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A pilot study to assess the validity of the Joint Task Force's Questionnaire for collection of data to be used in defining job descriptions, educational requirements, boundaries of practice, and promotion criteria for the clinical research enterprise

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A Pilot Study to Assess the Validity of the Joint Task Force's Questionnaire for Collection of Data to be Used in Defining Job Descriptions, Educational Requirements, Boundaries of Practice, and Promotion Criteria for the Clinical Research Enterprise

by

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Abstract

There is a movement in the clinical research community to define and develop core competencies for clinical research professionals. This pilot study was conducted to assess the validity of the Joint Task Force's Questionnaire as the appropriate tool for the collection of data to be used in defining job descriptions, educational requirements, boundaries of practice, and promotion criteria for the global clinical research enterprise. The respondents were academic clinical researchers with varying degrees of role responsibilities, experience, and exposure to industry-sponsored clinical trials versus grant-funded, investigator-initiated, and/or sponsor-investigator clinical research. Results from this pilot study validated the Joint Task Force's (JTF) questionnaire for collection of these types of data.

Table of Contents

Acknowledgments ii

Abstract iii

List of Tables v

List of Figures vi

Chapter 1. Introduction and Background 1

Chapter 2. Methods 2

Chapter 3. Results 3

Chapter 4. Discussion 21

Chapter 5. Conclusion 25

References 26

Appendix A Sample Joint Task Force Survey Form 27

List of Tables

Table		Page
1	Demographic Information for Study Participants	3
2	Descriptive Statistics for Competence and Significance Scales	5
3	Description and Frequencies of Profession Groups	8
4	Univariate Effects for Differences in Reported Competence by Current Position	13
5	Univariate Effects for Differences in Reported Significance by Current Position	14
6	Post hoc Follow-up Tests for the Effects of Current Position on Reported Competence in Scientific Concepts and Research Design	15
7	Post hoc Follow-up Tests for the Effects of Current Position on Reported Significance of Scientific Concepts and Research Design to Current Job Responsibilities	15

List of Figures

Figure		Page
1	Boxplot of competency ratings by current position group	9
2	Boxplot of significance ratings by current position group	10
3	Boxplot of competence ratings by whether one has a clinical research degree	11
4	Boxplot of significance ratings by whether one has a clinical research degree	12
5	Boxplot of last valid questionnaire item by current position group	17
6	Boxplot of last valid questionnaire item by whether one has a clinical research degree	18
7	Bar graph of questionnaire completion by current position	19
8	Bar graph of questionnaire completion by whether one has a clinical research degree	20

Chapter 1. Introduction and Background

"Medicines development and clinical research are among the most heavily regulated activities on a global basis" (Sonstein et al., 2014). Until the past decade, clinical research professionals had few academic degree options to obtain a knowledge base or a basic level of competency (Sonstein et al., 2014). Most employed in clinical research positions obtained their training through employer training programs, professional society certifications, attending professional conferences, or from just being on the job. Complexity of clinical trials (study procedures, data collection, regulatory submission requirements, etc.) has increased over the years (James et al., 2011), and the clinical research community and regulators have been assessing the need for change in how clinical research professionals become competent in medicines development and clinical research. "The latest version of the Declaration of Helsinki, dated October 2013, now states that 'medical research must be conducted by individuals with appropriate training and qualification in clinical research'" (Sonstein et al., 2014). There is a movement in the clinical research community to define and develop core competencies for clinical research professionals. The Joint Task Force for Clinical Trial Competency has developed a Core Competency Framework to be used by the research community as a foundation (Sonstein et al., 2014). This pilot study was conducted to assess the validity of the Joint Task Force's questionnaire as the appropriate tool for the collection of data to be used in defining job descriptions, educational requirements, boundaries of practice, and promotion criteria for the global clinical research enterprise.

Chapter 2. Methods

The JFT questionnaire was distributed to academic clinical research professionals at the University of Michigan (UM). Approval for the study protocol, informed consent, and survey questionnaire was obtained first from the Eastern Michigan University's (EMU) Human Subjects Review Committee. Once approval was granted by the committee, the study documents were submitted to UM's Investigational Review Board via UM's eResearch proposal system. The UM IRB determined that the study was exempt from their review.

The survey included demographic questions and a self-assessment questionnaire (Appendix A) based upon the Competency Framework for the Clinical Research Professional developed by the Joint Task Force for Clinical Trial Competence and the Consortium of Academic Programs in Clinical Research. An electronic consent and the survey were distributed to the UM clinical research staff using the University of Michigan (UM) Study Coordinator Highlights Newsletter and email distribution lists to clinical research professionals within the UM health system. The UM Study Coordinator Highlights Newsletter is distributed weekly by Michigan Clinical Health Research (MICHR) education coordinators via a centralized study coordinator email distribution list.

The survey was included in the newsletter for weekly distribution over the course of three months (September 2014 to November 2014). The timing of emailing the survey to other UM clinical research professionals coincided with the initial distribution of the newsletter with reminders sent in October and November 2014. The survey was closed December 15, 2014, with 117 respondents.

Chapter 3. Results

Demographic information is presented in Table 1. Eighty-six percent of participants were female, 11% were male, and 3% did not respond to the gender question. Ninety-one percent of participants consider their race to be White, 5% Black, and 4% Asian. At the time of data collection, the terminal degree of 2% was a high school diploma; 3%, a post-baccalaureate certificate; 4%, an associate's degree; 40%, a bachelor's degree; 40%, a master's degree; 4%, a PhD or DSc; 5%, an MD, DO, or DDS; and 2%, a PharmD. Seventy-six percent endorsed participation in education or training related to clinical research, and participants ranged in terms of years employed in clinical research: 2%, never; 11%, less than 2 years; 21%, 2–5 years; 31%, 5–10 years; 26%, 10–20 years; and 9%, more than 20 years.

Table 1

Demographic Information for Study Participants

	Frequency	Percent
Gender		
Male	13	11.5
Female	100	88.5
Race		
White	98	90.7
African American	6	5.6
Asian	4	3.7
Degree		
HS diploma	2	1.8
Post baccalaureate certificate	3	2.7
Associates degree	4	3.6
BA/BS	45	40.2
MS/MA/MBA	45	40.2
PhD/DSc	5	4.5
MD/DO/DDS	6	5.4
PharmD	2	1.8
Participation in education/training		
Yes	86	76.0
No	27	24.0
Years of experience		
None	2	1.8
<2 years	13	11.5
2 - 5 years	24	21.2
5 - 10 years	35	31.0
10 - 20 years	29	25.7
20+ years	10	8.8

The core competency questionnaire was composed of 51 items that are rated twice: first to assess self-reported competence and again to assess self-reported significance to current job responsibilities. The 51 items are classified into eight domains: scientific concepts and research design (5 items), ethical and participant safety considerations (8 items), medicines development and regulation (7 items), clinical trials operations (12 items), study and site management (6 items), data management and informatics (5 items), leadership and professionalism (4 items), and communication and teamwork (4 items). The competence level for each item is rated on a 6-point Likert scale from 0 (Not Applicable) to 5 (Mastery). Items on the competence scale were re-scaled into a 5-point scale so that items rated "Not Applicable" were treated as missing and not included in the total. Significance items are scored on a 6-point Likert scale from 0 (Unnecessary) to 5 (Essential).

Two variables were created to capture patterns of missing data on the core competency questionnaire. The first variable, an indicator of the last item responded to on the questionnaire, was created by examining the responses of each participant and manually entering in the number of the last item responded to on the questionnaire. The last completed item ranged from 0 (no items completed) to 104 (last item completed). Seventeen percent of participants did not complete any items on the survey. The second missing data variable was a dichotomous variable indicating whether the participant completed the questionnaire. Participants were coded "1" if they completed the questionnaire, even if they did not respond to all items, and "0" if they terminated the questionnaire before completing all items. Sixty-two percent of participants completed the questionnaire, and 38% terminated the questionnaire early.

