DO THE INNOVATION AND DIGITAL TRANSFORMATION STRATEGIES INDUCE SME PERFORMANCES IN NEW NORMAL ERA? STRUCTRUAL & CONFIRMATORY ANALYSIS MODELS

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Highlight
Exploratory and confirmatory factor analysis EFA, CFA, and SEM models, using SPSS.26.Smart PLS-SEM about the reasons of digitization process difficulties and recommendations for healthcare sector in Germany.

Abstract
One of major challenge in a sustainable growth, which organizations face is a slow adoption of the digital transformation. This research work presents the reasons that lead to the slow digitization process in medical device SMEs in southern Germany. In addition, by developing the conceptual model, this work highlights the effect of these improper implementations on SME's business performances and financial situation. The researchers applied correlational research design methodology, with simple random sampling techniques along with empirical and statistical study with primary data collection. The main study variables are SME's financial situation, SMEs organizational performance, and medical digitization rules. The study demonstrated the negative impact of delayed digital mechanisms in terms of businesses and financial performances.The extra transparency restrictions that add burdens for SMEs, and the lack of training for the employees, which in overall add more difficulties for adopting innovation and digital transformation are other factors negatively affecting the studied process.

Keywords
digitization; innovation theories; inferential statistics; confirmatory factor analysis; structural equational modelling.

Introduction
The Healthcare sector in general and medical device industry in specific are considered to be of paramount importance/need for most people, and it has faced significant challenges in recent times due to the outbreak of the COVID-19 pandemic. Hence, it is important for the SME to effectively implement changes and sustain competitive advantages. As the results of rapid globalization, the global market for medical devices is growing to sustain a delivery of appropriate healthcare services and find new distribution channels for their items. According to Wilson [1], the organization's senior management tried to find new strategies and take the necessary steps to capitalize on new markets or approach new market trends on a global level. Based on a study

of Padro & Green [2], the economic conditions have changed drastically in recent years, thus medical device companies should adapt to these changes as well. More innovation-based initiatives are therefore required to find solutions that reduce healthcare expenditures while enhancing the quality of healthcare services. The leadership position is seen as the most vital in this regard, with internal and external drivers that applied to medical SMEs do not provide the best offer according to the individuals' interest.

Modern technology introduces numerous opportunities for businesses concerning innovation protocols [3, 4]. Some of these technologies are ready to implement, low-price, flexible, highly customizable, and provide extra-quality for user interaction [5]. In addition, some studies have shown that the diversity of physical and digital technology significantly contributes to the development of innovation strategies and has a high potential to influence entrepreneurship outcomes in SME services and operations [5–7]. As for the digitization of products and performances, it implies a great degree of resilience through a supply that continues to evolve, even after entering the global market. Due to this type of technology, entrepreneurs can constantly reassess their market value and easily submit proposals according to the redefining potential business proposal [5]. As a result, entrepreneurs are moving towards finding more dynamic innovation and entrepreneurial pathways, as they cannot facilitate their implementation by use of innovative technologies [5]. Using innovative strategies enable entrepreneurial processes, and facilitates innovative business models, as well as maximum business scalability [8]. At the same time, it drives the capital ability to improve capabilities and performance easily and at a less cost. Furthermore, an organization's strategic and competitive goals can be achieved by adopting innovative technology to accelerate the process of transformation and digitization used by the organization to approach the strategic vision of the respective firms.

The Medical Device Industry is the one with increasing quality standards and rigorous compliance restrictions due to globalization and transparency issues. Hertling et al. [9] defined the process of digitization as an umbrella term used for referring to a society's digital transformation. They describe it as a transition from analogue technologies to digital ones, as well as to and digital innovation in general. This has an impact on all aspects of life, including healthcare industry. The purpose of this study is to explore to what extent adopting innovations and digital transformation processes can affect SMEs' performance in medical device sectors in the context of the new era after the outbreak of the COVID-19 pandemic. The scope of research focused on companies located in the Bavaria, the southern region of Germany, particularly on the SMEs that adopted the digital transformation process because of the pandemic. The research objective is to investigate how the leaders in the medical device industry are facing the current challenges and the process of transformation. Moreover, the research spotted factors that delayed the digitization protocols in SMEs [10], in addition this work aims to draft recommendations for senior management and management information system specialists on how to utilize the data and research aiming at overseeing the current situation in medical device industries. Medium and small companies need to identify and explore the opportunities introduced by innovative digital technologies, particularly in new start-ups [11]. SMEs are especially susceptible to crises [12]. Their strategic options for managing the COVID-19 situation have been limited by a lack of resources and poor readiness for a new situation. Therefore, innovation strategies are an important business channel for SMEs, large-sized companies, and start-ups in different fields [13].

