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Development of Requirements for Key Components and Infrastructure of Medical Computer-Aided Design Systems

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***Abstract*—The article is devoted to the development of requirements for software products and services that implement the technology of medical computer-aided design, as well as designed to support the development and implementation of medical computer-aided design systems as a class of computer systems. The review of achievements in the field of computer-aided design for solving medical problems is given. To ensure consistency in the development of medical CAD infrastructure, the Top-Down approach is used. The work describes the upper level of the architecture of the information infrastructure and the typical business process of using its elements in the development and implementation of medical CAD: as an example, is selected the Medical computer-aided design system of bioprinting and transplantation of the human limbs. General requirements for programs and components, and key functional requirements for medical CAD systems are developed. Methods for verifying compliance with the stated requirements are described. The results obtained allow to move on to the development of separate elements of the medical CAD infrastructure and their further integration into unified information environment.**

Keywords— medical computer-aided design, requirements development, information infrastructure

I. INTRODUCTION

Over the past 10 years in the medicine, there has been an increase in the number of cases of using computer-aided design systems to obtain high-tech solutions to problems faced by medical doctors of various fields [1]. In the field of plastic surgery, specialized systems for modeling the planned changes in the shape and appearance of parts of the human body are created and actively used. Scientists are developing detailed computer models of elements of the human body for the subsequent solution of research and educational medical problems. Software complexes for the development of medical equipment, tools and materials are being developed. Due to the wide development of 3D printing technology, significant advances have been made in the field of creating human organs from own tissues or biocompatible materials.

Such a level of development of computer design in the field of medicine allows us to conclude that it is possible and advisable to develop technologies for medical computer-aided design and the allocation of hardware and software systems that implement these technologies into a separate class of computer systems.

To stimulate the growth in the quantity and quality of medical computer-aided design systems in the Russian market, it is necessary to develop the information infrastructure of the corresponding scientific and technical direction. This article highlights the process and current results of the development of requirements for the designated systems and infrastructure, allowing to set goals for further theoretical research and practical implementation of applied computer systems.

II. OVERVIEW OF FIELD OF MEDICAL COMPUTER-AIDED DESIGN

The article [2] examined several examples of the practical use of technical CAD for solving the problems of treating defects and diseases of elements of the musculoskeletal system. The presented data demonstrate the practical value of CAD technology in the field of medicine. The author clearly described the goals of CAD implementation in practical traumatology and orthopedics:

- Reduction the time for selecting the optimal design of an external fixation device to solve a specific treatment problem.
- Improving the quality of installable assemblies that provide maximum fixation stability and the possibility of spatial positioning of bone fragments.
- Unification of assemblies and devices, the ability to create a library of assemblies of the device used for a specific task, with monitoring the effectiveness of its use.
- Increasing the treatment effectiveness due to a more thoughtful design selection.
- Reduction of the patient's time for treatment, preparation time for the operation, reduction in the number of unsatisfactory results and obtaining financial returns from funds invested in CAD [2].

These goals can be generalized to the field of medical CAD as follows:

- Improving the accuracy of patient exposure during treatment.
- Reduction the time for preparation and treatment.
- Reduction recovery time after treatment.

- Increasing duration of treatment effect.
- Reduction of time and financial costs for the preparation and treatment of patients, as well as for the rehabilitation period.

The Crisalix [3] and BodyNova [4] projects are examples of the development of special software for modeling cosmetic operations, which allows to predict the result of planned changes. In practice, visualization of the final result of plastic surgery allows dispelling the patient's doubts, approving and obtaining the desired result, eliminating misunderstanding between the customer and the contractor.

Information and communication technologies have found their application in the healthcare sector, including the frameworks of modern dentistry. CAD / CAM application in dentistry is the process by which is attained finished dental restoration through fine milling process of ready ceramic blocks [5].

Much attention in the field of computer modeling of the human body is given to the creation of detailed functional models of complex human organs, such as the brain and the heart. The article [6] provides an overview of the most important projects in the world devoted to the study of the human brain: Human Brain Project (Europe), BRAIN Initiative (USA), Human Connectome Project (USA), SYNAPSE (USA). The described studies will allow a deeper understanding of the basics of its [brain] functioning, as a result of which medicine will gain new opportunities in the study and treatment of mental illness [6].

