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Docket ID (BLS-2024-0001). Standard Occupational Classification (SOC) – Updates for 2028

Executive Summary

The Association of Clinical Research Professionals (ACRP) requests that the Bureau of Labor Statistics (BLS) recognize the distinct occupation of clinical researcher by introducing a detailed occupation code under the 29-0000 Healthcare Professionals classification. Our rationale is set out below.

Clinical research brings us new medicines and medical devices

- Clinical research is the global industry behind clinical trials and public health research. This industry drives the development of new prescription medicines and new medical devices for human use, carefully assessing their safety and effectiveness. Apart from the nuclear power industry, clinical research is the world's most globally regulated enterprise.
- The clinical research industry is growing rapidly. The number of registered clinical trials rose from 2,119 in 2000 to 433,207 in 2022[1] and is expected to increase still further to keep pace with the acceleration in drug discovery powered by artificial intelligence (AI) and evolving technology.
- The U.S. clinical trials market is forecast at $27.07 billion for 2024 and is expected to increase to $41.57 billion by 2033, growing at a compound annual growth rate (CAGR) of 4.88% over this period.[2]

Clinical researchers are distinct from other healthcare workers

- Clinical research professionals are specifically trained professionals who conduct and oversee clinical research. The remit of clinical researchers is to ensure that clinical research is conducted in accordance with rigorous scientific and ethical laws and guidelines, designed to protect trial participants and to safeguard data quality. To the best of our knowledge, the BLS SOC categories provide no indication of the existence of a large group of interrelated jobs dedicated to the field of clinical research.
- Clinical research is a distinct grouping of jobs with distinguishable competencies and responsibilities that require bespoke training and certification.
- The occupation includes physicians, nurses, pharmacists, scientists, project managers, coordinators, and others who may design study protocols, recruit patients, monitor study conduct, collect and analyze data, and prepare study reports and scientific publications.
- Most clinical researchers do only clinical research and do not have concurrent roles in healthcare. Their work is therefore distinct from that performed in occupations that already have a code.

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- Over a decade ago, the Joint Task Force for Clinical Trial Competency (JTF)—part of the Multi-Regional Clinical Trials (MRCT) Center of Brigham & Women's Hospital and Harvard—developed a framework of competencies that is unique to the clinical research occupation.[3] This covers eight subject domains defining the knowledge, skills, and attitudes needed to conduct safe, ethical, high-quality clinical research.
- Clinical researcher roles include but are not limited to: Physician Investigator, Clinical Research Coordinator, Clinical Research Data Manager, Clinical Quality Assurance Coordinator, Clinical Research Nurse[1], Clinical Research Associate, Clinical Research Project Manager, Clinical Research Site Director, Clinical Research Regulatory Coordinator, and Clinical Research Compliance Coordinator.
- One of these jobs, the Clinical Research Nurse (CRN) role, was endorsed as a specialty practice by the American Nurses Association in 2016; this association co-authored the 'scopes and standards' for CRNs with International Association of Clinical Research Nurses (IACRN).[4]
- These clinical researcher jobs are undertaken across a number of settings, including pharmaceutical, biotech, and medical device companies; contract research organizations; academic clinical research centers; site management organizations; institutional review boards; clinical study sites; government agencies; and training organizations.
- As of 2022, there were some 86,300 Clinical Research Coordinators (CRCs) in the U.S., with the job market for this role alone expected to grow by nearly 5% by 2032.[5] Other sources estimate growth of as much as 8.9% over this period.[6]

The clinical research occupation has changed significantly—and continues to transform

- The introduction of digital health technologies, including telemedicine and patient wearables—which enable some clinical research to be conducted wholly or partially remotely—has revolutionized the conduct of clinical trials. This has led to new guidelines on decentralized clinical trials (DCT) being issued by the U.S. Food and Drug Administration (FDA) and National Institutes of Health (NIH). Catalyzed by the COVID-19 pandemic, this shift has created major new requirements for specialist technical skills among clinical researchers, further distinguishing these jobs from other healthcare roles.
- In addition, multiple initiatives are underway specifically to progress the field of clinical research, including new laws, regulatory guidelines,

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federally funded public workshops, and industry-led initiatives. Examples are: the establishment of the Advanced Research Projects Agency for Health (ARPA-H); the FDA's *Digital Health Technologies for Remote Data Acquisition in Clinical Investigations* guidance and draft guidance on Diversity Action Plans;[7] the Consolidated Appropriations Act, 2023 (H.R. 2617), including promotion of diversity and streamlining of trials; the NIH Clinical Trial Diversity Act 2023; the National Academies of Sciences, Engineering, and Medicine (NASEM) public workshop *Envisioning a Transformed Clinical Trials Enterprise for 2030*; and a major collaborative venture between MRCT, the Clinical Trials Transformation Initiative (CTTI), NASEM, and FasterCures on clinical trial diversity, *Toward a Framework to Improve Diversity and Inclusion in Clinical Trials*.[8]

- Broader regulatory changes affecting clinical research include updates to the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects in clinical research (45CFR46[9]); NIH policy on use of a single IRB for multi-site studies,[10] and upcoming revisions to ICH GCP.[11]
- For many years, teams at Duke University and other institutions have worked to embed competency-based hiring and create career frameworks specifically for clinical research professionals. In 2023, NASEM held another public workshop dedicated to the clinical research occupation, *Preparing the Future Workforce in Drug Research and Development*.

