

Initial Analysis of the Self-assessed Competency Survey among Clinical Research Professionals in Low- and Middle Income Countries: Philippine Data



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Disclosure

- Project development officer and project lead in the National Clinical Trials and Translation Center
- Research faculty of the Institute of Clinical Epidemiology
- Involved in the development of various national CPGs (DOH-funded, society-funded) as project lead, project manager, and/or technical working group member.

“Medical research involving human subjects must be conducted only by individuals with the appropriate ethics and scientific education, training and qualifications...”

DECLARATION OF HELSINKI 2013





Joint Task Force for Clinical Trial Competency, 2014

Academy of Physicians in Clinical Research
Association of Clinical Research Professionals
Amgen
Alliance for Clinical Research
Excellence and Safety Clinical & Translational
Science Awards
Clinical Trials Transformation Initiative
Collaborative Institutional Training Initiative
Consortium of Academic Programs in Clinical
Research
Deloitte
Drug Information Association
Global Health Network
Inter-American Foundation for Clinical
Research
International Academy of Clinical Research
International Federation of Associations of
Pharmaceutical Physicians
Korea National Enterprise for Clinical Trials
MAGI
Multi-Regional Clinical Trial Center
Pfizer
PharmaTrain
TransCelerate Biopharma, Inc.
UK Clinical Research Collaboration

Moving from Compliance to Competency: *A Harmonized Core Competency Framework for the Clinical Research Professional*

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Rebecca Li, PhD | Honorio Silva, MD | Carolynn Thomas Jones, DNP, MSPH, RN |
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Additional information:

<https://mrctcenter.org/clinical-trial-competency/>

JTF Core Competency Framework

8 Competency Domains
47 leveled competency statements categorized per domain
3 levels: fundamental, skilled, advanced



JTF Core Competency Framework

Competency Domains



1. Scientific Concepts and Research Design
2. Ethical and Participant Safety Considerations
3. Investigational Products Development and Regulation
4. Clinical Study Operations (Good Clinical Practice)
5. Study and Site Management
6. Data Management and Informatics
7. Leadership and Professionalism
8. Communications and Teamwork

JTF Core Competency Framework

Example:

1. Scientific Concepts and Research Design

Fundamental Level

1.1 Recognize the need to apply scientific principles to studies

Skilled Level

1.2 Identify parameters or endpoints that will be used in data analysis

Advance Level

1.3 Develop protocol or source...



JTF Core Competency Framework

USES

1. Education
2. Job descriptions
3. Site qualification
4. Investigator selection
5. Development of accreditation standards
6. Training requirements



Competency survey in Low- and Middle Income Countries

- Study objectives:
 - To investigate the competency level of clinical research professionals
 - To investigate the relationship between each competency and job function
 - To investigate the training needs of each competency
- Participating countries: Indonesia, Democratic Republic of Congo, Philippines, Thailand and Vietnam



