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A NOVEL APPROACH TO COLLABORATIVE PRODUCT DEVELOPMENT IN THE MEDICAL-EQUIPMENT INDUSTRY

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ABSTRACT

In this study, we summarise the requirements for collaborative product development based on our investigation of the differences in the resources and tools that are needed for the various stages of collaborative product development and the needs of system users during these various stages. We proposed a user-oriented approach of collaborative product development for medical equipment and designed a collaborative product development system with the required functionalities to satisfy different areas according to their roles and workflow. The system we developed can drastically simplify the original complex and dispersed process of product development for intelligent medical equipment, thereby allowing the project team to develop new medical-equipment products and promote interactions among the research and development staff, clinical specialists, and the test participants successfully, thereby resulting in a user-oriented collaborative product development process.

Keywords: collaborative product development, medical-equipment industry, workflow management

1 INTRODUCTION

Due to intense competition in the international market, businesses must be cognisant of research, development, and innovation and must also respond rapidly to the demands of the market to survive and thrive in a globally competitive environment. Because technology develops rapidly with each passing day and consumer preferences are diverse and ever-changing, product life cycles are becoming shorter. In the face of such strong competitive pressure, a business must continually develop new products and consider new product development to be a key strategic activity (Thomas 1993). New product development (NPD) is a complex process involving cooperation in many areas, including the following seven steps: idea generation, project planning, concept development, embodiment design, detail design, testing and refinement, and production (Tseng et al. 2008). However, the key to successfully placing a new product in the market lies in whether the features and design of the product meet the expectations of the targeted consumers and the needs of the end users (Patnaik and Becker 1999, Fowler et al. 2000, Bruseberg and McDonagh-Philp 2001, Ernst 2002).

Product innovation has always been an important route to revenue and profit growth, particularly in the life-science and high-technology industries. These industries have the specific characteristics of generating products with a short life cycle, high technical complexity, and a low chance of success. Thus, to remain competitive, the companies that produce these products must invest large sums of money. In this case, both the management costs and the risks involved in the development of new products are beyond the capacity of many companies (Quinn 2000, Bhaskaran and Krishnan 2009), and the construction of a good model for product development has become urgent (Cooper 1990, George et al. 2005). However, product development occurs in many areas, and the needs of the users vary widely (Sherman et al. 2005). Therefore, an investigation of the construction of the new product

development process in this study is focused on the intelligent medical-equipment industry as an example of our methodology. Our aims were to improve clinical testing efficiency in the medical-equipment industry, to construct a system to facilitate the interaction between the manufacturer and the hospital, and to propose an approach for user-oriented collaborative product development to facilitate new product development.

Therefore, the remainder of this paper is divided into three sections. Section 2 proposes the overall framework of the proposed approach. Section 3 addresses the design and validation of the proposed system. In Section 4, conclusions are drawn, and the overall benefits of implementing the system are explained

2 THE PROPOSED APPROACH

Based on the differences in resources and tools among the various stages of collaborative product development and the needs of system users in the various stages, we constructed a user-oriented collaborative product development approach for medical equipment with a further description of the roles of the users and workflow design. Developers of medical equipment must not only consider the issues of marketing, design, and manufacturing but must also have an understanding of the relevant regulatory environment. Therefore, this investigation focused on intelligent medical equipment only; other issues related to product design for implantable medical devices were not examined in this study.

2.1 Role-based Access Control

In a collaborative product development workflow, and based on the goal of the cooperation, specific task workflows are generated among the team members of the project. The roles of each task and executable work in this workflow are defined, and each participating staff member is part of the same set of users in this interdisciplinary flow.

This workflow can be divided into the following two stages: in the first stage, users assume roles; in the second stage, users execute the tasks that are related to their roles. Each stage has corresponding constraints. The primary constraint in the stage in which users are assigned roles is in screening the quantity of the roles that are collected by the users; the constraints in the stage in which users execute tasks in their obtained roles include to judge whether the user has permission to execute the work in this role, to achieve the security principles of role-based access control (such as least privilege), and to distinguish between right and responsibility.

The users in this system are divided into the following five roles: general members, the supervisor of the collaborative workflow, directors of the collaborative workflow, the performance manager for the collaborative workflow, and the system administrator. The system functions correspond to the roles, and access control is also role-based.

2.2 Workflow Design

Workflow is used to attain cooperation among members through the same logical process. Workflow is used to integrate the distributed tasks (activities) into a unified process. The workflow contains considerable information, for example, the tasks (activities), relations between the executors of the collaborative workflow, the reference information on roles and the tasks of the members, and the roles or the tasks of these members. Workflow ensures the provision of appropriate suggestions to the collaborating team members with appropriate resources (Zhen et al. 2009).

