Designing A Community-based Social Trust System in Public Health Using Service Oriented Architecture

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Abstract—**One of the major challenges of community-based research is recruitment of community members who will participate in clinical trials, continue for the duration of the trial, and provide accurate, sensitive personal information. This challenge can be overcome by establishing greater trust between researchers and communities.**

This study focused on designing a system to address trust issues between a community and clinical researchers. The study described a methodology for translating non-functional wants and needs into technical requirements that were used as input to a Service-Oriented Architecture (SOA) approach to design a solution. Unlike a typical SOA that is derived from a single enterprise's business goals and processes, this solution was based on multiple stakeholder goals and general clinical trial processes.

The resulting architecture focused on improving communication between researchers and communities and was validated by mapping the technical requirements against a trust-building model and by modeling the solution using Petri nets.

Keywords-clinical data management system (CDMS); clinical trial management system (CTMS); clinical research; community trust building; healthcare system; Petri net design model; service modeling; service-oriented architecture (SOA); service-oriented modeling and architecture (SOMA)

I. INTRODUCTION

Clinical researchers use clinical trials "to evaluate the effectiveness and safety of medications or medical devices by monitoring their effects on large groups of people [1]." One of the major challenges of clinical research is the recruitment and retention of participants in clinical trials. Enough qualified candidates must be enrolled to ensure there is a valid sample size. Participants must be fully informed of the potential risks, as well as the benefits, of participating. The program must be designed to effectively and accurately elicit potentially sensitive personal information. Moreover, the program must be executed in a manner to ensure continued participation by trial subjects for the duration of the trial. Ineffective recruitment and retention practices can elongate trial phases and increase treatment development costs.

This paper focuses on a study to develop a software solution to address trust-building issues between clinical researchers and a community where clinical trials are being conducted. The primary goal of the study was to demonstrate how various modeling techniques could be used to architect a solution to improve communication between the researchers and members of the community. The output of the study was the architecture for a software system.

A methodology was developed to derive a set of technical requirements from non-functional wants and needs. To ensure that there was strong linkage and traceability between the business goals of clinical trial participants and the software solution, the architecture was developed using a SOA approach. Selected service components were modeled using Petri nets as part of solution validation.

The remainder of this paper is organized as follows: First, background information is provided, including a description of challenges associated with establishing trust and recommended solutions. Next, the requirements methodology and SOA approach are described. Last, conclusions and future work are noted. Throughout this paper, the tables show sample data due to space limitations.

II. BACKGROUND INFORMATION AND PROBLEMS IDENTIFIED

A. Trust-Building Challenges

According to Getz and Kremidas [2], there was significant public distrust in clinical research, especially among adults in minority communities. Surveys conducted in 1996, 2002, and 2006 [2] showed a decline of public trust in clinical research information from pharmaceutical companies, with 72% indicating trust in the information in 1996 and only 21% ten years later.

When there is lack of trust between clinical researchers and local communities, researchers may not be able to enroll a sufficient number of active participants into a clinical trial, those who do enroll may not continue to participate for the duration of the study, or the data provided by trial subjects may not be complete or truthful.

B. Trust-Building Solutions

The clinical trials process is divided into planning, execution, and outcome stages. Actions to build and maintain trust can be incorporated into each of these stages.

When multiple clinical trials are focused on the same community, additional trust-building actions may be required. For example, if the clinical trials process is inconsistent from sponsor to sponsor, or if trials offer different treatments for the same health issue, trial candidates may become confused. Providing a consistent approach across these trials can reduce inconsistencies and reinforce trust.

C. A Trust-Building Model

Trustworthiness is defined as being "worthy of confidence [3]." Lewicki and Tomlinson [4] further assert that the assessment of an individual's trustworthiness is based on three dimensions, ability, integrity, and benevolence. The more an individual exhibits these behaviors, the more that person is deemed trustworthy.

Although these dimensions were defined for assessment of individuals, they were used in this study to determine if the proposed solution could improve perception of researcher trustworthiness.

D. Commercial Software and Tools.

To successfully manage a clinical trial, general-purpose or specialized software is used for trial planning, monitoring, management, execution, and administration. Clinical Trial Management Systems (CTMSs) focus on trial management, while Clinical Data Management Systems (CDMSs) focus on the data associated with the clinical trial. Cancer Biomedical Informatics Grid Clinical Trials Suite (caBIG CTS) [5] is a SOA-based CTMS that was used with this study.