Acknowledgement

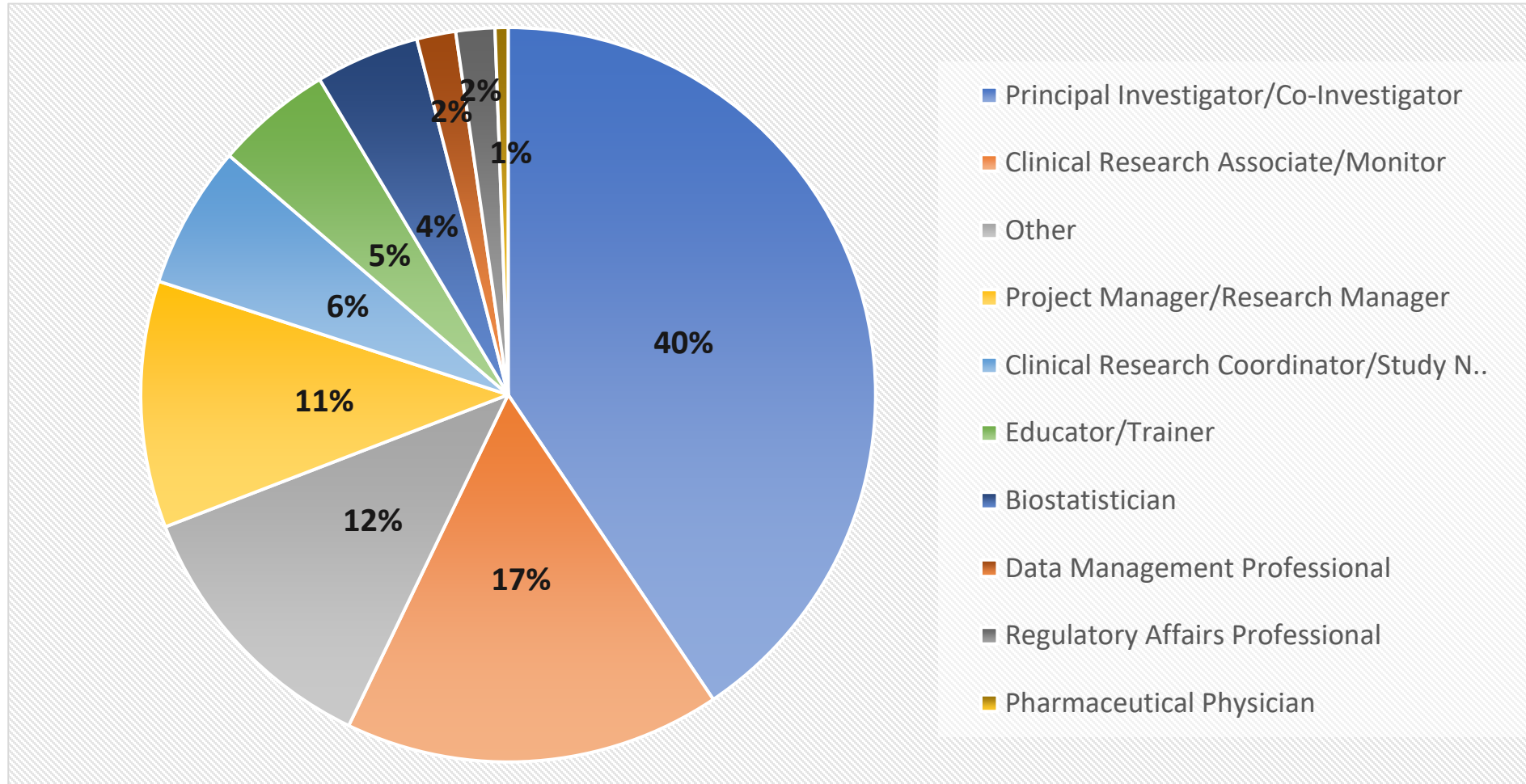
- Miwa Sonoda and National Center Global Health and Medicine
- Multiregional Clinical Trials Center, Brigham and Women's Hospital, Harvard Medical School
- Philippine Clinical Research Professionals Inc

Self-assessed Competency Survey among Clinical Research Professionals in the Philippines

- E-survey using the JTF Core Competency Framework for Clinical Research Professionals.¹
- Snowball sampling
- 175 clinical research professionals were able to complete the survey.

