The Necessity of an Electronic SOP Retrieval System

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Abstract

Objectives: Standard Operating Procedures (SOP) are part of the quality management system when carrying out clinical trials. It is therefore important for all those involved to know about them and act accordingly. This survey should help to detect problems concerning the handling of SOP during clinical trials. Method: Anonymous survey of all employees of the Koordinierungszentren Klinische Studien (KKS) in Germany by means of standardised questionnaires (238 employees in August 2004 according to the KKS homepage). Result: 58.8% of all evaluation sheets were sent back proving that paper-based as well as electronic SOP systems are not sufficiently integrated into everyday work procedures. Conclusion: Steps will have to be taken in order to increase the use of SOP. We propose a computer-based retrieval tool (SOP Information Retrieval System)

Keywords: Clinical Research, Clinical Trials, Standard Operating Procedures, SOP, Information Retrieval, Medical Informatics

1. Introduction

Due to new EU directives the quality standards required for clinical trials are higher than before[1][2]. These directives date back to May 1, 2004, providing that the new standards are binding for tests initiated by investigators [3] as well as for regular trials. Therefore, the creation of instruments assuring and improving quality (or making procedures easier) is an important goal.

The amendment no 12 to the law relating to the manufacture and distribution of medicines integrates the EU directive 2001/20/EG into German law [4]. It defines the requirements concerning clinical trials involving medicines and their control during GCP audits as well as official inspections. There is no longer any differentiation between regular trials and trials initiated by investigators (IIT). This amendment came to effect on August 6, 2004 [5].

In order to further improve quality standards centres for the coordination of clinical trials (Koordinierungszentren Klinische Studien, KKS) were founded all over Germany with the financial support of the Federal Ministry of Education and Research (Bundesministerium für Bildung und Forschung, BMBF) [6][7]. Today there are 12 of these centres located at university hospitals. Their goal is to support clinical trials (including IIT) concerning preparation, implementation, and evaluation in order to improve and maintain quality standards [8].
Part of this quality management are standardised procedures defined by the ISO/DIN-Norm (International Standard Organisation / Deutsche Industrienorm) [9]. These directives concerning SOP are obligatory for clinical research performed by GCP as well [10].

In order to guarantee utmost safety for the patient on the one hand and data quality on the other, it is imperative that the staff members are familiar with all relevant procedures. This can only be obtained by means of SOP [11].

These standardised procedures are manifold as well as complicated due to the involvement of different experts and legal requirements. As a result the SOP are likewise various and complex.

This variety of SOP leads to the assumption that their proper application can be a true challenge to staff members. Their tasks can probably only be performed with sufficient technical support. The first step to the creation of an electronic feature for SOP users was a survey in order to document the handling of SOP during clinical trials. Since the application of SOP should be documented in IIT as well as regular trials, the participation of employees connected with the KKS were of particular importance because of their assistance in regular trials as well as in IIT.

2. Objectives

According to ICH-GCP the sponsor of a clinical study is responsible for the observance of legal specifications and internal restrictions; the data has to be retrieved, documented and presented in accordance with those specifications [12]. In order to guarantee the observance of necessary limitations, the sponsor has to use SOP in the form of detailed written directives, for example [13]. If clinical trials are not carried out in accordance with those specifications recorded by the SOP, the validity of the entire clinical study can be called into question.

The sponsor has to guarantee furthermore that his staff members are familiar with SOP and that the access to the latest version of those procedures is ensured. This means that the sponsor has to carry out the following coordinational tasks: create, actualise, manage, examine, and replace obsolete SOP. Older versions of SOP have to be archived and supervised [14].

Due to the variety and complexity of SOP, the step-by-step retrievability of information is difficult. Staff members are therefore asked to keep the appropriate directives always at hand.

Searching for SOP demands a lot of time, especially when paper-based. A great effort is necessary to provide and record SOP for all persons involved because of their enormous impact on the quality and duration of a clinical study. This additional amount of time has to be refunded. Since especially the IIT lack money when completing a clinical study the reduction of cost-intensive factors such as working hours has to be kept in mind. It is therefore important that staff members work in accordance with SOP in order to be more effective.

This background shapes the following survey in order to determine possible improvements concerning the handling of SOP.

The following questions have to be answered:

Q1: How detailed is the staff's knowledge of the relevant SOP (existence)?
Q2: Do all persons involved have a SOP and is it available (availability)?
Q3: Is the latest version of the SOP available to each staff member (actuality)?
Q4: How do staff members work with SOP when attempting to retrieve information (efficiency)?
3. Method

To answer these questions a survey was conducted among employees of the 12 "Koordinierungscentren Klinischer Studien" in Germany by means of a standardised evaluation sheet.

In order to identify possible improvements concerning the handling of SOP, the focus of attention was the accessibility as well as the feasibility of SOP. Furthermore, it is of great importance that all participants take notice of all existing and relevant SOP.

After evaluating all members of one centre final evaluation forms were sent to the chief managers of the KKS. They were asked to pass on those forms to their employees. According to the homepage of the KKS, 238 people were employed there at that time.

The survey started in August 2004. All forms sent back until October 4, 2004, were included. To guarantee anonymity a neutral person collected them. Standardised answers were analysed by means of descriptive statistics; textual answers were summarised by the first author of this article.

4. Result

140 forms were sent back until October 4, 2004, or 58.8% respectively.

After a first, rough analysis the following conclusions can be made. The participants stated

- a low access rate of SOP during every-day work procedures
- accessing SOP and searching for relevant information is regarded as being an effort. This applies to paper-based versions as well as electronic versions
- rather than consulting SOP the participants ask their colleagues for help
- informing each staff member about SOP is difficult

The final results are to be presented at the conference.

5. Discussion

The participation rate of more than 50% suggests that the handling of SOP during everyday work procedures is important to staff members in order to maintain or even improve quality standards. It is therefore absolutely necessary to find out if all the persons involved in conducting clinical trials are sufficiently informed about those procedures. By means of this survey it will be possible to determine whether the access to and availability of SOP are guaranteed for paper-based as well as electronic SOP or not. Another important result of this survey concerns the relevance of SOP and the way each staff member gets relevant information. The participants of this study were further asked to define how data could be found more effectively in paper-based as well as electronic SOP in order to improve the retrieval of relevant information. This evaluation is therefore the starting-point for improving the usage and integration of SOP during clinical trials in accordance with internal restrictions, directives, and laws. Further plans involve the implementation of a computer-based retrieval tool (SOP Information Retrieval System) especially designed for clinical trials. This tool will be put to the test by further practical use. Another focus of attention is the improvement of SOP by means of a retrieval system whose design will also be based on the results of this survey.
6. Conclusion

After introducing the EU directive 2001/20/EG and the amendment no 12 to the law relating to the manufacture and distribution of medicines, certain quality standards concerning clinical trials have to be observed. A computer-based system may improve the usage and accessability of SOP in order to save money and improve the quality of clinical trials.

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8. References


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