3 SYSTEM DESIGN AND VALIDATION

Based on the user-oriented collaborative product development approach described above, a collaborative product development system for intelligent medical equipment was implemented to facilitate long-distance collaborative product design and development of medical equipment with a detailed description of its structure and the implementation approach.

3.1 System Architecture

A collaborative product development system was designed according to the workflow requirements of the product development life cycle for intelligent medical equipment. The related sub-function modules include a project management system, a document management system, a knowledge-based system, a clinical testing system, and an experiment application system. In addition, a video-conferencing system, e-mail system, newsletter system, forum, and file encryption mechanism are provided to facilitate the collaborative product development of medical equipment.

3.2 System Implementation

The core system and the associated modules of the developed system for intelligent medical equipment are both varied and complex. As an initial step, we implemented a collaborative product development system for intelligent medical equipment using the tree structure in Figure 1.

3.2.1 Project management system

The project management system is divided into the "New Project" and "Project Maintenance and Operation" modules. The "New Project" module is further divided into personal projects, subprojects, and human trial application projects, which are described as follows:

Personal project: This module is designed to assist members in defining the individually owned projects in a general new product development project. The project applicant, who is the supervisor of the collaborative workflow, is usually the project manager and is responsible for entering the basic information for the project, including the project name, and setting up the code for the project.

IRB application project: This module supports the application process for IRB during the validation period in the product development life cycle of intelligent medical equipment.

Subproject: After the personal project and human trial application project are created, the directors of the collaborative workflow can then choose the respective parent project and establish a subproject according to their needs.

The function of the "Project Maintenance and Operation" module is associated with the auxiliary systems and the following related functional modules that are required during the project: a workflow planning module, a video-conferencing system, a project management system, a forum module, a meeting system and a document management system. The users of the maintenance and operation functional modules are the supervisors and the executors of the collaborative workflow for the new project.

3.2.2 Knowledge-based system

Because information is rapidly changing in the intelligent medical-equipment industry, understanding all of the information from diverse sources is extremely time-consuming and difficult. The system administrator updates the new information periodically using the announcement management function in the system maintenance module (e.g., for system information, seminars, education, and training). This function can help members access the latest system information with seminars, education, and training information related to the intelligent medical-equipment industry.

3.2.3 Document management system

Many files are generated during the course of a project, and a portion of expertise depends on the sharing and accumulation of experiences. For this purpose, the tools in this function block provide file accessibility as shared resources for the members of this system, including file sharing, records of completed projects, and external links.

3.2.4 Accessibility

Due to the unique interdisciplinary nature of clinical testing projects for intelligent medical equipment, both the exchange of ideas and mutual consultations are crucial. To address these requirements, this system provides these accessibilities via e-mail, a forum, and a conferencing

system, and the results of the projects are presented in a newsletter that is published by the performance manager of the collaborative workflow.