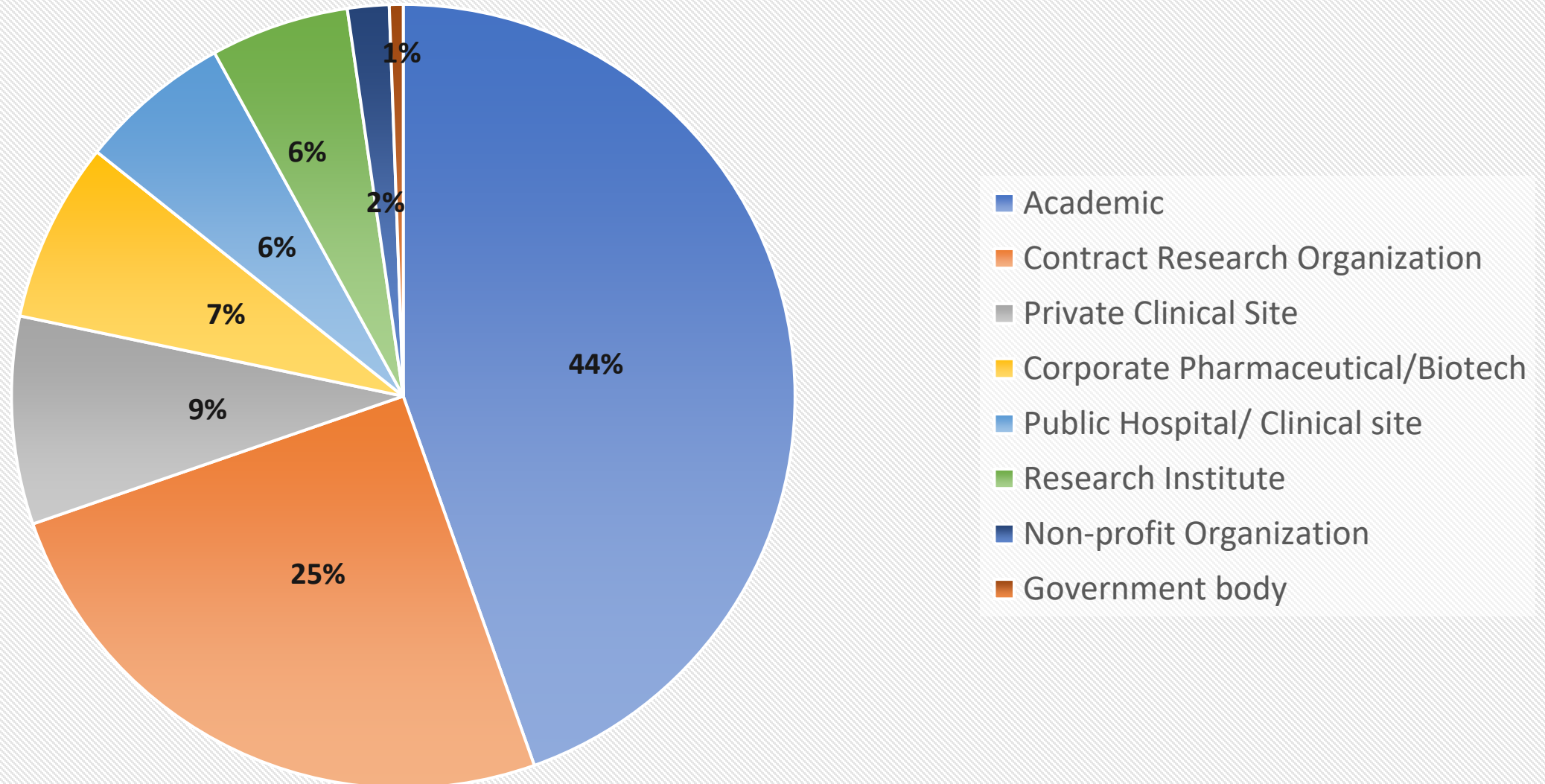
Stephen A. Sonstein, PhD; Jonathan Seltzer, MD, MBA, MA, FACC; Rebecca Li, PhD; Honorio Silva, MD;Carolynn Thomas Jones, DNP, MSPH, RN; Esther Daemen, BSN, PG, PMP, MBA. **Moving from Compliance to Competency: A Harmonized Core Competency Framework for the Clinical Research Professional.** Journal of Clinical Research Best Practices. 10(6) 2014

Participants' Profile (n=175)



