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Who is a Clinical Research Professional?

This article aims to portray the multidimensional structure of the clinical research identity by describing the profession through three unique lenses related to individuals, associations, and institutions.

Who is a clinical research professional? Although clinical research—which may be defined as "patient-oriented research, including epidemiologic and behavioral studies, outcomes research, and health services research"[1]—draws annual funding in excess of $30 billion from the U.S. National Institutes of Health alone[2] (not to mention from many other private and public sources), those working in the field cannot be circled distinctly into boundaries determined clearly by a robust professional identity.

In order to formulate a consolidated view, this article aims to portray the multidimensional structure of the clinical research professional identity by describing the profession through the unique lenses of:

- individuals who identify as clinical research professionals;
- collective associations of the membership who identify as clinical research professionals; and
- institutions of higher education that provide knowledge and skill sets to professionals who work or will work in the clinical research field.

The need to consolidate these different perspectives is significant, since a professional identity that is facilitated and nurtured by all stakeholders will likely result in better outcomes, not just for those who work in this industry, but also for other individuals and institutions who play their part in the advancement of medical treatments.

What Does "Professional Identity"Mean?

"Professional identity" is defined as "the constellation of attributes, beliefs, values, motives, and experiences in terms of which people define themselves in a professional role."[3] It is the self-definition, expressed from the perspective of a member belonging to a particular profession, regarding how that particular role is enacted.[3,4] The role that a person has at work contributes to the person's identity at work and also outside the workplace.[5,6] An individual's professional identity touches upon the sociological attributes of legitimacy, status, and boundaries of the person's occupational and organizational groups.[7,8]

Social identity theory[9] is a lens through which the social identification process for constructing professional identity at the individual and collective levels may be better understood. According to social identity theory, individuals categorize people into groups, with favored *ingroups* (i.e., we) competing with *outgroups* (i.e., they). This social classification is a cognitive process, whereby

individuals segment and order their environment, after which they use this segmentation to systematically define people in relation to their definition of self. In other words, people gravitate toward those who they think represent values similar to their own. Obviously, this social categorization or classification is self-referential, whereby one is motivated to identify with a group that enhances positive self-esteem and reduces perceived uncertainty in the environment.[10]

Not knowing what one does is often the root cause of a weak professional identity, as this limited understanding does not generate an awareness of who one is.[11] If individuals within a professional community do not fully form an understanding and appreciation of their roles—as experienced through personal practice—they are unlikely to develop a unified identity. A unified professional identity is constructed through building a group of stable and enduring characteristics, values, beliefs, and experiences that a person uses to define himself or herself in a professional role.[12] Given that the clinical research domain encompasses a wide range of professions with strong identities—such as medicine and nursing—it is often difficult for individuals to step into this fragmented domain and quickly develop a sense of self that is grounded in what they currently do, rather than what they had been doing previously.

Research emphasizes the influence of identity in structuring professional conduct,[13] with respect to clinical research, by stating that the "inherent ethical complexity, ambiguity, and tensions between potentially competing loyalties to science and care of patient volunteers"[14] can be effectively managed only by having those involved in clinical research become aware of and fully embrace their roles—as well as those of others with whom they work.

The Study: What the Fragmented Perspectives Describe

Methodology

In order to consolidate descriptions of the clinical research profession, the study team collected data from three major stakeholders: clinical research professionals, clinical research professional associations, and institutions of higher education offering clinical research programs. Mixed methods were used to analyze these data. The qualitative data were coded independently by two researchers to ensure credibility. The quantitative analysis consisted of descriptive statistics and frequency distributions. No inferential statistics were used to test any particular hypothesis.

Study Sample

Clinical Research Professionals—Convenience sampling was used to select clinical research professionals. Invitations to participate in the study were delivered in person and onsite at the Association of Clinical Research Professionals (ACRP) 2008 Global Conference & Exhibition held in Boston, Mass. North American participants were asked to complete a brief online survey (consisting of a mix of multiple-choice and open-ended questions) that was set up on a terminal at the conference location.

Of the 125 conference attendees who were invited to take the survey, 109 agreed. Of those, eight were excluded from the final analysis, as their surveys contained incomplete data, resulting in a sample size of 101. As Table 1 depicts, nearly half of the participants had 10 or more years of experience in the profession, and nearly a quarter had between five and 10 years of experience.

As illustrated in Table 2, 22% of the participants, which represents the highest percentage group, chose "Clinical Research Professional" as the role that best defined their involvement in clinical research, although other traditional roles were also offered as options in the survey.

When asked to choose roles that they thought should be included in the definition of a clinical research professional, participants selected Study Coordinator (91%), Project Manager (87%), Clinical Research Associate (86%), Monitor (86%), and Clinical Trials Manager (86%) as the top five choices. Percentages for the complete list of roles selected by participants are presented in Table 3.

