

Draft Vision and Scope
Participant Tracking Database Development Project
Medical Studies Center
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Purpose

This document outlines vision and scope of the project.

1 Business requirements

1.1 Background

The Medical Studies Center (MSC) screens possible study participants through initial use of a telephone survey. Responses are used to eliminate potential participants with characteristics inappropriate for the studies being established. A subset of the remaining candidates is randomly selected for inclusion in the study.

Occasionally, multiple efforts to contact a possible participant are required to obtain a survey response, and in some cases the phone call simply reveals that the individual is no longer interested in participating in a study.

Data from the telephone surveys are themselves subject to study. It is therefore desirable that these data be stored in a system that facilitates their later transfer to data analysis systems such as SPSS.

Additional information to be tracked includes:

1. assignment of persons to studies
2. assistance in scheduling visits in accordance to the parameters of the study at hand
3. tracking of whether planned visits are actually fulfilled
4. scheduling of providers to visits
5. originally planned visit schedule in cases where a participant drops out of the study prematurely (useful for evaluating project finances, etc.)

The current system used for these function is a web-based application which in several respects is not satisfactory. In particular, transfer of telephone survey data from this system into data analysis software is difficult and time consuming. Additionally, there are limitations regarding visual display of information for use by survey interviewers which are irritating.

1.2 Business opportunity

It seems quite plausible that a custom database application can be implemented which provides the required functions without the liabilities of the current web-based application. This would result in savings of time and expense during transfer of data to analysis software, with a possible reduction in errors that would otherwise accrue during repeat keypunching of the telephone survey data. In addition, the forms used by interviewers of telephone survey responses will be better arranged for convenience of the interviewers.

1.3 Business objectives

Reduce handling of data and improve quality of information tracking for telephone surveys and visit schedules.

1.4 Customer or market requirements

If the customer is viewed to be the potential or selected study participant, there are no formal standards or requirements applicable to the situation.

1.5 Value provided to customer

Potential participants are unlikely to sense the value of the new system directly. An improvement in tracking of contact records and requests for later contact may actually result in improved service to these individuals, even if this is undetected by those persons directly.

1.6 Business risks

A custom application will be subject to some level of ongoing maintenance expense due to changes in the underlying software platforms used for the application. For instance, future versions of the database software used (e.g. FileMaker, Access, etc.) may eliminate functions or features provided in the current version. This change in turn may necessitate changes in application features originally designed to use those features. With regard to FileMaker, a major revision has now been released which might result in such a situation. However Giant Health Sciences Facility personnel (Joseph Breeze, personal communication) have indicated that GHSF has no intention to change versions of FileMaker in the near future. In addition, GHSF holds a site license to the current version of FileMaker and runs several instances of FileMaker Server for use of employees and staff. Risks from this source therefore seem low.

A custom application may be subject to some additional level of risk from natural catastrophe, equipment failure, etc. However, the use of FileMaker together with residence of the application on an instance of FileMaker Server operated by GHSF information technology staff should practically eliminate risks from such sources, as FileMaker Server is extremely stable and GHSF can be expected to have effective practices for protecting data in such a situation.

2 Vision of the solution

2.1 Vision statement

The delivered system will facilitate tracking of potential study participants, telephone contacts with them, the responses provided to their screening interviews, and records of their assignment to studies and their scheduled visits within assigned studies.

2.2 Major features

2.2.1 Overview

The delivered system will be built using FileMaker Pro V6. Application files will be hosted by an instance of FileMaker Server operated by GHSF information technology staff. An “opener” database will be located on on each computer from which data will be accessed. The user will open FileMaker using this database, which will in turn connect to the shared files hosted by FileMaker Server.

