USER EXPERIENCE-BASED DESIGN METHOD APPLICATION IN ELECTRONIC MEDICAL RESEARCH DATA COLLECTION TOOL DEVELOPMENT

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Abstract
The functional requirements of a data collection automation tool for medical research projects are based on existing data collection automation tools and the current research project experience of Institute of Clinical and Preventive Medicine of the University of Latvia and were generalized to be applicable to a wider range of medical research projects. The tool use scenarios include design of the whole research project dataset content and its individual elements, as well as the creation of a data-recording interface application. The tool is designed as an Angular-based Web application that is used to provide prolific client-side functionality, NET REST services for server-side functionality, and SQL database and SMTP server for user management.
Key words: codebook, research data collection automation, user experience design.

Introduction

Medical research is very important because one of its main challenges is to find new methods and tools for the prevention and treatment of diseases. Compared to other industries, healthcare is facing many strict regulations which govern data collection and use. Data are being collected by using various methods and from various sources. Many data are acquired from filled-in forms (such as patient intake forms, consent forms, and health assessment forms), as well as from information systems that contain patient data – electronic health record (EHR), customer relationship management systems (CRM), and other sources.

Medical research data is usually highly sensitive. All documentation concerning data capture, storage and processing permissions must be approved before starting the data collection activities. Data entry template should correspond to the particular study, which means that besides the potential data quality issues (errors caused by manual data entry) there are also financial costs associated with all the major elements of data collection process, including database, codebook, and form design.

Analysis of the ongoing medical research projects at the Institute of Clinical and Preventive Medicine of the University of Latvia clearly shows that effort for the data collection effort and its costs vary from project to project and can be quite significant. Efficient use of information technologies in the data collection process will allow to reduce costs and to improve data quality.

Proper identification of user experience variables (Utility, Usability, Aesthetics, Identification and Value) leads to the better understanding of software user requirements which result in complete requirements and specifications and continually changing them through the suitable change management to control the different processes of the software development life cycle, identifying user's constantly changing opinions (Badran & Al-Haddad, 2018).

Therefore, the research goal was to develop a cloud-based tool for the automation of data collection and following main tasks were completed to reach this goal: (1) thorough analysis of data collection process and definition of the functional requirements of the IT tool, (2) analysis of the role of user experience as a facilitator of higher IT tool effectiveness, applying human-centred system design theory and carrying out practical UX (user experience) testing, (3) development of the data collection automation tool and its experimental testing.

Thus, the paper describes the main results achieved in this research, as well as the features of the developed automation tool, its experimental testing results, and the conclusions drawn from the study.

Materials and Methods

Human-centred system design and user experience

Already as early as in 1969 it was acknowledged that the future will need not so much computer-oriented people as people-oriented computers. The design of user/human-centred systems, user experience (UX), and human-computer interaction (HCI) are areas of research that are concerned with improving the interaction between people and computers. The early work in this field dealt with the design of visual layouts and the optimization of input devices (Ritter, Baxter, & Churchill, 2014).

During the 1970s and 1980s researchers studied human capabilities in computer use, focusing on cognitive psychology and ergonomics. The user was seen as a passive, unmotivated individual trying to efficiently use a computer. Later came a new and more insightful idea of the user as an active individual who controls the system, and the focus shifted to the ease of use and user-friendliness (Bødker, 2006). Since the advent of mass-market consumer electronic devices

created an ever-growing number of users with no prior experience, usability emerged to the forefront of the research of interface design and human-computer interaction.

Usability is characterized as a task-oriented and performance-based feature, it emphasizes the achievement of goals. However, this approach tends to see the person as a 'user' and the artefact as a tool, thus taking a limited view of people. Three canonical usability metrics – effectiveness, efficiency and satisfaction – define usability in ISO standard 9241-11 (International Organization for Standardization, 1998). Effectiveness characterizes the accuracy and completeness with which users achieve specified goals. Efficiency measures the resources spent in relation to the accuracy and completeness of achieving goals. Satisfaction is seen as freedom from discomfort and positive attitude towards the use of the product. In practice, the testing of the satisfaction element of usability often means investigating whether the product frustrates the user or not (Blythe *et al.*, 2005).

