



SPECIAL REPORT

An Assessment of the Adequacy of the Clinical Research Workforce

A Statistical Analysis of Workforce Trends and Issues from the Association of Clinical Research Professionals and TEconomy Partners



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INTRODUCTION

The performance of clinical trials involving research studies of humans for new and improved medical treatments, or what is often referred to as “clinical research,” is a critical component for biomedical research and innovation.

Clinical trials involve a rigorous and highly regulated multi-phase process to determine the safety and efficacy of new medical treatments required to gain approval by the U.S. Food and Drug Administration (FDA) and other regulatory bodies for use by patients. The clinical trial stage of biomedical research and innovation is highly workforce-intensive, involving identification of investigator sites, recruitment of patient volunteers, treating and monitoring of patients involved in the clinical trials, and administering the clinical trials in compliance with regulatory-required data and record keeping requirements.

The expansive clinical research infrastructure that now exists in the United States is conducting more than 34,000 active clinical trials at any one time and requires a professional workforce able to conduct these clinical trials. Yet, unlike other professions involved in biomedical research such as medical scientists, engineers or laboratory technicians, the clinical research profession is not well-defined or tracked by traditional occupational data sources. In a meeting regarding the coronavirus, Janet Woodcock, the director of the FDA’s Center for Drug Evaluation and Research, commented “This crisis underlies and points out, really, the need to have a better clinical trial infrastructure in place...” Additionally, a 2018 report by The Economist Intelligence Unit states: “The workforce is not large enough or adequately trained.” Certainly, a high-quality, competent workforce is a necessary component of a strong clinical research infrastructure.

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– Janet Woodcock
Director, U.S. Food and Drug Administration’s Center for Drug Evaluation and Research

The Association of Clinical Research Professionals (ACRP) is dedicated to leading innovation in clinical research workforce development by setting standards for professional competence, and building and validating competence in the workforce through a varied set of programs, initiatives, and services for its global community of more than 50,000 clinical research professionals. ACRP commissioned TEconomy Partners, LLC to examine job openings and other data to help shed light on the growing profession for conducting clinical trials in the U.S.

This analysis reveals a profession driven by high-quality jobs with significant demand from a growing clinical research industry and opportunities for entry-level positions to develop careers in the health innovation.

METHODOLOGY

Clinical research professionals perform and represent a diverse set of roles in research studies involving humans or with materials from humans involving the management, coordination, recruitment and treatment of patient volunteers and administration of clinical trials. biomedical research and innovation.

These roles span a range of practice settings each with their own unique contexts, experience and specialty requirements, and other workforce and talent demands. These settings include academia, hospitals, discrete clinical study sites, clinical research organizations (CRO), biopharmaceutical firms, and others.

These clinical research positions involve a wide number of job titles and descriptions which the TEconomy analysis tracks in order to provide a more complete aggregate picture of the workforce that makes up this profession. Coordinating with ACRP, TEconomy identified several clinical research-related job titles that were then used to examine data from job posting listings in the Emsi Job Posting Analytics database, a service that aggregates cross-listed job postings across a number of job search websites and state agencies to identify unique positions and descriptive data outlining the characteristics of the advertised positions. This information was used to help characterize the workforce from the perspective of the types of jobs being generated by industry “demand” for key roles.

The six major job titles identified in Emsi’s job postings database that were most directly related to ACRP’s membership and mission included:

- Clinical Research Coordinators (CRCs)
- Clinical Research Associates (CRAs)
- Clinical Trials Managers
- Clinical Trials Specialists
- Clinical Trials Assistants
- Research Nurses

Looking across these leading positions in clinical research in the context of the types of skilled labor being recruited by industry in the U.S., several key themes emerge that highlight the importance of this workforce as the engine of an increasingly complex and technical clinical research industry, as well as the need to further advance the professional support for this workforce in order to build capacity to meet rising demand.

KEY THEME — There is strong demand for clinical research professionals, but data indicate workforce growth may not be keeping pace with growth in clinical trial demand.