The delay and slow digital transformation have raised concerns about the insufficient efforts and implementation terms for transformation mechanisms, as well as worries the commercial benefits for SMEs [14]. This might have negative consequences on society and patient risk [15]. Medical devices are considered to be the key factor in medical and healthcare technology to enhance processes for millions of patients [16]. According to de Mol et al. [17], the firms' rules can promote creativity and innovation since they allow the replacement of outdated technology with more advanced, efficient and secure options [18]. Yet, the transformation rate is not enough to improve the company's performance. One of the most well-known theories of innovation is Rogers, which focuses on any innovative measures an entrepreneur takes to lower overall production costs or boost demand for his/her products [19]. Rogers et al. [19] stated that anybody desiring profits must innovate. After reviewing the literature in this regard, the scarcity of studies that focused on the point of digital transformation implications on healthcare SMEs in Germany, particularly in the southern region has been identified. Additional ambitions to conduct this research include the case studies techniques, which are relied on empirical evidence based to the research topic [19–21]. The previous studies spotted the phenomenon of the delayed digital transformation process in Germany [22]; however, the factors influencing the relations statistically the most followed by the recommendations are spotted in this work. Hence, the presented research opens the gate for

more study, especially for Management Information Systems (MIS) specialists to develop more protocols in digital transformation. This work demonstrates the empirical research study about the implications of adopting rapid digital transformation techniques on medical device companies. In addition, SME's innovation strategies and performances in the southern German region of Bavaria, two years after the outbreak of COVID-19. This work presents the primary data collection and robust empirical statistical validation tests to define the relationship between studied variables and illustrate the conclusions and recommendations accordingly.

Medical Device Industry in Europe.

Europe has faced a substantial growth in recent years in the field of patient care and medical devices sector. The medical devices industry is becoming crucial in clinical practices since it is improving the quality of life and health of its patients. The industry is appealing to, producers, developers, and investors due to the consistently high demand of patients and healthcare providers, as well as being a high profit margin business area [23,24]. On a global level, there are many SMEs operating in this field. The large number of businesses in the European market also supports this reality. Revolutionary medical devices are frequently created by small, medium-sized creative companies, and by small businesses in the field of medical devices. Smaller businesses expand more rapidly, as they are easier to manage in comparison to large businesses, since the inventor are often the owner, leader, and a decision-maker. Therefore, making decisions and calculating risks is straightforward. However, in larger businesses management, leadership and research are divided among diverse levels and do not a sole leader or decision maker. SMEs consist of 95% of medical device developers in Europe. Those small to medium-size businesses usually experience large administrative costs, which makes them vulnerable to failure. In order to succeed and bring up the SMEs' ideas to the market, they must engage with the medical device regulations [25]. As the industry has adapted to unavoidable change because of COVID-19, the adaptations and innovations adopted will result in permanent metamorphosis. With the acquisition of new digital and virtual skill sets, digital transformations within the industry that may have previously suffered from inertia have accelerated quickly. Companies have evolved to deliver better, more efficient ways of treating patients, providing services to healthcare professionals, and managing clinical studies [26].

Innovation and the New transformation in Medical Device Sector.

Medical Technologies equipment is changing rapidly and is facing pressure from all directions. Their widespread publicity is due to patients placing more demands on the newest discoveries. The Medical Device SME sought to change the inherent flaws as well as to catch up with the quick advancement of science and technology in the medical device industry by carrying out the digitization process, especially after the outbreak of pandemic [27]. Manufacturers and designers can use those technologies to their benefit and innovate, as they can follow clearer guidelines. The success of medical device development is based on a variety of factors, including financial analysis, planning, creativity, and customer feedback at the time of the development process, as well as business employee involvement in the development of new products [28]. In Rogers's words, innovation is a "procedure of many industrial practices that reshapes the economic structure from inside, erasing the old version and constantly building a new model" [19]. According to Roger the four aspects of innovation are invention dissemination, and imitation [19].Therefore, the importance of innovation in the field of medical services and its impact on the economy is usually related to the establishment of regulations on a national and international level [29]. The vast bulk of studies, which applied Rogers' Diffusion of Innovation Theory is related specifically to technological and scientific innovations, adoption, uses, and practices [30–32]. The Theory of Economic Development and the following writings classified the historical process of structural changes that characterizes development into five categories starting with the introduction of a new product alternative for the current product, then utilizing innovative manufacturing or marketing methods, in addition to penetrating and presenting the company portfolio in new markets" [33]. In addition, securing new sources of raw materials or industry inputs will lead to a different utilization of the available resources for productive methods in the economy [34].

