Design and Evaluation of an Intuitive Administration Dashboard for a Platform used to Monitor Clinical Trials

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***Abstract*—The IMPACT platform, an integrated mobile solution for simplifying the conduct of clinical trials, has recently been developed. To enhance the platform, a new administrative dashboard was designed and developed with the goal of ensuring the quality of data collected during the trial and facilitating the necessary actions for its conduction. To improve accessibility, a role-based access policy was implemented during the design and development of the dashboard, with different roles such as data and study administrators granted access to the newly developed dashboard. Usability of the dashboard was evaluated through task-based sessions with 14 participants, and the results were analyzed using custom-defined metrics. The analysis revealed that the dashboard was well-received and highly usable, as participants were able to complete tasks with minimal errors and a reasonable amount of time, after an initial period of acclimation to the layout of the dashboard.**

***Keywords*—Administrative dashboard, clinical trial management, platform, usability**

I. INTRODUCTION

Clinical trials play a vital role in advancing medical technology by providing a means to evaluate the effectiveness of new therapies and technologies in real-world conditions. However, these trials come with a host of challenges, one of which is effective subject and data management. Data collection from various sources such as sensors, questionnaires and patient diaries can be in various formats and must be effectively integrated into the trial framework. This data may also need to be made available to clinicians and other trial operators to monitor patients' conditions and ensure safety during the trial.

To address the challenges of clinical trial management, we have indeed developed IMPACT [1], an Integrated Mobile Platform for Automated Clinical Trials. This mobile platform automates the processes of data collection, organization, and display for monitoring, allowing for a predefined and modular approach. Currently, IMPACT consists of three components that communicate via a secure ad-hoc web API: a mobile application for use by trial participants to collect data during the trial, a website for clinicians to monitor all enrolled patients in real time, and a cloud database that stores all collected data and allows remote monitoring via the website. The schema of the platform structure and components is illustrated in Figure 1.

The mobile application component of IMPACT is designed to function as an electronic diary for trial participants, allowing them to log and track all events relevant to the study.

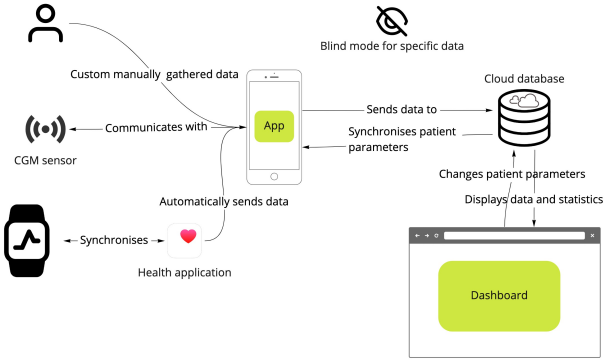

Fig. 1: Overview of the current structure of the IMPACT platform, illustrating the main components and data flow.

The application is able to automatically collect data without requiring any input from the user, reducing the burden of manual data entry. The modular approach of the application allows it to be adapted to the specific requirements of each trial, implementing solutions to collect all necessary data in the most reliable and least burdensome way for the patient.

The web application component of IMPACT is intended for use by clinicians to monitor patients' status and data in real-time, ensuring their safety and enabling them to make adjustments to trial parameters as needed.

Currently, the only way to verify the status of data collection and address potential issues is through the clinical web application, this method however is not ideal as it requires clinicians and data managers to share login credentials, which can lead to exposing personal information to data managers who may unintentionally modify data parameters. A more efficient approach is to clearly differentiate the responsibilities of data management and clinical tasks, ensuring that clinicians are only responsible for clinical duties and data managers are responsible for verifying the integrity of the data.

In this work, we present how we have implemented a solution to address this issue by implementing role-based access to the data and dividing tasks among different roles. This approach allows us to thoroughly verify the integrity of the trial conduction while also safeguarding the privacy of participants by clearly differentiating the responsibilities of data management and clinical tasks, and ensuring that only

authorized personnel have access to sensitive data.

