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Determinants and impacts of computer system validation on firm-level performance

MARIUS SCHONBERGER
TATJANA VASILJEVA

ABSTRACT

Purpose. Amendments to regulatory directives in the medical device industry are forcing manufacturers to constantly review and adapt their business processes. In this context, the current focus is on computer system validation (CSV). The aim of this research is to identify determinants and impacts of CSV on firm performance and to determine the associated challenges, especially for small and medium-sized enterprises (SMEs).

Design/methodology/approach. A structured literature review was carried out which analyses published studies, evaluates contributions, and summarises knowledge. For this purpose, a previously developed research model served as the basis for data collection.

Findings. A total of 233 research papers were examined and divided into different categories and classified according to different criteria. Most of the research papers are grounded on a resource-based approach and predominantly investigate the impact of IT resources or capabilities on firm performance. Moreover, the review reveals that no research could be identified that justified changes in firm performance due to the implementation of CSV.

Research limitations/implications. The results of this paper can only be generalized to the specific population of scientific publications within the selected literature databases. Implications for future research are suggested.

Originality/value. The findings are derived from an exhaustive literature review of quantitative and qualitative studies. Thus, this research serves as a theoretical foundation for the investigation of change in firm performance as a result of IT resources and the mediator role of CSV and provides a path for future research for this field of study.

Keywords: Literature review, Computer system validation, Firm performance, Resource-based theory (RBT), SME, Medical device industry.

INTRODUCTION

The importance of information and communication technology (ICT) in healthcare continues to grow, driven by various disruptive changes, such as an ageing population, advances in the biology of disease and the practice of medicine, and the spread of connectivity and mobile technology (Fiaidhi *et al.*, 2016; Schonberger and Vasiljeva, 2018). ICTs offer vast opportunities to support healthcare industries and improve their effectiveness and efficiency (Gomes and Romão, 2018). The aim of ICT for healthcare in Europe is to improve the quality, access and efficacy of health products and services for all citizens (Ammenwerth *et al.*, 2004). Therefore, more and more medical device manufacturers are relying heavily on software to develop devices that help patients lead better lives. Thus, software has become a significant economic factor and occupies an important role in the critical functions of medical devices (Schonberger and Vasiljeva, 2018). However, with the benefits of software comes the risk of defects and errors.

According to Fu (2011), software-based medical devices led to over 537 recalls between 2002 and 2010, affecting more than 1.5 million devices. During this period, 11.3% of all recalls were due to software errors (Fu, 2011). A study by the Commonwealth Fund (2005) showed that in the U.S. approximately 35% of all respondents reported a medical mistake, medication error, or lab error (Schoen *et al.*, 2005). In comparison, only 23% of respondents in Germany and 22% in the U.K. reported medical errors. The study was based on a survey of 700 patients in Australia, Canada and New Zealand and 1,500 adults in the U.S., the U.K. and Germany (Schoen *et al.*, 2005). According to an AAMI study from 2016, medical errors caused more than 250,000 deaths each year in the U.S. and accounted for almost one in ten deaths. As Appendix 1 shows, a total of 271 recalls for medical devices, resulting from software errors, were reported to the U.S. Food and Drug Administration (FDA) in 2018 alone (FDA, 2019). This corresponds to an increase of 76 recalls (around 39%) compared to 2017. In addition, it is evident that most recalls are due to failures in software design. Other software-related recalls are due to missing or inadequate software design controls and testing procedures as well as the increasing complexity of the medical device usage environment (see Appendix 1). In summary, medical devices are often exposed to a high number of failures with potentially catastrophic effects on patients (Alemzadeh *et al.*, 2013).

Against this background, regulations require specific documentation on product safety, efficacy, strength, quality and purity (Yogesh *et al.*, 2015) in order to be able to identify the source of the defect retrospectively in the event of damage. Consequently, regulations and laws within the medical technology industry influence the manufacture, ordering and delivery of medical products; handling in warehouses; distribution; and a variety of other activities in the areas of manufacturing, quality assurance, marketing and research and development (Bendale *et al.*, 2011). In summary, legal regulations control many aspects of how a company in the medical device industry must be operated. For this purpose, it is

essential that all computer and software systems involved in the aforementioned processes are validated and supported as well as controlled by procedures and documentation that ensure their conformity (Bendale *et al.*, 2011). However, the implementation of computer system validation (CSV) is not only necessary due to legal regulations, but also in terms of economic, social and technological aspects (Schonberger and Vasiljeva, 2018). The problem for many medical technology companies is that the regulations only stipulate that CSV must be applied and which ICT must be considered in the company (e.g. FDA, 2002; ISO, 2016); the exact scope or a structured approach are not specified (Schonberger and Vasiljeva, 2018; Von Culin, 2011). To ensure that regulatory requirements are met, the challenge for manufacturers is to determine which ICT needs to be validated and how much validation is appropriate (Schonberger and Vasiljeva, 2018; McDowall, 2005).

This research is part of an already started research project and deals with the analysis of the subject of CSV in small and medium-sized enterprises (SMEs) in the medical technology industry. The aim of this research project lies in developing a risk-based management model for CSV in SMEs within the medical device industry. Based on a previous study (Schonberger and Vasiljeva, 2018), a structured and comprehensive literature review will be conducted to identify and evaluate determinants and impacts of CSV on firm performance. With regard to the aforementioned key problem, the following research questions are to be answered within the scope of this research:

1. To what extent has the relationship between CSV and firm performance been investigated in the literature so far?
2. Which theories and concepts have been used so far in the literature to investigate the relationship between CSV and firm performance?
3. What are the implications and challenges for future research in the area of CSV?

This research is structured as follows: First, the necessary terminological basics are explained in section 2. In section 3, the underlying research methodology is described. In section 4, the results of the structured literature review will be explained and analysed. A critical discussion of the results of the literature review follows in section 5. In this context, the results are compared and evaluated with regard to the research questions. Finally, the contribution concludes with the limitations of this research and recommendations on further research activities in section 6.

BASIC TERMINOLOGY

The medical technology industry in Europe

Medical technology is defined as “any technology used to save lives or transform the health of individuals suffering from a wide range of conditions” (MedTech, 2018:5). The

medical technology sector is the most important part of the healthcare sector (Maresova *et al.*, 2015). According to a current study by MedTech (2018), around 7.2% of the total expenditure in healthcare was spent on medical technology in 2018. Furthermore, 95% of the 27,000 medical technology companies in Europe are SMEs employing more than 675,000 people (MedTech, 2018). With approx. 30% of the worldwide expenditure on medical devices, Europe holds one of the biggest markets for medical technology (Klein, 2016). In addition, the medical technology sector is one of the most innovative industries in Europe (Klein, 2016). According to the European Patent Office (EPO, 2018), more patent applications were filed for medical technology in 2017 (13,090 applications) than for any other field of technology, including digital communication (11,694), computer technology (11,174), and biotechnology (6,278).

As already explained in the introduction, the market for medical technology and devices is one of the sectors that is actively regulated by directives (Foe Owono, 2015). Two leading regulatory authorities are responsible for defining, updating and verifying compliance of medical devices in Europe: The Medical Device Regulation (MDR) regulates almost all areas of medical devices, e.g. developing, manufacturing, or placing on the European market (Wagner and Schanze, 2018), while the FDA uses the 21 CFR 820 Quality Systems Regulation in stipulating to medical device manufacturers how to establish and maintain a quality assurance system (Francum, 2014). Although the FDA is primarily responsible for the U.S. market, many European medical device manufacturers follow FDA regulations, even if they do not sell their medical devices in the U.S. (Schonberger and Vasiljeva, 2018).

The role of ICT in the medical technology industry

ICTs are an important economic factor for the health sector and make a significant contribution to the improvement of products and services provided to patients (Schonberger and Cirjevskis, 2017). The main objective of ICT in healthcare is to manage information from all health-related activities, including planning, monitoring, coordination and decision-making (Gomes and Romão, 2018). Thus, ICT in healthcare has been identified as a key instrument to facilitate communication (Häyrinen *et al.*, 2008). It is widely recognized that the use of ICT offers enormous opportunities to support healthcare professionals and increase the efficiency, effectiveness and appropriateness of care (Gomes and Romão, 2018). However, from a regulatory and business perspective, the benefits of using ICT can only be reaped if it is ensured that each system does what it claims to do, reliably and repeatably (Yogesh *et al.*, 2015). The introduction and application of CSV is mandatory for medical device manufacturers to ensure this state of their computer and software systems in use (see section 4).