Clinical research is an essential occupation that is currently in crisis

- Clinical research is a distinct occupation with distinctive skills and training requirements. It is also an essential occupation. It was clinical researchers who were tasked with—and succeeded in—developing the evidence in support of vaccines at unprecedented speed during the COVID-19 pandemic.[12] New and better treatments are still urgently needed for cancer, cardiovascular disease, mental illness, and dementia, among many other disease areas. Testing any potential new prescription medication fundamentally depends on clinical researchers.
- Nonetheless, clinical research has so far been an under-recognized occupation, with low public awareness and lack of career identity and infrastructure. Most clinical researchers end up in this occupation by chance, rather than purposefully choosing it as their career.
- There is currently a severe shortage of qualified clinical researchers, a situation that has reached a crisis point and that has significant implications for medical progress and future healthcare. This is due to the poor external recognition of the occupation, the lack of explicit entry points, the underuse of skills-based hiring criteria, and the absence of

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centralized training requirements. This also creates a turbulent staffing environment.

- The White House Office of Science and Technology Policy (OSTP) has recognized the importance of strengthening our country's clinical trial infrastructure to improve health outcomes and, as a result, collaborated with the Advanced Research Projects Agency (ARPA-H) to create the Advancing Clinical Trial Readiness initiative[13] to innovate clinical trials design, a goal that is supported by the White House.[14]
- New innovations demand an experienced workforce that can quickly learn new technology and processes, including decentralized research, where studies reach the population where they are.

Many organizations and initiatives are dedicated to the field of clinical research

- ACRP is a non-profit dedicated to representing, supporting, and advocating for clinical researchers and their contributions to improving public health. We have 16,000+ members and a community of 100,000+ clinical research professionals. The ACRP-affiliated Academy of Clinical Research Professionals has certified 40,000+ individuals since 1992.
- Multiple other professional groups, trade associations, and consortia are dedicated to clinical research, including the MRCT center; CTTI; the Consortium of Academic Programs in Clinical Research (CoAPCR); the Decentralized Trials & Research Alliance (DTRA); and the Society for Clinical Research Sites (SCRS).

Executive Summary Conclusion

- Clinical research is a distinct occupation and an essential one.
- ACRP believes that an SOC for clinical research will improve visibility and recognition of this important occupation, essentially putting it "on the map."
- Data collection for this new SOC code will improve understanding of the make-up of the clinical research workforce, its challenges, and its contribution to healthcare, and will help track and address the current workforce crisis. It will also allow for more accurate analysis and will inform policymaking for employers, researchers, sponsors, and lawmakers at national and state levels.

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Comments submitted by the Association of Clinical Research Professionals

We represent the Association of Clinical Research Professionals (ACRP)[15] and its Partners Advancing the Clinical Research Workforce (PACRW) Consortium.[16] We are writing to request the establishment of a new detailed Standard Occupational Classification (SOC) for the occupation of Clinical Researcher under the 29-0000 Healthcare Practitioners and Technical Occupations code.

We believe a new code is warranted by the existence of a large and distinct grouping of jobs within the clinical research occupation and by the substantially distinguishable competencies, training, and responsibilities demanded of the occupation. Many of the skills required of today's clinical researchers reflect transformational technological advances in drug and device development over the past decade. With the exception of Principal Investigators, who are physicians that mostly provide routine care to patients in parallel with their work on clinical trials, all other roles often perform only clinical research. The exceptional contribution of clinical researchers to the development of COVID-19 vaccines and antivirals at unprecedented speed[17] illustrated the essential nature of this workforce.

To the best of our knowledge, the BLS SOC categories provide no indication of the existence of a large group of interrelated jobs, all dedicated to the field of clinical research. The absence of an SOC for the clinical research occupation overlooks the contribution of a distinct workforce within the healthcare and life sciences sectors that employs many thousands of uniquely trained and certified individuals. The assignment of a new occupational code to this distinct grouping of workers will ensure that information about the occupation—employment levels, trends, pay and benefits, demographic characteristics, skills required, and many other items—can be standardized and widely used. This will inform individuals, businesses, researchers, educators, and public policymakers in a consistent and sustainable manner. It will be helpful across the Federal statistical system and throughout the life sciences, biotechnology, and drug development sectors. Assignment of the new code will also further help to define jobs for the STEM (Science, Technology, Engineering, and Math) sector. We are confident the BLS will be able to sustainably collect and report workforce data on the occupation through clinical research employers, which will allow accurate classification of the workers and the workforce (Classification Principle 9).

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Having an SOC code for the purpose of collecting, calculating, or disseminating data is essential to understanding the clinical research workforce, its challenges, and its contribution to improved patient care and public health. Data will help to increase awareness of clinical research, illuminate clear career paths, and help further align training to specific jobs. In addition, the accurate collection of data for the occupation of clinical researcher will provide the necessary granularity to track and address the decades-long clinical research workforce crisis.[18] This will also help build a sustainable workforce to enable the transformation of the clinical research enterprise, as set forth by the National Academies in its 2021 publication titled, *Envisioning a Transformed Clinical Trials Enterprise for 2030*. This publication outlined goals and key priorities for advancing a clinical trials enterprise that is more efficient, effective, patient-centered, and integrated into the healthcare delivery system.

