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**Module -1: Clinical Research**

- Introduction to Clinical Trails , Overview ICH GCP
- Investigation Responsibilities in clinical trails
- Roles and Responsibilities of Sponsor & Clinical Trial Monitor
- Informed Consent Process
- Serious Adverse Event (SAE), Adverse event reporting
- Site Initiation visit, Site close visit

**Module -2: Pharmacovigilance**

- Introduction to Pharmacovigilance
- Signal Detection and causality assessment
- Statistical reasoning and algorithms in pharmacovigilance
- Medical dictionary for Drug Regulatory Activities (MedDRA)
- Individual Case Safety Report (ICSRs)
- Periodic Safety update report (PSUR)

**Module -3: Drug Regulatory Affairs**

- Overview of Regulatory Environment in USA, Australia, Europe and India
- Clinical Trial Requirements in India
- Import- Export of Clinical Trial Drugs
- HIPAA Privacy Rule.
- IND/ANDA/New Drug Application

**Module -4: Clinical Data Management**

- Introduction to Clinical Data Management
- Clinical Data Management
- Medical Coding in Clinical Data
- Clinical Data Process
- Case Reporting Form
- Quality & Regulatory system

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## **Guide to Understand the Current Employment Prospects and Long Term Career Growth Potential in the field of Clinical Research in the INDIA, US and the World**

PHARMA RESEARCH has designed this guide to help professionals analyze and decide upon Clinical Research as a viable and lucrative career path. This guide can be used by fresh graduates or experienced professionals alike to independently verify the industry potential and make their own career decision. This is a methodical guide based on a stepwise approach to assess current and future career prospects and earning potential. For better decision making please consider the following:

- People with different qualifications / professional backgrounds have different career paths / employment prospects in the field of Clinical Research.
- The industry is always changing therefore we must understand the long term career growth potential within the industry. While choosing a career, long term career growth potential is as important as current employment prospects in the industry.
- Earning potential is an important consideration while choosing Clinical Research as a career path.

This guide is divided into 3 sections as follows:

Section 1: Understanding Current Employment respects

Section 2: Understanding Long Term Career Growth Potential Section

3: Understanding the Earning Potential

## Section 1 : Understanding Current Employment Prospects

Step 1: Identify the appropriate job title based on your professional qualifications. The following job titles are currently prevalent in the industry:

<div> <div>Job Titles</div> <div>↓</div> </div> <div> <div>Professionals</div> <div>→</div> </div>	Doctors	Nurses	Physiotherapists	Dieticians	Medical Technologists	Pharmacists	Life Sciences Graduates	Bioengineering, Biomedical Engineering Graduates	IT Professionals	MBAs with Life Sciences	Sociology and Psychology Graduates	Statisticians
Clinical Research Coordinator		X	X	X	X	X	X				X	
Clinical Research Associate	X	X	X	X	X	X	X				X	
Drug Safety Associate		X	X	X	X	X	X					
Drug Safety Specialist	X											
Medical Officers	X											
Medical Liaison	X											
Study Manager	X									X	X	
Biostatisticians												X
Quality Assurance						X	X					
Regulatory Specialist						X	X					
Clinical Data Coordinator								X	X	X		
Clinical Data Analyst								X	X			
Clinical Data Manager						X		X	X	X		
SAS Developer								X	X			X
Clinical Validation Specialist								X	X			
Clinical Business Analyst								X	X			
Project Manager										X		
Business Development										X		

**Step 2: Go to the following job search websites on the web:**

1. <https://jobsavenue.net>
2. [Monster.com](https://www.monster.com)
3. [Indeed.com](https://www.indeed.com)
4. [Yahoohotjobs.com](https://www.yahoo.com/hotjobs)
5. [Biospace.com](https://www.biospace.com)
6. <https://www.aerotek.com/>
7. <https://www.nature.com/>
8. <https://www.dice.com/>
9. <https://www.centerwatch.com/>
10. <https://pharma-research.in/submit-your-resume/>

The above listed job search websites are specific to the INDIA & USA. The above list is not conclusive, there are many more such job search websites which could be looked up on the web.

**Step 3:** Use the "Job Titles" from Step 1, which are appropriate to your professional qualification and use them as "Key Words" in the job search section in any of the websites listed in Step 2. The website will provide you total number of job openings currently listed on the site which matches with your "Key Words". To expand the search criteria, repeat the job search using each of the job titles relevant to you.

