RESEARCH STRATEGY ON DEVELOPING ADDITIVE MANUFACTURED BESPOKE OPHTHALMIC INSTRUMENTS ASSISTED BY AN ONLINE INTEGRATED PLATFORM

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Globally, the number of people of all ages visually impaired is estimated to be 285 million. Almost half of these visual impairments require surgical intervention by means of treatment. The current paper proposes a theoretical research strategy to set the background on developing innovative and affordable solutions to the global problem of accessibility to ophthalmological corrective surgeries. These solutions are reflected both in the application of additive manufacturing (AM) technologies to obtain bespoke ophthalmic surgical instruments and in providing a set of software tools designed to assist the medical process for improved overall results.

Keywords: bespoke ophthalmic instruments, medical informatics, additive manufacturing, functional analysis

1. Introduction

A study of the current trends in sight degeneration shows that over 30% of the world population suffers from some level of visual impairment [1, 2, 3], with 90% of those living in developing countries. Worldwide leading causes of vision impairment are uncorrected refractive errors (43%) and cataracts (33%) [1, 4, 5]. Of these, more than half require specific ophthalmic surgery [5, 6]. The World Health Organization (WHO) states that 80% of visual impairments could be prevented or treated [3, 7, 8].

The proposed research strategy is aimed to be implemented in Romania, a state of the European Union, and the results generated will be adapted and industrialised as market applications for commercialisation in this country. The WHO estimates that the proportion of the Romanian population suffering from

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permanent blindness ranges between 0.3% to 0.5% [5, 8, 9], which equates to between approximately 65,000 and 110,000 individuals. Another 2-3% of the population has low vision [5, 8]. The most common deficiencies are cataract, glaucoma and refractive errors [10, 11, 12].

Romania invests in health less than any other country in the European Union, equating to only 3.6% of the Gross Domestic Product (GDP) [13, 14]. According to a study conducted by Global Business Intelligence (GBI), the market and industry for ophthalmic instruments and devices could reach $28 billion by 2016 [15, 16]. Such growth would exhibit a 2.5% compound annual growth rate (CAGR) between the years of 2009 to 2016 [15, 16]. Despite the fact that in 2012, Romania inaugurated the largest private eye clinic in SW Europe - the Europe Eye Hospital [17] - in the country there is no manufacturer of surgical and microsurgical instruments [18].

In the medium and long term, the research presented aims to include Romania among the manufacturers of ophthalmic surgical instruments, allowing access to a share of this growing market. This opens a new opportunity for both investment and international cooperation between research and development units and commercial companies, thus starting a new market sector in the Romanian economy.

The Annual State of the Industry Report by Wohlers Associates [19] places the medical/dental industry in third place (15.9%), within the top industries that use additive manufacturing (AM; referred to rapid prototyping (RP) within the report) technologies in developing their own products. Europe is the second largest region in terms of the rate of adoption of AM technologies [19, 20]. In 2010 the AM technology market, comprised of all global assets, increased by 24.1% (CAGR) from US$1,068 billion to US$1,325 billion [19, 20]. Wohlers Associates believes that by 2016, sales of products and services worldwide will double from that experienced in 2010. It is expected that by 2020, the AM industry will cross the threshold of US$5 billion [19, 20].

Considering the aforementioned market/sector appraisal, approaching and incorporating the two areas, health and AM technology, the current research strategy arose from an attempt to keep pace with the requirements of national and global socio-economic environments. AM technologies in the manufacture of ophthalmic surgical instruments could bring significant advantages over standard manufacturing technologies [21]. Currently, most surgical instruments are manufactured in more than 70 stages [21]. Among the major advantages of the proposed research strategy is the significant shortening of this very laborious production cycle. Ophthalmic instrument manufacturers now offer only the possibility of customising the tools for the surgeon [18], as considering a patient customisation is typically extremely costly and unjustified. Recent achievements in the field of AM show that a mass production process for individual devices can

be designed and tailored [19]. The dental industry and the hearing aid industry are two applications that benefit from such complex AM production systems adapted for series manufacturing of bespoke products [19, 20]. According to *Smith et al.* [22] productivity loss due to visual impairments is a major issue of governments worldwide.

The research strategy proposed has three main stages, presented in Figure 1 below.

Fig. 1. Main stages of the research strategy for the development of AM-enabled bespoke instruments

The main contributions of the proposed research strategy relative to the current state of knowledge are: 1. Innovative application of AM technology in the manufacture of ophthalmic surgical instruments; 2. Development of new concepts of ophthalmic surgical instruments; 3. Double customisation of the developed instruments: in regard to the needs of the surgeon and to the patient needs; 4. Increase the versatility of the instruments, with implications in reduction of: operation time, number of instruments, the risk of complications, recovery and hospitalisation time, and last but not least, reduction of weight for a fatigue-free operation; 5. Launching an extremely complex innovative software product; 6. The initiative to access the market of manufacturing and commercialisation of ophthalmic instruments and devices.

The first stage is comprised of conceptual studies and redesign of existing ophthalmic surgical instruments. The first steps are identifying, defining, classifying and ranking useful functions for the chosen ophthalmic surgical instruments and will be conducted using a functional analysis (FA) method and Function Analysis System Technique (FAST) diagrams [23, 24, 25, 26]. Innovative CAD models will be provided after strict collaboration with surgeons and AM specialists. The second stage of the research strategy entails the manufacturing of the prototypes for the ophthalmic surgical instruments and in-vitro testing. Several interim prototypes and one final prototype will be manufactured using different AM technologies [23, 27, 28]. Interim prototypes will be sent to specialists for testing. The third stage implies development of an online integrated platform (OIP) architectural model for online services and

creating the functional model for online services. The stage ends with module integration and experimentation of the OIP.

In detail, the research strategy will be structured as shown in Fig. 2.