In the 1980s the approach to system design progressed towards user-centred design (Norman & Draper, 1986). It involves focusing on the user's needs, and the adoption of this approach means following six principles: (1) the design is based upon an explicit understanding of users, tasks and environments, (2) users are involved throughout the design and development, (3) the design is driven and refined by user-centred evaluation, (4) the process is iterative, (5) the design addresses the whole user experience, (6) the design team includes multidisciplinary skills and perspectives (International Organization for Standardization, 2010).

As computers moved out of the workplace and entered homes, leisure usage became more important. When technology is integrated into a user's everyday life, such aspects as satisfaction, entertainment, enjoyment, and a sense of community and identity play a significant role (Wright, McCarthy, & Meekison, 2003). All this contributes to a shift of focus from concrete functional aspects of the product design towards more abstract, subjective qualities of interaction, thus shaping user experience as a distinct concept (Hassenzahl & Tractinsky, 2006).

The term 'user experience' was first used by Donald Norman, Jim Miller and Austin Henderson (Norman, Miller, & Henderson, 1995) more than two decades ago. UX is influenced by 'the user's internal state (predispositions, expectations, needs, motivation, mood, etc.), the characteristics of the designed system (e.g. complexity, purpose, usability, functionality, etc.), and the context (or the environment) within which the interaction occurs (e.g. organizational/social setting, meaningfulness of the activity, voluntariness of use, etc.)' (Hassenzahl & Tractinsky, 2006). UX accentuates the importance of the subjectivity of users' experiences and quality judgements. These personal interpretations of a system quality can influence the future interaction with the system and can be communicated to other users with the potential of influencing their subjective experiences (Hassenzahl & Tractinsky, 2006).

'User experience' is often used interchangeably with the concept of 'usability', but there is a different focus: usability and usability engineering focus on task-related aspects, while UX and experience design focus on the users feelings, emotions, and values, as well as their immediate and delayed responses (Ritter, Baxter, & Churchill, 2014). However, when interpreted from the perspective of the users' personal goals, usability can include perceptual and emotional aspects that are typically associated with UX. Usability criteria can be used to assess aspects of user experience (International Organization for Standardization, 2010). The classic usability concept focused on single behavioural episodes and momentary evaluations, while UX can also be felt before the interaction and it can change over time. Furthermore, the relative importance of different qualities can also change over time (Roto *et al.*, 2011). As the user becomes more familiar with the product, its novelty wears off and the product becomes less exciting. At the same time, with prolonged use it can also become less frustrating. As a result, the perceived quality of a product is likely to change.

As a result of this shift of focus towards a more holistic view of users and interaction, the movement of human-centred design emerged. It expanded the focus to considering how human capabilities and characteristics are affected by the system beyond the direct interaction with the interface or system itself. According to this approach, humans should be seen as the most important element of the information systems (Ritter, Baxter, & Churchill, 2014).

User-centred (and human-centred) design methods tend to emphasize user participation in the design process for the ideation and evaluation of design options. The wide spectrum of methods allows for different degrees of active participation. Human-centred design consists of four activities that structure the development process: understanding and specifying the context of use; defining the user requirements; drafting the design solutions to meet user requirements; testing and evaluating the solutions against requirements (International Organization for Standardization, 2010).

The context of use analysis is a structured method for eliciting information about the context of using a system as a foundation for later activities, particularly user requirements. The context of use includes such factors as the user group, tasks, technical environment,

physical environment, and organizational environment (Maguire, 2001).

Design solutions arise through a logical progression from previous designs or ideas and go through an iterative development as they develop. Prototypes and simulation of the system are necessary to support this iterative design lifecycle. They can be produced quickly and easily in the early stages for evaluation by usability experts and prospective users. Changes in the design can be made rapidly in response to user feedback, so that major problems can be identified and corrected before the system development begins. Methods include brainstorming, use of design guidelines and standards, storyboarding, and low to high fidelity prototyping (Maguire, 2001).

