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CONTENTS

- 1 Stakeholders in a Tourist Destination – Matrix of Possible Relationships
Towards Sustainability
Iva Slivar
- 11 Features of Building Business Strategy for Introducing Innovative Medical
Technology to the Market
*Marina V. Markova, Aleksandr M. Alekseev, Mikhail U. Alekseev &
Andrey R. Siegle*
- 23 Challenges to Financial Audit in Enterprises of Public Interest
Plamen Kimonov Iliev



Stakeholders in a Tourist Destination – Matrix of Possible Relationships Towards Sustainability

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Abstract

Given that the fragile balance of sustainability is affected by several actors whose interests need to be harmonized, different forms of association among them are one of the mechanisms for achieving sustainability. A lot of understanding, research, and co-operative effort are required to create and sustain various forms of collaboration of tourism stakeholders. The role of collaboration in tourism destinations has been widely acknowledged, however it is still one of the key stumbling stones of sustainable tourism development in practice. The focus of this paper will be on two-way destination stakeholders' collaborations, presented systematically in a matrix of typical relationships, representing its theoretical contribution. A panel of experts from the academia, practice and public sector developed the matrix of relationships with the scope of spreading different forms of collaboration between stakeholders aimed at jointly improving the right balance needed for sustainable development in tourism.

Keywords: sustainable tourism, collaboration, stakeholders.

1. Introduction

Tourism is a complex phenomenon, since it aggregates different, often contradictory interests of stakeholders. There are various effects of tourism - from positive to negative. Numerous examples of tourist destinations, which were thrilled by the crowds of tourists, had given priority to economic interests and the devastating effects on the environment became important only when ecological problems escalated.

The problem is that the development of tourism is perceived as a goal in itself with an emphasis on economic benefits, while it should actually be a means of achieving overall prosperity of the local community and the environment in which it lives. This paradigm is the foundation of the concept of sustainable development.

Sustainability is a must for all tourism destination. Tourism development is moving towards the position of reciprocally useful partnership and balanced development (Magaš, 2010: 1046) whereas the right balance among various stakeholders has to be re-established with each change over and over again. This calls for an adequate management of relationships formed among key players who are in control of the major destination resources and power.

It is well known the competitive position of tourist destinations depend on the choice and the quality of management of destination resources (Armenski et al., 2012). At the end it all comes down to people in control of these resources and their interactions. Therefore, the suggested matrix of key relationships formed by crossing key stakeholders between them, aims at understanding better the typical forms of two-way collaborations, as a first step towards their successful implementation.

- There are four key concepts impacting sustainable tourism development: responsible governance, CSR, responsible tourists and responsible citizenship.
- Environmental preservation is the key goal of sustainability: without it, society cannot exist, thus neither industry.

This paper is composed of four parts. It starts with a theoretical review on the topics of sustainable management and collaboration of stakeholders in the destination. The third part provides an overview of possible relationships formed between two stakeholders based on expert assessment, whose methodology is presented in part two. The fourth and last section summarizes concluding remarks.

2. Theoretical review

2.1 *Sustainable tourism*

Sustainability is a sought-for concept of development with possibility of universal application, although it differs in its practical implementation (WTO, 1996; WTO, 2004; ETIS, 2014, etc.).

World's Commission of Environment and Development definition, coined in 1987 is the most frequently cited one: "Sustainable development is development that meets the needs of the present without compromising the ability of future generations to meet their own needs".

It relies on three main pillars called triple bottom line or 3P: economic (Profit), social (People) and environmental (Planet), although the accent is strongly on the latter two. From the tourist perspective, sustainability can be summarised into "respect nature, culture and your hosts" (Rafai, 2017).

An excellent representation of sustainability is given by ranking the three key elements (Placemakers, undated):

- (1) Environment,
- (2) Society,
- (3) Economy.

Namely, the three main pillars of sustainability are classified according their importance since there cannot be any economy without society nor society can exist without a preserved environment. Although sustainability is a well studied topic (e.g. Garcia-Rossel, 2014; Fisher & Rucki, 2016; Brandi, 2016; Goodwin, 2017; Maruf Hossain, 2018, etc.), the practical implementation is challenging (Hunter, 1997; Sharpley, 2000). One of the first such tasks lies in the preservation of non-renewable resources for the next generations, which is the key concern environmental sustainability (UN, 2005).

Tourism might affect all entities of sustainability; however, it also depends heavily on the landscape and culture of tourist destinations (Galant, Slivar & Periša, 2016). Sustainable tourism "ensures that development brings a positive experience for its actors – local people, tourism companies and the tourists themselves..." (Edgell, 2006) therefore, sustainability in

tourism stresses the continuity of the process of adaption and reorganization towards achieving the aimed balance between the three pillars of sustainability (Hall, 2009). Sustainable tourism strives to affect minimally the environment and local culture, while helping to generate income, employment, and the conservation of local ecosystems (Institute for Tourism of the Republic of Croatia, 2014).

Antonyms are used to explain the differences between sustainable and non-sustainable tourism in the following table.

Table 1. Selected differences among sustainable and non-sustainable development

Sustainable development	Unsustainable development
Slow development	Quick development
Controlled development	Uncontrolled development
Long term perspective	Short term revenue
Quality – based development	Quantity – based development
Local control / cooperation	Control without local community
Planned development	Unplanned development
Well developed concepts	Small projects
Local human resources	Imported workforce
Traditional architecture	Non authentic architecture

Source: Koncept održivog turizma u RH, Studija o konceptu održivog turizma – Hrvatska i svijet, Roland Berger Strategy Consultants, Zagreb, 2008.

The basic metrics (however not widely used) for measuring sustainability of tourist destinations is the carrying capacity which determines the maximum number of visitors that can visit a destination without any negative environmental and socio-cultural consequences (O'Reily, 1986: 254-258). It can be (Cooper et al., 1996: 80):

- physical (e.g. 4-6sqm are deemed appropriate for a beach),
- psychological (personal believe of crowd or not),
- biological (the amount of land available),
- sociological (the level of development that is acceptable to the local population).

Nevertheless of thirty years of study, the implementation of sustainability in practice is still insufficient, thus more research is needed (Oyola et al., 2012; Mihalić, 2016).