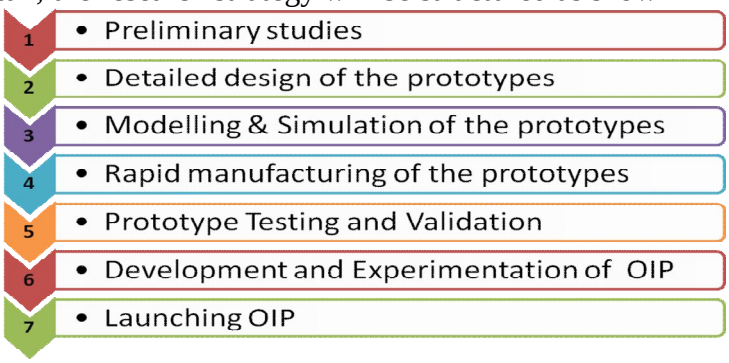

Fig. 2. Detailed planning of the research strategy

The objectives of the research are correlated with the purpose and the results as presented in Table 1 below.

The detailed objectives of the proposed research strategy are presented as follows:

- Adapting AM technologies to manufacture bespoke ophthalmological surgical instruments is necessary for obtaining useful research results. Parameters will be adapted, such as: technological parameters of the equipment, material, production volume, build volume layout and so on.
- The current research aims at adapting and transferring the research results to a wide range of ophthalmic devices, facilitating commercialisation.
- Development of innovative concepts for ophthalmic surgical instruments with high versatility and an accessible price point, achieved through the collaboration of specialists, whilst considering the technological advantages of AM. The instruments are developed with the aim of increasing the degree of multifunctionality and customisation of functional surfaces according to the patients' anatomy. The surgical instruments will be available with ergonomically refined features designed for the surgeons. Improving the outcomes of existing surgical procedures involves: simplified postoperative treatments, reduced time for hospitalisation and incapacity of the patient, reducing time for undertaking surgical procedures, etc.
- The sustainability of the research is promoted by the innovative information software, involving the development of a complex IOP.
- Managing the detailed medical history of patients is made possible by using the *Eye Care* interactive platform, designed for the clients that will use the bespoke ophthalmological surgical instruments.

- Creating an online community that brings together all the agents that interact throughout the lifecycle of ophthalmic products is achieved by launching the open platform *In a Blink of an Eye – IBE*.
- The compatibility of various ophthalmic instruments will be determined for simplification of future research and ease of application of the multifunctionality theories developed.
- The research is aimed at an interactive development of the surgical instruments concepts, based on feedback from specialised units.

The most significant novelty of the research strategy topic is the proposal of using AM technologies as a new approach for the manufacture of bespoke ophthalmic surgical instruments. State of the art, accessible and fast AM technologies will be used, to transfer bespoke geometries on functional surfaces without requiring specialised equipment and clean rooms. The main beneficiaries of the results of the research will be: the research strategy partners, private and state clinics, research centres with similar interests, ophthalmic instrument manufacturers, ophthalmology surgeons, and patients.

Table 1

Relationship between research purpose, objectives and results

HOW? ⟶		⟵ WHY?
Purpose	**Objectives**	**Results**
Application of AM technology to develop ophthalmic surgical instruments with personalised details with a high degree of versatility and accessible in terms of price.	**O1.** Adapting AM technologies to manufacture bespoke ophthalmological surgical instruments; **O2.** Applicability of custom technologies for a wide range of ophthalmic devices; **O3.** Development of innovative concepts for ophthalmic surgical instruments with high versatility and an accessible price; **O4.** Patenting original results.	**I.** AM functional prototypes
	O5. Implementing sustainable concepts.	**II.** Innovative information software product
	O6. Managing the detailed medical history of patients.	*Eye Care data base*
	O7. Creating an online community that brings together all the agents that interact throughout the lifecycle of ophthalmic products.	*IBE Open Platform*
	O8. Identify compatibility of various ophthalmic instruments; **O9.** Improving the outcomes of existing surgical procedures.	*Eye Multi Use Toolkit*
	O10. Interactive development of concepts based on feedback from specialised units.	Dedicated software modules

2. Methodology and concepts

2.1. Inter- and Trans- disciplinary characteristics of the research strategy

The scientific disciplines covered within the research strategy are: medicine, computer aided design (CAD), additive manufacturing technologies, ICT.

The relationship between the scientific disciplines is presented in Figure 3. Interdisciplinarity is observed throughout the proposed research strategy, with elements of each discipline that influence the results of each stage. However, a clear distinction can be made, between the proportions of each subject within each stage. Thus, in Figure 3, the representation of scientific disciplines identified in the logical structure of the main three stages is showcased.

The design discipline represents the conceptual component of the research and refers to both research design and planning, as well as to the design of ophthalmic surgical instruments. These activities are developed in the first stage (S1) of the research strategy. The design within this stage is not undertaken in a sequential approach (Figure 4a), but rather simultaneously (Figure 4b) [29, 30, 31]. This is done for linking the multidisciplinary concepts, whilst looking for their complementarity. Thus, the trans-disciplinary nature of the strategy components is ensured. The technical part of the research strategy is represented by the AM discipline. Manufacturing activities are conducted in the second stage (S2) and require optimisation of working parameters for surgical instruments. The scientific discipline of ophthalmic medicine predominantly occurs within S2. Ophthalmologists will perform in-vitro testing of functional prototypes, improving their final characteristics.