Over the last three years, there are signs that demand has been increasing with average compound annual growth in monthly job postings activity of 9.3% across all clinical research positions. Across clinical research professional job titles, growth has been strongest for clinical research coordinators, clinical trials managers and clinical trials assistants, each growing in double-digits on a compounded annual rate from 2016-2019.

TABLE 1. SUMMARY OF POSTING ACTIVITY TRENDS FOR CLINICAL RESEARCH-RELATED JOB TITLES IDENTIFIED IN EMSI JOB POSTINGS DATABASE

Clinical Research-Related Job Titles Identified in Emsi Job Postings Database	Average Unique Monthly Postings, 2016*	Average Unique Monthly Postings, 2017	Average Unique Monthly Postings, 2018	Average Unique Monthly Postings, 2019	CAGR in Unique Monthly Job Postings, 2016-2019
Clinical Research Coordinators	3,816	4,605	4,959	5,826	11.16%
Clinical Research Associates (CRA)	2,538	3,083	3,224	3,123	5.33%
Clinical Trials Managers	356	419	501	575	12.78%
Clinical Trials Specialists	141	184	192	207	9.97%
Clinical Trials Assistants	452	592	709	749	13.47%
Research Nurses	688	827	819	923	7.61%

*Available data for 2016 only includes 4 months, beginning in September.
Source: Emsi Job Posting Analytics, 2020.1

This 9.3% is substantial and is behind the average year-over-year growth in clinical trials activities of 12.2% over the 2016-2019 period, suggesting that the clinical research workforce may not be keeping pace with current clinical trials workload needs.

Clinical research professionals are in high demand with strong competition across employers. BDO's recent survey of CRO Industry Global Compensation & Turnover finds strong competition among employers that is generating over 25% turnover rates among clinical research professionals. This is consistent with narratives of high workloads and competitive hiring activity amongst major clinical research employers highlighted in past survey analyses and research literature on the topic.

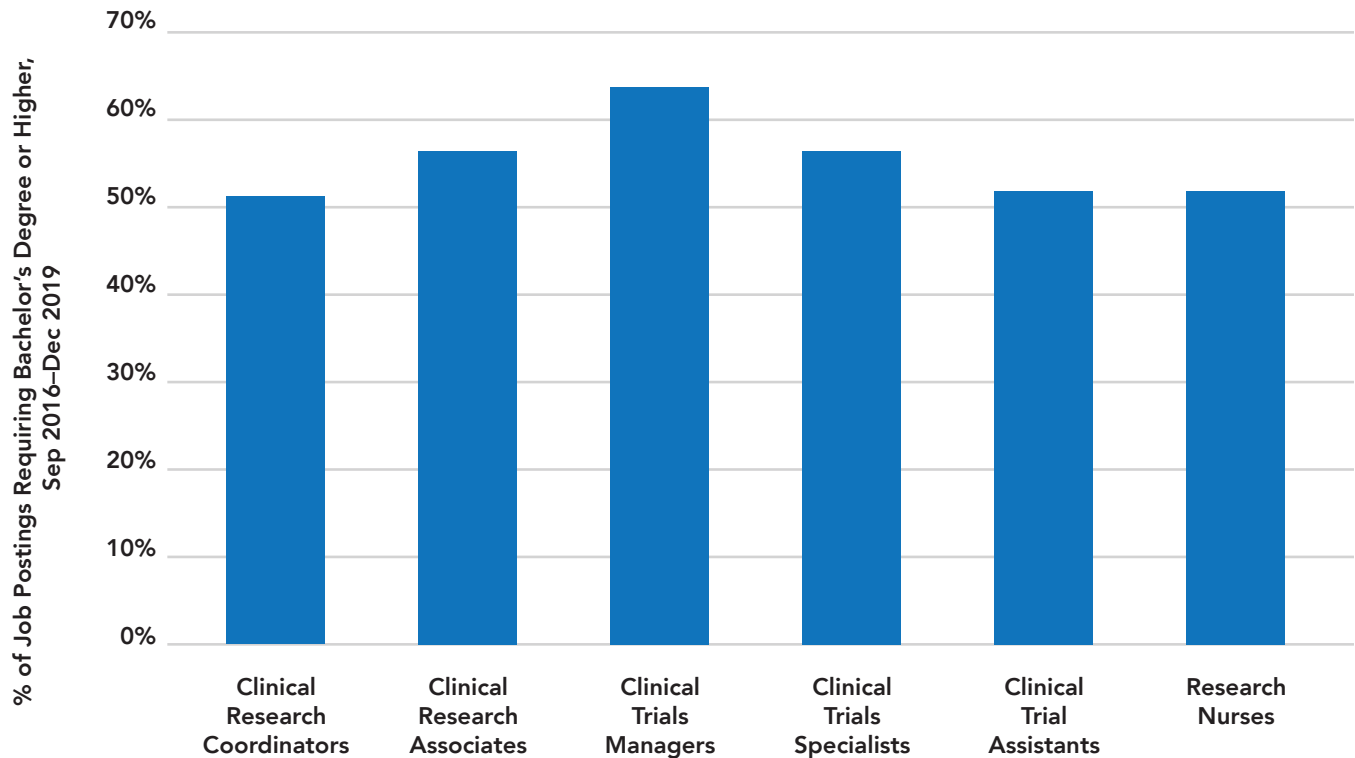
The clinical research workforce may not be keeping pace with current clinical trials workforce needs.