Table 1 Participants' Experience in Clinical Research

Experience	Number
Less than a year	6
1 to 2 years	10
3 to 5 years	14
6 to 10 years	26
More than 10 years	45

Table 2 Participants' Reported Role in Clinical Research

Role Choices	Number
Clinical Research Professional	22%
Clinical Trials Manager	15%
Study Coordinator	14%
Project Manager	12%
Clinical Research Associate	9%
Nurse	8%
Monitor	8%
Clinical Director	7%
Physician	2%
Biostatistician	2%
Clinical Investigator	1%
Data Manager	1%

Clinical Research Professional Associations—The two associations included in the study were those that held the largest membership of clinical research professionals in the United States: ACRP and the Society of Clinical Research Associates (SoCRA). ACRP has headquarters in Alexandria, Va., with more than 18,000 members in more than 65 countries.[15] SoCRA is based in Chalfont, Pa., and has more than 12,200 members.[16] Both have thousands of members who are certified in clinical research. Although there are other associations based in the United States, such as the Drug Information Association, with which a sizeable number of clinical research

Table 3 Roles Included in Participants' Definition of a Clinical Research Professional

Role Choices	Percentage
Study Coordinator	91%
Project Manager	87%
Clinical Research Associate	86%
Monitor	86%
Clinical Trials Manager	86%
Clinical Investigator	83%
Data Manager	75%
Biostatistician	75%
Nurse	69%
Clinical Director	69%
Physician	63%

professionals may hold membership, these were excluded from the study, as they do not explicitly refer to clinical research, clinical research professionals, or the clinical research profession in their name or mission statement and do not provide a formal definition of who a clinical research professional is on their websites.

The significance and relevance of information stated on a professional association's website is grounded in the understanding that this medium is a formal and institutional vehicle by which the organization communicates its identity—as well as values constituting that identity—to its stakeholders. Although this communicated identity may not be taken as the absolute truth, or even as a comprehensive representation of all attributes of the entire membership, for our purposes it is nevertheless a formal recognition and endorsement of key constructs that the leadership team chooses to use when describing the collective body of professionals constituting the association.

Institutions of Higher Education Offering Clinical Research Programs—Seventeen major educational programs—both classroom-based and online—located in the United States, offering undergraduate and/or graduate certificate or degree programs in clinical research, were included in the study. Table 4 lists the universities and the degrees offered at these universities.

Data regarding the types of individuals these programs were trying to recruit, as well as the language and tone used in representing identity, roles, and values associated with the clinical research profession, were obtained from universities' websites. As is the case with professional associations, the significance of information stated on an educational program's website is grounded in the understanding that this medium is a formal and institutional vehicle by which the organization communicates its identity—as well as values constituting that identity—to its stakeholders.

Limitations

The chosen sample—namely the clinical research professionals, professional associations, and higher education institutions—obviously limits the extent to which generalizations can be made regarding the study's findings. Although individuals who responded to the survey were all associated with the clinical research profession, it is difficult to argue that the study's findings would apply to all clinical research professionals. Using random sampling in future studies, instead of convenience sampling—which was the approach employed in this study—will likely provide more generalizable results. Also, including participants in future studies from the clinical research industry who do not necessarily self-identify as a clinical research professional might yield additional insights.

Readers should also take into account the limited sample size (n=101) when interpreting the results. A follow-up study with a larger sample size has the potential to provide more accurate and generalizable results, as well as a more comprehensive view of the clinical research profession as perceived by its members. To a lesser

Table 4 Major Academic Clinical Research Programs in the United States

University	Degree
Boston University	Master of Arts in Clinical Investigation
Campbell University	Bachelor's Degree in Clinical Research
Campbell University	Master's Degree in Clinical Research
Drexel University	Master's Degree in Clinical Research
Durham Technical Community College	Clinical Trials Research Associate
Eastern Michigan University	Master's Degree in Clinical Research Administration
Gateway Community College	Research Coordinator Certificate
University of Pittsburgh	Certificate in Clinical Research
The George Washington University	Master's Degree in Clinical Research Administration
Trident University International	Master's Degree in Clinical Research Administration
University of California, San Diego	Master's Degree in Clinical Research
University of California, San Francisco	Master's Degree in Clinical Research
University of Maryland	Master's Degree in Clinical Research Management
University of Medicine & Dentistry of New Jersey	Certificate in Clinical Recruitment Science
University of Medicine & Dentistry of New Jersey	Certificate in Clinical Trials Informatics
University of Minnesota	Master of Science in Clinical Research
University of Washington	Certificate in Clinical Trials

extent, the same argument holds true for both the number of professional associations and higher education institutions included in the study.

