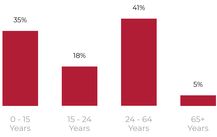
Clinical Trials in India

Year 2020 Research report

Location Data

The Clinical Trials industry in India is a subject of comparison with that of China, countries in Africa, and countries with similarly sized economies.[1] The country has a large-sized and very diverse population and plenty of trained workers in Healthcare industry – and at the same time carries 20% disease burden in the world. In accordance with ClinicalTrials.gov data India holds about 1% of all of clinical studies conducting Worldwide.

India Age Demographics Breakdown (2020)[2]



The country' population is 1,380 million people.[3] India is a single nation with a large, diverse population. Many potential research participants in India are treatment-naive and haven't previously taken any medical treatment.[11]

The doctor-to-population ratio in India is 0,857 : 1 000.[4] Insufficient funding from state governments has meant that public hospitals in India tend to be poorly equipped and overcrowded, with long waiting times for treatment.

This is more evident in rural parts of India where public health concerns are exacerbated by poor sanitation. At the same time private healthcare in India is of a high standard, so expats can rest assured that their medical needs will be well taken care of. One can expect well-trained medical professionals and state-of-the-art equipment at private hospitals in India.

The cost of treatment is generally much lower than in developed countries – India is fast becoming a popular medical tourism destination. Most private hospitals are located in the major Indian cities.[5]

The Central Drugs Standard Control Organization (CDSCO) is the National Regulatory Authority in India which is responsible for promoting the public health by ensuring the safety and efficiency of foods, pharmaceuticals, medical devices and cosmetics as well as supporting the development of the food and pharmaceutical industries. The main goal is to offer people safe foods and drugs.[7]

The Clinical Trials Registry India (CTRI) is a free and online public record system for registration of clinical trials being conducted in India.[8]

India - Clinical Trial Overview

As of now, India has a plenty of potential in the area of clinical research – due to large, various and treatment-naive population and overall "enough good" conditions of a clinical study initiation and conduction.

Approximately 4% of all clinical trials conducted in the Asia Pacific (APAC) region involve Indian investigative sites.

Regulatory & Ethics Approval Process

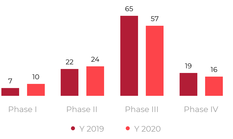
- The Central Drugs Standard Control Organization (CDSCO) is the National Regulatory Authority in India.[9] The Drugs Controller General of India (DCGI), an official of the CDSCO, is the final regulatory authority for the approval of clinical trials in the country. DCGI office is also responsible for inspections of trial sites, sponsors of clinical research and manufacturing facilities in the country. The DCGI review and approval process is conducted in parallel with the EC review, except in the case of clinical trials for academic/research purposes.
- The sponsor should obtain an approval from Ethics Committee for a new clinical study.
- All of the documents in clinical trial application should be translated into English language.
- India has a decentralized process for the ethical review of clinical trial applications, and requires ethics committee (EC) approval for each trial site. The majority of ECs are based at clinical or academic institutions and hospitals.
- After the completion of Ethics Committee approval process the clinical study should be registered in Clinical Trials Registry - India (CTRI).[10]
- To obtain approval of a clinical trial protocol in India, a foreign company should establish its local or representative's office.

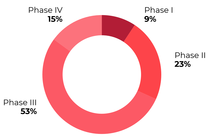
Trial Data

Based on data extracted from ClinicalTrials.gov, there were 236 clinical trials initiated in India (including local and bioequivalence studies) during the Year 2020. This translates to a 10% decline in the number of clinical trials initiated in comparison with the previous year when a total of 263 studies were initiated.

However, if one excludes bioequivalence studies and studies without a defined "Phase" there were only 107 clinical trials initiated during the Year 2020 compared to 113 studies initiated in previous year, representing a 5% decrease.

Breakdown of Clinical Trials in India by Phase (Year 2020)

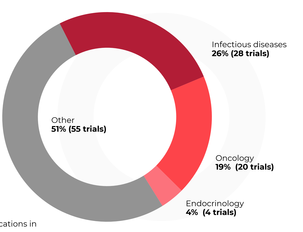




The majority of clinical trials conducted in India were interventional studies representing 77% of all studies conducted.

The most frequent phase of clinical trials conducted across the Indian sites by total number of studies was Phase III.

Breakdown of Clinical Trials in India by Therapeutic Area



The largest number of clinical trials initiated in India during the Year 2020 by therapy area were Infectious Diseases (28 studies), Oncology (20 studies) and Endocrinology (4 studies).

Also, during the same period there were 22 interventional studies initiated with the aim of evaluating different COVID-19 treatment methods with 42,116 subjects to be enrolled. In accordance with these studies' descriptions, Hydroxychloroquine, Nuvastatic, Itolizumab and Dapagliflozin became the most promising medications in this area.

Sponsor Data

By country / region of origin Europe accounted for the largest number of foreign pharmaceutical sponsored clinical trials initiated in Year 2020 in India.

The headquarters of foreign sponsor companies conducting clinical trials in the Year 2020 in India were split between Europe (7 companies) and the U.S. (2 companies).

At the same time there is one domestic innovative Indian company – Cadila Pharmaceuticals, conducting clinical studies in India and which appear in the TOP-10 ranking table.