Prior to analyses, data were cleaned and examined for missing data, central tendency, and issues of skew and kurtosis. Descriptive statistics for the competence and significance scales are

presented in Table 2.

Table 2

Descriptive Statistics for Competence and Significance Scales

Scale description	N	M	SD	α	Range		Skew	Kurtosis
					Potential	Actual		
Scientific concepts and research design								
Competence	50	1.76	1.03	.85	0.00-4.00	0.00-4.00	0.79	-0.91
Significance to current position	91	1.72	1.30	.84	0.00-5.00	0.00-5.00	2.66	-0.78
Ethical and participant safety considerations								
Competence	43	2.70	0.69	.81	0.00-4.00	1.00-4.00	-0.28	-0.13
Significance to current position	76	2.84	1.21	.86	0.00-5.00	0.00-5.00	-1.34	-1.19
Medicines development and regulation								
Competence	50	2.14	1.01	.93	0.00-4.00	0.00-4.00	-0.31	-0.53
Significance to current position	74	1.68	1.42	.94	0.00-5.00	0.00-5.00	1.85	-1.53
Clinical trials operations								
Competence	51	2.51	0.84	.94	0.00-4.00	0.00-4.00	-2.24	1.23
Significance to current position	65	2.80	1.22	.93	0.00-5.00	0.00-5.00	-0.79	-0.80

Table 2 Continued

Scale description	N	M	SD	α	Range		Skew	Kurtosis
					Potential	Actual		
Study and site management								
Competence	52	2.37	0.99	.88	0.00-4.00	0.50-4.00	-0.37	-1.46
Significance to current position	67	2.67	1.34	.86	0.00-5.00	0.00-5.00	-0.04	-1.65
Data management and informatics								
Competence	56	2.40	1.01	.86	0.00-4.00	0.00-4.00	-1.69	-0.61
Significance to current position	64	2.80	1.32	.84	0.00-5.00	0.00-5.00	-0.40	-1.49
Leadership and professionalism								
Competence	62	2.50	1.02	.87	0.00-4.00	0.00-4.00	-1.51	-0.38
Significance to current position	66	3.12	1.45	.89	0.00-5.00	0.00-5.00	-1.45	-1.30
Communication and teamwork								
Competence	60	2.39	0.98	.75	0.00-4.00	0.25-4.00	-0.88	-1.31
Significance to current position	66	2.83	1.33	.78	0.00-5.00	0.00-5.00	-0.32	-1.48

A considerable amount of missing data increased in later parts of the survey. More specifically, retention rates, which were examined by dividing the number of participants who completed all items for a given domain by the total number of participants (117), decreased from 78% for the scientific concepts and research design scale at the beginning of the survey to 57% for the communication and teamwork scale at the end of the survey. Skew and kurtosis values

were considered acceptable if the absolute value fell below 2.00. No substantial deviations from normality were found. Cronbach's alpha, a measure of internal consistency, was examined to determine the reliability of each scale. The scales demonstrated adequate reliability for competence (scientific concepts and research design, $\alpha = .85$; ethical and participant safety considerations, $\alpha = .81$; medicines development and regulation, $\alpha = .93$; clinical trials operations, $\alpha = .94$; study and site management, $\alpha = .88$; data management and informatics, $\alpha = .86$; leadership and professionalism, $\alpha = .87$; and communication and teamwork, $\alpha = .75$). The significance subscales also demonstrated high reliability (scientific concepts and research design, $\alpha = .84$; ethical and participant safety considerations, $\alpha = .86$; medicines development and regulation, $\alpha = .94$; clinical trials operations, $\alpha = .93$; study and site management, $\alpha = .86$; data management and informatics, $\alpha = .84$; leadership and professionalism, $\alpha = .89$; and communication and teamwork, $\alpha = .78$).

Multivariate analysis of variance (MANOVA) was used to test for differences first on the competence scales and then, as a separate analysis, on the significance scales. The independent variables were current position and whether participants held a clinical research degree. The current position variable was created by classifying participants into three groups based on their current reported profession (see Table 3).

Table 3

Description and Frequencies of Profession Groups

	n	%
Group 1	7	6.0
Principal Investigator		
Physician Co-investigator		
Co-investigator		
Group 2	25	22.5
Financial Specialist		
Financial Consultant		
IRB		
Research Lab Specialist		
Biostatistician		
Educator/Trainer		
Research Pharmacist		
Clinical Research Monitor		
Project Manager		
Clinical Research Project Manager		
Project Coordinator		
Group 3	79	71.2
Research Administrator/Manager		
Clinical Research Coordinator		
Regulatory Affairs Professional		
Data Management Professional		
Research Area Specialist		
Research Nurse		
Research Associate		
Research Area Specialist/Project Coordinator		
Research Process Coordinator		

Group 1 included principle investigators, physician co-investigators, and co-investigators (n = 7). Group 2 included financial specialists, financial consultants, IRB positions, research lab specialists, biostatisticians, educators/trainers, research pharmacists, clinical research monitors,

project managers, clinical research project managers, and project coordinators (n = 25). Group 3 included research administrators/managers, clinical research coordinators, regulatory affairs professionals, data management professionals, research area specialists, research nurses, research associates, research area specialists/project coordinators, and research process coordinators. Boxplots of the differences in reported competence and significance by current position group are presented in Figures 1 and 2.

