Fall 2010

Establishing Community and Research Trust in Public Health Using Service-Oriented Architecture (SOA)

Juanita Hun Mah
San Jose State University

ESTABLISHING COMMUNITY AND RESEARCH TRUST IN PUBLIC HEALTH USING SERVICE-ORIENTED ARCHITECTURE (SOA)

A Thesis

Presented to

The Faculty of the Department of Computer Engineering

San José State University

In Partial Fulfillment

of the Requirements for the Degree

Master of Science

by

Juanita H. Mah

December 2010

The Designated Thesis Committee Approves the Thesis Titled

ESTABLISHING COMMUNITY AND RESEARCH TRUST IN PUBLIC HEALTH USING SERVICE-ORIENTED ARCHITECTURE (SOA)

by

Juanita H. Mah

APPROVED FOR THE DEPARTMENT OF COMPUTER ENGINEERING

SAN JOSÉ STATE UNIVERSITY

December 2010

Dr. Weider Yu	Department of Computer Engineering
Dr. Jerry Gao	Department of Computer Engineering
Dr. Xiao Su	Department of Computer Engineering
Dr. Harini Srinivasan	IBM Corporation

ABSTRACT

ESTABLISHING COMMUNITY AND RESEARCH TRUST IN PUBLIC HEALTH USING SERVICE-ORIENTED ARCHITECTURE (SOA)

by Juanita H. Mah

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 focuses on a system to address trust issues between the San Jose Hispanic community and clinical researchers. It describes a methodology for translating non-functional wants and needs into technical requirements that are 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 is based on multiple stakeholder goals and general clinical trial processes.

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

ACKNOWLEDGEMENTS

I am deeply grateful to my advisor, Weider Yu, for his support in developing the ideas for this thesis, for his guidance in exploring different approaches to develop a solution, and for his encouragement while bringing these ideas to fruition.

I am indebted to those who volunteered their time to work on solution prototypes and to those who have reviewed and commented on drafts of this paper. I also offer special thanks to all who shared their insights into the health concerns of the local Hispanic community and the issues facing clinical researchers.

DEDICATION

This thesis is dedicated to the memory of my parents, my sons, and my husband. My parents, Harry and Pearl Mah, gave me a great love for learning, which was the key motivation that started me on this journey. My sons, Brett and Scott Mink, reminded me to enjoy the stops along the way. My husband, Steve Mink, provided the encouragement and support I needed to reach the end.

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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]. Clinical trials may be used to test new approaches for preventing, detecting, diagnosing, or treating disease and are concerned with issues such as drug safety, appropriate dosages and dose administration, efficacy, and treatment side effects [2].

Clinical trials may be sponsored by a variety of public and private concerns, such as government health agencies, hospital or university researchers, independent researchers, pharmaceutical companies, or biomedical device companies. Plans for a clinical trial must first be approved by the federal government. After approval, trial execution and results are monitored by government agencies. Typically, these agencies approve or disapprove new treatments based on the results of the trial [1], [2], [3].

A study may include multiple clinical trial phases. Each phase has its own purpose; and the number of participants increases with each subsequent phase. The duration of a phase varies. Typically, the earlier phases last one to two years, while the later phases are longer and can last 5 years or more [3].

Clinical trials can involve patients as well as healthy individuals. In most cases, these research subjects are volunteers; but sometimes they might be paid. Each candidate must

meet certain criteria in order to be eligible to participate in a study. In addition, researchers must ensure that all candidates are aware of the benefits and risks associated with participating in the trial prior to enrolling in the trial. The process of ensuring that participants know key facts about the trial is known as informed consent. The intent of informed consent is to ensure that the rights and welfare of human subjects are protected [2], [3].

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 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 that ensures 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.

One way to facilitate recruitment and retention is by taking actions to establish greater trust between researchers and a community. These actions can be incorporated into each major stage of a clinical trial phase. For example, during the planning stage, the informed consent process might be customized to meet the needs of a community. During the execution stage, actions might be taken to improve communication and information flow among those directly and indirectly involved. Later, after a trial is

completed, steps might be taken to inform participants of the results and to collaborate with them in planning the next trial phase.

A. Thesis Goals.

This thesis focuses on a software solution to address trust-building issues between clinical researchers and a community where clinical trials are being conducted. A community is "an association of people who gather together to share a common interest and/or relevancy during a period of time" [4]. A community may be based on common points of reference, such as geography, ethnicity, religion, culture, interests, or organization. This thesis specifically uses the San Jose Hispanic community as the basis for a case study to determine solution requirements and evaluate the results of the study.

The primary goal of this thesis is to demonstrate how various modeling techniques can be used to architect a flexible software solution that addresses a shared need between diverse stakeholders with different but related goals. The output of the study will be a software system architecture that is intended to improve communication between the researchers and members of the community. By establishing structured communications among clinical trial participants, clinical researchers should expect greater trust and collaboration, thereby increasing participation rates, yielding more valid data input, and facilitating subsequent research activities.

First, a methodology will be developed to derive a set of technical requirements for that system from non-functional wants and needs. Next, to ensure strong linkage and traceability between the business goals of clinical trial participants and the software solution, the architecture will be developed using a Services-Oriented Architecture (SOA) approach. The architecture definition will be in the form of a Service Model, Goal-Service Model, and Design Model. Last, selected service components will be modeled using Petri nets as part of solution validation.

B. Expected Contributions to the Body of Knowledge.

This study proposes a methodology for transforming non-functional domain-specific wants and needs, such as trust building, into technical requirements that can be implemented via a software system. This methodology will be generalized so it can be applied to other non-functional problem sets.

Currently, an SOA focuses on a single enterprise's information technology needs and strives to establish traceability from that enterprise's vision and business goals to individual services to be developed or called by the enterprise solution. This study extends existing SOA approaches in two ways. First, this study will demonstrate how an SOA approach can be used to define an architectural solution for a general problem domain, i.e., the clinical trials process, rather than for a specific enterprise. Second, this study will show how to define an SOA to achieve common goals of multiple stakeholders, with traceability back to their respective visions and goals. Last, this study

explores the use of Petri nets to model web services. Petri nets will be used to model individual services and relationships among web services within an SOA. Petri net simulations can be used to validate the architecture's correctness. These models can also be used to identify potential implementation issues such as deadlocks and concurrency.

C. Organization of This Thesis.

The remainder of this paper is organized into three parts: The first part contains four sections and provides background information. In Section II, some of the current challenges associated with establishing trust between clinical researchers and communities as well as recommended solutions will be described. Section III examines specific health and trust issues associated with the San Jose Hispanic community and introduces a case study. Section IV focuses on the current state of the art and identifies some existing software that is used by clinical researchers to design and manage clinical trials. Section V is a brief overview of SOA and its benefits. It also contains a description of Service-Oriented Modeling and Architecture (SOMA), an approach for modeling an SOA.

The second part consists of two sections where a proposed software solution will be derived. In Section VI, a methodology for translating non-functional wants and needs into technical requirements that can be implemented will be demonstrated. Specifically, the challenges and solutions identified in Section II will be mapped into requirements for a software solution. These requirements will be used in Section VII, where an SOA-

based solution using SOMA will be described. The third and last part contains two sections in conclusion. Section VIII contains an evaluation of the solution against the requirements of major stakeholders involved in the clinical trials process; and Section IX concludes with final thoughts.

II Trust-Building in Clinical Research

A. Challenges.

According to Getz and Kremidas [5], the state of public relations in the clinical trials industry declined during the 5-year period of 1999 to 2004 due to the significant lack of education among the general public, prospective volunteer communities, medical and health professionals, and media. The authors noted that most communications between clinical researchers and journalists focused on negative aspects of clinical trial execution or results.

A survey of nearly 6000 adults [5] showed that 69% of them were aware of clinical trials through various media and that one in seven were exposed to information through their primary care or specialty care physicians. However, less than 5% knew where to find information about relevant clinical trials. A report of approximately 700,000 medical and health professionals active in community practices showed that less than half of them had referred a patient to a clinical trial, averaging to less than one patient referral per practitioner per year.

Moreover, there was significant public distrust in clinical research, especially among adults in minority communities. Surveys conducted in 1996, 2002, and 2006 [5] showed a decline of public trust in clinical research information from pharmaceutical companies. In 1996, 72% of those surveyed trusted clinical research information. By 2006, this

percentage dropped to only 21%.

Other studies in 2004 and 2006 showed public belief in the effectiveness of the FDA to ensure consumer safety had declined from 56% to 37% [6]. In a 2004 survey of more than 5,800 adults, 84% of the Latino respondents gave a response of "not very safe/not safe at all" to the question, "How safe do you think clinical research studies are for people who participate [5]?"

Because of these types of issues, 90% of all clinical trials had to extend their timelines in order to enroll sufficient numbers of volunteers in a study. To complete a trial, research sponsors had to spend increasingly more resources on patient recruitment, thus increasing trial costs.

Research that is community-based brings additional challenges to trust-building, due to its collaborative nature and its need to understand and accommodate the language and culture of the community. Trust must be established between outside researchers and key participants within the community, including community leaders, community-based partners, prospective study subjects, and healthcare providers. Successful healthcare research involving socio-economically disadvantaged communities depends on the degree to which that research is "culturally appropriate and relevant to families in the communities where they live" [7].

To establish successful trusting relationships with medical and healthcare professionals focused on the health of specific communities, a number of barriers must be overcome. Sometimes researchers may be perceived as outsiders who take data and define research priorities but do not give back to the community; or they may be perceived as drains to local resources. In some cases, community members may be intimidated by the technical training of outside researchers; or they may be suspicious of the researchers' motives. If researchers only commit to a short-term partnership, it may be difficult to maintain trust [4], [7], [8].

There are also many potential barriers to establishing trust with prospective study subjects in these communities. This includes lack of understanding of the clinical trials process, lack of informed consent, lack of researcher sensitivity to individual needs, loss of control by the subject, skepticism about the quality of care received, or opinions of trusted influencers. When the research process is not thoroughly understood, subjects may not understand the difference between research and medical care. Therefore, they may have unrealistic expectations of study participation. They may also fear loss of medical records privacy. Language and literacy issues may inhibit understanding of the research process or make informed consent more difficult, so prospective subjects may not fully understand the benefits and risks of participating in a study. Subjects may feel a loss of control if they are not provided interim information about a study's progress. They may be skeptical of the quality of care they will receive, due to different values and beliefs. Furthermore, depending on the community culture, a potential subject's trust

may be dependent on the views of family, friends, community leaders, and his or her healthcare providers [4], [7], [9].

Previous experiences in clinical trials can erode trust. Potential subjects may have a sense of being over-researched but not helped. Lack of follow-up by researchers from previous trials, lack of follow-through on various commitments, or awareness of historical mistreatment may significantly impact levels of trust. A subject who participated in previous studies but did not see any benefits as a result of them is less likely to trust the clinical trials process. If researchers do not conduct appropriate follow-up during a trial or communicate study results, participants may become suspicious and less trustful [7], [8].

As mentioned earlier, physicians and other healthcare providers can play a significant role in lowering trust barriers and influencing their patients' decisions to participate in clinical trials. Some of the reasons for the low rate of referrals by physicians are lack of awareness or understanding of the clinical trials process, fear of loss of patient control, and concerns about the resource or time demands associated with trial participation. Healthcare providers may not understand the importance of clinical research or the potential benefits and risks associated with participation. If they do not have access to their patient's study data, they may not feel sufficiently informed to continue to adequately treat their patients; or they may fear they will lose their patients after the study is completed. They may also be reluctant to take on additional administrative work; or

they may have competing demands for their time [4], [6], [9].

List and Sempeera [7] also include an observation about the lingering effects from prior participation in community-based research. If a community had a negative experience from a previous study, it was less likely to participate in another study, even if the two studies were completely unrelated. This means that inconsistency in approach from study to study may impact levels of participation in future studies.

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. For a clinical trial to be successful in traditionally underserved communities researchers must collaborate with the community to address local problems in a meaningful and impactful way; and trust-building must be incorporated throughout the clinical trials process.

