UNSYS digital

International Journal of Robotics and Mechatronics

The Implementation of a User-Oriented Model for Collaborative Product Development: An Example from the Medical-Equipment Industry

Kevin C. Tseng[†§] and Chien-Lung Hsu[‡]

[†]Product Design and Development Lab., Dept. of Industrial Design, College of Management, Chang Gung Univ., Taoyuan, Taiwan

[§]Healthy Aging Research Center, Chang Gung University, Taoyuan, Taiwan

[‡]Department of Information Management, College of Management, Chang Gung University, Taoyuan, Taiwan

***Abstract*—**In this study, we summarize 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 developed a user-oriented model of collaborative product development for medical equipment and designed an interface module with the required functionalities to satisfy different areas according to their roles and workflow. In medical-equipment development, the issues related to marketing, design, and manufacturing must be considered; more importantly, the relevant regulatory needs must be thoroughly understood. Therefore, based on the unique features of the medical-equipment industry and the requirements for product development therein, we implemented a development system for collaborative product development in the intelligent medical-equipment industry, including a calendar function module, an announcements module, a knowledge-based information system, a project management system, a project operation and maintenance system, a file management system, an accessibility system, and a clinical test system. In addition, the results obtained with this system were verified with the following three possible cases: project operation and maintenance, clinical trial application, and medical equipment testing. The platform 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*—**Workflow design and management, user-oriented, medical-equipment industry, collaborative product development.

I. Introduction

Due to intense competition in the international market, businesses must be cognizant 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 [1]. New product development (NPD) is a complex process involving cooperation in many areas, including the following six steps: conceptual design, system design, detail design, testing, modification, and trial production [2]. 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 [3]-[6].

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 [7],[8], and the construction of a good model for product development has become urgent [9],[10]. However, product development occurs in many areas, and the needs of the users vary widely [11]. 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.

In this study, which was oriented to user needs, the most complicated stage of product development for medical equipment was effectively simplified, and the process and requirements of the clinical trial were studied in depth. Our aims were to improve clinical testing efficiency in the medical-equipment industry, to construct a platform to facilitate the interaction between the manufacturer and the hospital, and to build a model for user-oriented collaborative product development to facilitate new product development. Following the construction of the collaborative product development system for intelligent medical equipment, a network of clinical trial information and related resources was subsequently established; this network is expected to encourage professional medical personnel to engage in research collaborations in the areas of manufacturing and medicine, assist the manufacturer in successfully finishing the clinical

Corresponding author: Chien-Lung Tsu (e-mail: clhsu@mail.cgu.edu.tw).
This paper was submitted on December 4, 2015; revised on December 20, 2015; and accepted on December 27, 2015.

trial, and subsequently achieve the goal of user-oriented collaborative product development. However, to implement a user-oriented collaborative product development model, an effective product development process and method cannot be achieved without considering overall product functionality. In addition, the medical-equipment industry differs from other manufacturing industries in the development complexity of diverse medical-equipment products and in the rigors of the process, which is subject to strict regulation, as medical equipment affects human health either directly or indirectly. Without strict regulation, the safety of medical equipment cannot be ensured. Because the quality of medical equipment is closely related to human health and life, the prelaunch check is always strict and time-consuming under all governments, thus usually resulting in a relatively long product development life cycle within the medical-equipment industry.

During the development process, the test planning and reporting periods last for only six months to three years, which is a relatively short period given the long life cycle of medical-equipment development. Chen Bin, the president of the Taiwan Medical and Biotech Industry Association, stated that the development of medical equipment in Taiwan faces the key issues of weak product innovation, a lack of interaction among clinicians, insufficient familiarity with the regulations, and an insufficient capacity for verification and testing. In this study, solutions to these problems were included in the design of the collaborative development system for intelligent medical equipment, with overall consideration being a highly important factor.

In summary, we developed a platform for user-oriented collaborative product development technology that can effectively assist the medical-equipment industry in its fast-paced, competitive environment. The purposes of this study were to introduce the teams involved in all areas of the latter period of product development to the conceptual design process, to import a knowledge management model, to establish a long-distance collaborative design system for medical-equipment products, to provide a means for professional teams in different areas and/or regions to collaborate on product design (thereby expanding the environment for the product design activities of users), and to verify the feasibility of the conceptual product design supported by the platform of the collaborative product design system.

II. Collaborative Development Approach for Intelligent Medical Equipment

In accordance with the theory and topics described above, we summarized the requirements for collaborative product development. 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 model 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.

A. Role-based access control

In a collaborative 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.

