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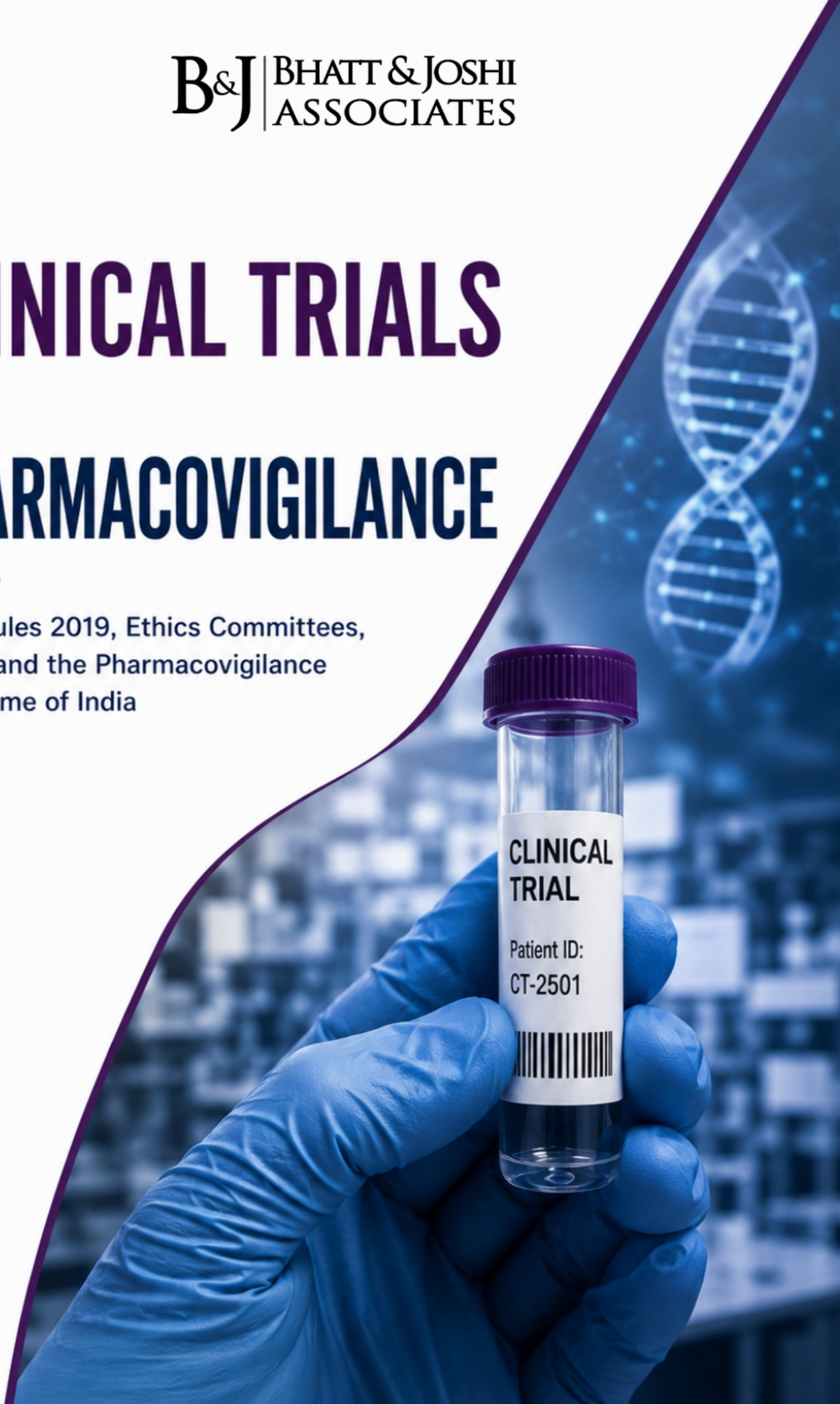
CLINICAL TRIALS AND PHARMACOVIGILANCE

NDCT Rules 2019, Ethics Committees, PSURs, and the Pharmacovigilance Programme of India



Clinical Trials and Pharmacovigilance

NDCT Rules 2019, Ethics Committees, PSURs, and the Pharmacovigilance Programme of India

A Practitioner's Handbook for the Pharmaceutical Industry

BHATT & JOSHI ASSOCIATES

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TABLE OF CONTENTS

FOREWORD

The New Drugs and Clinical Trials Rules, 2019 (NDCT Rules) — gazetted on 19 March 2019 as GSR 227(E) — represent the most comprehensive overhaul of India's clinical trial regulatory framework in over two decades. Replacing the fragmented Part XA and Schedule Y of the 1945 Rules, the NDCT Rules consolidate 13 chapters and 8 Schedules into a single, modernised instrument covering clinical trials, bioavailability/bioequivalence studies, new drug approvals, and post-marketing surveillance.