B. Solutions: An Industry Perspective.

The clinical trials process can be divided into planning, execution, and outcome stages. Actions to build and maintain trust can be incorporated into each of these stages, focusing on the specific needs of different types of community members, such as community-based partners, community leaders, prospective trial subjects, and trial subject influencers such as their healthcare providers, friends, and family. In addition, broad actions can be

taken, independent of any particular clinical trial, to increase understanding and literacy of the clinical trials process among the general public. More details about these actions are described in following sections.

1) Trial Planning Actions: During the research planning stage, researchers should involve the entire community in discussions on the local needs, issues, and concerns to ensure that the study is relevant and will be supported by the community. These needs should be used to establish research priorities [6], [7], [8]. Community members should also be engaged to act as research consumer advocates and be given the opportunity to contribute to trial design and to ensure that the patient perspective is incorporated into the process [6].

Researchers should work with community members to design the trial with culturally appropriate questions, translations, and interactions [7]. This includes collaborating with partners and leaders to ensure informed consent [6], [7].

Informed consent, a key interaction required in clinical research, is a procedure to ensure that trial subjects understand the nature of the proposed treatment, possible alternatives, and potential risks and benefits. Informed consent is a major issue in patient recruitment and retention; and it is even more important in community-based research, as it can be a way to empower participants in the decision-making process, thus engendering greater trust. Eliciting input from community members during the research planning stage can

make the informed consent process more effective.

To promote greater understanding and awareness of the clinical trials process, research consumer advocates should be engaged to educate prospective trial subjects about clinical trials. These research consumer advocates would include community-based partners, leaders, and influencers. In addition, community physicians and other healthcare providers should be engaged to talk to their patients about relevant trials and to identify and refer eligible patients. Community members who had participated in earlier phases of the clinical trial or who were, themselves, in the pool of eligible trial candidates could be trained to act as influencers to encourage trial participation [5], [6], [7].

To encourage greater power sharing and control, community members should be included on the research boards. This would give community representatives more say in how funds are distributed [6], [7], [8]. Other ways to share power and control might be to recruit community partners and physicians as study investigators or to utilize their facilities as part of the study [6].

2) Trial Execution Actions: During the trial execution stage, trust can be maintained by continuing to share power and control with the community. This should include community members as research consumer advocates who participate in trial monitoring. Other activities might include participating on data safety monitoring boards or gathering, analyzing, and disseminating trial information [6], [8].

Another way to empower the community would be to ensure frequent communication between researchers and the community. Primary and secondary physicians should continue to be informed of their patients' progress during the trial. Establishing two-way communication between physicians and researchers could eliminate feelings physicians might have of loss of control over their patients. Trial participants should also be continually informed of progress, status, and trial results so they can make informed decisions about their continued participation. Participants should have a way to communicate concerns or ask questions; and researchers should be responsive. Ongoing communication to the community-at-large during the trial would demonstrate concern for the community [6], [7].

Other ways to demonstrate concern for the community would be to provide health education to trial subjects, to continue use of culturally appropriate questions and translations, and to be sensitive to cultural values and beliefs when interacting with trial subjects [7]. It is also critical that all commitments made by researchers to individuals are met.

Trust between researchers and candidate trial subjects can be enhanced by using trusted research consumer advocates and community healthcare providers as intermediaries for trial recruitment [6], [7]. Trial execution processes should facilitate trial referrals from these advocates.

3) Trial Outcome Actions: When a trial is complete, researchers should work with community-based partners and leaders to determine the most effective ways to disseminate trial results to trial subjects and influencers to maintain trust [1].

4) General Awareness Actions: The Parkinson's Disease Foundation (PDF) [6] suggests addressing the trust issue through greater public disclosure and transparency. The goal would be to raise awareness of ongoing research and to improve clinical trials literacy. Pre-education could be used to counter the way the public was receiving information about clinical research.

To this end, the foundation developed a public web site [10] with extensive information about current clinical studies. The purpose was to integrate various study registries and to provide a one-stop shop for people with Parkinson's Disease (PD). Potential participants could view information about relevant research and requirements for participation, testimonials from other participants, and targeted Frequently Asked Questions (FAQs). Although the web site met the requirement for public disclosure, it was not producing the desired result. Because of this, PDF recommended additional actions to increase awareness of and education on clinical research through ongoing one-on-one and community communications [6].

Getz and Kremidas [5] suggest that outreach and advocacy programs are an effective way to address education and trust issues. Earlier programs were limited in scope and

duration, resulting in inconsistent messages or only short-term benefits. Because of this, the authors suggest that these programs be more broadly adopted and implemented across the entire clinical research professional community and integrated with all clinical research activities. The authors specifically recommend implementation of these types of communications: 1) educational materials for potential volunteers that address unique needs of each community; 2) broad outreach and advocacy to emphasize the important role of healthcare professionals in the clinical trial process and to educate the general public about the clinical trials process; 3) generation of messages that convey the important role that clinical research plays in improving public health and why it is so costly; and 4) acknowledgement and appreciation for community participation in clinical trials. Targeted audiences would include the general public, health professionals, policy makers, prospective trial subjects and their friends and families, and the media.

The proposed actions described above are consistent with the National Institute of Health's (NIH's) Roadmap for Medical Research [4], [11]. This roadmap provides funding mechanisms to assist communities in developing their own projects. It includes seven major recommendations for improving trust between researchers and the community [4]:

- Recommendation 1: Establish grant criteria.
- Recommendation 2: Enhance network and infrastructure by funding mechanisms for grass-roots studies and providing linkages to community groups.
- Recommendation 3: Integrate medical research into primary healthcare.

- Recommendations 4 and 5: Require certain criteria in study design.
- Recommendation 6: Provide access to information about clinical trials.
- Recommendation 7: Provide software to determine if a person meets clinical trial criteria.

These NIH recommendations are consistent with those previously stated and can be used as additional input into the requirements for a software solution. Establishing a common approach in the clinical trials process, common study design criteria, and software to support compliance to processes may improve consistency among various researchers conducting trials within a community. Consequently, a community's overall view of researchers and clinical trials may improve.

C. Solutions: A Community Perspective.

The solutions identified above do not take into account the possibility that there may be several clinical trials being conducted in a community during the same time period. When there are multiple clinical trials focused on the same community but sponsored by different researchers, additional trust-building actions may be required. For example, if the clinical trials process is inconsistent from sponsor to sponsor or if trials focused on the similar problems are offering different treatments, trial subject candidates may find it more difficult to determine which trials to participate in, if they choose to participate at all.

Providing a consistent approach across all clinical trials activity targeted at a community by adhering to the NIH recommendations can reduce inconsistencies and reinforce trust developed by previous researchers or other concurrent researchers. Working through a single interface to a community, such as a community-based research organization, can shield prospective trial subjects from significant differences. These community organizations can also serve as objective trusted advisors to guide community members to the most relevant trials.

III Health in the San Jose Hispanic Community

According to the National Alliance for Hispanic Health, obstacles to providing quality healthcare "…involve cultural misunderstandings and miscommunications with patient populations whose languages, experiences, and backgrounds differ from those of their providers" [12]. This section summarizes primary health issues in the Hispanic community and explores some cultural characteristics of the San Jose Hispanic community that may affect their trust in clinical researchers that are focused on these issues. Next, a case study will be introduced that will be used to guide and evaluate the solution developed in Section VI and Section VII.

A. Community Health Issues.

Pfizer conducted a study on health data of specific populations in the United States [13], including Mexican-Americans, and published the results in 2004. Because Mexican-Americans were the largest subgroup of the San Jose Hispanic community (more than 87% during the years 2006 to 2008), the results of the study are pertinent and summarized here [14].

Health data on high blood pressure, cholesterol, diabetes, and obesity from 1998 to 2000 were analyzed. Mexican-Americans were less likely than non-Hispanic whites to have high blood pressure or high cholesterol. However, they were more likely to have diabetes or be obese.

The data studied shows that the number of Mexican-Americans afflicted with high blood pressure grew during the study period. In comparison to non-Hispanic whites, the study found that Mexican-Americans were less likely to be diagnosed and treated. Of those receiving treatment, Mexican-Americans were less successful in their efforts to lower their blood pressure to recommended levels. Mexican-Americans were also less likely to be screened, diagnosed, or treated for high cholesterol. However, if treated, they were more successful in lowering their cholesterol to recommended levels.

The report shows that diabetes is more common among Mexican-Americans. Mexican-American women had nearly twice the rate of diabetes than non-Hispanic white women. Mexican-American women were also more aware of diabetes; and a larger percentage of them received treatment.

These three diseases are related to a person's weight; and the study shows that 33% of Mexican-Americans were considered obese, with middle-aged Mexican-Americans having the highest rate at 38% [13]. Obesity may be due to food selection that is based on cultural preferences, so it is important to understand that culture when developing recommendations for treatment [14].

B. Cultural Issues Affecting Healthcare.

According to a survey conducted by the American Community Survey in 2008 [14], the San Jose Hispanic community comprised 31.5% of the population in San Jose, California,

of over 900,000. Of the city's population who were 5 years or older, 23.7% spoke Spanish at home and 11.6% felt they did not speak English well. These significant percentages indicate that the language issues affecting trust, as described in Section II, must be considered when planning trust-building actions.

In addition to language, the National Alliance for Hispanic Health [12] identifies three common cultural characteristics that can influence trust. They include the importance of family, the need to show respect, and the value of personal relationships. Hispanics frequently consult with other family members about their illnesses and are more likely to involve their family members in discussions and decisions about treatments. It is also not unusual for family members to be asked to accompany a patient during medical visits so they can be involved in the discussions with the healthcare provider.

In the Hispanic community, respect is demonstrated through "appropriate deferential behavior towards others based on age, sex, social position, economic status, and authority" [12]. Because of their status, education, and training, Hispanics tend to value the opinions and recommendations of their healthcare providers. To avoid being disrespectful, Hispanic patients might not verbally disagree with their providers or express doubts.

They also expect that their healthcare providers will show them respect in return. This respect is demonstrated by the way the healthcare provider interacts with a patient. For

example, asking direct questions about personal problems such as alcoholism or mental health can be embarrassing and might be perceived as being disrespectful. Respect is also shown by listening carefully to patient concerns and responding to them [12].

Hispanics value personal relationships over institutional ones, so they rely on community-based organizations or clinics for their primary care. They also display loyalty to their individual providers. If a patient's physician moves to a different healthcare facility, it is not unusual for that patient to move to the new facility to keep the same provider. If a move is not possible, the patient might discontinue treatment completely.

C. Case Study.

Because obesity is a significant health issue in the Hispanic community, it will be the focus of the case study. This is a hypothetical study based on an actual study conducted by Stanford University in 2007 and targeted at mothers of Mexican descent in San Jose [15].

A subject participating in the study must: 1) be a mother of Mexican descent; and 2) be the parent of a child between the ages of 3 and 4.9. The trial data to be collected in this case study will include the study subject's BMI, 24-hour dietary recalls, household food inventories, activity monitoring, household food security levels, and food purchase motives.

D. Implications for Trust-Building.

"Over time, by respecting the patient's culture and showing personal interest, a health care provider can expect to win their confianza (trust)" [12]. If the solutions identified in Section II are implemented, most of the trust influencers specific to the Hispanic community will be addressed. Using culturally appropriate questions and translations can address language barriers and the need to demonstrate respect through tactful questioning. Recruiting community members as patient advocates addresses the need to have personal relationships with researchers. Encouraging more physician referrals may yield higher recruitment rates due to the loyalty and trust given to physicians by their Hispanic patients. Ensuring general awareness in the community is a way to engage family members and other decision influencers. Providing interim trial data to subjects and giving them the opportunity to ask questions and get feedback empower the subjects and demonstrate respect. Because trust issues specifically associated with the Hispanic community can be addressed by the actions identified in Section II, no additional ones are required here.

IV Software Tools for Managing Clinical Trials

A. Commercial Software.

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. During the earlier phases of a clinical trial, internally developed software or general-purpose software, such as spreadsheets, may be used. Later, as the number of participants or tests increase, researchers may migrate to commercially available software to obtain richer functionality [16], [17]. They may also engage external contract research organizations (CROs) to manage trials on their behalf.

