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Self-assessed Competency among Clinical Research Professionals in the Philippines Using the JTF Framework

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ABSTRACT

Background and Objective. The Philippines has significant potential as a clinical trial hub but faces a shortage of skilled clinical research professionals (CRPs). In 2022, a cross-sectional study assessed the self-assessed competencies of CRPs in four countries (Thailand, Vietnam, Congo, Philippines) using the Joint Task Force for Clinical Trial Competency (JTF) framework. This paper presents findings on the self-assessed competency and training needs of Filipino CRPs.

Methods. We conducted a cross-sectional online survey among Filipino clinical research professionals from March to April 2022. We asked for their self-assessed competency, relevance to their roles, and training needs in the competency domains according to the JTF framework. We also asked for the skills in community engagement and research grant application of the investigators. Results were summarized and analyzed according to their primary roles.

Results. One hundred seventy-five (175) Filipino CRPs participated in the survey. They described themselves as "skilled" across all competency domains in conducting clinical research but did not rate themselves at an advanced level. They reported the lowest confidence in their skills related to study management, investigational product development and regulation, and data management. They exhibited greater confidence in competencies such as ethical considerations, professionalism, and communication. Notably, surveyed investigators had the lowest ratings in research design.

Conclusion. This study provides a comprehensive assessment of the self-perceived competencies of a sample of Filipino CRPs using the JTF Clinical Research Competency Framework. It highlights key areas for capacity building, particularly in operational and regulatory competencies. However, due to the non-probability sampling and reliance on self-assessment, findings should be interpreted with caution.

Keywords: JTF Framework, research personnel, professional competence, self-assessment, needs assessment, Philippines

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INTRODUCTION

As of April 2024, there are at least 490,000 clinical studies registered in the ClinicalTrials.gov database.[1] Half of the clinical trials conducted worldwide took place in Asia, with 10% of the trial sites located in the Southeast Asian region.[2] In the past two decades, the pharmaceutical industry has conducted many Multi-regional Clinical Trials (MRCTs) in the Philippines and peaked in 2008.[3] However, since then, the number of MRCTs conducted in the Philippines has been declining. Compared to other countries in the ASEAN region, the Philippines has had the fewest MRCTs in recent years.[3] One of the challenges in conducting clinical trials is the shortage of competent and specialized personnel who can successfully implement and execute trials that meet the strict regulatory international standards.[4,5]

The Multi-regional Clinical Trial Center of Brigham and Women's Hospital and Harvard (MRCT Center) convened the Joint Task Force for Clinical Trial Competency (JTF) to develop a competency standard for clinical research professionals (CRP). The Core Competency Framework for CRPs was first established in 2014 by the JTF and has since undergone several iterations in response to the evolving field of clinical research.[6] This competency standard defines the knowledge, skills, and attitudes necessary for conducting safe, ethical, and high-quality clinical research. The JTF framework has had different uses since its inception such as standardizing roles and definitions in clinical trials, defining requirements for academic and professional certifications, evaluations of capacity and job performance, assessment of education and capacity needs, and also being used as a guide to create curriculums in clinical research courses.[7-10] Others have adapted the JTF to fit their specific context and field of research.[11,12]

Clinical research is vital in advancing medical knowledge and improving healthcare delivery in the Philippines. With over 100 million people and a diverse demographic profile, the Philippines offers a unique environment for clinical trials, characterized by a large patient pool, and competitive operational costs. Despite these advantages, the Philippines faces challenges in optimizing its clinical trials ecosystem, including regulatory complexities, limited research infrastructure in certain regions, and, more importantly, the need for capacity building to enhance both research professionals' and investigators' clinical trial competencies to be globally competitive and adherent to the highest scientific and ethical standards. In addition, clinical research professionals in the Philippines lack official regulation by law through a designated license process, such as that overseen by the Professional Regulation Commission (PRC). Presently, there exists no regulatory authority or compulsory licensure for roles such as Clinical Research Associates (CRAs), study coordinators, investigators, or other clinical research professionals inside the PRC framework.

There is no current research to measure the competency levels of clinical professionals in the country as of this writing. In 2022, the Japan National Center for Global Medicine (NCGM) and Multi-regional Clinical Trial Center Brigham and Women's Hospital and Harvard, conducted a cross-sectional study to assess the self-assessed competency of CRP in the Philippines, Thailand, Vietnam, and Democratic Republic of the Congo using the JTF framework. This paper describes the self-assessed competency of Filipino CRPs and explores how the perceived relevance and training needs of each competency vary according to the roles of the research professionals involved.

METHODS

Study Design

The study employed a cross-sectional analytic design using an online survey platform and was conducted from March to May 2022.[13]

Study Participants

Survey participants who possessed the following criteria were included in the study:

1. Filipino individuals employed in academic and medical institutions, contract research organizations (CRO), pharmaceutical industries, and any other research organizations that conduct clinical research in the Philippines.
2. Individuals who have worked or are currently working in clinical research, regardless of their role in the research.
3. Those whose online consent is voluntarily provided to participate in the study.