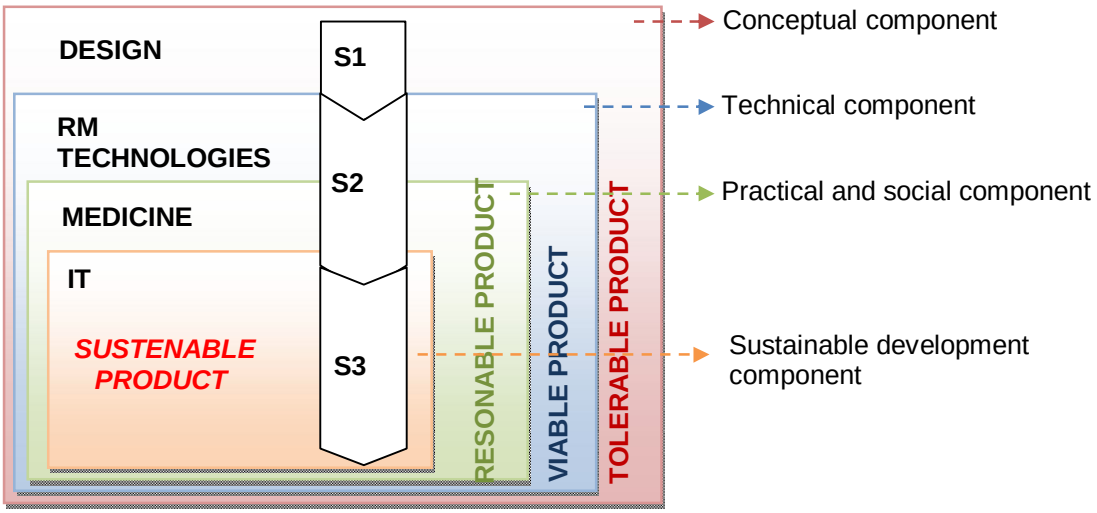

Fig. 3. Inter- and Trans- disciplinary characteristics of research-development-innovation activities of the research strategy

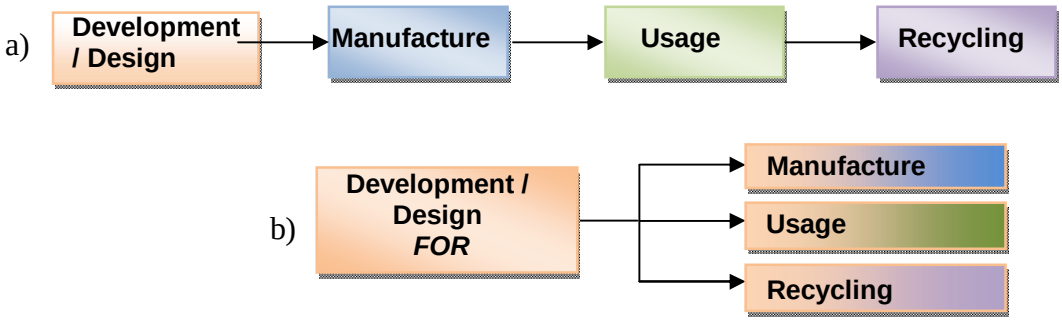

Fig. 4: a) Sequential classic approach; b) Simultaneous approach

In the third and final stage (S3) of the research strategy, the main activities developed are from the ICT scientific discipline, through integration and testing of the software modules and experimentation of the integrated platform for online services. By launching the innovative information software product, the sustainability of the developed products is ensured.

The interdisciplinary characteristics of the research strategy result from the combination and integration of the different disciplines mentioned, along with their methodologies and hypotheses. The methodologies and hypotheses belonging to different disciplines are connected and modified to adapt to the research needs. Thus, new theoretical methods are being developed, that allow the investigation of applying AM technologies to the design and development of ophthalmic surgical instruments, exceeding the possibilities of a single discipline approach. For example, using only AM technologies irrespective of medical, design or ICT hypotheses, the proposed results may not be achieved. The transdisciplinary characteristics of the research strategy crosses over four main disciplines (Fig. 3), aiming towards a holistic approach of the expected results. Transdisciplinary characteristics target in this case, a unit of knowledge of the research theme, beyond the isolated disciplines of medicine, AM technologies, design and ICT.

2.2. Ophthalmic Instruments concepts

Previous research in the field of designing ophthalmology instrumentation performed by the authors consists of designing a CAD model for a general speculum [23, 32, 33], resulting in a number of demonstration prototypes being manufactured. The current strategy aims to validate existing research by demonstrating the functionality of internal surfaces. The aim is also to customise the functional surfaces according to the characteristics of the patients' anatomy [34]. In addition, the research is aimed at obtaining a high versatility for every surgical instrument.

Several prototypes will be selected and proposed for development within the research strategy. Three instruments are already identified and others will be selected in consultation with ophthalmologists. The following main prototypes are identified:

- Functional prototype of the surgical instrument "Multifunctional Speculum";
- Functional prototype of the surgical instrument "Multifunctional Clamp";
- Functional prototype of the surgical instrument "Multifunctional Spatula";
- Functional prototypes for a range of dedicated surgical tools.

The design of CAD models will be followed by the production of intermediate demonstration prototypes using the ZPrinter 310 and Projet 1500 AM technologies. Intermediate prototypes will be used for discussion with practitioners and to establish final product geometries and features. The 3D Systems Form 1, Objet Eden 260V and Formiga P 100 SLS will then be used to manufacture the functional prototypes. These will be subject to new tests performed by the participating surgeons, followed by the manufacture of the final working prototype of each surgical instrument from biocompatible materials [35, 36].

Evaluation of the prototypes will be conducted according to the following success criteria: manufacturing of all prototypes in optimum operating conditions; establishing a stable co-operation with at least two medical specialists for the development of prototypes; feedback from at least five specialists from in-vitro testing of prototypes; feedback from at least one international specialist after in-vitro testing of prototypes; strong interest from at least one company for further development of prototypes for marketing.

The ophthalmic instrument concepts will be developed using Functional Analysis (FA), in accordance with the stages described in [23] and [32].

So far, research has been undertaken for two ophthalmic instruments: general use ophthalmic speculum (Fig. 5) and a bespoke spatula (Fig. 6). The spatula is in the CAD development stage and the ocular speculum in the intermediate prototype testing stage.

Using a FAST diagram [37, 38], the main functions of the speculum were identified (Table 2).

Table 2

Ocular speculum functions after performing FAST [23]

Main Function	Level 1 Functions	Level 2 Functions	Level 3 Functions
Ensure access to the eyeball	F1. Maintain the appropriate distance between eyelids	F1.1 Allow adjustable distance	
	F2. Keep away eyelashes		
	F3. Identify the injection point	F3.1 Measure 4 mm around the retina	
		F3.2 Mark the injection area	
	F4. Ensure safety in usage	F4.1 Ensure and maintain sterile environment	F4.1.1 Distribute anaesthetic

			F4.1.2 Maintain a moist environment
			F4.1.3 Ensure proper surface roughness
		F4.2 Ensure biocompatible material	
		F4.3 Allow easy and comfortable grip	
	F5. Allow reuse/recycling	F5.1 Ensure sterilisation	
		F5.2 Allow use for both eyes	
		F5.3 Ensure recyclable/biodegradable material	

The last intermediate prototye of the speculum is presented in Figure 5. Functions are identified on each element of the surgical device for improvement in overall functionality and costs [25, 39]. The device is currently with surgeons for testing [23, 40].