Although all clinical trials have some function requirements in common, many have their own unique requirements [16]. This suggests that solution customization is an important feature required by clinical researchers. They must be able integrate diverse software packages to manage the full scope of a clinical trial. They also must be able to extend and adapt existing software to accommodate their unique needs. Most existing software packages provide this adaptability through import/export techniques, use of code wrappers, or special purpose connectors. Cancer Biomedical Informatics Grid Clinical

Trials Suite (caBIG[1] CTS) [18] is a notable exception that is SOA-based, providing users greater flexibility.

It should be noted that these existing software solutions focus on management of internal clinical trial processes. With the exception of participant enrollment and management, there are few built-in features available in the software to support trust-building activities.

B. Infrastructure Software.

In 2004, the NIH Roadmap funded twelve (12) contracts [19]-[30] that focused on the development of an infrastructure of informatics, governance, and a common vocabulary to facilitate cooperation among research groups. These contracts were part of the Clinical Research Networks and National Electronics Clinical Trials and Research Network (NECTAR) initiative. Refer to Appendix C for a summary of the final reports. Relevant results of these contracts are summarized below:

The majority of projects developed systems focused on managing domain-specific data [19]-[28] or establishing common vocabularies for information interchange within existing networks [19]-[24], [30]. With the exception of CRN Harmony [25], these systems were custom-built applications rather than commercial off-the-shelf (COTS) ones. The resulting solutions created tighter alignment between the IT infrastructure and

[1] caBIG is a registered trademark of the National Cancer Institute.

local processes and procedures; but they might not be transferrable to other clinical research organizations.

The InterTrial project [26] suggests that "conventional software tools can help with some workflow problems… However, these tasks tend to represent only a small part of a complex system… There are also fundamental problems that cannot be solved with software alone. In the community practice sites studied, clinical research and patient care are parallel but disconnected…" This suggests that there needs to be a focus on tools that improve communications and infrastructure between clinical researchers and the community.

Some projects were able to relate their results to changes in community interactions or their ability to reach underserved populations. The Michigan Clinical Research Collaboratory (MCRC) project [19] improved communication to primary care providers (PCP) through extensions to the prompt and reminder system. The Health Maintenance Organization Research Network Coordinated Clinical Studies Network (HMORN CCSN) project [27] increased research participation by providing participating cardiologists greater access to research information. The Electronic Primary Care Research Network (ePRN) project [24] considered its ePCRN Gateway to be particularly suitable for underserved areas by promoting greater communication and collaboration. The system was being considered for use at Hispanic clinics in Los Angeles. The Research Involving Outpatient Settings (RIOS) Net project [29] used community outreach that included

Spanish-speaking staff; but it is not clear if this was through networked systems or via face-to-face interactions.

C. Web Sites.

Currently, web sites are the primary software tool used by researchers to communicate clinical trial information to the general public. Content on these sites can be from a single source; or they can be portals that consolidate information from multiple sources. The PDF web site [10] is an example of a portal site.

D. Summary of Tools.

In summary, progress has been made to develop common vocabularies or information models to support clinical research. Web sites are used to provide information about clinical research. Some solution developers are creating features to improve communication among trial participants and provide easier access to research information. However, the closed nature of the software architectures used by most commercial vendors and researchers makes it difficult to customize or extend existing solutions to support trust-building activity, leaving a high priority need unmet.

V Introduction to SOA and SOMA

In this section, key concepts of Service-Oriented Architecture (SOA) will be described along with the benefits of using SOA within an enterprise. Next, the high-level steps of Service-Oriented Modeling and Architecture (SOMA) will be covered. Finally, the applicability of SOA and SOMA to the issue of trust-building in the clinical research process will be explored.

A. Service-Oriented Architecture.

SOA is "an architectural style that supports service orientation. Service orientation is a way of thinking in terms of services and service-based development and the outcomes of services" [31]. It is focused on the construction of services that are aligned with business concerns and can be combined to perform business processes within the context of an enterprise [32]. These services may be developed internally or externally. They may be shared, distributed, and reused across multiple organizations within an enterprise.

There are many definitions of SOA, some of which are conflicting [33]. However, there are some ideas that all SOA definitions have in common, such as the concept of a service and service composition, a services registry that provides information about available services, and governance to manage creation and use of services.

A service produces well-defined outcomes that are defined in a service contract. Service providers perform the necessary actions to produce the outcomes; and service consumers use those outcomes. Each service can stand alone, can be combined with other services, or can be composed of other services. The actual service implementation is not visible to consumers or other services that incorporate it. The services contract specifies how the service provider and service consumer will interact.

A services registry is a mechanism for service providers to publish information about available services to potential consumers. The registry typically contains details such as services descriptions and policies.

SOA governance is concerned with the service life cycle and "focuses on the methods and processes around service identification, funding, ownership, design, implementation, deployment, reuse, discovery, access, monitoring, management, and retirement" [34].

One aspect that differentiates SOA from enterprise architecture (EA) is its emphasis on aligning an enterprise's business processes with its information technology (IT). A well-defined SOA establishes linkages from enterprise goals and business processes to services. As goals or business processes change, SOA facilitates service reuse. The loose coupling of services within an SOA provides IT organizations greater agility and flexibility to meet enterprise needs.

Figure 1 depicts an SOA reference architecture, showing the various layers of building blocks and how they relate to each other.

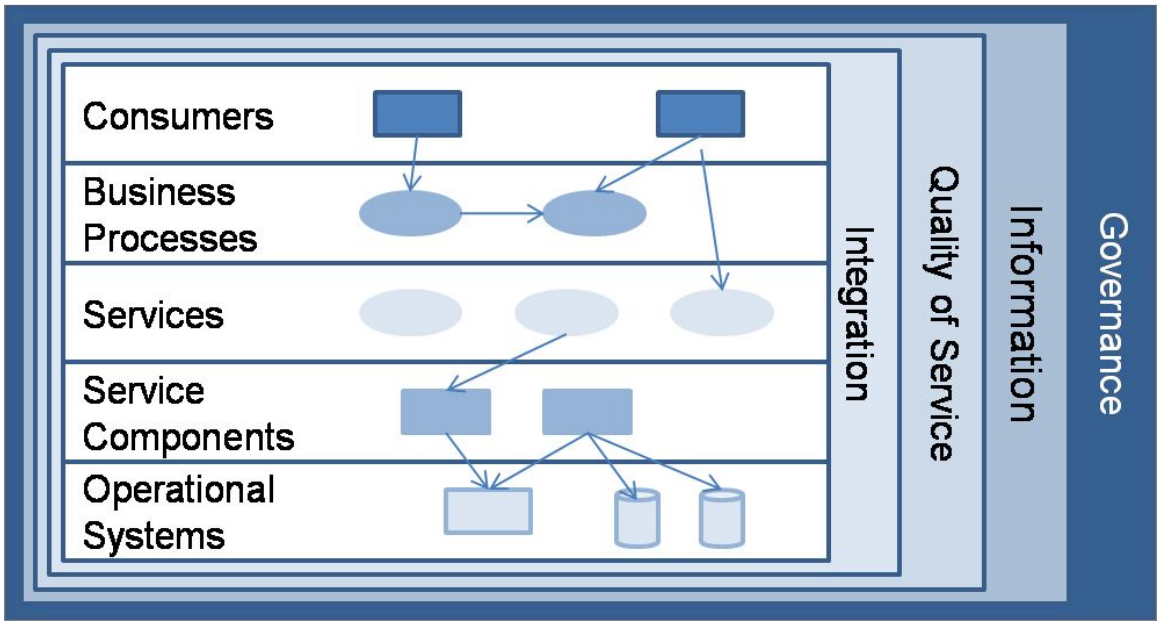

Figure 1. High-level view of an SOA reference architecture.

Starting from the bottom layer in Figure 1 and moving up, the operational systems layer contains applications, infrastructure programs, and data that exist within the enterprise. These are basic building blocks that are used to develop services. The service components layer contains other programs that are used as intermediaries to decouple services from the operational systems. For example, this layer would include program wrappers to make operational systems available for use by systems. The services layer contains services, services contracts, data used by services, and composite services. The business processes layer contains business processes and information used by business

processes. Last, the consumer layer contains users of the system and programs that interface to services [31].

Immediately to the right of the services building blocks in Figure 1 and continuing to move to the right, the integration layer enables the building blocks to communicate with each other. The Quality of Service (QoS) layer is concerned with monitoring and managing issues such as performance, security, and manageability. The information layer contains building blocks for transforming and managing data. Last, the governance layer contains rules and procedures for implementation and operational governance [31].

B. Why Use an SOA Approach.

A number of different architectural approaches were evaluated: 1) an entirely new system could be developed; 2) existing systems could be extended; or 3) an architecture could be developed that integrated new functionality with existing systems.

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, including the following:

- The system must be integrated with existing systems that are used by an enterprise to manage clinical trials. This includes general-purpose software, home-grown applications, or specialized CTMSs and CDMSs. Duplicate data and function overlap should be minimized.

- The system must accommodate multiple CTMS and CDMS back-ends, since communities may be involved in more than one clinical trial at any given time.
- The system must be sufficiently flexible to accommodate the specific requirements of each supported clinical trial. Trials may use different software tools, have different types of stakeholders involved, or require different trust-building actions. Support for community-based research may have to accommodate unique cultural, language, or interface requirements.
- The system must support rapid deployment and be cost-effective.

Using an SOA will address these needs. The benefits include the following: 1) the use of a service approach and loose coupling will enable easier integration with other systems; 2) the use of service composition allows the system to be customized and extended; 3) specific needs of a given community can be addressed through tailored front-end applications accessing common back-end services; 4) the ability to share development and maintenance of the services means lower costs for information interchange; and 5) the system will be transferable and reusable among a greater number of research organizations.

C. Service-Oriented Modeling and Architecture.

There are several published methodologies for defining an SOA. The Service-Oriented Modeling Framework (SOMF) and SOMA were evaluated for use in this study. SOMF takes a service-first approach to discover and analyze service opportunities [35]. SOMA,

on the other hand, supports both operation-first and service-first approaches. Since it was anticipated that this solution would require development of new business processes, using SOMA with an operation-first approach was deemed more appropriate.

In 2004, IBM[2] announced SOMA as a methodology for identifying, specifying, realizing, and implementing services, components, and their flows [35]. At that time, SOMA was integrated with Global Services (GS) Method, a proprietary methodology. In 2006, SOMA was integrated with IBM[2] Rational Unified Process[2] (RUP[2]), a commercially available product. RUP is a flexible tool that allows an organization to define and customize its processes. For example, it provides tailoring guidance on why certain outputs are needed and when they can be omitted. As part of the integration effort, SOMA tasks were modified to be more consistent with RUP.

Most recently, RUP has been subsumed by IBM Rational Method Composer[3] (hereafter referred to as Method Composer), another commercially available product that is Eclipse-based. Method Composer provides process descriptions, work breakdown structures that identify required activities and tasks, artifact templates for work products, and guidelines for usage. Support for SOMA is provided in RUP for SOMA (RUP/SOMA) Version 4.2, a plug-in for Method Composer. There are some differences between RUP/SOMA and

[2] IBM, Rational, Rational Unified Process, and RUP are trademarks or registered trademarks of International Business Machines Corporation in the United States, other countries, or both.
[3] Method Composer is a trademark or registered trademark of International Business Machines Corporation in the United States, other countries, or both.

SOMA methodologies. These differences are noted in Appendix D.

RUP/SOMA consists of three phases: 1) service identification; 2) service specification; and 3) service realization. The purpose of service identification is to identify an initial set of services that are aligned to business goals. Service identification can be performed operation-first or service-first. In the operation-first approach, business processes are modeled; and services are derived from those models. In the service-first approach, classes and components are identified. Then operations are identified and added to the classes. Services are identified through domain analysis [36].

Service identification consists of three major tasks: 1) domain decomposition; 2) goal service modeling; and 3) existing asset analysis. The output from this phase is an initial Service Model.

During the service specification phase, the structure of the service architecture is developed and refined; and the Service Model is developed further. The Service Model provides the external view of a particular service, such as its expected outcomes, how to request the service, its dependencies, its service composition, and its messages. The goal of this model is to design loosely coupled services that enable reuse [34].