According to Raynard [35], innovation is essential for competitiveness and economic development. In addition, the shared Rogers's viewpoint that innovation, is the driving force behind economic transformation and creative construction [19]. Back to Rogers's view [19], the actions of the entrepreneurs to innovate, using scientific and technological invasions open up new doors for employment, investments, and expansions. Additionally, small, and medium-sized businesses have access to a wide range of opportunities due to digital transformations and innovative technologies. These technologies can be utilized to create entirely new business models, acquire more business opportunities, and develop consumer loyalty [36]. Giebe, stated that German businesses are not in a bad situation in regard to digitization [21]. Germany is a leader in innovation, particularly in Europe, and it

excels in several key technologies that are crucial for the digitization of society. However, it seems that other nations, particularly the USA and China are frequently better at turning innovative ideas into profitable businesses. Meanwhile, Germany still not yet utilized the main benefits that small firms use from applying innovation, and productivity techniques. Since the start-up growth percentage in Germany is rather small and its reduced in the last few years [37]. One of reasons behind this is a need of the digital transformation and digital innovation [38], which in turn have a negative impact on a digital technology implementation [20]. Hence, it is important to encourage investment in Germany and, more importantly, to remove barriers, so that a transformation takes place and increases the companies' incomes [22].

Methods

Research Objectives.

The main objective of the research is to indicate the reasons behind the delayed stage of digital transformation and innovations process for SMEs in the medical sector and to define the implications of adopting modern technology in it, such as total transfer from paper and documentation work to the digitization and online communications system, as the total quality and management systems. Hence, the research objectives can be illustrated, as follow:

- to investigate the effect of implementing innovations & technologies on SMEs' financial situation.
- to highlight to what extent the new digitization processes induced the business performance in the medical devices field in Germany.
- to craft recommendations for better practices in the medical devices sector in terms of accelerating the transformation stages. This in turn translates into the following research questions:
    a. What is the impact of applying the innovation process on an SME's financial situation?
    b. To what extent are the SME's business performances affected by the implementation of medical digitization regulation MEDR?

Conceptual Framework

The conceptual framework shown in Figure 1 is based on the input-output process model. The input process consists of the following:

Dependent variables:

- The SME's financial situation (SMEF) includes two factors: Financial burdens and Commercial Performance;
- The SMEs organizational performance (SMP) with two factors, namely SMEs digitization Strategy and a Business Growth.

Independent Variable is Implementations of Medical digitization regulation (MEDR), which include two factors: Slow Innovation process and Transparency restrictions.

Process methods

The implementation of the conceptual framework has been carried by the processing of the collected data using inferential statistics techniques, Exploratory Factor Analysis (EFA) for validating and Confirmatory Factor Analysis (CFA) and Structural Equation Model (SEM).

Output Method

Discover the impact of applying digital transformation on SME performances, detecting the reasons for delaying a complete digital transformation.

Hypotheses development

Currently, there are different studies investigating the performances of multinational companies [39]. Nevertheless, the SME's performance after the outbreak of COVID-19 in the medical devices sector and the impact of innovation and digitization on business and financial performances still needs lighter to be shed on this sector. Therefore, the hypothesize of this study is as follows:

SME financial performances (SMEF)

The financial performances of SMEs are regarded as the main indicator of an organization's growth [40] hence, this the first hypothesis of this work is to investigate the relationship between an organization's financial performance (SMF) and its implementation of medical digitization technology and regulations (MEDR). This variable consists of two factors: firstly, the financial burdens; secondly, the commercial performance. H1:

Investigate the Relationship between SMEs' Financial Performances (SMEF) and Regulation Implementations (MEDR).

Since the financial situation reflects the rate of achievement of the organization [23], this work demonstrates the hypotheses H1.1 & H1.2 to highlight the relationship between delays in the digital transformation process and the SME financial burden. In addition, the transparency process, to reveal most of the essential data in the digitization process added more burdens to the transformation process [20]. Therefore, hypotheses H1.3 & H1.4 were proposed and are focused on the relation between transparency enhancement and restrictions in the digitization process and financial performances.

H1.1: The slow digital transformation process does not affect SME financial burdens.
H1.2: The slow digital transformation process does not affect SME commercial performances.
H1.3: The transparency restrictions in SMEs do not affect financial burdens.
H1.4: The transparency restrictions in SMEs do not affect commercial performances.

SME organisational performances (SMP).
H2: Investigate the relationship between SMEs' organizational Performances (SMP) and Regulation Implementations (MEDR). Digital transformation and innovation models have put an extra load on traditional companies [41]. By reviewing the extant literature, the acceleration rhythm and strategies for the digitization process in multinational companies [42] have been identified, however the point of SME is still voided. For that purpose, we developed hypotheses 2.1 & 2.2 to detect the relationship between the delayed digital transformation process and SME performances as implementation strategies for the complete digitization process. In meantime the hypotheses 2.3 &2.4 will define the impact of transparency restrictions on digital transformation and business growth.