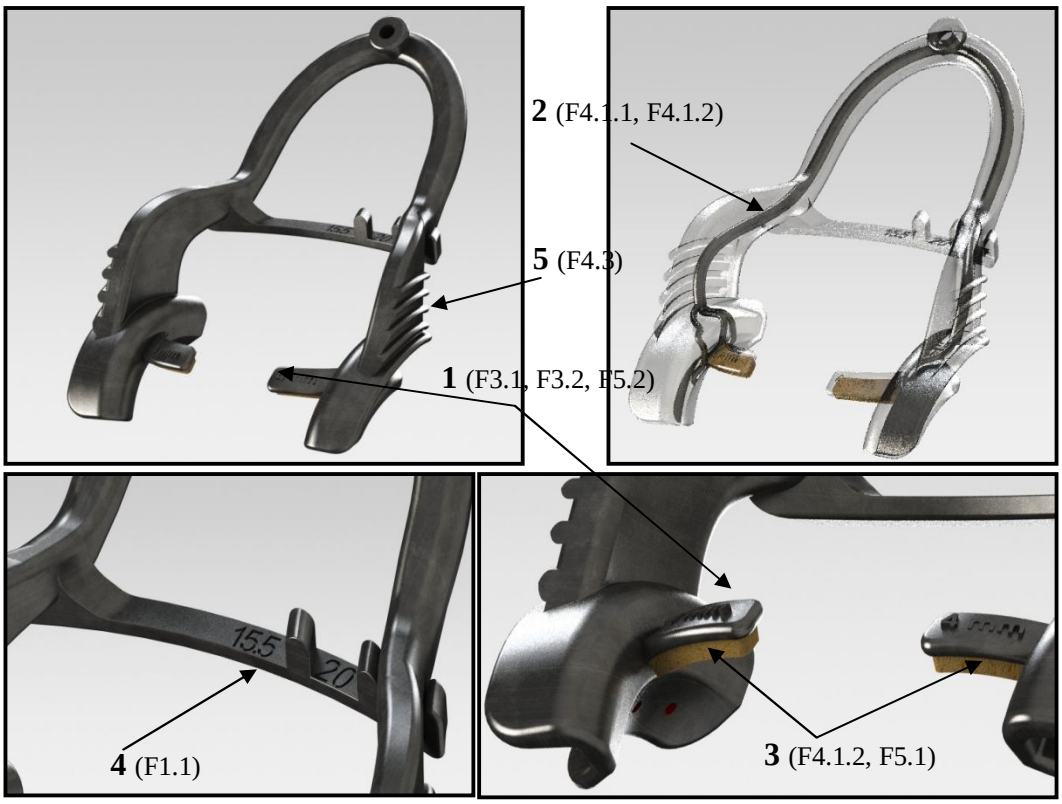

Fig. 5. Final Model of the Eye Speculum – Component identification
(1-measuring element; 2-antibiotic delivery internal channels; 3-absorbent pads; 4-adjustable diameter element; 5-comfortable grip element) [23]

Common complications of the intravitreal interventions [41, 42] led to a thorough analysis of the solutions provided by FA. The most important contributions brought to the ocular speculum after conducting the FA research, are as follows [23, 32, 33]:

- Inclusion of a measuring element in the single part ocular speculum;
- Designing an internal channel for the distribution of the antibiotic solution or anesthetic – the feature is still in prototype testing stage;
- Designing a specific element in order to adjust the diameter of the speculum for better fitting according to each patient;
- Incorporating absorbent pads, for excess fluids;
- Replicating the surface of the eyeball for comfort improvement and reduction of lesions and lacerations caused by the original product;
- The possibility of utilisation of the same item for both eyes;
- Re-usage after sterilisation in an autoclave;
- Recycling of the product in accordance with European standards for medical waste.

The bespoke ophthalmic spatula is designed for a specific “handprint” and presents lightweight features for a fatigue free operation. This instrument is in the concept phase and the final design will take into consideration the possibilities afforded from utilisation of AM technologies [43, 44, 45] and its final usage destination.

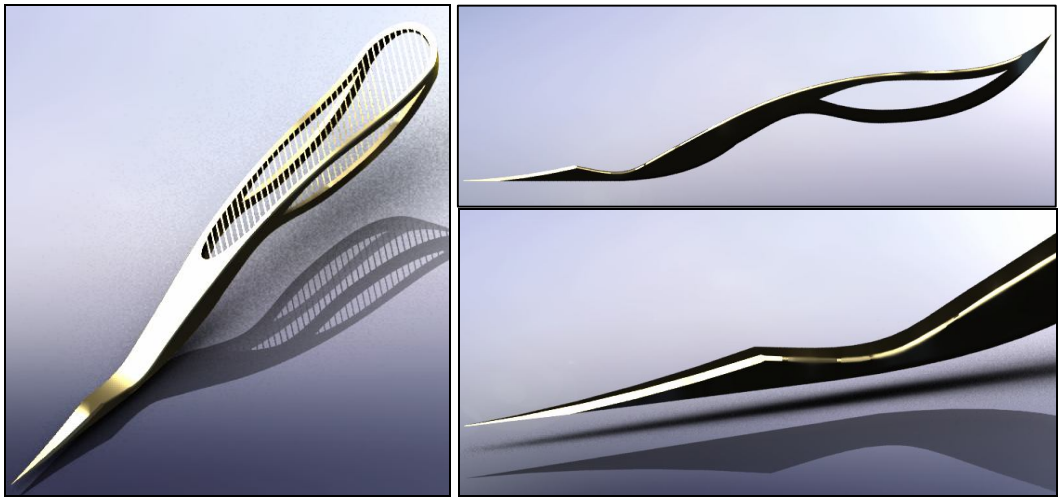

Fig. 6. Bespoke ophthalmic spatula

The advantages brought about by the development of the surgical ophtalmic instruments gain a greater importance in the global context. Figure 7 shows the losses from GDP broken down for each World Health Organisation (WHO) subregion of Europe and globally [22].