B. 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 [12].

III. The Platform Architecture for Collaborative Development of Medical Equipment and Its Implementation

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

A. Development description

To provide a synchronous environment for discussion and collaborative work among the groups, the collaborative development system for intelligent medical equipment was

constructed using a three-tiered architecture consisting of the client, server, and data. The client tier connects to the server using the HTTP protocol. Users can log onto the system using any generic browser. Interdisciplinary cooperation involves two or more participating organizations that all belong to the client tier. The server tier contains a programming interface for the application system to interact with external systems and integrate the clinical testing data for intelligent medical equipment. The data tier is the system database that stores the clinical testing workflow, the operational details, the tables and data related to the clinical trial, and the physiological parameters for the intelligent medical equipment. This system was implemented in the ASP.NET and PHP programming languages on the Windows Server 2003 platform with the IIS Server web server and the Microsoft SQL Server database.

B. System architecture

A collaborative development platform 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 system, a market information system, a file management system, a human resources system, a clinical testing system, an experiment application system, a supply chain system, a knowledge-based system, and a computer-aided design system. In addition, a video-conferencing system, e-mail system, newsletter system, forum, and file encryption mechanism are provided to facilitate the collaborative development of medical equipment.

C. System implementation

A collaborative development platform 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 system, a market information system, a file management system, a human resources system, a clinical testing system, an experiment application system, a supply chain system, a knowledge-based system, and a computer-aided design system. In addition, a video-conferencing system, e-mail system, newsletter system, forum, and file encryption mechanism are provided to facilitate the collaborative development of medical equipment.

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

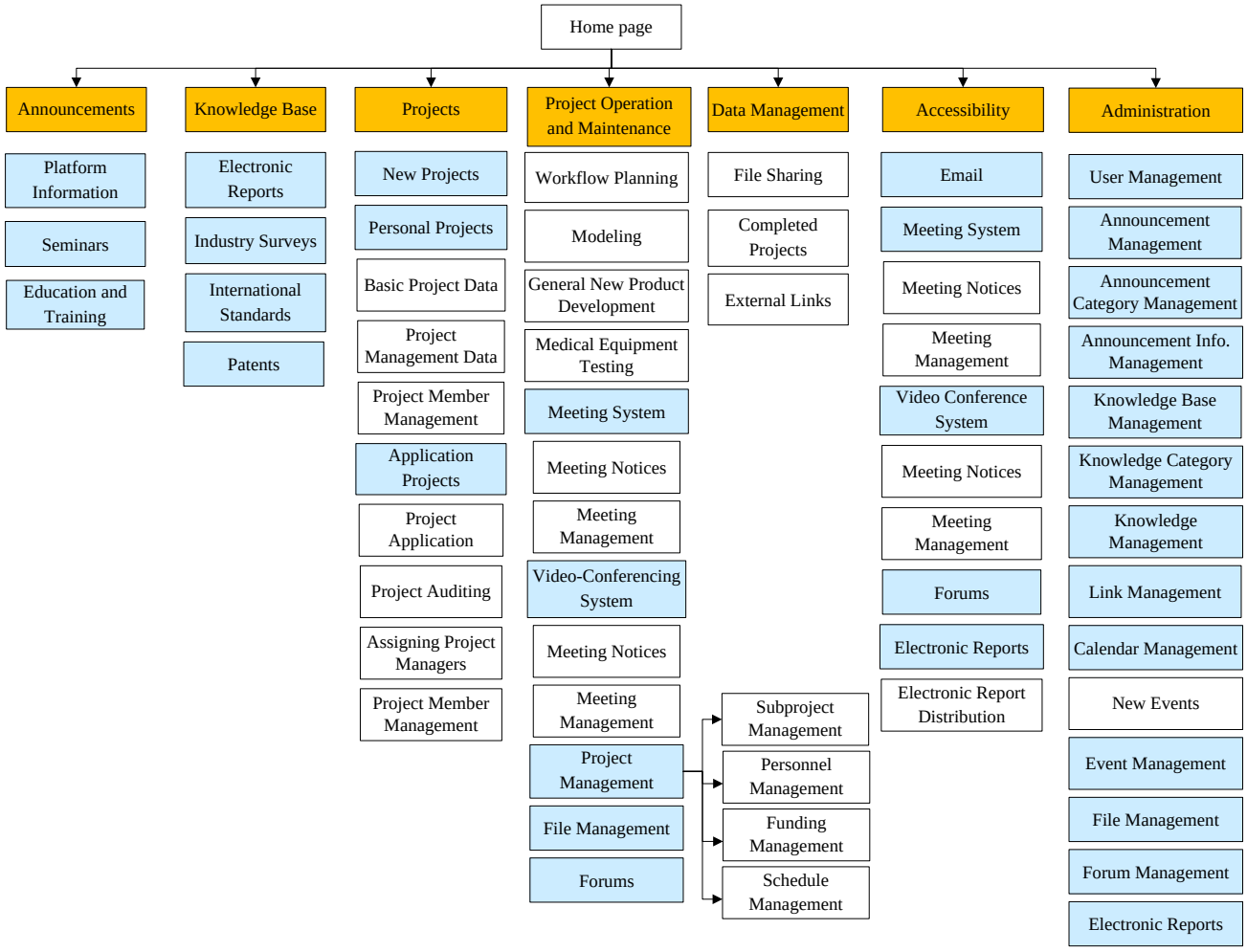

Figure 1 Architecture of the collaborative project management system for intelligent medical equipment

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.