In the article [7] says, that the electrophysiological function of the heart can now be simulated with a high degree of detail and accuracy, opening the doors for simulation - guided approaches to anti - arrhythmic drug development and patient - specific therapeutic interventions.

Dassault Systèmes company has developed a computer model of the human heart [8]. Using this model, device manufacturers, researchers and medical specialists will be able to carry out virtual tests of devices and visualize the sensitivity of the heart when it interacts with certain devices in a way that was not possible previously with traditional physical tests [9].

In research centers and hospitals around the world, advances in 3D printing and bioprinting provide new opportunities for treating people and research. In the coming decades, bioprinting may be the next important milestone in healthcare and personalized medicine [10]. 3D printing technology in medicine is similar in principle to CAM technology in technical fields. Thus, the three-dimensional model prepared in the CAD system is sent to the 3D bioprinter for the production of the final product, i.e. growing tissue or organ. What proves the feasibility of developing medical CAD / CAE / CAM technologies.

Despite the existence of separate developments of a high technological level, neither in Russia nor in the world there is a massive creation and implementation of medical CAD systems. This is due to several factors:

- The combination of a high level of complexity of CAD systems and a high level of complexity of designed objects - biological objects in general and medical - in particular.
- The lack of theoretical foundations and of systematic approach to the creation and use of medical CAD, the lack of the principle of heritability of developments.
- The need for close interaction between specialists from various fields of medicine and technology in the absence of a specialized information infrastructure.

In order to develop the theoretical foundations of medical CAD, the article [11] first proposed the classification of biological and medical CAD, describes the features of the composition and structure of medical CAD.

According to [12], significant changes in platforms arise because a successful application first appears, and then this application inspires the creation of an infrastructure that simplifies the creation of similar applications and facilitates their mass distribution. In this regard, further material is devoted to the development of requirements for the information infrastructure and key components of medical CAD systems.

III. Development of a high-level architecture of information infrastructure of medical CAD

The main entry point into the infrastructure environment of medical CAD systems is the website medcad.pro, in which 3 large areas are highlighted (Fig. 1):

- Knowledge base in the field of medical CAD.
- Own and third-party services.
- Store of software products and modules of medical CAD.

By analogy with the definition of a web service [13], services within the framework of this article are understood as web resources operating online and providing:

- For users - data and specialized capabilities for solving problems in the field of medicine and medical CAD.
- To other software systems - information and results of calculations and transformations upon request.

In contrast to the broad definition of a software product [14], in the framework of this article, products are understood to mean programs that work both online and offline and designed to be downloaded and installed on personal computers, laptops, tablets, smartphones.

The theoretical foundations are presented in the form of texts of scientific articles and dissertations (for example, [15, 16]), are reflected in training courses and modules, and are also supported by news reports about the system, etc.

To ensure a fully functional implementation, it was necessary to highlight the key services of the infrastructure, which are:

- HR service in the field of MedCAD.

- Storage of medical 3D models.

Significant software products are:

- MedCAD integration platform.
- MedCAD development framework.
- 3D human anatomical atlas.

The main purpose of the platform for integrating medical CAD systems is to simplify the management of a set of software products on the end-user work computer.

The growing heterogeneity of hardware architectures and diversity of operating system and communication platforms make it difficult to build correct, portable, efficient, and inexpensive applications from scratch [17]. For this reason, the framework for the development of medical CAD systems is designed to facilitate the work of specialists in creating systems of this class by supplying ready-made architectural solutions and software modules, i.e. saving developers from implementing a large volume of standard non-core functions.