Sampling

We used a non-probability, purposive snowball sampling technique. The initial pool of potential participants was identified through the Philippine Health Research Registry and institutional websites. The survey was also disseminated through the Philippine Clinical Research Professionals (PCRP). Participants were encouraged to share the survey link with other eligible colleagues. Due to the survey's anonymous design, we were not able to track which participants came from the original lists and which were referred. The target sample size of 150 participants was calculated using the standard formula for estimating proportions, assuming a 95% confidence level ($Z = 1.96$), a population proportion of 0.5 (for maximum variability), and an 8% margin of error. The estimated population size of clinical research professionals (CRPs) was approximately 1,500, based on employment data from organizations in Indonesia, which was used as a reference point given its larger research workforce. The 8% margin of error was selected as the maximum acceptable difference between the sample estimate and the true population value.

Data Collection

The online survey was conducted from March 13 to May 14, 2022, and this period included both recruitment and

data collection. The survey link was disseminated via email and through the Philippine Clinical Research Professionals (PCRP) network. Two general reminder emails were sent—one during the third week and another a week before survey closure—to encourage participation. A structured online questionnaire was created, pre-tested, and modified to collect data. The survey link (https://www.surveymonkey.com/r/NIH-UPM) was sent to the e-mail addresses of potential participants. The link was also disseminated by PCRP to its active members. The online questionnaire has 3 parts - the first section contains the informed consent. Non-consenting participants were automatically directed to the last page to end the survey. The second part contains the checklist for the eligibility of the participants. If the participant is not eligible, the participant was directed to the last page of the questionnaire to end his/her participation. The third section is the survey proper which contains demographic characteristics, self-perceived competency level, self-perceived relevance competency, and self-reported learning needs across each of the competencies.

The framework covers competency domains of eight areas reflecting a research professional's knowledge, skills, and attitudes in conducting clinical research at three levels: fundamental, skilled, and advanced. These domains include the following (MRCT):

1. Scientific Concepts and Research Design covers the design and analysis of clinical trials
2. Ethical and Participant Safety Considerations covers protection, safety, and care of participants during the conduct of the trial.
3. Investigational Products Development and Regulation covers knowledge on how investigational products are developed and regulated.
4. Clinical Study Operations covers the ability to manage the study (including reporting and identification of adverse events, post-study reporting such as post-market surveillance, and pharmacovigilance), and handling of investigational products.
5. Study and Site Management covers the knowledge and skills required to run a study at the site level, such as financial, personnel, and operations management, which are not covered by regulatory or GCP principles.
6. Data Management and Informatics covers data collection, management, quality control, and protection.
7. Leadership and Professionalism covers leadership and professionalism in clinical research.
8. Communications and Teamwork covers all aspects of communication and working together within and between sites, and stakeholders (sponsor, contract research organization, and regulators).

Self-assessed competency for each domain was rated on a 10-point Likert scale, where responses were mapped to three levels: Fundamental (1–3), Skilled (4–7), and Advanced (8–10), in accordance with the JTF framework's recommended structure. This structure allowed for more granular responses within each category while preserving alignment with the established competency levels. The self-perceived relevance competency is answerable by ticking the 5-point Likert scale (Highly irrelevant, Likely to be irrelevant, More or less relevant, Likely to be relevant, and Highly relevant). The self-reported learning needs across each competency are answerable by ticking the 5-point Likert scale (Not at all necessary, Slightly necessary, Moderately necessary, Very necessary, Extremely necessary). Aside from the JTF framework questions, additional questions on competency in community engagement and fund acquisition were also included.

The MRCT Center provided the tool as part of a broader, multi-country study conducted in the Philippines, Thailand, Vietnam, and the Democratic Republic of the Congo. This framework has been used in several published studies internationally. For local adaptation, the questionnaire was pre-tested among four Filipino clinical research professionals. Based on their feedback, minor adjustments were made to enhance clarity. Formal psychometric validation was not conducted.

Analysis

The demographic profile of all the respondents, as well as the self-perceived competency level, self-perceived relevance, and self-reported learning needs across each of the competencies, were reported as a proportion in percentage. For each competency level, the mean and standard deviation were used to summarize the response. A subgroup analysis was conducted based on CRP roles to examine differences or similarities in competency ratings, relevance to their roles, and learning needs. Since the responsibilities for community engagement and attracting research funding primarily fall to investigators, only their self-assessed results for these two competency domains were presented and analyzed. Only fully completed responses were included in the analysis.

Ethical Considerations

The study was granted ethical clearance by the University of the Philippines-Manila Research Ethics Board (UPMREB 2021-0723-01). Prior to answering the online questionnaire, informed consent was secured. The respondents remained anonymous, and the data were kept in compliance with the Data Privacy Law of the Philippines and the National Ethical Guidelines for Research Involving Human Participants.

RESULTS

A total of 222 individuals accessed the online survey link. Of these, all passed the eligibility screening and provided informed consent. However, only 175 participants completed all required sections of the questionnaire and were included in the final analysis. The remaining 47 responses were excluded due to incomplete survey data. Most were affiliated

with academic institutions (n=78, 45%) or contract research organizations (n=44, 25%), serving as investigators, managers, or research monitors. Experience levels among those involved in clinical research varied, with a notable distribution to those with fewer than three years of experience (n=45, 25.7%) and those with over 10 years (n=70, 40%). A few participants reported having a formal clinical research degree or a professional certification (Table 1).