RESEARCH METHODOLOGY

As described in the introduction, the medical device industry faces major challenges in implementing and applying suitable CSV approaches (see section 1). To investigate this complex problem, a systematic literature review was carried out, which analyses published studies, evaluates contributions, and summarises knowledge. For this purpose, a previously developed research model served as the basis for data collection (Schonberger and Vasiljeva, 2018; see Appendix 2). As the conceptual model in Appendix 2 shows, firm performance, IT capability, risk management capability, and CSV are the focus of the literature review. The aim of this review is to identify determinants and impacts of CSV on firm performance and to determine the associated challenges, especially for SMEs. The structure of the literature review, which is based on the methods of Schonberger *et al.* (2014), Mikelsone and Liela (2015) and Schonberger (2018), is described below.

Problem formulation

In general, the literature review described within this research is intended to give an overview of the content and thematic orientation of the literature. The primary aim of the review is to obtain a comprehensive overview of the current status of the literature. As a result, the review should identify literature that can explain the relationships between the variables in the conceptual model (see Appendix 2). Thus, within the scope of the review, the following main question should be answered: "How does IT capability and risk management capability (RMC) impact firm performance due to the implementation of CSV in SMEs from the medical device industry?" (Schonberger and Vasiljeva, 2018). This question is connected to the first research question stated in this paper (see section 1). In order to investigate this problem, the underlying literature review process is described and explained below.

Literature review process

The publications identified by the systematic literature review should refer as comprehensively as possible to the problem statement already described before. For this purpose, various literature databases were selected at the beginning of the review and an extensive keyword search was carried out. Therefore, based on the variables of the conceptual model, the following main keywords were used: IT Capability, Risk Management, Computer System Validation, and Firm Performance. In addition, while most of the research papers within the information system literature are grounded on a resource-based or dynamic capability approach (Schonberger and Vasiljeva, 2018), the existing keywords were supplemented as follows: Resource-based Theory and Dynamic Capability. The following literature databases were searched for literature: Google Scholar, Scopus, EBSCO Academic Search, ScienceDirect, Emerald Insight and Sage Journals.

The search was carried out in several steps. First, a full overall search was performed. Here, the previously mentioned keywords were combined in an appropriate way: Each main keyword was AND-linked to the corresponding thesaurus terms, while these were OR-linked. For example: “Computer System Validation” AND “Computer Validation” OR “Software Validation” OR “CSV”. Afterwards, each search string was inserted into the search of the respective literature databases. The search was then restricted to article titles, abstracts and keywords. The findings of the first overall search are listed in Table 1.

Table 1.

First search –
Overall search of the main keywords in article titles, abstracts and keywords

Databases	RBT	DC	IT cap.	CSV	FP	RM
EBSCO	206	176	135	96	1419	52221
Emerald Insight	927	874	246	1	8803	12630
Google Scholar	23100	19100	12200	680	449000	1020000
Sage Journals	451	323	81	26	4369	13206
ScienceDirect	1291	1290	757338	86	15377	61647
Scopus	866	2998	923	69	10626	99371
Total:	**26841**	**24761**	**770923**	**958**	**489594**	**1259075**

(Legend: RBT = Resource-based theory, DC = Dynamic capability, IT cap. = IT capability, CSV = Computer system validation, FP = Firm performance, RM = Risk management)

In the second step, the first results were restricted to fully accessible publications only. While all databases have the possibility to narrow down the results by several search criteria, in the case of Google Scholar it was not possible to filter the results by only fully accessible publications. Therefore, after each search term the specification “filetype:pdf” had to be added, meaning that only results in PDF format were listed in Google Scholar. The findings of the second search are listed in Table 2.

Table 2

Second search –
Restriction of the first results to fully accessible publications only

Databases	RBT	DC	IT cap.	CSV	FP	RM
EBSCO	53	49	57	49	364	13258
Emerald Insight	13	18	3	0	165	148
Google Scholar	10300	6710	2760	132	26800	121000
Sage Journals	38	33	8	4	283	1423
ScienceDirect	155	153	62921	2	1442	6390
Scopus	3	47	7	0	84	1891
Total:	**10562**	**7010**	**62996**	**187**	**29138**	**144110**

(Legend: RBV = Resource-based theory, DC = Dynamic capability, IT cap. = IT capability, CSV = Computer system validation, FP = Firm performance, RM = Risk management).

In the next step, the duplicates within the findings were eliminated and linguistic restrictions were performed afterwards. For reasons of better comparability, only English-language literature is taken into account for this study. Due to considerable differences between the definition of SMEs in the U.S. and the proposal of the European Commission (SBA, 2017), literature sources referring to the definition of SMEs in the U.S. are excluded, as this makes it difficult to compare the English-language literature.

Following the linguistic restrictions, content limitations were also defined. First, the results of the literature review were reduced to ranked journals and proceedings according to the ABDC and ABS quality lists. These scales were selected because they are currently widely used in academic research (Rowlinson *et al.*, 2015). In addition, articles published in scientific journals are considered to be certified knowledge, as these articles must undergo a consistent review process (Koseoglu, 2016; Ramos-Rodrigues and Ruiz-Navarro, 2004). Furthermore, although it is acknowledged that books or dissertations also influence scientific thinking, academic journals and conferences are generally regarded as the dominant communication platform for researchers (Schonberger *et al.*, 2018). Second, according to the research background, European SMEs from the medical device industry are the focus of the literature review. Therefore, the publications were examined again with the help of a keyword analysis. The following keywords were selected: small and medium enterprises, small and medium-sized enterprises, SME, medical device industry, and medical device manufacture. This ensured that only publications related to the introductory problem were selected (see section 1).

Finally, at the end of the literature review, the results were analysed by reading the abstracts and references of the remaining research papers. Again, publications were eliminated that were not focused on the problem formulation. However, other relevant literature was also included which was listed in the references of the publications. Figure 1 shows the entire literature research process.

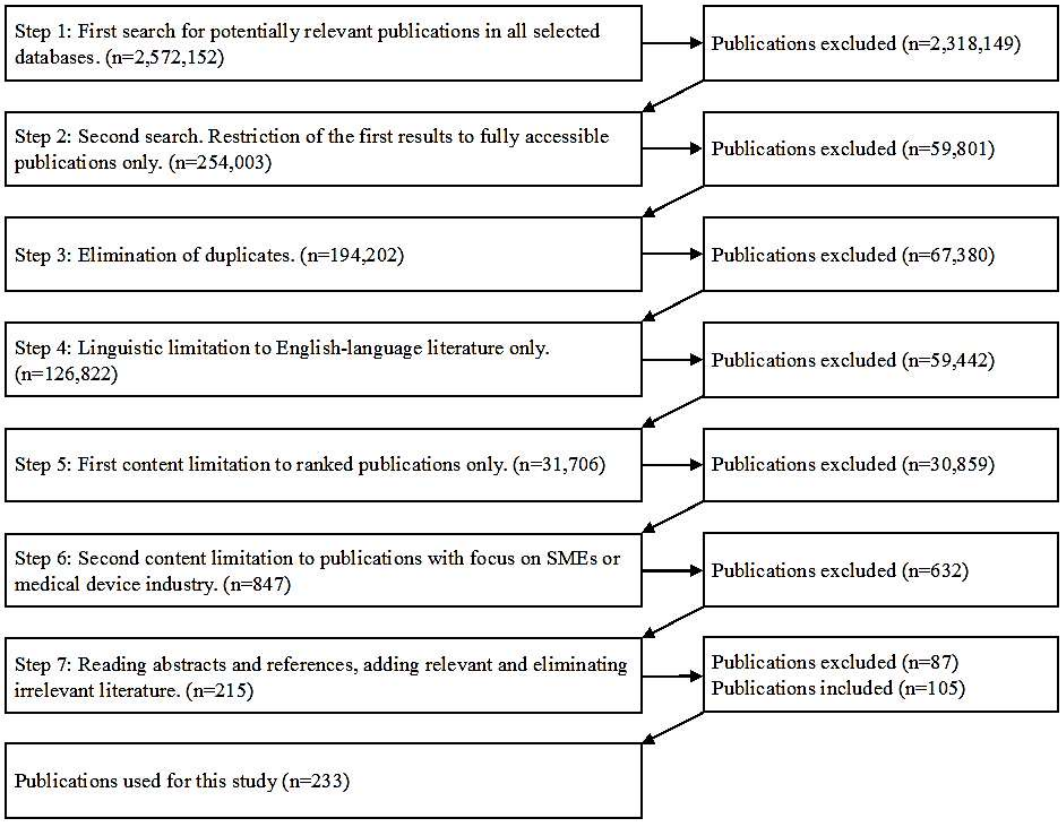

Figure 1. **Flowchart of the literature review process**

In order to achieve the best possible and most adequate results through the literature review, research papers, conference papers, proceedings, monographs, books, dissertations and postdoctoral theses are examined and evaluated. As the focus on SMEs implies the identification of only a few literature sources, there is no limitation regarding the time of the publication. A time limitation could thus possibly prevent the consideration of older relevant sources of literature. This also applies to the term “Computer System Validation”, which has already been identified in previous studies (Schonberger and Vasiljeva, 2018; Schonberger, 2018). Nevertheless, a consideration of current literature is aspired to. Furthermore, for better comparability of the literature, the term “SME” is used universally without any specific industry reference.