Evaluation is a very important activity as it demonstrates how far the requirements have been met and provides information for refining the design. There are three levels of formality when performing evaluation studies: (1) participative (least formal) – suitable in the early stages of design process; includes asking the participants about their impressions of a prototype, what they think different elements may do, and what result they expect from their next action. The participants may also be asked to suggest how individual elements could be improved; (2) assisted (intermediate) – the participant is requested to perform tasks and is invited to 'think aloud'. The objective is to obtain the maximum feedback from the user while trying to maintain as realistic an operational environment as possible; (3) controlled evaluation (most formal) – replicates the real environment as closely as possible; can be used to determine whether people can use product successfully via usability metrics (Maguire, 2001).

Functional requirements of data collection automation tool

General requirements for an automation tool of research project data collection should address several key aspects – the development of the research protocol, the generation of data registration application and data acquisition from external data sources.

After the analysis of research data collection process and the evaluation of most popular existing EDC software (MedRED, OpenClinica, Castor, Dacima Clinical Suite), the functional requirements were defined and divided into several categories – dataset identification and data logistics description, data collection phase and data acquisition from external data sources.

Dataset identification and data logistics description requirements are related to the research protocol development phase. In this phase, the research team members must discuss and agree upon all the relevant issues and tasks to minimise mistakes in the research protocol. The following requirements relate to this category:

Requirement 1. The development of datasets in the research protocol by means of the pre-prepared templates (codebook elements and codebook element versions). Designed codebook elements should represent the realisation of individual medical concepts that can be added to the research project datasets.

Requirement 2. Accruation and reuse of existing experience. Codebook elements and their versions are a way of formalizing the already existing experience. It should be noted that a research team mostly works within a specific domain (e.g. a team that works with cancer is more likely to continue to work with cancer). As a result, the codebooks created in previous research projects can be used to prepare research protocols for future projects, thus reducing the time needed to completely redefine the datasets.

Requirement 3. In the process of preparing datasets, it is necessary to provide their visualization that allows to demonstrate the potential data input form.

Requirement 4. Ensuring the possibility to generate a part of the research protocol documentation by describing the datasets required for the research project.

When the research protocol is approved, it is necessary to ensure an operational transition to the data collection (capture) phase. At this point, a fully operational data registration application is needed. The following requirements apply to this phase:

Requirement 5. It is necessary to generate an application and user interface that allows data capture as it is defined in the research protocol. It is possible if the research project datasets were created by using the codebook element version templates.

Requirement 6. It is necessary to allow an easy regeneration of the data collection application in case of changes to the research project.

If the data required for a research project are available in an external data source, an automated data acquisition process can reduce the workload when dealing with these data. However, it should be noted that the acquisition of data from an external source should be critically evaluated, as not all data from external sources are available for such purposes. The following requirements relate to accomplishment of these tasks:

Requirement 7: Ensuring the import of data into the data collection tool from a pre-prepared file.

Requirement 8: Ensuring the response to the personalized (using a patient identifier) data request to the external system in the generated data registration capture system.

Requirement 9: To simplify the design of the generated data capture system, requests to external

data sources should be made through the interlayer of web services. Therefore, encapsulating the interfaces of the different external data sources shall be applied.

All above mentioned requirements were implemented into the data collection automation tool which is evaluated in this research project.

Adaptive design development through UX testing process

After the analysis of literature on prototyping and usability evaluation methods, it was decided to use two-step prototyping: starting with a low-fidelity original prototype and further refining it into a medium-fidelity prototype. Such an approach is effective when it is necessary to identify potential problems as early as possible in the design process, before they become too significant and difficult to resolve. A medium-fidelity prototype later allows for a more detailed user interaction with the interface elements and is more suitable for interface testing and presentation purposes for stakeholders.

From the perspective of the prototype dimensions, it was decided that: (1) the prototype would be designed with medium visual fidelity, containing wireframes for assessing the layout and perception and readability of visual elements, (2) the prototype would be horizontal and shallow, providing the maximum possible range of functions but with little detail, as opposed to a vertical prototype which focuses on only a few functions but with a lot of detail.