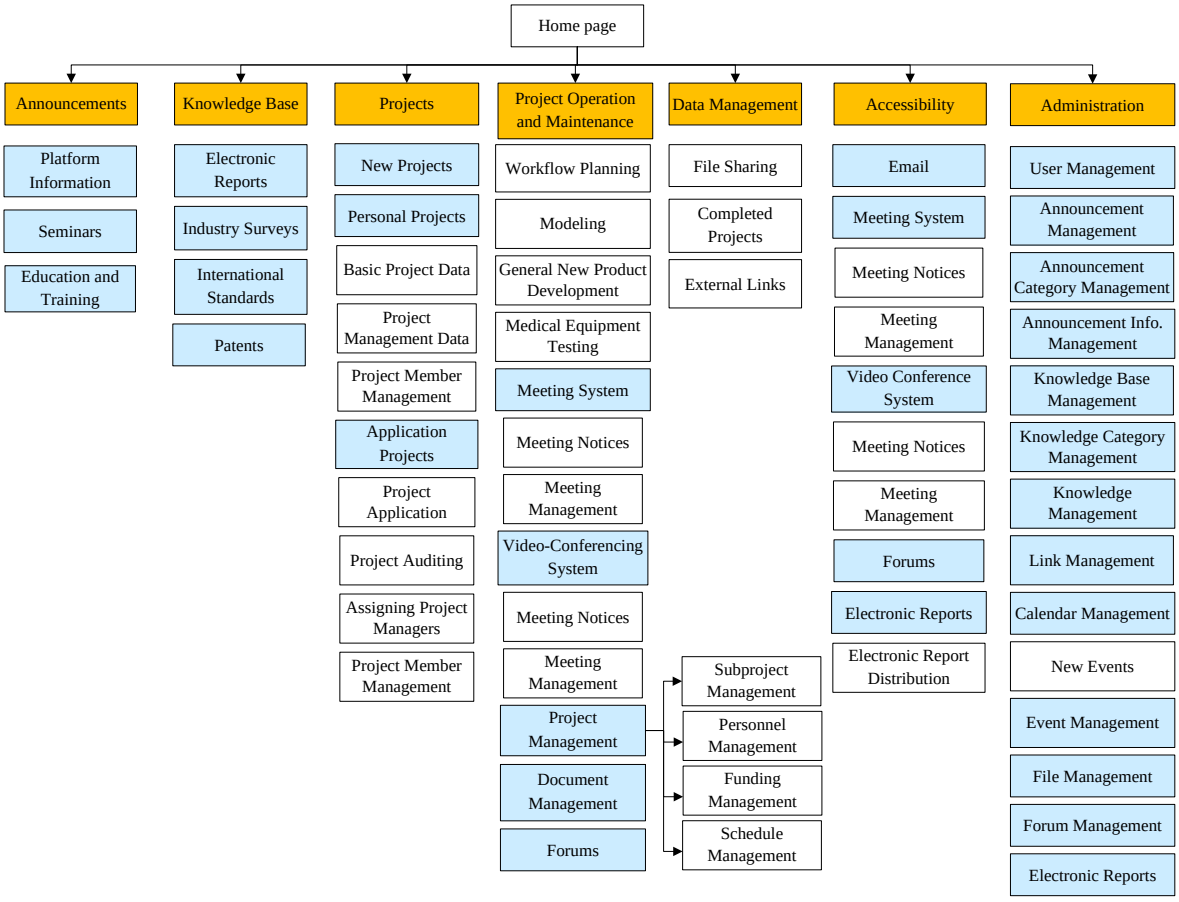

Figure 1: Architecture of the collaborative project management system for intelligent medical equipment.

3.3 System Validation

System authentication was performed with workflow validation for a simulated clinical case using this system. The project tested the acceptance of interactive computer systems in a senior citizen community and can be used as a reference for further development of practical applications for seniors. The scenario begins with the registration of members by the company and the entry of each member's basic information. Next, this information is distributed and verified by the system administrator who allows user login through membership, as shown in Figure 2. The manufacturer subsequently submits an application for testing the project as a member, as shown in Figure 3. Next, the performance manager reviews the collaborative workflow. Following a satisfactory review, the performance manager designates an appropriate staff member to join this clinical validation project as the collaborative workflow supervisor. The supervisor subsequently assigns tasks to each executor of the collaborative workflow, and the application stage for human trials begins. Task assignment involves completing the various parts of the application for IRB. After completing and sending out the forms, the components are entered into the system electronically such that their progress can be quickly retrieved and audited. The clinical trial for the medical equipment is subsequently completed using this system.