Perceived Competency

The mean scores across all domains translated to "Skilled" (score of 4-7) with the highest scores on Leadership and Professionalism, and Ethical and Participant Safety Considerations. They are least confident in Investigational Products Development and Regulation, Data Management and Informatics, and Study and Site Management. Roles that have oversight responsibilities during the conduct of a clinical trial (investigators, monitors, managers, and coordinators), have the highest confidence in the domains of Ethical and Participant Safety Considerations, Leadership and Professionalism, and Communications and Teamwork, while they have consistently scored low on Investigational Products Development and Regulation, Scientific Concepts and Research Design, and Data Management and Informatics. Among all the roles, the research managers showed the highest perceived competency in all domains (Table 2).

Across all domains, self-assessed competency showed a consistent upward trend with longer experience in clinical research (Figure 1).

Perceived Relevance

Overall, most participants rated all domains as relevant to their roles as CRP. In particular, a higher proportion of participants rated Ethical and Participant Safety Conside-

Table 1. Demographics of Participants

Demographics (N=175)	n	%
Age Group (years)		
<25	10	5.7
25 to 34	51	29.1
35 to 49	68	38.9
>50	46	26.3
Sex[†]		
Female	115	65.0
Male	59	33.0
Finished Post-secondary Degree		
No post-secondary degree	2	1.1
Associate's degree/diploma	5	2.9
Baccalaureate degree	58	33.1
MD	56	32.0
PharmD	1	0.6
Master's Degree	37	21.1
Doctorate Degree (PhD)	16	9.1
Primary Organization		
Academe	78	44.6
Contract Research Organization	44	25.1
Private Clinical Site	15	8.6
Corporate Pharmaceutical/Biotech	13	7.4
Public Hospital/ Clinical site	11	6.3
Research Institute	10	5.7
Non-profit Organization	3	1.7
Government Body	1	0.6
Roles		
Principal Investigator/Co-Investigator	71	40.6
Clinical Research Associate/Monitor	29	16.6
Project Manager/Research Manager	19	10.9
Clinical Research Coordinator/Study Nurse	11	6.3
Educator/Trainer	9	5.1
Biostatistician	8	4.6
Data Management Professional	3	1.7
Regulatory Affairs Professional	3	1.7
Pharmaceutical Physician	1	0.6
Other[¶]	21	12.0
Years Doing Clinical Research		
<3	45	25.7
3 to <6	35	20.0
6 to <10	25	14.3
>10	70	40.0
With Clinical Trial Experience[‡]	117	66.9
Years Doing Clinical Trials		
0 to <3	36	30.5
3 to <6	17	14.4
6 to <10	22	18.6
>10	43	36.4
With a Clinical Research Degree[#]	41	23.4
With Professional Certification[§]	58	33.1
Trainings Taken*		
Leadership and Professionalism	43	24.6
Ethical and Participant Safety Considerations	110	62.9
Investigational Products Development and Regulation	33	18.9
Clinical Study Operations (GCP)	140	80.0
Study and Site Management	51	29.1
Data Management and Informatics	41	23.4
No coursework and training	10	5.7

[†] *One participant did not indicate sex.*

[¶] *The survey tool did not allow free-text responses, limiting further characterization of these roles.*

[‡] *This refers to participants who reported having participated in at least one clinical trial, regardless of role. This includes all 175 participants. 117 reported having clinical trial experience, while 58 indicated no such experience.*

[#] *This refers to completion of a formal academic program specifically focused on clinical research or clinical trials.*

[§] *This refers to possession of a recognized credential in clinical research (e.g., ACRP, SOCRA, or accredited GCP certification).*

[*] *Multiple responses were allowed. "No coursework and training" refers to respondents who indicated they had not taken any formal training related to the eight JTF competency domains.*

Table 2. Mean Self-assessed Competency Rating of Clinical Research Professionals per Domain and Roles (SD)*

Domain (N=175)	Principal Investigator / Co-investigator (n=71)	Clinical Research Associate / Monitor (n=29)	Project Manager / Research Manager (n=19)	Clinical Research Coordinator/ Study Nurse (n=11)	Educator / Trainer (n=9)	Biostatistician (n=8)	Others (n=28)	All Roles
Domain 1 Scientific Concepts and Research Design	4.22 (0.25)	5.38 (0.44)	7.37 (4.48)	4.64 (0.77)	5.43 (0.60)	6.86 (1.14)	5.78 (2.79)	6.51 (2.49)
Domain 2 Ethical and Participant Safety Considerations	7.80 (0.24)	6.31 (0.45)	7.68 (0.52)	6.36 (0.88)	7.44 (0.50)	6.13 (0.97)	6.43 (2.61)	7.14 (2.37)
Domain 3 Investigational Products Development and Regulation	4.75 (0.33)	5.0 (0.49)	6.74 (0.62)	4.46 (0.80)	4.11 (0.55)	3.5 (0.78)	5.64 (2.87)	5.04 (2.8)
Domain 4 Clinical Study Operations (Good Clinical Practice)	6.83 (0.27)	6.24 (0.51)	7.36 (0.56)	6.64 (0.85)	5.44 (0.83)	5.63 (0.94)	5.43 (2.76)	6.43 (2.59)
Domain 5 Study and Site Management	6.21 (0.31)	6.18 (5.18)	7.42 (0.61)	5.82 (0.74)	4.44 (0.97)	4.63 (0.96)	5.32 (2.95)	6.01 (2.77)
Domain 6 Data Management and Informatics	6.08 (0.28)	5.24 (0.49)	7.0 (0.50)	5.45 (0.60)	5.66 (1.02)	8.36 (0.49)	5.32 (2.57)	5.97 (2.49)
Domain 7 Leadership and Professionalism	7.25 (0.27)	6.83 (0.40)	8.31 (0.37)	6.27 (0.70)	6.056 (0.96)	5.38 (1.19)	7.61 (2.35)	7.18 (2.34)
Domain 8 Communications and Teamwork	7.17 (0.24)	6.27 (0.44)	8.11 (0.50)	5.81 (0.81)	5.67 (0.94)	5.25 (1.03)	6.82 (2.74)	6.82 (2.4)