E. Introduction to Service-Oriented Modeling and Architecture (SOMA)

SOMA is an IBM methodology integrated with IBM Rational Unified Process (RUP/SOMA), a tool for defining and customizing processes. RUP/SOMA consists of three phases, service identification, service specification, and service realization.

The purpose of service identification is to identify an initial set of services that are aligned to business goals. During the service specification phase, the structure of the service architecture is developed and refined. The service realization phase focuses on an internal view of a service. The model developed during one phase can be traced to models in the next or previous phase, thus providing traceability.

F. Why Use a SOA Approach

An ideal framework for architecting a software solution that supports trust-building capabilities is one that lets the architect address key requirements for the solution. The system must be integrated with existing systems. The system must accommodate multiple CTMS and CDMS back-ends. The system must be sufficiently flexible to accommodate the specific requirements of each supported clinical trial. The system must support rapid deployment and be cost-effective.

Using a SOA will address these needs. Loose coupling enables easier integration. Service composition allows the system to be customized and extended. Specific community needs can be addressed with tailored front-end applications accessing common back-end services. Sharing services development and maintenance means lower costs. The system will be transferable and reusable among a greater number of research organizations.

III. Our Approach in Solving the Problems

A. Translating Problems to Requirement Specifications

Abstract needs such as trust and the solutions for building trust are not specific enough to be able to derive a software functional specification. Before a system can be architected, these high-level needs and the actions to address them must be synthesized and refined in order to identify an implementable set of software requirements.

A survey of research on requirements engineering [6] did not reveal an existing methodology that could be used to transform non-functional wants and needs. Because of this, we developed a new methodology.

In this section an approach to translate needs into software requirements will be demonstrated. This approach consists of four steps [28]:

- Problem Analysis - Needs are analyzed and grouped into common themes.
- Solution Analysis – Suggested actions are mapped against problem themes, and candidates for implementation via a software system are identified. Risk analysis is performed against the candidates to understand which actions are most likely to yield the most benefit and which carry the most risk to implement.
- Solution Mapping – Selected actions are mapped to existing business use cases, and candidates for implementation are further refined.
- System Conceptualization – A high-level, external view of a proposed system is defined. This view is used to define technical requirements via requirements analysis.

These steps and their relationship to a typical software development lifecycle are illustrated in Fig. 1.

1) Problem analysis: Needs are elicited from domain experts, are usually expressed in an unstructured manner, and may be described in terms of problems to be solved. These descriptions may be different facets of the same set of core problems, so the purpose of this first step is to aggregate the problems into common problem themes. Table I shows the partial results of aggregating the challenges associated with trust. Note that each problem theme is numbered to permit traceability later.

2) Solution analysis: During this step, suggested actions are identified through techniques such as brainstorming and mapped against the problem themes identified in the previous step to ensure that all themes have been addressed. If an action is mapped to a problem theme, it is considered to be a solution

to that problem. As with problem themes, each suggested action is numbered to permit traceability.

Fig. 2 illustrates a partial mapping for problem theme T-1 and for suggested action A-1. Note that there is a many-to-many relationship between problem themes and suggested actions.

After this mapping was completed, the suggested actions were grouped according to the clinical trial stage where the actions were most appropriate. Table II shows the initial results of this analysis. Review of the table showed that all problem themes were addressed.

Solution mapping: Next, the actions defined in the previous step are mapped to existing business processes. Mapping an action to a business process implies that the business process will incorporate that action. If an appropriate existing business process cannot be identified for an action, a new business process must be created.

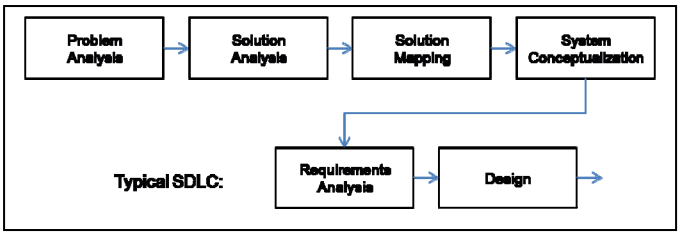

Figure 1. Approach to map needs to requirements.