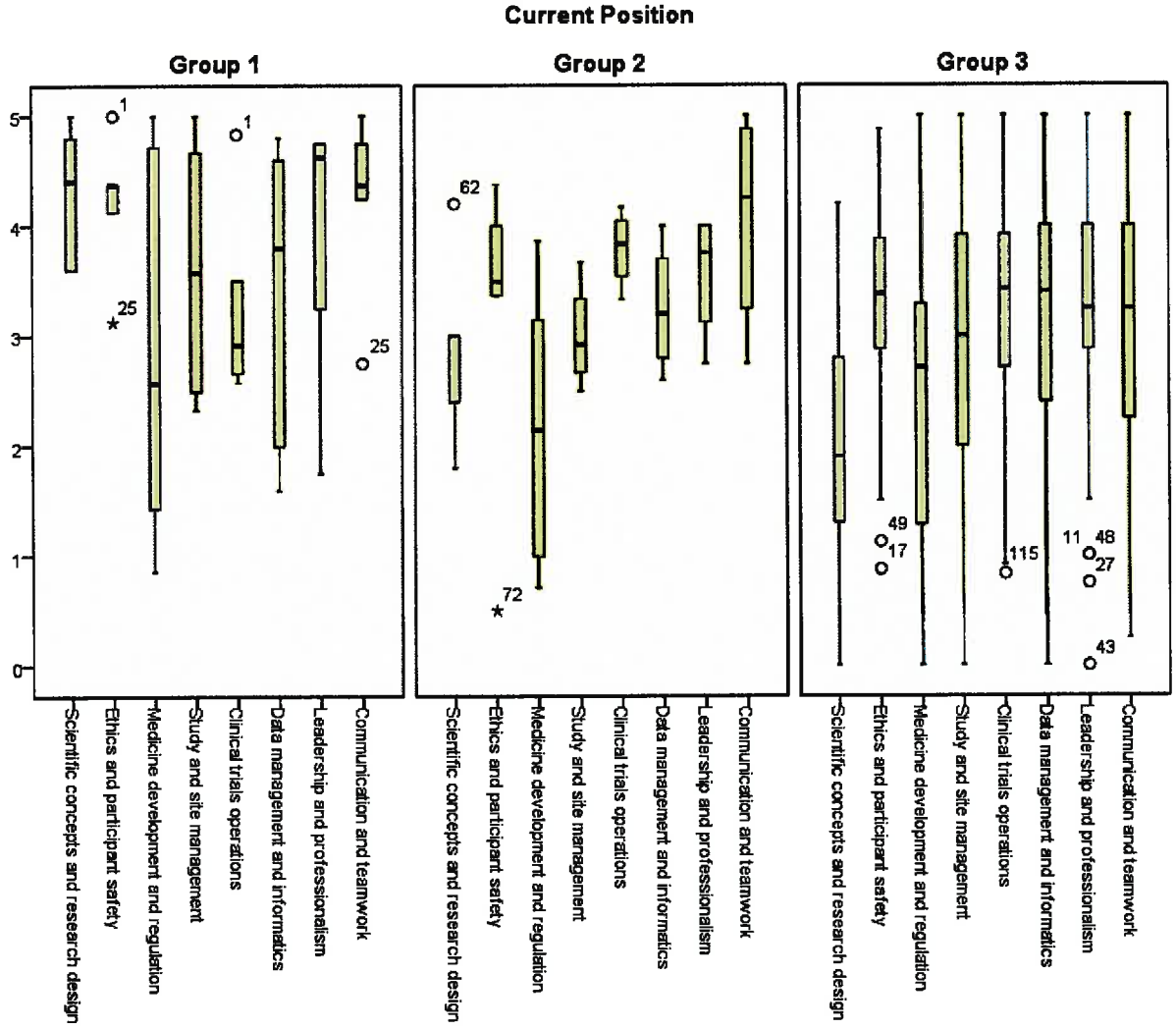

Figure 1. Boxplot of competency ratings by current position group.

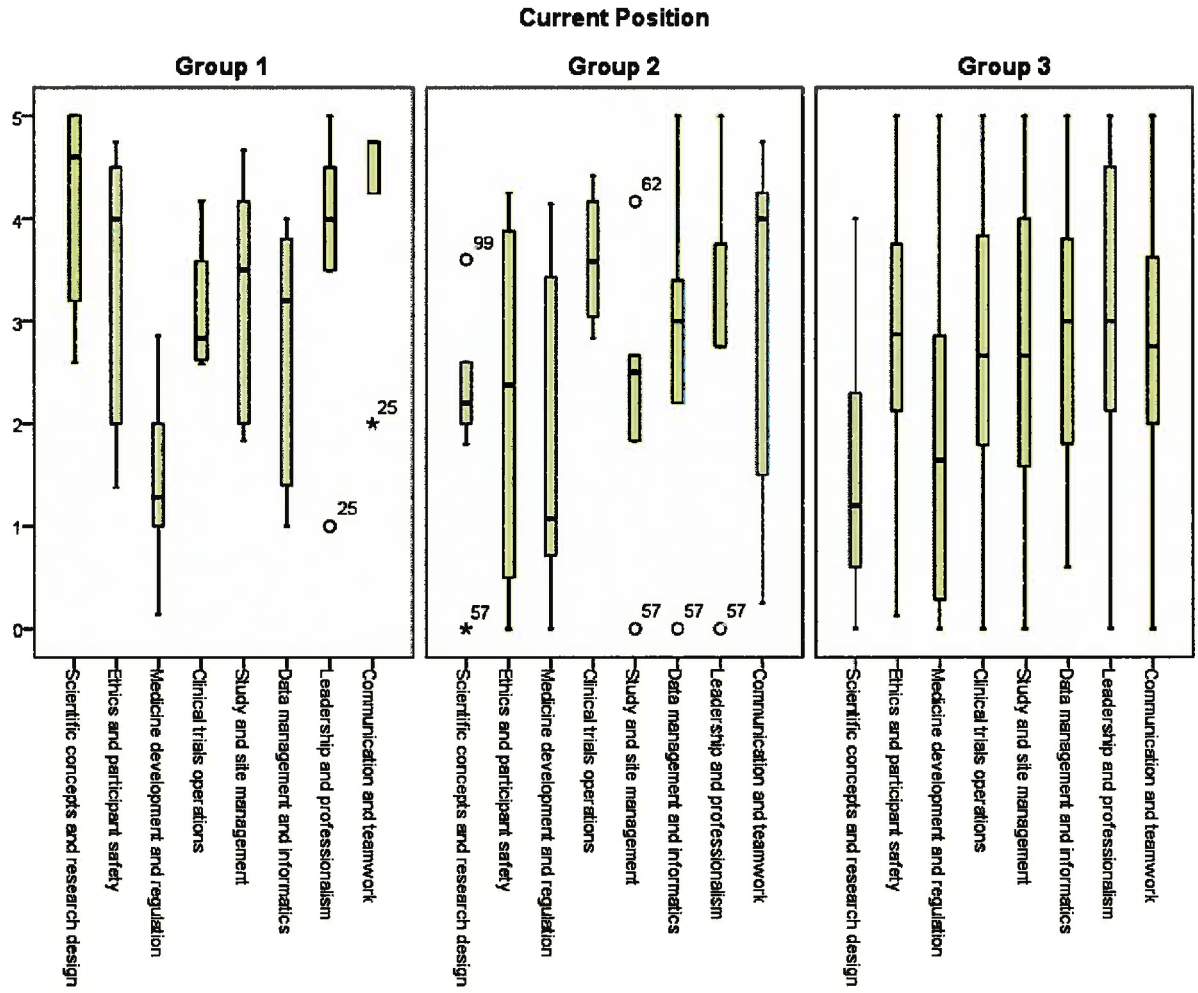

Figure 2. Boxplot of significance ratings by current position group.

Whether participants hold a clinical research degree was assessed dichotomously (Yes or No). Boxplots of the differences in reported competence and significance by whether participants hold a clinical research degree are presented in Figures 3 and 4.