2.2 Stakeholders in a tourist destination

Stakeholders refer to any physical persons or any kind of organization affecting or being affected by a business (Freeman (1984), which is applicable to tourism. Alike the tourism product - heterogeneous and complex (Middleton & Clarke, 2001; Ferri & Aillo, 2017) – also tourism itself reflects the same characteristics. It is comprised of many businesses, predominantly SMES (Scott, Parfitt & Laws, 2000) thus involving many players just at the offer side, among others. Various stakeholders have different goals and interests and with their activities, they affect sustainability (Scott, Parfitt & Laws, 2000; Krce Miočić, Razović & Klarin, 2016). Many authors approached the task to classify stakeholders in the tourist destination at different levels of depth. Cooper, Fletcher, Gilbert et al. (2005) list locals, tourists, tourism industry, public sector and others as the key stakeholders in tourism, while the following table.

Table 2. Key stakeholders in tourism and their roles

	INTERESTED STAKEHOLDERS	THE ROLE OF INTERESTED STAKEHOLDERS
PRIVATE SECTOR	tourism offer holders (tourism suppliers)	They are main employers and they affect the complete tourism value chain.
	intermediaries	They influence market accessibility through setting conditions to tourism offer holders (tourism suppliers) and tourism destinations.
	transport business	They influence the market and financial sustainability.
	private sector (excluding tourism businesses)	They assure revenues and prosperity.
	professional associations	They lead and direct sectoral developmental activities.
PUBLIC SECTOR	public (government) sector	They define the direction and influence sustainability through public politics, plans and financial support.
	local and regional government	They influence the sustainability of tourism through planning on the local and regional level (lower level plans), they affect the infrastructure development and support the local economic development.
	tourism organizations	Directly related to tourism, primarily responsible for stimulating market demand through destination marketing.
CIVIL SECTOR	NGOs	They influence the sustainable tourism development and facilitate the cooperation of interested stakeholders.
	vocational education	They help in tourism market research and in strengthening competences in tourism.
LOCAL COMMUNITY AND CUSTOMERS	local community	Tourism employees and other sub-creators of hospitable tourism destinations.
	tourists	By making their decisions, they influence the sustainability and profitability of tourism products.

Source (modified according to): Duanesrt (2014): Responsible tourism product development <https://www.slideshare.net/duanesrt/responsible-tourism-product-development>

There is no consensus about the ideal methodology to approach this task (Krce Miočić, Razović & Klarin, 2016) therefore nor a universally accepted classification of stakeholders. Their identification is crucial for the adequate managing of the tourist destination, especially in terms of synergistic activities, which affect heavily the sustainability agenda (Maiden, 2008; Fathmath, 2015).

So, who should be the dominant stakeholder? The interests of the local community should be a priority among other stakeholders, however, “only to a certain point whereas their aspirations don’t impact negatively other sustainability elements” (Galant, Slivar & Periša, 2016). Nature has no direct stakeholder making it thus difficult to be adequately represented, which brings us back to stress the priority of its preservation.

Sustainable or vice versa unsustainable tourism is the consequence of social relationships and adequate coordination among all key players (Gergen, in Garcia-Rosell, 2014), therefore it is important to explore more deeply possible levels of interactions in order to maximally benefit from collaborations.

Some of the possible forms of two-way collaboration are given in the next chapter framed in a matrix.

3. Methodology

The research was compiled thank to a selection of six experts in tourism. In order to develop the announced matrix, the authors have asked tourism experts to point out the key interactions between two players. Six experts in sustainable tourism from Croatia (two from the academia, two practitioners and two from the public sector involved in tourism) were purposely selected and asked to help out in order to compile their points of view. They were given the above presented matrix, however completely empty. Their task was to answer how one stakeholder interacts with others. Their collective results are presented in Table 1. The methods of analyses and synthesis during the formulation of the below table were applied.

The research was conducted in March 2018 in written form and the responses were sent by e-mail. The task was explained by telephone or in person.

4. Research results: matrix of possible relationships between stakeholders aimed at reaching sustainability

The results of research are presented in Table 3.

Table 3. Matrix of possible relationships between tourist destination stakeholders

	PUBLIC SECTOR	PRIVATE SECTOR	TOURISTS	LOCALS	Sustainability is achieved through:
PUBLIC SECTOR	<p>G2G</p> <ul style="list-style-type: none"> - Governance - Business (rarely) 	<p>G2B</p> <ul style="list-style-type: none"> - Governance - Support - Education - Business (rarely) 	<p>G2T</p> <ul style="list-style-type: none"> - Governance - Support - Education... 	<p>G2L</p> <ul style="list-style-type: none"> - Governance - Support - Education... 	<p>→</p> <p><i>Responsible governance</i></p>
PRIVATE SECTOR	<p>B2G</p> <ul style="list-style-type: none"> - Business (e.g. classic B2G, Public-private partnership) - Governance (Participation in formulating tourism strategies) 	<p>B2B</p> <ul style="list-style-type: none"> - Classic B2B - Partnership - Networking - Integration 	<p>B2T</p> <ul style="list-style-type: none"> - Classic B2C (customers are tourists) - Customer relations - Co-creation of tourism products 	<p>B2L</p> <ul style="list-style-type: none"> - Classic B2C (customers are locals) - Employment - Community-based interactions - Pro-poor tourism - Peer to peer - CRS initiatives 	<p>→</p> <p><i>Corporate social responsibility</i></p>
TOURISTS	<p>T2G</p> <ul style="list-style-type: none"> - Users of different services (police, public health care, tourist information etc.) 	<p>T2B</p> <ul style="list-style-type: none"> - Classic B2C (customers are tourists) 	<p>T2T</p> <ul style="list-style-type: none"> - P2P (peers are tourists) - Co-existence 	<p>T2L</p> <ul style="list-style-type: none"> - Business/P2P - VFR (tourists are visiting relatives and friends) 	<p>→</p> <p><i>Responsible tourists</i></p>

	<ul style="list-style-type: none"> - Co-valorisation - co-interpretation - Co-creating tourism strategies 				
LOCALS	<p>L2G C2G (Citizens to Government) - Participation in formulating tourism strategies - Employees</p>	<p>L2B - Classic B2C (customers are locals) - Employment - Community-based interactions - Pro-poor tourism - Peer to peer</p>	<p>L2T - Business / P2P (Peer to Peer) - Co-existence</p>	<p>L2L - Business / P2P (peer to Peer) - VFR (Visiting relatives and friends) - Co-existence</p>	<p>→ <i>Responsible citizenship</i></p>

Source: authors' research and according to Slivar, Floričić and Grgurić, 2016.