KEY THEME — Clinical research jobs are high-quality positions nationally with entry-level opportunities to start careers in biomedical research.

Across all of the job titles for clinical research professions that are commonly used, the job openings data reveals:

- Median salaries of leading clinical research positions in job postings are above average overall U.S. salaries of \$53,000, with an overall median advertised salary of \$63,104 across the cohort of clinical research-related jobs. Among the different job titles for clinical research professionals, the average salaries range from \$57,216 for clinical research coordinators to \$100,224 for clinical trials specialists.
- Slightly more than 50% of clinical research positions cite the requirement of a bachelor's or higher degree, indicating significant variance in the educational backgrounds defined for these positions.
- There is little variation across the different clinical research professional job titles in the share of job postings requiring a bachelor's degree or higher, ranging from 52%-64% of all job postings.

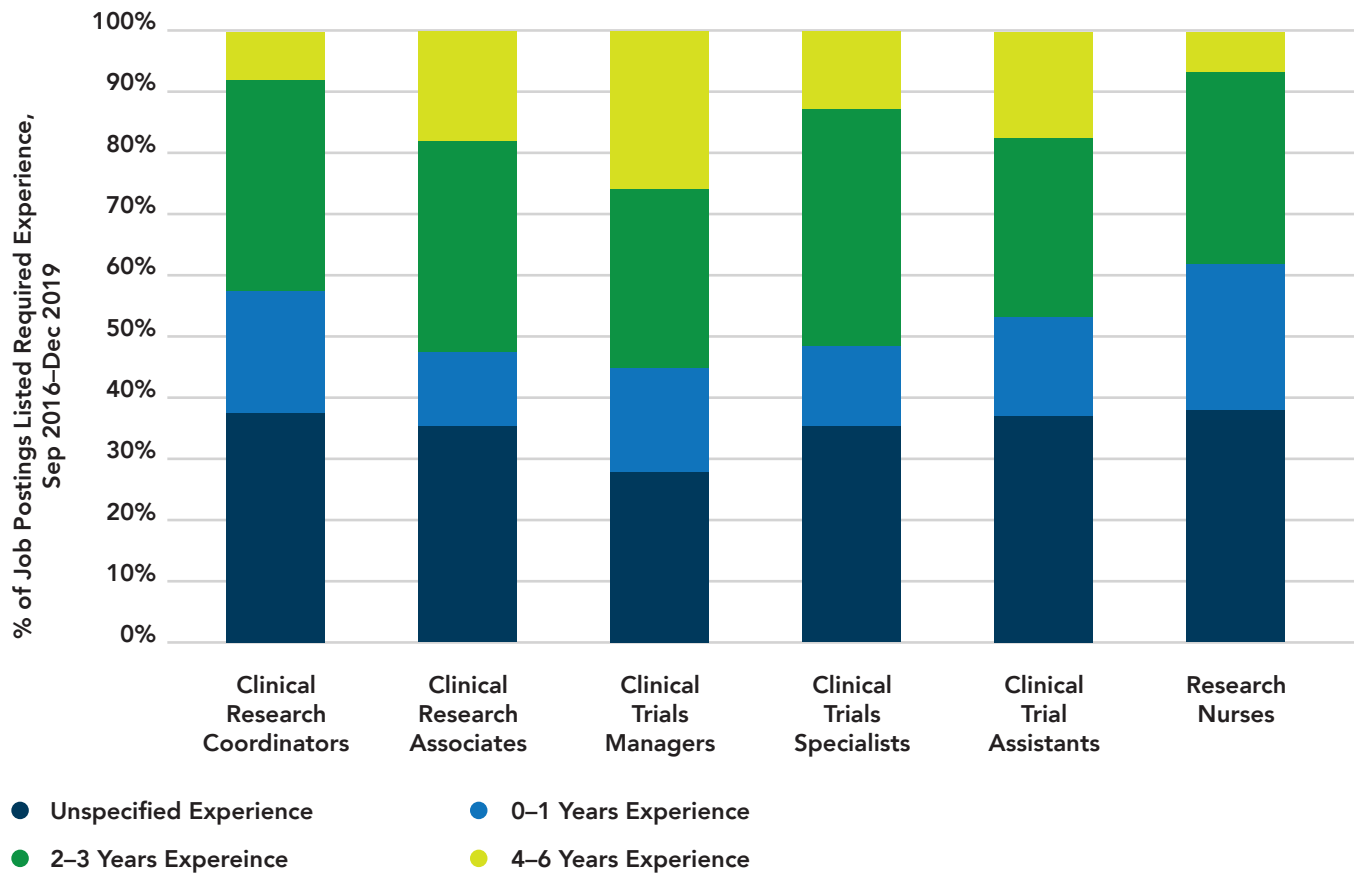
FIGURE 1. EDUCATIONAL REQUIREMENTS FOR CLINICAL RESEARCH-RELATED JOB TITLES IDENTIFIED IN EMSI JOB POSTINGS DATABASE