Literature analysis

In order to be able to analyse the identified publications more precisely, they were stored in an Excel spreadsheet. This made it possible to create a comprehensive literature database on the one hand and to use the Excel functions for statistical evaluation of the results on the other. For the construction of the literature database, the names of the

authors, the title of the publication, the year, the publication type or the name of the journal, the volume of the journal, the page numbers as well as the keywords of the authors specified in the publication were inserted into the Excel spreadsheet for each publication. The transfer of articles from the literature databases was done by exporting the data into a text file and importing this file into Excel with one exception: The transfer of articles from Google Scholar was done manually.

Since data retrieved from bibliographic sources usually contain errors (Cobo *et al.*, 2011), e.g. spelling mistakes in the name of the author, in the journal title or in the reference list, a content analysis could not be carried out directly and manual data processing of the retrieved data was necessary. In order to improve the quality of the data and thus achieve better results in content analysis, the data was therefore manually checked and cleaned up by adding information to incomplete or incorrect original records, e.g. if the author's name was incomplete or keywords had to be split if they were stated in a string and not separately. Finally, the abstracts and references of the 215 publications were read and further relevant literature referenced in the publications was also stored in the Excel spreadsheet. Furthermore, irrelevant literature was excluded. Thus, publications were also included in this study which do not correspond to the limitation of ranked journals or proceedings (see Figure 1).

RESEARCH FINDINGS

Structure of the literature base

Based on the literature review, a total of 233 publications were identified, of which most are journals (n=159), followed by conference proceedings (n=20) and books (n=18; see Appendix 3). The top cited journals are the MIS Quarterly Journal (n=16), followed by the Strategic Management Journal (n=11) and the Information and Management Journal (n=8). According to the ABDC quality list from 2016, nearly 20 percent of the findings are ranked in A*-Journals, and 22 percent are ranked in A-Journals. The quality of the journals according to the ABS quality list from 2018 is a little bit different: here only seven percent are classified as a 4*-Journal, and four percent as a 4-Journal. However, although non-ranked publications were eliminated, there are several non-ranked publications within the literature database (see Appendix 4). This can be explained by the fact that in the analysis of the references of the publications from the first results (Step 7), publications were also included in the literature database that do not belong to the defined limitations and restrictions from the literature review process (see Figure 1). The top cited proceedings are from the European Conference on Information Systems (ECIS, n=6), followed by the International Business Information Management Conference (IBIMA, n=2) and the International Conference on Information Systems (ICIS, n=2). The conference proceedings

are, according to the ERA database from 2010, mainly classified as A-Conferences (50 percent, see Appendix 5).

The analysis of the keywords contained in the literature database shows, not surprisingly, that the initially used main keywords are among the top ten. The most frequently mentioned keyword was Resource-based theory (n=24), followed by IT capability (n=23) and Dynamic capability (n=21). More interesting is the fact that related keywords that were not selected at the beginning of the review were mentioned more often than some main keywords. For example, the keywords Competitive advantage (n=16) or Information Technology (n = 13) were mentioned more frequently than the keyword Computer System Validation (n=8). Another interesting fact is that although SMEs are the focus of this research, the keyword SME was not included in the initial keyword analysis but is now in the top ten keywords (n=11).

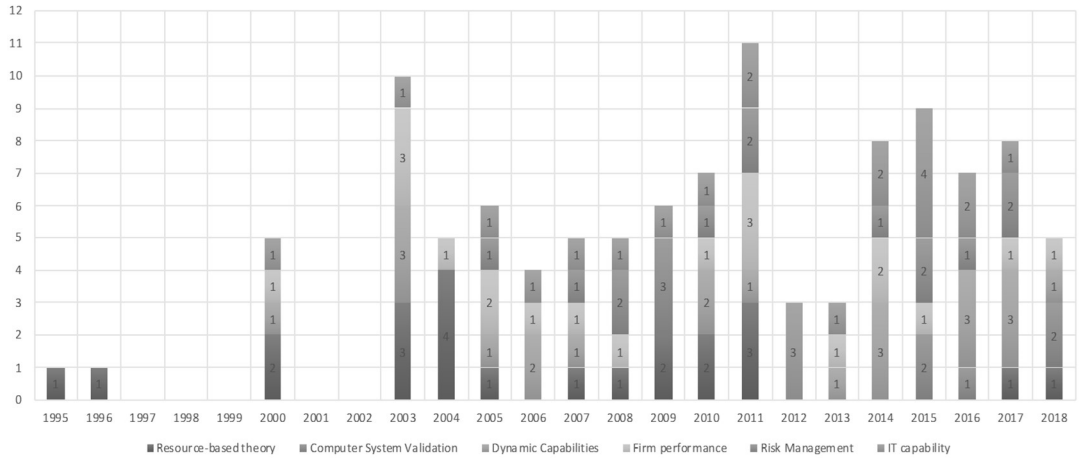

Figure 2. **Historical trends of main keywords used for the literature review**

Figure 2 gives an overview of the historical trends of the main keywords. It is obvious that most keywords appeared after the year 2003. In addition, it can be observed that keywords such as Resource-based theory or Firm performance occur almost every year. An exception is the keyword Computer System Validation, which was first mentioned in the year 2015. The reasons for the lack of literature between 1997 and 2003 could be explained by Kondratiev waves, an economic theory that describes economic fluctuations over a period of 40-60 years (Goransson and Soderberg, 2005). The last wave corresponding to this theory began to rise in the early 1970s to mid-1990s and describes economic effects based on the use and diffusion of information technology (IT) (Goransson and Soderberg, 2005). With the beginning of this wave, scholars were increasingly researching the impact of IT on the economy. The usual delay in publishing research results may have led to a lack of scientific literature between 1997 and 2003.

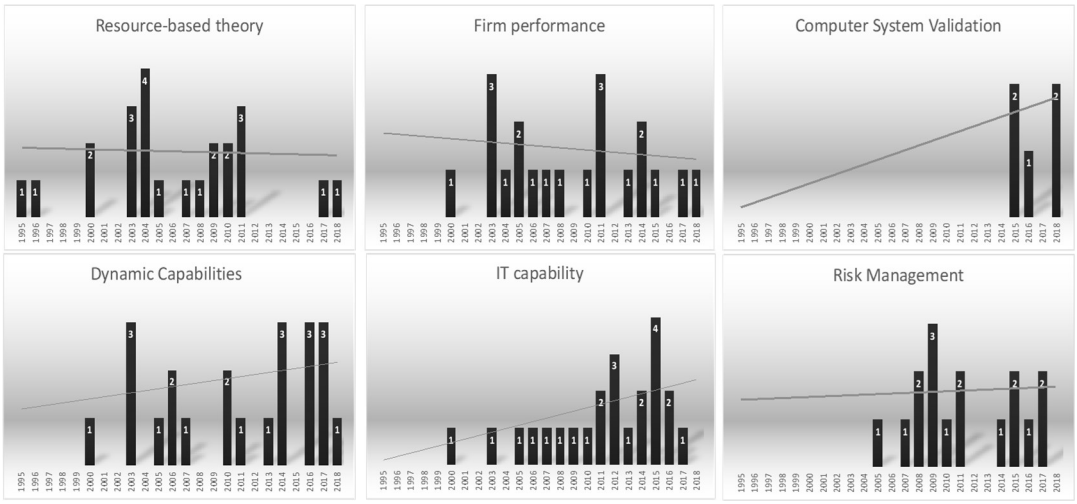

Figure 3. **Historical trends of the main keywords in detail**

In the following, the historical trends of the individual main keywords are examined in detail (see Figure 3). It can be seen that in terms of the keywords Resource-based theory and Firm performance, research activities have declined slightly over the last few years, while activities in terms of the keywords Dynamic capability and IT capability have increased significantly. Literature on the keyword Risk Management is more or less stable and increasing slightly. However, no statements can be made about trends regarding the keyword Computer System Validation, as there is a major gap in the literature.

