

# A Web Based Application for Investment Evaluation of Medical Devices Development

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## ABSTRACT

The present research investigates investment evaluations in the context of medical device development, with an emphasis on a web-based application as the likely solution. In recent years, the medical industry has seen an evolution with new innovations revolutionizing how healthcare, treatments and patient wellbeing are handled and managed. This has allowed companies not only to look towards innovation to help with new products but also as a means to procure better profits and competencies. The solution lies in a web-based application which is both user-friendly and efficient. This research examines the need for a model that looks at the process of development in stages and so that the entirely process is not only based on data and information but is also geared towards cost efficacy and control. The fine line between the success and failure of any product or innovation lies in how needed it is and how well the market responds to it.

**Keywords:** *CBA, medical devices, biomedicine, investment efficiency evaluation, web based application*

## 1. INTRODUCTION

This paper is aimed at exploring the investment evaluation of medical device development through the use of a web-based application.

The field of medical device development has experienced rapid growth in the last many years. Innovation has become a hallmark of this growth. If anything, innovation can be seen as an accelerator of growth in several industries, so it is no surprise that it has made its presence felt in the medical industry as well. However, innovation is accompanied with risks – when these risks are not properly understood, innovation can lead to failure instead of success [1- 2].

Businesses are now using new models to help them create solutions that grab user attention and market share. Innovation can help grab this market share and create competitive advantage for companies. Technology is making the medical industry more effective and more efficient. In the past, processes that took a substantial amount of time now take a couple of minutes because of digital solutions. Iftikhar & Mariappan [3] documented Otorob or Ortho Robot, which has an extremely useful remote application in developing countries. The era of doctors being replaced with robots has arrived; such is the reach of innovation.

Modern innovations have therefore augmented accessibility, efficiency and reduced costs for both the companies producing the solutions and the users having to pay for them. This is not to say that innovation has only

made things simpler. If anything, regulatory frameworks have become more pronounced and detailed with much stricter conditions. Guerra-Bretaña & Flórez-Rendón [4] note that it is imperative that stakeholders collaborate so that the issues that medical device innovation faces can be overcome. The potential that such innovation has to offer should be overshadowed by the complexities of achieving said innovation.

The area medical devices development is very specific. On the one hand, innovations are in high demand because they touch one the most valuable thing we have, our health. Unlike innovations in other areas, such as mobile or IT technologies, the development of the medical device itself is influenced and regulated by a number of factors, such as legislative, medical, technical, functional, but also economic. The development of medical devices highly risky and might lead to economic losses. Usually these are long-term and demanding projects, which are involving company in a broad range of business activities and consuming its resources. For the above reasons, it is very important to analyze the investment in medical devices, define appropriate methods that would allow us to approach and formalize the process itself. Another important point is to propose an application that would enable to answer a potential investor, whether the investment is economically efficient or not.

For the reasons mentioned above, this article is focused on the analysis of suitable economic method, economic model respectively, for calculating the economic efficiency of medical device development. Furthermore, this paper presents the Medcal, a web-based application, which was developed to calculate the potential economic return with a

focus on key quantifiable and qualitative parameters that affects the actual development process of the medical device.

## **2. REVIEW OF METHODS FOR BIOMEDICAL DEVICES INVESTMENT EFFICIENCY MEASUREMENT**

For a company to grow, decision making in terms of fresh investments is imperative. This is true for the ICT market, that has been on a growth trajectory for several years now and has been rapidly evolving. In the current business environment, innovation is the key to grow and succeed. However, innovation is not a simple course of action that can guarantee success and presents its own risks. Therefore, what is truly imperative is to innovate but in a manner that considers the efficiency of the investment being made. The most common methods can be split into three main categories i.e. strategic and financial valuation, weighting and scoring of products, and finally human decision making.

The World Health Organization (WHO) notes in a 2016 study [5] that augmenting the understanding and use of evidence on efficiency is imperative if the right kind of policies are to be made and concrete management is to be executed. This is true for countries that face problems with funding from the public sector. Policies that are borne of a lack of data can lead to more bad than good. The report's overall theme ties in with our assertion that efficiency is key if innovation is to succeed.