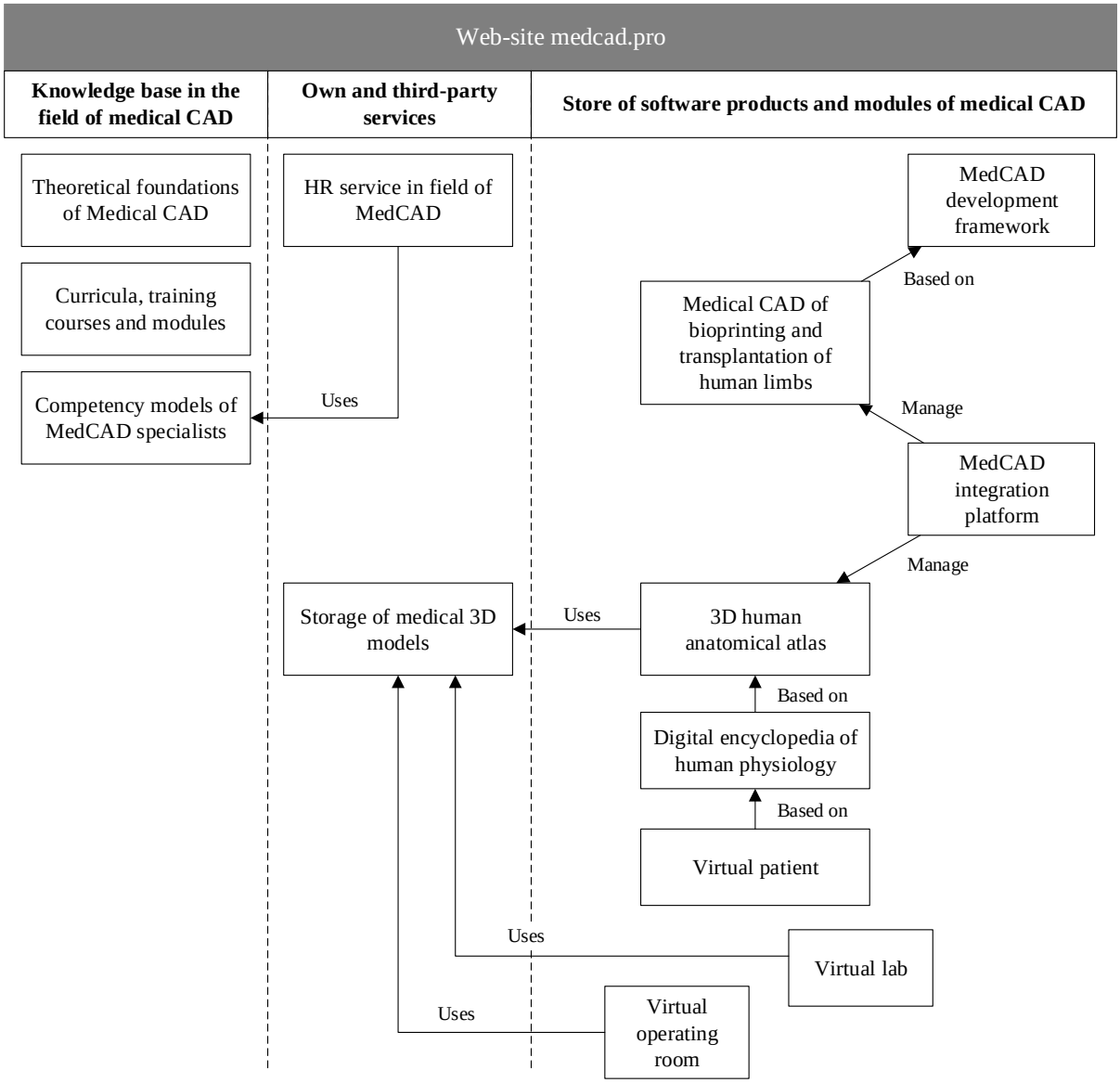

Fig. 1. High-level architecture of information infrastructure of medical CAD

Based on a three-dimensional anatomical atlas, an electronic encyclopedia of human physiology is building.It, in turn, is the technological base for simulating the conditions and behavior of the patient within the framework of the Virtual Patient product. Three-dimensional models of elements of the human body, medical equipment and instruments can be used to design specialized medical rooms, equipment and laboratories.

IV. Typical business process for using the information infrastructure of medical CAD

When using elements of the information infrastructure at various stages of the development and implementation of medical CAD systems, a synergistic effect arises, expressed in increasing the efficiency of the supported business process.

The application of the developing infrastructure elements is considered on the example of creating a medical computer-aided design system for bioprinting and transplantation of human limbs (Fig. 2).