II. MATERIAL AND METHODS

On the IMPACT platform, several new roles have been implemented, each with specific functions and permissions. These roles are:

- Superuser
- Data administrator
- Study administrator
- Researcher

The superuser role serves as the primary system administrator and is responsible for the technical management of the platform. This role has the authority to carry out any action within the system, including accessing all system data, registering any type of user, and creating new studies. Below the superuser in terms of privileges and permissions are the data administrator and the study administrator. The data administrator has almost the same privileges as the superuser, including access to all system data and the ability to register any type of user except for the superuser. However, the data administrator is not able to delete another data administrator or a superuser. This role is responsible for managing the data and ensuring its integrity. The study administrator, who is ranked below the data administrator, has access to all data related to a specific study. However, its authority is limited to only registering new clinicians. Overall, the study administrator has similar privileges to the data administrator, including the ability to create and modify details for patients, clinicians, and clinical centers within the study, as well as delete them. However, the main limitation for both the study administrator and the data administrator is their inability to enroll patients, a task that is reserved for clinicians. The researcher role has access to all data related to the specific study they are a part of, but cannot access data from other studies. A researcher is able to view the complete list of patients within their study, but can only see the clinicians who have access to the data of the study and are considered active, rather than those who do not have access and are inactive. Only data administrators have the ability to create a researcher and give it access to a study.

Access rules for the platform are directly implemented and can be managed through an administrative interface. This interface allows the study and data administrator to view all relevant information for their role and perform all actions they are authorized to take. The access rules are deeply integrated into the platform server, ensuring that all requests and actions made by each user are authorized by the platform based on their role. In this way, the system ensures that all access and permissions are granted to the right person and with clear limits and responsibilities, thus allowing for a thoughtfully secure, efficient and user-friendly management of the clinical trial data.

The mobile application and clinician dashboard have been developed using Flutter [2], a cross-platform framework that allows for the creation of a single codebase that can be deployed on mobile, desktop, and web platforms. This capability enabled the reuse of most features and design elements from the clinician dashboard for the administrative interface.

The administrative dashboard allows study and data administrators to log in and access a version of the dashboard that is tailored to their privileges i.e., the study administrator does not have access to the researchers and administrators management pages. The other main pages of the dashboard include the study overview, enrolments, clinicians, patients, and clinical centers management pages. These pages provide an overview of the trial characteristics and personnel and allow for various actions such as adding, modifying, or deleting users. For example, the patients page, shown in Figure 2, lists all patients in the study with their study-related information such as the clinical center responsible for their care and whether the patient has requested to be removed from the system in accordance with GDPR [4] regulations. Each row also includes buttons to perform relevant actions for each patient, such as modifying their information, transferring them to a new clinical center, deleting the patient from the system, and accessing a page with information on the patient's data quality and details.

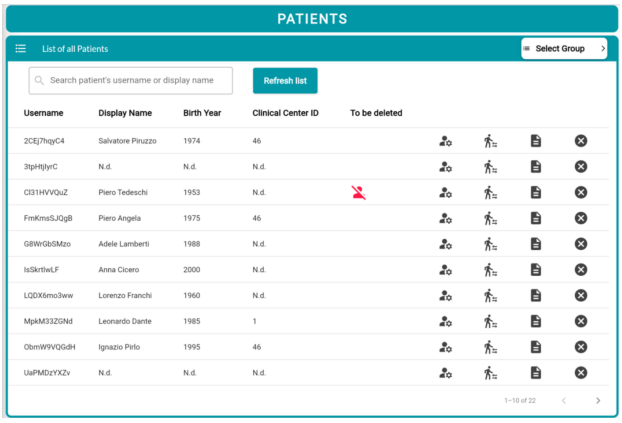

Fig. 2: Patients page of the administrative dashboard.

III. USABILITY ASSESSMENT

Usability is a crucial aspect of any tool as it directly impacts the effectiveness and efficiency with which tasks can be completed. A user-friendly dashboard that allows administrators to easily navigate and access the necessary features and functions can significantly reduce the time and effort required to perform their duties. Therefore, ensuring the usability of an administrative tool is crucial for its success and widespread adoption.