The Results

How Clinical Research Professionals Perceive the Profession

Survey participants who emphasized the process of clinical research itself, choosing to concentrate on its various components and those involved in workflow, described clinical research as a profession that "investigates new therapies and treatments" through "clinical trials in which drugs and medical devices are tested." According to the participants, the process was firmly grounded in the "research and discovery" of "new therapies and ways of understanding disease."

Various phases of the process consisted of "researching, discovering, testing, and bringing to market medicines and/or devices with the cooperation of human subjects" and involved "conducting studies, managing studies, monitoring studies, and reviewing studies," with the majority of work being "performed in a clinical research environment." All participants agreed that one way or another, clinical research was the process of "taking medicine from the laboratory and studying if it is safe and efficient when used on humans," which inevitably involved "writing regulatory documents associated with the clinical research and [U.S. Food and Drug Administration] approval of drugs."

Survey participants who emphasized the purpose of the process of clinical research, choosing to concentrate on its goals and outcomes, described clinical research as a process aimed at "developing treatments for diseases" that was strongly "dedicated to improving public health." According to participants, the profession targeted the "development of new treatment modalities for various disease processes" and involved "everything that has to do with enhancing one's health, while caring and protecting the wellbeing of those who volunteer to make it happen."

Although some participants indicated that the emphasis was on "investigating the human response to disease processes and investigational treatments" and "submitting marketing applications to regulatory authorities," others stated that the focus was on "supporting and/or enhancing the wellness of humanity by treating or preventing disease, dysfunction, or impediments to a complete state of wellness," while "ensuring responsibility in claims made by marketing of medical products" and "protecting the human participants."

Participants emphasized the need for establishing clear role definitions and upholding the highest of ethical standards, in terms of dealing with pressures caused by being "caught in a crossfire between patient safety, sponsor need of sales, and regulations." Participants seemed to be concerned most by those chasing the "highest financial return possible" in an industry in which ethical practices were not meant to be challenged by alternative motivations. The "lack of consistency in approach by clinical sites and sponsor companies" was another significant cause for concern among many participants, who noted that "guidelines can be subjective" more often than not. In summary, participants believed that "as a whole, the clinical research profession needs to establish well-defined and standardized roles applied across the profession" that do not vary "by individual corporate climates."

What Clinical Research Professionals Like Most and Least About Clinical Research

Participants' comments regarding what they liked most about clinical research could be grouped under three main themes:

- opportunity to advance scientific discovery (24.75%);
- ability to improve individuals' lives (38.61%); and
- involvement in a challenging and exciting career (36.64%).

The first two themes seemed to carry greater weight in participants' judgment than the last.

Participants' comments regarding what they liked least about clinical research could be grouped under five main themes:

- negative image associated with the pharmaceutical industry (22.77%);
- challenges associated with maintaining a desirable work-life balance (27.72%);
- excessive paperwork and regulations (10.89%);
- lack of standards (20.79%); and
- unethical practices (17.83%).

How Professional Associations Define the Profession

SoCRA defines individuals who work in the field of clinical research as follows:

> A Clinical Research Professional functions as a clinical investigator, sub-investigator, clinical researcher, research nurse, administrator, coordinator, consultant, or educator in clinical trial management. A Clinical Research Professional is involved in one or more aspects of clinical trials research, including data collection, analysis, or monitoring; case management of protocol participants; recruitment and enrollment of human subjects; protection of subjects and subjects' rights through [institutional review board] relations; development of informed consents; preparation of adverse event experience reports; construction or monitoring of case report forms; maintenance of drug accountability records; grant and budget development; report preparation; education of other health-care professionals, patients or families regarding clinical trials, protocol development, program administration; and research program audit.[17]

This description clearly portrays the wide range of professional sub-identities that are nested within the overarching identity of a clinical research professional. Although certain individuals may enter the profession with educa-

tion and experience received solely in the domain of clinical research, more often most others enter the profession having been oriented in another professional discipline—such as medicine, nursing, pharmacy, statistics, or business administration. Regardless of their educational and professional backgrounds, all individuals involved in clinical research must work together as a dynamic team.

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ACRP acknowledges and brings this team-based approach to the forefront when describing who clinical research professionals are and what they do:

> The clinical research team includes, but is not limited to, the clinical research coordinators who work most directly with the human subjects at specific test sites, such as hospitals, academic centers, and independent laboratories; the clinical research associates (monitors) who travel from site to site to oversee multiple studies for the companies that sponsor the research or for contract research organizations (CROs) that help sponsors conduct the studies; the physician and non-physician investigators who lead the full team and are ultimately responsible for the overall conduct of the research; the data managers who collect and process results from the studies; a host of specialists within and beyond the sites and sponsors in the areas of subject recruitment, sales/marketing, research ethics (institutional review boards), regulatory affairs, quality assurance, safety/medical affairs, site management, project management, training, and other research-related functions; and the directors and executives in charge of the drug/device companies, the research sites, and the CROs.[18]

As this comprehensive description implies, clinical research professionals each play a unique part in testing potential new products. Furthermore, these individuals take part in activities that span a wide range of phases, extending all the way from premarketing research to postmarketing studies.