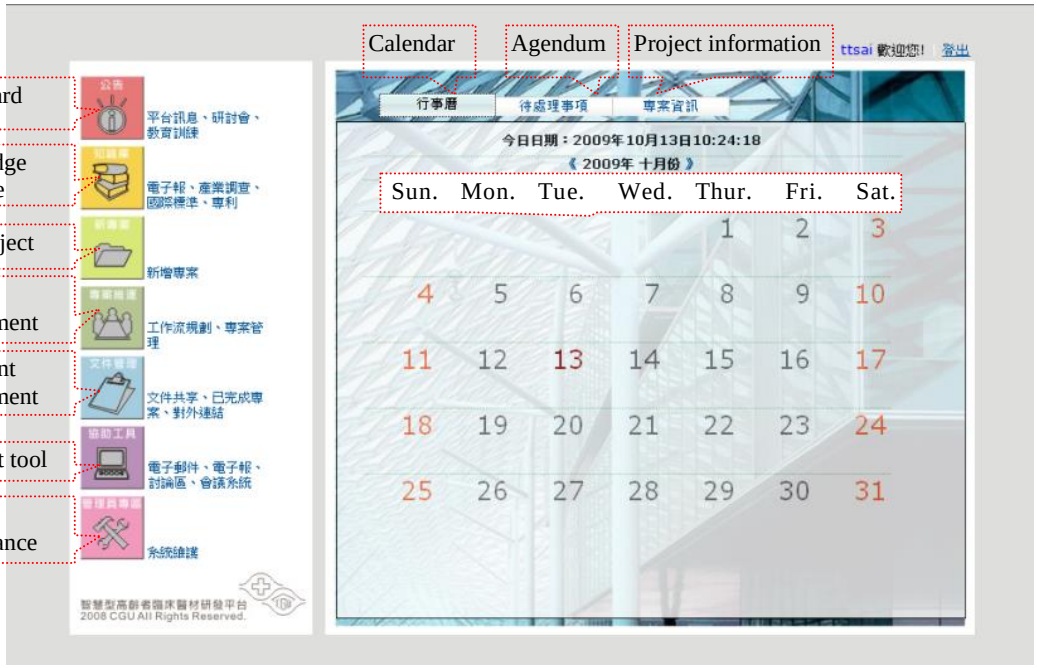

Figure 2: Homepage of the membership login system.

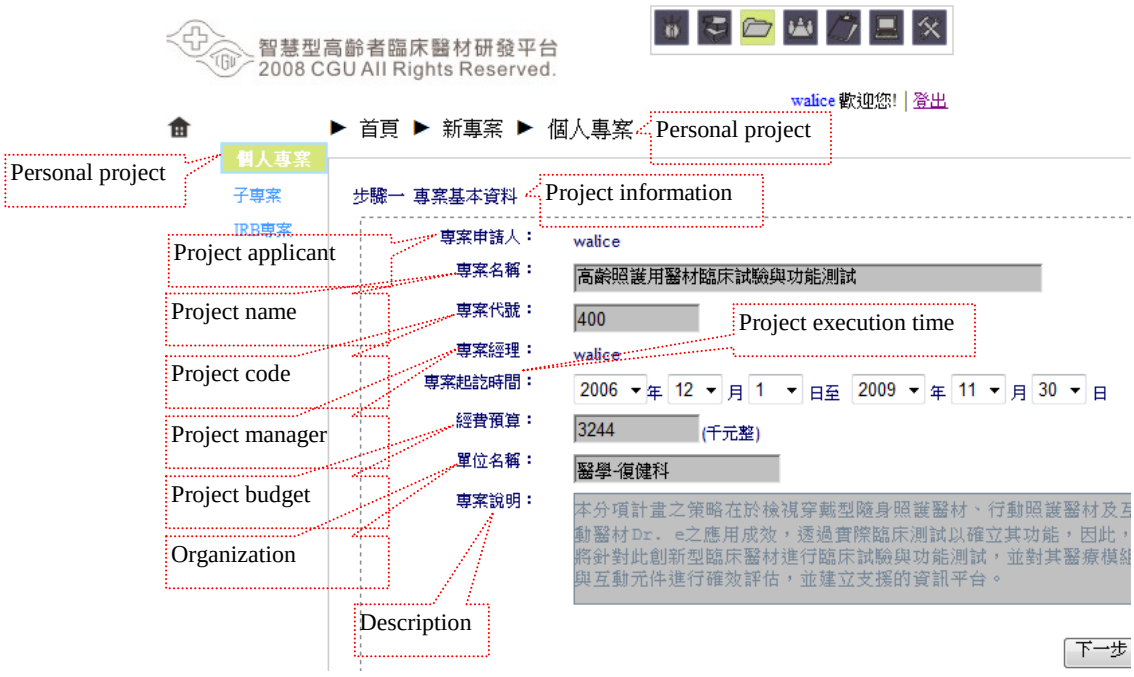

Figure 3: The application data fields of the testing project that are filled out by the members.

4 CONCLUSIONS

Based on previously published research studies, we analysed the development process and the resources and tools that are required for medical-equipment product design in which the user needs in each phase of the development process were considered, and a user-oriented collaborative product development approach was proposed for medical equipment. In addition, this study considered further the needs of practical applications in the development of medical equipment by examining realistic cases of medical-equipment development. Based on the functions, specifications, restrictions, and

projects that were applied to the testing phase of the clinical development cycle of medical equipment (classified into user roles and their corresponding tasks and workflows), the user interface and the function modules were designed to meet the requirements of the user roles and their associated tasks, and a user-oriented collaborative product development system was constructed for intelligent medical equipment. The developed system provides the functionality of database creation for professionals in academia, medicine, industry, and other areas that are related to the clinical testing of medical equipment. These users are classified according to their area of clinical and research expertise as a resource for the clinical testing of the medical equipment. With the integration of the relevant units of research and industry, an integrated system of advanced technology with research and development capability can be established for the collaborative product development of intelligent medical equipment.

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