Emsi Job Posting Analytics, 2020.1

- The clinical research profession shows high variance in requirements. Over one-third of job positions in postings having no minimum experience requirement and 50% requiring 3 years or less.

FIGURE 2. REQUIRED EXPERIENCE FOR CLINICAL RESEARCH-RELATED JOB TITLES IDENTIFIED IN EMSI JOB POSTINGS DATABASE



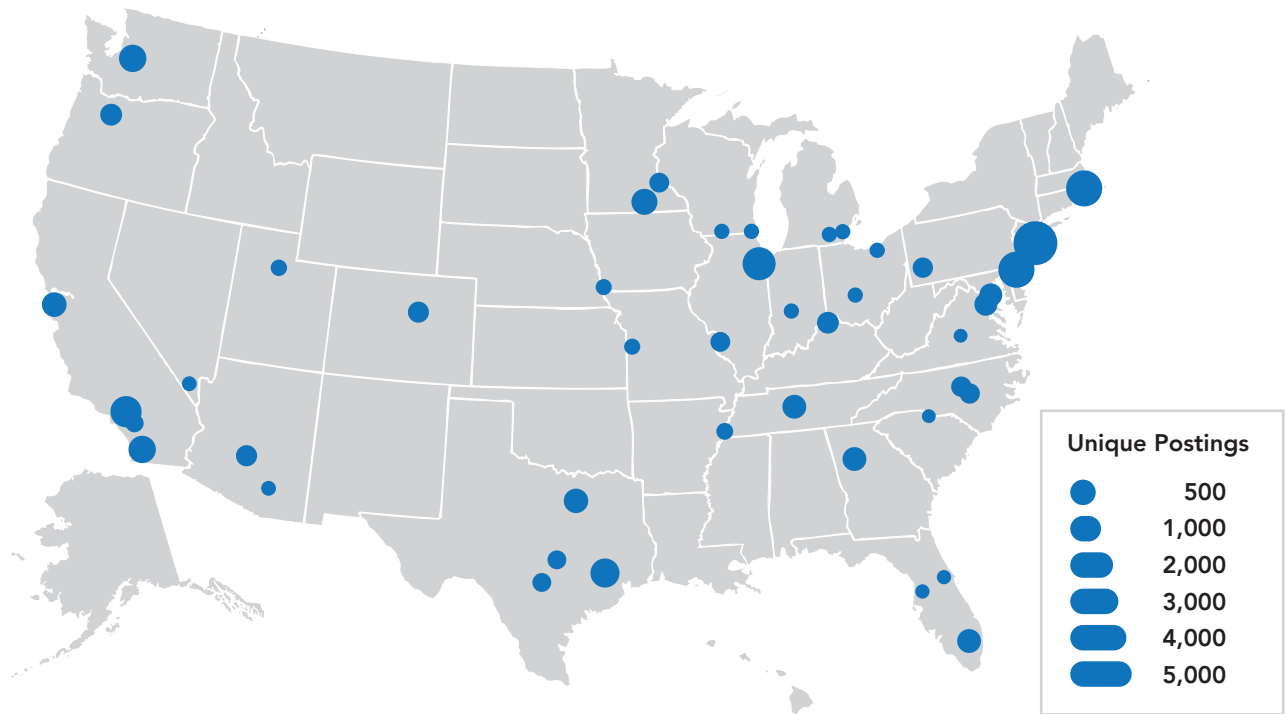
Emsi Job Posting Analytics, 2020.1

- Across the nation, 39 major metro regions were hiring volumes of at least 500 clinical research positions over the last three years.

The leading regions are focused in major metro areas on the coasts, including:

- California, which has highest total volume of postings (~16.6k)
- Single metro areas which are responsible for most of volume on east coast such as NYC, Boston, Philadelphia
- Texas also has significant footprint of activity at a state level

FIGURE 3. CRP-RELATED JOB POSTINGS ACTIVITY IN MAJOR US METRO AREAS, SEP 2016-DEC 2019



Emsi Job Posting Analytics, 2020.1

The majority of activity in job postings related to clinical research professionals is driven by major CROs, hospital systems, and biomedical staffing agencies

TABLE 2. SUMMARY OF POSTING ACTIVITY BY LEADING EMPLOYERS (>500 POSTINGS DURING TIMEFRAME) FOR CLINICAL RESEARCH-RELATED JOB TITLES IDENTIFIED IN EMSI JOB POSTINGS DATABASE

Company	Total Unique Postings (Sep 2016 - Dec 2019)
IQVIA	3,652
Covance Inc.	3,470
PRA Health Sciences, Inc.	2,367
Aerotek, Inc.	2,028
University of California	1,925
Medix	1,690
Virtual Vocations	1,539
Icon Clinical Research, Inc	1,364
St Peter Community Hospital Foundation	1,317
University of Pennsylvania	1,121
Massachusetts General Hospital	993
Anthem, Inc.	949
