criteria

3. The Dilemmas Afflicting Clinical Research in India

- 3.1 Overview
- 3.2 Developing a Culture of Research and Innovation: The Clinical Research Perspective

- 3.3 Regulatory Landscape for Clinical Research of Countries in the Sample

4. Under Trial: The Challenge of Clinical Trials in India

- 4.1 Use of Formulae for Calculating Compensation for Trial Related Injury/Death
- 4.2 Use of a 'Standard of Care'
- 4.3 Use of Placebos in a Placebo Controlled Trial
- 4.4 Clinical Trial Waivers
- 4.5 Mandatory Local Filing of Marketing Authorisation After the Clinical Trial
- 4.6 Audio-visual Recording of Informed Consent
- 4.7 Message Fidelity in Translated Informed Consent Forms
- 4.8 Trends in Clinical Research in Other Countries
- 4.9 Policy Recommendations

5. Conclusions

References
Appendices

TEAM LEADER:

Ali Mehdi established and leads the Health Policy Initiative at ICRIER. His research interests include—the process, design and assessment of health policies; prevention of chronic diseases along with policy instruments and institutional design for its promotion; social determinants of health; metrics of health inequities; health financing, governance and manpower; fertility and mortality; demographic dividend; drug regulation. A couple of his books are in the pipeline—India Health Report 2018 (Oxford University Press), A Shot of Justice (2 volumes) (Oxford University Press), Chronic Diseases in South Asia (Springer), Freedoms and Fragility: The Challenge of Job Creation in Kashmir, India (Routledge). Ali did his MA at the University of Freiburg, Germany and completed his PhD at Humboldt University in Berlin. He can be reached at amehdi@icrier.res.in.

AUTHORS:

Rahul Mongia is a Consultant at ICRIER, and a research scholar at the Centre for Studies in Science Policy (CSSP), Jawaharlal Nehru University. He has been working on issues related to the biopharmaceutical industry and health policy broadly. He has contributed to opinion columns in several national dailies and blogs. His research interests include intellectual property, technology transfers, FDI, trade negotiations, universal health coverage and issues related to the pharmaceutical product supply chain and drug development.

Deepmala Pokhriyal is a Consultant at ICRIER. She has worked on the assessment of the regulations of the clinical trials industry in India, and recommending potential changes based on the industry's global environment. She is also a graduate student at the Andrew Young School of Policy Studies, Georgia State University. Prior to this, she was engaged in a NABARD-sponsored project on evaluation of rural connectivity projects in Gujarat at Indian Institute of Management, Ahmedabad. She holds a graduate degree in Economics from Gokhale Institute of Politics and Economics, Pune.

Seema Rao is an External-Consultant at ICRIER. She is a practicing advocate in the Supreme Court of India and Delhi High Court. She has been a Panel lawyer for the Government in the Supreme Court as well as Standing Counsel on behalf of Ministry of Environment and Forest in the National Green Tribunal. During this time she dealt with matters relating to key policy making issues in environment laws, company laws, criminal laws, PILs etc. She has various national and international publications to her credit on topics relating to criminal laws, banking, environment laws etc.

ORDER FORM

To,

**Academic Foundation,
4772-73 / 23 Bharat Ram Rd.
(23 Ansari Road), Darya Ganj,
New Delhi - 110 002. INDIA.**

Tel : 23245001 / 02 / 03 / 04.

Fax : 011-23245005.

e-mail: books@academicfoundation.com

www.academicfoundation.com

Dear Sir,
Please supply at the address mentioned alongside, your publications as listed in the enclosed sheet with their respective quantities as specified by us. (List to be enclosed by the buyer).

Discount applicable

to educational / research institutions :

10% on below 5 copies

15% on 5 copies & above

Note: Only 'US Dollar Price' applicable for copies to be shipped outside the Indian subcontinent.

Box-packing & courier delivery FREE

(within India). Outside India: No extra charge for ordinary surface mail delivery. For express delivery by air, add USD 15.00 extra, per copy. PAYMENT TERMS: Full payment in ADVANCE by Banker's Cheque / Demand Draft in favour of **Academic Foundation payable at Delhi** For cheques payable outside Delhi, kindly add Rs. 100 (INR) or USD 5.00 to the final amount.

Accordingly, enclosed please find our payment:

Demand Draft / Cheque No.

Dated..... amounting to

favouring **Academic Foundation** and

preferably payable at Delhi.

Books to be sent at the following address :

NAME.....

DESIG.

DEPT.

ORG.

ADDRESS

.....

CITY.....

STATE.....

PIN..... COUNTRY.....

TEL . ..

FAX.....

E-MAIL