Academic Sciences Asian Journal of Pharmaceutical and Clinical Research

Vol 5, Suppl 3, 2012 ISSN - 0974-2441

Research Article

QUANTITATIVE EVALUATION OF GCP TRAINING NEEDS IN CLINICAL RESEARCH

UMESH CHANDRA GUPTA

Medical Affairs and Clinical Research, Fresenius Kabi India Pvt. Ltd. Pune, India. Email: gupta.umesh15@gmail.com

Received:23 May 2012, Revised and Accepted:15 July 2012

ABSTRACT

Background and Purpose: Adequate training of clinical research professionals has been among the major success factors for the quality conduct of clinical trials complying with international standards and assessment of their training needs may provide valuable information. This study was conducted to evaluate quantitatively the training needs of clinical research professionals.

Methods: Questionnaires, designed to identify training needs, were fed to the clinical research professionals both from sponsor and investigator site categories. Based on predefined training need criteria and threshold scores the training need of individual respondents was identified. Absolute and relative training needs, on cumulative basis, were also evaluated both for sponsor and site categories.

Results: Overall scores of study site respondents were lower (40-70%) as compared to the scores of respondents from sponsor category (60-90%) reflecting greater training need for the trial site respondents. Cumulative scores were 78% and 56% for sponsor and site category respectively. Relative and differential training needs for site category versus sponsor category were 1.393 and 39.3% respectively.

Conclusion: Quantitative assessment of individuals' training needs may represent a feasible method and results may help determine further course of action and can be used for trial-related planning and various decisions such as site selection, allocation of training resources and extent of monitoring. Assessment of training need is recommended for newer clinical research professionals and trial sites, especially prior the conduct of larger confirmatory clinical trials.

Keywords: Training, Clinical research, Clinical trials, GCP, Good Clinical Practice

INTRODUCTION

Not remaining untouched with economic globalization, in last few decades, pharmaceutical industry has adopted the global business and research model which has led to the globalization of commercial and research activities, especially of clinical trials.[1] Under the umbrella of International Conference on Harmonisation-Good Clinical Practice (ICH-GCP) guideline[2] and intellectual property protection and by realizing the potential benefits including cost savings, speedy and timelines conduct of clinical research, large pool of potential participants, wide range of disease prevalence, and expanding markets with additional drug approvals pharma majors have started shifting or partnering their clinical trials in rapidly developing countries and both India and China have emerged as an ideal destination for the clinical research.[3-8]

India is rapidly developing into a global center for clinical trials. Whilst sponsor companies and clinical research organizations (CROs) are showing positive attitude concerning the possibilities of carrying out high quality research in India, concerns are still there in addition to the distance and time difference leaving a question over capability to maintain and grow the clinical research sector. Having a limited practical experience in the area of clinical research the most important concern in India is the lack of adequately trained and competent clinical research professionals to conduct clinical trials and generate data meeting international standards.

Competencies and training in the highly specialized and new field of clinical research has been advocated to have potentially positive influence on the operational efficiency, effectiveness, and development of the clinical research professionals.[9-13] Previous literature has, so far, indicated primarily the various critical domains of skills and expertise, and the importance and need of training in Indian clinical research scenario. This study tries to identify quantitatively the real time GCP training needs of clinical research professionals and aims to provide a quantitative method for evaluating and identifying training needs that can be equally applied to other specific domains of the clinical research such as ethics, research methodology, regulations, data management, and clinical trial execution.

MATERIALS AND METHODS

Quantitative evaluation of the GCP training needs was done with the questionnaire evaluation method whereby the questionnaires were designed and fed to the respondents and their respective training needs were identified by evaluation of obtained responses based on predefined scores and training need criteria. All respondent included in the study were clinical research professionals involved directly in carrying out the trial-related activities and were primarily from two basic functional categories i.e. sponsor and study/trial site. Two different sets of questionnaires were designed for the respondents of each functional category taking into consideration their different roles and responsibilities in conducting a clinical trial.

Questionnaires for both functional categories were designed as multichotomous close-ended questionnaires i.e. each question was provided with five responses being only one correct response out of them as per GCP. For each question quantitative scores of one and zero were defined in the background for the correct response one and all other remaining four incorrect responses respectively. Both sets of questionnaire contained twenty questions each. The questions were self-explanatory and the instructions and abbreviations required for responding the questions were provided with the questionnaires.

Total scores (in percentage terms) were calculated both at the level of individual respondents for all the respondents and cumulatively at the level of functional categories by taking averages (arithmetic mean) of individual total scores of respondents pertaining to a specific functional category. Training needs were evaluated both at the levels of individual respondents and the functional categories based on the total scores as per the following criteria: (a) for scores > 80%, a formal GCP training may not be required; (b) for scores 60-80%, an abbreviated GCP training is required emphasizing on the lacking areas; (c) for scores < 60%, full-fledged GCP training is required prior the intended clinical trial begins. Relative and differential training needs were also evaluated. Relative training need was calculated as a relative fraction and differential need was defined as the required excess or affordable deficit for the required training efforts and resources.