The low-fidelity prototyping included iterative usability reviews. Review sessions were organised remotely, in the form of videoconferencing that involved a moderator, participants who were medical researchers, medical IT support staff, and a UX expert. Review sessions were held over a period of 3 calendar months. During a session the moderator demonstrated the prototype to the prospective end-users and other participants and explained the sequence of steps necessary to carry out typical user tasks. The participants were encouraged to offer their comments and suggestions for improvement. The shortcomings identified during a review session were addressed and corrected before the next review session. Detailed recommendations covered general usability aspects, layout, form field types, adaptive design, keyboard navigation, and touch-sensitive interfaces.

Although the general principles of usability and methods for evaluating the user experience are also relevant to the software in the medical sector, literature studies show that the importance of user experience in the medical field is mainly addressed in the context of medical software and healthcare critical information systems, focusing on user performance and security. Very few studies address the usability aspects of the software used in medical studies. It was also concluded that the most recent user experience studies mainly focus on the following directions – the experience of specific user groups (children, seniors, people with special needs such as dementia, autism, dyslexia, etc.), and a limited range of products (games, mobile apps, virtual reality, interactive installations).

Therefore, the particular prototype of this project does not fall within any of the above categories. Seeing that the prospective users of the data collection tool being designed were pre-trained and experienced, attention was devoted to more specific recommendations applicable to user experience design of generated data recording interfaces. Even though the form design has been studied very extensively, considering that forms are an important interaction technique, and the recent sources are just referring to previous studies, it should be noted that there has been no detailed investigation of form design for specific domains and contexts of use.

Data recording interfaces were designed by combining versions of mutually independent codebook elements that are specific to the field of medical research, thus resulting in a single data-recording interface. In order to produce a uniform and harmonious interface for data recording, the following optimal subset of usability requirements was defined for the codebook element version: (1) visual representation of the codebook element version must contain standardized CSS class markers so that they can be overwritten at the dataset level, providing a single stylistic solution, (2) the validation included in the version of the codebook element must provide a standardized validation method, allowing the visual presentation of error messages to be defined at the dataset level, (3) when adding a new data field to the codebook element, the default visual representation of the field (generation path) must be provided in accordance with the basic principles for creating interface elements. (4) the generated data fields should have expanded 'clickable areas', (5) data fields for each version of the codebook element should be adaptive, (6) the data field interface elements should allow data entry and moving to the next data field by using keyboard features solely, (7) interface should be compatible with tablet computers.

Additional parameters and requirements for codebook elements were introduced in the research project dataset:

(1) CSS to define a uniform style for all the codebook element versions added to the dataset, (2) a group name that allows to group the versions of the codebook element defined in a single dataset while maintaining a visual hierarchy, aesthetics, and minimalist design, (3) a mechanism to determine how the user will transfer the data entry focus (cursor) from one version of the codebook element to the next by using keyboard only, (4) data registration interfaces

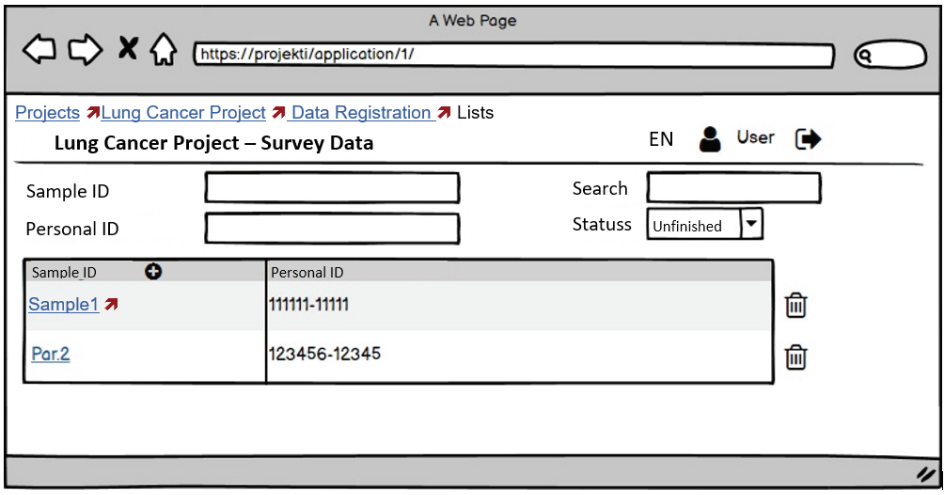

Figure 1. Codebook element example.