To assess the usability and ease of use of the IMPACT platform's administrative dashboard, we conducted a task-based testing session. Participants were asked to perform 10 different tasks, designed to simulate common actions that an administrator would take on the dashboard. These tasks were carefully crafted to evaluate the usability of the tool and identify any potential issues or areas for improvement. This task-based testing approach allows for an in-depth evaluation of the tool's usability, by providing insights on the participants'

experience and perception of the interface, and providing valuable feedback on how to improve it. Furthermore, this methodology is a trustable and efficient way to evaluate the user interface usability as it allows to measure the performance, satisfaction, and error rate of the tasks assigned to the participants. The 10 different tasks have been designed as follows:

1) Starting from the "Log In" screen, perform the log in and read the clinical study report on the main page, called "Study Overview." On this page, the user must then change the name of the clinical study to "Type 2 Diabetes Study," save the preferences, and log out.
2) Starting from the "Log In" screen: perform the log in and go to the "Enrollments" section. Here, the user must pause enrollment number X and then terminate enrollment number Y, entering a date of their choice and the end-of-enrollment reason "Adverse event."
3) Starting from the homepage, find the identification number (ID) of the Clinical Center associated with Padova.
4) Starting from the homepage, find the clinician "USERNAME," assign them the name "Mario Rossi" and the ID of the Clinical Center in Padova, and save the changes.
5) Starting from the homepage, the user has to find the patient "USERNAME," change their Display Name to "Mario Rossi" and their date of birth to "DATE OF BIRTH".
6) Starting from the homepage, the user must transfer patient "USERNAME" to the Clinical Center in Padova.
7) Starting from the homepage, grant researcher "USERNAME" access to study data until December 15, 2023.
8) Starting from the homepage, the user must find and view all patients enrolled with clinician "USERNAME."
9) Starting from the homepage, the user must create a new study administrator, find it, and delete it. The user must then log out.
10) Log in as a study administrator. Starting from the homepage, the user must create a new clinician and assign them to the center in Padova, giving them the Display Name "FIRST AND LAST NAME." The user must then delete the clinician.

To evaluate the ease of use, efficiency, and subjective satisfaction with the administrative dashboard, we considered a comprehensive set of evaluation metrics. These metrics, including the Task Success Rate (TSR), Time on Task (ToT), Number of Clicks, Difficulty Rating and Errors, were carefully selected to provide a thorough understanding of the performance of the dashboard from various perspective.

- Task Success Rate (TSR): Defined as the normal rate of task completion, TSR is calculated by dividing the number of users who successfully completed a task by the total number of subjects who attempted the task. A high TSR indicates that most users were able to complete the task successfully. Additionally, to evaluate the number of errors made during the task completion, the error-free task success rate (ef-TSR) was also calculated, which is defined as the number of people who completed the task without making errors divided by the total number of people who attempted the task.
- τ: the normalized increase in percentage of time required to complete the task in relation to the minimum task time (MTT)
- χ: percentage increase in clicks compared to the minimum number of clicks required to complete the specific task. Similarly to the previous metric, after defining the minimum number of clicks (MC), we have normalized the number of click done above the minimum by the minimum number of cliks.
- Difficulty: at the end of each task, users were asked to rate the difficulty of the task as low, medium, or high (corresponding to values 1, 2, and 3, respectively). The average rating was then calculated using the arithmetic mean.
- Errors: these are defined as the number of incorrect clicks made per task (as opposed to clicks, which refer to the total number of clicks made per task). The number of critical errors, or errors that resulted in the failure of a task, was also taken into account. The average number of errors and critical errors per task was also calculated using the arithmetic mean.

Furthermore, to evaluate the overall satisfaction with the administrative dashboard, participants were asked to complete the System Usability Scale (SUS) questionnaire [3] at the end of the tasks. The SUS is a widely-used tool for efficiently evaluating the usability of websites and other systems. The SUS provides a single score between 0 and 100, the higher the score, the more usable is considered the system.