An estimated 158.1 million cases of visual impairment resulted from uncorrected or undercorrected refractive error in 2007. The global economic productivity loss in dollars ($) associated with this burden is estimated [22] at $ 427.7 billion before, and $ 268.8 billion after, adjustment for country-specific labour force participation and employment rates.

In this context, there is a clear need for innovation in the design and development of opthalmic surgical instruments.

Estimated total number of cases with VI, including blindness, and both unadjusted GDP loss and GDP loss adjusted for LFPR and ER, for each WHO subregion

WHO region and subregion[a]	Total cases of VI (thousands)	Blind among cases (thousands)	Unadjusted GDP loss (millions I$)	LFPR	ER	Adjusted GDP loss (millions I$)	Ratio adjusted:unadjusted
European							
A	8 343.9	0.0	71 443.4	0.583	0.884	38 998.0	0.55
B	3 224.6	0.0	7 924.4	0.553	0.768	3 645.0	0.46
C	3 737.4	0.0	12 198.1	0.599	0.906	6 923.2	0.57
Total	15 305.9					49 566.2	
Global	**158 053.9**	**8 724.5**	**427 743.4**			**268 837.8**	

Fig. 7. Estimated total number of cases with Visual Impairment [22]

3. General architecture of the online integrated platform

The ophthalmic prototypes are intended to be assisted in usage by an OIP that provides intuitive software tools, an open platform and general information about the tools designed in order to improve the accessibility and the visibility of the conducted research. The general architecture of the OIP is presented in Figure 8 below.

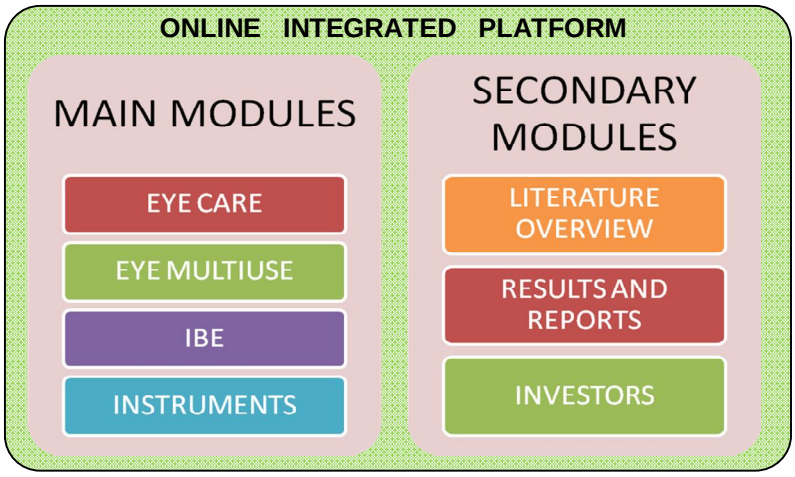

Fig. 8. General architecture of the innovative information software product

The detailed breakdown structure of the innovative information software product is the following:

- ✓ Seven main modules: “Interactive database for patient medical history management - *Eye Care*", The toolkit "Multifunctionality for ophthalmic user friendly products - *Eye MultiUse*", “Multifunctional Speculum", "Multifunctional Clamp", "Multifunctional Spatula", "Dedicated surgical instruments", The open platform *"In a Blink of an Eye - IBE*".
- ✓ Ten secondary modules: "Literature Overview", "International Context," "Purpose and Objectives", "Research Team", "Funding", "Results and Reports", “Investors", "Events" "Opinions", "Contact".

Of the seven main modules, three modules will be interactive, with private, restricted or public access, depending on the timing of the research strategy.

The success criteria for the OIP is: Online traffic on the website of at least 20 visitors per month during S1; 35 visitors per month during S2; 50 visitors per month during S3; At least five standard online feedback forms, provided for each dedicated software module; Collaboration with at least two specialists during the development of the open platform "*In a Blink of an Eye – IBE*”, the interactive database "Eye Care” and the toolkit "Multifunctionality for ophthalmic user friendly products - *Eye MultiUse*"; - Collaboration with at least one international AM specialist in the development “*Eye MultiUse* “; At least 50 positive feedbacks on the official website from readers; Usage of the software information product by clients/investors for further development of their activities.

The software modules of the innovative OIP are detailed below, for better understanding of their contribution to the current state of knowledge in the field.

1. The software module **“Interactive database for patient medical history management - *Eye Care*"** is destined for ophthalmology hospitals that will use the tools developed.

Eye Care contains information such as: patient personal data; personal patient imaging: 3D scans, CTs.; patient's medical history to date: previous surgical and medical treatments, previous results; current treatment; surgical operations performed with the developed instruments: imaging, pictures, postoperative treatment, results; CAD images of previously used instruments: details of custom elements and surfaces; details of instrument manufacturing: materials, manufacturing technology; CAD files with the ergonomic "handprint" of each surgeon.

Currently there are toolkits that allow access to patients’ personal information management on medication and surgical procedures. The novelty that the *Eye Care* database brings is the storage possibility of the following information: manufacturing technologies and procedures for application of the surgical instruments, customised CAD images for each patient and the surgeons’

ergonomic "handprint". The information in this database allows surgeons and manufacturers of custom tools to find a direct relationship between the developed surgical instruments and the practical outcomes of the ophthalmological surgeries. Access to personal patient information is severely restricted.

2. The software module **"Multifunctionality for ophthalmic user friendly products - *Eye MultiUse*"** is destined for initial stages and the development phase of the research strategy. At the end of the first stage (S1) the module will include:

- Components of the ophthalmic surgical instruments;
- Presentation and detailed description of each identified instrument (including images);
- Technical functional analysis of each instrument - FAST diagrams [31, 38].