Observational clinical trials and clinical trials without FDA-defined phases (from I to IV) were not counted in this ranking. More than one Sponsor company may be involved in a clinical trial.

Top-10 clinical trial Sponsors in India in Y 2020

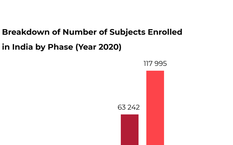
№	Company Name	Studies	Subjects
1	AstraZeneca	14	9 249
2	Pfizer	9	1 010
3	Eli Lilly	8	17 629
4	Novartis	8	2 567
5	Bayer	3	11 500
6	Sanofi	3	1 902
7	Cadila Pharmaceuticals	2	4 480
8	Janssen	2	1 300
9	Novo Nordisk	2	1 102
10	GlaxoSmithKline	2	836
	Combined share	**50%**	**41%**

Subject Data

The overall number of subjects enrolled (or planned to be enrolled) in clinical trials initiated in India during the Year 2020 (including multi-center international studies) jumped to 126,794 subjects in comparison with the 68,983 subjects enrolled (or planned to be enrolled) in clinical trials in the Year 2019 – with overall year on year growth rate of 84%.

The most prevalent Phase of clinical trials by total number of participating subjects was Phase III.

Breakdown of Number of Subjects Enrolled in India by Phase (Year 2020)



* Studies indicated by sponsors as Phase I-II were counted as Phase II; Phase II-III – as Phase III, Phase III-IV – as Phase IV.

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Data Search and Analysis Approach

All of stats data used in this document were downloaded from the ClinicalTrials.gov website as a .CSV file with the download options listed in the table below.

.CSV file export was completed with the following options:
Number of studies [to download]: all studies.
Select table columns: All available columns.
Select file format: Comma-separated values.

№	Item Name	Fields in Pivot Table	Details
1	Total number of CTs conducted in India vs. APAC in Y 2020	NCT	
2	Breakdown of Clinical Trials in India in the Year 2020 by Phase	NCT, Phases	Exclude “Not Applicable” and empty values in “Phase” field
3	Percentage Breakdown of Clinical Trials in India in the Year 2020 by Phase	NCT, Phases	Exclude “Not Applicable” and empty values in “Phase” field
4	Breakdown of Clinical Trials in India in the Year 2020 by Therapeutic Area	NCT, Conditions, Phases	See below *
5	Breakdown of Interventional vs. Observational Trials in India Y 2020	NCT, Study Type	
6	Sponsors Ranked By Number of Studies and Number of Subjects	NCT, Enrollment, Phases, Sponsor	See below **
7	Breakdown of Number of Subjects Enrolled in India in the Y 2020 by Phase	NCT, Phases, Enrollment	See below ***

* Use “Phases” filed as a filter. Exclude “Not Applicable” and empty values in “Phase” field. Use a simple Dictionary of Nosologies (see below) to count the number of studies for each nosology.

** Use “Phases” filed as a filter. Exclude “Not Applicable” and empty values in “Phase” field. Use “Number of values” by “NCT Number” field. Use “Sum” by “Enrollment” field. Use decreasing sorting of the table by “NCT Number” field.

*** Exclude “Not Applicable” and empty values in “Phase” field. Use “Number of values” by “NCT Number” field. Use “Sum” by “Enrollment” field.

If you want to use the same source .CSV file used in this report – just let us know via info@across.global and we’ll send it to you.

Dictionary of Nosologies used for Breakdown by Therapeutic Area

№	Therapeutic Area	Filter String
1	Gastroenterology	*gastr + colon + liver + cron + nash + pancrea*
2	Hematology	*hema + blood*
3	Dermatology	*derm + skin*
4	Urology	*urolog + nephr*
5	Immunology	*immun*
6	Infectious diseases	*infect + virus*
7	Cardiology	*cardi + heart + stroke*
8	Neurology	*neuro + cognitive*

№	Therapeutic Area	Filter String
9	Oncology	*cancer + phoma + noma + tumor + sarcoma*
10	Ophthalmology	*eye + ophtalm*
11	Rheumatology	*rheum + arthr*
12	Endocrinology	*endocrin + insulin + diabete*
13	Mental health	*mental + psych + depress + anxiety*
14	Surgery	*surger + transplant*
15	Geriatrics	*alzh + parkins*

About The White Paper

The White Paper is a free publication produced by ACROSS Global (CRO) Alliance for decision makers in the pharmaceutical industry. The document pulls together data from numerous public sources into a single brief document to aid decision makers planning to conduct clinical trials.

All of the data contained in this document are actual as of 28-JAN-2021.
For more information or if you would like to review a .CSV file of the data extracted from ClinicalTrials.gov (used in this White Paper) please write to: info@across.global.

About ACROSS Global

ACROSS Global is a global alliance of local contract research organizations successfully operating in 99 countries and covering more than 25 therapy areas.

High recruitment rates combined with innovative technology allows ACROSS partner companies to offer our clients conduct faster, more cost-effective studies without sacrificing quality for our clients.

All clinical studies conducted by ACROSS Partners conform to Good Clinical Practice (GCP) as well as local and international regulations ensuring the highest level of quality of the final study data.

We apply continuous improvement methodology to our working practices and IT infrastructure – and replace outdated R&D strategies by novel, more efficient approaches to clinical research.

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