In summary, an answer can already be given to the first research question. The literature review carried out in this paper has shown that the subject of CSV is still largely unexplored in current ICT literature (see Table 1 and Figure 3). Furthermore, most of the research papers are grounded on a resource-based approach and predominantly investigate the impact of IT resources or capabilities on firm performance. Moreover, the review reveals that no research could be identified that justified changes in firm performance due to the implementation of CSV.

Results of the literature review

In the following, the results of the literature review are explained, whereby the focus here is more on the contents of the identified publications. The following paragraphs concentrate on the analysis of the main keywords (see section 3) and thus on the evaluation of the previously established conceptual model (see Appendix 2).

Resource-based theory and IT resources

The understanding of the relationship between IT-related capabilities and firm performance has been the subject of numerous studies in recent years and has commonly

been investigated by resource-based theory (RBT) (e.g. Bharadwaj, 2000; Chen and Tsou, 2012). To understand how organizations achieve a sustainable competitive advantage, RBT analyses and interprets organizations' resources (Madhani, 2009; Ray *et al.*, 2005; Wade and Hulland, 2004). The concept behind RBT focuses on the unique combination of resources of a firm that are economically valuable, rare, and difficult to imitate (Barney, 1991) and considers them as sources of superior performance and competitive advantage (Grant, 1991; Wade and Hulland, 2004). An overview of various definitions of the term "RBT" is provided in Table 3.

Table 3

Selection of definitions related to the term "Resource-based theory"

Author(s)	Definitions
Conner (1991:121-122)	"A resource-based approach […] focuses on costly-to-copy attributes of the firm as sources of economic rents and […] as the fundamental drivers of performance and competitive advantage."
Maijoor and Van Witteloostuijn (1996:549)	"The resource-based view of the firm is a recent management theory that seeks to identify the resources that may provide firms with a sustainable competitive advantage."
Bharadwaj (2000:170)	"The resource-based view […] focuses on costly-to-copy attributes of a firm which are seen as the fundamental drivers of performance."
Galbreath (2005:979)	"RBT […] is built upon the theory that a firm's success is largely determined by the resources it owns and controls."
Madhani (2009:3)	"The […] resource-based view analyzes and interprets internal resources of the organizations and emphasizes resources and capabilities in formulating strategy to achieve sustainable competitive advantages."

However, although RBT provides a useful theoretical perspective to assess the heterogeneity of firm performance, the existing IT literature lacks clarity in the definition and conceptualization of IT resources (Wade and Hulland, 2004; Aral and Weill, 2007). This is evident from the fact that in recent years researchers in the field of RBT have subsumed a multiplicity of different terminologies under the heading "resource", including competencies (e.g. Prahalad and Hamel, 1990), skills (e.g. Grant, 1991), strategic assets (Amit and Schoemaker, 1993), assets (Ross *et al.*, 1996), assets and capabilities (e.g. Wade and Hulland, 2004), and stocks (Capron and Hulland, 1999). In summary, firm resources are broadly defined to include assets, organizational processes, firm attributes, information, information technologies, or knowledge, which can be used to implement value-creating

business strategies (e.g. Galbreath, 2005; Mata *et al.*, 1995; Barney, 1991; Wernerfelt, 1984).

As this research project, as described before (see section 1), focuses on computer systems and ICT in SMEs of the medical technology industry, IT-related resources are therefore the focus of the analysis of RBT. According to Wade and Hulland (2004), RBT started to emerge in ICT research in the middle of the 1990s (which confirms the theory of Kondratiev waves; see section 4.1). Ross *et al.* (1996) separated IT-related resources into three IT assets which, together with IT processes, would contribute to business value. These three IT resources were defined as human assets (e.g. technical capabilities, business understanding), technology assets (e.g. physical IT assets, IT infrastructure) and relationship assets (e.g. partnerships with other departments). This categorization was later redefined by Bharadwaj (2000) to include IT infrastructure, personnel IT resources and IT-capable intangible assets. An overview of further various classifications according to the term "IT resource" is provided in Table 4.

Table 4

Overview of IT-related resources examined in previous studies

Author(s)	IT-related resources
Mata *et al.* (1995)	Access to capital, proprietary technology, technical IT skills, managerial IT skills
Ross *et al.* (1996)	Reusable technology base, IT-business partnering relationship, IT human resources
Feeney and Willcocks (1998)	Design of IT infrastructure, business and IT vision, delivery of IS services
Bharadwaj *et al.* (1999)	IT infrastructure, business process integration, internal IT partnerships, external IT partnerships, IT management, strategic vision of IT
Bharadwaj (2000)	IT infrastructure, human IT resources, IT-enabled intangibles
Sambamurthy *et al.* (2003)	IT investment scale, IT capabilities
Aral and Weill (2007)	IT (technical) assets, IT (human) capabilities

As can be seen from Table 4, over the years different IT-related resources have been examined. However, there are often overlaps, for example IT capabilities (e.g. Mata *et al.*, 1995; Sambamurthy *et al.*, 2003; Aral and Weill, 2007), IT infrastructure (e.g. Feeney and Willcocks, 1998; Bharadwaj *et al.*, 1999; Bharadwaj, 2000), or Human IT resources (e.g. Ross *et al.*, 1996; Bharadwaj, 2000; Aral and Weill, 2007). In this context, ICT is an important factor in making organisational resources accessible and divisible so that firms can respond more flexibly to changing market needs (Bharadwaj, 2000).

Dynamic capability and IT capabilities

As markets are dynamic, the resources of a firm also need to change over a period of time to become relevant to changing market conditions (Lin and Wu, 2014; Madhani, 2009). The dynamic capabilities (DC) approach is based on this perspective, extending RBT to include environmental and technological change (Daniel *et al.*, 2014; Madhani, 2009; Aral and Weil, 2007). DC refers to a firm's ability to integrate, build, and reconfigure internal and external competencies (Cirjevskis, 2016; Liu *et al.*, 2013; Teece *et al.*, 1997). Thus, the DC perspective is a widely applied paradigm to explain variance in performance across competing firms (Cirjevskis, 2016; Liu *et al.*, 2013; Barreto, 2010; Zott, 2003; Teece *et al.*, 1997). An overview of various definitions of the term "DC" is provided in Table 5.

Table 5

Selection of definitions related to the term "Dynamic capability"

Author(s)	Definitions
Teece *et al.* (1997:516)	"[…] the firm's ability to integrate, build, and reconfigure internal and external competences to address rapidly changing environments."
Eisenhardt and Martin (2000:1107)	"The firm's processes that use resources – specifically the processes to integrate, reconfigure, gain and release resources – to match and even create market change. Dynamic capabilities thus are the organizational and strategic routines by which firms achieve new resource configurations as markets emerge, collide, split, evolve, and die."
Zott (2003:98)	"[…] the ability to generate alternative resource configurations by way of imitation and experimentation."
Wade and Hulland (2004:131)	"[…] by acting as a buffer between core resources and the changing business environment, dynamic resources help a firm adjust its resource mix and thereby maintain the sustainability of the firm's competitive advantage […]."
Cepeda and Vera (2007:427)	"[…] the processes to reconfigure a firm's resources and operational routines in the manner envisioned and deemed appropriate by its principal decision makers."
Lin and Wu (2014:408)	"[…] the capabilities of a firm to integrate, learn and reconfigure internal and external resources."

Since the DC perspective was first introduced by Teece *et al.* (1997), numerous definitions for DCs have emerged. Some scholars define DCs as routines (e.g. Pavlou and El Sawy, 2011; Helfat and Peteraf, 2009; Zollo and Winter, 2002), while others describe them as processes (e.g. Cepeda and Vera, 2007; Eisenhardt and Martin, 2000). In addition, various researchers define DCs as high-level capabilities to adapt operational processes and

routines to develop new value-creating strategies (Daniel *et al.*, 2014; Liu *et al.*, 2013; Cepeda and Vera, 2007; Helfat and Peteraf, 2003; Eisenhardt and Martin, 2000).

