



ClinTrial Mobile Platform

Final Report for ECE 1778

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Word Count: 1741

Introduction

Participants enrolled in clinical trials (CTs) are exposed to significant health risks. Safety of patients is a key issue in research since participants are vulnerable and are participating voluntarily. CTs have been slow to adapt to new technological developments and still largely depend on paper to track progress in research. Decisions in CTs require integration of complex pieces of information with many variables that the human mind is not always able to handle well. The ability to follow standardized research protocol, document clinically relevant occurrences, and quickly react to adverse events is crucial. With this in mind, we have designed the ClinTrial Mobile Platform (CTMP) to aid in the:

- Reduction in paperwork and increased security of personal health information through computerization
- Reduction in medical errors that may occur during clinical research through automation and review capabilities
- Standardization among various research staff and various locations through utilization of a centralized database server
- Increase in research protocol adherence and mobility of CT research through on device ability to quickly retrieve information
- Quicker response time to adverse events through real-time submission of entries to a centralized database which can allow quicker analysis of cumulated data.

The CTMP was developed for tablet devices running the Android Operating System (OS), version 3.0 or higher. The current application was developed with the following features:

- User Login
- Support for multiple CTs
- Search functionality for appointments via Patient IDs
- Calendar view for finding patient appointments by date
- Only accommodates patients contained in the patient databases
- Support for creation of a custom independent form for each visit, for each CT

- Ability to fill forms; store forms and retrieve completed forms
- Centralized server to store and retrieve data

Overall Design & Functionality

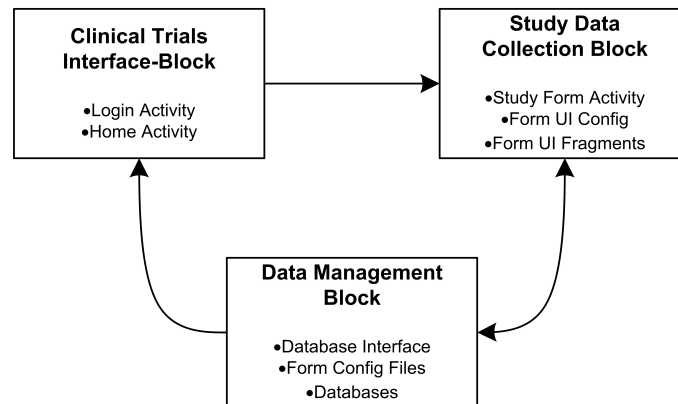


Figure 1: Top Level Block Diagram of the System

The system, as simplified in Figure 1, is comprised of three main blocks:

1. Clinical Trials Interface Block - Manages access to the app; selection of CTs and patients.
2. Study-Data Collection Block - Manages collection of data for a specific patient.
3. Data Management Block - Manages access to data located on a server.

Clinical Trials Interface Block

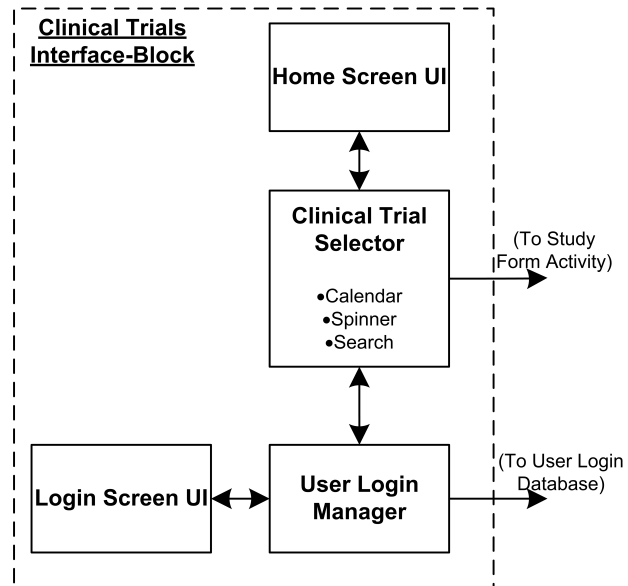


Figure 2: The Clinical Trials Interface Block

The Clinical Trials - Interface Block (See Figure 2) contains 4 sub-blocks:

- Login Screen UI
- User Login Manager
- Home Screen UI
- Clinical Trial Selector