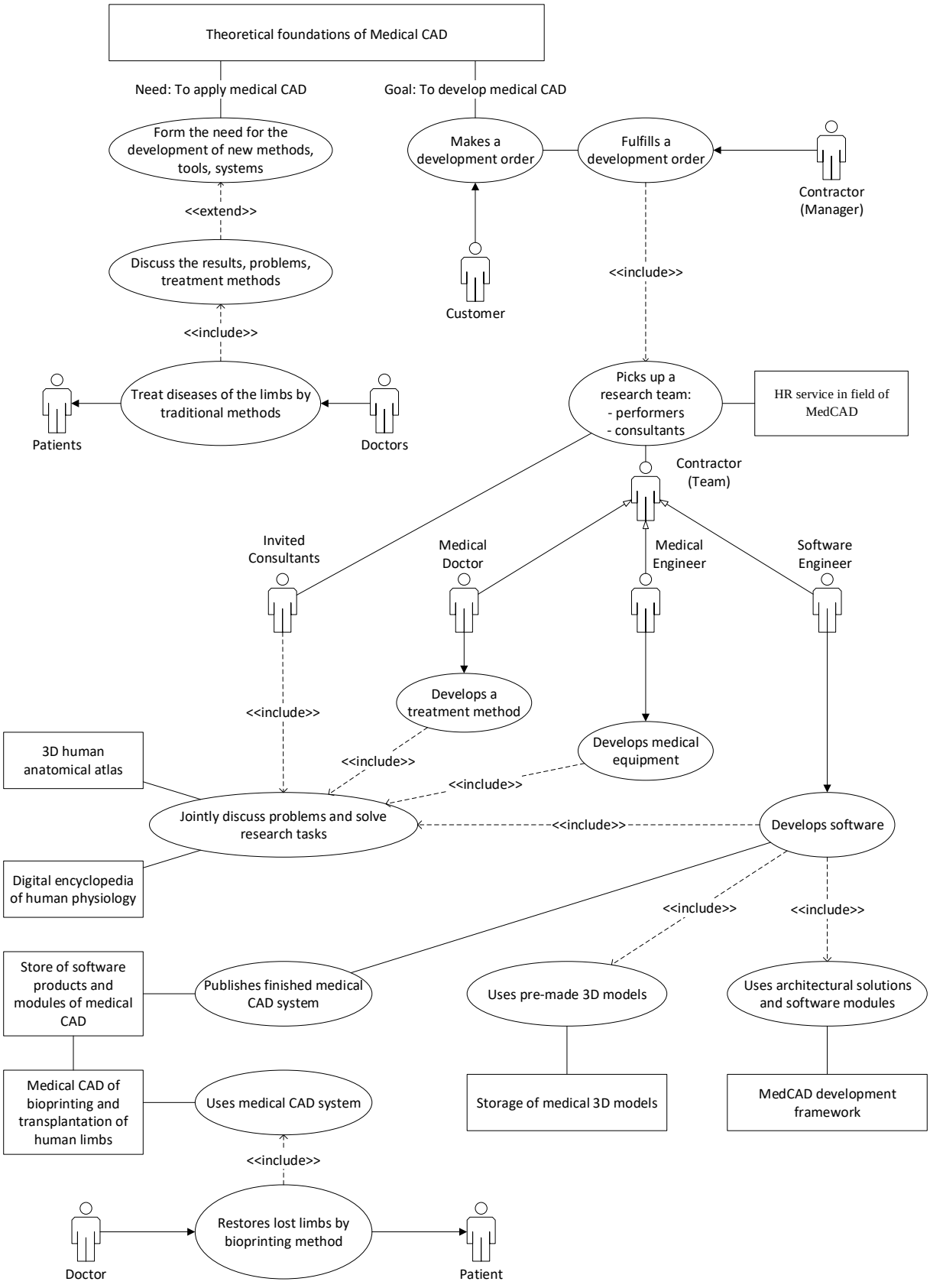

Fig. 2. The process of applying information infrastructure in the development and implementation of medical CAD

When treating diseases leading to limb amputation, by traditional methods, doctors carry out a set of measures to prevent limb loss, amputate the limb if necessary, and after a certain time, transplant or prosthetics of the limbs are performed to compensate or replace lost functions [18]. In the process, specialists discuss the accumulated results, relevant treatment problems and possible methods for their solution at specialized conferences and forums. Accumulated knowledge forms the basis of scientific publications, which in turn are accumulated in the knowledge base on medical CAD.