Table 6

Selection of definitions related to the term "IT capability"

Author(s)	Definitions
Bharadwaj (2000:171)	"A firm's IT capability is defined […] as its ability to mobilize and deploy IT-based resources in combination or co-present with other resources and capabilities."
Marchand *et al.* (2000:73)	"A company's capability to effectively manage information-technology (IT) applications and infrastructure to support operations, business processes, innovation and managerial decision making."
Aral and Weill (2007:765)	"IT resources are combinations of investment allocations and a mutually reinforcing system of competencies and practices that together represent organizational IT capabilities."
Stoel and Muhanna (2009:182)	[…] 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."
Parida *et al.* (2009:537)	[…] "ICT capability is defined as a firm's ability to use strategically ICT functions or applications for their business purposes and competitive advantage."

Within the ICT domain, scholars have shaped the term IT-enabled capabilities to measure a firm's performance in exploiting its IT resources, competencies and capabilities (Van de Wetering *et al.*, 2017). In this context, IT capabilities in current IT business value research are considered as lower-order capabilities that enable the development of higher-order capabilities, such as agility (e.g. Sambamurthy *et al.*, 2003), knowledge management (e.g. Tanriverdi, 2005), or operational capabilities (e.g. Pavlou and El Sawy, 2011). Rai *et al.* (2006:227) also define IT capability as "a lower-order capability that can be leveraged to develop a higher-order process capability, which is a source of significant and sustained performance gains for the firm." An overview of further various classifications according to the term "IT capability" is provided in Table 6.

Previous research focusing on IT capabilities is mainly rooted in RBT (Pavlou and El Sawy, 2011). Thus, there are similarities between the various characterizations of IT resources and the different definitions of IT capability (see Table 6). In the vast majority of empirical studies, IT capabilities are conceived merely as an aggregation of IT resources and other IT-related resources or competencies (Van de Wetering *et al.*, 2017; Wade and

Hulland, 2004). In summary, IT capability has been seen as a sophisticated, multidimensional construct, and the literature has recommended several distinct IT-related resources that aggregate into IT capability (Pavlou and El Sawy, 2011).

Computer System Validation and Risk Management

The term "validation" is used in the current ICT literature with very different meanings (Schonberger, 2018). Rooted in the software engineering and software developing literature, Sommerville (2011:41) defines validation as follows: "Software validation […] is intended to show that a system both conforms to its specification and that it meets the expectations of the system customer." A similar definition is provided by the DIN ISO 9000:2015 norm, which describes validation as a "confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled" (ISO, 2015). The definitions demonstrate that in the software development industry, validation usually relates to testing software against its specifications and requirements.

Table 7

Selection of definitions related to the term "Computer System Validation"

Author(s)	Definitions
FDA (2002:6)	"[…] confirmation by examination and provision of objective evidence that software specifications conform to user needs and intended uses, and that the particular requirements implemented through software can be consistently fulfilled."
Veverka (2002:52)	"Computer systems validation ensures that systems perform according to their defined specifications."
Hrgarek (2008:2)	"Validation is a process of obtaining evidence and determining that a final software system meets the user's needs and expectations."
Bendale *et al.* (2011:27)	"[…] the process by which all aspects of a process (including computer systems) are shown to meet all quality requirements, and comply with applicable rules and regulations regarding product quality, safety and traceability."
Yogesh *et al.* (2015:445)	"Computer System Validation provides documented proof that the system (e.g. hardware, software, peripherals and network) will repeatedly and reliably do what it is designed to do […]."

However, the understanding of validation in this research is addressed to manufacturers of medical devices who need to verify that their processes provide consistent product quality. In this context, CSV is a requirement on the quality system of each manufacturer (Schonberger, 2018; Bendale *et al.*, 2011; Hrgarek, 2008; FDA, 2002) and must therefore

prove that the computer systems operate according to their specifications and that this declaration is confirmed by formal documentary evidence (Yogesh *et al.*, 2015; Bendale *et al.*, 2011; Tracy and Nash, 2002). Following this understanding, a computer system in the healthcare domain includes not only software and hardware, but also devices and instruments associated with the computer system as well as trained personnel operating the system and/or devices using standard operating procedures and manuals (Yogesh *et al.*, 2015; Bendale *et al.*, 2011; Yin, 2010; Hrgarek, 2008). The primary objective of CSV is to achieve and maintain regulatory compliance (see section 1) while ensuring the peak performance and functionality of these systems (Bendale *et al.*, 2011; Veverka, 2002). An overview of various definitions of the term "CSV" is provided in Table 7.

In summary, the main task of CSV is to prove that each computer system fulfils its intended purpose within the production and quality processes of a medical device manufacturer. In doing so, the validation of computer systems exceeds the activities of pure software testing by far (Bendale *et al.*, 2011). The aim is to avoid software problems that could have serious consequences for the patient, the user or third parties. To eliminate these problems, researchers have developed various risk-based approaches to CSV implementation over the last few years or pointed out that risks should be identified and assessed during CSV (e.g. Charan and Vishal Gupta, 2016; von Culin, 2011; Hrgarek, 2008; Tracy and Nash, 2002). This stream was also fostered by the fact that in 2003 the FDA proposed the introduction and implementation of risk-based validation (Charan and Vishal Gupta, 2016; McCaffery *et al.*, 2012; Yin, 2010; McDowall, 2005). However, according to von Culin (2011:32), the medical device industry "seems to be facing several challenges implementing a risk-based approach with computer system validation."

The reasons for this include the fact that it is unclear when a computer system is risky and when it is not (von Culin, 2011; McDowall, 2005). The FDA regulations do not necessarily facilitate the situation: "For lower risk devices, only baseline validation activities may be conducted. As the risk increases additional validation activities should be added to cover the additional risk." (2002:12). Another reason is the lack of essential decision-making tools, which can lead to "over-validation" for some computer systems and "under-validation" for others (Veverka, 2002). Nevertheless, the current CSV literature contains several risk analysis approaches that can be used for CSV (e.g. Charan and Vishal Gupta, 2016; von Culin, 2011; McDowall, 2005). However, one of the main conclusions is that one risk approach does not fit all validation situations; thus, the person in charge of risk assessment should select the best methodology for the problem (McDowall, 2009). This in turn poses the problem that each company has to decide for itself which ICTs need to be validated, what risk they bear and how much validation is appropriate to ensure compliance with regulatory requirements (Schonberger and Vasiljeva, 2018; McDowall, 2005).

In conclusion, CSV within the medical device industry is highly dependent upon an established quality management and quality assurance system (Yogesh *et al.*, 2015;

Bendale *et al.*, 2011). Even though difficulties in interpreting regulations and applying CSV techniques have overshadowed their intended purpose, implementing systematic CSV helps prevent software problems from entering the production environment (Bendale *et al.*, 2011; Veverka, 2002). Although the FDA's regulations mainly apply in the FDA-regulated environment, the suggestions and recommendations to implement and apply a risk-based approach to CSV have also been implemented within the non-FDA-regulated environment, e.g. in many European companies.

Firm performance

Firm performance is a relevant construct in current ICT-related research and frequently used as a dependent variable (e.g. Liu *et al.*, 2013; Stoel and Muhanna, 2009; Aral and Weill, 2007; Bharadwaj, 2000). Within the strategic management literature, stakeholder theory is often used as the basis for determining firm performance (e.g. Harrison and Wicks, 2013; Santos and Brito, 2012; Richard *et al.*, 2009). Stakeholder theory allows one to solve the question of the distinction between performance requirements and performance outcomes, enabling performance measurements to evaluate the satisfaction of at least one group of stakeholders (Santos and Brito, 2012). As Carneiro *et al.* (2007) observed, this conceptualization of firm performance can be applied across different companies. This insight has also been confirmed by the use of RBT. According to Ray *et al.* (2005), RBT explains differences in performance in terms of the types of resources and capabilities that different companies control, regardless of whether these are at the firm or process level. Furthermore, empirical studies of firm performance using RBT have identified differences not only between companies in the same industry, but also in groups within industries (Wade and Hulland, 2004). However, Ray *et al.* (2004) warn against the difficulties of testing RBT using aggregated measures of performance and suggest the use of indicators directly connected to the resources under analysis. Therefore, the application of stakeholder theory is more appropriate, as each stakeholder can distinguish between high and low performers (Carneiro *et al.*, 2007).