H2.1: The slow digital transformation process has a negative impact on SME digitization strategies.
H2.2: The slow digital transformation process affected SME business growth negatively.
H2.3: The transparency restrictions in SMEs do not affect digitization strategies implementation.
H2.4: The transparency restrictions in SMEs do not affect business growth.

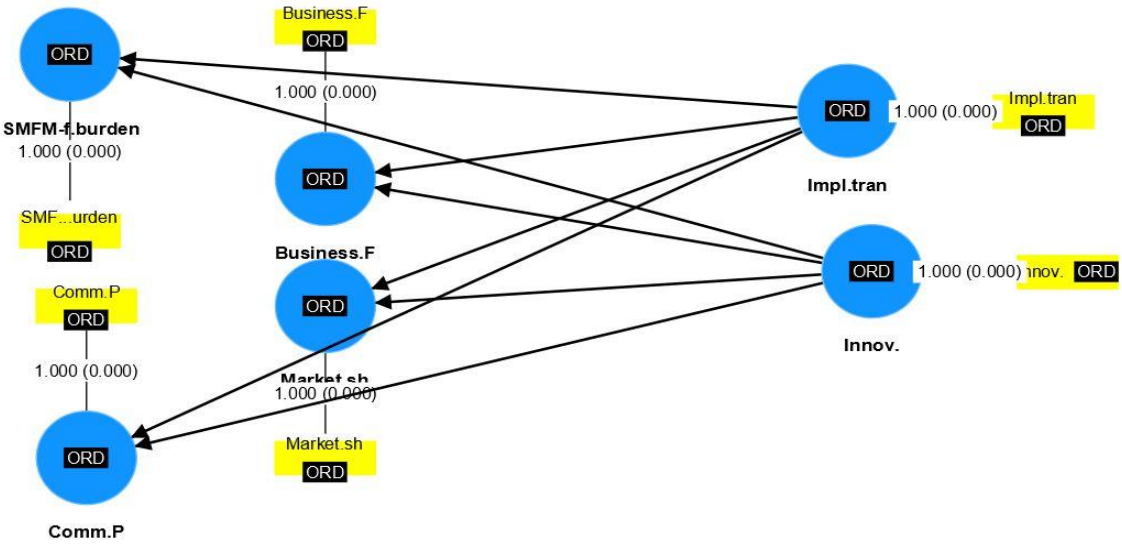

Figure 1. Conceptual framework, relations between study variables SME's financial situation (SMEF), SMEs organizational performance (SMEP) and Medical Digitization Regulations (MDR) by using PLS-SEM 4. *Source: [31].*

Research Design

The research design is based on correlational design. The data were collected from the selected samples of his population to investigate the outputs of correlational research, and then to examine the relationship between study-dependent SME's financial situation (SMEF), organisational performance (SMP) and independent variables of medical digitization regulations (MEDR). Usually, the correlational design determines the relation between studied variables in both directions, either positive, negative, or zero relations, and explores

the frequent or infrequent relation among variables [43]. The data were gathered and administered by a survey of 105 respondents from medical device companies in the southern of Germany. The reason behind implementing this research design was to gather socio-economic data to explain the effect of applying (MEDR) on the SME's organisational and financial performance in medical field companies, the respondent's profiles and their feedback on the MEDR process and the extent and consequences of applying this technology in different companies. The data finding is calculated by inferential statistics for investigation of the correlational research design approach**.**

Research Population

The study geographically focused on the major SMEs in the Bavarian region represented by in Munich and Baden-Württemberg Region especially in Stuttgart, Nürnberg, and Frankfurt. The German Federal Statistics Office and Medtech Europe facts and figures from 2021 defined the number of medical device companies in Bavarian and Baden-Württemberg territories at 193, and 274, respectively. Therefore, the total medical device companies' population is 467. These two regions were chosen to conduct the study since the majority of healthcare SMEs and medical devices are localized in these areas. Top of that, they are easily accessible, well-staffed, and organized companies. The other business in other provinces have very few individuals to be represented in this research.

Research Sampling

The probability sampling concept by conducting a simple random technique was used in this work. In a simple random sampling method, every company of the population has an even chance to be involved in the sampling process. The sample size is formulated by a formula, which calculated the sampling size using the probability factor for population (P) formula, as follows: $P = 1 - (1 - (1/N))n$. where N represents the main population, and n represents the sampling size, considering P of 0.10, and N of 467, the obtained value of n is 47. By such means 47 companies were randomly selected from the population of 467 SMEs. The purpose of selecting this method is because it is the most reliable technique among probability approaches, as it performs a single random selection step, and it considers the awareness about the general population. Moreover, the randomization in the sampling technique requires a high value of validation process for the collected data [44].