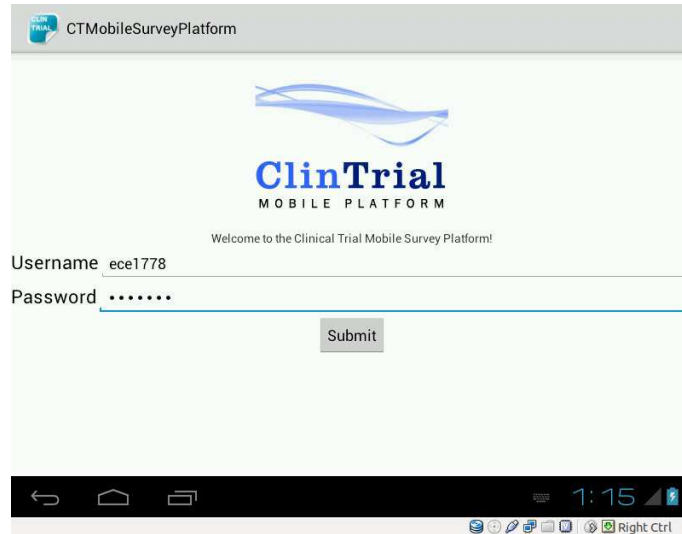


Figure 3: Login Screen UI

The Login Screen UI and User Login Manager interact with each other to allow the user to login to the application. The Login Screen UI is where the user enters their username and password (shown in Figure 3). The User Login Manager verifies the entered username and password against the values stored in a user database. Upon successful verification of the username and password, the user is redirected to the Home Screen UI (shown in Figure 4)

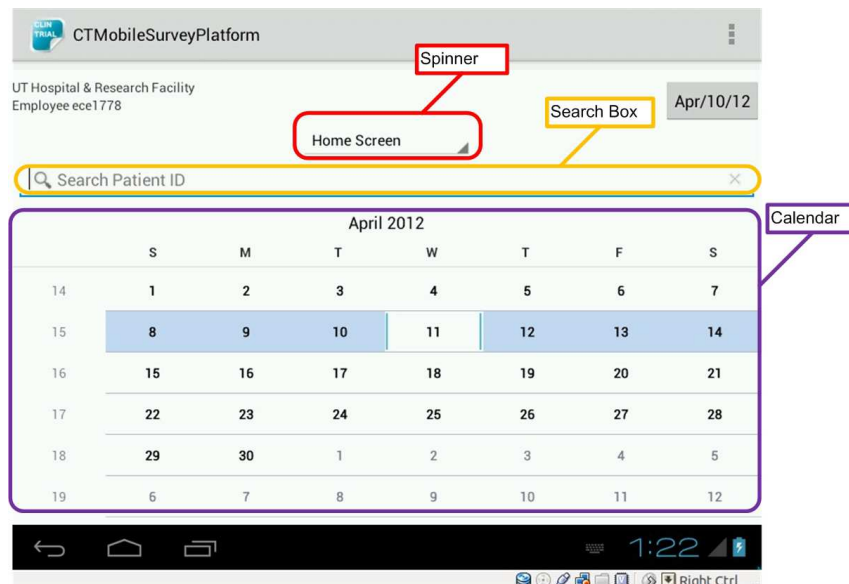


Figure 4: Home Screen UI (highlighting widgets)

The Home Screen UI contains the widgets for the Clinical Trial Selector. The Clinical Trial Selector manages the following widgets:

- A spinner, to select a specific CT.
- A search box, to search for a patient ID across all CTs.
- A calendar, to view patients with appointments on a selected date

An expanded spinner is shown in Figure 5. Selection of a CT from the spinner's list directs the user to a summary screen for the selected CT as shown in Figure 6. From a CT summary screen the user can start a Study Form Activity (in the Study-Data Collection Block) via the Study Form button.

Figure 7 shows a list of appointments generated by selecting April 11th from the calendar. Selecting one of the appointments from the list will start a Study Form Activity with the appropriate information for the selected appointment.

Figure 8 shows a sample search result. In a similar fashion to the appointment list, selecting a result starts a Study Form Activity with the appropriate information.