Table 8

Performance constructs and sample indicators for firm performance
(Santos and Brito, 2012:103)

Performance constructs	Sample indicators
Profitability	Return on assets, EBTIDA Margin, Return on investment, Net income/Revenues, Return on equity, Economic value added
Market value	Earnings per share, Stock price improvement, Dividend yield, Stock price volatility, Market value added (market value/equity), Tobin's q (market value/replacement value of assets)

Continuation of Table 8

Performance constructs	Sample indicators
Growth	Market-share growth, Asset growth, Net revenue growth, Net income growth, Growth in number of employees
Employee satisfaction	Turn-over, Investments in employee development and training, Wages and rewards policies, Career plans, Organizational climate, General employee satisfaction
Customer satisfaction	Mix of products and services, Number of complaints, Repurchase rate, New customer retention, General customer satisfaction, Number of new products/services launched
Environmental Performance	Number of projects to improve / recover the environment, Level of pollutant emission, Use of recyclable materials, Recycling level and reuse of residuals, Number of environmental lawsuits
Social Performance	Employment of minorities, Number of social and cultural projects, Number of lawsuits filed by employees, customers and regulatory agencies

The definition of firm performance and its measurement continues to challenge scholars due to its complexity (Santos and Brito, 2012). Combs *et al.* (2005) developed an approach to managing this complexity by analyzing published articles in the Strategic Management Journal between 1980 and 2004 about the application of different measurement scales to the study of firm performance. The findings of their research were based on 238 empirical studies in which 56 different indicators were used. In the majority of cases, financial performance was used (82 percent), with profitability measures being the most common choice (52 percent). Comparable studies had similar results analyzing different databases in other time periods (e.g. Santos and Brito, 2012; Richard *et al.*, 2009; Carton and Hofer, 2006). Over the last few years, various indicators have been established within the literature that are either unidimensional or multidimensional (Santos and Brito, 2012). Since unidimensionality would mean that all stakeholders have similar requirements and needs, based on stakeholder theory, this would be a simplified representation of such a complex construct and thus unlikely (Santos and Brito, 2012; Combs *et al.*, 2005). This makes multidimensional constructs more suitable for measuring firm performance, as multidimensionality proposes that each dimension symbolizes an aspect of the firm's overall performance and is represented by a distinct set of indicators (Santos and Brito, 2012). In this context, Santos and Brito (2012) provide an overview of sample indicators for firm performance based on seven performance constructs (growth, profitability, market value, customer and employee satisfaction, and social and environmental performance) as shown in Table 8.

In research on ICT-enabled firm performance, recent literature questions the direct effects of IT capabilities on firm performance by contending that the effects are mediated by other

capabilities (Liu *et al.*, 2013; Mithas *et al.*, 2011; Pavlou and El Sawy, 2011; Ray *et al.*, 2005). Wade and Hulland (2004) state that information systems exert their influence on the company through complementary relationships with other company-related assets and capabilities. Other researchers assume that knowledge management and agility represent important mediators that help to establish the nomological network for the impact of IT capabilities on firm performance (Sambamurthy *et al.*, 2003). Mithas *et al.* (2011) argue that IT capabilities affect firm performance by enabling higher-order business capabilities. Thus, the impacts of IT capabilities, as lower-order capabilities, on firm performance are mediated by dynamic and operational capabilities, as higher-order capabilities (Liu *et al.*, 2013; Pavlou and El Sawy, 2011; Rai *et al.*, 2006; Sambamurthy *et al.*, 2003; Kohli and Grover, 2008; Mithas *et al.*, 2011). Ong and Chen (2014) identified that the impact of IT capabilities on firm value is greater than on firm performance. In this context, they defined firm performance as backward-looking measures and short-term influences and firm value as forward-looking performance and long-term influences (Ong and Chen, 2014). Overall, scholars examining ICT-enabled firm performance have usually used financial-based or accounting-based indicators to measure the impact of ICT on firms (e.g. Liu *et al.*, 2013; Mithas *et al.*, 2011; Aral and Weill, 2007; Bharadwaj, 2000).

DISCUSSION, CRITICAL REVIEW AND CONCLUSION

In this section, the results of the literature review are critically discussed, leading to a revision of the initial conceptual model for the underlying research project (see Appendix 2). Furthermore, answers to the research questions posed in the introduction of this paper (see section 1) are provided.

According to the results of the literature review, and to answer the second research question, the most important theories underlying the investigation of ICT on firm performance are RBT, DC and stakeholder theory. However, according to Bharadwaj (2000), only a limited number of studies have explored RBT of IT. Similarly, Wade and Hulland (2004) state that only a few discussions on RBT have been conducted in the field of information systems. In view of the findings of the above literature review, these statements appear to have been disproved. It is shown that since the work of Bharadwaj (2000) and Wade and Hulland (2004) numerous studies have been done to examine the effects of RBT on ICT (e.g. Parida *et al.*, 2009; Stoel and Muhanna, 2009; Aral and Weill, 2007; Ray *et al.*, 2005).

Although Bharadwaj (2000) states that RBT provides a framework for the conceptual analysis of the impact of IT on firm performance, scholars argue that investments in IT systems per se do not offer sustainable benefits as these investments can easily be duplicated by competitors (e.g. Ray *et al.*, 2004; Bharadwaj, 2000; Mata *et al.*, 1995). Such a simplified view, however, assesses the value of IT systems exclusively on the basis of

their individual components, assumes that IT assets can be separated, and neglects the synergies of the integrated system (Bharadwaj, 2000). According to RBT, physical, human and organizational resources and capabilities can serve as a source of competitive advantage for a company; however, these assets must outperform equivalent resources and capabilities of the competitors (Barney, 1991). In this context, researchers have analysed numerous IT resources for their impact on the competitive advantage of enterprises (see Table 4), where parallel to the taxonomy proposed by Barney (1991) (physical, human, organizational resources and capabilities), the flexibility of IT infrastructure, the competence of IT personnel and the ability of IT management are the primary dimensions of IT capabilities (e.g. Rockmann *et al.*, 2015; Chen and Tsou, 2012; Kim *et al.*, 2011; Wade and Hulland, 2004; Chung *et al.*, 2003; Byrd and Turner, 2001).

Synthesizing from the above, RBT argues that competitive advantages arise from unique combinations of resources that are economically valuable, scarce and difficult to imitate (Barney, 1991). DCs are an appropriate framework to explain how companies can differentiate and compete in a turbulent environment, acknowledging that they need to evolve and reconfigure their ICT operations co-evolutionarily in order to remain competitive (Van de Wetering *et al.*, 2017). Based on RBT, firms have learned to combine their IT resources in order to achieve a competitive advantage by developing complicated-to-acquire and difficult-to-imitate IT resources, thus creating an overall IT capability (Bharadwaj, 2000). In light of this, for the current research, the term "IT resource" is defined according to Aral and Weill (2007) as the overall term that explains IT assets of the company on the one hand and IT capabilities in connection with employees working in the company on the other. IT assets represent IT investments intended for specific strategic purposes, e.g. the flexible IT infrastructure or business applications within an enterprise, while IT capabilities comprise interlocking systems of practices and competencies that complement IT, e.g. human IT resources or the quality of IT management (Aral and Weill, 2007).

One of the main findings of the literature review is that CSV has not often been at the forefront of either current or past research. This is somewhat surprising as, on the one hand, the different regulatory directives force manufacturers of medical devices to implement and document CSV and, on the other hand, there are no suitable approaches for implementing CSV for companies, especially for SMEs (Schonberger, 2018). Moreover, it is apparent that within the literature the wording for CSV varies, e.g. system validation (von Culin, 2011), validation of software and computer systems (Huber, 2005), software validation (FDA, 2002; Hrgarek, 2008), validation of computerized systems (Esch *et al.*, 2007), computer validation (Bhusnure *et al.*, 2015), or computer software validation (Bendale *et al.*, 2011). In developing a risk-based approach to CSV in SMEs of the medical device industry, uncertainty about the term "CSV" in particular will lead to difficulties both in the implementation of validation tasks and in the development of a long-term validation concept (Schonberger and Vasiljeva, 2018).

Although the literature analysis focused on risk management approaches with the intention to transfer these approaches to the application of a risk-based CSV approach, it has been shown that the approaches identified are not suitable for application within the scope of CSV. For this reason, risk-based approaches have developed in the CSV literature to date which contain risk management concepts. However, these concepts are mostly based on subjective scales for risk assessment. The exceptions are the studies by McDowall (2005) and Charan and Vishal Gupta (2016). McDowall (2005) bases his risk-based approach on risk assessment according to the Boston grid of system use and nature of the software as well as on the GAMP 5 guide to classification of computer systems. The approach of Charan and Vishal Gupta (2016) is also based on the GAMP 5 guideline, but the risk-based approach according to DIN ISO 14971 is proposed for the assessment of risk. However, this again poses the problem that SMEs in particular will have problems with the implementation of such large frameworks, in addition to the increased financial and personnel expenditure required for the implementation (Schonberger, 2018).