Human trial application project: This module supports the application process for human clinical trials 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 conferencing system, a project management system, a forum module, and a collaborative design studio. The users of the maintenance and operation functional modules are the supervisors and the executors of the collaborative workflow for the new project.

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 platform information, seminars, education, and training). This function can help members access the latest platform information with seminars, education, and training information related to the intelligent medical-equipment industry.

File-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 platform, including file sharing, records of completed projects, and external links.

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.

D. Roles and their functional structure

The users in this system are divided into the following five roles: general members, the supervisor of the collaborative workflow, executors of the collaborative workflow, the performance manager of the collaborative workflow, and the system administrator. The corresponding relationships for the system functions and roles, including role-based access control, are discussed in this paper.

Figure 2 Homepage of the membership login system

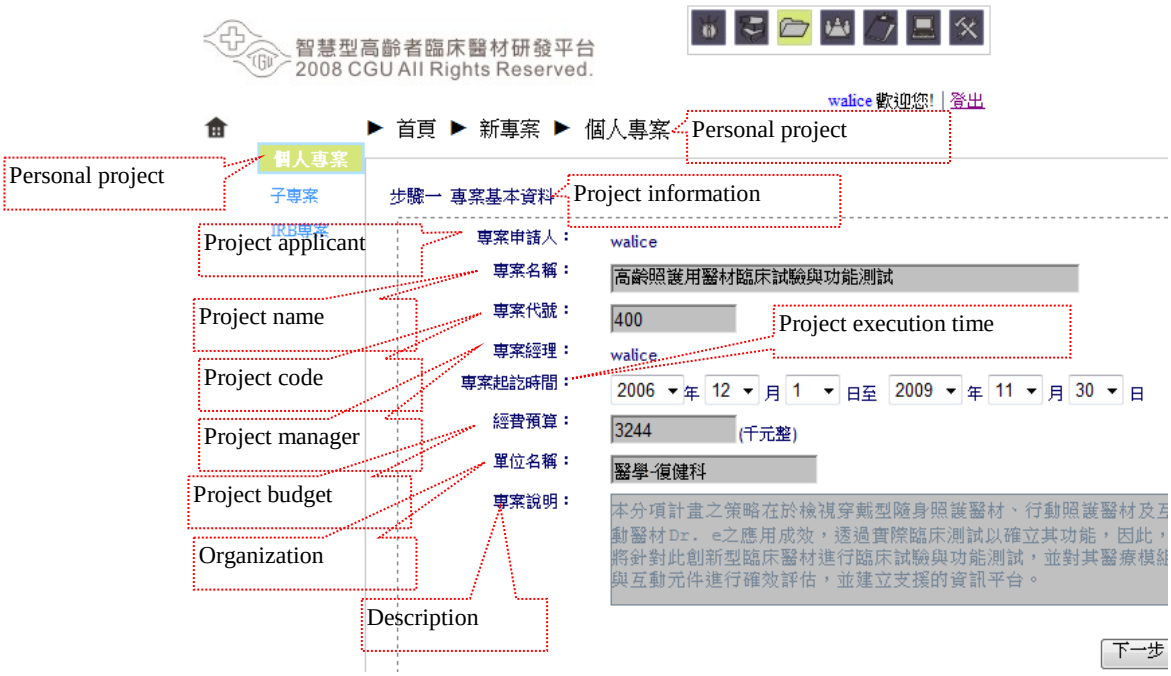

Figure 3 The application data fields of the testing project that are filled out by the members

IV. System Authentication

One characteristic of this system is to focus on project management for medical-equipment development and the construction of a platform for manufacturers and medical resources; therefore, clinical validation of the intelligent medical equipment —with the cooperation of a company and a hospital— was chosen for the initial system authentication. The following three cases were applied to verify the system: project maintenance and operation, an application for a clinical trial, and a test of the medical equipment.