2.2.2 Information Subjects

Major information areas to be tracked will include:

1. **Person** – Information about a potential/actual study participant. Includes address.
2. **Phone** – An arbitrary number of phone numbers may be stored for each person, with indication of the type of phone (fax, mobile, etc) and the person's preferred use of that phone number ("weekends", "evenings", etc.)
3. **Contacts with potential participants** – Record of an individual phone call to a person, with a brief account of the outcome of that contact, need for follow-up, a record of which staff member made the call, etc.
4. **Survey responses** – Record of a person's responses to the telephone survey
5. **Study** – A very brief description of a study to which persons may be assigned as participants.
6. **Study participants** – Assignment of persons to a study, together with an indication of whether they are a candidate for removal from the study, or whether they have been removed.
7. **Study visit template** – A "template" describing a standard set of "target visits" to be used for all participants in a specified study, including time offsets between visits, visit purpose, etc.
8. **Target visit** – A specific visit required of the study participant by the study protocol.
9. **Scheduled visit** – A specific schedule planned to correspond to a "target visit". It is possible that several visits will be scheduled/attempted before a "target visit" is actually fulfilled. This may happen due to transportation problems, illness, etc. [LB – I felt the distinction between the "target visit" and a "scheduled visit" was perhaps the easiest way to track the application of time windows for visits while simultaneously maintaining a record of visits that had been postponed, missed, etc. It seemed to me that this additional information could be very useful...]
10. **Provider** – Health care provide involved in examinations, etc.
11. **Provider appointment** – An appointment scheduled for a participant with a specific provider [LB – I believe it was mentioned to me that a single "visit" by a participant might involve interactions with several providers, and that all of these participant/provider interactions should be tracked individually. That is the function of the "appointment" here as distinguished from the "scheduled visit". A single "scheduled visit" may include several provider appointments...]
12. **Staff member** – Very brief summary of staff expected to work with database. Used primarily to characterize phone contacts, follow-up responsibilities, etc.

2.2.3 Specialized Functions

Specialized functions to be provided will include:

1. **Report** of visit schedule for an individual study participant, suitable for provision to the participant
2. **Report** of all appointments of study participants with a selected provider for a specified day
3. **Report** of all appointments of study participants with a selected provider for a specified week
4. **Ability** to print an envelope addressed to a specified person
5. **Report** of all participants involved in a specified study

6. **Mechanism** to allow efficient search for a specific person using name, phone number, address
7. **Ability** to rigorously disconnect study records from identifying information for a person
8. **Functions** to highlight persons who have not completed required visits within the required time window, etc.
9. **Ability** to establish a full set of visits for a study participant in essentially a single operation
10. **Ability** to mark all scheduled visits for a participant as “cancelled” while still maintaining records that these visits had been scheduled. To be used in cases where a participant drops out of a study.
11. **Export** of data to format readily used in SPSS.
12. **Export** of data on persons, suitable for ready use in mail merges using Microsoft Word
13. **Functions** to highlight possible duplicate entries of the same person via checks for similar phone number, addresses, etc. These will be designed to provide warnings automatically as a record for a new person is entered. [LB – Should a check of first name and last name also be tried? This would seem the most obvious way to detect duplicates...]

2.2.4 Security

Data access will be governed using FileMaker Pro’s inherent security features. A single group and password will be established for each user group defined in this document, with appropriate privileges defined in all component databases of the application.

2.2.5 Multiple User Features

The system will allow use by up to 10 individuals, probably with no more than 3-4 simultaneous users at a time. It is unlikely that users will be accessing/editing the same record simultaneously.

2.2.6 Value List Management

All value lists used throughout the system will be defined in a single database to facilitate maintenance and upkeep. Copies will be distributed to all other component databases in the application via FileMaker’s inherent abilities to copy value lists.

2.2.7 Application Upgrade Automation

The application will include automation designed to facilitate transfer of data from an obsolete copy of the application into a new revision. This process will not be totally automated, but will streamline data transfer considerably.

2.2.8 Data Volume

The system is expected to contain roughly 600 persons to begin, and roughly 1000 after a year. Each of these will have at least 1-3 phone numbers, 1 to several contact records, and one survey response.

Roughly 10-20% will be accepted as study participants. Each of these may have around 15 visit records associated.