The service realization phase focuses on an internal view of a service by using the Design Model. This model represents how a service will be realized [34].

A model resulting from a particular phase of RUP/SOMA can be traced to models in the next or previous phase, thus providing traceability from the business processes to each service. Refer to Appendix E for more information about the content of the Service Model and the Design Model.

VI Translating Needs to Software Requirements

Abstract needs such as trust and the solutions for building trust as described in Section II 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 to identify an implementable set of software requirements and to ensure that the system does, in fact, address the original needs.

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

- 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 also to understand which actions 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 Figure 2.

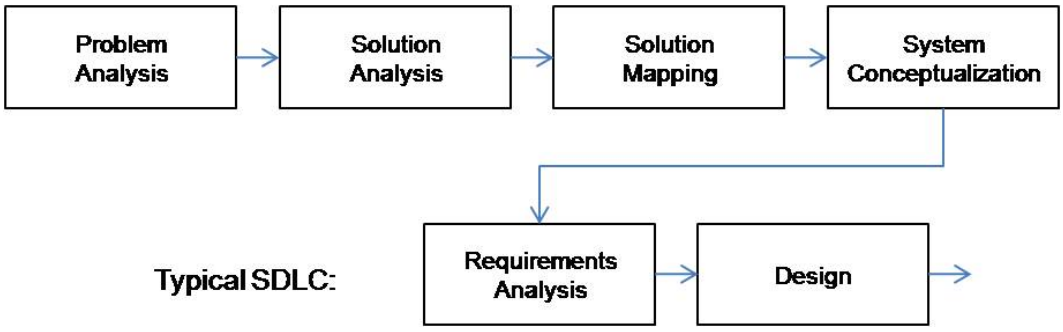

Figure 2. Approach to map needs to requirements.

A. Problem Analysis.

Needs are elicited from domain experts and 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 1 shows the results of aggregating the challenges associated with trust that were identified in Section II. Note that each problem theme is given a unique number to permit traceability later.

Table 1. 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.
T-3. Ineffective informed consent	• Informed consent cannot be adequately performed due to illiteracy or differences in language.
T-4. Research relevancy	• Research is not sensitive to candidate subject needs. • Research disregards the perspective of the community and their needs and priorities.
T-5. Loss of power/control	• No interim information is provided about study progress, so candidate trial subjects cannot make informed decisions. • The community cannot determine how data should be collected or used.
T-6. Quality of care	• Candidate trial subjects are skeptical of the quality of care they will receive. • Treatments may not be consistent with trial subject values or beliefs.
T-7. Lack of commitment to community	• People may feel over-researched. They are sought out for research but get limited access to healthcare. • There is inadequate follow-up. Researcher commitment is only for the duration of the study. • Researchers are perceived as taking data without any give back.
T-8. Opinion of others	• Candidate trial subjects may be aware of historical mistreatment during clinical trials. • Candidate trial subjects are affected by attitudes of family and friends. • Candidate trial subjects may be unwilling to go against their personal physicians' wishes.

In Section II, it was noted that clinical trial referral rates by physicians have been low. Because candidate trial subjects value and trust the guidance of their personal physicians and healthcare providers, problems associated with engaging these professionals should be considered when defining possible solutions for building trust between candidate trial subjects and researchers.

Additional problem themes associated with physician referrals are identified in Table 2. Note that some of the themes are repeated from Table 1.

Table 2. Themes Associated with Physician Referrals.

Problem Theme	Problem
T-5. Loss of power/control	• Physicians fear their patients won't return after they are referred. • Referring physicians receive no feedback about the outcome and/or status of their patients.
T-9. Lack of awareness or understanding	• Physicians are not aware of trials that are available to their patients. • Physicians do not understand the potential benefits and risks to their patients of participating in clinical trials. • Physicians lack awareness of clinical research and why it is important.
T-10. Resource/time demands	• Physicians often have competing demands and concerns. • Physicians are concerned about the administrative burden associated with patient participation.

Additional problem themes can be derived by analyzing the trust-building solutions from a community perspective, as described in Section II.C. These problem themes are identified in Table 3.

Table 3. Themes from a Community Perspective.

Problem Theme	Problem
T-11. Inconsistent processes and interfaces	• The clinical trials process is inconsistent across trials being conducted in the community. • There are multiple interfaces between candidate trial subjects and researchers.

B. Solution Analysis.

During this step, suggested actions are identified through techniques such as brainstorming and then are 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 given a unique number to permit traceability.

Figure 3 illustrates the mapping between problem themes and suggested actions. Note that there is a many-to-many relationship between the themes and actions, as shown for problem theme T-1 and action A-1.

Table 4 shows the initial results in a tabular format. Because the actions suggested in Section II are based on trial stages, the table is divided into subsections corresponding to each stage. Review of the table shows that all problem themes have been addressed.

Note that the NIH recommendations and solutions from a community perspective have not been mapped to themes. This is because they are general policy statements and cannot be mapped to specific trust issues.

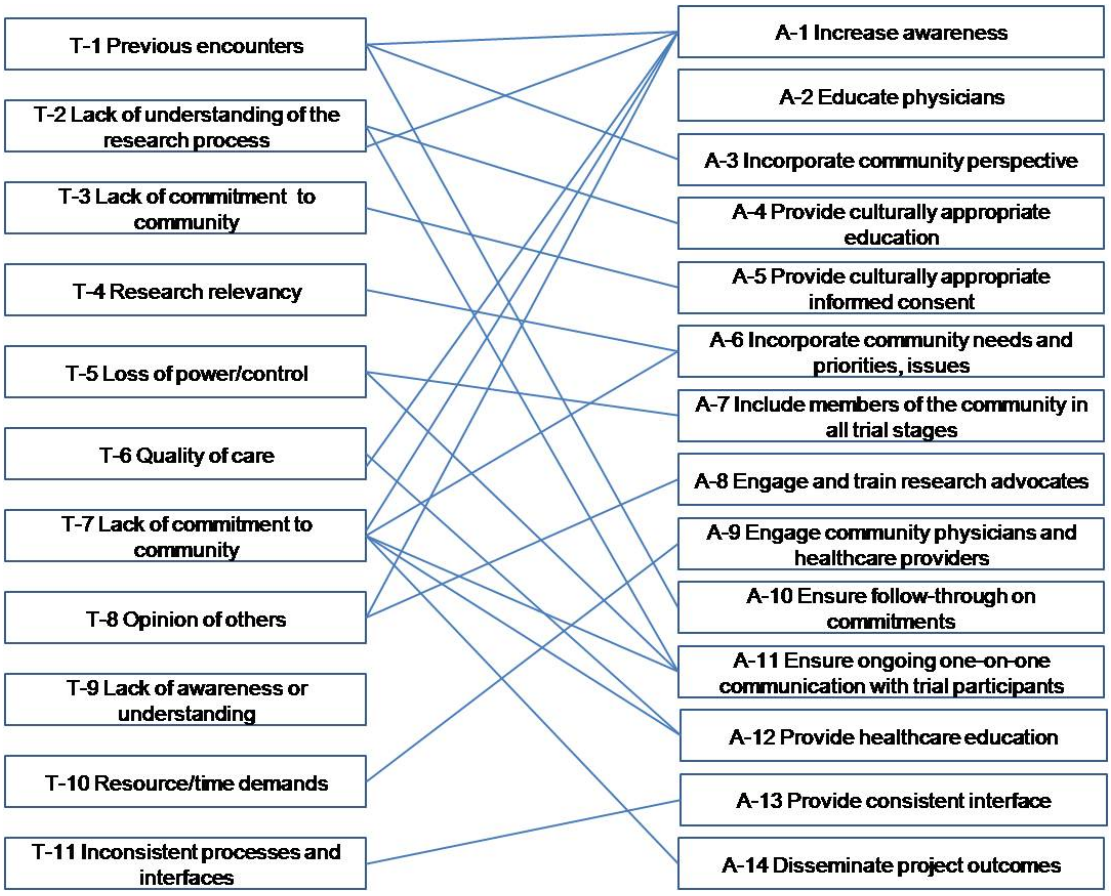

Figure 3. Mapping between problem themes and suggested actions.

Table 4. 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	
	T-7. Lack of commitment to community	
	T-8. Opinion of others	

	T-9. Lack of awareness or understanding	A-2. Educate physicians on the benefits to their patients and themselves of participating in clinical trials.
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.
	T-3. Ineffective informed consent	A-5. Use culturally appropriate questions and translations to ensure comprehension and accessibility of informed consent.
	T-4. Research relevancy	A-6. Incorporate community needs, patient perspectives, priorities, issues, and concerns in trial design.
	T-5. Loss of power/control	A-7. Include members of the community in all stages of the clinical trials process for input, monitoring, and decision-making. This includes participation on review boards and data safety monitoring boards.
	T-7. Lack of commitment to community	A-6. Incorporate community needs, patient perspectives, priorities, issues, and concerns in trial design.
	T-8. Opinion of others	A-8. Engage and train research advocates to participate in all stages of the clinical trials process, including subject recruitment.
	T-10. Resource/time demands	A-9. Engage community physicians and healthcare providers as study investigators or by utilizing their facilities.
Execution	T-1. Previous encounters	A-10. Ensure follow-through on commitments to trial subjects.
	T-2. Lack of understanding of the research process	A-11. Ensure ongoing one-on-one communication with trial participants throughout the trial and be responsive to concerns.
	T-3. Ineffective informed consent	A-5. Use culturally appropriate questions and translations to ensure comprehension and accessibility of informed consent.
	T-5. Loss of power/control	A-11. Ensure ongoing one-on-one communication with trial participants throughout the trial and be responsive to concerns.
		A-7. Include members of the community in all stages of the clinical trials process for input, monitoring, and decision-making. This includes participation on review boards and data safety monitoring boards as well as involvement in gathering, analyzing, and disseminating information.
	T-6. Quality of care	A-12. Provide health education to trial subjects that is sensitive to cultural values and beliefs.
	T-7. Lack of commitment to	A-12. Provide health education to trial subjects that is sensitive to cultural values and beliefs.

	community	A-11. Ensure ongoing communication to the community-at-large throughout the trial.
	T-8. Opinion of others	A-8. Engage and train research advocates to participate in all stages of the clinical trials process, including subject recruitment.
	T-11. Inconsistent processes and interfaces	A-13. Provide a single consistent interface between the community and different researchers.
Outcome	T-7. Lack of commitment to community	A-14. Disseminate project outcomes.

C. Solution Mapping.

Next, the actions or solutions 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.

This study will use a business architecture model for clinical trials that has been developed by caBIG [37] to identify existing business processes. Table 5 shows the mapping and indicates if a new process must be defined or if an existing one must be modified.

Table 5. Mapping Proposed Solutions to Business Processes.