The goal of this qualitative study was to classify the various forms of stakeholder collaboration at the destination level which are related to sustainable tourism.

Based on the research, 16 mutual interactions between stakeholders in tourism were identified. Either way read – horizontally or vertically - it is possible to conclude that the various ways in which individual stakeholders influence each other are in fact summarized into well-known concepts. Namely, the interaction of service providers in tourism falls into the concept of corporate and social responsibility. The collaboration of the local population and public sector but also other stakeholders are transposed into the concept of responsible citizenship. The overall interaction of tourists in accordance with sustainability is reflected into the concept of responsible tourists (see more in: Slivar, Floričić & Grgurić, 2017).

It is however evident, that there are no known terms to identify some relationships especially in the case of tourists and the public sector. This gap represents a call to action.

Based on the proposed interactions, the concept of sustainability in a tourism destination is decomposed into the following key concepts:

- responsible governance,
- corporate and social responsibility (CSR),
- responsible tourists,
- responsible citizenship.

Each of these concepts contains a variation of the word “responsibility” which emphasizes the role of each and every stakeholder in their interactions with other stakeholders. The conclusion of this expert assessment is very similar to the presented model by Slivar, Floričić and Grgurić (2017), although based on VICE model and stakeholder positive influences and outcomes.

5. Discussion and conclusion

The presented matrix of key relationships was synthesized in a model of sustainable development with the following key elements: responsible governance, CSR, responsible tourists and responsible citizenship. This model adds responsible governance to remaining the three concepts in common with the previous model of Slivar, Floričić and Grgurić (2017) instead of the preserved environment. The latter one can't namely be directly represented by just one stakeholder and is thus the key goal of sustainability.

The limitations of the presented model derive from a bi-dimensional understanding of co-operation between stakeholders. Another upgrade of the presented forms of cooperation can be supplemented by the extension of expert opinions outside of Croatia, in order to extend the possible types of relationships formed.

The presented matrix emphasizes there are no negligible interactions if the paradigm of sustainable tourism development aims to be reached. Each stakeholder must play its part in maintaining a destination's sustainability agenda. The matrix of typical interactions could be the base for further study in order to achieve synergistic effects of multiple forms of collaboration.

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Features of Building Business Strategy for Introducing Innovative Medical Technology to the Market

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Abstract

This research article is devoted to joint study of authors, conducted to develop business strategy for implementation of the developed innovative method of electrocardiologic diagnostics of coronary heart disease and acute myocardial infarction in the market of electrocardiologic devices. Business strategy is based on promotion of the product “Tozka” that is telemedicine system “DoctorPatient”. The system allows performing diagnostics in outpatient and home conditions with the highest accuracy and in real time. The prototype of the diagnostic system was created and successfully tested on 290 patients and 40 healthy people. The research included formalizing socially significant problems, solution of which the innovation is aimed at, determining ways in which the innovation will solve these problems, identifying existing competitors in the field under study and competitive advantages of a new product, identifying potential buyers and assessing demand. On this basis, the authors developed schemes for commercialization of innovation and a plan for development of project for its dissemination in national and foreign markets.

Keywords: business strategy, business model, commercialization, innovation, electrocardiologic diagnostics, medical technologies.

1. Introduction

Purpose of this study was to develop differentiated business strategy for introducing innovative system of electrocardiologic diagnostics to the market.

Development of the strategy involved description of the following elements: market research results, competitive situation and competitive advantages of a new product, market segments and commercialization schemes for innovation, product development plan and strategy implementation program.

Innovativeness of the proposed system is based on the fact that to date there are no clear quantitative criteria for assessing level of myocardial blood supply shortage in each lead of

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electrocardiologic device. The indicators used to date have a low reliability of diagnostics: in the range of 37-51%.

- Modern technology of electrocardiologic diagnostics is characterized by low reliability of results.
- Authors proposed innovative method for increasing sensitivity of electrocardiograms.
- Developed product has a relatively low cost of production and allows users to assess risks of disease occurrence independently on their own and in a timely manner.
- Developed schemes for the commercialization of innovation include sales of the device to medical institutions and individual users and sale of licenses.
- Potential markets for the new device: Russia, CIS countries, Central and Eastern Europe, potential buyers: hospitals, sanatoriums, treatment and rehabilitation centers, polyclinics, medical centers, family doctors, individual users.

2. Method

In determining methodology of the study, the authors relied on traditional for management theory works of such authors, as Aaker and McLoughlin, (2007), Vikhanskiy (2003), Lamben, Chumppatis and Schuiling (2007), who considered the need to perform certain functions of strategic management in developing the strategy: internal and external analysis, positioning, strategic planning, implementation control. In the context of innovation, the authors emphasize the need for planning stage of commercialization and cash flows. The absence of these elements of business strategy will not allow a company to assess market potential of a new product and may cause unsuccessful promotion and sales, even if there is a significant development potential.

The main hypothesis of the study was the assumption that at present time there are significant problems in electrocardiologic diagnostics technology associated with low reliability of the results and high cost. Thus, technological solution that allows solving these problems, which is the basis of a new electrocardiographic device, is required in the market and will be in demand, both from medical institutions and from individual users.

3. Research methodology

The research involved collecting data on the market and capabilities of the technology developers to form each specific element of the strategy, as well as conducting relevant analysis and assessments:

(1) analysis of problems of the technology and the market of electrocardiologic diagnostic devices – to determine strategically important properties of a new product and ways to solve market problems;

(2) analysis of the competitive situation in the market of electrocardiologic diagnostic devices – to determine competitive advantages of a new product;

(3) assessment of market parameters and identification of potential markets for sales of a new product – to formulate market positioning.

The implementation of the above research areas, as a result, allowed the authors to formulate elements of the business strategy for introducing innovation to the market.

3. Results

The description of the problem which this innovative technology resolves:

(1) High mortality level in different countries from cardiovascular diseases. In 2015 17.7 millions of people died in different countries from cardiovascular diseases (CVD), and this amounts 31% from all mortality causes. From them 7.4 millions of people died from coronary artery disease (CAD). In Europe was registered 11.3 million and in the European Union – 6.1 million new cases of CVD. CVD amounts 45% from all deaths in Europe and 37% in the European Union. In absolute values IHD is the cause of 335 000 deaths in males and more than 297 000 in females in European Union.

