

Clinical Trials in India

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Clinical Research

India makes up one-sixth of the world's population and therefore has a large portion of the world's health problems. Many pharma and biotech companies are looking to enter the Indian market and look at the potential of higher revenues based on 1.2 B people. They are conducting trials in India not just to recruit patients but also to market the products in India. In addition to pharma/biotechs, many NGOs like Gates foundation work on specific tropical diseases like Malaria, Leishmaniasis, Tuberculosis etc.

Indian Population is polygenetic and is an amazing amalgamation of various races and cultures. There are many diverse ethnic groups among the people of India. The 6 main ethnic groups are Negrito, Australoids, Mongoloids,

Mediterranean or Dravidian, Western Brachycephals and Nordic Aryans.

The Indian government has recently overhauled the approval process. CDSCO is (<https://cdsco.gov.in>) similar to FDA in terms of role and regulatory oversight. There are more checks and balances that have been put in for certification of sites, ethics committees and limiting # of concurrent trials by a PI. All clinical trials are registered, and information is available online at <http://ctri.nic.in>. Introduction of Online SUGAM portal and periodic meetings of Subject Expert Committee meetings are making approvals easier and faster. Typical approval time lines are 3-4 months. Overall - this translates to better a more predictable Clinical Trial conduct.

Other than the huge patient population, India has enough trained and qualified medical personnel to perform clinical trials. While all medical doctors cannot conduct clinical trials, there are many who are passionate about research and understand the processes that need to be followed. India also follows the global ICG-GCP standards. The standard of care in most of the hospitals conducting the clinical research is as good as, and in some cases, better than the western counterparts.

Clinical Research is also supported by good IT infrastructure as most trials now use software for data collection and analysis. Other than standard software for clinical trial management systems, the next generation of researchers are getting innovative and using free application like WhatsApp to stay connected with the PIs and their teams to access data instantly.

Asiatic is a boutique clinical CRO headquartered in Bangalore, India with a focus on P2-P4 trials. We have been in business since 2005 and conducted trials in different therapeutic indications for pharma/ biotechs in USA and Europe. We hope to open an office in GA by Q4 2019 or early 2020. How can we assist you?



Sources:

- <https://www.drugdevelopment-technology.com/news/newsmmedical-research-funders-and-ngos-agree-on-new-who-clinical-trial-policies-5818523/>
- <https://www.webindia123.com/india/people/people.htm> (poly genetic diversity)