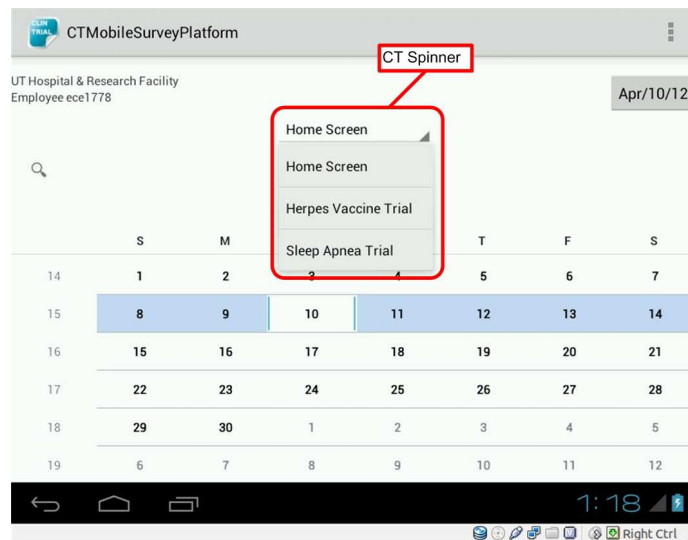


Figure 5: Home Screen UI, Highlighting the CT Spinner

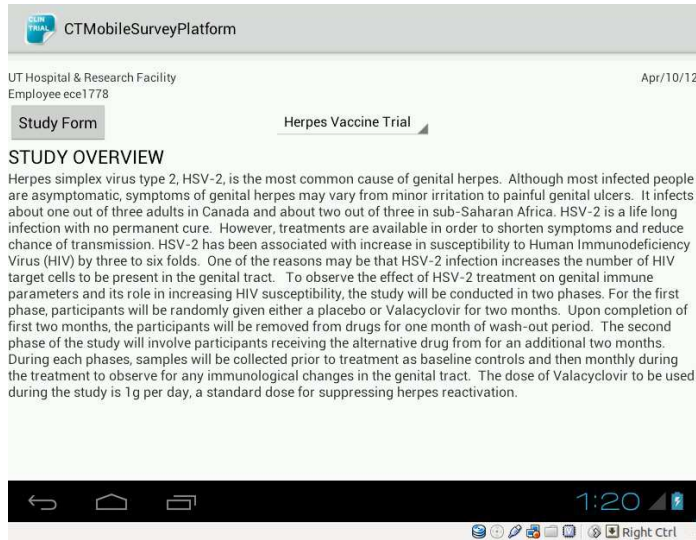


Figure 6: Protocol Screen for a Selected CT



Figure 7: View of appointments for April 11th 2012

| CTMobileSurveyPlatform | | | |
|----------------------------|-------|--------|------------------------|
| CT1 : Herpes Vaccine Trial | BB001 | Visit1 | April 03, 2012 9:00pm |
| CT2 : Sleep Apnea Trial | BB001 | Visit1 | April 03, 2012 9:00pm |
| CT1 : Herpes Vaccine Trial | BB002 | Visit1 | April 03, 2012 9:30pm |
| CT2 : Sleep Apnea Trial | BB002 | Visit1 | April 03, 2012 9:30pm |
| CT1 : Herpes Vaccine Trial | BB003 | Visit1 | April 03, 2012 10:00pm |
| CT2 : Sleep Apnea Trial | BB003 | Visit1 | April 03, 2012 10:00pm |
| CT1 : Herpes Vaccine Trial | BB004 | Visit1 | April 03, 2012 10:30pm |
| CT2 : Sleep Apnea Trial | BB004 | Visit1 | April 03, 2012 10:30pm |
| CT1 : Herpes Vaccine Trial | BB005 | Visit1 | April 03, 2012 11:00pm |
| CT2 : Sleep Apnea Trial | BB005 | Visit1 | April 03, 2012 11:00pm |

Figure 8: Results of a search for Patient IDs starting with 'BB'