** Competency scores were rated on a 10-point Likert scale and mapped to three general categories based on the Joint Task Force (JTF) framework: Fundamental (1–3), Skilled (4–7), and Advanced (8–10).*

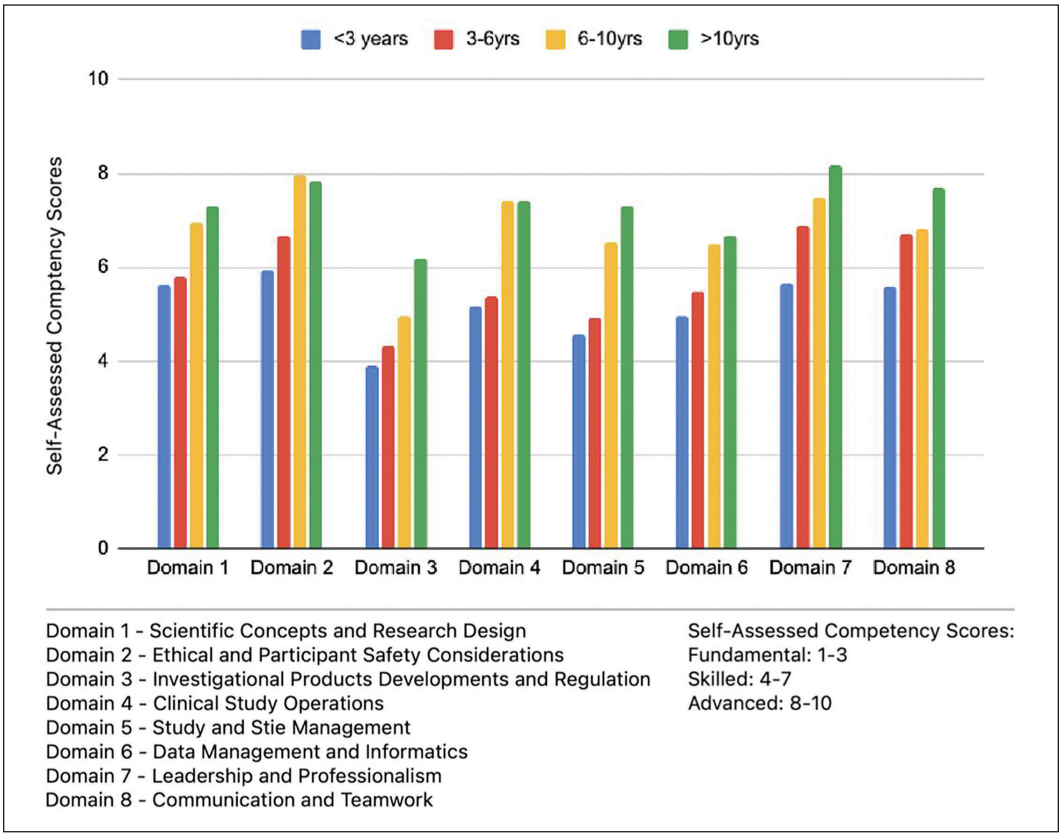

Figure 1. Self-assessed competency across domains based on years of experience.

rations (n=111, 63%), Clinical Study Operations (n=114, 65%), Leadership and Professionalism (n=108, 61%), and Communications and Teamwork (n=100, 57%) to be highly relevant. Scientific Concepts and Research Design was also found to be relevant by half of the participants. Investigational Products Development and Regulation (n=57, 33%), had the fewest participants who found it relevant (Figure 2).

Perceived Training Needs

In general, participating CRPs rated Data Management and Informatics as very to extremely necessary for training (n=120, 69%). These were followed by Communications and Teamwork (n=115, 65%) and Leadership and Professionalism (n=112, 64%) (Figure 3).