A. Project maintenance and operation

The collaborative workflow supervisors manage projects through the system. The first step is to enter basic information for the project, including project name and project code, set starting and ending time for the project, a budget, a unit name, and a description of the project. The next step is to recruit new project members for task assignment. After the basic setup of the project is completed, the newly generated event acts as a reminder in the members' personal event calendars. Through information queries, the directors of the collaborative workflow can adjust the project resources and assign work control in a timely manner. The directors of the collaborative workflow can establish subprojects based on the demands of the given tasks and use resources to complete tasks on schedule.

B. Application for a clinical trial

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 a human trial. 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.

C. Testing of the medical equipment

The collaborative workflow executors test the medical-equipment product using this platform. In our example, the product was tested using a questionnaire system. The collaborative workflow executors designed a new test procedure using the test system. The first step was to establish the basic parameters for the testing case, including the theme of the test, a description of the test, and whether the results are public data. The choices for establishing the test items for the project can be either self-generated or imported as raw data from a CSV file. If self-generation is chosen to establish the test items in this system, the design of the questionnaire can be processed once the parameters are established. The design of the questionnaire includes filling in the project name, selecting the project type, setting the required fields, and other memos

and/or annotation. The questionnaire can be flexibly designed by adding items to the project on which to base the design of questionnaire items. The collaborative workflow executors can first determine the current number of test cases to be performed by viewing a list presented by the system, and they can subsequently make any necessary changes. The test is performed through the completion of this page by the participants. The entire process of clinical testing is completed, and the physiological data are collected automatically by the questionnaire system and the intelligent medical equipment.

V. Conclusion

Based on previously published research studies, we analyzed 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 model 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 development system was constructed for intelligent medical equipment.

The user-oriented collaborative development system for intelligent medical equipment that is proposed in this study includes a calendar function, an announcements module, a knowledge-based information system, a new project system, a project operation and maintenance system, a file-management system, and an accessibility system to achieve effective control of a clinical test project, interdisciplinary communication, and resource sharing. The platform in our 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 platform of advanced technology with research and development capability can be established for the collaborative development of intelligent medical equipment.

Acknowledgment

This work was supported in part by the Ministry of Science and Technology, Taiwan, ROC under Contract MOST 103-2628-H-182-001-MY2 and MOST 104-2410-H-182-025-MY2, by the Chang Gung Medical Foundation (fund no. CMRPD290063 and CMRPD3E0371), and by the Healthy Aging Research Centre, Chang Gung University (fund no. EMRPD1E1691, CMRPD1B0331, and CMRPD1B0332). The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

References

[1] R. J. Thomas, *New Product Development: Managing and Forecasting for Strategic Success*, 1 ed. New York: Wiley, 1993.

[2] K. C. Tseng, "An IPDD approach for systematic innovation of products, processes, and services: a case study on the development of a healthcare management system," in *The 5th International Congress of International Association of Societies of Design Research*, Tokyo, Japan, 2013.

[3] H. Ernst, "Success factors of new product development: a review of the empirical literature," *International Journal of Management Reviews*, vol. 4, pp. 1-40, 2002. CrossRef

[4] A. Bruseberg and D. McDonagh-Philp, "New product development by eliciting user experience and aspirations," *International Journal of Human-Computer Studies*, vol. 55, pp. 435-452, 2001. CrossRef

[5] S. W. Fowler, A. W. King, S. J. Marsh, and B. Victor, "Beyond products: New strategic imperatives for developing competencies in dynamic environments," *Journal of Engineering and Technology Management*, vol. 17, pp. 357-377, 2000. CrossRef

[6] D. Patnaik and R. Becker, "Need finding: The why and how of uncovering people's needs," *Design Management Journal*, vol. 37-43, 1999.

[7] S. R. Bhaskaran and V. Krishnan, "Effort, revenue, and cost sharing mechanisms for collaborative new product development," *Management Science*, vol. 55, pp. 1152-1169, July 1 2009. CrossRef

[8] J. B. Quinn, "Outsourcing innovation: The new engine of growth," *Sloan Management Review*, vol. 41, pp. 13-28, Summer 2000.

[9] R. G. Cooper, "Stage-gate systems: A new tool for managing new products," *Business Horizons*, vol. 33, pp. 44-54, 1990. CrossRef

[10] M. L. George, W. James, and K. Watson-Hemphill, *Fast Innovation*. Sigapore: McGraw - Hill Education 2005.

[11] J. D. Sherman, D. Berkowitz, and W. E. Souder, "New product development performance and the interaction of cross-functional integration and knowledge management," *Journal of Product Innovation Management*, vol. 22, pp. 399-411, 2005. CrossRef

[12] L. Zhen, G. Q. Huang, and Z. Jiang, "Recommender system based on workflow," *Decision Support Systems*, vol. 48, pp. 237-245, 2009. CrossRef