RESULTS

Respondents from the sponsor category (coded as X) were at the levels of executives and senior executives, whereas respondents from the trial site category (coded as Z) were of clinical research coordinator and sub-investigator levels. Questionnaires were fed to a total of ten respondents, five each from both the functional categories i.e. sponsor and trial site and responses from the individual respondents were obtained. In order to maintain the confidentiality of the respondents' identity, individual codes were assigned to each respondent for the purpose of analysis. Codes for

the five respondents from the sponsor category were X01 to X05; whereas study site respondents were from two institutions: two respondents (ZA01 and ZA02) from site A and three others (ZB01 to ZB03) from site B. Standards of ICH-GCP guideline were used in framing and composing the questionnaires with underlying principles of functions, duties and responsibilities to be carried out by the respondents which they are responsible for and are crucial for achieving compliance with the GCP (Table 1.). While framing the questions emphasis was given over the essential clinical trial activities and knowledge required for conducting a clinical trial.

Table 1: Composition of Questionnaires

Respondents' Category – Trial site	
Function Item	**No. of Questions**
IP handling and accountability	2
Study initiation procedures & requirements	3
Subjects' safety, withdrawal, and unblinding	5
Data/document handling/recording	3
Protocol deviation and amendment	2
Handling of serious adverse events	2
Informed consent & IRB/IEC communication	3
Respondents' Category – Sponsor	
Function Item	**No. of Questions**
Subjects' safety and unblinding	3
IP handling, accountability, and retention	4
Protocol, deviation, non-compliance, and amendment	3
Quality assurance and quality control	4
Data and document handling	2
IRB/IEC approval	2
Handling of serious adverse events	1
Suspension/premature termination of trial	1

Individual scores of the study site respondents were 55%, 70%, 45%, 40%, and 70%; whereas individual scores for the sponsor category respondents were 80%, 90%, 90%, 70%, and 60% (Figure 1.). Overall scores of study site respondents were lower (40-70%) as compared to the scores of respondents from sponsor category (60-90%). Of the study site respondents, full-fledged GCP training need was identified for three respondents (one from site A and two from site B) and abbreviated GCP training need was identified for two respondents one each from both sites. On the other hand lesser training needs were identified for the respondents in the sponsor category including abbreviated training need for the two respondents only and other respondents crossed the criteria of their training need.

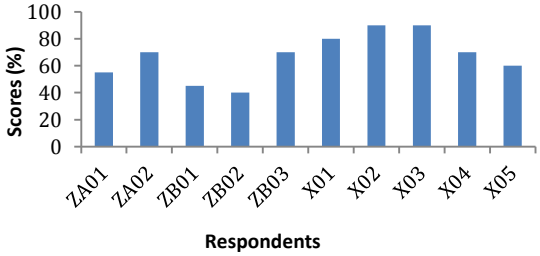

Figure 1. Quantitative Scores of All Respondents

Cumulative scores for the study sites A and B were 62.5% and 51.7% respectively depicting the abbreviated and full-fledged training need respectively on a cumulative basis. Overall cumulative scores at the level of functional category were 56% and 78% for the study site and sponsor categories respectively. Relative and differential training needs, intra site category, were greater for site B as compared to site A; whereas, inter category, relative and differential training needs were greater for site category in comparison to sponsor category (Table 2.).

Table 2: Relative and Differential Training Needs

	Relative groups	**Relative training need (fractional)**	**Relative training need (%)**	**Differential training need (%)**
Intra category	Site A vs Site B	0.827	82.7	-17.3
	Site B vs Site A	1.209	120.9	+20.9
Inter category	Sites vs Sponsor	1.393	139.3	+39.3
	Sponsor vs Sites	0.718	71.8	-28.2

DISCUSSION

Overall training need identified for the study site respondents was greater as compared to the sponsor end respondents. These results indicate that more training resources and efforts are required for the study site professionals for the quality conduct of the clinical trials and becoming compliant with the international standards. Institutions and site management organizations involved actively in the conduct and management of clinical trials, particularly newer institutions, are required to give emphasis over the training needs and adequate training of the involved clinical research professionals. Clinical research organizations and trial sponsors are also recommended to assess the training needs periodically and provide the adequate training to the clinical research professionals.

The methodology used for the study could be applied to identify the individual training needs for the clinical research professionals and collective and differential training needs of the functional categories and may help determine the probable course of action required for rectifying the quality shortcomings. Although it's difficult to quantify the required training efforts based on the quantified training needs; it can be used for a variety of decisions pertaining to the conduct of clinical trials, for example selection of study sites, allocation of training resources, frequency and extent of monitoring. However, the smaller sample size was a limitation; this study recommends questionnaire evaluation method as a feasible option for identifying the training needs of clinical research professionals.