Research Respondents

The questionnaire was circulated to the randomly selected SMEs and was available at the time of data collection to function as research respondents. The researchers received 105 complete responses from 27 companies of the considered population.

Instrumentation

The research instrument consisted of three variables, with a total of 36 factors. The first section considered the medical digitization regulation variables parts including innovation, transparency, and implementation. The second part of the questionnaire was designed for the SMP organizational performance, the context of corporate development and existing challenges. Equally important regarding the SME's overall output were the consequences of applying the contemporary restrictions to emphasize the beginning of the proper corporate supervision in order to develop the staff and fulfil the scientific inquires. The survey's third section was related to the financial and marketing burdens for SMEF. Each broad category, into which the questionnaire was organized, was composed of several relevant questions. The specific questions highlighted the possibilities of the chosen indicators that were approved in the activities with responses [45]. The survey adopted a Likert pattern of five points rating scale starting from "completely agree" to "completely disagree". The numerical system for responses facilitates the interpretation of the collected data.

Survey Construct Validation

To validate the collected data, the composite reliability approach was applied to assess the internal consistency after conducting factor loading analysis. The non-observable variable that affects more than one known indicator and explains the relations between these observed variables was called a factor. A relatively small number of variables used to indicate relationships between a group of items on a measure or a set of data can be found using statistical approach as shown elsewhere [46].

Composite reliability

Cronbach's Alpha composite reliability measures the internal consistency of scale items [47]. According

to Brunner and Süß [48], it is equal to the entire amount of actual score variance and the total scale score variance. The obtained results are shown in Table 1.

KMO & Bartlett's Test of Sphericity

In the second step of the validation process, the Bartlett test and Kaiser Measure of Overall (KMO) were calculated to validate sampling adequacy, since the larger data size makes it overly sensitive to even minor deviations in the adequacy of KMO-test samples concerning the appropriateness of the data for factor analysis [49].

The result of the KMO test was 0.883, i.e., more than 0.80, which means that it is statistically significant [50]. As such, in regard to Bartlett's test, p = 0.000, which means that it is statistically significant, and the values refer to the adequacy of the sample for both the KMO and the Bartlett's tests.

Table 1. Composite reliability results computed using Excel & SPSS 26. *Source: Authors.*

No	Variables	Composite Reliability coefficient
1	SMP	0.82
2	SMEF	0.77
3	MEDR	0.83

Factor Analysis

The exploratory factor analysis (EFA) was applied to highlight the presence of latent variables in the collected data [51]. The EFA factor structure allows resulting in each variable representing a different construct [52]. The factor analysis for the study variables produced six factors distributed in two for each variable as shown in Tables 2-4.

Table 2. Factor lading for SMEs Financial situation results. *Source: Authors.*

Factors	Components	
	Financial Burdens	Commercial Performance
SMEF4	0.890	−0.109
SMEF2	0.843	−0.169
SMEF1	0.619	
SMEF5	0.612	
SMEF3	0.417	
SMEF6	−0.112	0.993

Table 3. Factor lading for MEDR implementation results. *Source: Authors.*

Factors	Components	
	MEDR Implementation	Transparency
MEDR7	0.80	−0.371
MEDR1	−0.690	0.345
MEDR11	0.670	0.252
MEDR6	0.670	−0.262
MEDR4	0.650	−0.162
MEDR8	0.596	
MEDR2	0.520	−0.311
MEDR9		0.918
MEDR5		0.567
MEDR3	−0.208	0.384

Table 4. Factor lading for SMEs performance SMP results. *Source: Authors.*

Factors	Components	
	Innova	Business Growth
SMP2	0.760	−0.124
SMP1	0.720	−0.264
SMP5	0.70	
SMP3	0.660	
SMP7	0.650	−0.226
SMP6	0.460	0.135

Results and discussion

The dataset was statistically computed by using (SPSS) Statistical Package for Social Science version 26 and Smart PLS-SEM 4. The studied design was assessed using inferential statistical methods. The inferential contains regression for the independent variable, correlation, and linear regression to investigate the relationship between research variables followed by the SEM path analysis model.

Inferential Analysis Finding

The inferential statistical method is a producer applying statistical tools to investigate the conclusion and properties of the main population by using a simple random sample to approve or reject the hypotheses [53]. The researchers computed the inferential statistics techniques to illustrate the final findings and results of this research by using multicollinearity regression, Pearson correlation, and multi-regression.