Clinical research brings us new medicines and medical devices

Clinical research is the bedrock of the drug and medical device development industry. In 2019, the pharmaceutical industry spent $83 billion on research and development (R&D).[19] The clinical research industry is growing rapidly:

- The U.S. clinical trials market is projected at $27.07 billion for 2024 and is forecast to rise to $41.57 billion by 2033, growing at a CAGR of 4.9% in 2024-2033.[20]
- As of 2022, there were some 86,300 Clinical Research Coordinators (CRCs) in the U.S., with the job market for this role alone expected to grow by nearly 5% by 2032.[5]
- Numbers of registered clinical trials have risen from 2,119 in 2000 to 433,207 in 2022[1] and the U.S. job market for clinical research coordinators predicted to grow by 4.9% between 2022 and 2032.[5]
- Clinical trials are becoming more complex, with the number of data points captured increasing three-fold in Phase III trials over the last decade.[21]

Clinical researchers are distinct from other healthcare workers

Fundamentally, clinical researchers are responsible for the quality and safety of clinical trials that underpin the development of new drugs and medical devices. Clinical research involves trials conducted in human volunteers that are designed to answer specific questions about the safety and/or effectiveness of drugs, vaccines, and other therapies, or to assess new ways of using existing treatments.[22] In some disease areas, being able to offer patients a clinical trial is an integral part of care pathways. Clinical research also includes observational studies, in which particular groups of patients are tracked and monitored over time to learn more about the course of diseases.

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The core remit of clinical researchers is to ensure that clinical research is conducted in accordance with rigorous (and evolving) scientific and ethical rules and guidelines, designed to protect trial participants and to safeguard data quality. Among the distinct responsibilities of clinical researchers is engaging with prospective research participants and their caregivers as a primary point of contact. In this role, clinical researchers help prospective participants to navigate the challenging process of informed consent and continue to interface with enrolled participants to increase the rate of participant retention in a study or trial. Effective participant recruitment and retention is a well-recognized driver of success in clinical research. Just as important are clinical researchers' responsibilities for reliable and accurate data capture, protocol adherence, and regulatory compliance, all of which may ultimately determine the validity of trial findings. Data integrity is central to study success, with a need for ongoing quality control to ensure data accuracy and reliability. Achieving these requires specific expertise in data management and quality control.

Multiple individual jobs comprise the distinct occupation of clinical researcher. The definition of a clinical researcher is someone who implements study designs, conducting and overseeing clinical research that is intended to investigate and evaluate the safety and efficacy of new drugs, medical devices, and other treatments. The occupation includes physicians, nurses, pharmacists, scientists, project managers, coordinators, and other members of study teams who may design clinical study protocols, recruit patients, monitor study conduct, collect and analyze data, and prepare study reports and scientific publications. It excludes physicians, nurses, and other healthcare professionals who are not specifically trained to conduct clinical research.

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Many jobs and titles are grouped under the clinical research occupation (*Figure 1*), including:

- Principal Investigator
- Clinical Research Coordinator
- Clinical Research Associate
- Clinical Trial Project Manager
- Clinical Research Site Director
- Clinical Research Regulatory Coordinator
- Clinical Quality Assurance Coordinator
- Clinical Research Compliance Coordinator
- Director or Manager of Clinical Trial Operations
- Clinical Research Nurse
- Research Manager
- Regulatory Specialist
- Research Technician or Assistant
- Clinical Research Scientist
- Patient Recruiter
- Clinical Data Coordinator
- Medical Director
- Business Development
- Site Selection and Start Up
- Data Manager
- Pharmacist
- Director or Manager of Regulatory Affairs
- Clinical Trial Management System (CTMS) Administrator
- Medical Affairs
- Clinical Data Scientist
- Medical Research Scientist
- Medical Writer
- Statistician
- Director of Scientific Affairs
- Drug Safety Manager
- Billing Compliance Officer
- Drug Safety Physician
- Medical Safety Officer
- Director of Pharmacovigilance

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Figure 1: The wide variety of distinct roles in clinical research

