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3DIAMOND: SOFTWARE FOR PRODUCT LIFE-CYCLE MANAGEMENT IN 3D PRINTING MEDICAL APPLICATIONS

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Abstract

BACKGROUD: 3Diamond represents a software product that enables efficient management of the data needed to control 3D printing tasks in a hospital or clinical settings.

METHODS: The softwarethat de-facto resembles a product life--cycle (PLM) system, has been designed by a common effort of biomedical engineers, software developers, clinical data managers, and clinical experts.

RESULTS: The PLM software 3DIAMOND has been powered by Clade-IS, which is an EDC (Electronic Data Capture) system, commonly used in clinical research for the facilitation of data management in clinical studies and real-world data projects.

DISCUSSION: Due to cyber threats and data privacy regulations, 3D printing tasks need to be handled through valid information systems rather than WhatsApp and USB flash drives.

Keywords

3D printing in medicine, 3Diamond software, product life-cycle management, PLM , electronic data capture, EDC

Introduction

3D printing represents a specific type of additive manufacturing consisting of a computer-controlled process that creates three dimensional objects by depositing materials, usually in layers. For more than 20 years, 3D printing in medicine has represented a very solid approach to more personalized treatment and better patient care. The 3D print technology has a wide range of medical applications, including: (i) printing parts of the scene for simulations used for pre-operative preparation, (ii) printing artifacts, such as bending templates, used during surgery and other procedures to reduce operating time and often to make the patient safer, (iii) printing biocompatible implants, and also (iv) pharmacological applications aimed at novel personalized drug formulations. For many clinical disciplines such as oral and maxillofacial surgery, neurosurgery, cardiac surgery, vascular surgery, and disciplines dealing with the musculoskeletal system, it has been concluded that 3D printed devices outperform their conventional comparators [1].

The penetration of this technology into the healthcare system varies from region to region. For example, in the Czech Republic, the production associated with 3D printing for preoperative preparation or to reduce operating time is not reimbursed. Pioneers - both clinicians and biomedical engineers - thus find themselves in a grey area of healthcare and are often forced to use unsuitable tools, such as USB flash drives for transferring patient data or WhatsApp messenger for interdisciplinary communication.

Product lifecycle management (PLM) is the process of managing a product or its part from the first idea, through its design and manufacture, servicing, to final decommissioning. A PLM software represents a computer software that is designed to help organizations develop new products and put them into operation. To our best knowledge, this type of information technology has not been used to facilitate 3D printing applications in the hospital/clinical environment.

Conventional data collection in clinical research involves recording data in paper case report forms (CRF), followed by double entry in a relational database. Continuous technological advancements in computer science, life sciences and health care have given rise to electronic data capture (EDC) systems, which have proved to be a more efficient and cheaper alternative to the paper data capture. EDC systems enable investigators to enter data directly into electronic case report forms (eCRF) and study coordinators to oversee and control them in real time even in multicenter research studies. EDC systems have become predominant because they are not only time and cost effective, but also contribute to quality assurance, as they allow data access to be controlled and all changes made to them using audit trail features to be traced [2].

This article summarizes the efforts of biomedical engineers, software developers, clinical data managers and clinical experts in the development of the 3Diamond (3Dprint Imaging Accurate Monitoring and OperatioNal Delivery) software product. It is actually a PLM system that enables efficient management of the data needed to control 3D printing tasks in a hospital or clinical settings.

Methods

The 3Diamond software has been developed on the grounds of a particular EDC system referred to as the Clade-IS (CLinicAl Data warEhousing – Information System) – a robust, modular, web-based software for electronic data capture and clinical trial management. It contains a huge amount of real-world data from many clinical specialties. At the very beginning of all developments, however, it was necessary to compose accurate user specifications for the PLM system so that it was possible to clearly understand whether everything could be implemented in the mentioned EDC system and, if so, whether its simple customization by the hands of clinical data managers would be sufficient or whether further software development would be needed.

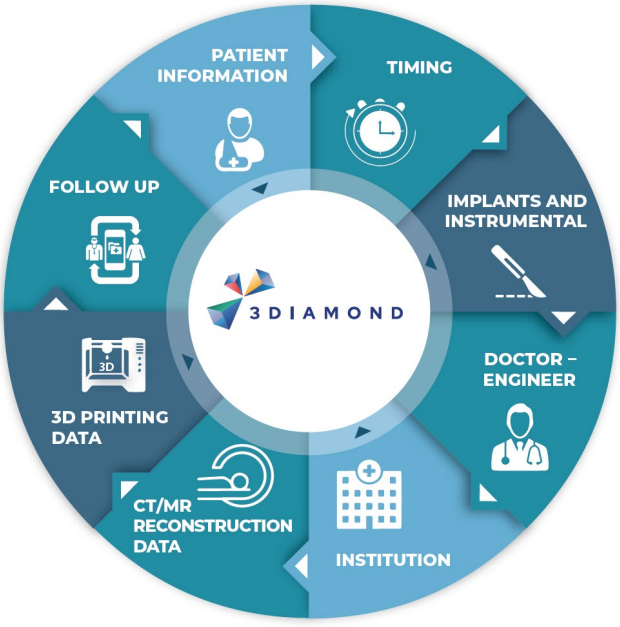

Figure 1 – The use-cases of 3Diamond software consists of user stories from the perspective of (i) biomedical engineer, (ii) clinician, (iii) quality manager

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The requirements for the PLM system were compiled in natural language without unnecessary technicalities in order to maximize understanding between the clientsand developers. The authors agreed on input documentation in the format of user stories – a proven concept for agile software development [3], accepting the following syntax of specifications, which consists of three main parts: (i) user role, (ii) requirement, (iii) acceptance test: "As a __(i)___, I ___(ii)___, so that ___(iii)_____." Three user roles were detected: (A) biomedical engineer, (B) clinician, (C) quality manager. Their user stories were classified as must-haves, nice-to-haves,and very-nice-to-haves. All user stories then described in detail various use cases of the PLM system, see Figure 1.