Table 5. Pearson correlation between variables. *Source: Authors.*

	Variables	1	2	3	4	5	6
1	MEDR. Implement	1					
2	Transparency	0.22	1				
3	Innovation	−0.41 **	−0.62**	1			
4	Buss. Growth	−0.63 **	−0.16	0.41 **	1		
5	Finance. Burdens	−0.55 **	−0.11	0.56 **	0.63 **	1	
6	Comm. Perform	−0.48 **	−0.26 **	0.43 **	0.52 **	0.70 **	1

N = 105. ** p < 0.01. level.

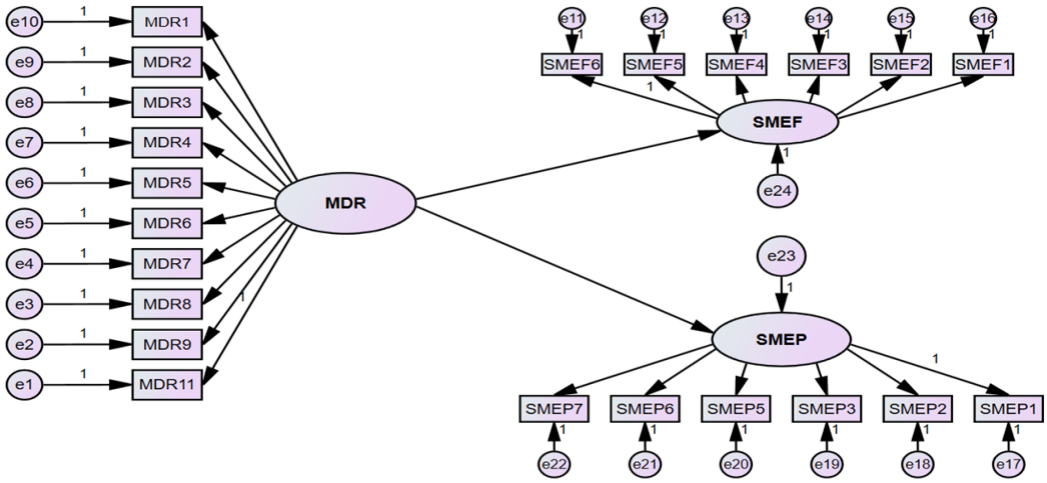

Figure 2. Structural Equation Model (SEM) for study variables using SPSS AMOs-26. *Source: Authors.*

Table 6 Regression weights default SEM model by SPSS AMOs-26. *Source: Authors.*

			Estimate	**S.E.**	**C.R.**	**P**
SMEP	<---	MDR	-2.253	0.672	-3.354	***
SMEF	<---	MDR	-1.935	0.595	-3.251	0.001

Standard Error - S.E, Critical Ratios - C.R

The computed model was fit based on the model shown in Figure 2. The fit indexes of this CFA model (chi-square 300.605; degrees of freedom (df) 207; CMIN/df : 1.452, root mean square error of approximation (RMSEA): 0.066; comparative fit index (CFI) 0.929; standardized root means square residual (SRMR) 0.055 showed an acceptable fit with the data and met the conventional thresholds suggested by Hu et al. [54].
According to Table 6, the effect of MDR implementations on SME's business performance and the link between dependent (SMEP) SME's business performance and independent variables (MDR implementation) & (transparency protocols) is indicated by the estimated value. The value shown in Table 6 is -2.253, which is statistically significant (p-value for MDR is 0). Additionally, the p-value of SMEF is .001 also showed the significance of this regression model. Estimated values explain the degree of variations, which take place in dependent variables SMEP and SMEF, as the results of the independent variable (MDR). As shown in Table 8 for each 1% MDR implementation increase, the SMEP business growth will decrease by 2.253%. Likewise, for commercial performance, the results detected the relation with MDR as follows: for each 1% of MDR implementation increase the SMEP innovation strategies will decrease by 1.935%.

Hypothesis testing

- Hypothesis 1

As shown in Table 6, the results detected a significant negative relationship between MEDR slow implementation and financial burdens and commercial performance. The values of both variables at correlations are −0.55 ** and −0.48 **, respectively with p-value of 0.000, <0.01. This means that the H1.1 &H1.2 can be rejected, and the alternative hypothesis is valid. According to this finding, the impractical and slow implementation of digital transformation, MEDR adds an extra financial burden for SMEs in the medical devices industry in Germany. The current rhythm is not sufficient to apply the full MEDR effectively. In addition, insufficient training added extra limitations and barriers to apply the recent technology advances. Regarding hypothesis 1.3, the obtained value is 0.11 (Table 6), hence, there is no meaningful relationship between MEDR implementation and SMEF financial burdens. On the other hand, there is a committed relationship between MEDR transparency enhancement and SME's commercial performances (SMEF), for which the value is 0.26**, p-value = 0.000, <0.01. These results reject the null hypothesis 1.4 and approve the alternate one by detecting the meaningful relationship between two variables.