Solution	Add or Modify Process	Business Process
A-1. Increase awareness about clinical research and the clinical trials process through education, outreach, and advocacy.	Add a community outreach process. Target media, policy makers, healthcare providers, and the community-at-large.	Perform Outreach

A-2. Educate physicians on the benefits to their patients and themselves of participating in clinical trials.	Add a community outreach process. Target media, policy makers, healthcare providers, and the community-at-large.	Perform Outreach
A-3. Incorporate a community perspective in clinical trials process.	Modify processes per other business requirements.	All existing business processes, where appropriate
A-4. Build community awareness of researcher presence; provide clinical trials education that is culturally appropriate.	Add a community outreach process. Target media, policy makers, healthcare providers, and the community-at-large.	Perform Outreach
A-5. Use culturally appropriate questions and translations to ensure comprehension and accessibility of informed consent.	Modify Plan Study and Initiate Study processes to incorporate tasks to make them more culturally appropriate.	All informed consent processes
A-6. Incorporate community needs, patient perspectives, priorities, issues, and concerns in trial design.	Modify Plan Study processes to include input from community members.	All existing business processes, where appropriate
A-7. Include members of the community in all stages of the clinical trials process for input, monitoring, and decision-making. This includes participation on review boards and data safety monitoring boards.	Modify Plan Study processes to include participation by community members.	All existing business processes, where appropriate
A-8. Engage and train research advocates to participate in all stages of the clinical trials process, including subject recruitment.	Add new business processes to manage patient advocate recruitment, training, and registration.	Manage Patient Advocates
	Add a new business process to register a patient advocate for a trial.	Register Patient Advocate
	Add a new business process for referral from the Enrolling Physician.	Refer Subject
A-9. Engage community physicians and healthcare providers as study investigators or by utilizing their facilities.	Modify Plan Study processes to include consideration of community members.	All existing business processes, where appropriate
A-10. Ensure follow-through on commitments to trial subjects.	not applicable	not applicable

A-11. Ensure ongoing one-on-one communication with trial participants throughout the trial and be responsive to concerns.	Add a new business process to permit monitoring and Q&A by study subjects and their enrolling physicians.	Monitor Study Obtain Trial Data
A-12. Provide health education to trial subjects that is sensitive to cultural values and beliefs.	Add a new business process to provide health education during a clinical trial.	Provide Health Education
A-13. Provide a single consistent interface between the community and different researchers.	not applicable	not applicable
A-14. Disseminate project outcomes.	Add a new business process to communicate outcomes to the community.	Disseminate Trial Results

In most cases, trust-building activities can be incorporated into the model by updating existing business processes. However, some new business processes are needed to define interactions with the community. Also, two new business processes, Perform Outreach and Manage Post-Study, have been identified to manage activities before and after clinical trials, respectively. The Business Process column shows "not applicable" if the corresponding business requirement describes an action that is more effectively implemented through some means other than a business process.

D. System Conceptualization.

A view of the new business processes and their relationships to existing ones is then developed. The results are shown in Figure 4. Manage Community is shown as a separate group of new 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.

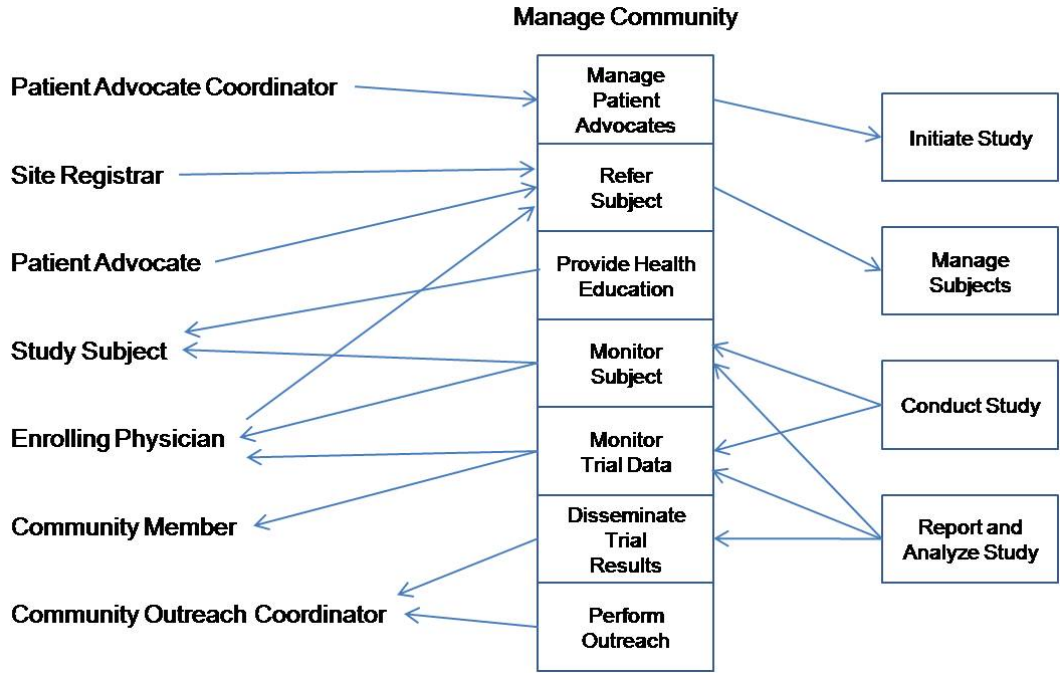

Figure 4. Interaction between new and existing business processes.

E. Requirements Analysis.

Using the external view defined in the previous step, more detailed technical requirements can be developed. Requirements for each of the processes are shown in

Table 6. Requirements have not been specified for Perform Outreach or Provide Health Education because they will be specific to the implementing organization.

Table 6. Manage Community Requirements.

Req ID	Description
CR1	The system shall support the Manage Community process.
CR1.1	The system shall support the Manage Patient Advocates process
CR1.1.1	The Manage Patient Advocates subsystem shall provide a way for a community research coordinator to create, retrieve, update, or delete (CRUD) contact information about patient advocates and enrolling healthcare providers within the community.
CR1.1.2	The Manage Patient Advocates subsystem shall provide a way to register a patient advocate for a particular clinical trial.
CR1.2	The system shall support the Refer Subject process
CR1.2.1	The Refer Subject subsystem shall provide shall provide information about clinical trials being conducted in the community.
CR1.2.1.10	The Refer Subject subsystem shall provide a list of clinical trials that are currently seeking participants.
CR1.2.1.20	The Refer Subject subsystem shall provide a description of a selected active clinical trial.
CR1.2.1.30	The Refer Subject subsystem shall list eligibility requirements for a selected active clinical trial.
CR1.2.1.40	The Refer Subject subsystem shall provide information about benefits and risks of participating in a selected active clinical trial.
CR1.2.2	The Refer Subject subsystem shall provide a way for a patient advocate or enrolling physician to refer a subject to a trial.
CR1.2.2.10	The Refer Subject subsystem shall provide a way to list all candidates associated with a patient advocate and the status of each candidate.
CR1.2.2.20	The Refer Subject subsystem shall provide a way to create, retrieve, update, or delete (CRUD) information about a candidate subject.
CR1.2.2.30	The Refer Subject subsystem shall provide a way to submit a candidate for consideration.
CR1.2.2.40	The Refer Subject subsystem shall provide a way to link each candidate to the enrolling patient advocate or physician.
CR1.2.3	The Refer Subject subsystem shall provide a way to register candidates for an active trial.
CR1.2.3.10	The Refer Subject subsystem shall provide a way for a site registrar to review all candidates for a trial.
CR1.2.3.20	The Refer Subject subsystem shall provide a way for a site registrar to determine if the candidate meets eligibility requirements.
CR1.2.3.30	The Refer Subject subsystem shall provide a way for a site registrar to register a selected candidate for a trial.
CR1.3	The system shall support the Monitor Subject process

CR1.3.1	The Monitor Subject subsystem shall provide a way for a trial subject to monitor his or her progress during a trial.
CR1.3.1.10	The Monitor Subject subsystem shall provide a way to request a report of the subject's trial data.
CR1.3.1.20	The Monitor Subject subsystem shall provide a report of a subject's trial data.
CR1.3.1.30	The Monitor Subject subsystem shall provide a way to submit an ad hoc question.
CR1.3.1.40	The Monitor Subject subsystem shall provide a way to respond to an ad hoc question.
CR1.3.2	The Monitor Subject subsystem shall provide a way for an enrolling healthcare provider to monitor a patient's progress during a trial.
CR1.3.2.10	The Monitor Subject subsystem shall provide a way to request a report of the subject's trial data.
CR1.3.2.20	The Monitor Subject subsystem shall provide a report of a selected subject's trial data.
CR1.3.2.30	The Monitor Subject subsystem shall provide a way to submit an ad hoc question.
CR1.3.2.40	The Monitor Subject subsystem shall provide a way to respond to an ad hoc question.
CR1.4	The system shall support the Monitor Trial Data process
CR1.4.1	The Monitor Trial Data subsystem shall provide a way to request a report of the trial status.
CR1.4.2	The Monitor Trial Data subsystem shall provide report of trial status.
CR1.4.3	The Monitor Trial Data subsystem shall provide a way to submit an ad hoc question.
CR1.4.4	The Monitor Trial Data subsystem shall provide a way to respond to an ad hoc question.
CR.1.5	The system shall support the Disseminate Trial Results process.
CR1.5.1	The Disseminate Trial Results process shall provide a way to request a report of trial results.
CR1.5.2	The Disseminate Trial Results process shall provide a study results report.
CR2	The system shall be accessible via the Internet.
CR2.1	The system shall be accessible through standard browsers on Windows and Mac clients.
CR2.2	The system shall be accessible through mobile devices.
CR3	The system shall provide a secure environment.
CR3.1	The system shall meet all applicable government regulations for privacy and security.
CR3.2	The system shall support authentication and authorization.
CR4	The system shall provide translated information, where appropriate, to ensure informed consent.
CR5	The system shall support multiple, concurrent active trials.

VII An SOA-Based Solution to Build Trust

Now that technical requirements have been defined, the design phase of the software development lifecycle can begin. During this phase, the architecture is developed.

The RUP/SOMA methodology, as defined by IBM Rational Method Composer Version 7.5.0.1 [36], will be used to architect and model a solution for increasing trust between the San Jose Hispanic community and clinical researchers. It will be used as the basis for determining the process phases and activities to be followed. Each task in the RUP/SOMA work breakdown structure corresponds to a subsection in this section. If there are templates or alternative modeling notations defined in the original SOMA methodology, they will be given preference over RUP/SOMA. Any deviations, such as modeling notations, from the RUP/SOMA methodology will be noted.

Because most clinical trials use some form of information technology to manage their processes, the assumption of this study is that any new services must fit within the context of existing systems. In 2008, the National Cancer Institute launched an information initiative to encourage collaboration among the cancer community. To that end, they created the Cancer Biomedical Informatics Grid (caBIG) [38]. This initiative includes activity to architect and develop a clinical trials management system based on open standards, including SOA, to support cross-organization collaboration [39]. For this study, caBIG will be used as the basis for any enterprise-level modeling that must be

created as part of implementing the RUP/SOMA methodology.

A. Service Identification.

This is the first phase of RUP/SOMA. During this phase, the Service Model and Goal-Service Model are developed. To ensure alignment of business processes to services, an operation-first approach will be used. Service Identification consists of Domain Decomposition, Goal-service Modeling, and Existing Asset Analysis activities.

1) Domain Decomposition: This activity is used to identify candidate services and associated service flows. It is performed top-down to ensure that services that align with the business. This step is also used to understand the relationships among different business functions within a business to identify commonalities where services may be shared. Table 7 summarizes the tasks and their inputs and outputs.

Table 7. Domain Decomposition Tasks, Inputs, and Outputs.

Task	Inputs	Outputs
Function area analysis	Business Domain	Business Analysis Model Business Architecture Document
Refine a business use case	Business Actor Business Use Case Business Use Case Model	Business Actor Business Use Case Business Use Case Model
Business process analysis	Business Analysis Model	Service Model
Business use case analysis (SOA)	Business Analysis Model Service Model	Service Model

a) Functional area analysis: The purpose of this task is to partition a business into its functional areas and to understand the relationships among them. The outputs are a Business Analysis Model and a Business Architecture Document. The Business Analysis Model is an abstraction of the business and shows how business workers, business entities, and business systems interact to fulfill the goals of that business. The Business Architecture Document provides a comprehensive view of the business and is used to describe the structure of the business, including its organizational structure and how responsibilities and business work are allocated within that structure.

Per RUP/SOMA guidelines, if the objective of the project is to specify a needed behavior, a Business Analysis Model is not required. The Business Architecture Document serves as the basis for making informed decisions about a project and does not directly affect the architecture of the information technology solution itself. Because the project is focused on trust-building, a specific behavior, and is of interest to only one business function, these two work products will not be produced for this study.

However, some general comments about business functions and the role that the clinical trials function plays within a business will be covered briefly here. This information can be used when investigating opportunities for service reuse, either as a consumer or as a provider, and when deciding on service ownership.

If a business has public relations, communications, or marketing/sales functions, those functions may already be involved in activities associated with community outreach or with local physicians and other healthcare providers who are their customers. If so, the systems they use should be explored to determine if there is potential for service reuse. For this study, the assumption is that no other functions within the business have systems that can be reused.