**Step 4:** Repeat Step 3 in each of the job search websites listed in Step 2 and any other similar websites that you have identified on the web. These job searches will give you a good estimate of the total number of current jobs postings in the USA.

Based on the above steps, we estimated that as of August 2021, there are over 1, 20,000 jobs available in the INDIA & USA in the field of Clinical Research. The number of available jobs is more than the qualified professionals available in the US to fill these job openings. This presents a huge career opportunity for fresh graduates and an excellent growth potential for experienced and qualified professionals.

This method could also be used to find job openings outside the INDIA & USA. To find jobs in your home country or any other country of your choice, go to the country specific job search websites and run the search as defined in Step 3 and 4. The clinical research industry is growing at a rapid pace throughout the world, which presents a huge opportunity for the qualified professional looking for a global career opportunity in this industry.

## **Section 2: Understanding Long Term Career Growth Potential**

Bigger Picture - The Healthcare Industry in the United States:

As of 2021, the healthcare industry comprises 16% of the US economy. This industry is expected to grow by 24% between 2012 and 2021. About 26 percent of all new jobs created in the U.S. economy will be in the healthcare industry, or 4 million new jobs will be created in the healthcare industry between 2012 and 2021. The healthcare industry in the United States is expanding faster than any other sector of the economy. Employment growth will be driven by an aging population and longer life expectancies.

Source: Occupational Outlook Handbook, 2020-21 Edition, Overview of the 2012-21 Projections

Clinical Research - The Emerging and Recession Proof Sector within Healthcare Industry

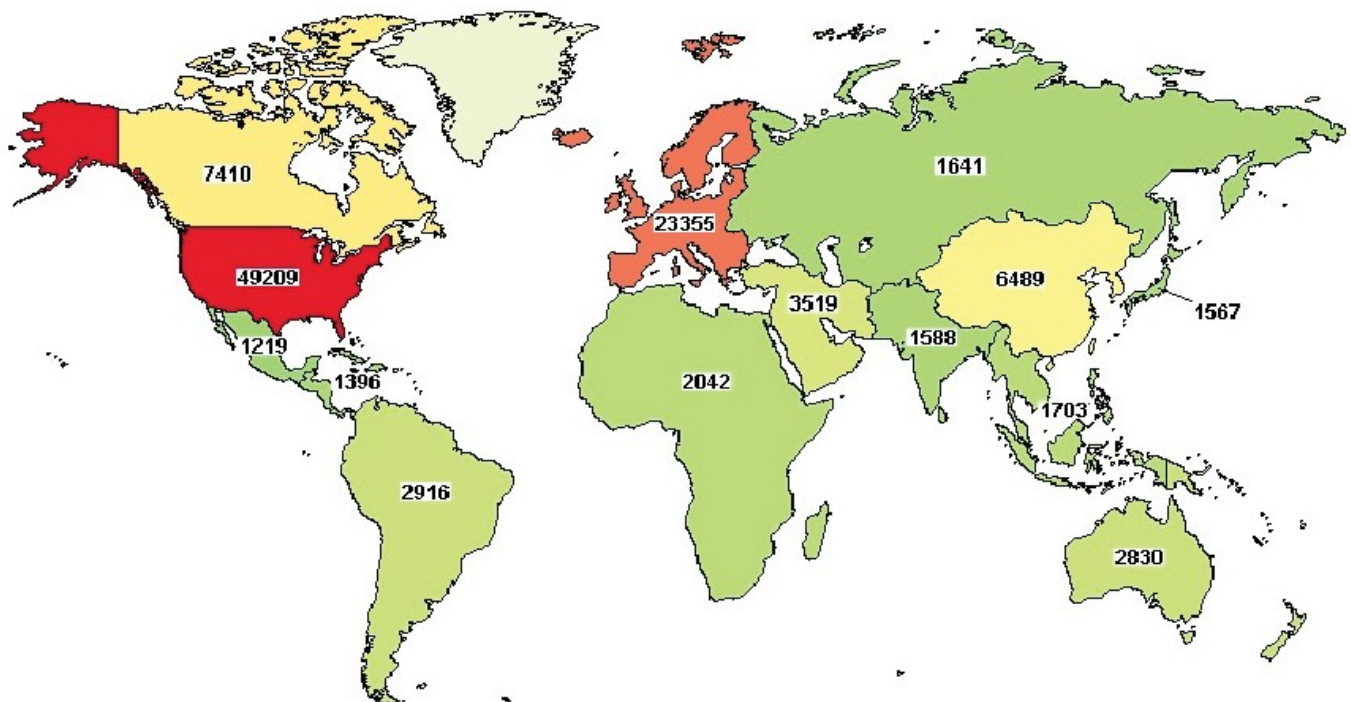
Clinical Research is an important part of the healthcare industry. Rapid advances in technology have made many new drugs, procedures and methods of diagnosis possible. Before these investigational drugs or devices become available to the common man, Clinical Research trials are necessary to test their safety and efficacy. Combine the overall growth of the healthcare sector with rapid growth in technology, and the Clinical Research sector presents a huge employment opportunity which is bound to grow at a rapid pace.