2.3 Development Standards

The application will employ standard FileMaker Pro development templates used routinely by the developer. Naming conventions will be closely modeled after Core Solutions standards.

2.4 Assumptions and dependencies

The system does not track the schedule of availability of providers, but rather assumes that their schedules are documented outside the current system. The system as now conceived also does not attempt to prevent or warn the user of “double-scheduling” of participants’ visits to providers, etc.

3 Scope and limitations

3.1 Scope of initial release – Survey Tracking

The initial release will provide ability to track and store the following information areas outlined above under “information subjects”:

1. person
2. phone
3. contact
4. survey responses
5. staff member

Specialized functions provided in this release will include:

1. Ability to print an envelope addressed to a specified person
2. Mechanism to allow efficient search for a specific person using name, phone number, address
3. Export of data to format readily used in SPSS.
4. Export of data on persons, suitable for ready use in mail merges using Microsoft Word
5. Functions to highlight possible duplicate entries of the same person via checks for similar phone number, addresses, etc.

3.2 Scope of subsequent releases

Several subsequent releases will be used to provide the additional functionality required of the complete product.

3.2.1 Second Release – Study Visit Scheduling

The second release will add the ability to schedule participant visits. This will include features designed to handle the following information areas outlined in the “information subjects” section above:

1. Study
2. Study participants
3. Target visit
4. Scheduled visit
5. Provider
6. Provider appointment

Specialized functions provided in this release will include:

1. Report of visit schedule for an individual study participant, suitable for provision to the participant
2. Report of all appointments of study participants with a selected provider for a specified day
3. Report of all appointments of study participants with a selected provider for a specified week
4. Ability to rigorously disconnect study records from identifying information for a person
5. Functions to highlight persons who have not completed required visits within the required time window, etc.

3.2.2 Third Release – Automated Visit Scheduling

The third release will add the ability to automatically schedule the full slate of visits required of a study participant. This will include features designed to handle the following information areas outlined in the “information subjects” section above:

1. Study visit template

Specialized functions provided in this release will include:

1. Ability to establish a full set of visits for a study participant in essentially a single operation

3.2.3 Fourth Release – Feature Enhancements

Specialized functions provided in this release will include:

1. Ability to mark all scheduled visits for a participant as “cancelled” while still maintaining records that these visits had been scheduled. To be used in cases where a participant drops out of a study.

3.2.4 Maintenance Releases - Revisions

These releases will address user needs for interface changes to enhance ease of use, repair of programming errors, etc.

3.3 *Limitations and exclusions*

The system as now conceived

4 Business context

The application will be used by staff of the Medical Studies Center during routine work.

4.1 *Customer profiles*

The term “Customer” here is used to refer to any person directly or indirectly benefiting from use of the product.

4.1.1 Telephone Interviewers

These individuals will be involved in contacting prospective study participants and recording responses to the surveys used to identify those persons who are appropriate for participation in studies.

4.1.1.1 Major Benefits

Reduced keypunching [LB – Are these the same users that would be involved in keypunching data 2d time to transfer information from ClinicVisitScheduler to SPSS?] , improved ease of entry for survey responses, improved ease in recording/using contact histories.

4.1.1.2 Likely Attitudes Toward the Product

It is likely this group will feel very well served by the new application – they are likely to be quite positive.

4.1.1.3 Key Product Features of Interest

These features are key for this user group:

1. Survey response edit forms
2. Person search functions
3. Contact history functions
4. Phone number storage/retrieval

4.1.1.4 Success Drivers

Success drivers include:

1. Ease of use of person search functions
2. Clarity of interface for

4.1.1.5 Known Complaints That Must Be Addressed

Problematic interface for entry of survey responses, labor intensive data transfer of survey data from current system to SPSS, etc.

4.1.2 Clinic Visit Staff

These individuals interact with participants and providers to schedule visits required for a study.

4.1.2.1 Major Benefits

Person search functions and reporting functions applied to scheduled visits should be of great benefit.