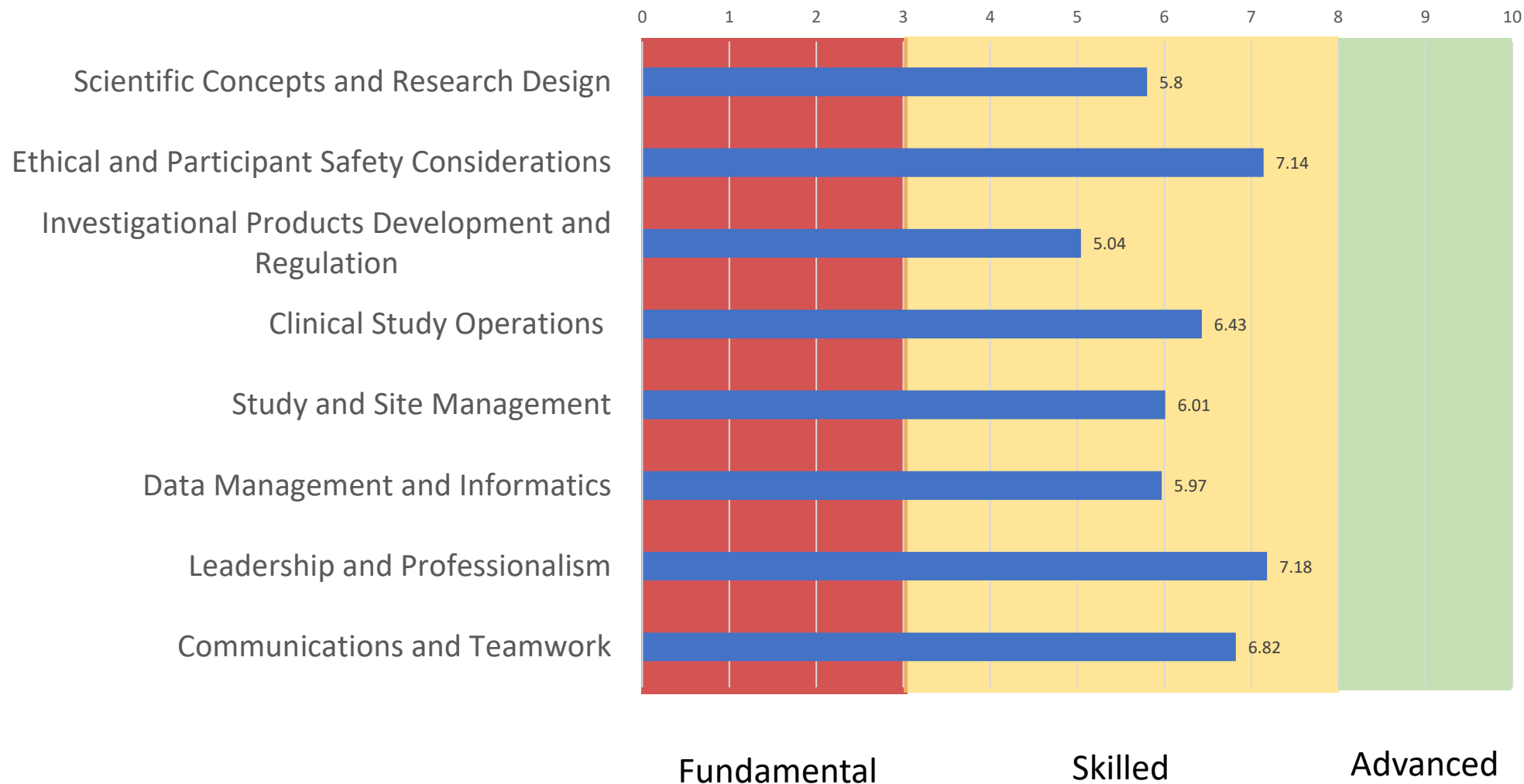
Source: Cabaluna I., Sonoda M., Ruamero E. et al. 2022. Philippine Data on Self-Assessment of Clinical Research Competence: An Online Survey of Clinical Research Professionals in In Low- and Middle- Income Countries in Asia and Africa. Unpublished.

Participant's Primary Organization (n=175)