(2) High cost of healthcare systems in the field of CVD in different national budgets. CAD holds leading position in mortality all over the world and is the main expenditure item in healthcare systems. The total value of CVD appraises at 210 billion of euro annually. 53% (111 billion of Euro) is the direct cost of healthcare systems, 26% (54 billion of Euro) – loss of labor productivity, 21% (45 billion of euro) – informal help to the patients with CVD.

(3) The dependence of diagnostic quality and treatment of CVD, the level of mortality from CVD and the level of income of the population. Countries with low level of income of the population are characterized by high mortality rates from CAD. The mortality from CAD and stroke, in general, higher in Central and Eastern Europe, than in Northern, Southern and Western Europe. In Russian Federation mortality in absolute values estimates 385.6 people per 100 000 population, on average, annually.

For comparison, the mortality from the same cause on the territory of EU countries estimates 95.9-105 people per 100,000 population annually, what is 4 times lower, than in Russia.

(4) High level of out-hospital mortality in Russia. One of the most important mortality features in Russian Federation is the fact, that vast majority of deaths happen outside hospitals: at office, at work, at home, at country house, at social places and others. In 2014 400 000 people died from ischemic heart disease outside hospital, or 82% from all deaths from this cause. The level of out-hospital mortality in Russia in 3-5 times higher, than in Western Europe and USA.

(5) Expensive diagnostics of ischemic heart disease. The “golden standard” of diagnostics is coronary angiography. In a view of high cost of one examination, patients go to the election according their subjective complaints, rest or stress-test ECHO-cardiography results. Sometimes clinics use stress-Echocardiography, computed tomography angiography (CT angiography), but there are very expensive and have limitations. However, according to the data from USA, Canada and Germany, approximately 40% of coronary angiograms carry out with coronary artery correction (with balloon angioplasty and stent implantation), another 60% - normal or near normal coronary angiograms without treatment.

(6) High time expenditure on diagnostics of ischemic heart disease. Approximately 30-40% patients with chest pain have cardiac cause of pain, other 60-70% - other causes: more than 40 diseases. Today, for an exception of cardiac cause of pain physician needs from 8 to 72 hours at the time when every minute is vital. Additionally, 24-27% of all patients with CAD are asymptomatic before and acute myocardial infarction (AMI) development or sudden cardiac death (SCD).

(7) Comparatively low diagnostic accuracy of ischemic heart disease. Diagnostic reliability of rest electrocardiographic examination is 37-51% (a few data showed 21%) and stress-test 60-70% at best. In these conditions the most vital is the question of cost of one examination and limited time for it.

Suggested innovative diagnostic technology of electrocardiography signal processing contributes in described problems resolution. The innovation provides:

(1) The developed system increased significantly the sensitivity (85.4-96.7%) and specificity (96.87%). Examination is carried out as usual rest echocardiography, but the recording duration lasts 2-4 minutes. Total time as maximum of examination is 10 minutes, including imposing of electrodes.

(2) One of the worked out criteria has a strong correlation with the level (in percentages) of coronary lesion according percutaneous coronary angiography (correlation coefficient 0.89) on 152 cases. It gives the possibility to elect patients on coronary angiography with low number of normal or near normal angiograms. The critically high level of this criterion coincides with AMI development.

(3) Second criterion has correlation with the severity of ischemic heart disease patient. Patient's complaints and its intensity are classified according functional classes of Canadian cardiovascular society. It provides the possibility to exclude ischemic heart disease in 10 minutes.

(4) The system is simple in use it means that it can be utilized in screening of big amount of patients to reveal asymptomatic patients and patients on early stages. It means that it is possible to reveal patients with high risk according quantitative criteria and start pharmacological treatment in time or coronary angiography long before AMI and SCD.

(5) These 2 criteria are very sensitive to pharmacological influence on the heart, what gives the possibility to assess the efficacy of treatment individually.

(6) Utilizing dynamic examination (every week or month) it is possible with mathematical accuracy to assess the time of AMI development individually according to the growth rate of criterion from one examination to another and achievement its critical level for AMI.

(7) Early and authentic diagnostics of ischemic heart disease allows significantly lowering the costs on additional examinations (for example, stress tests) and monitoring patients in emergency departments for better results.

The developed new product on this technology – “Tozka 6” is individual diagnostic device, which gives remote self-monitoring patient's heart everywhere and every time for those, who take care of their health.

4. The concept of the new product “Tozka-6”

Goal of the mobile diagnostic device “Tozka-6” is adaptation of existing breakthrough approaches in professional medicine for individual use, with a great deal of attention paid to the non-invasive method, simplicity of tests and visibility of diagnostic results.

The developed device “Tozka-6” will allow self-examination of heart, registration and analysis of main medical indicators of electrocardiography, as well as receiving recommendations for therapy and lifestyle, including normalize health status through Biological Feedback. This procedure consists in the continuous monitoring in real time of clinically relevant indicators and conscious control (normalization) by them using multimedia and other techniques.

Using “Tozka-6” device during biological feedback sessions will make it safe, as high sensitivity of diagnostic system “Tozka” allows adjusting therapy to a patient in time.

“Tozka-6” is a software and hardware complex, which includes software and hardware components divided into 4 groups according to their functional purpose:

- (1) Main focus is on the analysis of electrocardiogram image;
- (2) Compact docking station;

(3) Software for smartphones with operating systems iOS, Android;

(4) Cloud data storage.

The concept assumes that there are two categories of measurements performed by the new device: continuous measurements of human indices in motion and measurements performed in quiet condition of sitting or lying down. Body movement control channel is used for:

- monitoring work of heart;
- exclusion of artifacts in removal of electrocardiograms caused by patient movements;
- measuring time and nature of response to incentives;
- monitoring phases of sleep, forming optimal “sleep-wake” schedule; MEMS accelerometer. Possible supplier: Analog Devices, ST Microelectronics.