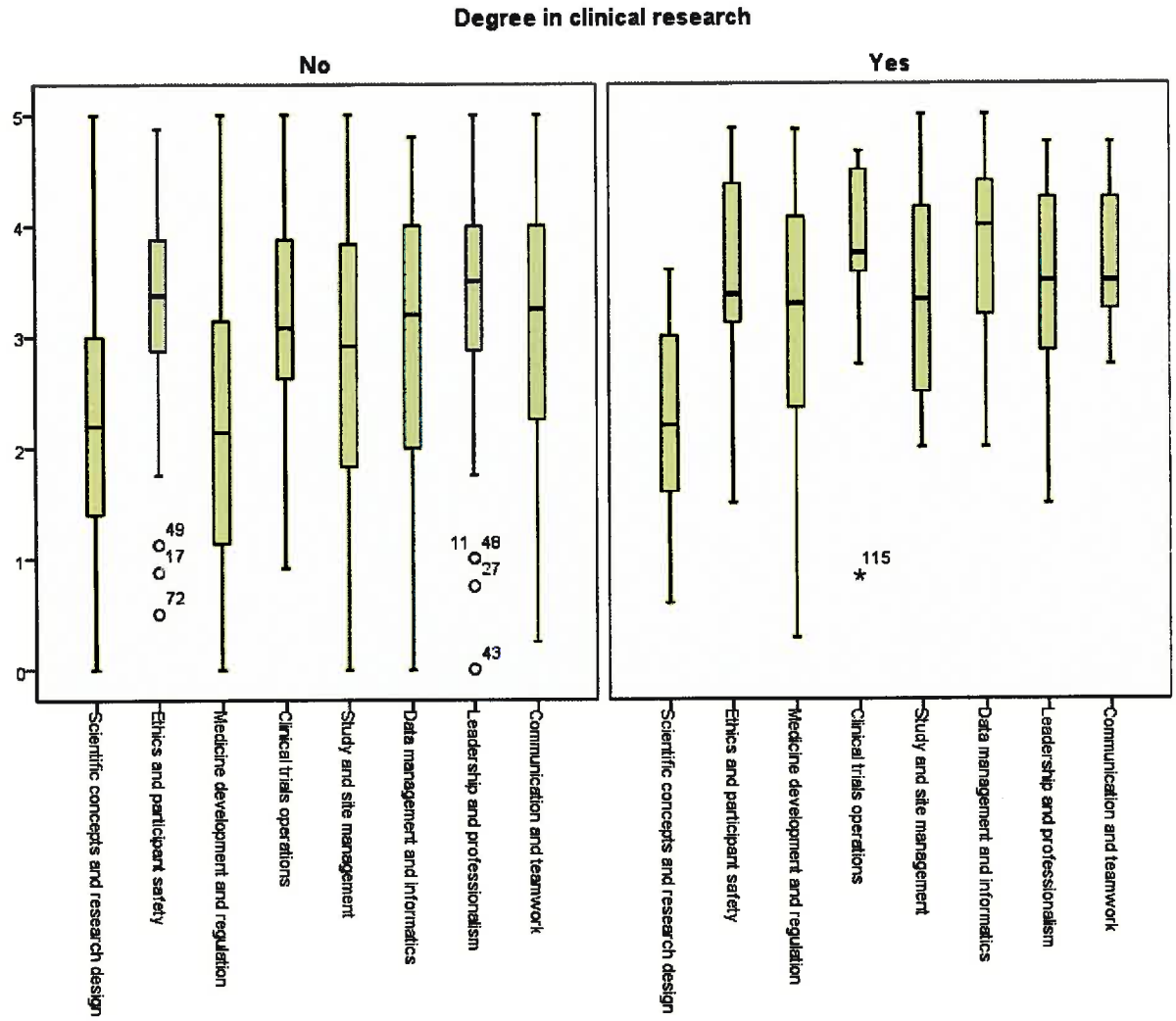

Figure 3. Boxplot of competence ratings by whether one has a clinical research degree.

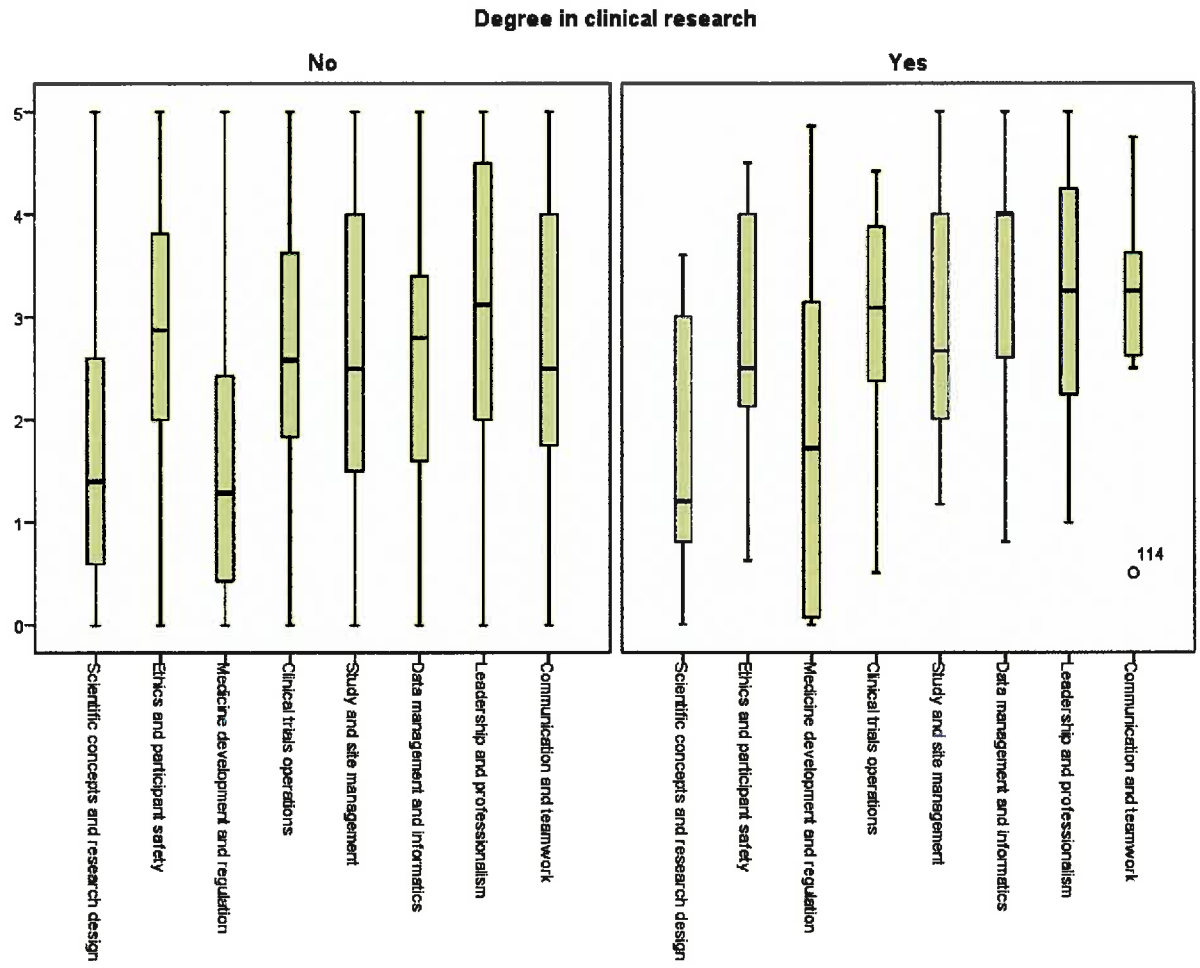

Figure 4. Boxplot of significance ratings by whether one has a clinical research degree.

ANOVAs were used to follow up a significant omnibus multivariate statistic (Wilks' lambda) with a Bonferroni adjustment applied to correct for inflated Type-I error rate due to multiple comparisons. This adjustment takes the nominal alpha value used for significance (typically .05) and divides by the number of tests being performed. With 8 dependent variables, the ANOVAs can be interpreted as significant when the F ratio yields a p-value less than .05/8 = .0063. Homogeneity of the within-group co-variances of the dependent variables is typically examined using Box's M test. However, the small cell sizes resulted in singularity of the

covariance matrix used to estimate Box's M, and hence it was not used. Alternatively, an examination of Levene's test of equality of error variances was used and suggested no significant deviations ($p = .051$ to $p = .995$), indicating that the follow-up univariate ANOVA estimates are reliable.

MANOVA results revealed statistically significant mean differences according to current position in reported competence ($F (16, 86) = 2.34$, $p < .01$, $\eta 2 = .30$) and significance ($F (16, 84) = 2.00$, $p < .05$, $\eta 2 = .28$). The significant omnibus test does not, however, show which dependent variables were significantly different across the three groups for current position. Thus, univariate analysis of variance (ANOVA) tests for the effects of current position on reported competence are presented in Table 4, and the effects on reported significance are presented in Table 5.