TABLE I. SAMPLE RESULTS OF PROBLEM ANALYSIS

Problem Theme	Problem
T-1. Previous encounters	Previous researchers did not follow through on commitments. There is inadequate follow-up.
T-2. Lack of understanding of the research process	The research process is not thoroughly explained. Candidate trial subjects misunderstand the difference between research and medical care. Candidate trial subjects fear loss of medical records privacy.

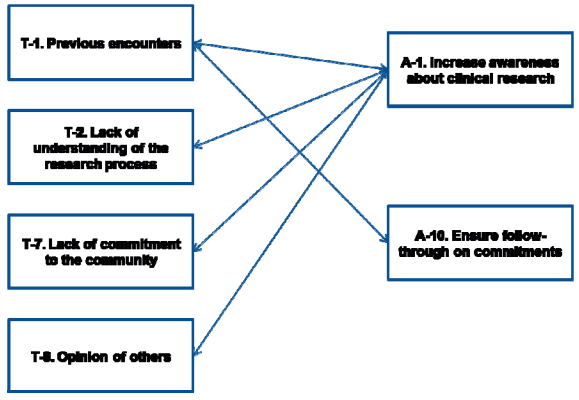

Figure 2. Sample mapping between problem themes and suggested actions.

This study used a business architecture model for clinical trials that was developed by caBIG [7] to identify existing business processes. Table III shows the mapping and indicates if a new process must be defined or if an existing one must be modified.

3) System conceptualization: A view of the new business processes and their relationships to existing ones is then developed. The results are shown in Fig. 3. Manage Community represents new business processes and is shown as a separate group of business processes that manages interactions between the community and clinical trials personnel. This approach shields the community from differences in business processes used by various researchers who may be operating within the community and from different clinical trial systems used for managing trials of interest.

The roles on the left side of the figure correspond to major actors involved in the processes. The boxes on the right represent systems used by clinical trials personnel. The arrows represent the flow of information between actors, processes, and systems. This external view is then used to define more detailed functional and non-functional requirements as part of requirements analysis.

B. Using a SOA-Based Solution to Build Community Trust

Because most clinical trials use information technology to manage their processes, this study assumed that new services had to fit within the context of existing systems. For this study, caBIG [9], [10] was the basis for any enterprise-level modeling that was required.

TABLE II. SAMPLE RESULTS OF SOLUTION ANALYSIS

Trial Stage	Problem Theme	Suggested Action (Solution)
Pre-Planning	T-1. Previous encounters	A-1. Increase awareness about clinical research and the clinical trials process through education, outreach, and advocacy.
	T-2. Lack of understanding of the research process	
Planning	T-1. Previous encounters	A-3. Incorporate a community perspective in the clinical trials process.
	T-2. Lack of understanding of the research process	A-4. Build community awareness of researcher presence; provide clinical trials education that is culturally appropriate.

TABLE III. SAMPLE MAPPING OF SOLUTION TO BUSINESS PROCESSES

Suggested Solution	Add or Modify Process (Details)	Business Process
A-1. Increase awareness	Add a community outreach process. Target media, policy makers, healthcare providers, and the community-at-large.	Perform Outreach
A-3. Incorporate community perspective	Modify processes per other business requirements.	All existing business processes, where appropriate
A-4. Provide culturally appropriate education	Add a community outreach process. Target media, policy makers, healthcare providers, and the community-at-large.	Perform Outreach

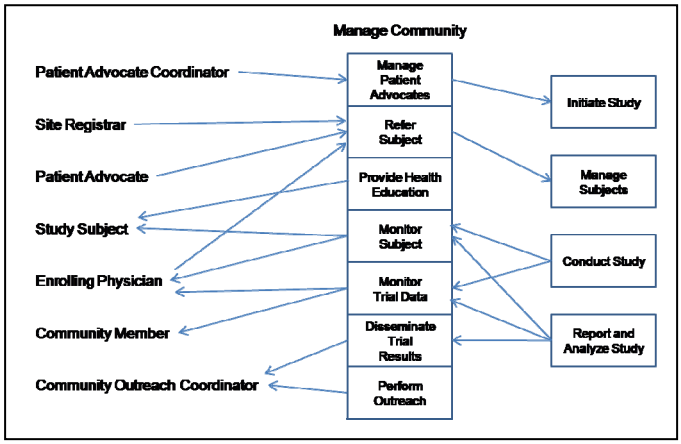

Figure 3. Interaction between new and existing business processes.