The study evaluated the relative and differential training needs cumulatively only at the level of functional categories, because evaluation of these parameters at the level of individual respondents may jeopardize the individual autonomy and do not add much towards allocation of training resources and other decisions of the project management. Potential uses of questionnaire evaluation method may include identifying training needs (specific or overall), evaluating the competency level, and identifying with more clarity the training needs of site staff if used at the time of site evaluation visits. Size of the questionnaire may vary depending on overall or specific competencies required under the considerations of organizational processes/systems and study aspects.

This study used a single questionnaire covering different aspects of clinical operations; however, there is a need felt to develop validated questionnaires specifically designed for different aspects or sub-categories of clinical operations such as adverse event reporting, IP accountability, source documentation, data handling etc. Further, in lieu of different responsibilities, questionnaire tools are required to be developed specifically for investigator site and sponsor (and/or CRO) personnel. Also, apart from the GCP training need, the questionnaire evaluation method may also be deployed identifying training needs in other knowledge and skills areas such as research ethics, research regulations, clinical research methodology, project management, data management, clinical trial execution, and statistics for the concerned clinical research professionals.

Intra-category differences in the training needs at the individual level may affect the overall training need at the level of functional categories. For higher magnitude of intra-category differences, emphasis could be given on the identified individuals for the optimized use of training resources. Further, relative training needs

of the functional categories can predict where the training efforts and resources need to be shifted more, in order to enhance and maintain the quality and compliance in the conduct of clinical trials.

Compliance in the conduct of clinical trials may be defined as the extent/degree of adherence of clinical trial activities to the applicable regulations. Therefore, the questionnaire evaluation method could also be used for a rough quantitative prediction of the future and past compliance level based on the assumption that respondents apply their knowledge fully at their workplace and this prediction may be used for various decisions related to the trial conduct, quality control, quality assurance, and project management plans.

This study was conducted in 2008 and since then varied efforts have been put towards the competency enhancement of clinical research professionals both at the academia and industry level. Therefore, evaluating training needs may not be a usual practice all the times; however, it is recommended to evaluate the training needs: (a) for new clinical research professionals for whom training need has not been evaluated prior to begin a clinical trial; (b) during induction programs of new professionals; (c) For staff of a new study site which has not been encountered so far; and (d) for the professionals who were not actively involved in the operational activities and for whom training needs have not been evaluated since last two years.

Conclusively, the competency of clinical research professionals is among the most important parameters for the assurance of accuracy, credibility, integrity, and completeness of the data generated in a clinical trial in compliance with the international standards; therefore, identifying areas for required training prior to the beginning of a clinical trial is of potential significance especially in cases of larger pivotal and confirmatory clinical trials.

ACKNOWLEDGEMENT

The study conduct was supported by Mr. Anuj Kapoor, Manager, Health outcomes, Heron Health, Chandigarh.

REFERENCES

1. Glickman SW, McHutchison JG, Peterson ED, Cairns CB, Harrington RA, Califf RM, et al. Ethical and scientific implications of the globalization of clinical research. N Engl J Med 2009;360:816-823.
2. ICH Harmonised Tripartite Guideline: Guideline for Good Clinical Practice, E6(R1). Available at: http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6_R1/Step4/E6_R1__Guideline.pdf. Accessed 29 August 2011.
3. Garnier JP. Rebuilding the R&D engine in big pharma. Harv Bus Rev 2008;86:68-76.
4. Bailey W, Cruickshank C, Sharma N. Make your move: taking clinical trials to the best location. Available at: http://www.atkearney.com/index.php/Publications/make-your-move.html. Accessed 4 October 2010.
5. Making the most of existing health workers. In: Working together for health: the World Health Report 2006. Geneva: World Health Organization, 2006:66-95. Available at: http://www.who.int/whr/2006/chapter4/en/index.html. Accessed 4 October 2010.
6. Stough WG, Zannad F, Pitt B, et al. Globalization of cardiovascular clinical research: the balance between meeting medical needs and maintaining scientific standards. Am Heart J 2007;154:232-8.
7. Rai S. Drug companies cut costs with foreign clinical trials. New York Times. Available at: http://www.nytimes.com/2005/02/24/business/24clinic.html. Accessed 4 October 2010.
8. Schmidt CW. Monitoring research overseas. Modern Drug Discovery 2001;4:25-6.
9. Bhatt A. The challenge of growth in clinical research: training gap analysis. Pharma BioWorld 2005;march-april:56-8.
10. Rajadhyaksha V. Training for clinical research professionals: Focusing on effectiveness and utility. Perspect Clin Res 2010:1:117-119.
11. Ajay S. Bhatt A. Training needs of clinical research associates. Perspect Clin Res 2010;1:134-138.
12. Ghooi R. Trials and tribulations of clinical research teaching and training. Pers Clin Res 2010;4:139-42.
13. Zodpey SP, Negandhi HN. Training in clinical research in India: potential and challenges. Indian Journal of Community Medicine 2009;34:173-74.