The authors studied main technological and market trends in the industry under consideration. They are the following:

(1) Improving visualization of condition of coronary arteries by coronary angiography, computed tomography with contrasting coronary arteries. Development of intracoronary investigation technology of atherosclerotic plaques and their injuries, as well as pharmacological test with visualization on a computer tomography or magnetic resonance tomograph. These methods are very expensive, require availability of qualified personnel and do not have ability to evaluate physiological processes in the myocardium in dynamics.

(2) Non-invasive methods use conventional electrocardiography at rest and with exercise (veloergometer, treadmill test, pharmacological test). Stress-ECHOCardiography is used to detect violations of myocardial contractility in places of possible coronary heart disease. The essence of the modern electrocardiographic study consists in recording patient within 10-15 seconds with subsequent construction of averaged complex over all leads and calculation of diagnostic criteria with high error rate in diagnostics.

(3) According to innovative scenario of experts forecasting volumes of the Russian market of electrocardiographic devices, in 2018-2022, there will be stabilization and steady increase in sales volumes. In general, Russian producers offer more attractive pricing conditions for supplied electrocardiographic devices to foreign customers, in comparison with price conditions for supply of devices to Russia by foreign manufacturers.

(4) Starting from 2015, market began to show clearly a trend of growth in domestic production of devices with relatively stable volumes of imports of electrocardiographic devices to Russia. Volume of imports is, on average over the past three years, tenth or less of volume of Russian production.

(5) Rating of devices by country of production in the order of increasing average price is as follows: China, Russia, Japan, Europe, USA. In the Russian market there are already quite a large number of users of Chinese devices.

(6) Currently, Russian market includes cardiographs from leading European companies: Schiller Cardiovit (Switzerland), Innomed Medical (Hungary), Cardioline (Italy), Esaote (Italy), GE Marquette Hellige (Germany). In addition, cardiographs produced in Asia and Japan, are widely represented in Russian market: Fukuda Denshi (Japan), Nihon Kohden Corporation (Japan), Bionet (Korea), Trismed (Korea), Biocare (China). Domestic producers (Altonika, Valenta) also occupy their own niche, offering budget inexpensive models of electrocardiographic devices.

(7) Main advantage of Chinese cardiographers is their low price, which for medical institutions with a small budget in some cases is determining factor of purchase. For comparison,

average cost of Chinese device is \$700, while the average price of device of Japanese or European production is about \$ 2,000. According to statistics, the share of Chinese electrocardiographs imported into Russia is currently approaching 20%.

(8) Domestic cardiographs are traditionally in demand, both among Russian consumers and in CIS countries. They are more expensive than Chinese devices, but cheaper than similar European ones. Consumers of Russian models are attracted by quick and inexpensive repairs, as well as affordability, compared to products from companies with well-known brands. According to reviews of practicing doctors, the less electronic functionality is in the domestic apparatus, the more stable and trouble-free its work is.

(9) There is still a shortage of certified medical devices for measuring cardiac activity in Russian market: most clinics and hospitals use wearable monitors to record a long-term electrocardiography. Patient carries it with him for a certain period of time, after that a doctor decodes the data. Mobile cardiogadgets are not yet widely used.

5. Discussion

The conducted research allowed allocating competitive advantages of the innovative electrocardiologic system and the new product "Tozka-6". Among the companies conducting the same or similar developments, the following were distinguished:

- Schiller AG (Switzerland);
- General Electric (GE), (USA, China, India);
- Mortara Instrument Inc., Welch Allyn Inc., Philips Medical Systems (USA);
- Fukuda Denshi Co. Ltd., Nihon Kohden Corp., Suzuken Co., Ltd. (Japan);
- Kaden Yasen Medical Electronics Co., Ltd., Edan Instruments Inc., Shenzhen Comen Medical Instruments Co., Ltd. (Comen), Shenzhen ECGMAC Medical Electronics Co., Ltd. (China);
- OOO NPP Monitor, JSC Concern Axion, LLC Altonika (Russia).

Advantages of new product are the following:

(1) Electrocardiologic test is suitable for mass examination of patients.

(2) The developed diagnostic criteria are calculated in automatic mode, their calculation by a doctor is impossible, but he can check correctness of the calculation at the first stages of system work.

High performance, reliability and low cost are due to the fact that most of processing and analysis of research results are carried out automatically. Calculation of diagnostic criteria is performed only by computer technology without the participation of a doctor.

(3) These criteria more than 2 times increase diagnostic value of electrocardiologic study.

(4) The developed diagnostic criteria make it possible to quantify depth of ischemic process on a scale of 1.4 to 11.5.

(5) Diagnostic criteria allow identifying high-risk patients at preclinical stage and beginning medical treatment.

(6) Sensitivity of the criteria to pharmacological effects on the myocardium will allow a doctor to evaluate effect of drugs on heart for minutes, hours or days.

Using telesystem in combination with automatic analysis allows monitoring patient's heart condition over days and months. In this case, in the case of worsening heart function, an alarm system is automatically switched on regardless of clinical manifestations of disease.

(7) Possibility of early selection of patients for coronary angiography.

(8) Lower production costs.

Formulation of competitive advantages of the product allowed the authors to determine main market parameters for promoting innovation. In particular, as an element of the business strategy, markets were identified where the new product could potentially be realized: geographic markets, main consumers, approximate market volume, market dynamics and future product positioning.

(1) Russia (Moscow, Moscow region and other regions)

Main consumers: hospitals, sanatoriums, treatment and rehabilitation centers, polyclinics, medical centers, family doctors, individual users.

Approximate volume of the market: 90 million rubles a year with estimated growth of 5-10%.

Positioning: low price compared to devices made in Europe and United States, high reliability of measurements, presence of only basic necessary functional of devices.

(2) CIS countries (Belarus, Moldova, Tatarstan, Uzbekistan, Kazakhstan, etc.)

Main consumers: hospitals, treatment and rehabilitation centers, polyclinics, medical centers, individual users.

Approximate volume of the market: 80 million rubles a year with estimated growth of 3-5%.

Positioning: relatively low sale price; analysis of main medical electrocardiographic indicators and obtaining recommendations for healthy lifestyle, including normalization of human health condition through Biological Feedback; high level of measurement reliability.

(3) Countries in Central and Eastern Europe

Main consumers: hospitals, treatment and rehabilitation centers, polyclinics, medical centers, family doctors, individual users.

Approximate volume of the market: 120 million rubles a year with estimated growth of 2-3%.