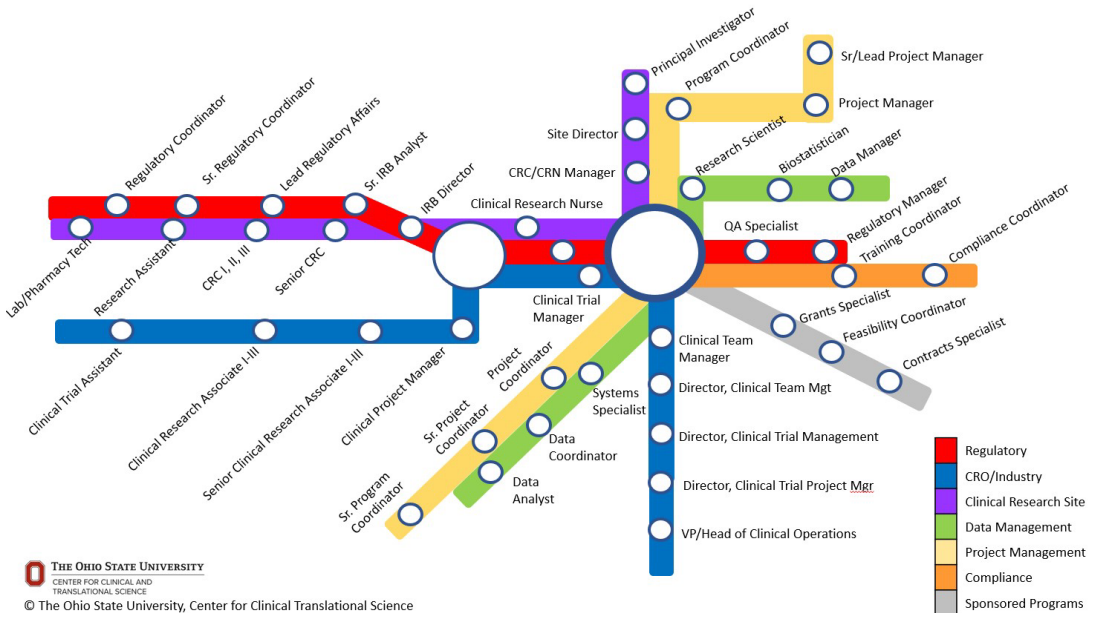

Figure 2 illustrates the broad range of clinical research roles held by ACRP members.

Figure 2: ACRP members by role

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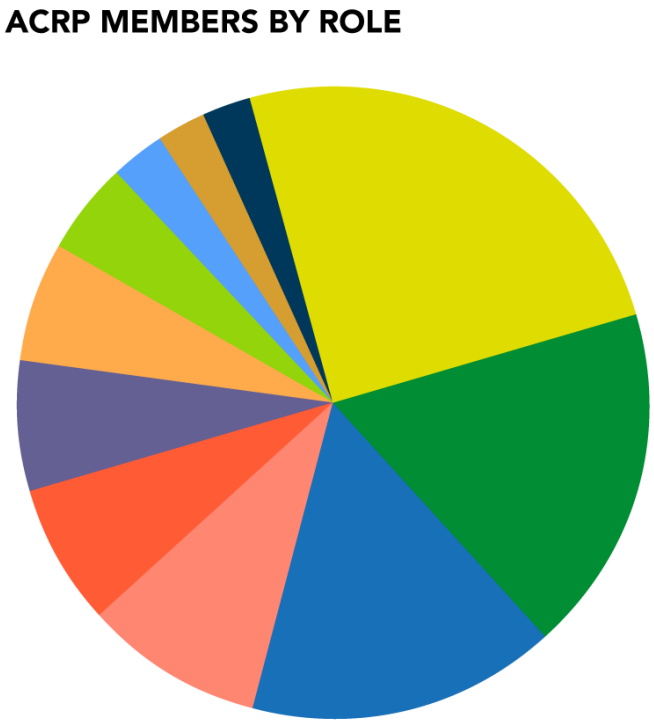

ROLE	COUNT	% OF TOTAL
Clinical Research Coordinator	3674	24.92%
Monitor or Clinical Research Associate	2630	17.84%
Other	2303	15.62%
Director or Manager of Clinical Trial Operations	1368	9.28%
Project Manager	1055	7.16%
Clinical Research Nurse	989	6.71%
Research Manager	917	6.22%
Investigator	693	4.70%
Regulatory Specialist	391	2.65%
Research Technician or Assistant	369	2.50%
Clinical Research Scientist	353	2.39%

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Outlined below are definitions of commonly used job titles that are grouped under the clinical researcher occupation. Most of the titles are unique to the occupation, and the titles can vary depending on the organizational structure used by the employer of the clinical researcher. The nature of the work performed requires bespoke training and certification based on complex regulatory guidance to ensure the quality and safety of clinical trials (Classification Principle 2). The occupation and its jobs are interdependent and based upon successful performance by people operating throughout the system. Clinical research job titles may include, but are not limited to:

- **Principal Investigator**: The main duty of a Principal Investigator is to ensure the research study is conducted correctly in accordance with the protocol. This individual is accountable for patient safety, the performance of procedures required by the protocol, and the collection of data. According to FDA, "*Investigator* means an individual who actually conducts a clinical investigation (*i.e.*, under whose immediate direction the drug is administered or dispensed to a subject). In the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team. '*Subinvestigator*' includes any other individual member of that team."[23]

- **Clinical Research Coordinator (CRC)**: A Clinical Research Coordinator is a study staff member trained in Good Clinical Practice (developed under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and adopted by the Food and Drug Administration), human subject protection, and clinical study ethics, among other educational topics, who is assigned by the Principal Investigator to help manage clinical research studies. The main duties of this site-based, patient-facing role are to ensure that clinical research and related activities are performed in accordance with federal regulations, the sponsor's protocol, and other stakeholders' policies and procedures. These duties can include recruiting study participants, preparing study documents, scheduling study visits, submitting regulatory applications, and collecting study data.

- **Clinical Research Associate (CRA)**: The main duty of a Clinical Research Associate is to monitor the clinical trial. This job is also sometimes known as Clinical Monitor or Trial Monitor. Clinical trial monitoring aims to verify that: human subjects are protected; reported trial data are accurate, complete, and verifiable from source documents; and the trial complies with the protocol, with GCP, and with relevant regulations.[24] These

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individuals ensure compliance with the clinical trial protocol, monitor clinical site activities, and review case report forms. They ensure the scientific integrity of the data collected and that any adverse events are documented and reported.