Upon completion of the second research stage (S2), the database will be improved by an algorithm to identify the compatibility between various instruments. The algorithm will work on criteria identified in the initial study, and design and manufacture phases of the ophthalmic surgical instruments. This will allow the selection of two or more general tools from the database, aimed to identify immediate opportunities for complementarities and similarities of the general instruments. The *Eye MultiUse* toolkit concept is the first initiative of its kind that allows association of ophthalmological surgical instruments through an automated algorithm.

3. The open platform ***"In a Blink of an Eye - IBE"*** is designed as an open source online environment that will give access to a variety of specialists. Accessible both in Romanian and in English, the platform will be used internationally. The information will be divided into the general sections of the platform:

- *The results of the research strategy*: technologies, instruments, innovative techniques;
- *Young researchers*: ideas and opinions of young researchers with the opportunity to be validated by experts accessing the platform;
- *Universities and Research Centres*: opportunities for further research and collaboration with national and international universities;
- *Manufacturers*: Ability to identify new products for marketing, research centres, or interns/employees;
- *Innovative Technologies including AM*: recent developments in AM technology used in ophthalmology;
- *Ophthalmological Microsurgery Technologies*: Latest news in eye surgery;
- *Authorities*: legislation; standards and rules; authorised procedures; ongoing bills; possibilities of authorisation/approval of developed technologies; standards for recycling and environmental protection.

Access to the *IBE* platform will be restricted, during the research strategy implementation, to the research team members, manufacturers and hospitals involved.

IBE is the first Romanian initiative to bring together specialists from various fields to discuss an issue of such global importance: a continual rise in the number of people with visual impairments. Internationally, there are specialised platforms that promote solutions to solve this major problem. The novelty element brought about by *IBE* is the concept of linking-in all agents that interact throughout the product lifecycle: research and development units, manufacturers, health care facilities, freelance specialists, patients and local authorities.

4. The modules “Multifunctional Speculum", "Multifunctional Clamp", "Multifunctional Spatula" and "Dedicated surgical instruments" are presented as databases that include all the research methodologies and their results. The novelty of the online specific modules is that each will be provided with a feedback section from surgeons. Standard forms will be completed online. The surgical tools developed are delivered to ophthalmologists for in-vitro testing. After thorough analysis, opinions will be formulated by means of standard forms available online. Also, apart from the existing software products, the modules will have a FA of the specific individual surgical instruments, accompanied by a FAST diagram.

5. The secondary modules of the software information product will include testimonials from those involved in the research.

4. Discussions and Results

4.1. Possible applications with market potential

There are real transfer possibilities of the results obtained to potential beneficiaries: private clinics, research centres with similar interests, organisations with responsibilities regarding the health and protection of the population, surgeons, and patients.

The research strategy is aimed at further developing the prototypes for specific applications, by the potential clients/investors. The functional prototypes for the surgical instruments “Multifunctional Speculum", "Multifunctional Clamp", "Multifunctional Spatula" and the functional prototypes for the "Dedicated surgical instruments" will be used by interested commercial companies for the further development of the final products.

The exploitation of the innovative information software product is immediate, the commercial investors intending to integrate it into their current solutions, for the development of their current commercial activity.

Significant interim results will be used for dissemination through publications in high impact journals and will be communicated in national and international conferences. The scientific reports generated will be used to design new research strategies and projects by consensus partnership (with respect to intellectual property rights). Thus, the national and international visibility of the research strategy will increase.

4.2. Estimated improvements in the quality of life, with respect to current performance of products and services

The research strategy results, will contribute to the improvement in the quality of life, with the following particular aspects that are directly related to the strategy contributions:

- Increasing the versatility of the developed ophthalmic surgical instruments brings two major advantages: reducing the number of instruments used in the surgical theatre, implicitly reducing the stages of the operation and its duration; improving accuracy of the ophthalmic surgery, thus, reducing the risk of complications;
- The ophthalmic surgical instruments adapted to the patient anatomy brings advantages such as: reducing the risk of complications, reduce recovery and hospitalisation time of the patient and increase the comfort of the patient during the surgical procedure and the recovery period;
- Adapting the surgical instruments to the surgeons' specific ergonomic "handprint" reduces fatigue, thus, improving personal performance, as well as reducing the time to perform the actual surgical intervention;
- The development of innovative instrument concepts will lead to improving current surgical techniques and will influence the development of completely new techniques;
- Improvement in the correlation of the surgery results with the used surgical instruments, leads to the optimisation of the main selection process of surgical techniques and instruments according to the diagnosis, for reducing complications further in time. This is enabled by using the interactive *Eye Care* database for patient history management;
- By using *Eye MultiUse* toolkit, a more efficient process is designed, of identifying common characteristics of surgical instruments, enabling the development of completely new tools; The toolkit brings major advantages in the treatment of patients with specific malformations, where it is imperative to use customised specific tools;
- The *IBE* open platform will have a major impact on the Romanian scientific community in the area, involving all agents in the lifecycle of products: R&D units, manufacturers, healthcare facilities, specialists, patients and local

authorities. Their interaction will generate new concepts, partnerships, projects, commercial activities etc., targeting economic, technological, environmental and social progress;

- The results obtained after the research strategy implementation will contribute to completing the doctoral and postdoctoral research of the team members. Also, the results of the research will lead to the development of new doctoral and post-doctoral theses themes, with an international significance.

Considering the aforementioned points, the main benefits generated by the available products and services are:

- Lightweight construction surgical instruments, by designing porous structures, which can be obtained using AM technologies. It aims to reduce the total weight of an instrument by up to 70% compared to the conventional design;
- Modular construction of the surgical instruments, thus streamlining the series manufacturing process;
- Reduced production costs by 30 - 50% compared to a classic instrument, by optimising the manufacturing parameters, the geometry of the instrument, the layout within the build envelope of the manufacturing equipment, and also optimising an experimental model for mass production manufacturing;
- The correlation of the surgery outcomes with the techniques and tools used, by running the interactive *Eye Care* database;
- Reduced design/redesign timescale, by running an automated algorithm for identifying the surgical instruments compatibilities, within the *Eye MultiUse* toolkit;
- Reduced manufacturing time by eliminating some of the steps in the conventional production processes; It is expected that at least three stages of the classic manufacturing process will be eliminated;
- Reduced surgical procedure time, by multifunctional and double-customised instruments: for the patient and surgeon. It is aimed at reducing the surgery time by 10 - 15% of a specific operation performed with conventional instruments;
- Accuracy and high reliability by adjusting the post-processing technologies and customising functional surfaces;
- Easy communication with potential investors and attracting new funding for research and development, using the client database from the industrial sectors.