Positioning: relatively low sale price; analysis of main medical electrocardiographic indicators and obtaining recommendations for healthy lifestyle, including normalization of human health condition through Biological Feedback; high level of measurement reliability.

In accordance with selected market segments, the authors developed a differentiated model for commercialization of innovation in format of sales of new product "Tozka"'s versions and license for technology.

(1) Segment "business-to-customer": sale of experimental lots of "Tozka-6" device

Product description: mobile diagnostic electrocardiographic device for remote monitoring of patients at risk and anyone who worries about their health.

Application: for individual use.

Scheme of income generation: sale through distributors.

Planned retail price: 45 thousand rubles.

Status of the scheme: preliminary negotiations with 7 profile distributors of medical equipment and gadgets were held, agreement with MED Llc (<http://maximed.pro/en>) on the implementation of the device in the markets of Russia, CIS and EU, was reached.

Forecast of financial flows for the period 2020-2021: 2020 – 10 million rubles, 2021 – at least 50 million rubles.

(2) “Business-to-business” segment: sale of “Tozka-1” device

Product description: outpatient electrocardiographic device for early diagnostics of patients with coronary heart disease (reliability about 96%) and control of therapy effectiveness.

Scheme of income generation: sale through distributors.

Application: for treatment and prevention institutions.

Planned retail price: 140 thousand rubles (at production cost of about 42 thousand rubles).

Status of the scheme: preliminary negotiations with 5 profile distributors of medical equipment were held, agreement with the company 10 MED Llc (<http://maximed.pro/en>) on sales in the markets of Russia, CIS and EU, was reached.

Forecast of financial flows for the period 2020-2021: 210 million rubles.

(3) Sale of the license

The main commercial goal of the developer’s activity will be building portfolio of intellectual assets that protect technology, as well as refinement and commercialization of technology, mainly through licensing of relevant intellectual property. By 2022, it is planned to sell IP for at least 200 million rubles, or reaching license agreement with major industrial partner with the payment of royalties in the amount of 5-7% of sale turnover of the developed medical equipment and gadgets.

6. Conclusions

Thus, the formed elements of the business strategy for the commercialization of innovative medical technology took into account main known theoretical approaches to strategic and business planning. As peculiarity of the proposed strategy was consideration of problems of modern technology of electrocardiologic diagnostics and corresponding social problems in general. In addition, the model of commercialization has differentiated character, depending on specifics problems to be solved for each market segment. This condition determines anticipated high speed of innovation distribution process in format of the new device “Tozka”.

As a result, the authors formulated main directions for technology and new product development, taking into account findings of the research:

(1) Creating and preclinical testing device versions in 2019-2020;

(2) Developing of Russian market with a turnover of about 90 million rubles in 2020-2021;

(3) Scaling of the product in the international market: entering markets of CIS countries in 2020-2021, and countries of Central and Eastern Europe – in 2021-2022, with a turnover of about 200 million rubles by 2022.

Generalized plan for subsequent development for the next few years includes the following stages:

By 2020 – creation of distribution network in the markets of CIS and countries of Central and Eastern Europe. Sales in Russia - not less than 500 devices of “Tozka-1” and 1000 devices of “Tozka-6”.

In 2021 – sales in the Russian Federation, test sales in the markets of the CIS and countries of Central and Eastern Europe, in total number of not less than 1000 devices of “Tozka-1” and 5000 devices of “Tozka-6”.

In 2022 – sales of technology license to a large industrial partner from among such well-known companies, as: Siemens, Medtronic, Roshe, Philips, Samsung.

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Challenges to Financial Audit in Enterprises of Public Interest

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Abstract

The material examines the new moments set forth in the Regulation EU/537/2014 and Directive EU/56/2014, regulating its application Independent financial auditing, including in public interest. Attention is drawn to the new moments in our relationship, namely joint audit, rotation of auditors, new reporting moments, joint auditors and the increased powers of the Public Oversight Commission on work on registered auditors.

Keywords: financial audits, shared auditors, public enterprises interest, rotation.

On 29 November 2016, the new Independent Financial Audit Act (IFAA) was promulgated in the State Gazette, which fully transposed the requirements of Directive EU/43/2006, as amended by Directive EU/56/2014 and Regulation EU/537/2014. It contains substantial changes, in particular with regard to the duties of audit committees, as well as auditing in Public Interest Enterprises (PIE). In this respect, in 2018, for the first time, the new requirements of the law were applied in the annual financial report approvals for 2017, which introduced a number of new principles, such as shared audit, mandatory rotation of registered auditors, a ban on certain services, and wage restraints services other than auditing. Audit committees are already subject to oversight by the Commission for public supervision of registered auditors.

Public interest entities are defined in the Accountancy Act (AA), and these are the following:

- undertakings whose transferable securities are admitted to trading on a regulated market in a Member State of the European Union;
- credit institutions;
- insurers and reinsurers;
- pension insurance companies and the funds managed by them;
- investment intermediaries, which are large enterprises within the meaning of the AA;
- collective investment schemes (CIS) and management companies within the meaning of the Law on the activity of CIS and other collective investment undertakings which are large enterprises within the meaning of the AA;
- financial institutions within the meaning of the Law on Credit Institutions, which are large enterprises within the meaning of the Insurance Act;

- “Holding BDZ” Ltd and its subsidiaries; National Railway Infrastructure Company;
- commercial companies whose main business is to produce and/or to transfer and/or sell electricity and/or heat and which are large enterprises;
- commercial companies whose main business is to import and/or transport, and/or distribute and/or transit natural gas, and which are major AA enterprises;
- Plumbing contractors within the meaning of the Water Supply and Sewerage Services Regulation Act, which are medium and large enterprises.

All PIE must have an already established audit committee under the IFAA, which strengthens the importance of audit committees in public interest entities. Within six months of the entry into force of the law, by the end of April 2017, these companies had to comply with the new requirements, having already set up audit committees and defining its functions, rights and responsibilities in relation to the financial audit, internal control and internal audit, as well as its relations with the company's management bodies.