In the same vein, Stefko [6] notes that regional disparities can present as growth constraints. Policy makers therefore require decent amount of data to be able to create policies that are effective. The study looks at healthcare in Slovakia within the 2008-2015 period using data envelopment analysis (DEA). This helps evaluate how efficient the system is and sheds light on other economic aspects as well. The window approach is used in this work in addition to the DEA models to help understand efficiency in specific regions and then create a relevant quantification that looks at discrepancies and disparities therein.

Vernon [7] explained the mechanism of cost-effectiveness thresholds that correspond to the unit of health benefit in the form of reimbursements. This helps the firm decide whether an innovation they have selected will prove to be commercially viable or become a problem. Values such as the net present value (NPV) was traditionally used to see whether a project should be taken up or discontinued i.e. if  $NPV < 0$ . The study put forth the importance of the unit of health benefit being tied to the economic value. Where the reimbursement makes sense, it is okay to move forward. Thresholds that are both too high or too low do not work and produce inefficiencies when it comes to the spending budget being allotted to the project.

Vallegjo Torres [8] go on to note that the Bayesian methods can be implemented so that the right information is fed into the product lifecycle properly. The study notes,

and rightly so, that reimbursement is a major aspect of whether a project will be implemented to ignored. The Bayesian method can help during the three main stages, i.e. the early phase, the mid-phase and the final phase. During the initial stage, information is collected on competing products, thereafter, a decision model is created, and finally all the information collected is put together in the last stage to build a complete picture. This model allows the lifecycle to be an informed one, based on real data and information instead of guesswork. On the other hand, a complex system such as this one may not be easy to adapt to for all companies. Surveys show that the most appropriate methods include discounted cash flow (DCF), scoring checklists, peer reviews, and decision tree analyses.

Rosina [9] introduces a different set of methods to chasing this aim i.e. the health technology assessment (HTA) methods. Despite its regular implementation during drug trials, HTA can prove to be complicated when it is applied to medical devices. This approach emphasizes on the procurement and/or incorporation of the project or device in question rather than the costs attached. The methods are oriented towards the strategic or operational evaluation of the innovation under consideration. Rogalewicz & Jurickova [10] also discuss HTA applications that have come from pharmacoeconomics. Medical devices come with a particular set of specificities that impact all processes considerably.

Markiewicz [11] developed an overview of existing assessment methods to find optimum options. Their literature view looked at 1,961 articles and finalized thirty that were used for the final analysis. Another 31 theoretical papers were added alongside 82 application papers. The methods used in most of the studies did not repeat often. Literature reviews, cost-effective analyses, clinical trials and other measures of clinical effectiveness were found to have been deployed multiple times.

## **3. THEORETICAL MODEL AND METHODS FOR APPROACHING MEDICAL DEVICE DEVELOPEMENT PROCESS EVALUATION**

The present proposed theoretical model meant for assessing the effectiveness is based on medical device development phases, much like the solutions looked at by Vallegjo Torres [8].

Medina [12] discussed the process of medical device development. The study notes that the development has a complex nature and offers a model that helps designers working on such devices. It allows for a conceptual framework that comes with a set of formalisms that help outline the landscape of development for the devices in question. The different phases involved are outlined, and are accompanied by a content validation survey alongside a case study.

Another example is that of Panescu [13], who notes that development a good product necessitates expertise in

marketing, business, regulatory understanding and clinical understanding. This is on top of expertise and optimum efforts towards designing the product itself. It breaks the process down into steps that go from the development of a concept to the creation of the solution, its verification and then finally its validation, approvals from the relevant regulatory bodies and then ultimately its introduction to the market it is meant for.

Pietzsch [14] also looks at a stage-based model for developing such devices. In this era of new technology, regulatory requirements have become more stringent, and any deployment of a new product requires effective planning and a proper business plan. Companies now understand the risks that they are facing when they enter the market and this hyper awareness comes with its own set of requirements. The study looks at the stage-gate process which includes five main stages i.e. initiation, formulation, design and development and final validation. During the initiation process, an outline is made to understand the risks linked with the opportunity a product presents. In the second phase, a concept is created for execution against data and information that suggests that it is feasible to create. The third stage involves creating a design and development plan, after which the product is tested and validated. The stage before the final stage has to do with quality control, where preparations are made to launch the product. In the final stage, an assessment is done after the product is launched.