Kelly Services, Inc.	746
Merck & Co., Inc.	724
Genesis Healthcare, Inc.	663
HCA Holdings, Inc.	661
Mount Sinai Hospital	627
Kaiser Permanente	617
Medtronic, Inc.	608
City of Hope	594
Medpace, Inc.	593
Oregon Health & Science University	580
Pharmaceutical Research Associates, Inc	571
University of Michigan	558
Bayer Corporation	556
Cirrus Medical Staffing	554
University of Washington	532
PPD Development, LLC	532
Columbia University	530
Mayo Clinic	517
Memorial Sloan-Kettering Cancer Center	514
Indiana University	500

KEY THEME — To attract and retain more people in clinical research careers there is a need for industry-wide occupational definitions, standards, and certifications.

The lack of many industry-wide standards beyond minimum education and experience, both of which are ill-defined, means that career paths in clinical research are not visible or accessible to the broader workforce. Job postings data show that most prevalent requested qualification is having some kind of licensed nursing credentials, but this only represents 14.5% of all postings Sep 2016- Dec 2019 collectively. Many skills requested in job postings are generic descriptions of experience with clinical research (51% of postings) or clinical trials (43%), while more formal qualifications such as Good Clinical Practices (GCP) certification, experience with Institutional Review Boards (IRBs), or use of clinical trials management software/systems are far more infrequent (26%, 18%, and 7% of all postings respectively). This gap represents a key opportunity for leaders in the clinical research enterprise to help align job requirements around defined competencies, training, and professional certification.

