MEDINFO 2015: eHealth-enabled Health
I.N. Sarkar et al. (Eds.)

doi:10.3233/978-1-61499-564-7-1029

Clinical Trial Feasibility Study Questionnaire Analysis

Iñaki Soto-Rey[a], Martin Dugas[a], Fleur Fritz[a]

[a] *Institute of Medical Informatics, University of Münster, Germany*

Abstract

With the growing complexity and cost of clinical trials (CTs) over the past few decades, Protocol Feasibility (PF) studies have become one of the most critical CT steps in order to avoid costly protocol amendments and ensure the success of CTs. The PF process includes interaction with clinicians located at targeted clinical sites, which results in slow and cumbersome process steps. These process steps are normally supported by information systems that allow users to create, share and collect responses to feasibility questionnaires. This investigation analyzes the systems and questionnaires utilized at several clinical research companies for PF. In addition, it provides recommendations that could eventually improve current methods and systems in place.

Keywords:

Clinical Trials as Topic, Feasibility Studies, Questionnaires.

Introduction

Clinical trials (CTs) often suffer delays, and their initial budget is adjusted upwards due to both recruitment rates not being met, and costly protocol amendments. A good trial protocol feasibility (PF) study has been proven to be an effective method to avoid such issues.[1]. The design of PF studies is currently supported by clinicians located at the targeted sites, often resulting in slow and cumbersome process steps that involve a great amount of resources and time [2]. This research analyzes common processes, information systems, and feasibility questionnaires (FQs), and advises how they could be improved.

Methods

The European Federation of Pharmaceutical Industries and Associations (EFPIA) companies participating in the EHR4CR project[1] were asked to deliver examples of FQs. Furthermore, we analyzed how they are designed and which process steps are required to obtain their responses. The received FQs and templates were manually reviewed and the following information was extracted: Name and number of sections, question types, and number of questions per section.

Results

Feasibility experts from seven EFPIA companies collaborated in this study. Seven processes, five PF questionnaire templates, and sixteen FQ examples were analysed.

One of the companies uses a word processor to build the FQ, three corporative systems and three free-to-use online survey systems. The number of FQ sections varies between 3 and 13 with one to 47 questions per section and 22 to 100 questions per questionnaire. In Table 1, the question types and number of questions are presented.

Table 1– Question types and number (N) of questions (Q)

Q type	Total QN	Q per template	Q per questionnaire
Free text	532	21,2	26,6
Radio Button	299	13,6	14,4
Radio Button +Comment	251	12	11,9
Number	230	4	13,1
Checkbox	62	4,8	2,4
+Comment Checkbox	14	0,2	0,7
Free text table	12	0,4	0,8
Date	6	0	0,4

Discussion

This research identified a total of eight different question types in FQs, of which free text was the most common one. Most of the companies use templates or pre-defined questions to build the FQs but – even though the questions are frequently repeated – the analysed systems do not use historical records to allow auto-completing answering. Interviewees reported the number of PF design tools and the long-time interval to obtain the FQ responses as the most critical PF design issues.

The use of free text questions should be reduced due to the intricacy of free text answer completion and analysis. Electronic survey systems must be improved with the re-use of historical data to auto-complete responses, which facilitates responding and speeds up the entire PF process.

Conclusion

Free text questions in feasibility questionnaires need to be avoided and PF survey systems need to re-use data to automatize responses. There is need for a system that congregates all features of PF design and streamlines the methods in place.

References

[1] K. Getz, “Improving protocol design feasibility to drive drug development economics and performance,” *Int. J. Environ. Res. Public. Health*, vol. 11, no. 5, pp. 5069–5080, May 2014.

[2] I. Soto-Rey, B. Trinczek, T. Karakoyun, M. Dugas, and F. Fritz, “Protocol Feasibility Workflow Using an Automated Multi-country Patient Cohort System,” *Stud. Health Technol. Inform.*, vol. 205, pp. 985–989, 2014.

Address for correspondence

Iñaki Soto Rey – Inaki.SotoRey@uni-muenster.de

[1] http://www.ehr4cr.eu/