Study-Data Collection Block

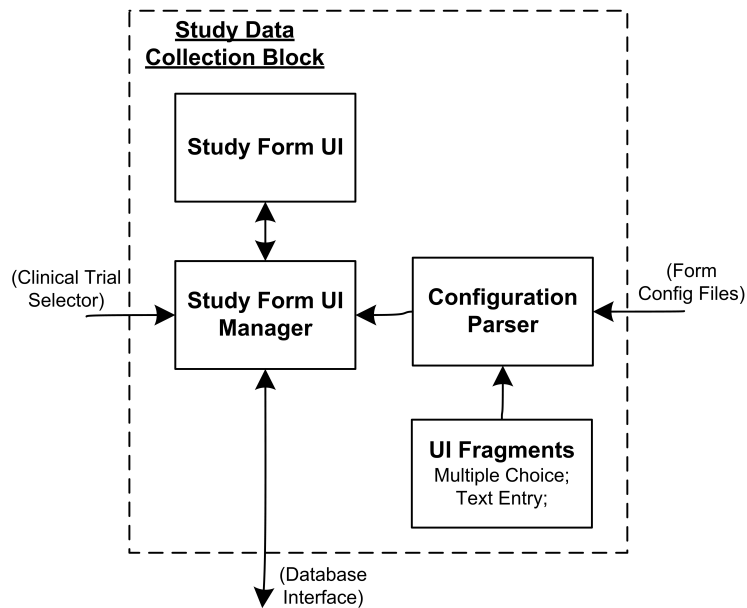


Figure 9: The Study-Data Collection Block

The Study-Data Collection Block, shown in Figure 9, contains 4 sub-blocks:

- Study Form UI - contains user interactive elements

- Study Form UI Manager - manages the elements on the Study Form UI Manager
- Configuration Parser - generates part of the Study Form UI
- UI Fragments - used by the configuration parser.

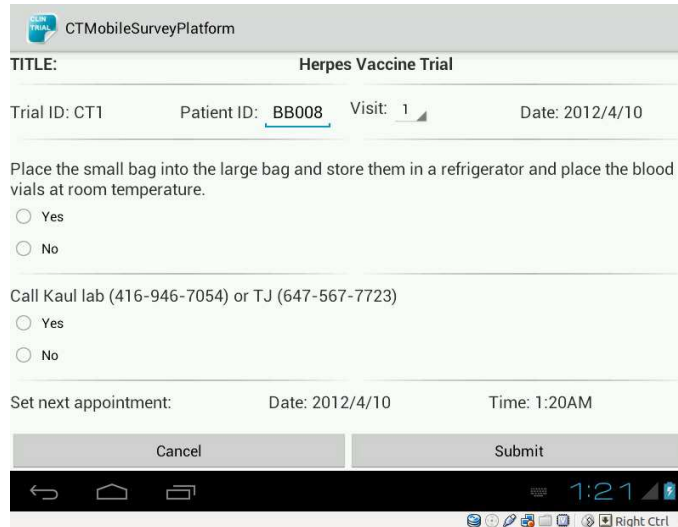


Figure 10: Study Form UI

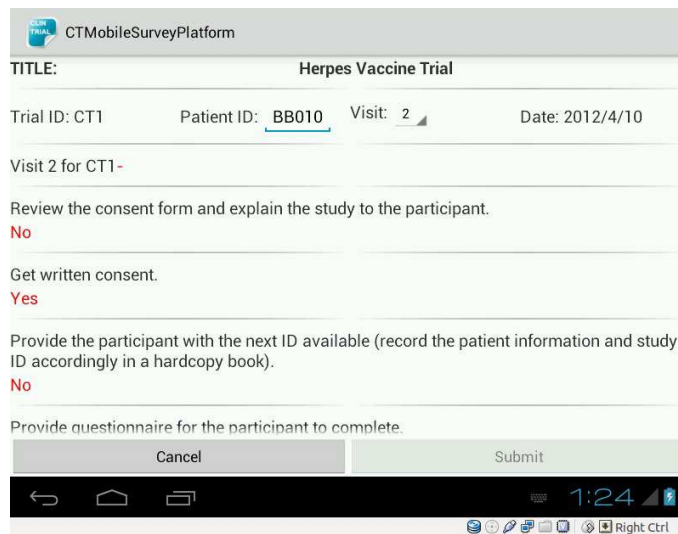


Figure 11: Study Form Review, for Visit 2 of Patient BB010

The Study Form UI, shown in Figure 10, contains elements for the following:

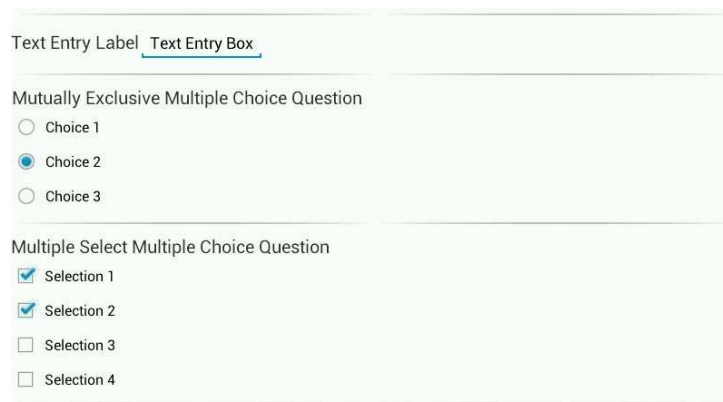
- Trial title
- Trial ID

- Patient ID
- Visit number
- Date
- A study form
- Next appointment-date selector

The Study Form UI Manager, for a given trial and patient ID, populates the Study Form UI with the appropriate data and study form interface, as shown in Figure 10. The study form which is loaded is the next new visit form for the specified patient ID, otherwise, a review form from the first visit is loaded (as shown in Figure 11). In general, it is possible to review previously filled forms by changing the visit number for a specific patient ID. The study form loaded by the Study Form UI Manager is generated by the Configuration Parser.