The role of the clinical trials function within a business will depend on the purpose of that business. For example, it would be a supporting function in a business that develops drugs or treatments for commercial use; whereas it would be the primary function in a research organization. It would be the core business for a contract research organization that manages clinical trials on behalf of outside researchers. Thus, the question of ownership must be decided on a specific case-by-case basis.

Although RUP/SOMA is only focused on internal functional areas, it is also important to understand how the business interacts with external entities that are critical to the success of the business. In the case of this study, volunteers for clinical trials and their communities perform a function that is vital to any business that requires clinical trials. Therefore, the business architecture should also consider the role of communities within their business.

b) Refine a business use case: The purpose of this task is to refine existing business use cases so they contain sufficient detail to be realized. The outputs are Business Actor, Business Use Case, and Business Use Case Model for each refined business use case.

Inputs to this task are Business Actor, Business Use Case, and Business Use Case Model. RUP/SOMA assumes these inputs were created at an earlier point in time; and it does not include tasks for creating them in the work breakdown structure. The caBIG CTMS architecture model [37] defines business actors, business processes, and business use cases in sufficient detail to permit realization, so no additional work is required for this step. Refer to Appendix G to see the subset of business use cases that are relevant to this study.

c) Business process analysis: The purpose of this task is to analyze business processes to identify candidate services. In this task, business processes are decomposed into more and more levels of detail until user interfaces start being considered. The most detailed levels are considered leaf-level sub-processes and are candidates for services. The output is an initial version of the Service Model where the service portfolio is identified and organized into a service hierarchy.

This task should consider both existing and new business processes. Refer to Appendix G to see the new business processes. The initial analysis is shown in Figure 5, Figure 6, and Figure 7, using a SOMA notational form to show the relationship between business

processes and services. Business processes and their flows are represented in the Business Aspect; and use cases are represented by bubbles in the IT Aspect. Due to the large number of sub-processes in this domain, only new sub-processes are shown. On an actual project, all sub-processes would be included in the analysis. This would ensure that the relationships between the business and IT are maintained.

Figure 5 shows the highest level of business processes. Figure 6 shows the decomposition of the first three processes. Figure 7 shows the decomposition of the last two processes. RUP/SOMA states that the mapping between use cases and services are typically one-to-one. Note that services have not been defined for Perform Outreach and Provide Health Education business processes because they are not expected to have significant IT requirements. Obtain Trial Results does not appear because it is not specifically associated with a business process.

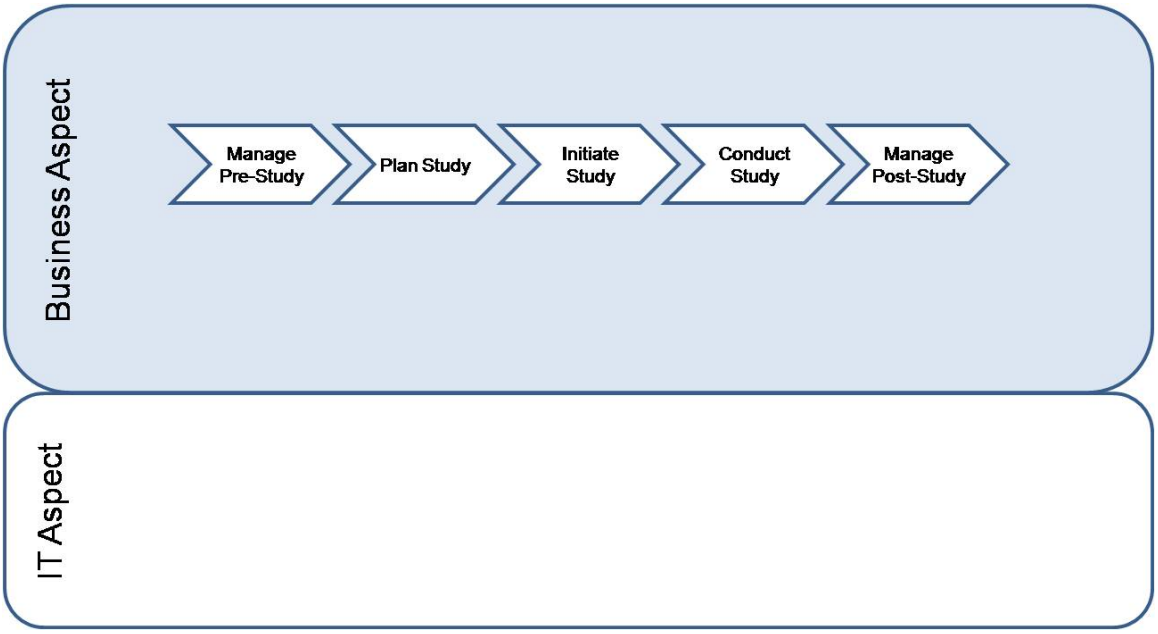

Figure 5. Top-level business processes.

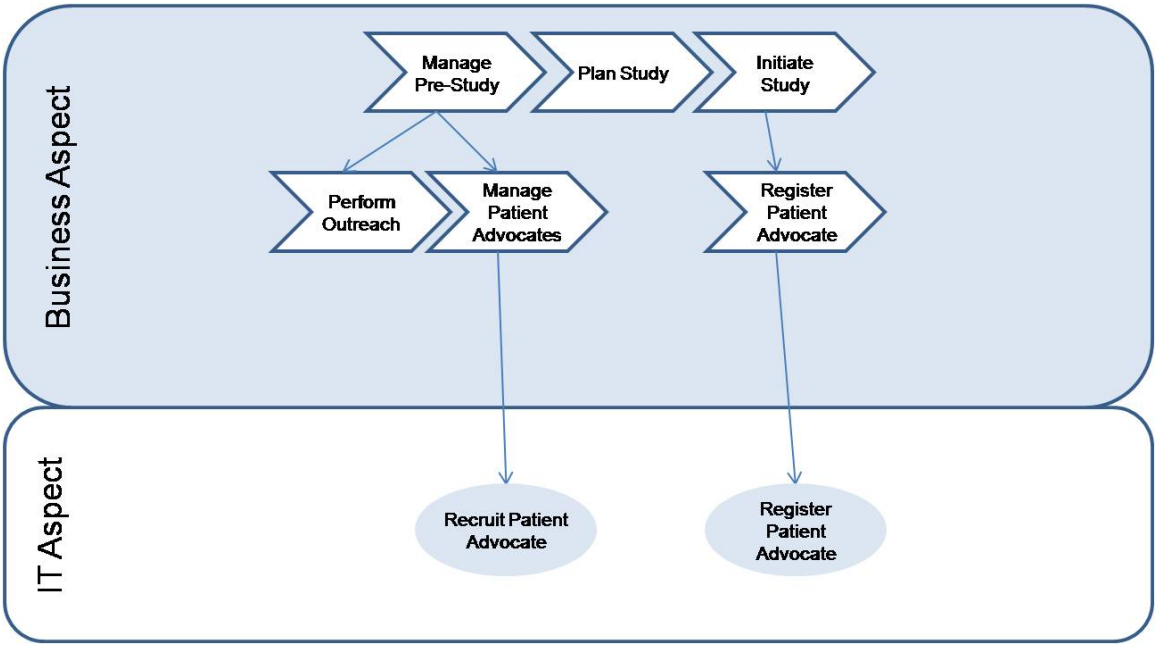

Figure 6. Sub-processes and use cases - Part 1.

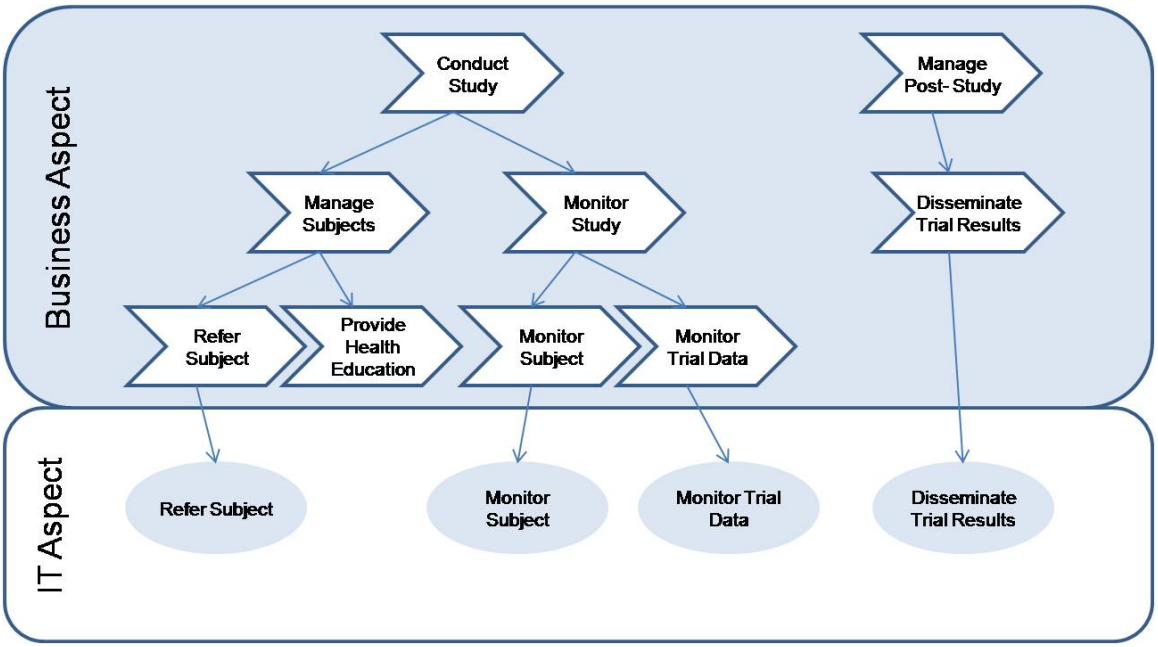

Figure 7. Sub-processes and use cases - Part 2.

Although not required by RUP/SOMA at this point, it is useful to repeat Step b) to refine the new business use cases so there is sufficient information for realization. These are defined in Appendix H.

After refinement of the new business use cases some changes have been identified:

- Manage Patient Advocates has been decomposed into two business use cases, Recruit Patient Advocate and Train Patient Advocate. A service will not be created for Train Patient Advocate, since implementation will have minimal IT requirements.
- Refer Subject has been decomposed into three business use cases, Manage Trial Candidate, Request Subject Referral, and Manage Referral Request.

- Obtain Trial Data has been added to the Report and Analyze Study Category.

RUP/SOMA uses a service hierarchy to organize services into a classification scheme. The caBIG classifications will be used to facilitate better integration with the caBIG architecture because they roughly approximate the different functions associated with clinical trials. Figure 8 shows the service classification hierarchy for candidate services based on the results of business process analysis.

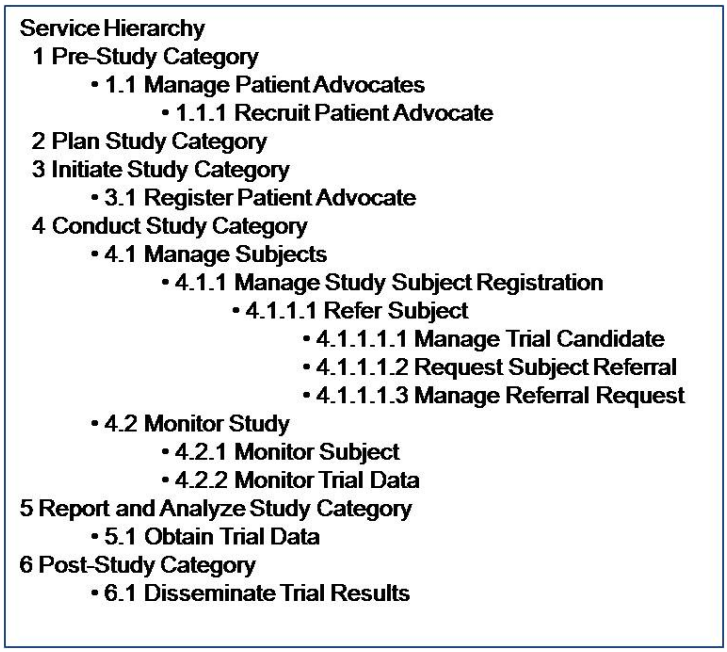

Figure 8. Service Model: service hierarchy.