Investment in Clinical Research and new drug development is increasing at a rapid pace. Patents for most top selling drugs are expiring in 2021, creating an immense need for pharmaceutical companies to invest in R&D. Clinical Research industry's annual revenue is projected to double from \$22b to \$46b globally in next 5 years.

Source: [www.clinpoge.com](http://www.clinpoge.com); Frost report on CROs, Sep'21

### Section 3: Understanding the Earning Potential

As of August 2021, 94,676 registered clinical trials are in progress in 173 countries around the globe.



Source: ClinicalTrials.gov

USA has the largest number (over 50%) of clinical trials in the world followed by Europe (approx. 25%)

(Source: www.clinicaltrials.gov, 2021)

India: Clinical trial market forecast to grow at a CAGR of around 31% during 2020-2021 (Source: Budget Incentives to Boost Indian Clinical Trial Market, 23 Mar 2020 <http://www.pr-inside.com>)

China: Clinical trial market revenues to continue double digit growth from 2020 through 2022. (Source: Clinical Trial Strategies for Small Pharma <http://www.pharmafocusasia.com>)

The worldwide distribution of clinical trials presents a global opportunity for qualified clinical research professionals, for starting and growing their careers in their home countries, or another country of their choice.

### **Section 3: Understanding the Earning Potential**

Knowing the earning potential in any career path is an important consideration. Salary information will depend on experience and the needs of the hiring companies. Typical starting salaries for new Clinical Research Associates (CRA) are around \$5,000 and higher. Salaries quickly rise with experience. With a couple years' experience, you can expect to earn between \$60,000 and \$75,000. Some of the

Companies pay up to \$120,000 and supply their CRAs with a company car. The following table outlines the current salary ranges for various job titles.

	Job Title	Annual Salary { USD}	
		Low	High
1	Clinical Research Coordinator	41,291	72,865
2	Clinical Research Associate I	45,364	68,057
3	Clinical Research Associate II	56,159	87,176
4	Clinical Research Associate III	67,790	1,06,700
5	Drug Safety Associate	61,368	86,090
6	Drug Safety Specialist	62,355	96,025
7	Drug Safety/Medical Information Specialist I	46,571	70,093



8	Drug Safety/Medical Information Specialist II	53,205	80,539
9	Drug Safety/Medical Information Specialist III	48,648	1,02,397
10	Drug Safety/Medical Information Specialist IV	76,871	1,23,897
11	Medical Officers	1,25,663	2,95,694
12	Medical Liaison	92,419	1,26,406
13	Study Manager	1,01,620	1,32,942
14	Biostatisticians I	50,438	85,319
15	Biostatisticians II	73,833	1,13,696
16	Biostatisticians III	90,476	1,35,883
17	Biostatisticians IV	1,23,691	1,57,142
18	Quality Assurance Manager	59,090	87,724
19	Regulatory affairs Specialist	51,552	75,081
20	Clinical Data Coordinator	43,470	62,959
21	Clinical Data Analyst	48,401	73,192
22	Clinical Data Manager	79,430	114,932
23	SAS Developer	57,930	82,638
24	Clinical Validation Specialist	52,122	82,088
25	Clinical Business Analyst	46,759	65,991
26	Project Manager I	45,549	85,811
27	Project Manager II	63,109	1,07,301
28	Project Manager III	77,791	1,22,997
29	Business Development	90,239	1,10,897

Source: [www.salary.com](http://www.salary.com), [www.payscale.com](http://www.payscale.com), [www.hatjobs.yahoo.com/salary](http://www.hatjobs.yahoo.com/salary)

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