RESULTS OF A QUALITATIVE SURVEY ON THE APPLICATION OF COMPUTER SYSTEM VALIDATION IN EUROPEAN SMEs OF THE MEDICAL DEVICE INDUSTRY - FIRST FINDINGS OF AN ONGOING RESEARCH PROJECT

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Abstract

Research objective/questions: Medical devices offer health benefits to millions of people but can also lead to adverse events and incidents with serious consequences for patients. Therefore, the medical device industry in Europe is one of the sectors that is actively regulated by directives. In particular, compliance with and implementation of these legal regulations pose special challenges for manufacturers of medical devices. In the context of current trends and discussions on digital transformation, one focus is on computer system validation (CSV). In this context, the CSV is a documented and systematic process that consistently and reproducibly ensures that a computer-based system does exactly what it was designed to do. Due to the obligation to implement a CSV, legislators hope to reduce the risks associated with medical devices for patients, users and third parties. The implementation and maintenance of a complete CSV, however, is associated with high expenditure of time, personnel and financial resources. SMEs in particular, which often suffer from a lack of resources and technologies, face major challenges in implementing the legally required CSV. In addition, the regulations only stipulate that a CSV must be carried out and which type of system or software is to be taken into account in the company; the exact scope of the validation or a structured approach are not specified.

This study follows on from an ongoing research project aimed at developing and providing a resource-saving and risk-based CSV approach for European SMEs. In a previous study, existing CSV models and procedures were analysed and evaluated and the associated problems for SMEs were explained. The focus of this study is the development and pretesting of a questionnaire to test the hypotheses derived from an already developed research framework. Fur-

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thermore, with regard to the re-use of the questionnaire for further quantitative studies, statements should be made about the necessity of a formal and substantive revision of the questionnaire. To this end, the following research questions form the basis of this paper:

1. What is the status quo in European SMEs with regard to the implementation and application of the CSV?
2. Do the results of the study reveal commonalities and differences in the implementation and application of CSV?
3. Does the implementation and application of CSV have an impact on the firm performance of SMEs?

Conceptual development: As mentioned before, this study is part of an already started research project to develop a risk-based approach to CVS for European SMEs. In an earlier study, a research framework was developed that helps to investigate the relationship between company-specific information technology (IT) capabilities, CSV, and the firm performance of SMEs in the medical device industry.

The research framework is structured as follows: The dependent variable of firm performance is influenced both directly by measures of CSV and indirectly by the IT resources of the respective company. Furthermore, IT resources can be leveraged to implement a management model for CSV. In this study, IT resources are considered as a combination of IT capability and IT assets. IT assets include IT infrastructure and existing business applications. The focus here is on the one hand on the flexibility of the IT infrastructure to adapt to changing circumstances and on the other hand on the ability to use the existing applications to implement the business strategy and achieve the business objectives. IT capabilities are defined "as complex bundles of IT-related resources, skills and knowledge, exercised through business processes, that enable firms to coordinate activities and make use of the IT assets to provide desired results." Thus, the focus of this study is on the human IT capabilities and the IT management quality within the respective company. The mediation variable of the risk-based CSV was chosen because the current literature shows that several studies refer to risk management methods for the CSV. The emerging interest in this research area can be explained by the results of recent studies, which have shown that the identification and evaluation of operational and financial risks in the implementation of IT projects must be permanently reviewed in order to ensure later project success. It is therefore assumed that the better the risk for a validation project is determined, the better the validation project and its objectives can be planned and defined. Finally, control variables are implemented to analyse changes in firm performance by implementing a

CSV procedure that takes into account the impact of IT resources. Therefore, firm-specific variables, such as the size and capital of the organization, as well as product-related variables, such as compliance with medical standards, product quality, and the number of complaints, are analysed, as these control variables are often used in similar studies.

Methodology: To answer the above research questions, the focus of this study is on developing a questionnaire based on the variables of the conceptual model. Due to the complexity of the research topic, the heterogeneity of existing business applications on the market and the fact that the human factor and its individual needs and expectations are not directly measurable variables, a qualitative and explorative approach was chosen for both data collection and data analysis. In a first step, already tested and validated variables from similar research are identified based on a literature review and analysed and selected for use within this study. This ensures that the planned survey is based on standardized and tested measures. In addition to developing the questionnaire, another goal is to apply it to a test group and collect real data from selected medical device manufacturers. In order to be able to evaluate the collected data, the results of the surveys are discussed with experts from the international regulatory environment, as they have a broad knowledge of CSV as well as insights into many different SMEs and their CSV-related processes.

Results: The evaluation of the survey had not been completed at the time this abstract was submitted. Therefore, no information about the results of the survey can be provided. However, the limited IT capabilities of the workforce are a major reason that the implementation and application of CSV in SMEs often takes place without proper planning. In particular, uncertainty about the term of "computer system validation" means that employees have difficulty in implementing validation tasks and developing a long-term validation approach. This situation is made even more difficult by the fact that government policies and legal regulations must be taken into account. The authors assume that the lack of IT capability results in a limitation of the performance for these firms. Furthermore, implications for future research are suggested.

Contribution: The research attempts to address the gaps in Information systems (IS) literature. Furthermore, this research is the first of its kind that examines the change in firm performance as a result of IT resources and the mediating role of CSV in SMEs in the medical device industry. Finally, through the evaluation of experts in the field and broad acceptance in science and practice, the new model provides managers with a method for better decision-making in the context of CSV.

Keywords: Qualitative study**,** Computer system validation, Firm performance, Resource-based view (RBV), SME, Medical device industry.