RUP/SOMA provides a template for capturing information about services that will be used to support service identification and service specification. During the service identification phase, the primary concerns are mapping services to business functions and

goals, identifying existing assets, and noting the status of the service. Table 8 is a completed template for the services that have been identified in Figure 8. At this point, all services are in candidate status, so all services have a status of "C."

Table 8. Service Model: Service Portfolio After Business Process Analysis.

Service	Description	Status	Associations		
			Function / Process	Goal	Asset
Recruit Patient Advocate	Manage potential patient advocate.	C	Pre-Study		
Register Patient Advocate	Register patient advocate as participant in clinical trial.	C	Initiate Study		
Manage Trial Candidate	Manage potential subject, including information about him/her.	C	Conduct Study		
Request Subject Referral	Request to register subject into a trial	C	Conduct Study		
Manage Referral Request	Review request to register subject into a trial.	C	Conduct Study		
Monitor Subject	Generate a view of trial data for a specified subject, submit questions, and review answers.	C	Conduct Study		
Monitor Trial Data	Generate a view interim trial data.	C	Conduct Study		
Obtain Trial Data	Query CDMS to retrieve data.	C	Report and Analyze Study		
Disseminate Trial Results	Send a final report in a format that can be viewed.	C	Post-Study		

d) Business use case analysis (SOA): The purpose of this task is to review business use cases to identify and refine the candidate services. Reviewing the set of operations for a business use case realization may reveal some services that are conversational in nature. In those cases, the architect should consider aggregating those services into a single one. The output is an updated Service Model. After review of the business use cases, none

have been identified to be conversational. As a result, no changes are required.

2) Goal-Service Modeling: This activity is used to determine which services will help the business achieve desired goals and to identify where there may be a services gap. Metrics are defined to measure how well services perform against those business goals. A Goal-Service Model is created to map business goals to specific metrics and services. Table 9 summarizes the tasks and their inputs and outputs.

Table 9. Goal-Service Tasks, Inputs, and Outputs.

Task	Inputs	Outputs
Identify business goals and KPIs	Business Vision	Business Goal
Identify and associate services to goals	Business Goal Service Model	Goal-Service Model

a) Identify business goals and KPIs: The purpose of this task is to identify the goals that are relevant to the project and to identify ways to measure the effectiveness of the services being developed to meet those goals. The output is Business Goal, a hierarchical list of goals and one or more key performance indicators (KPIs) for each goal.

As discussed in Section II, lack of trust between clinical researchers and the communities where they operate can impact the ability to recruit and retain subjects in clinical trials. This, in turn, affects the total cost of a clinical trial. Figure 9 reflects this linkage.

Note that some goals do not have KPIs. This is because it may be difficult to measure that specific goal. In these cases, the KPI for a goal higher or lower in the hierarchy can serve as an indirect KPI. Also note that this is not a strict hierarchy. Goals 1.1.1, 1.2.1, and 2.2.1 are identical and show that implementing a single sub-goal can help an organization achieve multiple higher-level goals. Finally, note that this is only a subset of goals that a business might have. Only those that are relevant to the project are shown.

The specific percentage improvements in goals 1, 1.2, and 2.2 should be determined by the sponsoring organization. For this study, placeholders have been used.

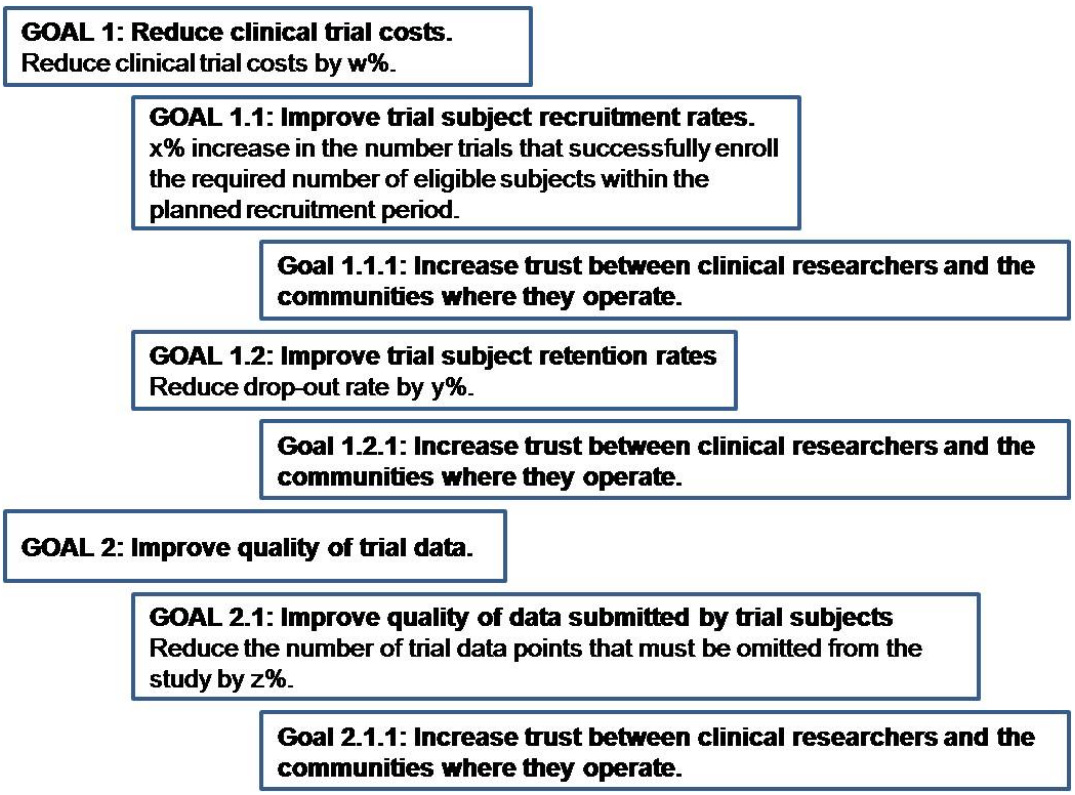

Figure 9. Business goal hierarchy.

Because these business processes focus on the interactions between researchers and the community, the services must also be effective in helping the community meet their goals. Community goals are focused on improving the health of community members, as shown in Figure 10.

Figure 10. Community goal hierarchy.

b) Identify and associate services to goals: The purpose of this task is to link services to business goals. The output is a Goal-Service Model in tabular form that maps the information from Business Goal in Figure 9 and Figure 10 to specific metrics and services, as shown in Table 10. Note that services related to recruitment and patient referral are mapped to the community goal. This is based on the assumption that participation in relevant clinical trials can result in effective treatment of health concerns.

Table 10. Preliminary Goal-Service Model.

Goal or Sub-Goal	KPIs	Metric	Services
1: Reduce clinical trial costs.	Reduce clinical trial costs by w%.	Record recruitment spending.	
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
1.2: Improve trial subject retention rates.	Reduce drop-out rate by y%.	Record status of each subject enrolled in a trial.	Monitor Subject Monitor Trial Data
1.2.1: Increase trust between clinical researchers and the communities where they operate.	Reflected in KPI for Goal 1.2.	n/a	Obtain Trial Data Disseminate Trial Results
2: Improve quality of trial data.	Reflected in KPI for Goal 2.1.	n/a	
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 Monitor Subject
2.1.1: Increase trust between clinical researchers and the communities where they operate.	Reflected in KPI for Goal 2.1	n/a	Obtain Trial Data Disseminate Trial Results
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 Request Subject Referral Manage Referral Request Monitor Subject Monitor Trial Data

3) Existing Asset Analysis: This activity is used to identify existing assets. Table 11 summarizes the tasks and their inputs and outputs.

Table 11. Existing Asset Analysis Tasks, Inputs, and Outputs.

Task	Inputs	Outputs
Existing asset analysis	Service Model	Service Model
Data model analysis	Service Model	Service Model
Business rule analysis	Service Model	Service Model
Construct Architectural Proof-of-Concept (SOA)	Service Model	

a) Existing asset analysis: The purpose of this task is to review existing applications to identify candidate services for the solution. For this task, the business application portfolio is examined to understand the functionality the applications provide. This application portfolio includes custom applications and COTS. A coarse-grained mapping of business functions to services is performed to identify candidate services from these applications. The output is an updated Service Model.

For this study, it is assumed that the caBIG systems are the only ones in the business that have relevant applications. There are three caBIG systems that are used in this study. caBIG Clinical Trial Suite 2.0 (CTS) [18] is a services-based system for use at clinical trial sites. caGrid 1.3 [40] is the underlying platform and infrastructure that integrates caBIG tools and provides common services such as authorization and authentication. caBIG Integration Hub [41] is a service bus that manages access to services provided by components of CTS. The specific services that are available are documented at caBIG Knowledge Center [42].

Based on this assumption, the Service Model has been updated with additional candidate services, Patient and Registration. These are shown in bold type in Table 12. Although not explicitly included in the RUP/SOMA methodology, the Goal column has been updated with goals from the goal hierarchies in Figure 10 and Figure 11, since that information is now available.

Table 12. Service Model: Service Portfolio After Existing Asset Analysis.

Service	Description	Status	Associations		
			Function / Process	Goal	Asset
Recruit Patient Advocate	Manage potential patient advocate.	C	Pre- Study	**1.1.1 2.1 3**	
Register Patient Advocate	Register patient advocate as participant for a trial.	C	Initiate Study	**1.1.1 2.1 3**	
Manage Trial Candidate	Manage potential subject, including information about him/her.	C	Conduct Study	**1.1 3**	
Request Subject Referral	Request to register subject into a trial	C	Conduct Study	**1.1 3**	
Manage Referral Request	Review request to register subject into a trial.	C	Conduct Study	**1.1 3**	
Monitor Subject	Generate a view of trial data for a specified subject, submit questions, and review answers.	C	Conduct Study	**1.2 2.1 3**	
Monitor Trial Data	Generate a view interim trial data.	C	Conduct Study	**1.2 3**	
Obtain Trial Data	Generate a report of trial data or outcomes.	C	Report and Analyze Study	**1.2.1 2.1.1**	
Disseminate Trial Results	Send a final report in a format that can be viewed.	C	Post-Study	**1.2.1 2.1.1**	
Patient	**Manage and query patients.**	**C**	**Conduct Study**	**1.2**	**CTS**
Registration	**Manage and query registration.**	**C**	**Conduct Study**	**1.1**	**CTS**

b) Data model analysis: The purpose of this task is to examine the business domain model to identify additional candidate services for the solution. The domain model is examined for business entities that overlap with those of the solution domain. By identifying the systems that operate on those entities within the business, one may find other applications that are candidates for services. The output is an updated Service Model.

Because this study assumes that CTS is the only system with relevant applications, no additional candidate services have been added.

c) Business rule analysis: The purpose of this task is to examine the business rules to identify additional candidate services for the solution.

Business rules are examined to determine if any can be externalized via a service. Externalizing these rules from the logic will allow the rules to evolve independently without affecting the application logic, thus removing variability. The output is an updated Service Model.

Trial eligibility criteria are business rules to determine if a prospective subject meets the requirements to participate in a clinical trial. These criteria are unique to each clinical trial. An application that automatically evaluates the eligibility of a prospective subject would be a candidate service. However, at the time the study was conducted, CTS did

not have such an application or service, so there is no change to the Service Model.

d) Construct architectural proof-of-concept: The purpose of this task is to develop a prototype of the architecture or a conceptual architecture to evaluate its feasibility. In the proof-of-concept, non-functional requirements, such as exception handling and data availability, are evaluated to determine if the proposed solution is feasible. No output is defined for this task.

A conceptual architecture is illustrated in Figure 11. Access to web services will be through caBIG Integration Hub, which is an enterprise service bus based on open standards [41]. Exception handling and message conversions will be handled by caBIG Integration Hub. Data associated with a trial will be in a separate CDMS. caBIG Integration Hub can access these CDMSs through a Clinical Connector. At the time of this study, four popular CDMSs were being evaluated for implementation. This study assumes that a supported CDMS will be used for implementing the solution.