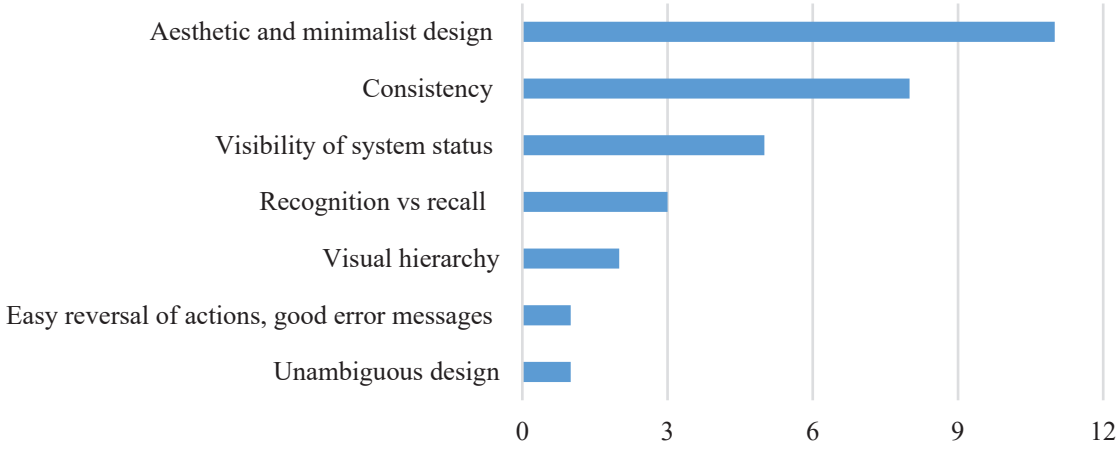

Figure 2. Number of recommended changes per category.

may include datasets with dozens of data elements; therefore, it is important to provide feedback to the user through a progress indicator solution.

After the evaluation of the low-fidelity prototype, a medium fidelity prototype was designed. It included the following major improvements: (1) visual interface adjustments, minimizing the cognitive load of users (including the features identified during the best practices research), (2) devoting more attention to medium-sized devices, including tablets, (3) supplementing the prototype with a partial interactivity that allows limited simulation of the system behaviour and user interaction.

Versions of 31 codebook elements had been created and associated with the project dataset 'Patient Survey'. When creating a version of a codebook element, a visualization of the default (automatically generated) its version of the codebook element had been used (Figure 1).

Two interrelated testing sessions took place for the medium-fidelity prototype. The first test session was organized as a remote usability test (with a moderator), involving two medical researchers, one IT support specialist in the field of medical research, one UX expert, and two system analysts. A prototype demonstration was performed by the moderator, following the user story step by step. The testing session was recorded for review after the testing session. The recording was then analysed by the UX expert assessing interaction affordances and prototype conformance to general usability heuristics and guidelines (Johnson, 2014).

During the second testing session, users had to interact independently with the medium-fidelity prototype by performing typical user tasks. The testing resulted in recommendations for improvement (total number of recommendations 31). These recommendations can be categorized into several groups (Figure 2). The categories were derived from the most widely used usability heuristics and guidelines summarized by J. Johnson (Johnson, 2014).

After the testing sessions, recommendations were reviewed by the UX expert and implemented into the medium-fidelity prototype. At the end of the prototyping process, the medium-fidelity prototype was demonstrated to a group of end-users, with no important outstanding problems identified.

Results and Discussion

Assessment of the tool impact on the effectiveness of the medical trial data collection process was performed to validate success of the study. Such an assessment is complex because the tool is intended to be used in real research, and its impact on the research project can only be fully evaluated at the end of the research project, but projects can last up to 2-3 years and do not fit into the timeframe of this research project. In addition, the impact assessment requires finding another, equivalent research project that has already been carried out without using the prototype.

For these reasons, an alternative approach was chosen. A project 'Screening for cancer with respirable volatile organic compounds using a hybrid capture approach' of the Institute of Clinical and Preventive Medicine of the University of Latvia, where the research protocol preparation phase was already completed, was selected as a research facility. Information was available about the progress of the development phase of the research protocol, the project team, the problems identified during the protocol development phase and the implementation of the data recording solution and the technological platform.