By comparing the current scope of public interest entities with that of the former (in the IFAA), it is noticeable that the telecommunication companies are not included in the present scope. The new version defines companies engaged in the production and/or transmission of electricity and/or heat and those engaged in the import and/or transmission and/or distribution and/or transit of natural gas as such, from public interest only if they are large, according to the requirements of the Accountancy Act. Within the scope of public interest entities, collective investment schemes and management companies, as well as financial institutions, are included only in cases where those enterprises meet the criteria for “large” within the meaning of the law. Public water power plants were included in the scope of public interest companies regardless of their size. For the reporting period during which a public interest entity ceases to meet the requirements for the period, the same as at 31 December of the current year is considered to be an undertaking in the public interest.

The new requirements in the IFAA provide for the introduction of so-called shared audit when it comes to public interest entities. These companies will also be able to use a single audit company for a maximum of 7 years. In the discussions and debates before the adoption of the law, according to the Finance Ministry, the changes will bring about harmonization of the Bulgarian legislation with the European legislation. The main objectives are to strengthen the protection of investors and the quality of the audits carried out.

One of the main changes is the introduction of the obligation for two audit firms to audit the annual financial statements of public interest companies and then to prepare a joint report. According to the Ministry of Finance, the texts were introduced according to a prescription of the European Commission in its 2010 Green Paper entitled *Audit policy: Lessons learned from the crisis*. The aim is to break the dominant position of the major auditors and to provide the possibility for non-systemic companies to enter the financial sector and reduce the concentration of audit services, which entails the creation of systemic risk in the sector.

Against the introduction of this requirement, then the banks said that the shared audit would increase banks' spending by about 25%, but according to the draft bill, rising costs can not be an argument against joint audits, and the argument is better to costing someone's business, but saving money for citizens and society.

In this regard, the Ministry of Finance recalled the situation in 2014, when due to weaknesses in the audit and oversight, bankruptcy of the fourth largest bank in Bulgaria – Corporate Commercial Bank (CCB) took place. The strengthening of the supervision of the financial system is on the recommendation of the European Commission to Bulgaria from the beginning of 2015 and the International Monetary Fund (IMF) has also recommended strengthening the supervision processes and drawing lessons from the CCB case.

Amendments introduced and so-called mandatory rotation of audit firms. Public interest companies will be able to work with one auditor for a maximum of 7 years. Representatives of foreign business organizations insisted on using the maximum allowed term in the European directive – 10 years. However, the Ministry of Finance ruled that the risks to the independence of auditors of public interest entities have been reduced by this deadline.

The rotation of auditors is one of the options to achieve to a large extent independence and objectivity. This issue became relevant in the United States in 2002 with the adoption of the Sarbanes-Oxley Act, which is in response to corporate accounting scandals with Enron WorldCom.

Two forms of rotation are known:

- the key auditor or auditor responsible;
- the audit firm as a whole.

The rotation of audit firms has both positive and negative sides.

The positive ones are that it reduces auditing risk, reduces closer auditor/employee relationships and improves the quality of audit services.

Negative is the increase in the cost of validating the annual financial report, restricts specialization and experience, increases auditing errors, reduces incentives to increase efficiency and quality, reduces understanding and knowledge of the enterprise, and so on.

There are a few more changes to this effect. A minimum statutory audit period of three years is introduced, tax audits are granted to the audited entity by the registered auditor, and restrictions are placed on the audited entity's revenue from non-audit services in the public interest as well as on cases of the revenue from this. Where, for three or more consecutive financial years, an auditor provides to a publicly-owned establishment non-audit services, the total amount received for such services may not exceed 70% of the average paid during the last three consecutive financial years for a statutory financial audit in the audited enterprise. The changes are also the following:

- The PIE auditor's report is in a different format and volume – apart from other changes, it should also include a description of key audit questions;
- the Registered Auditor must prepare and submit to the Audit Committee an additional report (in addition to the Audit Report). This also applies to the group auditor – an additional report is provided to the audit committee of the parent. At the request of a competent authority supervising the PIE, the registered auditor shall immediately submit the relevant supplementary report;
- when conducting a statutory audit at the PIE, the registered auditor should inform the management and the audit committee of the entity of any circumstances that are or would impair its independence in the performance of the audit engagement.
- the PIE auditor should promptly report to the relevant body of the entity and to the Commission for public supervision of registered auditors any information that has caused or is likely to cause one of the following consequences: (1) a material breach of the regulatory provisions which lay down licensing conditions or which specifically regulate the performance of the PIE activities; (2) a material threat or suspicion of continuing the activity of the PIE; (3) response from audit opinion, negative or qualified audit opinion. The auditor is required to provide an additional report to the audit committee.

In 2017, the Commission for public supervision of registered auditors and the Institute of Certified Public Accountants have developed *Guidelines for the implementation of a shared audit* in PIE aimed at assisting registered auditors, business executives and audit committees in carrying out a joint audit to achieve the objectives of the financial audit, auditing standards.

The Guidelines set out the key principles and approaches of the shared audit, including the role and responsibilities of joint auditors, additional audit procedures, communication and auditing documentation requirements when performing joint audits of individual or consolidated financial statements of enterprises under the Act of Independent Financial Audit.

They think:

- *shared audit* is a commitment to a mandatory financial audit where two or more registered auditors - natural persons and / or audit firms have undertaken to audit a company's financial statements through shared work and jointly issue an audit report on that report, are jointly and severally liable for the expressed audit opinion;
- *a shared auditor* is a registered auditor (natural person or auditor company) that has undertaken a joint audit commitment;
- *a balanced distribution of work* is such a distribution of work between the joint auditors where the ratio of the planned hours for the implementation of the audit procedures to cover areas with significant risk is not more than one third (for example, for two joint auditors a balanced distribution of work is in proportion to 60/40 percent of the total hours planned); the allocation for simultaneous execution of shared audits of individual and consolidated financial statements is made separately according to the terms in the letters of assurance for each of the audit engagements.

Joint auditors should prepare and submit proposals for competitive auditing in accordance with the requirements of the Independent Financial Audit Act, International Auditing Standards (ISAs) issued through the International Standards on Auditing and Standardization Standards and the Code of Ethics for Professional Accountants (CEPA) issued through the International Ethics Standards Board for Accountants of the International Federation of Accountants. Under the terms of the request for an audit proposal, the shared auditor may propose the joint auditor may offer shared audit services individually or together with another auditor(s).