Skills Mentioned in Job Postings	Frequency in Clinical Research-Related Postings (Sep 2016 - Dec 2019)
Clinical Research Experience	51%
Clinical Trials Experience	43%
Good Clinical Practices (GCP) Credentials	26%
Nursing Credentials	22%
Institutional Review Board (IRB) Credential	18%
Clinical Research Coordination	17%
Oncology Experience	16%
Auditing	14%
Pharmaceuticals Experience	13%
Data Collection	13%
Case Report Forms	11%
Standard Operating Procedure	10%
Data Management	9%
Medical Terminology	7%
Clinical Trial Management Systems	7%
Biology	7%
ICH Guidelines	7%
Medical Records	6%
Human Subject Research	6%
Electronic Data Capture (EDC)	6%
Clinical Monitoring	6%
Basic Life Support	6%
Research Experiences	5%
Life Sciences	5%

Emsi Job Posting Analytics, 2020.1

Estimation of the actual employment footprint of clinical research professionals is difficult because there is not a clear definition of clinical research occupational segments that translates well into the existing occupational categories that drive employment projections. Due to the cross-cutting nature of the profession as well as inconsistent use of job titles to describe key roles, estimates of the employment footprint of clinical research professionals can vary widely based on the methodology employed. Clinical research coordinators form the largest segment of this workforce and appear to be in the highest demand over the last three years. The wide range of estimated employment across each job title highlights the need for further standardization and presents another place where stakeholder efforts to inform the occupational definitions of clinical research professionals could drive significant value.

KEY THEME — Collaboration among clinical trial stakeholders paramount to addressing challenges.

The data in this report suggest key actions that need to be taken, including:

- The competencies of the workforce need to be defined and aligned across industry.
- The workforce needs to grow to keep up with the demand for clinical research data output.
- Clinical trial stakeholders need to provide more equitable career paths and consistent salaries in order to sustain the workforce.

ACRP's Partners in Workforce Advancement – whose members include representation from sponsors, CROs, investigator sites, academic institutions, regulatory agencies, and more – have begun working to address these challenges. Partners in Workforce Advancement is a collaborative initiative to grow the clinical research workforce and to set and support standards for workforce competence and sustainability.

To date, ACRP's Partners in Workforce Advancement have developed the following competency guidelines and resources which are available free:

- Entry-Level CRC Competency Development and Assessment Roadmap
- Hiring Guidelines for Entry Level Clinical Research Coordinators
- Core Competency Guidelines for Clinical Research Coordinators
- Functional Competency Guidelines for PIs and Sub Investigators
- Core Competency Framework for Clinical Trial Monitoring

Visit acrpnnet.org/standards to access these resources.

HOW YOU CAN HELP...

ACRP recommends the following actions for all organizations and individuals who want to be part of the solution:

- Join ACRP's Partners in Workforce Advancement.
- Use the competency standards and other resources developed by the Partners in Workforce Advancement to build and develop your workforce.
- Demand workforce competency be validated by independent third parties through certification.

Visit acrpnnet.org/pwa to learn more about Partners in Workforce Advancement.

References

- ⁱ Suz Redfearn. Pandemic Prompts Trials to Reinvent Themselves, Woodcock Says. CenterWatch. April 2020
- ⁱⁱ Emsi Job Posting Analytics, 2020.1. Job postings are collected from various sources and processed/enriched to provide information such as standardized company name, occupation, skills, and geography.
- ⁱⁱⁱ BDO 2019/2020 CRO Industry Global Compensation & Turnover Survey
- ^{iv} Getz KA. Assessing Global CRA Workload and Utilization. Monitor (Association of Clinical Research Professionals). 2013
- ^v 2015 CenterWatch-ACRP Salary and Career Survey, The Clinical Research Coordinator Perspective
- ^{vi} U.S. Bureau of Labor Statistics, May 2019 National Occupational Employment and Wage Estimates United States