Another problem with the implementation of CSV in SMEs is the documentation required to be compliant with the regulations (Bendale *et al.*, 2011; von Culin, 2011). The basis for proper documentation of CSV is the validation master plan (VMP), which describes the acceptance criteria, necessary validation activities with assigned responsibilities, and priorities and schedules for the execution of the validation activities (McDowall, 2009; Hrgarek, 2008). Moreover, the core of the VMP is the list-inventory of the computer systems to be validated (McDowall, 2009). As generally no one involved in the CSV process has all the necessary capabilities to identify all necessary computer systems and assess their specific systemic risks (Veverka, 2002), the development of a VMP is often problematic, especially for SMEs. In addition, there is the danger that inadequate analysis of the IT systems will not identify faulty systems, which on the one hand complicates risk assessment within the CSV process and on the other can result in hazards for patients, users or third parties.

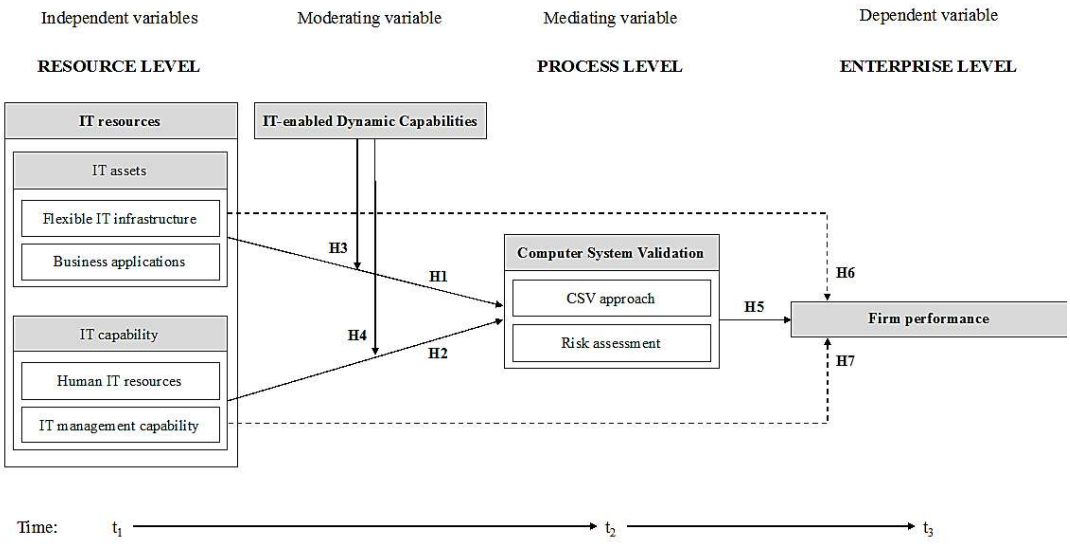

Figure 4. **Revised conceptual model based on the results of the literature review**

The critical analysis of the findings of the literature review led to far-reaching changes in the initial conceptual model (see Figure 4). Based on RBT and on the new understanding of IT resources, the variable "IT capability" was extended to "IT assets", enabling a differentiated view of physical resources (flexible IT infrastructure, business applications), human resources (human IT resources) and organizational capabilities (IT management capability). The last two dimensions are combined to form the variable "IT capability". Finally, the variables "IT capability" and "IT assets" were integrated into a higher-level construct, "IT resources". The variable "Risk management capability" was removed from the resource level and integrated into the variable "Computer System Validation" at the process level (Risk assessment). The dependent variable of "Firm performance" has remained unchanged. The changes, however, preserve the original statement of the model: The dependent variable of "Firm performance of SMEs" is influenced by the independent variables of "IT assets" and "IT capabilities" (IT resources) of the SME, while the mediating variable "Computer System Validation" helps to explain how these IT resources bring about firm performance. Finally, the results of the literature review can be summarized in the following hypotheses of the conceptual model:

- H1: Enterprises' degree of IT assets is positively associated with better CSV.
- H2: Enterprises' degree of IT capability is positively associated with better CSV.
- H3: The relationship between IT assets and CSV is positively mediated by IT-enabled DCs.
- H4: The relationship between IT capability and CSV is positively mediated by IT-enabled DCs.

- H5: Enterprises' degree of CSV is positively associated with better firm performance.
- H6: Enterprises' degree of IT assets is positively associated with better firm performance.
- H7: Enterprises' degree of IT capability is positively associated with better firm performance.

In conclusion, the results of this literature review provide significant contributions to ICT research, RBT, the DC perspective, and general management and organization literature in several ways and represent the first published attempt to explore the effects of CSV on the firm performance of SME medical device manufacturers. Moreover, the findings of this study contribute to theoretical development in the field of CSV. Finally, since CSV is a practice-centred field, the findings may also help CEOs and managers in formulating and implementing strategies in their enterprises. Thus, ICT researchers as well as practitioners from the medical device industry can benefit from the results of this research paper.

LIMITATIONS AND RECOMMENDATIONS FOR FUTURE RESEARCH

Although the authors of this paper have endeavoured to achieve a high degree of objectivity, accuracy and validity, this research has several limitations. RBT has emerged as a leading theory within strategy research, providing a framework for identifying and analysing the sources of competitive advantage (e.g. Madhani, 2009; Galbreath, 2005); however, the theory assumes that resources are always used in their best way, saying little about how this actually occurs (Melville *et al.*, 2004). In addition, the theory ignores the place of long-term competitive advantage in dynamic markets as well as changing business conditions (Van de Wetering *et al.*, 2017). Therefore, extending RBT by DC seems to be useful in understanding long-term competitive advantages in dynamic markets characterized by rapid change (Melville *et al.*, 2004).

As described in section 3, the selection of articles for literature review was carried out according to a well-defined procedure (see Figure 1) in order to achieve complete objectivity and comprehensiveness. However, the selection process may have been affected implicitly by existing biases. Furthermore, the procedure for identifying full accessible papers in Google Scholar using the "filetype:pdf" search suffix led to papers being output in PDF format, while papers in other formats, e.g. DOC or DOCX format, were excluded. Thus, the results of this research would gain further quality through the inclusion of other document formats.

In particular, research into the implementation of a risk-based approach to CSV and the identification of all necessary computer systems for validation still reveals major gaps.

While larger companies often have sufficient resources to outsource CSV to external service providers, the question arises as to how SMEs in particular, which often have limited resources (Nguyen, 2009; Razak *et al.*, 2009; Buschfeld *et al.*, 2011), can fulfil this task. Moreover, this situation eventually has a negative impact on the performance and competitiveness of SMEs, which are threatened by the lack of information on the hazards and risks that can arise in the development of medical devices (Schonberger and Vasiljeva, 2018).

After evaluating the available information and scientific content on CSV, it becomes clear that the importance and relevance of the subject is increasing in both practical and academic terms. However, the main question still to be answered is whether CSV contributes to the long-term firm performance of medical device manufacturers and, if so, to what extent its contribution is measured. This type of assessment can only be done retrospectively, but there is a limitation due to the scarcity of data so far, and this will not change if clear, standardised indicators are not established and if they are not measured regularly over a longer period of time. For this purpose, and to answer the third research question, this work provides several connecting factors for further research work in line with the overall research project. Thus, the next step is to identify how SMEs in the medical device industry have already implemented CSV approaches within their company. In this context, a questionnaire will be developed to help gather the necessary information on the use of CSV in European companies in the medical device industry. Once it is clear what role CSV plays in the development and production of medical devices, the challenge will be to provide manufacturers with an appropriate CSV approach, which is particularly important for SMEs in the medical device industry.

In addition, as the literature review shows, further research will also be necessary beyond the scope of the overall research project. Thus, a recommendation for further research consists of identifying suitable risk processes for CSV. In particular, it is necessary to examine which risk approaches are appropriate for CSV and how much risk assessment is sufficient to comply with the regulatory requirements. A further recommendation is analysis of the legal regulations mentioned in the context of this research, in particular closer examination of their necessity or correctness as well as their applicability to SMEs in the medical technology industry. Finally, another recommendation is research of SME medical device manufacturers in Europe, more precisely analysis of their existing resources and capabilities (not only IT resources or capabilities) and thus identification of further indicators to evaluate business performance in the respective industry.