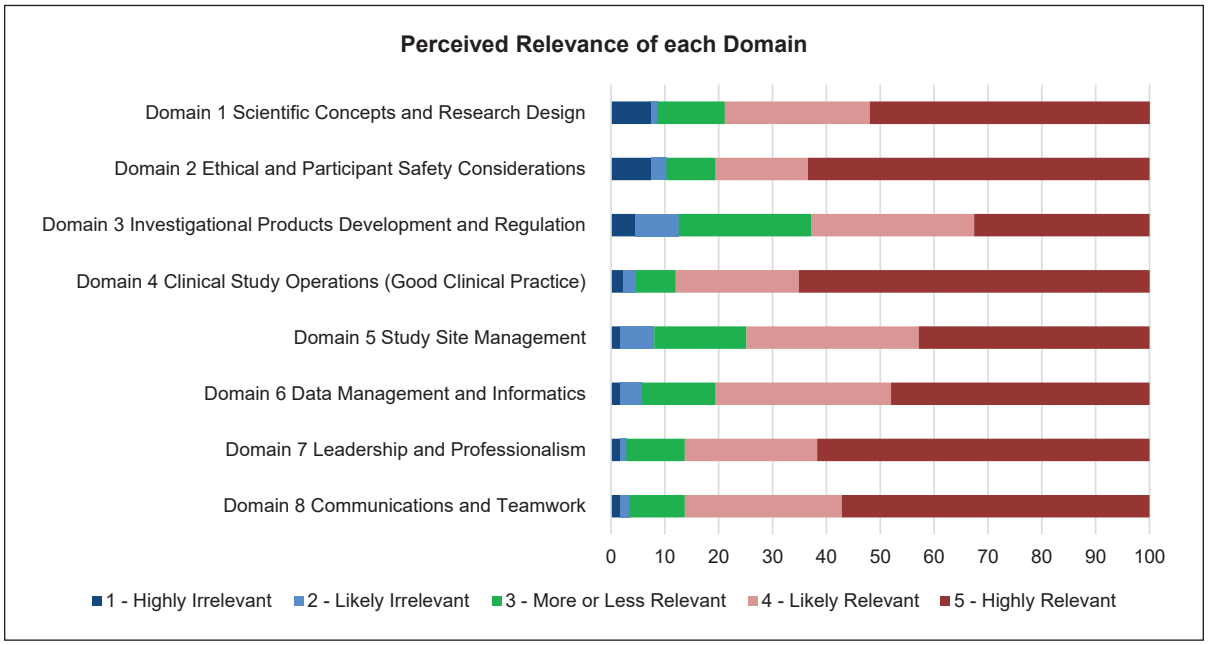

Figure 2. Perceived relevance for each domain.

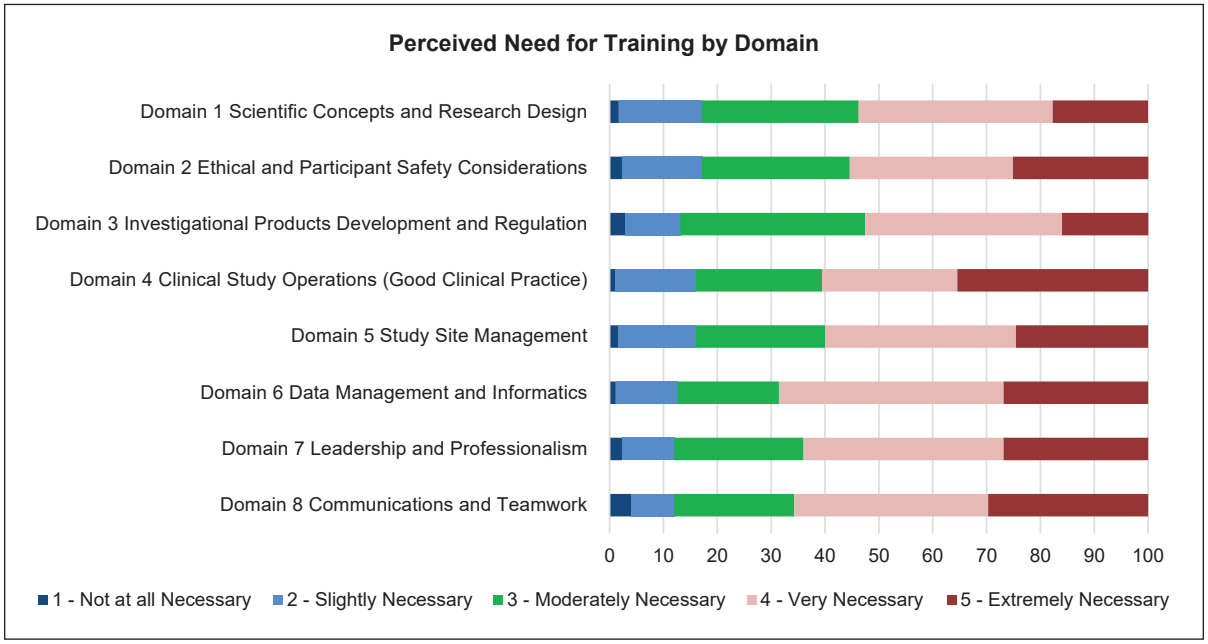

Figure 3. Perceived training need for each domain.