- **Clinical Research Project Manager**: Clinical Trial Project Managers work with study team members to supervise the work of the study team. These workers oversee activities such as implementing protocols in line with meeting scientific standards and government regulations. They maintain safety standards, monitor a trial's budget, and ensure the timely completion of the trial activities.

- **Clinical Research Site Director**: These individuals plan, implement, and track a clinical trial's progress at the research site location. Their duties include overseeing every aspect of multiple trials being conducted at the site level, including staffing, business operations, strategic communication, sales, and patient recruitment. Site Directors are responsible for communication with clinical trial sponsors, ensuring that every protocol requirement is met to its exact specifications.

- **Clinical Research Regulatory Coordinator:** The main duties of this job include maintaining data integrity, reviewing records, assisting with preparation of internal audits, tracking study activity, and ensuring that clinical research proceeds according to proper rules and regulations. This role maintains a working knowledge of all federal, state, and institutional guidelines regarding clinical trials, prepares and submits regulatory documents to the sponsor and institutional review board (IRB), and works with clinical research team to ensure submission documents are up to date.

- **Clinical Research Compliance Coordinator:** The duties of this worker include performing administrative reviews and enforcing the regulations for clinical research. They ensure that organizations are committed to adhering to high standards of ethics, integrity, and responsibility in their research programs.

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Number of Workers in the Occupation

At the present time, there is no standard method to track the number of workers in the occupation of clinical research, although based on the large grouping of roles within the occupation and associated job postings with these roles, it is estimated to be in the hundreds of thousands. At present, ACRP reports membership of 16,000+ in multiple practice settings (*Figure 3*).

Types of Employers

Jobs that comprise the occupation of Clinical Research are most commonly located in the following practice settings, which are distinct to the clinical research occupation:

- Pharmaceutical/Biotech Companies (Sponsors)
- Contract Research Organizations (CROs)
- Academic Medical Centers
- Site Management Organizations (SMOs)
- Institutional Review Boards (IRBs)
- Clinical Study Sites
- Medical Device Companies
- Private and Government-Owned Hospitals
- Private Medical Practices
- Healthcare Organizations/Associations
- Government Agencies (NIH, NHS, NCI)
- Patient Recruitment Companies
- Staff Recruitment Firms
- Training Organizations

Figure 3: ACRP Members by Employer Type

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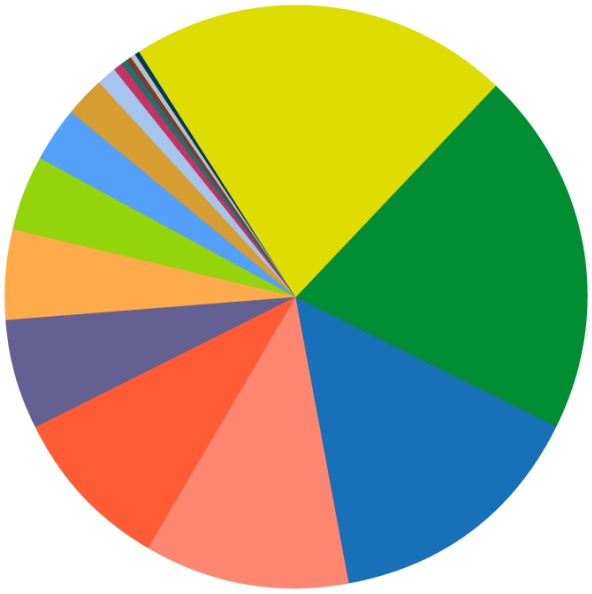
ACRP MEMBERS BY EMPLOYER TYPE



EMPLOYER TYPE	COUNT	% OF TOTAL
Contract Research Organization (CRO)	3148	21.12%
Clinical Study Site (free standing/independent)	3021	20.27%
Academic Medical Center/University	2230	14.96%
Hospital	1664	11.17%
Pharmaceutical/Biotech Company	1369	9.19%
Healthcare Organization/Association	920	6.17%
Medical Device Company	730	4.90%
Private Medical Practice	661	4.44%
Consulting Practice	432	2.90%
Site Management Organization (SMO)	332	2.23%
Government Agency (NIH, NHS, NCI, etc.)	157	1.05%
Patient Recruitment Company	71	0.48%
Training Organization	65	0.44%
Phase 1 Unit	44	0.30%
Staff Recruitment Company	33	0.22%
Institutional Review Board/Ethics Committee	26	0.17%

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The clinical research industry has changed significantly—and continues to transform

The introduction of digital health technologies has brought marked changes in how clinical trials are conducted. Technological innovations in digital health have created new requirements for specialized skills, with only 30% of new clinical research postings matching conventional job descriptions. While new and innovative technology platforms are helping to streamline elements of data collection in clinical trials, the job of the clinical researcher has become more complex, requiring additional and specialized training across multiple digital software platforms especially designed for trial management and data collection.