- Hypothesis 2

The correlation matrix results detected a significant negative relationship between MEDR implementation, SMP innovation digitization strategy, and business growth, as shown in Table 6. The values of both are −0.41 ** and −0.63 **, respectively, with p-value of 0.000, <0.01, which approved the hypotheses H2.1 and H2.2. According to a study finding, the slow implementation of MEDR inhibited the innovation strategies in SMEs. As a result, the extended time for applying the digital transformation from 13 to 18 months has a negative impact on business growth. In the same way, the correlation matrix results spotted strong negative relation between the MEDR transparency restrictions and improving the innovation strategies in SME with −0.62 ** and p-value = 0.000, <0.01, which rejects the null hypothesis H2.3 and approve the alternate hypothesis about the negative effect of transparency shortage and non-relevant data on the innovation strategies. On the contrary, the correlation test for the study variables could not detect any relation between the MEDR transparency restrictions and SME's business growth, which approved H2.4 null hypothesis.

Regressions Values

In this work, multi-regression analysis between study variables was conducted as the second step of inferential statistics after CFA and SEM and was used for interpretating and investigating the direct effect of independent variable MEDR on dependent SMEF & SMP variables to answer the research questions.

Regression Values for Question Number 1

The effect of implementing the MEDR on SMEF's financial situation. The link between the dependent(SMF) SME's

financial performance and independent variables (MEDR implementation and transparency restrictions) is indicated by the R-value. Normally, the value should be more than 0.4 [55]. The value shown in Table 7 is 0.784, which is favourable for further examination. R^2 displays the overall variation of the dependent variable, which help the independent factors interpret in the regression models [56]. The obtained value is 0.614, i.e., higher than 0.5 and indicates that the model is applicable for identifying the relationship. The adjusted R-square demonstrates the generalization of the results or the variation of the sample results from the main population. It should have a slight difference between the R-square and Adjusted R-square of about ±10%, which is observed in this case too.

ANOVA significance value is calculated with a confidential interval CI rate of 95% and the significant value should be less than 0.05% [57]. The results in Table 7 are 0.000, which is an applicable percentage. Therefore, for F, the value refers to the emphasis of variables predictions, which fit in the regression model as the expected value should be above 1 [58], whereas the result is 22.690. The p-value shows the validity and significance of bothindependent variables, MEDR implementation and transparency restrictions to be stated in this regression model separately. The results for the MEDR variable are 0.000, which is statistically significant. Conversely, the p-values of transparency are 0.836, 0.063, which means that these variables are not relevant for these regression models. This in turn fits to the same findings as those from the correlation matrix, and the application of transparency protocols did not affect the financial performance of SMEF. Beta (B) values explain the degree of variation occurring in dependent variables (SMEF) as the result of an independent variable (MEDR) [59]. As shown in Table 8, for each 1% of MEDR slow implementation increase, the SME's financial burdens will decrease by 0.486%. Likewise, for commercial performance, the results detected the relation with MEDR as below: for each 1% of MEDR implementation increase, the SME's commercial performance will decrease by 0.445%.

Table 7. Question 1 R values and ANOVA values in the regression model using SPSS 26. *Source: Authors.*

Model Summary						
Model	R	R Square		Adjusted R Square		Std. Error of the Estimate
1	0.784	0.614		0.611		0.271
ANOVA						
Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	18.340	2	9.170	22.690	0.000 [b]
	Residual	41.222	102	0.404		
	Total	59.562	104			

[a] Dependent Variable: SMEF; [b] Predictors: (Constant), MEDR Transparency, MEDR. Implement.

Table 8. Question 1 Coefficient values a1 & a2 in the regression model. using SPSS 26. *Source: Authors.*

Model a1		**Unstandardized Coefficients**		**Standardized Coefficients**	**T**	**Sig.**
		B	Std. Error	Beta		
a1	(Constant)	3.788	0.319		11.869	0.000
	MEDR. Implement	−0.486	0.074	−0.559	−6.611	0.000
	Transparency	0.015	0.073	0.018	0.208	0.836
Model a2		**Unstandardized Coefficients**		**Standardized Coefficients**	**T**	**Sig.**
		B	Std. Error	Beta		
a2	(Constant)	4.322	0.380		11.368	0.000
	MEDR. Implement	−0.445	0.088	−0.445	−5.081	0.000
	Transparency	−0.160	0.087	−0.162	−1.847	0.068

a1. Dependent Variable: Finance. Perform; a2. Dependent Variable: Comm. Perform.