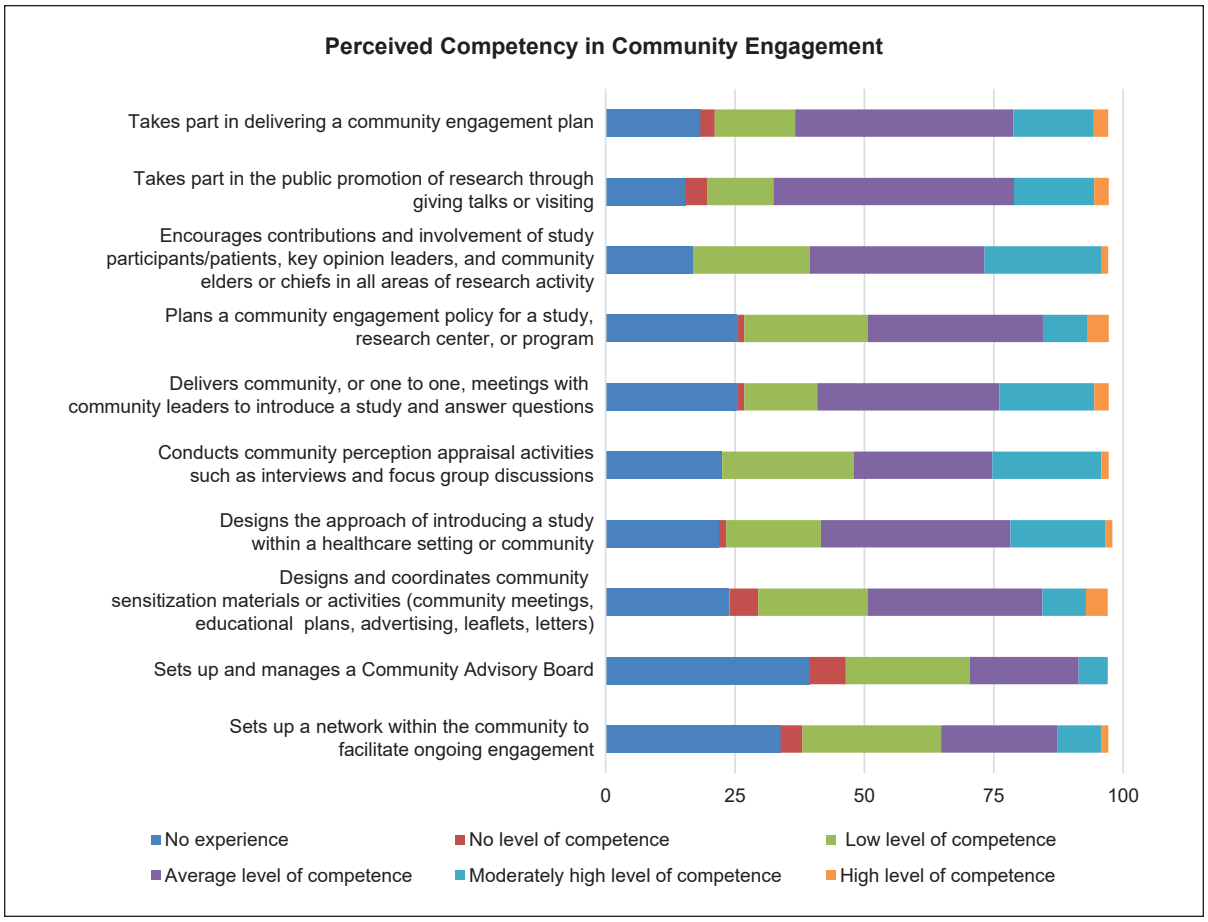

Figure 4. Perceived competency in community engagement.

Two investigators (2.8%) answered "not applicable" and were not included in the bar graph.

Competency on Community Engagement and Applying for Research Grant

Seventy-one (71) principal investigators answered regarding their competency in community engagement and applying for research funding support. Two respondents (2.8%) answered "not applicable" for all the domains of community engagement, while one answered the same specifically for "writes and submits grant application for significant research project or program" under the Research Funding application competency. Most investigators (n=30, 42%) rated their competency on community engagement tasks as "Average," with the exception of Setting up a network within the community, and Setting up and managing a Community Advisory Board, which a majority had no experience with. On the other hand, the activities that had the highest "Average" competence were participating in a community engagement plan and public promotion of research (Figure 4).

The majority of the respondents scored themselves at an average to moderately high level of competence in terms of planning their budget, writing or contributing to the writing, and submitting the proposal to funding agencies (Figure 5).

DISCUSSION

Surveyed Filipino CRPs rated themselves "skilled" across all competency domains in conducting clinical research; however, none of the domains were assessed at an advanced level. They expressed the lowest confidence in study and site management, investigational product development and regulation, and data management and informatics. Conversely, respondents demonstrated greater confidence in competencies such as ethical and participant safety considerations, leadership and professionalism, and communications and teamwork.

Investigators who participated in the survey reported the lowest confidence in their competency in scientific concepts and research design, despite recognizing its critical relevance to their work. This finding is particularly concerning given the Philippines' aspiring role in global clinical research and highlights the unique challenges faced by local investigators. In contrast, a global study conducted in 2020 involving 661 participants across multiple countries found that primary investigators demonstrated higher confidence in this domain, highlighting a disparity that underscores the need