Table 4

Univariate Effects for Differences in Reported Competence by Current Position

Variable	F	df1	df2	p value	η2
Scientific concepts and research design	16.94	2	50	.000	.40
Ethical and participant safety considerations	2.55	2	50	.088	.09
Medicines development and regulation	0.26	2	50	.776	.01
Clinical trials operations	0.59	2	50	.559	.02
Study and site management	0.22	2	50	.807	.01
Data management and informatics	0.02	2	50	.977	.00
Leadership and professionalism	0.36	2	50	.699	.01
Communication and teamwork	3.09	2	50	.054	.11

Table 5

Univariate Effects for Differences in Reported Significance by Current Position

Variable	F	df1	df2	p value	η2
Scientific concepts and research design	11.38	2	49	.000	.32
Ethical and participant safety considerations	3.06	2	49	.056	.11
Medicines development and regulation	0.57	2	49	.572	.02
Clinical trials operations	0.82	2	49	.446	.03
Study and site management	1.07	2	49	.352	.04
Data management and informatics	0.99	2	49	.378	.04
Leadership and professionalism	1.09	2	49	.345	.04
Communication and teamwork	3.94	2	49	.026	.14

Using the Bonferroni-adjusted criterion of $p < .008$, only the scientific concepts and research design domain varied significantly by current position for reported competence ($F(2, 50) = 16.94$, $p < .001$ $\eta 2 = .40$) and significance ($F(2, 49) = 11.38$, $p < .001$ $\eta 2 = .32$). A separate MANOVA was conducted to examine differences on reported competence and significance according to whether participants hold a clinical research degree to prevent the further dissection of the small sample into even smaller groups. MANOVA results did not reveal significant differences according to whether participants held a clinical research degree for reported competence ($F(8, 43) = 1.04$, $p = .423$, $\eta 2 = .16$) or significance ($F(8, 42) = 0.64$, $p = .744$, $\eta 2 = .11$).

Post hoc follow-up tests were conducted to further examine the effects of current position on reported competence and significance in the domain of scientific concepts and research design (see Tables 6 and 7, respectively).

Table 6

Post hoc Follow-up Tests for the Effects of Current Position on Reported Competence in Scientific Concepts and Research Design

		Mean difference	SE	p-value
Group 1	Group 2	0.84	0.63	0.566
	Group 3	2.19	0.41	0.000
Group 2	Group 3	1.35	0.52	0.034

Table 7

Post hoc Follow-up Tests for the Effects of Current Position on Reported Significance of Scientific Concepts and Research Design to Current Job Responsibilities

		Mean difference	SE	p-value
Group 1	Group 2	1.25	0.96	.604
	Group 3	2.64	0.58	.000
Group 2	Group 3	1.39	0.80	.273

Bonferroni adjustments were again used to control Type-I error rates. For reported competence, Group 1 rated themselves as having more competence in scientific concepts and research design than Group 3 (mean difference = 2.19, SE = .41, $p < .001$). The difference between Groups 2 and 3 was initially significant before applying the Bonferroni correction (mean difference = 1.35, SE = .52, $p < .05$), in the direction that Group 2 rated themselves as having more competence in scientific concepts and research design than Group 3. For reported significance to current job responsibilities, Group 1 rated scientific concepts and research design as more significant for their current position than Group 3 (mean difference = 2.64, SE = .58, $p < .001$).

After observing the substantial portion of missing data on the questionnaire, it was hypothesized a posteriori that those with a clinical research degree and/or experience in a relevant profession were more likely to complete more survey items and ultimately finish the survey. Two variables were used to capture patterns of missing data. The first variable was an indicator of what questionnaire item was the last one responded to, and the second was a dichotomous variable indicating whether the participant completed the questionnaire. Separate univariate ANOVAs were conducted to test for differences on the last valid questionnaire item, first by current position and then by whether one held a clinical research degree. No significant differences were found on last valid questionnaire item according to current position ($F(2, 108) = .963$, $p = .39$, $\eta 2 = .02$) or whether one held a clinical research degree position ($F(1, 109) = 1.16$, $p = .28$, $\eta 2 = .01$), indicating that missing data, as measured by the last completed item, were not associated with current position or whether participants held a clinical research degree (see Figures 5 and 6).

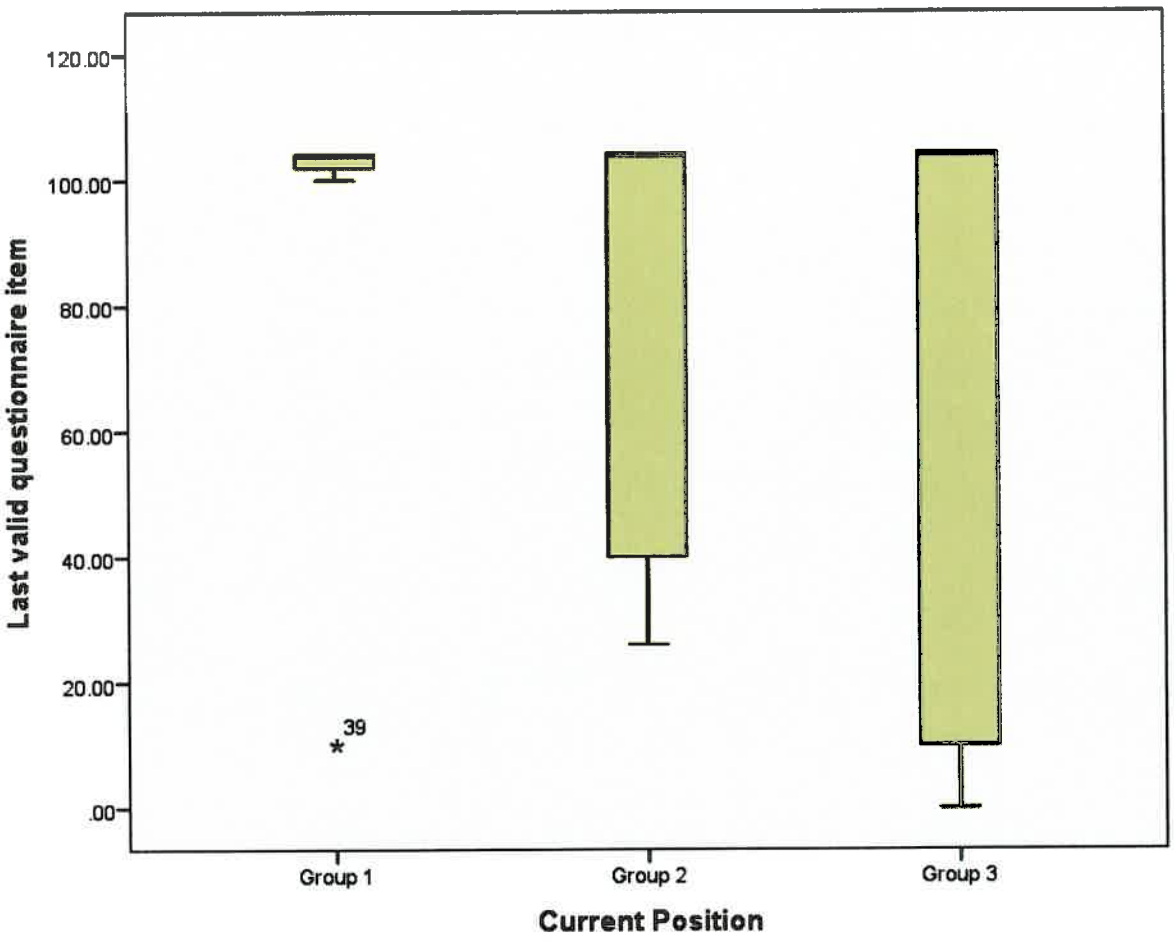

Figure 5. Boxplot of last valid questionnaire item by current position group.