1) Service identification: During this phase, the SOA Service Model and Goal-Service Model are developed. Because community members are important participants in the clinical trial process, we extended SOMA to include the community when performing domain decomposition, and we included goals of the community in the goal hierarchy.

Table IV illustrates the relationship between services and goals. Researcher goals are represented by sub-goals 1.1, 1.1.1, and 2.1; and community goals are represented by sub-goal 3.

TABLE IV. SAMPLE GOAL-SERVICE MODEL

Goal or Sub-Goal	Key Performance Indicators (KPIs)	Metric	Services
1.1: Improve trial subject recruitment rates.	X% increase in the number trials that successfully enroll the required number of eligible subjects within the planned recruitment period.	Record planned enrollment time lines versus actual.	Manage Trial Candidate Request Subject Referral Manage Referral Request
1.1.1: Increase trust between clinical researchers and the communities where they operate.	Reflected in KPI for Goal 1.1.	n/a	Recruit Patient Advocate Register Patient Advocate
2.1: Improve quality of data submitted by trial subjects.	Reduce the number of trial data points that must be omitted from the study by z%.	Record status of data points for a given trial subject.	Recruit Patient Advocate Register Patient Advocate
3: Receive effective treatment for a health concern.	Medical condition is cured or successfully managed.	Recorded as part of trial execution. Identified during trial planning	Recruit Patient Advocate Register Patient Advocate Manage Trial Candidate

2) Service specification: During this phase, the SOA Service Model is updated with service exposure decisions, service interdependencies, and service messages. The SOA Design Model is created to provide services and component details.

To enable early automated validation, the internal component flows were modeled with Petri nets using Platform Independent Petri net Editor 2.4 (PIPE2) [11]. Fig. 4 shows the component flow for Register Patient Advocate [29], [30]. Annotations for places and transitions are shown in Table V.

3) Service realization: During this phase, the Service Model is updated with realization decisions, and a proof-of-concept is conducted. The proposal to use 3rd-party services brought significant risks, such as loss of service or data, performance problems, unreliability of service, lack of interoperability, and format changes [12], [18] so the proof-of-concept focused on accessing caBIG's Patient service.

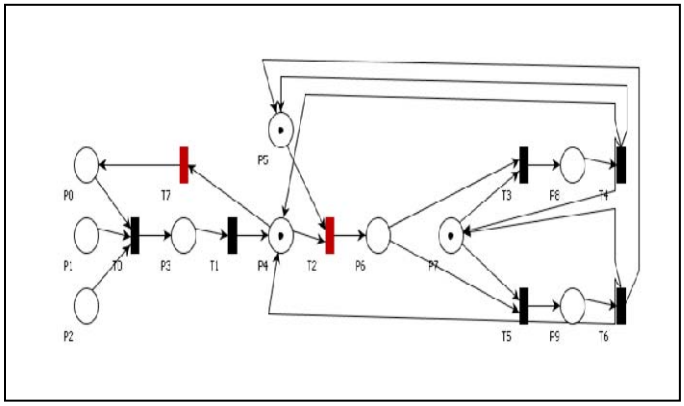

Figure 4. Component internal flow for Register Patient Advocate.

TABLE V. SAMPLE GOAL-SERVICE MODEL

Place / Transition	Interpretation	Description
P0	User	Not logged in
P1	Web Page	Application logon page (web server is available)
P2	Data	List of authorized users
P3	User	Logged in
P4	Web Page	Patient Advocates page
P5	Database	Connection to Advocates database
P6	Data	Retrieved database entry
P7	Database	Connection to Trials database
P8	Data	Registered patient advocate
P9	Data	Dropped patient advocate
T0	Task	Log in user
T1	Task	Display Patient Advocates page
T2	Task	Obtain database thread; retrieve database entry for patient advocate
T3	Task	Obtain Trials database thread; register patient advocate to trial
T4	Task	Release database threads; display home page
T5	Task	Obtain Trials database thread; drop patient advocate from trial
T6	Task	Release database threads; display home page
T7	Task	Log out user