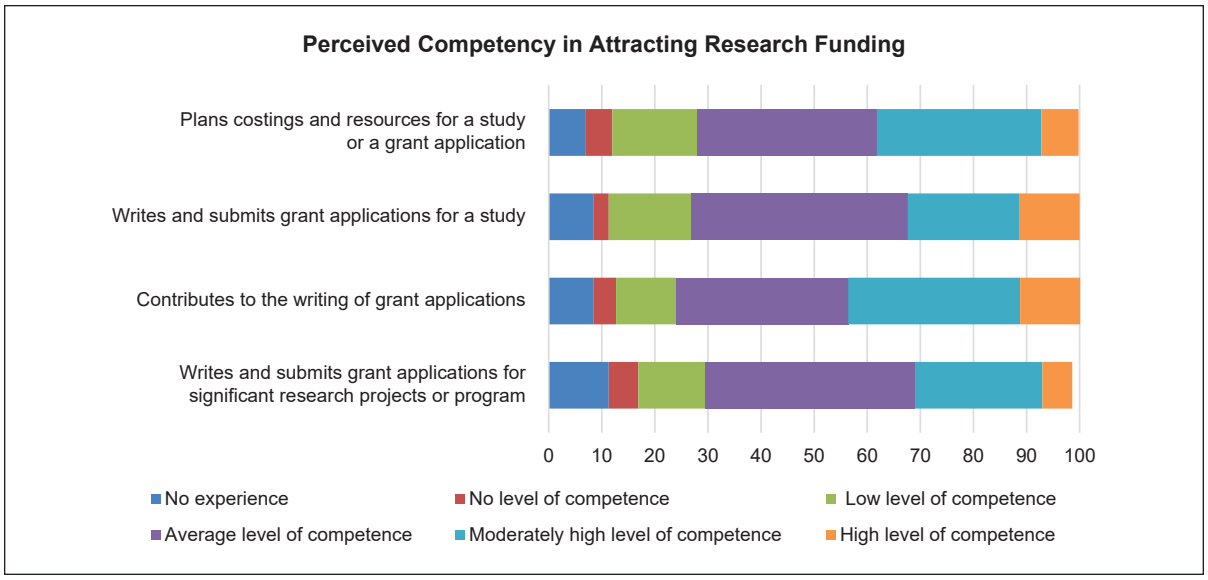

Figure 5. Perceived competency on research funding application.

One respondent answered "not applicable" and was not included in the bar graph.

for targeted capacity-building efforts in the Philippines.[14] The implications of these competency gaps are significant for the local context. Protocol violations, often linked to gaps in competency in research design and execution, have been reported in 40% of non-US clinical trials.[15] Moreover, protocol deviations in phase 2 and phase 3 clinical trials—observed in 27% to 46% of studies across major disease categories—further highlight the risks associated with insufficient competency in this critical area.[16]

In 2022, 80% of clinical trials done in the Philippines were sponsored by pharmaceutical companies.[17] Industry-sponsored trials (ISTs) because of a larger operational fund, are able to hire different scientific and management experts, including clinical research organizations, to design and implement their clinical trials.[18] Investigators who are used to doing trials that are IST may not be as confident in their ability to design a clinical trial and may explain the low confidence of investigators in this domain. A survey of health research professionals involved in a global network of academic research institutions found that investigator-led trials often face problems with knowledge and experience in the conduct of clinical trials as compared to industry-sponsored trials (ISTs).[18] To overcome this problem, the same study recommends that investigators should ask for support from academic research institutions to deliver a quality trial.

Philippine legislation requires the protection of human research participants, which includes mandatory ethics training for all researchers, including Clinical Research Personnel (CRPs). This training is designed to ensure that researchers adhere to ethical obligations and follow guidelines for responsible conduct in research. A higher score in this area indicates the effectiveness of mandatory ethics training.[14]

Most respondents considered investigational product development and regulation to be irrelevant to their work, which likely contributed to their low self-assessed competency in this area. These align with findings from other studies.[14,19,20] While the Philippines is seen as an attractive pharmaceutical market in the ASEAN region, the focus has mostly been on compounding and manufacturing existing drugs. However, recent efforts like the Tuklas Lunas Program of the Philippine Council for Health Research and Development (PCHRD), which leverages the country's biodiversity for drug discovery, aim to change this focus.[21,22] The WHO emphasizes that a lack of competency in investigational product development and regulation can hinder clinical trial quality and efficiency, especially in meeting regulatory requirements and avoiding delays.[4] ICH GCP E6 R2 includes investigational product manufacturing, handling, and storage as key components of GCP principles. Even for Multi-Regional Clinical Trials (MRCTs), CRPs must understand Good Manufacturing Practices (GMP) and regulatory processes, as these directly impact clinical trial operations and quality.[23] This gap highlights the need for specialized training to improve CRPs' understanding of regulatory principles and enhance their contribution to global clinical research practices.[4,20]

Filipino participants in the survey recognize the importance of adhering to the principles of GCP in running clinical research. Self-assessed competency on Clinical Study Operations is skilled across all roles, with a general agreement of its relevance and need for continuous training. Clinical study operations encompass multiple aspects of the life cycle of a clinical trial, hence a need to continually improve on this.[4]

Recognizing the importance of project management, the Joint Task Force (JTF) Core Competency Framework was revised in 2020 to incorporate project management

competencies.[24] These updates emphasize the role of performance optimization, resource utilization, and strategic oversight in enhancing trial execution and aligning with global standards. Similar studies highlight the growing role of project management competencies, particularly in resource-limited settings.[14,20] Our findings reinforce the need to train Filipino CRPs in project management as they reported average competency in managing budgets, resources, and timelines effectively.