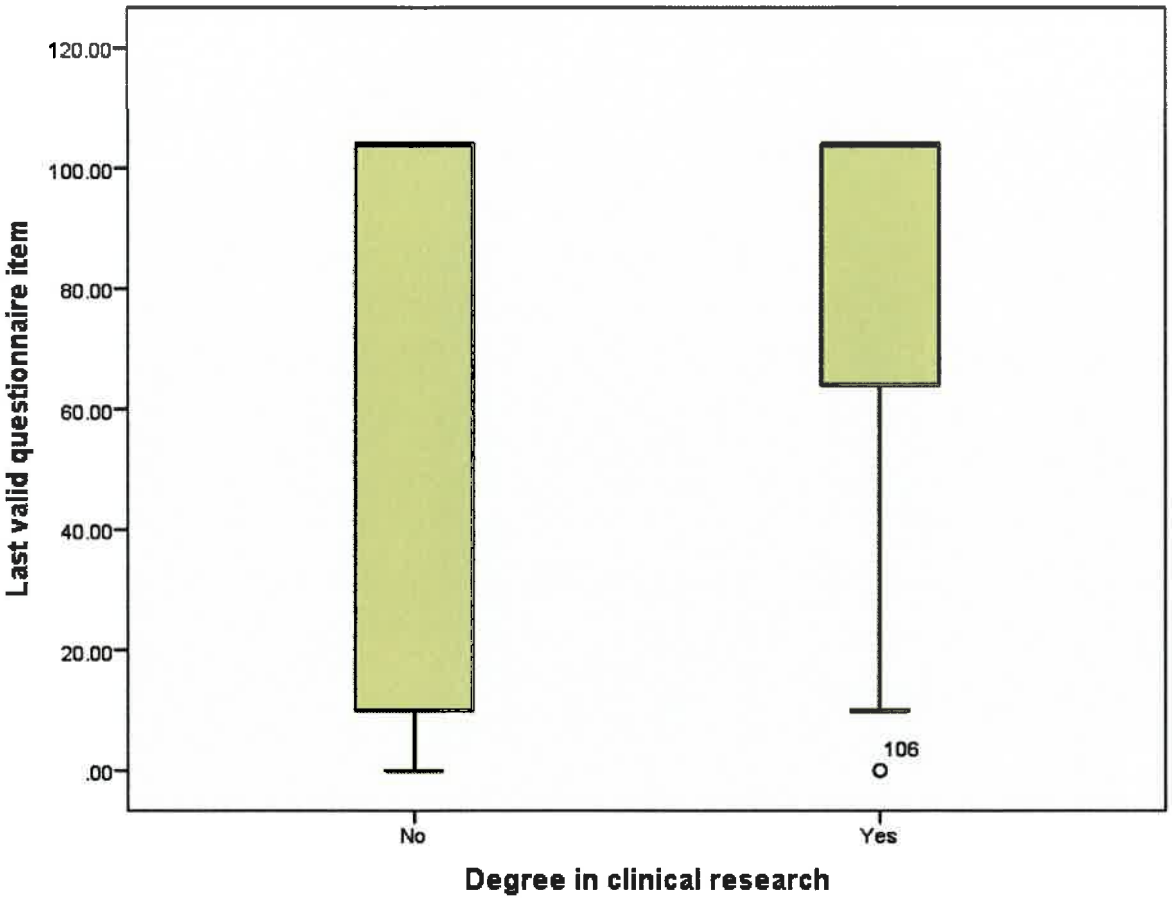

Figure 6. Boxplot of last valid questionnaire item by whether one has a clinical research degree.

Separate chi-square analyses were conducted to test for differences on whether participants completed the questionnaire, first by current position and then by whether one held a clinical research degree. Chi-square was used because both the independent and dependent variables are categorical and contain two or more independent groups. No significant differences were found on whether participants completed the questionnaire according to current position ($X2(2) = 1.43$, $p = .49$, $\varphi = .11$) or whether one held a clinical research degree position ($X2(1) = 1.11$, $p = .29$, $\varphi = .10$), indicating that missing data, as measured by whether the questionnaire was completed, were not associated with current position or whether participants held a clinical research degree (see Figures 7 and 8).

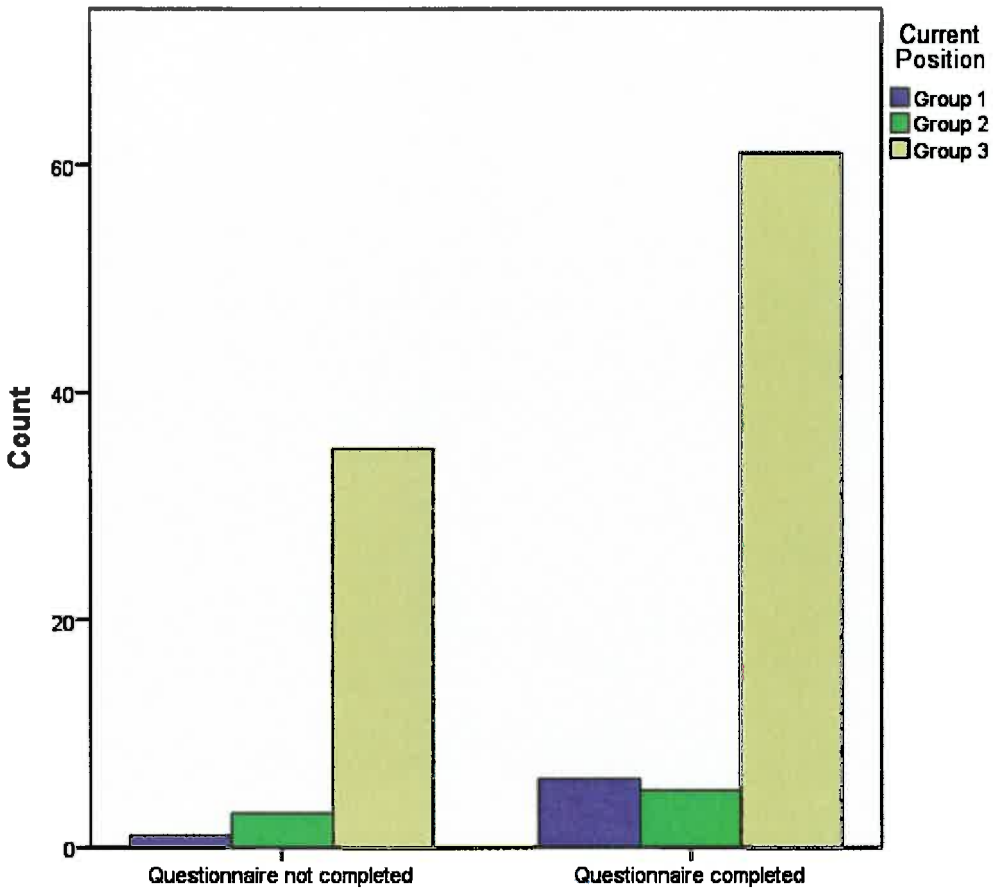

Figure 7. Bar graph of questionnaire completion by current position.