Martin [15] offers a user-focused outlook in terms of developing a correct set of requirements that can fulfil the needs of the end user. The study uses industry examples to make its case. The study correctly notes that the healthcare industry necessitates well-designed medical devices. The only manner in which this is possible is if the design itself is focused on the end-users i.e. the patients or caregivers that the technology or product will be relevant for. The study made use of open-ended semi-structured interviews with end users.

Our web-application was implemented into the following steps:

- Initiation
- concept proposing,
- design and development,
- verification and validation,
- production and market device deployment.

The main focus of this study is to create a user-friendly solution when it comes to the web-based application. Borrowing from the approach used by Martin [15] we will also keep the end-user as the main goal during the initiation and concept proposing phase. This will also be kept in mind during design and development so that the product proves to be successful.

Table 1 represents the first of three areas of monitored parameters that are specified on the website. Here are all the variables in relation to the characteristics of the company and the intended markets, from which one can outline the potential of the target market.

**Table 1** Characteristics of the enterprise and target markets

<b>Input information/query</b>	<b>Value</b>
Company size by number of employees	<i>Count</i>
Turnover	<i>Billion CZK</i>
Contribution of outsourcing to MD development - dependence on suppliers and stability	<i>%</i>
What type of MD according to risk class?	<i>I/II/III</i>
What is the planned scope of patent protection?	<i>National/ Europe/ USA/ individually foreign countries</i>
Market coverage - to which countries is the sale planned?	<i>National/ Europe/ USA/ individually foreign countries</i>
How much is the share of R&D expenditure in relation to GDP in the country where development is intended?	<i>%</i>

The selected monitored parameters of the individual phases are listed in Table 2 and their values, which users enter on the web solution.

Last but not least, it is necessary to specify the anticipated revenues from sales (Table 3).

NPV (net present value), ROI and TCO indicators are chosen for the calculation of investment efficiency. For indicators that change over time, both the discount rate and the expected inflation rate play a crucial role. In general, the discount rate can be defined as the interest rate provided by alternative investments of similar magnitude and risk. However, there is no general rule to determine what interest rate to use. In this case, a discount rate of 10% is considered, which approximately corresponds to both the discount rate according to the type of project or the price of business loans in the Czech Republic. Sensitivity analysis is always applied to the values to take account of possible estimation bias.

#### **4. MEDICAL APPLICATION**

As the most suitable method, robust JAVA-based platform and the model of primary service distribution via web pages were chosen, which would allow to expand service distribution model nearly in any way in the future, including the connection to external systems. Afterwards, the economic model had to be converted into algorithmic model, which was the first step in automating the whole process. The last step was to create a use-case and a data model.

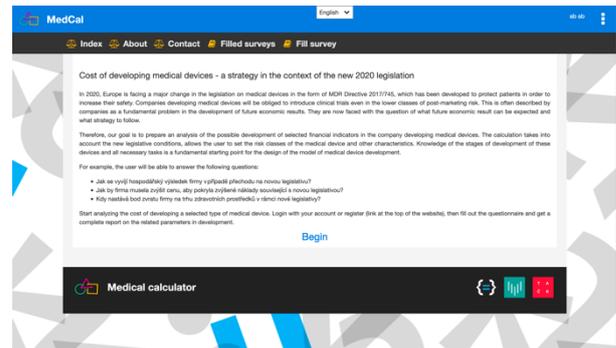
**Table 2** Characteristics of medical device development