When the concentration of scientific information on a relevant topic in the minds of an individual specialist or group of specialists reaches a certain level, comes the realization of the need to develop new methods of treatment. Over time, this need acquires a sufficient degree of formalization, then it could be transforms into order for research and development. A customer may be a research institute, a commercial company, an independent researcher, etc.

To fulfill the order, the responsible person (in commercial company, for example, it is a project manager) needs to pick up a team of specialists. HR service in field of MedCAD ensures the effectiveness of this task by automating the search for the most suitable performers. Key roles in the core team are:

- Medical Doctor – a medical expert responsible for the development of a new treatment method.
- Medical Engineer – an equipment specialist responsible for the selection and / or development of medical equipment necessary for the implementation of a new treatment method.
- Software Engineer – a software specialist responsible for creating a computer program that implements medical design technology.

To solve complex, specific, highly specialized and auxiliary tasks as part of the study temporary consultants can be invited.

All specialists participate in the discussion of current problems and research tasks. To increase the degree of communication and demonstration of the features of the object of research and computer-aided design, the 3D human anatomical atlas and the Digital encyclopedia of human physiology are used.

To improve the efficiency of the medical CAD development, the software engineer uses ready-made architectural solutions and software modules implemented in the MedCAD development framework. For visualization and parameterization of designing objects, ready-made three-dimensional models of human limbs are used. Bank of medical 3D models also contains models of medical equipment and tools. The developed computer program publishes in a specialized Store of software products and modules of medical CAD, from where it can be downloaded for further use by a doctor in the process of restoring the patient's limbs by bioprinting and transplantation method.

V. REQUIREMENTS DEVELOPMENT

When developing requirements for infrastructure services and products, the principle is followed: each user requirement must be verifiable. Clarity of content of the requirement increases the possibility of it's verification. It is believed that the user's requirement is verifiable if a method can be proposed that convincingly confirms that the software product allows this requirement to be implemented [19]. However, since the current stage of the work is devoted to the development of only the highest level of architecture, some requirements are not decomposed

A. Services requirements

HR service in the field of MedCAD is a specialized online platform for increasing the efficiency of the collaboration process of specialists involved in the development or research in the field of medical informatics, medical computer systems, medical equipment, etc.

The main objectives of the service are:

- Search for specialists for a development or research team (search for an executor). Can be checked by formal test cases of specialist search using the parameter filter.
- Search for development or research teams for individual specialists (search for an employer). Can be checked by formal test cases of search of teams using the parameter filter.
- Search for highly qualified experts to provide advice in the development or research process (execution on a contract basis). Can be checked by formal test cases of consultant search.

The HR service in the field of CAD should have the functions of similar services operating in the Russian segment of the Internet, and also reflect the specifics of the subject area. For this, when developing this service, the requirement for the availability of catalogs of medical organizations, specialties and positions, medical competencies and skills in working with medical software and equipment must be met. A dictionary of medical terms, diseases and sections of medicine should also be used.

Storage of medical 3D models is an electronic library of three-dimensional models of human organs, biological materials, as well as medical instruments and equipment. This service is important for the development of medical CAD systems, because:

- Is the basis for creating new, more complex spatial models.
- Is the basis for the visualization of anatomical, physiological and other medical information, which improves the efficiency of communication and knowledge transfer in the field of medical education, research, engineering and software development.
- Is the basis for the subsequent geometric parameterization of medical objects. Parameterization is a process of identifying the main structural features of models of human organs,

their numerical characteristics and the relationships between them [20].

An important requirement for a Storage of medical 3D models is the ability to organize the storage and exchange of 3D content, primarily on a free basis. A paid model for the distribution of medical 3D models can also be implemented to commercialize the newest complex models containing the latest research and development results.