Both of these associations cover the major processes and roles that comprise the clinical research process. However, ACRP's description is slightly more detailed and comprehensive in the sense that it specifically links clinical research roles to clinical research functions, whereas SoCRA's description lists both the roles and the functions, but does not create associations between them. Although ACRP's pairings may not be all-encompassing, perhaps it is a step in the right direction, in terms of more clearly defining specific roles that constitute a unified professional identity.

How Institutions of Higher Education Portray the Profession

When promoting their programs to prospective students, regardless of whether the program was one awarding a degree or a certificate, universities invited "a variety of professionals," including—but not limited to—physicians, physician assistants, physical therapists, nurses, pharmacists, psychologists, nutritionists, study coordinators, managers, and attorneys. Programs that made references to *groups* of professionals used terms such as "biopharma professionals," "clinical trials professionals," "drug/device development professionals," or simply "healthcare professionals." Programs listing degree prerequisites made reference to degrees in "health-related professions," "biological or chemical sciences," "clinical health sciences," "clinical professions," or "public health."

The specific roles within clinical research that were explicitly mentioned in informational content presented on the program websites mainly consisted of independent investigators, research associates, research coordinators, biomedical scientists, research nurses, database administrators, statisticians, clinical data coordinators, clinical systems analysts, project managers, and patient recruitment specialists. The curricula of programs offered in clinical research reveal its multidimensional nature grounded in "regulatory requirements, ethical issues, processes for product development, the business of clinical research, and scientific method processes for patient care product development."

What a Unified Professional Identity Might Provide

This article began with a question: Who is a clinical research professional? The findings of our study suggest that this person is likely someone from a primary background in healthcare, who—under the broad and complex process of clinical research—works as part of a fluid team and is mainly driven by the opportunity to advance scientific discovery and the chance to improve people's lives. This person, though uncomfortable with the negative image associated with the pharmaceutical industry, nevertheless tries to balance various aspects of medicine, research, regulatory, and commercial aspects all in the same flow. When doing so, this person seeks and looks up to established standards and high ethical values for guidance to resolve the conflict between altruistic motivations and business needs.

Perhaps the clinical research professional is in need of some institutional help, when articulating and communicating the professional identity to others. This help is likely to come from professional associations. As social identity theory suggests, membership to these ingroups will help clinical research professionals better identify the core, dominant, and enduring values that define who they are, in relation to outgroups—in other words, to who they are not.[9,10] These institutions, by clearly defining

clinical research roles and explicitly linking them to tasks that constitute the entire process of clinical research, can assist greatly in eliminating ambiguity that is responsible for inter-role conflict and fragmentation, while allowing members to converge toward a unified professional identity.

The clinical research professional is also someone who looks at institutions of higher education to better align educational offerings with the values, roles, and tasks that govern industry practice. If this person were a seasoned veteran, the expectation would be to welcome and work with newcomers who—through their formal education—have been oriented socially in the unified identity of the profession. For newcomers, the expectation would probably be to step into roles for which they have been adequately trained. Regardless, the wish is likely for tighter alignment and less discrepancy between the values, knowledge, and skill sets transferred to clinical research professionals in classrooms and those that will be demanded of them as they are asked to carry out their roles in the industry.

Although the benefits of a unified professional identity are obvious, looking ahead, perhaps it is fair to acknowledge the need to further investigate factors that reinforce and build professional identity among individuals who are engaged directly in or support clinical research. Such investigations will likely lead to deeper questioning as to whether or not certain roles should be excluded in efforts to strengthen the professional identity. Furthermore, some of the biggest threats to the profession and its standards might surface through these efforts. Additionally, it might make sense to investigate how the beliefs and values of clinical research professionals who enter the field with strong professional identities in other fields, such as medicine and nursing (both self-regulating groups with professional values, scopes of practice, licensure, and professional associations) might offer guidance or pose dilemmas when the patient becomes a research subject.

Through such investigations, we are liable to realize that the answer as to who a clinical research professional is will likely not remain fixed, but will evolve over time under the influence of environmental dynamics and scientific breakthroughs. However, it is important not to lose sight of the multiple dimensions that constitute the profession when contemplating this definition. It is equally important to understand the content and continued progress along each dimension. Through these types of explorations, the clinical research professional community can effectively investigate, articulate, and communicate its defining values to its own members and, equally as important, raise awareness and recognition among other members of society whose lives are in one way or another influenced by the conduct and outcomes of clinical research.

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