The Configuration Parser does the following:

1. Gets the trial ID and visit number from the Study Form UI Manager
2. Retrieves the appropriate form configuration file from the server
3. Parses the configuration file to generate the study form for the Study Form UI



The image shows a screenshot of a form interface with three distinct sections. The first section is titled 'Text Entry Label' and contains a 'Text Entry Box' with a blue underline. The second section is titled 'Mutually Exclusive Multiple Choice Question' and features three radio button options: 'Choice 1', 'Choice 2' (which is selected with a blue dot), and 'Choice 3'. The third section is titled 'Multiple Select Multiple Choice Question' and features four checkbox options: 'Selection 1' (checked), 'Selection 2' (checked), 'Selection 3' (unchecked), and 'Selection 4' (unchecked).

Figure 12: UI Fragments Supported By Configuration Parser

The Configuration Parser supports 3 form elements (via UI Fragments), shown in Figure 12:

1. Multiple-select multiple choice
2. Mutually-exclusive multiple choice
3. Labeled text entry

The form configuration file, used by the Configuration Parser to generate the study form, is a user editable plain text file. Figure 13 shows the sample configuration text used to generate the fragments shown in Figure 12.

```

te:Text Entry Label
Text Entry Box

mcqx:Mutually Exclusive Multiple Choice Question
Choice 1
Choice 2
Choice 3

mcq:Multiple Select Multiple Choice Question
Selection 1
Selection 2
Selection 3
Selection 4

```

Figure 13: Sample Form-Configuration File

Data Management Block

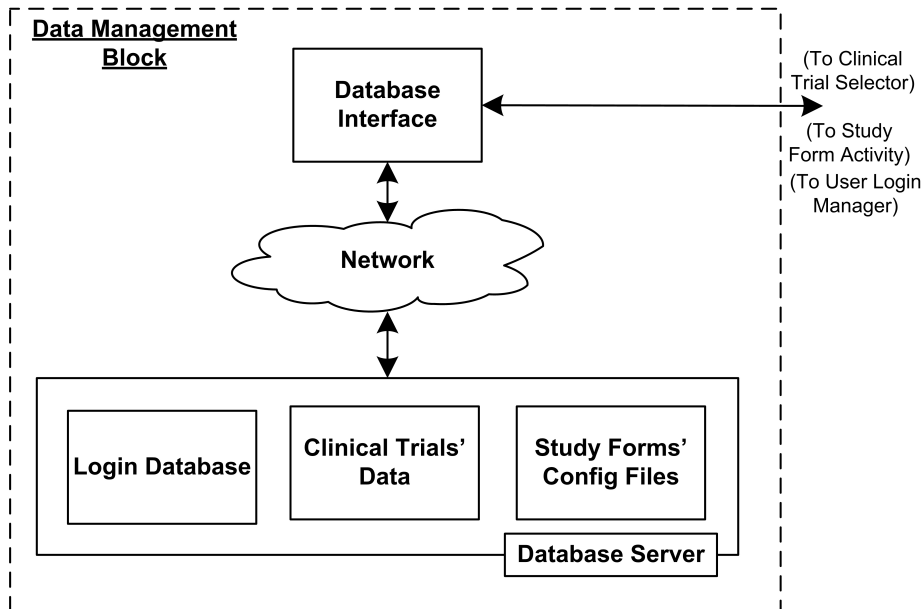


Figure 14: Data Management Block

The Data Management Block, shown in Figure 14, consists of:

- Database Interface
- Database Server

The Database Interface handles the network connection and queries between device and server. Any block requiring access to the database on the server uses an instance of the Database Interface.

The network connection to the server is always executed on a separate thread. The server is an Apache server, with PHP support and MySQL, running on a Linux Operating System. The interface to the server is a PHP script which redirects SQL queries to a MySQL database on the server.