Regression Values for Question Number 2

The effect of MEDR implementations on SMEs' business performance.

The link between the dependent (SMP) SME's business performance and independent variables (MEDR

implementation) and (transparency protocols) is indicated by the R-value. The value shown in Table 9 is 0.921, which is favourable for further examination. R-square is 0.849, which is also acceptable, since the adjusted R-square value is 0.847 which is favourable. According to the results in Table 9, the p value is 0.000%, which mean it is statistically significant. Meanwhile, the result for the F value is of 10.896, which is favourable.

The p-value for MEDR is 0.000 which is statistically significant. Conversely, the p-values of transparency are 0.806 and 0.334, which means that these variables are not relevant for these regression models. Beta (B) values explain the degree of variations that happens in dependent variables (SMP) as the result of the independent variable (MEDR). As shown in Table 10 for each 1% MEDR implementation increases the SMP business growth will decrease by 0.657%. Likewise, for commercial performance, the results detected the relation with MEDR as below: for each 1% of MEDR implementation increase, the SMP innovation strategies will decrease by 0.325%.

Table 9. Question 2, R and ANOVA values in regression model. *Source: Authors.*

Model Summary						
Model	R	R Square		Adjusted R Square	Std. error of the estimate	
1	0.921	0.849		0.847	0.154	
ANOVA						
Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	7.880	2	3.940	10.896	0.000 [b]
	Residual	36.882	102	0.362		
	Total	44.762	104			

[a] Dependent Variable: Innovation; [b] Predictors: (Constant), Transparency, MEDR. Implement.

Table 10. Question 2, Coefficients values a2.1 & a2.2 in regression model. *Source: Authors.*

Coefficients						
Model a2.1		**Unstandardized Coefficients**		**Standardized Coefficients**	**T**	**Sig.**
		B	Std. Error	Beta		
a2.1	(Constant)	4.426	0.364		12.175	0.000
	MEDR. Implement	−0.657	0.084	−0.621	−7.836	0.000
	Transparency	−0.020	0.083	−0.019	−0.246	0.806
Model a2.2		**Unstandardized Coefficients**		**Standardized Coefficients**	**T**	**Sig.**
		B	Std. Error	Beta		
a2.2	(Constant)	3.203	0.302		10.610	0.000
	MEDR. Implement	−0.325	0.070	−0.430	−4.668	0.000
	Transparency	0.067	0.069	0.089	0.970	0.334

a2.1 Dependent Variable: Business Growth; a2.2 Dependent Variable: Innovation

Impact

The results highlighted a negative relationship between the slow pace of the digitization implementation strategy and financial burdens. According to a study, the unpractical and slow implementation of digital transformation adds an extra financial burden for SMEs in the medical devices industry in Germany. The current rhythm is not sufficient to apply the full digital transformations effectively. In addition, the lack of training added extra limitations and barriers to applying modern technology solutions. Additionally, there is a negative impact between transparency enhancement and SME's commercial performances (SMEF), as the restriction in transparency and data revealing process creates more difficulties for SMEs to fulfil the digital transformation process requirements. Consequently, numerous SMEs could be withdrawn from the market because of delayed in the processes. The slow implementation of MEDR inhibited the innovation strategies in SMEs. The research finding and collected dataset would be applicable for decision support system specialists (DSS) to develop strategies and business plans for the digitization process in other sectors.

Conclusions

The research's main objective was to elucidate out the reasons that lead to the slow digitization process in medical device SMEs in southern Germany, as well as to highlight the effect of improper implementations on SME's business performances and financial situation. The results concluded that the main reason for the slow digital transformation process was the lack of training for the company's employees, in addition to the short-term transition period. Moreover, improper digital transformation can result in a negative impact on business performance. However, it is not only the transformation processes that can affect the business, but also the working environment and to what extent the staff is ready for this drastic development. In the light of this, businesses must consider both the technological and human sides of digitization. It would be wise for the firms to ensure that their employees have control over the change process and access to the specialized knowledgeand skills they need to fulfil their assigned responsibilities. Besides that, continuous training is also one of the key factors for any enterprise to be competitive in the current digital context [8]. Concluding the main advance in this area can be achieved by considering the training programmes and extended period for the digitization process to facilitate the mission of SMEs in the medical devices field as well as to consider implementation the classified policies and transparency restrictions for the data handling and revealing process. This in turn, would help to overtake the limitations and help to address the future research. The key aspect would be to conduct future research on the larger sample of companies in Germany and Europe.

Conflict of interest

There are no conflicts to declare.

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