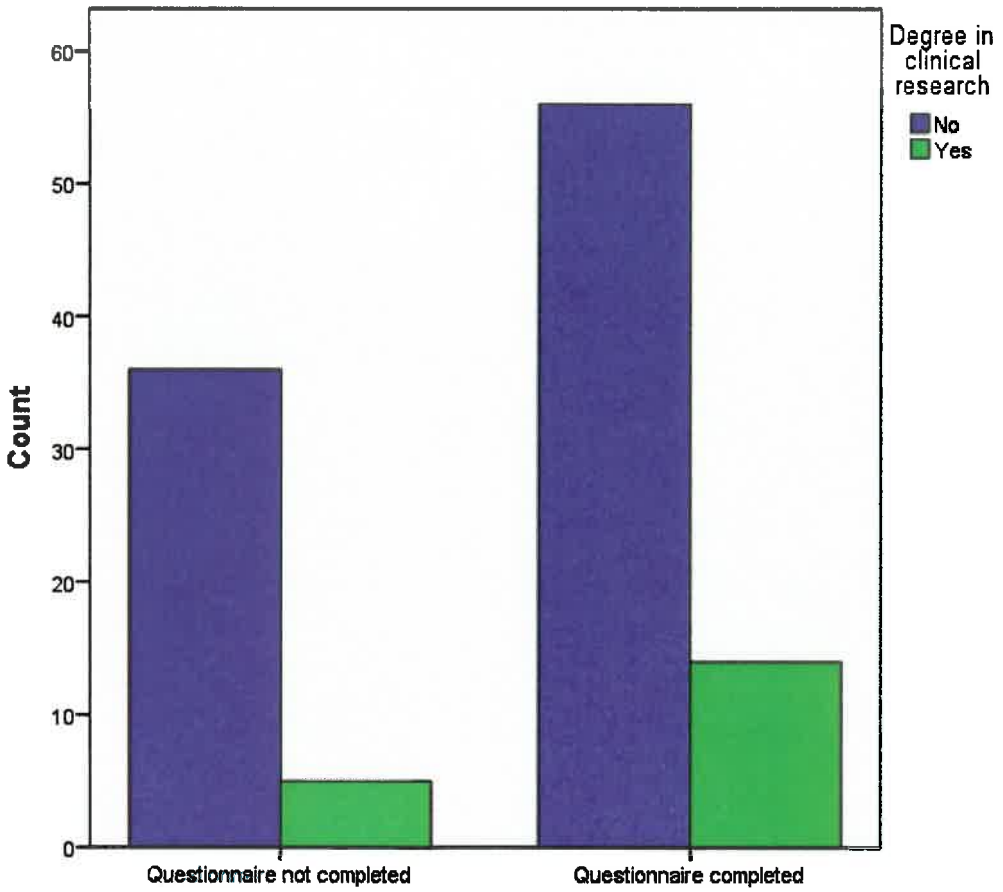

Figure 8. Bar graph of questionnaire completion by whether one has a clinical research degree.

Chapter 4. Discussion

The study data demonstrated that the JTF questionnaire is a valid tool for the collection of data for self-assessment of competency and significance to role in each of the eight categories (scientific concepts and research design, ethical and participant safety considerations, medicines development and regulation, clinical trials operations [GCPs], study and site management, data management and informatics, leadership and professionalism, and communication and teamwork) for use in defining job descriptions, educational requirements, boundaries of practice, and promotion criteria for the global clinical research enterprise.

There were some noted limitations of the questionnaire during the conduct of the study: for example, differences in academic sites' clinical research focus, terminology and technologies used by academic sites, numerous University of Michigan role titles, and centralized versus decentralized UM service models.

The following survey questions may not reflect the academic site's respondents' clinical research focus and therefore may not represent a competency requirement to perform their role:
Question: Medicines Development and Regulation

- Describe the roles and responsibilities of the various institutions participating in the medicines development process.
- Explain the medicines development process and the activities which integrate commercial realities into the life cycle management of medical products.
- Summarize the legislative and regulatory framework which supports the development and registration of medicines, devices, and biologicals and ensures their safety, efficacy, and quality.

- Describe the specific processes and phases which must be followed in order for the regulatory authority to approve the marketing authorization for a medical product.

This category focuses on the development process of bringing a medicine, device, or biologic to market. Academic clinical research is focused on answering scientific questions, not necessarily for the purpose of taking medicines, devices, or biologicals to market.

Question: Clinical Trials Operations (GCPs)

- Evaluate the conduct and management of clinical trials within the context of a Clinical Development Plan.
- Compare and contrast the regulations and guidelines of global regulatory bodies relating to the conduct of clinical trials.
- Describe how global regulations and guidelines assure human subject protection and privacy during the conduct of clinical trials.
- Describe the reporting requirements of global regulatory bodies relating to clinical trial conduct.

This GCP category included questions (listed above) with references to global regulations and clinical development plan. When an academic center is receiving federal funds and the clinical researcher is participating in only government-funded research, their main focus of competency will be with the Health and Human Services (HHS) regulations (45 CFR 46 Protection of Human Subjects) rather than the United States Food and Drug Administration (FDA) regulations. Per the FDA's website, "In 1991 FDA's regulations were harmonized with the Common Rule to the extent permitted by statute. Differences in the rules are due to differences in statutory scope or requirements. HSS has special subparts relating to vulnerable populations, e.g., children, prisoners, pregnant women, etc. FDA does not have comparable

provisions for these populations. The HHS regulations require assurances and certifications from the grantee institution. FDA regulations generally require assurances of compliance from either or both the sponsor of the research and the clinical investigator" ("Comparison of FDA and HHS Human Subject Protection Regulations," 2009).

Question: Communication and Teamwork

- Discuss the relationship and appropriate communication between Sponsor, CRO, and clinical research site.
- If the academic researchers were only conducting federally-funded clinical research, then this would not be a competency they would require.

As evidenced by the various role titles entered into the survey by the participants, there are a number of job titles implemented at UM with varying degrees of role responsibility per job title. For meaningful data analysis, the respondents were categorized into three groups based on role descriptions and clinical research support models being used by the differing medical divisions (centralized, decentralized, or hybrid service models): Group 1 (investigator, co-investigators, physician co-investigator), Group 2 (financial specialist, financial consultant, IRB, research lab specialist, biostatistician, educator/trainer, research pharmacist, clinical research monitor, project manager, clinical research project manager, project coordinator), and Group 3 (research administrator/manager, clinical research coordinator, regulatory affairs professional, data management professional, research area specialist, research nurse, research associate, research area specialist/project coordinator, and research process coordinator).

For the clinical research coordinator role, UM does not have standardized job descriptions delineating roles and responsibilities. The hiring investigator may not have administrative support to assist with selecting the correct research position level to hire based on

clinical study's complexity. Also, salary support provided in the grant may not be commensurate with experience required to support the clinical trial execution.

The UM respondents represented a clinical research site's perspective versus a pharmaceutical/industry perspective. Feedback received from participants in Groups 2 and 3 demonstrated that terminology used in some of the questions was unfamiliar or they did not understand how the questions pertained to their role. The respondents were academic clinical researchers with varying degrees of role responsibilities, experience, and exposure to industry-sponsored clinical trials versus grant-funded, investigator-initiated, and/or sponsor-investigator clinical research. The dropout rate was greatest for participants without a clinical research degree and/or experience in the clinical research profession. The investigator hypothesizes that this is due to a number of factors:

1. A higher level of education/experience enabling the respondent to understand the relevance of the questions to the global clinical research enterprise;
2. Bias of the questionnaire towards the role definitions and responsibilities of the pharmaceutical industry; and
3. Survey fatigue.

Chapter 5. Conclusion

This study validated the Joint Task Force's (JTF) questionnaire for collection of data to be used in defining job descriptions, educational requirements, boundaries of practice, and promotion criteria for the global clinical research enterprise. The investigator believes the questionnaire does not collect the necessary data to fully address the needs of the academic clinical researcher in the United States. It is recommended that the JTF either amend some of the questions addressed earlier in this paper or create an academic site-specific questionnaire that addresses the particular competencies necessary for conducting clinical research in the academic settings—specifically, questions to assess the competency needs of the investigator and clinical research coordinator in executing clinical trials that are not conducted under FDA Investigation New Drug (IND) regulations.

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APPENDIX

Please select the box which best reflects your current level of competency for each statement and the box which reflects the significance of that competency to your current job responsibilities: NA – unnecessary; Exposed – sufficiently aware of knowledge to be able to look up relevant information; Competent – able to interpret or discuss concepts and use knowledge to solve simple problems based upon application concepts; Mastery – able to apply knowledge to complex problems, integrate information and create solutions.

