



CLINICAL AND DATA OPERATIONS IN INDIA

PRA International is one of the world's leading clinical development organizations, with more than 3,600 employees working from 26 offices across North and South America, Europe, Africa, Australia, and Asia.

PRA International is a global CRO with clinical and data operations centers throughout the world, including India. PRA's Clinical Operations Center, located in Mumbai, is home to India's leading medical institutions and enjoys strong relationships with the country's top investigators within the medical community. Just 100 miles to the southeast of Mumbai is PRA's Global Data Management Center in Pune, one of the four Data Management Centers that PRA maintains globally, along with PRA's own Drug Depot and pharmacy facility for drug storage.

PRA's Mumbai team has experience across multiple therapeutic areas, and is capable of providing numerous services ranging from Project Management, Clinical Monitoring, detailed Feasibility studies, Site Selection and Validation, submissions with EC/IRB and regulatory authorities, and the identification of service providers such as central laboratories and translators.

Opportunities for Clinical Development in India:

- Large population and growing health sector
- Access to patients with diseases of both the tropical and industrialized world
- Highly trained English-speaking investigators
- Urban centric and cost-effective health care system
- Robust IT infrastructure and resources
- Stable regulatory environment

Opportunities for Data Management in India:

- An educated and highly trained workforce
- Advanced resources in the technology sector with opportunities for growth
- Full range of clinical data management services for global studies
- Low infrastructure, resource, and operating costs

Access to Leading Medical Institutions:

Mumbai is India's leading city for clinical research and development.

- Besides providing healthcare to nearly 20 million inhabitants in the metropolitan area itself, Mumbai attracts patients from neighboring states, and is the focal point for the treatment of certain diseases, especially all types of cancers, within the entire country. PRA in India has access to GCP trained Investigator sites and has experience working with these sites and Investigators across the country, both in smaller cities and in major metropolitan cities like Mumbai, Delhi, Chennai, Kolkata, Hyderabad, Bangalore. The list below includes medical institutions and facilities that PRA has access to and experience working with.

Clinical trial sites in Mumbai

- Tata Memorial Cancer Hospital
- KEM group of hospitals
- B.Y. Nair hospital
- Hinduja Hospital
- Bombay Hospital
- Jaslok Hospital
- Sir H.N. Hospital

Clinical trial sites in Bangalore

- St John's Medical College Hospital
- Kidwai Memorial Institute of Oncology
- National Institute of Mental Health & Neurosciences

Access to Certified Laboratories

- PRA has experience managing and working with the College of American Pathologists certified laboratories in India, and these labs are used as central laboratories within the region. PRA has also established working relationships with newer global central laboratory systems such as Quest Diagnostics, and is actively developing its network of contacts with other labs throughout India.

Experience Counts

Led by Dr. Pramod Kabra, PRA's Director of Clinical Operations, Product Registration, India, the clinical team in India has considerable experience in conducting Phase II - IV clinical trials in the areas of oncology, central nervous system disorders, cardiovascular disease, endocrinology, and respiratory disorders, as well as many others.

Dr. Kabra is a physician and internist by training and has more than 10 years of experience in clinical research including Phase I, Phase II-IV, Bioequivalence, and Clinical Practice, and has also worked on more than 80 clinical trials in the therapeutic areas of oncology, psychiatry, gastroenterology, cardiology, ophthalmology, HIV and infectious diseases. As the Head of Early Development at a large Indian CRO prior to joining PRA, Dr. Kabra was part of the team that filed the organization's first IND in India. With his significant clinical experience and extensive knowledge of India's regulatory environment and local healthcare practices, Dr. Kabra is vital to accelerating PRA's growth and development in India and the surrounding regions.

PRA Clinical Trial Experience in India

PRA has considerable study experience in India across multiple therapeutic areas and phases. The table below shows the studies PRA has conducted that have included sites and subjects in India. In addition to the experience below, the PRA team in India itself also has significant experience and expertise in oncology, neurology, infectious diseases, cardiology, gastroenterology, endocrinology, metabolic disorders, psychiatry, dermatology, ophthalmology, and nephrology.

Therapeutic Area/Indication	Phase	Sites	Subjects
Cardiovascular	IIB	125	600
Dermatology	III	44	92
Endocrinology			
Diabetes Mellitus - Type II	III	90	275
Neonatal Hyperbilirubinemia	IIB	10	72
Infectious Disease	IV	28	1,550
Neurology			
Epilepsy	II/III	182	690
Multiple Sclerosis	II/III	226	1,243
Vascular Dementia	III	3	17
Oncology			
Non-Small Cell Lung Cancer	I/II	340	2020
Non-Hodgkin's Lymphoma	II	28	64
Advanced Blood & Bone Marrow Cancers	II	5	20
Metastatic Pancreatic Cancer	III	200	600
Metastatic Breast Cancer	III	182	1,100
Cancer Vaccine in unresectable stage III Non-small Cell Lung Cancer	III	247	1,322
Ophthalmology	III	123	530



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