5. Conclusions

The research strategy aims to develop innovative and affordable solutions to the global problem of accessibility to ophthalmological corrective surgeries. These solutions are reflected both in the application of AM technologies to obtain bespoke ophthalmic surgical instruments and in providing a set of software tools

designed to assist the medical process for improved overall results. Providing state-of-the-art and globally competitive, technological results in this field, is one of the main strategic objectives of the proposed research strategy. Thus, it would increase the international visibility of Romanian research in unconventional manufacturing technologies, with direct transfer of the results into socio-economic practice. The expected results help to increase the social quality and support social development.

The present strategy aims to include Romania among the leading surgical instrument manufacturers worldwide. It is the first initiative of this kind. It aims to increase the competitiveness of the Romanian economy through medical innovation, with impact on the economic agents, and to transfer AM technology knowledge into economic practice.

The research team will provide an efficient co-operation between different categories of professionals: doctors, engineers, physicists, computer scientists, economists, teachers, psychologists, and demographers, key element to optimal management of the medical-technology-information field. Young professionals and experienced researchers are attracted within the research for maximum utilisation of their creative powers.

Information technology, an essential element in a knowledge economy, represents a widely accepted and accessible penetrating means of knowledge and education to prevent and treat visual impairments, with major long-term practical implications economically and socially.

The proposed information software product, with internet accessible databases, is a tool that, in the context of the increasing rate of visual impairments globally, contributes to the dissemination of the research results on optimisation of AM technology to the manufacture of innovative ophthalmic surgical instruments. At the same time, an important contribution to the implementation and effectiveness of the research is made by creating the framework and the multidisciplinary collaboration opportunities among specialists within this field and by disseminating health information at citizens' level.

R E F E R E N C E S

[1] *World Health Organization*, Global Data On Visual Impairments 2010, 20 Avenue Appia, 1211 Geneva 27, Switzerland, 2010.
[2] ****Causes of Blindness and Visual Impairment WorldWide*, vision-and-eye-health.com
[3] *World Health Organization, VISION 2020: The Right to Sight*, World Health Organization (WHO) and the International Agency for the Prevention of Blindness (IAPB), 18 February 1999
[4] ****Visual Impairment and Blindness*, Fact Sheet N°282, WHO, June 2012
[5] ***http://www.curableblindness.org/region/europe/romania.html
[6] ***http://www.katalystsurgical.com/oin/articles/whereistheophthalmicindustryheaded/

[7] *World Health Organization,* ANNEX V. Implementation of Vision 2020 Objectives by WHO Region at December 2006, 4 May 2010, accessible at : <http://www.who.int/blindness/Pages%20from%20Vision2020%20-report.pdf>
[8] *World Health Organization*, "Global Blindness Map." Map. WHO | Data and Maps. World Health Organization. Web. 1 Jan. 2011. <http://www.who.int/blindness/data_maps/en/>
[9] *World Health Organization*, "Romania – Country Cooperation Strategy.", Apr. 2007. Web. <http://www.who.int/countryfocus/cooperation_strategy/ccsbrief_rou_en.pdf>
[10] *World Health Organization*, "Global Low Vision Map." Map. WHO | Data and Maps. Web. 1 Jan. 2011. <http://www.who.int/blindness/data_maps/en/>
[11] ***"Country Profile: Romania." (2006). Library of Congress – Federal Research Division. Web. <http://lcweb2.loc.gov/frd/cs/profiles/Romania.pdf>
[12] *Valceanu, D., and S. Muşat*. "Utilization of Ophthalmology Services by Patients with Cataract in Public Hospitals in Romania, in the Year 2007." Oftalmologia 52.4 (2008): 105-09. Web. <http://www.ncbi.nlm.nih.gov/pubmed/19354172>
[13] *Lungescu, O.,* "Romanian Healthcare on Verge of Collapse." BBC News Europe. 11 Aug. 2010. Web. 11 Apr. 2011. <http://www.bbc.co.uk/news/world-europe-10914678>
[14] *** "CIA – The World Factbook — Romania." Welcome to the CIA Web Site Central Intelligence Agency. Web. 9 April 2011. <https://www.cia.gov/library/publications/the-world-factbook/geos/ro.html>
[15] ***Excel Spreadsheets – WHO Health Statistics – DALY estimates for 2004. http://www.who.int/healthinfo/global_burden_disease/estimates_country/en/index.html >
[16] ***"Estimates for the Use of Improved Sanitation Facilities [Raport], WHO/UNICEF Joint Monitoring Programme for Water Supply and Sanitation, Mar. 2010. Web. 30 March 2011. < http://www.wssinfo.org/fileadmin/user_upload/resources/ROU_san.pdf>
[17] ****Cel mai mare spital privat de oftalmologie din sud-estul Europei a fost inaugurat în Capitală* [Articol Ziar Național], Ziarul Adevărul, 13 mai 2011 adevarul.ro/news/bucuresti/cel-mai-mare-spital-privat-oftalmologie-sud-estul-europei-fost-inaugurat-capitala 1_50bdebcc7c42d5a663d0005b/index.html
[18] ****Ophthalmic instruments and equipments manufacturers – global* [Excel Data Sheet], LIONS ARAVIND INSTITUTE OF COMMUNITY OPHTHALMOLOGY (LAICO), WHO, http://laico.org/v2020resource/files/manufacturers_instruments.xls
[19] *T. Wohlers*, Wohlers Report 2010: Additive Manufacturing State of the Industry Annual Worldwide Progress Report, Wohlers Associates, Inc., Colorado, USA, 2010.
[20] *T. Wohlers*, Wohlers Report 2011: Additive Manufacturing State of the Industry Annual Worldwide Progress Report, Wohlers Associates, Inc., Colorado, USA, 2011.
[21] ***How it's made: http://www.factproduct.com/pages.php?ID=18
[22] *Smith TST*, Frick KD, Holden BA, Frike TE & Naidoo KS, "Potential lost productivity resulting from the global burden of uncorrected refractive error", *Bulletin of the World Health Organization*, Vol. 87 Issue 6, p431, 2009.
[23] *Lupeanu, M.E.*, Research regarding the application of technical functional analysis to the development of new products fabricated with unconventional technologies of additive manufacturing, Doctoral Thesis, Scientific Coordinator : Prof.Em.Dr.Ing. Neagu Corneliu, Politehnica University of Bucharest, Bucharest, Romania, 2012.
[24] *Bento C., Peças P., Henriques E., Silva A.*, Product Development guided by Value Analysis through Collaborative R&D, 14th International Conference on Concurrent Enterprising, Lisboa, Portugal, 23-25 June, 2008.
[25] *Miles L.D.,* Value Methodology: A Pocket Guide to Reduce Cost and Improve Value through Function Analysis. GOAL/QPC Publish, ISBN 1576811050, 2010.

