A COMPARATIVE RISK ANALYSIS COMPARING THE CONVENTIONAL AND FULLY AUTOMATED MANAGEMENT OF CLINICAL TRIALS IN AN ONCOLOGY PHARMACY

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BACKGROUND

A software module (APOTECAtrial) was introduced in the clinical practice to manage clinical trials and investigational drugs, thereby minimizing manual activities and ensuring maximum traceability (1). APOTECAtrial was developed in accordance with the Good Clinical Practice (GCP) guidelines, in particular with regard to subject safety, outcome reliability, characteristics of electronic systems/data, and quality management with a risk-based approach.

AIM AND OBJECTIVES

The objective of this study was to assess the risk associated with the pharmacy-based management of clinical trials before and after the implementation of the software module APOTECAtrial.

MATERIAL AND METHODS

The conventional manual process and the improvements introduced after the implementation of APOTECAtrial were assessed through a comparative risk analysis. First, the process was divided into seven phases (delivery to the pharmacy, preparation/dispensing, returns management, disposal, storage, data management, monitoring). The activities related to each phase and the corresponding potential failures were identified. The risk was assessed by rating the severity (S), frequency (F), and detectability (D) of the potential effect of the failures. The risk index (S×F×D) was calculated for each activity (RI) and for the entire process (RItotal). The index of improvement (IR before implementation divided by IR after implementation) was calculated for each area (IM) and for the entire process (IMtotal).

RESULTS

Overall, 37 activities were assessed. The RItotal decreased by 53%, from 449 (before implementation) to 207 (after implementation). The IMtotal amounted to 2.2. The highest IR reduction was found in the preparation/dispensing phase (from 152 to 42) with a IM equal to 3.6. IM values ranged between 1.7 and 4.5. Most of the improvements introduced (79%) referred to traceability and data integrity, while 21% impact on the quality of the drug dispensed.

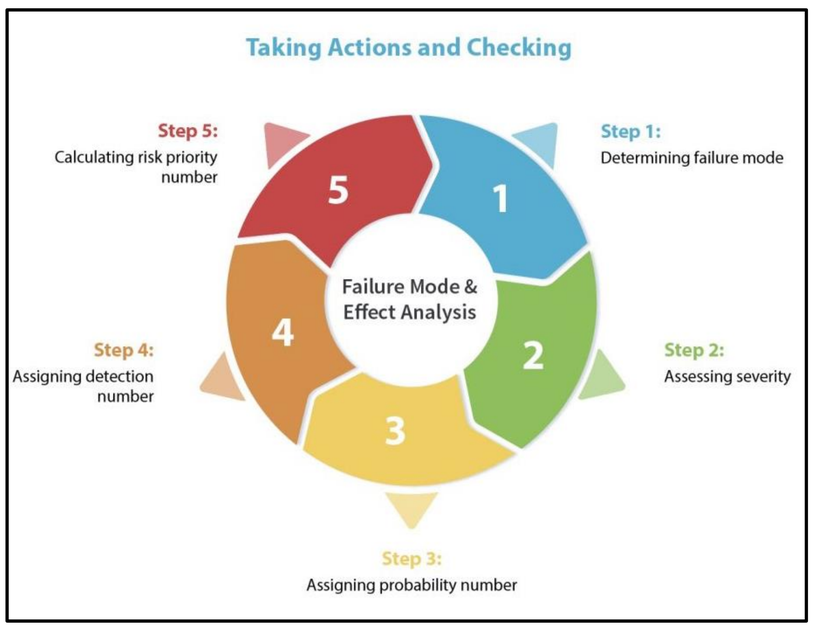

Figure 1. FMEA risk analysis

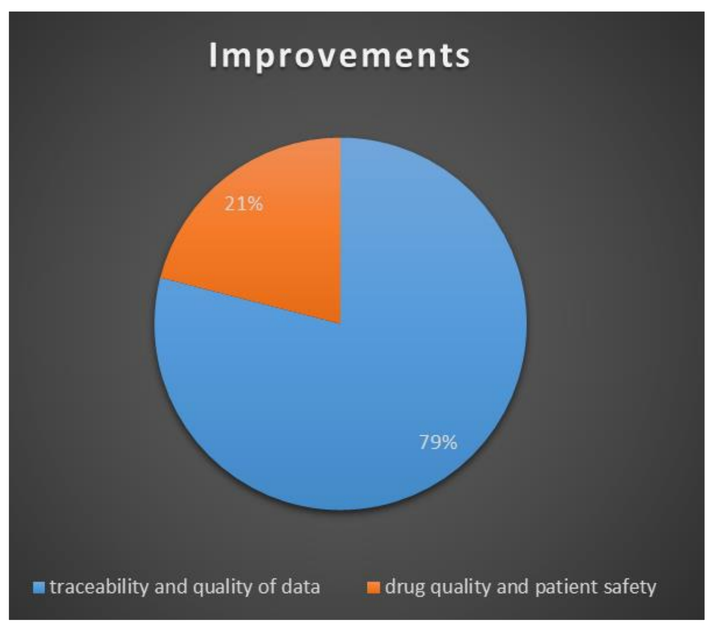

Figure 2. Type of improvements introduced with APOTECAtrial

CONCLUSION

The risk analysis revealed that fully-automated management of clinical trials represents an important improvement of the clinical pharmacy practice in terms of safety. Since the potential risks are significantly reduced, the automated process guarantees high quality standards and GCP-compliance. Several manual and repetitive activities were simplified, thereby allowing pharmacists to spend more time for clinical and patient-oriented tasks.

References: Leoni S. et al. Integration of clinical trials management into a safe and fully-automated onco-haematology workflow.

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