On average, the surveyed CRPs assessed themselves as skilled in Data Management and Informatics, with biostatisticians rating themselves with advanced skills. Biostatisticians are often delegated the task of defining what relevant data to collect and the best statistical analysis plan to interpret them. However, there is recognition that data management is more than just statistical analysis. Data management is an integral part of any clinical research as it dictates the quality of clinical research results.[25] Additionally, there is a global call for making data transparent and available to the scientific community. As such, all aspects of the data life cycle must be planned meticulously.[4,26] This may be why this domain had the highest perceived need for additional training. This result is also in line with the result of Sonstein et al., who showed that this domain is one of the skills that CRP feels is the least competent in.[14] Funders are now looking at Data Management Plans to ensure they adhere to quality and data-sharing principles, highlighting the need for all CRPs to be knowledgeable about them.[26,27]

Respondent Filipino CRPs acknowledged the importance of leadership and communication, especially since inequities in leadership within clinical trials, particularly in low- and middle-income countries (LMICs), remain a persistent barrier to conducting high-quality clinical research.[4] This underscores the critical need to cultivate local leaders in clinical research who can navigate the unique challenges of their settings. Despite this, there is a notable lack of training initiatives focused on leadership and communication, further exacerbating the need.[28]

The WHO emphasizes the importance of patient and community involvement in the planning and implementation of clinical trials, as these practices enhance transparency, relevance, and participant retention.[4] Weaknesses in community engagement were evident in tasks like establishing advisory boards and networks, which Filipino investigators rated as areas of low competence. These gaps highlight the critical need for capacity building in this domain to improve trial execution and adherence to protocols.[4]

The self-assessed competency levels of participating Filipino CRPs in grant application tasks reveal that while many rate themselves as having average to moderately high competence, there is room for improvement in advanced tasks, such as writing and submitting grant applications for significant research projects or programs. WHO emphasizes the critical role of grant-writing skills in securing research funding, particularly in regions with limited resources. Grant applications are not only essential for sustaining clinical research activities but also for fostering innovation and addressing region-specific health challenges.[4]

To address gaps in research grant applications, the WHO advocates for tailored training programs focused on financial planning, proposal development, and submission processes. These programs should include practical, scenario-based exercises to enhance CRPs' ability to develop competitive grant proposals. Additionally, mentorship initiatives that pair less experienced CRPs with skilled grant writers can provide valuable guidance and support, fostering both skill development and confidence.[4] By strengthening these competencies, Filipino CRPs can enhance their capacity to secure funding, align with international standards, and contribute to the sustainability and growth of clinical research in the Philippines

To the best of our knowledge, this study was the first to measure the self-assessed competency of CRP in the Philippines using the JTF Clinical Research Competency Framework. The results of this study are vital information that can enhance future trainings i.e., development of modules for global competencies required for the conduct of clinical studies in addition to the required ICH-GCP training. Moreover, given that the Philippines is often involved in multiregional clinical trials, institutionalizing or certification of professionals using a global framework, although not required or mandated by law, can add value by ensuring that our clinical research professionals are equipped with the minimum required skills that are not only at par with international standards but also ensure high-quality conduct of clinical studies.

Our study poses several limitations that may affect the generalizability of the findings to the broader population of clinical research professionals (CRPs) in the Philippines. The majority of respondents were recruited through academic networks and referrals, which likely led to an overrepresentation of experienced CRPs—40% reported more than 10 years of experience in clinical research and 36.4% in clinical trials. This may have resulted in an overestimation of self-assessed competency levels.

Although the questionnaire was adapted from an internationally recognized and widely published framework (the Joint Task Force Clinical Research Competency Framework), it was not subjected to formal reliability or validity testing in the local context. While pretesting with four Filipino CRPs was conducted to improve clarity and contextual appropriateness, further psychometric validation is recommended for future use.

The assessment relied on self-reported measures of competency, relevance, and training needs using a 10-point Likert scale. Although the scale was aligned with the JTF's three competency levels (fundamental, skilled, and advanced), it lacked detailed descriptors for each point, which may have introduced subjectivity, variability, and measurement error. Self-assessment is also inherently susceptible to biases such

as social desirability. Additionally, while Likert-scale data are ordinal in nature, we summarized responses using means and standard deviations to align with established reporting practices in prior MRCT studies. However, this choice may introduce limitations in interpretation and does not capture distributional skew, which could have been better reflected using medians and interquartile ranges

The use of non-probability, snowball sampling, and reliance on professional networks may have introduced selection bias and limited representativeness, particularly for CRPs outside academic or formal institutional affiliations. While the survey platform was configured to limit responses to one per device or session, the risk of duplicate responses or uneven demographic coverage could not be completely ruled out.

Finally, 12% of respondents selected "Other" for their professional role, but the closed-response format of the questionnaire did not allow for further specification. This limited our ability to fully interpret role-related differences in perceived competency, which is a key dimension in competency analysis.

CONCLUSION AND RECOMMENDATIONS

This study offers a comprehensive assessment of the self-perceived competencies of a sample of Filipino CRPs using the JTF Clinical Research Competency Framework. The findings highlight strengths and areas requiring improvement, particularly in study and site management, investigational product development and regulation, and data management. Addressing these gaps through targeted, competency-based training programs is critical to enhancing the capacity and professionalism of Filipino CRPs. These programs should encompass training modules in research concepts and design, regulatory compliance, data management, site management, research grant applications, and community engagement.

With its growing population and significant burden of communicable and non-communicable diseases, the Philippines presents a potentially valuable environment for conducting diverse and impactful clinical trials. Strengthening the competencies of Filipino CRPs will enable the country to contribute to culturally diverse research, support global research priorities, improve trial quality, and foster international research partnerships.

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Statement of Authorship

All authors certified fulfillment of ICMJE authorship criteria.

Author Disclosure

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