[26] *Lentz V.A.*, Lerner B., Functional Analysis for Existing Products: a Detailed Procedure, Connecticut, USA, 2005.
[27] *Liou F.W.*, Rapid Prototyping and Engineering Applications, CRC Press-Taylor & Francis Group, P535, ISBN-10:0-8493-3409-8, USA, 2008.
[28] *Barboliniof R., D. Berselliof and J. Jones*, Industry Case Studies - Rapid Manufacturing of Customised products, Additive Manufacturing Association, 2008.
[29] *Antti S., Anselmi I.*, Product Lifecycle Management, Springer, Finland, Helsinki, 2005.
[30] *Anil M., Anoop D., Anand S., Aashi M.*, Product Development – A Structured Aproach to Consumer Product Development, Design and Manufacture, Butterworth – Heinemann, February, 2008.
[31] *Ulrich K., Eppinger S.*, Product Design and Development, 4th Edition McGraw Hill Publishing Company Ltd., 2009.
[32] *Lupeanu, M.E., Brooks, H.L., Rennie, A.E.W., Hill, D.*, „Research on deploying Technical Functional Analysis for additive manufacturing of a surgical device for intravitreal interventions", U.P.B. Sci. Bull., Series D, Vol. 75, Iss. 1, pp. 141-160, ISSN 1454-2358, 2013.
[33] *Lupeanu, M.E., Roşu, M.M., Rennie, A.E.W., Neagu, C., Brooks, H.L.*, "The role of Technical Functional Analysis in innovative design of bespoke Rapid Manufactured parts: medical industry applications", *Proceedings of the 6th International Conference on Manufacturing Engineering, Quality and Production Systems (MEQAPS '13)*, Mathematics and Computers in Science and Engineering Series, Vol 13, ISSN 2227-4588, ISBN 978-1-61804-193-7, pp. 227-232, 2013.
[34] *Băcescu D.M., Băcescu D., Petrache S., Duminică D.,* "Modeling and simulation of the eyeball optical system", U.P.B. Sci. Bull., Series D, Vol. 73, Iss. 2, pp. 98-106, ISSN 1454-2358, 2011.
[35] *Bártolo P., Bidanda B.* (Editors), Bio-Materials and Prototyping Applications in Medicine, Springer Publishing, 2007.
[36] *Crişan N., Trufino-Sfarghiu A.-M., Gordin D., Stoica G., Berthier Y., Gheorghiu H.*, Experimental determination of the titan alloy, Ti12Mo, behaviour, with biomedical application, U.P.B. Sci. Bull., Series D, Vol. 74, Iss. 2, pp. 121-134, ISSN 1454-2358, 2012.
[37] *Bolton J. D., Gerhardt D. J.*, Value Methodology: A Pocket Guide to Reduce Cost and Improve Value Through Function Analysis, L.D. Miles Value Foundation, 2009.
[38] *Bytheway C.*, FAST Creativity & Innovation : Rapidly Improving Processes, Product Development and SolvingComplex Problems , J. Ross Publishing, January, 2007.
[39] *Ion D.C., Geacăr C., "*Estimation of the cost function using Bayesian approach", U.P.B. Sci. Bull., Series D, Vol. 74, Iss. 4, pp. 53-60, ISSN 1454-2358, 2012.
[40] *Eke T.*, Consultant Ophthalmologist at Norfolk & Norwich University Hospital, A device for simpler, safer intra-vitreal (eye) injections, Health Enterprise East Innovation Competition, September, 2010.
[41] *Busquets M.*, Intravitreal Injections: Technique and Infection Prophilaxis, (Retina Today, January/ February 2007), pp. 19, 2007.
[42] *Sampat K.M., Garg S.J.*, Complications of Intravitreal Injections, Current Opinion in Ophthalmology, Volume 21 (3), pp. 178–183, 2010.
[43] *Taylor J.C.*, Additive Manufacturing Centres of Excellence – An update to the Quality approach, Morris Technologies Inc., Rapid Quality Manufacturing, MBA, 2009.

[44] *Hao L., Raymond D., Strano G., Dadbakhsh S.*, Enhancing the sustainability of Additive Manufacturing, 5th International Conference on Responsive Manufacturing – Green Manufacturing, Ningbo, China, 11-13 January, 2010.

[45] *Lupeanu, M.E., Rennie, A.E.W., Eggbeer, D., Neagu, C.,* "Redesign of custom-fitted surgical guide with targeted Functional Analysis fabricated via SLM", *Proceedings of the 12th Rapid Design, Prototyping & Manufacturing Conference*, Editura CRDM Ltd, High Wycombe, Editori: Rennie A.E.W., Bocking C.E., Lancaster, United Kingdom, ISBN 978-0-9566643-1-0, pp. 173-181, 2011.