Competency Domains

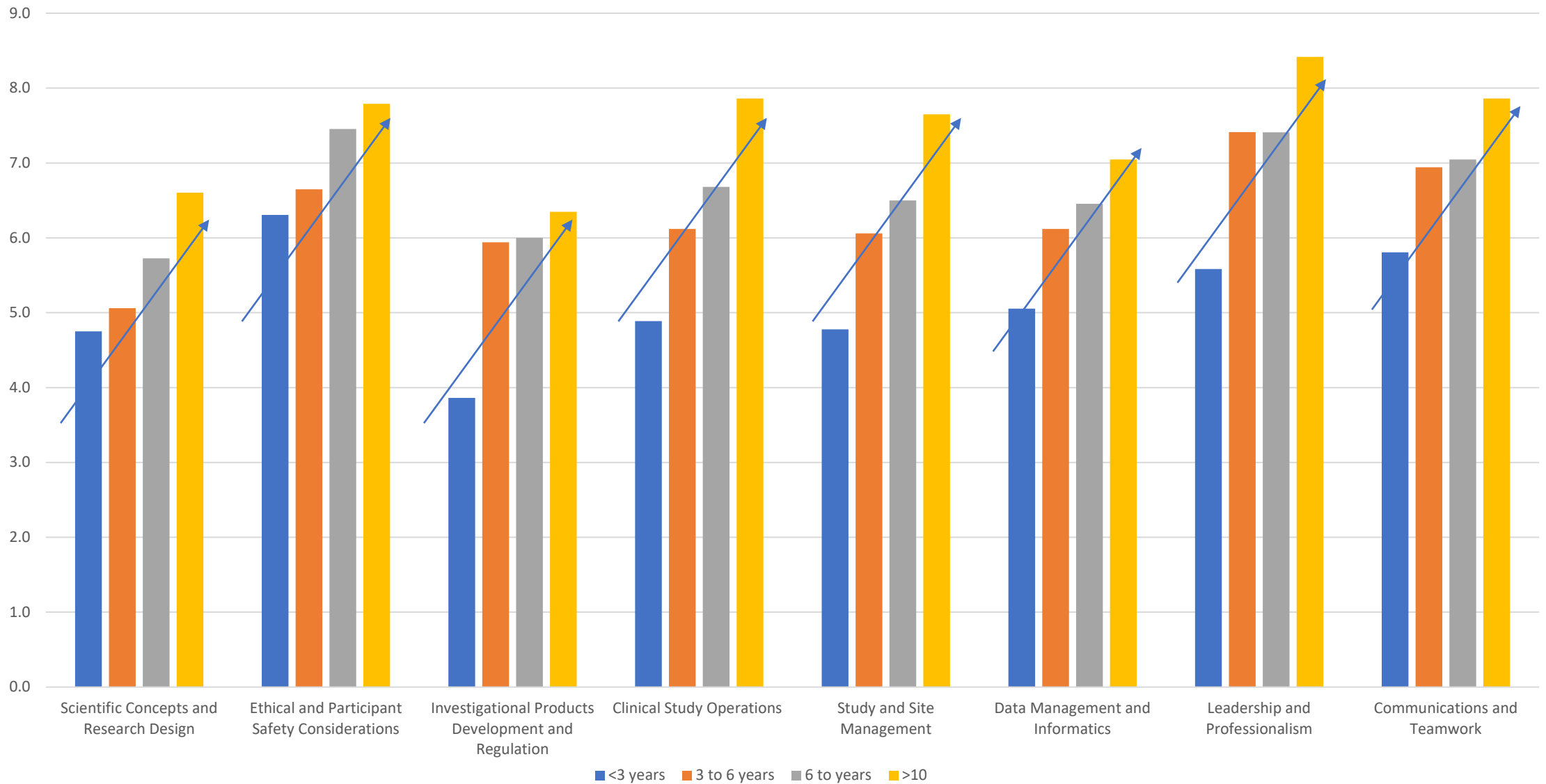


Self Assessed Competency Level



	Scientific Concepts and Research Design	Ethical and Participant Safety Considerations	Investigational Products Development and Regulation	Clinical Study Operations	Study and Site Management	Data Management and Informatics	Leadership and Professionalism	Communications and Teamwork
Principal Investigator/Co-Investigator	6.4	7.8	4.7	6.8	6.2	6.1	7.2	7.2
Clinical Research Associate/Monitor	4.4	6.3	5.0	6.2	6.2	5.2	6.8	6.3
Project Manager/Research Manager	6.4	7.7	6.7	7.4	7.4	7.0	8.3	8.1
Clinical Research Coordinator/Study Nurse	4.5	6.4	4.5	6.6	5.8	5.5	6.3	5.8
Educator/Trainer	6.0	7.4	4.1	5.4	4.4	5.7	6.6	5.6

Domain scores according to years of experience



Community Engagement

Community Engagement Activities	Scores (1-5)
Takes part in delivering a community engagement plan	2.32
Takes part in the public promotion of research through giving talks or visiting	2.3
Encourages contributions and involvement of study participants/patients, key opinion leaders, and community elders or chiefs in all areas of research activity	2.36
Plans a community engagement policy for a study, research center, or program	2.01
Delivers community, or one to one, meetings with community leaders to introduce a study and answer questions	2.16
Conducts community perception appraisal activities such as interviews and focus group discussions	2.17
Designs the approach of introducing a study within a healthcare setting or community	2.15
Designs and coordinates community sensitization materials or activities (community meetings, educational plans, advertising, leaflets, letters)	2.07
Sets up and manages a Community Advisory Board	1.42
Sets up a network within the community to facilitate ongoing engagement	1.71



TRAINING NEEDS



Source: Sonoda M., Cabaluna I., Ruamero E. et al. 2022. *Philippine Data on Self-Assessment of Clinical Research Competence: An Online Survey of Clinical Research Professionals in In Low- and Middle- Income Countries in Asia and Africa. Unpublished.*

Limitations

- **Not representative** of all clinical research professionals in the country.
- **Need to be validated** with objective measures.

Conclusion

- Clinical research professionals in the Philippines rated themselves as skilled but not advanced in doing clinical research.
- They scored higher on domains on 1. Leadership and Professionalism 2. Communications and Teamwork 3. Ethical and Participant Safety Considerations
- They scored lower on 1. Investigational Products Development and Regulation, 2. Data Management and Informatics, and 3. Scientific Concepts and Research Design
- The study identified areas where we can train our professionals.