IV. CONCLUSIONS AND FUTURE WORK

The focus of this study was to architect a software solution to address trust-building issues between clinical researchers and a community where clinical trials are conducted. The objective of the solution was to increase trust to encourage greater participation in trials and to drive down clinical trial costs. The intent was to design a services-based application that would: 1) manage a database of potential trial subjects, healthcare providers, and patient advocates; 2) give trial subjects and their primary healthcare provider's access to trial data; and 3) provide a means for community members and clinical researchers to interact with each other.

A SOA approach was explored using the RUP/SOMA methodology. Because RUP/SOMA assumes that requirements analysis has been completed, another methodology was needed to map non-functional wants and needs to technical requirements. The resulting requirements specification was input to RUP/SOMA, a methodology for modeling and architecting a SOA. Petri nets were used for initial validation of the architecture.

Fig. 5 illustrates the proposed solution, including both service and web application components. Because the requirements methodology and RUP/SOMA both maintain traceability from the original trust-building problems to the requirement specification and later to the SOA models, linkage between the project requirements and goals and the proposed solution can be demonstrated.

In addition, by mapping problem themes to the trust dimensions defined by Lewicki and Tomlinson [4], it can be shown that each trust dimension is addressed.

Fig. 6 maps the problem themes identified in Section III to the trust dimensions defined by Lewicki and Tomlinson. The problem themes that cannot be mapped directly to one of the trust dimensions are aspects that influence an individual's assessment of trustworthiness. This is illustrated in the upper left corner of the figure.

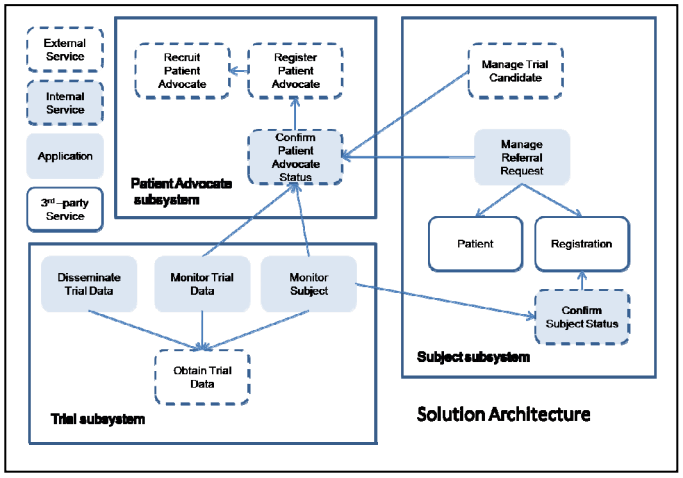

Figure 5. Solution architecture.

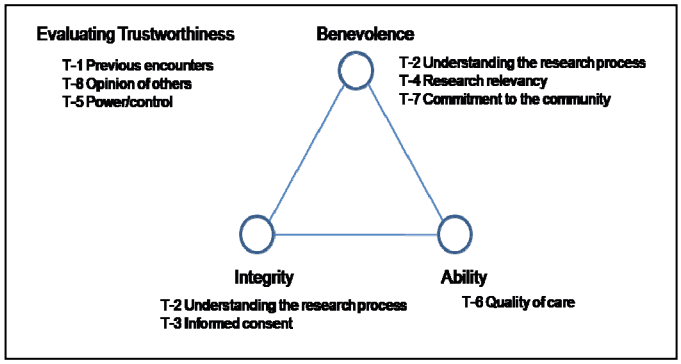

Figure 6. Mapping problem themes to dimensions of trust.

Based on this mapping, this study concluded that a solution addressing these problem themes would increase community trust in clinical research and would positively impact a community's assessment of clinical research trustworthiness.

Future work includes execution of the architecture proof-of-concept and implementation. Metrics should be defined and tracked after deployment to determine actual impacts on trust.

It should be noted that the methodology defined to map non-functional requirements to technical requirements is not domain-specific so it may be sufficiently general and complete to be used for other problem sets. Further work is needed to confirm this.

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