4.1.2.2 Likely Attitudes Toward the Product

Assuming the product offers an amount of process streamlining that is easy to envision at present, members of this user group will be pleased with the product. However, some members of this group are anxious about working with computers, and may need individual assistance/training to overcome their fears.

4.1.2.3 Key Product Features of Interest

Key features will include:

1. Interfaces used to review and edit visit scheduling.
2. Interfaces used to review and edit provider information
3. Reports of visit schedules

4. Automation to highlight participants who are in danger of violating study guidelines for visit timing, etc.

4.1.2.4 Success Drivers

The key success drivers will include:

1. Ease of use for scheduling interfaces
2. Clarity and utility of output for scheduling reports

4.1.2.5 Known Complaints That Must Be Addressed

The current system really does little or nothing to address visit scheduling, and the improvised techniques adopted to apply the current system prevent ready changes of scheduling and/or rescheduling of visits.

4.1.3 System Administrators

These individuals will be involved in backup and maintenance operations for the system. They may also occasionally be involved in troubleshooting solutions to problems with the application.

4.1.3.1 Major Benefits

Probably not relevant, since there is essentially no current system administration associated with the web-based approach in current use.

4.1.3.2 Likely Attitudes Toward the Product

In general, maintenance should be fairly simple. The inclusion of features to offer reminders of needed maintenance tasks might be viewed positively.

If security is handled via individual user accounts, this group may find the administration of these accounts somewhat painful. This will depend partly on the rate of staff turnover. However, with a group of 10 users, it is probably likely that an on-staff administrator would not get enough practice establishing new user accounts to make this an easy task. If staff is very stable, this task may be so rare that it becomes a non-issue.

4.1.3.3 Key Product Features of Interest

Overall system architecture/design.

4.1.3.4 Success Drivers

System design must result in a reliable, stable system with predictable behavior. This group will not want to be often involved in troubleshooting VisualBasic programming, etc.

4.1.3.5 Known Complaints That Must Be Addressed

Changes in administrative details of current system require a call to technical service for the software manufacturer. Response is often unacceptably slow, despite the best efforts of all involved parties. There is really no replacement for having an on-site administrator.

4.1.4 Primary Researchers

These individuals will be involved in reviewing information entered by others. A specific distinction with "Clinic Workers" is that the ability to designate a study participant as no longer in the study will be reserved to this group.

4.1.4.1 Major Benefits

The new system should reduce staff time spent in data management and transfer of data from the “participant tracking” system to the data analysis system. This should result in more staff time available for other work.

4.1.4.2 Likely Attitudes Toward the Product

Almost entirely determined by gains in efficiency and ease of use realized by research staff during use of the application.

4.1.4.3 Key Product Features of Interest

The following features are of particular interest to this group:

1. Ability to restrict authority to remove individuals from a study to the “primary researchers” user group.
2. Ease of data transfer to SPSS

4.1.4.4 Success Drivers

The most likely success drivers are:

1. Reasonable development cost
2. Ease of maintenance, lack of need for highly proficient system administrators for reliable operation of system
3. Overall efficiency gains of group resulting from implementation of new system

4.1.4.5 Known Complaints That Must Be Addressed

Transfer of data to data analysis software must be much easier than the current system.

4.2 Project priorities

The following features are first priorities:

- Survey response data entry and storage
- Survey response data exporting
- Person search functions
- Contact history
- Phone tracking
- Tracking of study assignments
- Tracking of scheduled visits
- Report of participant’s scheduled visits
- Report of provider’s scheduled daily visits

The following features are of smaller priority:

- Ability to automatically schedule a series of visits in a single action
- Ability to track individual provider appointments within a single scheduled visit

- Ability to maintain a history of scheduled visits for a participant who has been dropped from the study
- Ability to reserve final authority for removing a participant from a study for the “research leader” user group (This could always be provided via training of database users rather than through system automation... although automation would be more reliable.)
- Search features for participants using name, etc.

5 Product success Factors

Timing is essential, as use during studies currently planned for the near future is expected. However, these timelines currently seem to provide enough time to complete the development in a comfortable fashion.