<b>Input information / question</b>	<b>Variable</b>
Initiation phase	
What is the planned product lifetime in years (key parameter for calculating return and efficiency)	<i>Count</i>
Determining customer needs	<i>Number of hours * price / hour</i>
Description of functionality and advantages over existing solutions, decision on type of medical device	
Verification of manufacturability	
Estimate of costs and revenues	
Other costs associated with initiating the first idea for a new product	
Total other overhead / indirect costs per initiation phase	
Design concept	
Specification of strategy and development plan, market analysis and evaluation of product potential, estimation of development time, provision of personnel security	<i>Number of hours * price / hour</i>
Determination of product characteristics (product function, material requirements, etc.)	
Cost of production specification	
Costs of decisions on MP class and estimation of related legal and legislative acts	
Patent search for concept design	<i>CZK</i>
Design and development	
Refining strategy and development plan, costs and revenues, business plan	<i>Number of hours * price / hour</i>
Detailed production plan including material specification	<i>hour</i>
Estimation of the total cost of testing and evaluation in relation to the type of medical device under consideration (PMFC, clinical trials, risk analysis aFMEA, dFMEA, creation of accompanying documentation, etc.)	
Verification and evaluation	
Design validation and certification	<i>Number of hours * price / hour</i>
Testing costs included above (biological assessment, electrical safety, possibly other tests in relation to the nature of the product)	<i>CZK</i>
Creation of instructions for use, finalization of technical component	<i>Number of hours * price / hour</i>
Production	
Material	<i>CZK</i>
Team work on production	<i>Number of hours * price / hour</i>
Finalizing activities in relation to risk management	<i>hour</i>
Finalizing activities in relation to design validation and verification	
Reserve fund, costs associated with product risk insurance	<i>CZK</i>
Market launch	
Patent application (European patent / Czech Republic etc.)	<i>CZK</i>
Training of sales representatives and doctors	<i>Number of hours * price / hour</i>

Parameters linked to the existence of the product on the market	
Clinical trials over the life of the product	<i>CZK</i>
Post Market Surveillance	<i>Number of hours * price / hour</i>
Feedback evaluation, planning and setting changes	

**Table 3** Estimated revenue

Input information / question	Variable
Number of units sold for the entire product lifecycle.	<i>Count</i>
Estimated sale price per piece	<i>CZK/piece</i>
Total sales revenue	<i>CZK</i>
Revenue from licenses / patents	<i>CZK/licence</i>
Revenue from service activities	<i>CZK/ year</i>
Sales of partial activities	<i>CZK/year</i>



**Figure 1** Application homepage

**4.1. Web-based Interface**

The web-based interface (Figure 1) is solved by the simple Server Side Rendering technique, specifically represented by JavaServer Faces (JSF) standard, version 2.2. This is quick access which does not require more time-consuming development of the user interface. Its downside is binding the application logic layer with the presentation layer into a single package, which can, however, be divided later. PrimeFaces package components are used to further facilitate the development of the user interface. These also enable focusing the time allocation on the research part of the project, while the presentation part remains appropriately representative.

In the system, JavaServer Faces templates are tied to so-called Backing Beans in pairs. In our system, the life cycle of these Backing Beans is operated by the same standard as the parts of application logic, i.e. CDI, version 2. Individual Backing Beans always have the same name as their template, the only two differences being the use of the .java extension instead of the .xhtml extension of the template, and the presence of the postfix View. For instance, the template named editSurvey.xhtml is associated with logic in the file editSurveyView.java.

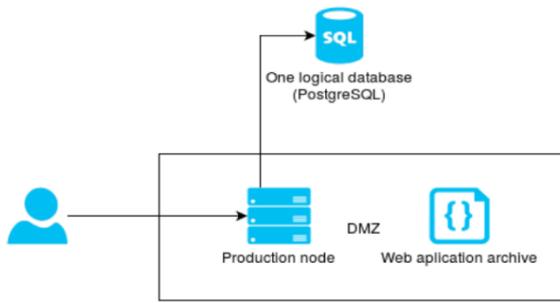
The web-based interface does not save so-called cookies with the user’s personal information. The nature of the system does not require this, as the user is identified based on the log-in. It uses so-called user sessions. Their expiration limit is determined by the specific implementation of the JSF standard and is fully configurable. The default expiration limit is set to be 30 minutes.