Issues & Limitations

The current application has the current issues and limitations:

- The calendar view does not support choosing an already selected date, that is, the default selected date at start of the widget (the current date in this case) cannot be selected to view the appointments. This is a limitation in the Android OS. To overcome this issue, a button was put on the Home Screen UI to allow viewing the appointments on the current date.
- A table in the database must be manually created on the server for every visit form before data can be collected. Also, if the number of entries in the visit form changes after table creation, then the table needs to manually updated on the server.
- CTs and patients cannot be added to the database from the application - it must be done on the server.
- Previously filled forms cannot be modified in the application. This can only be done on the server.
- There is no encryption on the server and application-server connection

Future Work

To the current application the following features will be added:

- ❖ Note taking - the ability to capture hand written notes
- ❖ Multimedia capture - the ability to record images, video and audio
- ❖ Geo-Tagging - the ability to store the location where the form was filled
- ❖ Improved security:
 - Encryption of application-server connection
 - Encryption of server data
 - Implement different user security levels to allow functionality dependent on user security level
- ❖ Analysis of cumulated data - for use by principal investigators
- ❖ Patient self-monitoring and feedback - for use by study patients

What We Would Do Differently

What we would do differently if we were to restart the project from the beginning:

- More careful planning of modules and their interfaces before development - It was found that in the tight spiral design we were using, we often had to redo interfaces between blocks whenever a new functionality was added.
- A less tight spiral design model - this would allow better planned function module development between spirals.
- Develop in collaboration with clients - having feedback from actual CT staff would be helpful in evaluating our features and interface.
- Gain a better understanding of Android OS before development - would make planning easier because the Android OS do not allow certain programming constructs. One example is network connection - it is absolutely necessary to put the network connection on a separate thread otherwise Android OS would not allow the application to execute.

Division of Labour

| Member | Responsibility / Work |
|-------------------|--|
| Dario Kuzmanović | <ul style="list-style-type: none">• Mock-up of the app• Conceptual input on design and current practices in CT research• Examination of relevant literature• Design of the logo |
| Colin Chung | <ul style="list-style-type: none">• On-device database (for Spiral 1)• Clinical Trials-Interface Block• Integration of logo, background and fonts for final app |
| Valmiki Rampersad | <ul style="list-style-type: none">• Study-Data Collection Block• Data Management Block• Generation and maintenance of test data |

Apper Context

Clinical research trials are done all over the world in order to test the safety and efficacy of drugs and devices. One thing that unites all clinical trials (CTs) is that they operate on a system that is regulated by a combination of laws, guidelines, and privacy regulations. Most of these laws and regulations are quite dated and only describe research data as existing in paper format. To this day, most CTs are done using paper forms known as Case Report Forms (CRFs). The ClinTrial Mobile Platform (CTMP) app that we designed has the potential to increase efficiency and security in CT research. Currently this type of mobile device is not covered anywhere in the guidelines. CTMP would require some further development in close conjunction with people carrying out CTs. There might be some hesitation about using novel technologies in such a regulated profession; therefore, CTMP would require piloting and testing with staff to make it tailored and optimize its use in research. Nevertheless, this is one of the first mobile apps to specifically target CT staff as users. Interestingly, most of the literature I found described apps which are developed for use by trial participants. CT staff are an

ideal target for a mobile app since they are usually medically trained and if they deviate from the standard protocol, they may negatively affect the study results as well as the health of many research participants. CTMP offers quick and easy access to research protocol, easy form generation, a centralized database that increases security, and automation of research and safety procedures. Use of CTMP can improve the complex process of coordinating and executing CTs.

Currently, there is very little research on *how* CTs are done. CTMP would also be an interesting tool for use in research. For example, two CT research sites working on the same protocol could be compared for efficacy and rate of medical errors. One site would use the traditional paper CRFs and the other site would use CTMP to assist them with research procedures. The findings from a study like this would provide more definitive answers and give CTMP legitimacy for use in a discipline that is driven by research results. Even though most research trials do not use tablets or other mobile devices, they often depend on computer databases for things such as medical records. Further development on CTMP would need to take compatibility with other types of data into consideration. In conclusion, CTMP is a welcome addition and could help trial coordinators, investigators, and other personnel in several aspects of the process. I believe that the use of CTMP can facilitate improvement in the quality and reliability of clinical studies.

Conclusion

The application met the functionality we had planned to implement. However, some of the future work will have to be implemented (specifically, the security enhancements) before the application can be used in the field.