MedCAD Store is a platform for the distribution of medical CAD and their modules on a paid and free basis. The key importance of the service in the overall information infrastructure of MedSAPR is to increase the efficiency of the process of commercialization (and, therefore, development) of medical CAD by increasing the degree of communication between developers and users. Unlike classical application stores [13], the MedCAD Store has additional requirements for classifying applications and their modules based on medical specificity, i.e. sections of applied medicine. A proprietary and free software licensing and distribution model should be developed and implemented with equal importance.

B. Products and Modules Requirements

The *MedCAD Platform* is a computer system for managing medical CAD systems (modules, dependencies, updates, connections, etc.). It is assumed that the work of users of MedCAD should begin with this system. Therefore, the main requirements are:

- Providing cross-platform. Can be validated by the launch and use under various operating systems.
- The presence of a developed, thoughtful, tested graphical user interface. Can be validated by user interface research and user experience research.
- Providing support for the access control based on user roles model. Can be validated by formal tests of typical scenarios for different user roles.
- Implementation of security and encryption during data storage and transmission. Can be checked by formal tests of correspondence of encryption keys.
- Availability of full documentation for the administrator and user of the system with examples and links to training courses and modules. It should be checked the actual availability of documentation, training courses and modules, as well as compliance of their contents with the list of the main tasks of automation of activity.

The key functional feature of the Platform should be the ability to integrate with external programs and services, the presence of an open, documented API (can be checked by open-source programs to test the basic functions).

The MedCAD Framework is a combination of architectural solutions and ready-made software modules for implementing a medical computer-aided design system. The framework, as well as the platform, must support the most common technology stacks to enable the implementation of the final application for different operating systems. The requirement is verified by configuring the technology stack and then checking each element of the stack. The key functional modules delivered as a part of the Framework are:

- The registration and authorization module, based on the subsystem for user access control.
- License Management Module.
- Update module.
- Module for managing connections to third-party services.
- Documentation management module, etc.

The functionality of each module should be checked by the follow test scenario: installing the module, connecting the module, calling the test function, outputting the returned result, checking the declared result of the test function.

To implement the objective design function, the framework must provide the basic modules:

- Project management: create, save, load, edit, import and export.
- Three-dimensional modeling and visualization.

The requirements for Specialized MedCAD are developed on the example of the Medical computer-aided design system of bioprinting and transplantation of human limbs, which is the final independent software product designed to automate the process of growing tissues of the patient's limbs from their own cells or from substitute biomaterials by 3D printing, subsequent assembly and transplantation of the limb. The input data for the system are medical images, so there is a requirement for receiving and processing data from medical equipment, such as an X-ray machine and an MRI device, according to the DICOM standard [21]. Support of this standard will provide the ability to integrate the product with systems of class Computer-Aided Detection (CADe) and Computer-Aided Diagnosis (CADx) [22]. The output is three-dimensional models for 3D printing on specialized bioprinters, so a requirement is introduced to support 3D printing formats (can be checked by the 3D printing scenarios).

The requirements for the Three-dimensional anatomical atlas and the prospects for its implementation are discussed in detail in the article [20]. This product is an important component of the medical CAD information infrastructure, as It is the technological basis for:

- Development of an encyclopedia of human physiology, i.e. descriptions of normal structural and functional states of the body and pathological processes, by modifying and animating finished anatomical models. By the functional state of a complex system we mean the totality of various processes, functions, characteristics of an individual, which largely determine the level of his activity and general characteristics of behavior [23].
- Development of libraries of standard elements for medical CAD, by parameterizing digital anatomical models.

- Improving the communication efficiency of medical and technical specialists in the process of developing medical software and hardware systems, by visualizing information in relevant subject areas.

VI. CONCLUSION

A review of the subject area was carried out and the feasibility of developing medical systems for computer aided design as an independent class of computer systems was substantiated.

An approach to construction is proposed and a top-level model of the architecture of the information infrastructure of the scientific and technical direction “Medical CAD” is developed.

A model of a typical business process for using the information infrastructure of medical CAD systems has been developed.

Formulated requirements for key services, products and components of the medical CAD infrastructure.

Methods for checking of developed requirements are described.

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