**4.2. General Software Description**

Medical Calculator is a program file developed for creating questionnaires in the field of health care, and their subsequent analysis. The purpose of this software is to process input information about a given business entity or company in a user-friendly manner, and apply data analysis on this information. The analysis itself can be variable. A single user can fill in more versions of a questionnaire over time, which is one of the greatest assets of the system. Questionnaires, as well as the applied analysis, can be adjusted within certain limits by one type of user (administrator) to respond to the market development over time and therefore to correspond better with the current state. A part of the system is retrospection, enabling the user to display data input in the past and the result of their processing. This system can generally be divided into four basic parts:

1. Database system
2. Logic for creating and processing of questionnaires
3. Users management
4. Web-based interface

All these parts are hidden to the user, with the exception of the web-based interface, which various types of users interact with. The database system is a common part used by the users management and the logic for creating and processing of questionnaires. The database system is not developed separately and it is appropriately chosen based on the needs of the currently deployed instance of the entire software. The system is developed in Java, using tools from its ecosystem. In particular, the standard Jakarta EE 8 and Eclipse MicroProfile 3.2 are used.



**Figure 2** Application logic

As you can see on Figure 2, the design utilizes JAVA and WildFly platforms with connection to PostgreSQL database. WildFly, previously known as JBoss, is an application server authored by JBoss. WildFly is written in Java, and implements the Java Platform, Enterprise Edition (Java EE) specification. WildFly is free and open-source software which supports multiple platforms. Data can be saved into other databases or formats, such as Open Source JAVA application server. Fundamental overview of application infrastructure is described on the following picture.

**4.3. Database System**

The system is agnostic to the database system, provided that the database is relational and implements the domain-specific language SQL (ISO 9075). It is possible to ensure the deployment of the system in the future due to its linking to the standard, rather than a specific database. The database schema has not been versioned yet.

The communication with the database and the creation of the database schema is provided by the JPA standard, version 2.2 (JSR 338). It abstracts entities in the Java language away from the database counterparts and it also generated codes necessary for operating the database. The advantage of this approach is fast adaptation to changes in the database model of the application during its further development. Above the JPA standard, there is a specific application library named Apache Deltaspike, in particular its part “Data”. This removes a recurrent code in the database layer of the application during its development by generating the code while the program is running, which occurs only once on the start-up of the program.

The system has been designed as multi-user since the beginning. This approach affects the database part of the application, which utilizes technical means for the reuse of database connections in such a way that fast discarding of current means and frequent creation of new connections are prevented. This part is again provided by the JPA standard, more precisely its specific implementations.

**4.4. Application Logic**

Logic for users management and their questionnaires and the program logic for creating and processing of questionnaires use the same technical means and from the perspective of software design exist on the same level/layer. Here belong the following:

- User accounts management
- security (passwords hashing, data transfer encryption, user authentication),
- reports generation (PDF format),
- data collection,
- user transactions management.

The aforementioned parts can be considered to be partial layers on the level of application logic, which cooperate with each other. The cooperation is enabled using the Dependency Injection technique, which is present mainly for the purpose of simple usage of means of the database layer and the presentation layer (web-based interface). It is secured by the Context & Dependency Injection (CDI) standard, version 2.0, which is also part of Jakarta EE 8 standard family.

Key layers of the application logic are separated. In particular, the security is separated in such a way that it is easily serviced and adjustments in this layer are easily applicable everywhere they are used (i.e. in other layers).

**5. CONCLUSION**

The aim of this article has been to discuss the issue of biomedical facilities investments. The process of introducing a new product to the market in the field of health care is highly demanding and expensive. For this reason, current trends and individual economic methods used in scientific community have been analyzed. Subsequently, the CBA (Cost Benefit Analysis) has been used, leading to the creation of an economic model. The advantage of the proposed model is the utilization of qualitative variables and evaluation of costs; furthermore, the solution assesses the suitability concerning the data character, legislative restrictions and geographical spread. The risk factor of the proposed method is primarily a distortion due to an inaccurate data input, which is then reflected in the calculation of the price as well as to the actual efficiency. The result of this project is an application with a web-based interface, which enables the user to input the expense of a medical device development in individual phases of the life cycle, and receive the information regarding whether the development of such a device is financially advantageous, using relevant economic methods.

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