This volume provides a practitioner's guide to the NDCT Rules, the Ethics Committee framework, serious adverse event (SAE) reporting obligations, compensation mechanisms, and the Pharmacovigilance Programme of India (PvPI).

PART I — THE NDCT RULES 2019

Chapter 1: Structure and Scope

1.1 Architecture

The NDCT Rules 2019 are organised into 13 chapters:

1.2 Key 2024 Amendments

GSR 581(E) dated 19 September 2024 — introduces mandatory CRO (Contract Research Organisation) registration with CDSCO. All CROs conducting clinical trials in India must now be registered.

2022 deemed-permission amendment — protocol-related approval applications receive deemed permission if CDSCO does not respond within 60 days.

Chapter 2: Ethics Committee Framework

2.1 Composition

An Ethics Committee must have a minimum of 7 members, of whom at least 50% must be non-affiliated with the institution:

2.2 Registration

Ethics Committees must be registered with CDSCO. Registration is valid for 5 years. The EC must maintain records of all proceedings, decisions, and voting for at least 5 years after completion of the trial.

Chapter 3: Clinical Trial Permission and Registration

Every clinical trial must receive permission from CDSCO and must be registered with the Clinical Trials Registry - India (CTRI) before enrolment of the first subject. The timeline for CDSCO permission is 90 days for new chemical entities and 60 days for clinical trials forming part of drug discovery.

Chapter 4: Serious Adverse Event (SAE) Reporting

The SAE reporting timeline is one of the most critical compliance obligations:

PART II — PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI)

Chapter 5: PvPI Architecture

The Pharmacovigilance Programme of India (PvPI) was launched on 14 July 2010 under the aegis of CDSCO. The National Coordination Centre (NCC) is located at the Indian Pharmacopoeia Commission (IPC), Ghaziabad (since 15 April 2011). India has been a full member of the WHO Programme for International Drug Monitoring since July 2017, contributing adverse drug reaction (ADR) reports to the WHO-UMC global database (VigiBase) in Uppsala, Sweden.

5.1 ADR Reporting Network

Over 250 Adverse Drug Reaction Monitoring Centres (AMCs) across India collect and report ADR data to the NCC. Healthcare professionals, patients, and pharmaceutical companies can report ADRs.

Chapter 6: Periodic Safety Update Reports (PSURs)

6.1 PSUR Submission Requirements

PSURs must contain: a comprehensive summary of the product's safety profile; all ADRs received during the reporting period; risk-benefit analysis; and any risk minimisation measures proposed.

6.2 CDSCO Guidance on PSURs

CDSCO issued a Guidance Document on PSURs specifying the format (aligned with ICH E2C(R2)), submission procedures, and evaluation criteria. The document is available on the CDSCO website.

PART III — COMPENSATION FRAMEWORK

Chapter 7: Compensation for Clinical Trial Injury

Chapter VIII of the NDCT Rules provides a structured compensation framework for participants who suffer injury or death during clinical trials:

Compensation determination: Based on the formula in the Seventh Schedule to the NDCT Rules, which factors in age, income, and severity of injury

No-fault compensation: Available where the injury is directly attributable to the clinical trial

Timeline: The sponsor must provide compensation within 60 days of determination by the Ethics Committee

Insurance: Sponsors must maintain adequate clinical trial insurance throughout the trial period

PART IV — PRACTICAL COMPLIANCE TOOLS

Chapter 8: Clinical Trial Compliance Checklist

Pre-Trial:

- CDSCO Clinical Trial Permission obtained
- Ethics Committee approval obtained from each trial site
- CTRI registration completed before first subject enrolment
- CRO registered with CDSCO (mandatory from September 2024)
- Clinical trial insurance arranged
- Informed Consent Form (ICF) approved by EC and CDSCO
- Investigator's Brochure current and complete
- SAE reporting procedures documented and staff trained

During Trial:

- SAE reporting within 24 hours (death/life-threatening) / 14 days (other)
- Annual EC renewal of approval
- Protocol deviations reported to EC and CDSCO
- Data integrity maintained (source data verification)
- Monitoring visits documented

Post-Approval:

- PSURs submitted six-monthly (first 2 years), then annually
- Post-marketing surveillance as directed
- ADR reporting to PvPI/NCC
- Risk Management Plan implemented

REFERENCES

New Drugs and Clinical Trials Rules, 2019, GSR 227(E) dt 19.03.2019

NDCT (Amendment) Rules, 2024, GSR 581(E) dt 19.09.2024

CDSCO Guidance Document on PSURs

PvPI — Pharmacovigilance Programme of India (IPC Ghaziabad)

WHO-UMC — Uppsala Monitoring Centre

Clinical Trials Registry - India (CTRI, ctri.nic.in)

ICH E2C(R2) — Periodic Benefit-Risk Evaluation Report

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