IV. Results

The usability and ease of use of the administrative dashboard were rigorously evaluated through a task-based testing session with 14 volunteers (8 males, with an average age of 33 ± 13.5 years). The participants were selected to ensure a diverse range of expertise and familiarity with telemedicine, with 9 of the participants reporting low levels of knowledge, and half reporting some prior experience with telemedicine platforms.

The tests were conducted using the Zoom online video conference software, with the participants sharing their screens as they logged into the administrative interface with provided credentials and completed the tasks. Table I shows the reference values for the τ and χ metrics, which are the minimum time (MTT) and minimum number of clicks (MC) required to complete each task.

The findings of the experiments are documented in Tables II and III. The results of the task-based testing session indicate that the administrative dashboard has a high level of usability and ease of use.

TABLE I: Reference values for each task in minimum number of clicks and time of task

Task	MTT [s]	MC
1	25	8
2	27	13
3	11	3
4	19	5
5	29	5
6	13	4
7	23	7
8	19	5
9	36	12
10	51	19

The overall success rate for completing tasks was high, with the exception of one participant who made an unintentional error in one task, which resulted in a critical failure and prevented the completion of the task. Despite this, the overall success rate is commendable, particularly in light of the fact that many of the participants reported minimal prior experience with telemedicine and a significant proportion had not previously utilized a telemedicine interface.

TABLE II: Numeric results on the average success rate, time on task and clicks

Task	TSR	ef-TSR	τ	χ
1	100%	79%	195,90%	12,14%
2	93%	79%	262,50%	27,32%
3	100%	71%	332,47%	63,31%
4	100%	100%	196,70%	26,20%
5	100%	100%	59,93%	30,25%
6	100%	71%	201,25%	47,19%
7	100%	79%	240,51%	57,54%
8	100%	29%	496,17%	116,81%
9	100%	43%	360,62%	82,13%
10	100%	100%	94,18%	8,58%

TABLE III: Numeric results on average self-reported difficulty, errors and critical errors for each task

Task	Difficulty	Errors	Critical errors
1	1,00	1,00	0
2	1,50	1,79	1
3	1,50	1,36	0
4	1,14	0,50	0
5	1,00	0,43	0
6	1,21	0,93	0
7	1,64	2,50	0
8	2,21	3,21	0
9	2,36	4,93	0
10	1,21	2,36	0

From the results, it can be concluded that the dashboard is characterized by high usability and great intuitive use. Test users, who did not have much familiarity or expertise with similar sites, needed more time to become familiar with the interface. This is evident from the results presented in the τ and χ columns of Table II. While these metrics show that participants required more time and clicks than the minimum needed to complete the tasks, they also demonstrate that once participants were familiar with the interface, they were able to complete tasks with ease. However, it is worth noting that, notwithstanding the aforementioned results, only two tasks (8 and 9) presented more challenges for participants in terms of time taken, clicks, difficulty and errors. Specifically, the τ parameter shows a time increase of 500% and 360% respectively for tasks 8 and 9, compared to the minimum time required to complete the same tasks. The χ parameter also reports an increase, respectively for tasks 8 and 9, of 116% and 82% of clicks compared to the minimum number of clicks necessary to complete them. Moreover, these tasks were rated by participants as harder than the others. These results indicate that there may be room for improvement in these specific tasks, devising ways to make them less cumbersome for users and making them more trustworthy.

Nevertheless, aside from these two tasks, the metrics used to evaluate the usability of the dashboard, such as task success rate, time on task, number of clicks, and user ratings of task difficulty, generally showed low levels of difficulty and errors for the majority of tasks. Notwithstanding this, the results of the System Usability Scale (SUS) questionnaire were favorable, with a mean score of 89.3 and a standard deviation of 5.5, which indicates that the dashboard is considered to be highly usable, versatile, and user-friendly.

V. Conclusion

In conclusion, this study has presented the results of a usability evaluation of a telemedicine administration interface, which was developed to support a real clinical study. Overall, the findings of the experiments indicate that the dashboard is an easy-to-use, intuitive and reliable tool. Nonetheless, the difficulties encountered in tasks 8 and 9 should be taken into account and further research could be done to address any seasonality issues with the use of the platform, in order to ensure a thorough user experience.

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