Modern clinical trials employ various digital-based tools and technologies designed to increase the speed, accuracy, and ease of conducting clinical research. Workers within the clinical research occupation must be trained to operation numerous technology platforms (*Figure 4*). These clinical trial platforms are software-based, web-based, and/or cloud-based solutions that facilitate clinical trial research throughout its entire lifecycle. They offer a complete technology ecosystem that connects patients, research sites, and trial sponsors from patient recruitment to close out and data submission. At their core, these platforms help connect, collect, display, and steward clinical trial data, offering convenient access for users. They include electronic patient-reported outcome (ePRO) and clinical outcome assessment (eCOA) modules for data collection, as well as electronic informed consent (eConsent), virtual training, live chat, telehealth, and more. They may employ intelligent automation, artificial intelligence/machine learning, and other technologies as needed.

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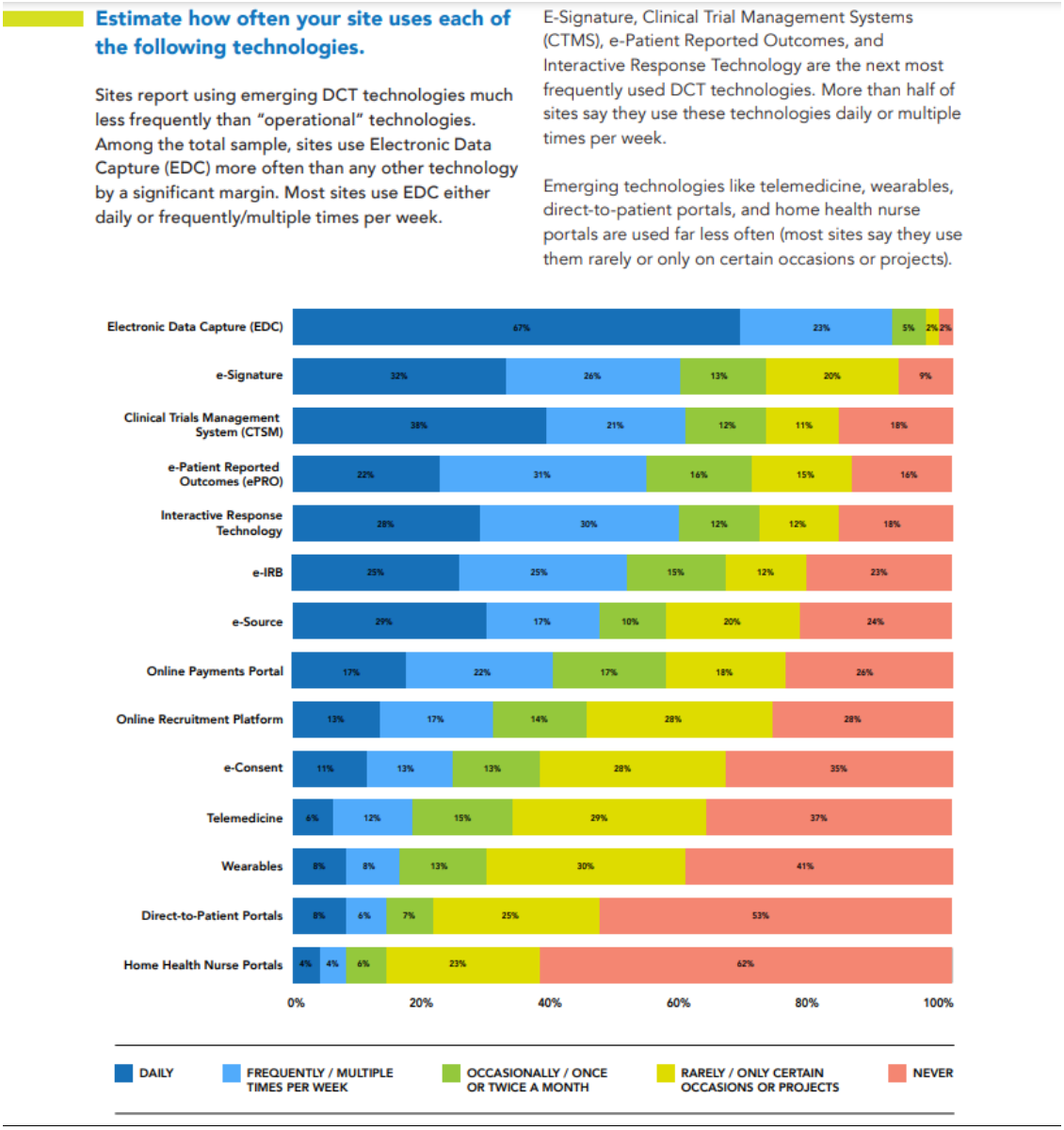
Figure 4: Survey responses from clinical research professionals relating to use of myriad technologies that support implementation of clinical research studies and trials[25]



In addition, new laws have been enacted, several draft regulatory guidance documents have been published, federally funded public workshops have been conducted, and industry-led initiatives have been organized in support of

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advancing and validating the essential and distinct occupation of clinical researchers. Some of these notable activities include:

- The creation of the Advanced Research Projects Agency for Health[26] (ARPA-H) to improve the U.S. Government's ability to speed biomedical and health research. Public Law 117-103 was enacted on March 15, 2022, to advance high-potential, high-impact biomedical and health research that cannot be readily accomplished through traditional research or commercial activity. This includes clinical trials for underserved populations.[27] In furtherance of this is ARPA-H's newly formed Advancing Clinical Trials Readiness initiative.
- The Consolidated Appropriations Act, 2023 (H.R. 2617), an omnibus appropriations bill, which includes the Food and Drug Omnibus Reform Act of 2022[28] (FDORA), with several provisions intended to promote diversity in clinical trial enrollment, encourage the growth of decentralized clinical trials, and streamline clinical trials.
- The NIH Clinical Trial Diversity Act 2023,[29] legislation that sets out requirements to increase the diversity of clinical trial participants and requires other activities to foster participation in clinical trials.
- NASEM's *Envisioning a Transformed Clinical Trials for 2023*,[30] which considered a transformed clinical trials enterprise for 2030 and laid out key priorities for advancing a clinical trials enterprise.
- The U.S. FDA Digital Health Technologies for Remote Data Acquisition in Clinical Investigations guidance[31] (December 2023), which provides recommendations on the use of digital health technologies to acquire data remotely from participants in clinical investigations that evaluate medical products.
- NASEM's Preparing the Future Workforce in Drug Research and Development Workshop, which sought to identify the expertise and disciplines needed to achieve the aspirations for a transformed clinical trials enterprise by 2030 and enable a workforce that can better support the evolving needs of drug R&D.
- The collaborative venture between MRCT, CTTI, NASEM, and FasterCures, *Toward a Framework to Improve Diversity and Inclusion in Clinical Trials*.[8]
- The Clinical Trial Modernization Act, introduced in May 2024 by Congressman Raul Ruiz, M.D. (D-CA) and Congressman Larry Bucshon, M.D. (R-IN) to improve participation in clinical trials by underrepresented populations.
- The Communities Advancing Research Equity (CARE) for Health, a $30 million initiative launched by NIH for fiscal years 2024 and 2025. This

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aims to improve health outcomes by integrating research into primary care settings.[32]

- Broader regulatory changes that have an impact on clinical research include updates to the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects in clinical research (45CFR46[33]); NIH policy on use of a single IRB for multi-site studies,[34] and upcoming revisions to ICH GCP.[35]

Clinical research is an essential occupation that is currently in crisis
The critical contribution of clinical researchers to society was spotlighted during the COVID-19 pandemic by the exceptionally rapid development of three effective COVID-19 vaccines. The work of these clinical researchers was a distinct and unique contribution to public health during this unprecedented period.

The COVID-19 pandemic was also transformational in terms of the design and conduct of clinical trials, catalyzing the development of remote technologies to enable continuation of studies during periods of lockdown and social distancing. Regulatory agencies including the U.S. FDA, the European Medicines Agency (EMA), the NIH, and China's National Medical Products Administration issued various guidelines for conducting trials during the pandemic to support the implementation of decentralized clinical trials and virtual services. The introduction of these decentralized elements into the conduct of clinical research has resulted in significant revisions to workers' duties and skillsets that further distinguishes the jobs of clinical researchers from those of other healthcare roles.

As explained, clinical research is an essential and distinct occupation with distinctive skills and training requirements. Clinical researchers are central to life science industry efforts to develop much-needed new and improved therapies across disease areas.

Unfortunately, there is a severe shortage in the clinical research workforce. This has been a looming threat for over a decade but was exacerbated by the COVID-19 pandemic, when the gulf between supply and demand widened. The situation has now reached a crisis point with the potential to curtail medical advances for years to come.[36] Today, the clinical research workforce is required to meet rising expectations for quality, safety, speed, study complexity, novel technologies, and diversity—all amid a shortage of human resources and a lack of professional infrastructure. The workforce shortage has led to unprecedented staff turnover, with the resignation rate in 2022 60% higher than in 2020.

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Critically, the clinical research profession is faced not only with a workforce shortage but also with a lack of diverse representation. Diversity in this profession is needed to ensure diversity among clinical research participants, in turn supporting the applicability of trial findings to heterogenous real-world populations.[37] There is a need to create more opportunities for the existing and future clinical workforce to learn about research opportunities and to help address workforce shortages.[38] Adding a new code for clinical researchers could also support increased diversity by allowing for the workforce demographic data to be collected.

Clinical research demands specialized training and certification

The occupation of clinical researcher demands specialized training and certification to ensure the safety and quality of research conduct. This specialized training could include:

Course Title
Introduction to Good Clinical Practice (GCP)
Investigator Responsibilities
Building Quality Management Systems for Sites and Sponsors
Clinical Trial Monitoring Basics
Mastering the Event Reporting Cycle: Understanding Adverse Events (AEs)
Investigational Product
Essential Documents
Understanding Clinical Trial Protocols
Informed Consent Simulation
Implementing a Patient-Centered Informed Consent Process

Clinical Research Competencies: Education and training for the clinical research profession is built upon a framework that defines the knowledge, skills, and attitudes necessary for conducting safe, ethical, and high-quality clinical research. The Joint Task Force for Clinical Trial Competency (JTF) has developed a framework that is distinct to the clinical research occupation (*Figure 5*).[3] This is used to define professional roles and performance

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evaluations, education and training requirements, and certification criteria and continuing professional development needs, and to facilitate regulatory compliance, quality improvement, and financial status of the clinical research process.