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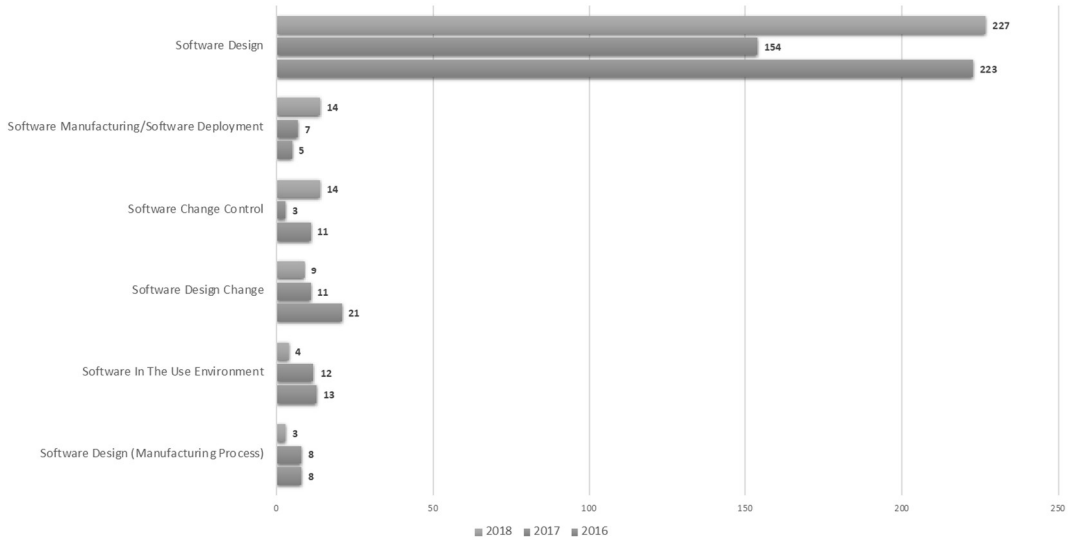
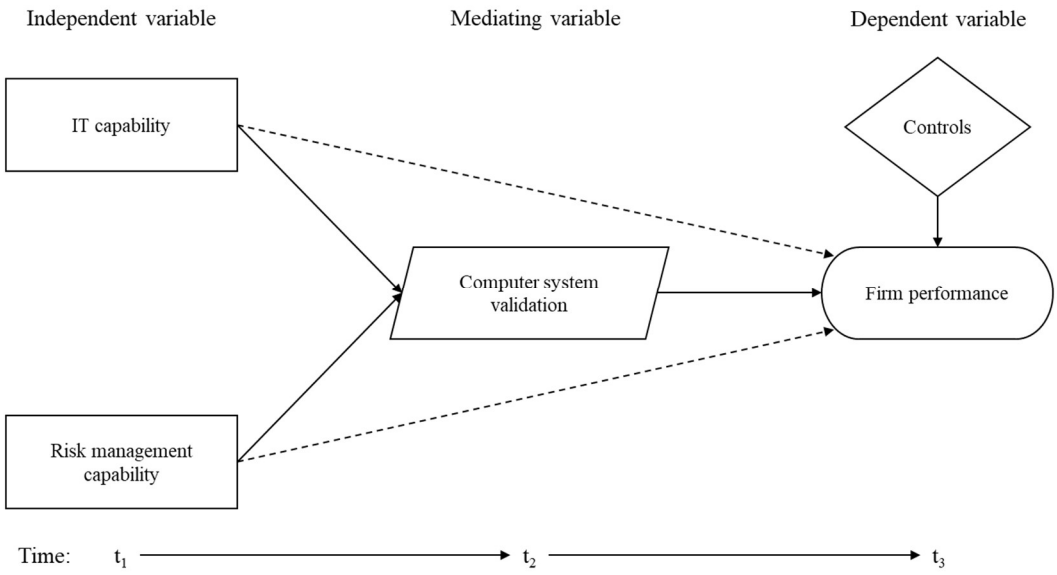
APPENDIX

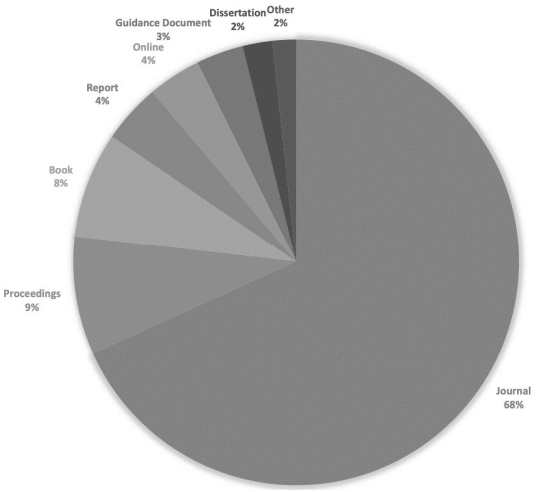


Appendix 1. **Total medical device recalls resulting from software errors in 2018. Authors' own elaboration using the FDA Medical Device Recall Database. Recall date from 01/01/2018 to 31/12/2018.** (FDA, 2019)

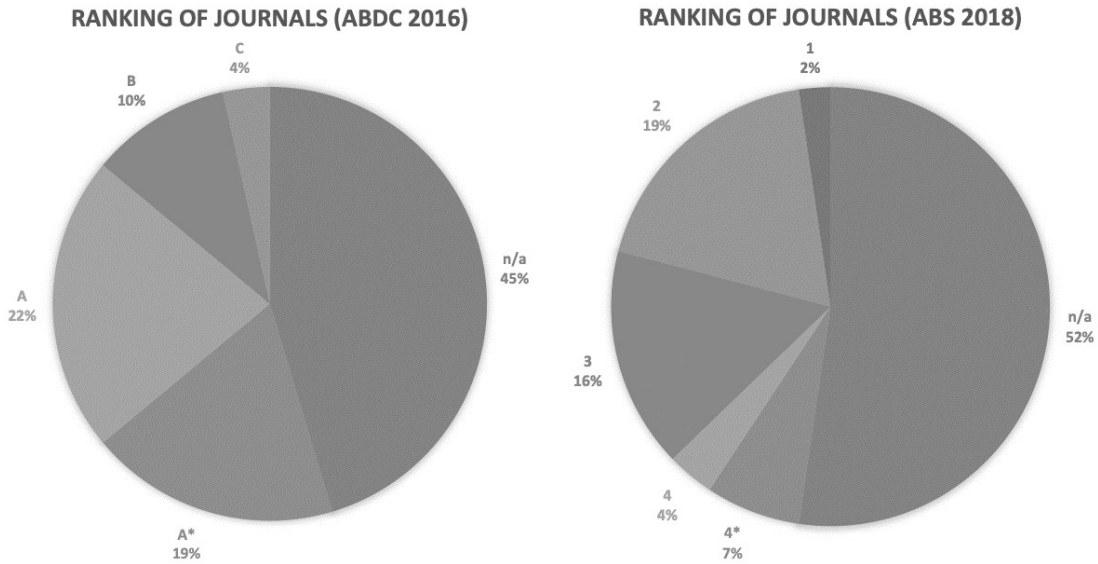


Appendix 2. **Conceptual model from the research by Schonberger and Vasiljeva (2018), which served as a basis for the literature review of this study**

Publication type	Amount of publications
Journal	159
Proceedings	20
Book	18
Report	10
Online	9
Guidance Document	8
Dissertation	5
Other	4
Total:	**233**



Appendix 3. **Overview of the literature database**



Appendix 4. **Quality of the journals according to the ABDC (2016) and ABS (2018) quality lists**

Top 10 cited proceedings	Amount
Proceedings of the European Conference on Information Systems	6
Proceedings of the International Business Information Management Conference	2
Proceedings of the International Conference on Information Systems	2
Proceedings of the International Conference on Software Engineering	2
Proceedings of the Americas Conference on Information Systems	1
Proceedings of the Annual Hawaii International Conference on Systems Sciences	1
Proceedings of the Central European Conference on Information & Intelligent Systems	1
Proceedings of the International Conference on Advanced Management Science	1
Proceedings of the International Product-Focused Software Process Improvement Conference	1
Proceedings of the International Workshop on Software quality	1

Appendix 5. **Amount and quality of conference proceedings according to the ERA (2010) quality list**