	Scientific Concepts and Research Design	**NA**	**Exposed**		**Competent**		**Mastery**	**Significance to my position 0 Unnecessary/5 essential**					
		0	1	2	3	4	5	0	1	2	3	4	5
	▪ Demonstrate knowledge of pathophysiology, pharmacology and toxicology as they relate to medicines discovery and development	0	1	2	3	4	5	0	1	2	3	4	5
	▪ Identify clinically important questions that are potentially testable clinical research hypothesis, through review of the professional literature	0	1	2	3	4	5	0	1	2	3	4	5
	▪ Explain the elements (statistical, epidemiological and operational) of clinical and translational study design	0	1	2	3	4	5	0	1	2	3	4	5
	▪ Design a clinical trial	0	1	2	3	4	5	0	1	2	3	4	5
	▪ Critically analyze study results with an understanding of therapeutic and comparative effectiveness	0	1	2	3	4	5	0	1	2	3	4	5
	Ethical and Participant Safety Considerations												
	▪ Compare and contrast clinical care and clinical management of research participants	0	1	2	3	4	5	0	1	2	3	4	5
	▪ Define the concepts of "clinical equipoise" and "therapeutic misconception" as they relate to the conduct of a clinical trial	0	1	2	3	4	5	0	1	2	3	4	5
	▪ Compare the requirements for human subject protection and privacy under different national and international regulations and ensures their implementation throughout all phases of a clinical study	0	1	2	3	4	5	0	1	2	3	4	5
	▪ Explain the evolution of the requirement for informed consent from research participants and the principles and content of the key documents which ensure the protection of human participants in clinical research	0	1	2	3	4	5	0	1	2	3	4	5
	▪ Describe the ethical issues involved when dealing with vulnerable populations and the need for additional safeguards	0	1	2	3	4	5	0	1	2	3	4	5
	▪ Evaluate and apply an understanding of the past and current ethical issues, cultural variation and commercial aspects on the	0	1	2	3	4	5	0	1	2	3	4	5

	medicines development process ▪ Explain how inclusion and exclusion criteria are included in a clinical protocol to assure human subject protection ▪ Summarize the principles and methods of distributing and balancing risk and benefit through selection and management of clinical trial subjects	0 0	1 1	2 2	3 3	4 4	5 5	0 0	1 1	2 2	3 3	4 4	5 5
	**Medicines Development and Regulation**												
	▪ Discuss the historical events which precipitated the development of governmental regulatory processes for drugs, devices and biologicals ▪ Describe the roles and responsibilities of the various institutions participating in the medicines development process ▪ Explain the medicines development process and the activities which integrate commercial realities into the life cycle management of medical products ▪ Summarize the legislative and regulatory framework which supports the development and registration of medicines, devices and biologicals and ensures their safety, efficacy and quality ▪ Describe the specific processes and phases which must be followed in order for the regulatory authority to approve the marketing authorization for a medical product ▪ Describe the safety reporting requirements of regulatory agencies both pre and post approval ▪ Appraise the issues generated and the effects of global expansion on the approval and regulation of medical products	0 0 0 0 0 0 0	1 1 1 1 1 1 1	2 2 2 2 2 2 2	3 3 3 3 3 3 3	4 4 4 4 4 4 4	5 5 5 5 5 5 5	0 0 0 0 0 0 0	1 1 1 1 1 1 1	2 2 2 2 2 2 2	3 3 3 3 3 3 3	4 4 4 4 4 4 4	5 5 5 5 5 5 5
	**Clinical Trials Operations (GCP's)**												
	▪ Evaluate the conduct and management of clinical trials within the context of a Clinical Development Plan ▪ Describe the roles and responsibilities of the clinical investigation team as defined by Good Clinical Practice Guidelines ▪ Evaluate the design conduct and documentation of clinical trials as required for compliance with Good Clinical Practice Guidelines ▪ Compare and contrast the regulations and guidelines of global regulatory bodies relating to the conduct of clinical trials ▪ Describe appropriate control, storage and dispensing of	0 0 0 0	1 1 1 1	2 2 2 2	3 3 3 3	4 4 4 4	5 5 5 5	0 0 0 0	1 1 1 1	2 2 2 2	3 3 3 3	4 4 4 4	5 5 5 5

	investigational product	0	1	2	3	4	5	0	1	2	3	4	5
	▪ Differentiate the types of adverse events which occur during clinical trials, understand the identification process for AEs and describe the reporting requirements to IRB's/IEC's, sponsors and regulatory authorities	0	1	2	3	4	5	0	1	2	3	4	5
	▪ Describe how global regulations and guidelines assure human subject protection and privacy during the conduct of clinical trials												
	▪ Describe the reporting requirements of global regulatory bodies relating to clinical trial conduct	0	1	2	3	4	5	0	1	2	3	4	5
	▪ Describe the role and process for monitoring of the study												
	▪ Describe the roles and purpose of clinical trial audits	0	1	2	3	4	5	0	1	2	3	4	5
	▪ Describe the safety reporting requirements of regulatory agencies both pre and post approval	0	1	2	3	4	5	0	1	2	3	4	5
	▪ Describe the various methods by which safety issues are identified and managed during the development and post-marketing phases of clinical research	0	1	2	3	4	5	0	1	2	3	4	5
		0	1	2	3	4	5	0	1	2	3	4	5
	Study and Site Management												
	▪ Describe the methods utilized to determine whether or not to sponsor, supervise or participate in a clinical trial	0	1	2	3	4	5	0	1	2	3	4	5
	▪ Develop and manage the financial, timeline and cross-disciplinary personnel resources necessary to conduct a clinical or translational research study	0	1	2	3	4	5	0	1	2	3	4	5
	▪ Apply management concepts and effective training methods to manage risk and improve quality in the conduct of a clinical research study	0	1	2	3	4	5	0	1	2	3	4	5
	▪ Utilize elements of project management related to organization of the study site to manage patient recruitment, complete procedures and track progress	0	1	2	3	4	5	0	1	2	3	4	5
	▪ Identify the legal responsibilities, issues, liabilities and accountability that is involved in the conduct of a clinical trial	0	1	2	3	4	5	0	1	2	3	4	5
	▪ Identify and explain the specific procedural, documentation and oversight requirements of principal investigators, sponsors, CRO's and regulatory authorities which relate to the conduct of a clinical trial	0	1	2	3	4	5	0	1	2	3	4	5

	Data Management and Informatics		
	▪ Describe the role that biostatistics and informatics serve in biomedical and public health research	0 1 2 3 4 5	0 1 2 3 4 5
	▪ Describe the typical flow of data throughout a clinical trial	0 1 2 3 4 5	0 1 2 3 4 5
	▪ Summarize the process of electronic data capture (EDC) and the importance of information technology in data collection, capture and management	0 1 2 3 4 5	0 1 2 3 4 5
	▪ Describe the ICH GCP requirements for data correction and queries	0 1 2 3 4 5	0 1 2 3 4 5
	▪ Describe the significance of data quality assurance systems and how SOPs are used to guide these processes	0 1 2 3 4 5	0 1 2 3 4 5
	Leadership and Professionalism		
	▪ Describe the principles and practices of leadership, management and mentorship, and apply them within the working environment	0 1 2 3 4 5	0 1 2 3 4 5
	▪ Identify and implement procedures for the prevention or management of the ethical and professional conflicts that are associated with the conduct of clinical research	0 1 2 3 4 5	0 1 2 3 4 5
	▪ Identify and apply the professional guidelines and codes of ethics which apply to the conduct of clinical research	0 1 2 3 4 5	0 1 2 3 4 5
	▪ Describe the impact of cultural diversity and the need for cultural competency in the design and conduct of clinical research	0 1 2 3 4 5	0 1 2 3 4 5
	Communication and Teamwork		
	▪ Discuss the relationship and appropriate communication between Sponsor, CRO and clinical research site	0 1 2 3 4 5	0 1 2 3 4 5
	▪ Describe the component parts of a traditional scientific publication	0 1 2 3 4 5	0 1 2 3 4 5
	▪ Effectively communicate the content and relevance of clinical research findings to colleagues, advocacy groups and the non-scientist community	0 1 2 3 4 5	0 1 2 3 4 5
	▪ Describe methods necessary to work effectively with multidisciplinary and inter-professional research teams	0 1 2 3 4 5	0 1 2 3 4 5