Figure 5: Joint Task Force for Clinical Trial Competency (JTF) Framework: Core Competencies

Education: Education can be gained through specialized academic clinical research programs, such as those offered by members of the Consortium of Academic Programs in Clinical Research (CoAPCR). This consortium facilitates the development of high-quality educational programs encompassing all areas of clinical research that are based in academic credit-granting institutions. Entry-level roles in clinical research do not always require a degree but do demand a specialized skill set in line with the application of regulatory rigor, leadership, and project management expertise.

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Training: Whether serving in a Principal Investigator job or a study staff job, such as a CRC, specialized training in clinical research is mandatory to ensure patient safety and compliance with federal and global regulations. Training in clinical research is provided by non-profit organizations, such as ACRP, and by for-profit organizations, such as the Collaborative Institutional Training Initiative (CITI) and Barnett. ACRP currently offers more than 200 courses in clinical research training that address all jobs and levels of training required.

Principal Investigators are required to ensure that all personnel involved in study conduct are adequately qualified and trained for their role. Some district trainings for personnel could include:

- Good Clinical Practice (GCP)
- The Belmont Report
- Declaration of Helsinki (ethical principles for research on human subjects)
- ICH E6 R2 (covering clinical safety data management)
- Essential Documents
- Ethics and Human Subject Protection
- Informed Consent for Research
- Investigator Responsibilities
- Mastering the Event Reporting Cycle
- ALCOA+ (principles that ensure data integrity)
- Clinical Trial Monitoring Basics

Clinical Research Certification: Currently, certification in clinical research is not required by U.S. government entities but is considered by stakeholders to be a recognized and respected endorsement of clinical research competency. Today, accredited certification is offered by only two organizations in the U.S.: ACRP and the Society of Clinical Research Associates (SOCRA). Certification denotes in-depth knowledge across a range of clinical research competencies and many different role-based duties.

Many organizations are dedicated to the field of clinical research
With more than 16,000 members, ACRP is the only non-profit organization in the U.S. solely dedicated to representing, supporting, and advocating for clinical researchers and their contributions to improving public health. Founded in 1976, ACRP is a registered 501(c)(3) charitable organization whose mission is to promote excellence in clinical research and whose vision is that clinical research is performed ethically, responsibly, and professionally everywhere in the world.

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The ACRP community includes more than 100,000 clinical research professionals who engage through the association's annual conference, online knowledge-sharing community, and digital communication platforms. The occupation of clinical research demands distinct and advanced skills and training, and ACRP provides high-quality, competency-based educational programs for the workforce in addition to accredited certification for the roles of certified clinical research coordinators (CCRCs), certified clinical research associates (CCRAs), and certified physician investigators (CPIs). ACRP's certification programs are accredited by the National Commission for Certifying Agencies/Institute for Credentialing Excellence and governed by the Association's affiliated Academy of Clinical Research Professionals. The Academy has certified more than 40,000 individuals since 1992.

ACRP's Partners for Advancing the Clinical Research Workforce (PACRW) Consortium is a multi-partner initiative supported by more than 25 pharmaceutical sponsors, contract research organizations, clinical research sites/site organizations, and academic institutions. The Consortium's goal is to promote the development of a diverse, research-ready clinical research workforce to sustain the life sciences industry. This industry drives the development of therapeutic advances that ultimately improve individual and population health. The Consortium's goals directly align with ACRP's mission to promote excellence in clinical research globally.

There are several other professional and trade associations that support the occupation of clinical research, along with several consortia. Examples include:

- Multi-Regional Clinical Trials (MRCT) Center at Brigham and Women's Hospital and Harvard University
- Clinical Trials Transformation Initiative (CTTI)
- Consortium of Academic Programs in Clinical Research (CoAPCR)
- Decentralized Trials & Research Alliance (DTRA—non-profit)
- Society for Clinical Research Sites (SCRS—for profit)
- Regulatory Affairs Professionals Society (RAPS)
- Society for Clinical Data Management (SCDM)
- Clinical Research Project Management (CRPM) Association
- Society of Quality Assurance (SQA)
- Public Responsibility in Medicine and Research (PRIM&R)
- Health Care Compliance Association (HCCA)
- International Association of Clinical Research Nurses (IACRN)

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- Alliance of Academic Health Centers (AAHC)
- Association for Clinical and Translational Science (ACTS) Clinical Research Professional Special Interest Group

Conclusion: A new SOC code for clinical researchers is necessary and important

ACRP strongly encourages the Bureau of Labor Statistics to recognize the distinct role of clinical research by introducing a new detailed SOC Code under the Healthcare Professionals classification. This would take place pursuant to the BLS' authority to review the *2018 SOC Manual* for possible revision in 2028. This authority includes the ability to determine whether to develop definitions for major occupation groups, whether to consider the addition of new detailed occupations or occupational groups, including specifically care workers, and to assess possible changes to the STEM occupation framework and its domains.

The SOC Code for clinical research will improve visibility and recognition of this occupation, helping to track and address the current severe shortage of qualified clinical researchers and advance medical research to the benefit of public health. By effectively putting clinical research "on the map," the new SOC will support purposeful choice of clinical research as a career option, including by individuals from diverse populations. Data collection for this new SOC code will improve understanding of the make-up of the clinical research workforce, including its demographics, its challenges, and its contribution to healthcare.

Finally, the new code will maintain the utility and continuity of the data that characterize and monitor this essential workforce. This will also allow for more accurate analysis and will inform policymaking for employers, researchers, sponsors, and lawmakers at national and state levels.

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