The database model of the Clade-IS EDC system, which forms the foundation of the 3Diamond PLM system, is an entity--attribute-value (EAV) model, also known as a vertical database model, which is known to be able to efficiently capture entities with sparse features. Such a feature is advantageous for clinical or patient registries, which typically contain many parameters, but their completion with specific values is usually poor. The following data structures are used to build an eCRF: arm - phase - form - question group - question - answer, where a question--answer pair represents an attribute-value pair, respectively. Figure 2 exemplifies the basic setup of the eCRF entities in the 3Diamond PLM system.

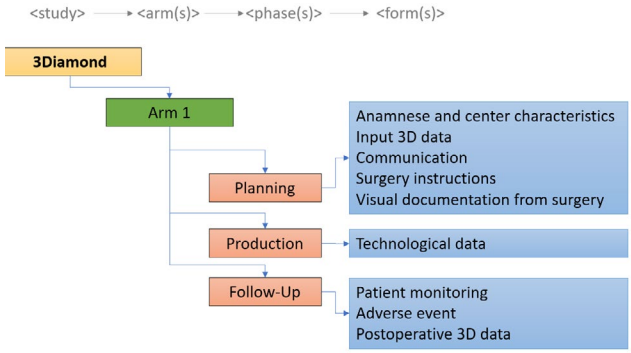

Figure 2 – The structure of entities (arms, phases, forms, question groups) and attributes (questions) used for structuring the 3Diamond eCRF. Questions are logically grouped into question groups, a form is composed of question groups, forms are grouped into phases (Planning, Production, Follow-Up), and phases are grouped into one single arm in the registry.

Results

Thanks to the fact that the PLM system was not built from scratch, but exploited the solid foundations of the robust EDC system Clade-IS, it was possible to make a working prototype of the system available to users within one month from completing the user specifications. The eCRF was further debugged on the functional prototype, with parallel communication between the lead biomedical engineer and several clinical experts in the fields of neurosurgery, maxillo-facial surgery, traumatology and orthopaedics.

Only three months after the start of development, the 3Diamond PLM system was ready with all the functionalities classified as must-haves, see Figure 3. The software is available in two deployment modes: SaaS (Software as a Service), i.e. offered as a service of the IT infrastructure of the developing company Institute of Biostatistics and Analyses, and also under on-premise licensing, i.e. in the IT infrastructure of a hospital. Thus, the collection of experience with the facilitation of 3D printing at the specific environment of the Liberec Regional Hospital could begin.

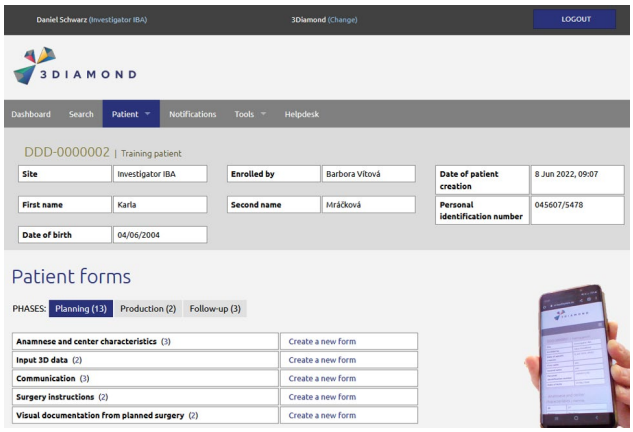

Figure 3 – A screenshot from the 3Diamond PLM system showing the main screen with available forms of a training patient.

Discussion

After the 20 case studies had been conducted, two meetings with stakeholders in the area of 3D printing medical applications were organized. The first one was focused on applications in healthcare, the second one invited also stakeholders from medical simulation centers.

The discussion with stakeholders confirmed the authors' concerns about the inappropriate practice of handling patient documentation necessary to perform 3D printing tasks. There are two particular issues which present risks for the hospitalsand indeed opportunities for a wider deployment of the 3Diamond PLM system: (i) the interdisciplinary communication between biomedical engineers and clinicians via WhatsAppor other unsuitable messaging applications, and (ii) file transfer via physical USB flash drives. At the very least, these are deviations from recommendations that make sense to follow, especially in a time of established strong data privacy regulations, fines imposed, and not a few breakthroughs in hospital networks. Furthermore, unmet needs for various stakeholdershave been also formulated, in order to support further business development process.

Further development of the 3Diamond PLM system features is expected especially in the area of image data handling, with the focus on the rendering of STL files that carry information about 3D printing models. Displaying STL data on the web is possible in several ways. Besides PDF format, the most suitable way seems to be to use the HTML <canvas> element and render it on the client device using WebGL and the three.js library.

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