For the purposes of assessment, a partial execution of the research protocol was carried out and an interface for data recording was developed by using the tool. Attention was also paid to the problems identified during the project and on how the use of the prototype could reduce the potential problems and their impact. The result was an estimation of the required effort for carrying out a research project with and without using the tool.

The assessment process focused on three prototype functions: (1) supporting the development of a research protocol by reducing the necessary work capacity and potential errors, (2) reducing work effort to develop a research project data registration solution, (3) enabling an online retrieval of individual data fields from external information systems.

The actions included obtaining patient data and tissue samples from patients, where an invasive manipulation for obtaining a sample of suspicious tissue was risky because of the patient's health status. The duration of the project is 3 years. The development of the research protocol was completed in 12 months, and the matching of datasets for the active research project had been done in 6 months. The rest of the time was spent on starting the project, completing the research protocol, and elaborating and approving the accompanying documentation.

The following problems were noted during the development phase of the research project protocol. Their impact extended the time period of developing the protocol: (1) The dataset could not be properly visualized to the researchers during the development of the protocol. The dataset had been created as a Microsoft Word document table and was difficult to review. Only at the final stage of drafting the protocol, when the development of the data registration solution was already underway, a number of misconceptions in the definition of datasets were identified, and the developed data registration solution had to be adjusted; (2) An outdated technology (Microsoft Access, connected to SQL database) was used to develop the data registration solution.

The total amount of data for the research project consists of 8 datasets and 294 data fields. An assessment of the datasets in the lung cancer project showed that the highest level of variation in the fields used was in the patient survey dataset, and the number of fields in the patient survey was sufficiently representative. It was decided to carry out one set of data in the research project during the approval process and to extrapolate the results to the other datasets.

The time taken to implement this dataset within the prototype was 2:44 hours. By extrapolating the results to the creation of all project datasets, it was assumed that the total time for this task was approximately 25 hours.

As a practice during the development of the research protocol, meetings of the project participants were held to discuss the datasets required for the research project. The use of the tool allows to use a dataset template, demonstrating the overall content of datasets and the content of each individual element. Such approach takes much less time to get the field sequence, look, validation conditions and potential value issues by putting a substantial part of the decisions in real time into the datasets, while leaving the rest for the next meeting.

Consequently, the development and refinement of datasets in the research protocol, which took approximately 6 months for the reviewed project, could be reduced by 3–4 months, thus significantly saving time spent on this phase of the research. Moreover, the creation of a data-recording interface app took about one month, which can be reduced to one week in the case of tool involvement. Generating a data-recording interface app also reduced the likelihood of potential errors in the research project, as well as the costs of these error.

Conclusions

The research produced requirements and prerequisites for the development of a functioning

prototype of the data collection tool, based on a medium-fidelity prototype that considers recommendations related to existing good practices in the field of user experience and to the prototype testing carried out with the involvement of a user experience expert and the target group (medical researchers).

The new tool made it possible to significantly improve the conduct of project team meetings during the development of the research protocol where the datasets needed for the research project are discussed. If, during the initial meeting, the IT support person is able to use a real-time data collection support tool, it helps to define the datasets and at least a part of the dataset fields already during the meeting by registering a missing dataset or by preparing them until the next meeting.

At the next meeting, the data collection tool enables researchers to discuss the dataset template by demonstrating the whole content of datasets and the content of each individual element. Consequently, the field sequence, visualization, validation conditions and potential value issues can be solved during the second meeting.

Such an approach allows to hold only two to three meetings to reach the content matter of the datasets needed for the research project, and to start a discussion on data acquisition and transportation solutions, incorporating validation conditions into the datasets, and improving visual layout in parallel. As a result, significant economy of research team time and resources for development and refinement of the research protocol datasets can be achieved.

Acknowledgements

This research was funded by the European Regional Development Fund project 'Competence Centre of Information and Communication Technologies', (1.2.1.1/18/A/003), individual research project 1.5 'Creating a research support model for improving the process of collecting medical research data'.

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