Each joint auditor is required to be equally responsible for complying with the independence requirements and other ethical requirements under the IFAA, as well as the competence and expertise required to perform the joint audit. He has to make sure that any other joint auditor has been selected in accordance with these requirements. It has the right to refuse joint work with another selected auditor or to reject the engagement as a whole on the basis of evidence of non-compliance or refusal of co-operation by the other auditor, regardless of the manner in which the audit proposal is made under the provisions of Independent Financial Audit Act.

Sentient auditors are jointly responsible for accepting the client and engaging in accordance with the Independent Financial Audit Act and the Code of Ethics for Professional Accountants. Client acceptance and engagement procedures are implemented jointly, including endorsement of the final decision.

The terms of the shared audit engagement shall be governed by a *joint audit engagement letter* that shall be agreed and signed by the joint auditors in accordance with the requirements of the applicable auditing standards. Any other arrangements and terms, such as financial or specific legal terms that are not related to the arrangements in the letter and are not in contradiction with the applicable auditing standards and the law, may be agreed by the joint auditor with the management of the entity individually in a separate agreement.

The audit engagement letter also mentions the terms and procedure *for sharing work between the joint auditors*, as well as resolving any differences of opinion or disputes between them.

The joint auditors *are jointly and severally responsible for the performance of the audit engagement and for the audited opinion*, in compliance with the requirements of applicable

ethical norms, for Independence, established by the FIGF, the ETUC and the applicable auditing standards.

The nature, timing and extent of the work to be performed in a joint audit is the same as when performing a stand alone audit engagement.

Therefore, they agree and jointly develop a common audit strategy and engagement audit plan setting a common materiality level and uncorrected deviation profile for the entire engagement as well as other materiality levels in line with applicable audit standards. In case of disagreement resulting from different methodologies applied by the auditors, the lowest relevant materiality level is used.

At the planning stage, the joint auditors agree on the distribution of the work to be done to implement the audit engagement. Client acceptance and engagement procedures, risk assessment, engagement quality control, and communication with those charged with governance and evaluation of audit results can not be distributed and should be implemented jointly.

The Joint Auditors *shall draw up a written memorandum* for the allocation of audit procedures. Such allocation could be made as follows:

- understanding the Entity and risk assessment – implemented jointly; audit strategy and audit plan – implemented jointly;
- audit procedures – are performed separately by the joint auditors of the basis of the agreed work distribution;
- analytical procedures at the end of the audit engagement – performed jointly;
- audit report – prepared jointly.

Part of the audit work involves getting information and explanations from the management. These procedures are performed jointly by the joint auditors, except if they do not agree in writing on a specific allocation of this to a specific joint auditor to obtain the necessary information and explanations from the management and to provide them with the relevant other joint auditor.

Each shared auditor is required to satisfy himself that the other joint auditors have performed their part of the joint audit work in accordance with applicable auditing standards and to provide the other joint auditors with all the information about any deviation, misstatement or reporting from the audited entity.

The joint auditor analyzes the areas in the financial statement with assessed significant risks and determines the scope and degree of peer review on the work of the other joint auditors.

When a shared auditor considers that the work of another joint auditor is inadequate or can not rely on it, he should write in writing to the other joint auditor to arrange for the performance of the additional work that is required.

The joint auditor should identify and implement policies and procedures for differences of opinion with another joint auditor. Procedures should ensure early identification of differences of opinion, provide clear guidance on the steps to follow, and require documentation of the resolution of differences and the implementation of the conclusions reached.

If a controversial issue can not be solved by the joint auditors, the responsible auditors should document in their audit file the disagreements on material audit issues and / or areas of judgment and the reasons for doing so. This document must contain: a description of the controversial issue; applicable auditing standards; proposed resolution of the problem; information about the actions taken to resolve the problem.

When differences of opinion can not be resolved, the joint auditors promptly inform the management, the Audit Committee and others charged with governance.

It is of great importance that each joint auditor should make the necessary efforts to resolve differences with other joint auditors prior to the issuance of the audit report. In rare cases where this is not possible and refers to significant differences that would lead to a modification of the audit opinion, the IFAA requirements are applied.

The shared auditors shall implement the policies and procedures adopted for the engagement quality control review in compliance with the IFAA requirements and applicable auditing standards.

The quality control review should be performed, documented and completed before the date of the joint audit report.

Joint auditors express or form a final unified audit opinion as to whether the financial statements are prepared and presented in all material respects, in accordance with the applicable financial reporting framework. In the event of differences of opinion, the joint auditors shall implement policies and procedures that have been agreed in advance.

The communication between the shared auditors shall be implemented on an agreed plan and in an effective manner consistent with the size and complexity of the audit engagement. Joint auditors should establish an appropriate communication process between themselves in the planning phase of the joint audit by documenting it.

Written communication with management and those charged with governance is jointly prepared and signed by all joint auditors.

Joint auditors should comply with the requirements for communication with the competent authorities supervising the activities of audited entities arising from current legislation and applicable auditing standards.

The requirements of applicable auditing standards for documentation and storage of audit file engagement and applicable legal and regulatory requirements for documentation. All documents certifying joint work are signed by each of the jointly responsible auditors and each joint auditor collects, maintains and archives a complete audit engagement file.

Instead of concluding

When we talk about the benefits or the positive aspects of the application of the financial audit, including auditing in public interest entities, we should first of all say:

- *Support for accountants* – the best effect is when financial audit work begins before the end of the financial year so that there is time to be done if adjustments are needed in the coverage of transactions or events;
- Next, *security for management* – independent highly qualified specialists – auditors inspect all processes and their correct reporting in the financial statements. Confirms the honest and faithful work of the accounting department and the compiler of the report. So managers are confident that the reports are a true reflection of the financial situation, or they are shown areas that need improvement, and how to apply appropriate changes and adjustments;
- *The audit may reveal inaccuracies and inconsistencies in the records of an organization*, which may be signs of a weak financial organization;
- The audit also applies to the protection of the owners – the owners receive confirmation from an independent party about the reliability of the financial statements, information about any mistakes, misuses or frauds committed by persons employed in the company's business, as well as its management;
- The audit provides sufficient and reliable information to all other stakeholders of the business, such as financial institutions, investors, contractors, contracting authorities;

- The audit presents and leads to greater trust for the creditors and business partners of the company – for the business community, regular audits enhance the company's reputation and make it a desirable business partner. Financial audits are a prerequisite for lower investment risk for almost every type of business credit.

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