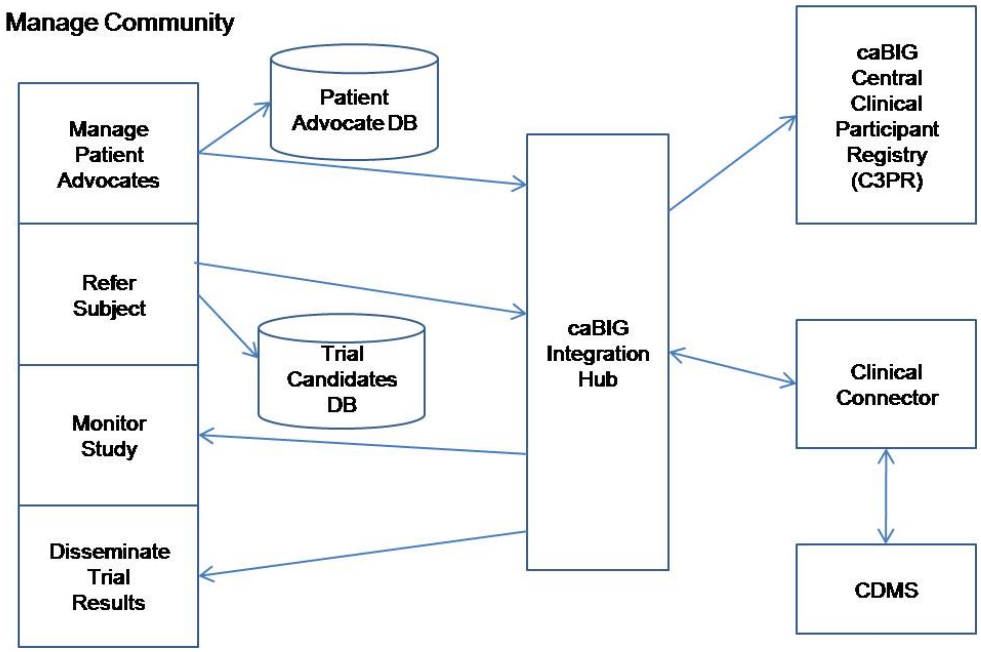

Figure 11. Conceptual architecture.

B. Service Specification.

This is the second phase of RUP/SOMA. During this phase, the Service model is updated to document service exposure decisions, to identify interdependencies among services, and to define service messages. The Design Model is developed to provide greater details about services and to describe the components of the solution and relationships among them. Service Specification consists of Perform Service Specification, Perform Subsystem Analysis, and Perform Component Specification.

1) Perform Service Specification: This activity is used to further specify the services. Table 13 summarizes the tasks and their inputs and outputs.

Table 13. Perform Service Specification Tasks, Inputs, and Outputs.

Task	Inputs	Outputs
Apply services litmus tests	Service Model	Goal-Service Model Service Model
Service specification	Service Model	Service Model
Message design	Service Model	Service Model
Identify security patterns	Software Architecture Document	Software Architecture Document

a) Apply services litmus tests: The purpose of this task is to select which of the candidate services are to be exposed. The outputs are an updated Goal-Service Model and an updated Service Model.

For this task, each candidate service is evaluated against a set of criteria:

- Is the service aligned with the business?
- Is the service composable? For example, is the service stateless and is it self-contained? Is it technology neutral?
- Does the service have an external description? This would be applied to existing applications.
- Can this service be reused?
- Is the service technically feasible?

Candidates that do not meet all these criteria will not typically be exposed. However, this evaluation is an iterative process, so the decision may change as more information about eliminated services is discovered. Regardless, the eliminated services will still be

implemented in some manner, perhaps as applications on top of service components or as internal services.

Table 14 maps each candidate service against the criteria. Note that there are a number of services that will be exposed, even though they do not meet the external description criteria. This is because these services have not been implemented yet and external descriptions do not exist. While performing this task, it was noted that Register Subject duplicates an existing service, so this service will not be exposed at this time.

Table 14. Service Model: Service Exposure Decision.

Service	Expose	Service Litmus Test Results					
		Aligned	Composable	External Description	Reusable	Feasible	Comments
Recruit Patient Advocate	Y	x	x		x	x	new service
Register Patient Advocate	Y	x	x		x	x	new service
Manage Trial Candidate	Y	x	x		x	x	new service
Request Subject Referral	N	x				x	new service
Manage Referral Request	N	x				x	new service
Monitor Subject	N	x				x	new service
Monitor Trial Data	N	x				x	new service
Obtain Trial Data	Y	x	x		x	x	new service
Disseminate Trial Results	N	x			x	x	new service
Patient	Y	x	x	x	x	x	
Registration	Y	x	x	x	x	x	

Based on the litmus test, the Service Model is updated, as shown in Table 15, where the Status column has been updated to be either “A” to indicate the associated service has been approved for implementation or “E” to indicate the associated service will be exposed. The Services column in the Goal-Service Model is updated, as shown in Table 16.

Table 15. Service Model: Service Portfolio After Litmus Test.

Service	Description	Status	Associations		
			Function / Process	Goal	Asset
Recruit Patient Advocate	Manage list of potential patient advocates.	**E**	Pre- Study	1.1.1 2.1 3	
Register Patient Advocate	Register patient advocate as participant in clinical trial.	**E**	Initiate Study	1.1.1 2.1 3	
Manage Trial Candidate	Manage list of potential subjects, including information about them.	**E**	Conduct Study	1.1 3	
Request Subject Referral	Request to register subject into a trial	**A**	Conduct Study	1.1 3	
Manage Referral Request	Review request to register subject into a trial.	**A**	Conduct Study	1.1 3	
Monitor Subject	Generate a view of trial data for a specified subject, submit questions, and review answers.	**A**	Conduct Study	1.2 2.1 3	
Monitor Trial Data	Generate a view interim trial data.	**A**	Conduct Study	1.2 3	
Obtain Trial Data	Generate a report of trial data or outcomes.	**E**	Report and Analyze Study	1.2.1 2.1.1	
Disseminate Trial Results	Send a final report in a format that can be viewed.	**A**	Post-Study	1.2.1 2.1.1	
Patient	Manage and query patients	**E**	Conduct Study	1.2	CTS
Registration	Manage and query registration	**E**	Conduct Study	1.1	CTS

Table 16. Goal-Service Model After Litmus Test (Exposed Services Only).

Goal or Sub-Goal	KPIs	Metric	Services
1: Reduce clinical trial costs.	Reduce clinical trial costs by w%.	Record recruitment spending.	
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
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
1.2: Improve trial subject retention rates.	Reduce drop-out rate by y%.	Record status of each subject enrolled in a trial.	
1.2.1: Increase trust between clinical researchers and the communities where they operate.	Reflected in KPI for Goal 1.2.	n/a	
2: Improve quality of trial data.	Reflected in KPI for Goal 2.1.	n/a	
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
2.1.1: Increase trust between clinical researchers and the communities where they operate.	Reflected in KPI for Goal 2.1.	n/a	
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

b) Service specification: The purpose of this task is to define each service in greater detail, including the service dependencies, composition, flows, and non-functional

requirements. The output is a Service Model that is updated with this information.

RUP/SOMA defines two types of dependencies, functional ones and temporal ones. When a service is a composition of other services, the composing service has a functional or Type 1 dependency on the composed services. When services are used in the context of business processes, the services may have to be executed in a particular order. These services have temporal or Type 2 dependencies and need to be choreographed.

None of the new exposed services have Type 1 dependencies. Manage Referral Request has Type 1 dependencies on Patient and Registration. However, it is has not been earmarked as an exposed service. The temporal dependencies are shown in Figure 12 using a SOMA notational form.

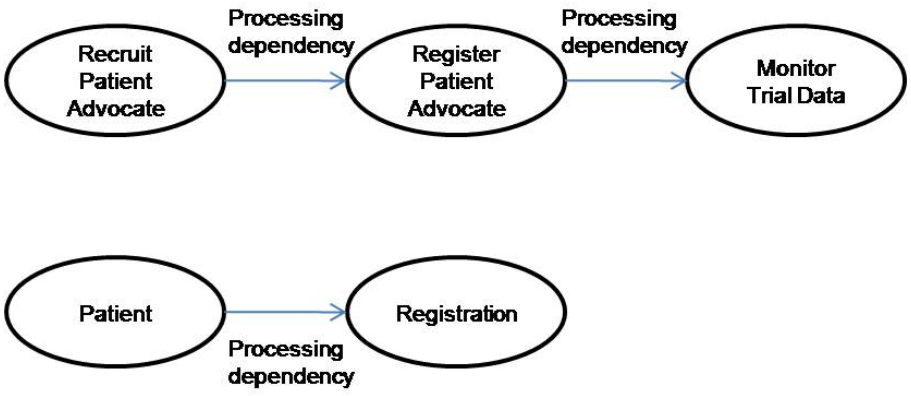

Figure 12. Service Model: temporal (Type 2) dependencies.

Service composition is used to group together a set of short-running non-interruptible processes or a set of long-running processes. In this study, composition is not required since these processes are short-running and interruptible.

Nonfunctional requirements, such as availability, operational window size, response time, and peak throughput, are considerations that should be noted. The services in this study do not have nonfunctional requirements beyond typical web application response times.

c) Message design: The purpose of this task is to develop a message design model that describes the message exchange patterns. The output is an updated Service Model that identifies the operations for each service along with its signature.

The RUP/SOMA template requires a separate table for each service. To preserve space, a different format containing the same information was used. Table 17 includes messages for each new exposed service.

Table 17. Service Model: Service Messages.

Service	Topic	Input Message	Output Message
Recruit Patient Advocate	createPatientAdvocate	PatientAdvocate	
	updatePatientAdvocate	PatientAdvocate	PatientAdvocate
	deletePatientAdvocate	PatientAdvocate	
	findPatientAdvocate	PatientAdvocate	PatientAdvocate
Register Patient Advocate	createRegistration	AdvocateRegistration	
	updateRegistration	AdvocateRegistration	PatientAdvocate
	deleteRegistration	AdvocateRegistration	
	findRegistration	AdvocateRegistration	PatientAdvocate
Manage Trial Candidate	createSubject	Subject	
	update Subject	Subject	Subject

	deleteSubject	Subject	
	findSubject	Subject	Subject
Obtain Trial Data	getSingleSubject	TrialDataQuery	SubjectData
	getMultipleSubjects	TrialDataQuery	MultiSubjectData

d) Identify security patterns: The purpose of this task is to identify and select security patterns that will ensure security requirements will be met. The output is an updated Software Architecture Document.

There are three key security patterns for these services: 1) Identity and Authentication; 2) Authorization; and 3) Message Protection. These patterns are required because of the sensitive and personal nature of the information being handled.

e) Document service state-management decisions: This is a SOMA task that is not included in the RUP/SOMA process description. The purpose of this task is to determine if state information must be maintained across the invocation of composed services.

Subject will assigned various states (e.g., candidate or eligible) as part of executing business processes. However, the state does not need to be maintained across composed services. No other entities require state information.

2) Perform Subsystem Analysis: This activity is used to understand the relevant subsystems within the business and map them to their IT counterparts. Table 18

summarizes the tasks and their inputs and outputs.

Table 18. Perform Service Specification Tasks, Inputs, and Outputs.

Task	Inputs	Outputs
Subsystem design	Business Analysis Model Design Subsystem Interface	Design Model

a) Subsystem design (SOA): The purpose of this task is to link business models to their counterparts. To do this, functional areas are mapped to subsystems. Then the subsystem behaviors, internal structures, and dependencies are defined. The output is a component-level Design Model.

The first step in this task is to use output from functional area analysis to identify the supporting subsystems. In Table 19, functional areas of interest in this study are mapped to existing subsystems. To implement the new capabilities introduced in this study, a new functional area, Community, has been added. The new subsystems are based on the business object being processed. Refer to Figure 17 for depictions of each subsystem.

Table 19. Design Model: Functional Area Analysis of Clinical Trials Function.

Domain	Functional Area	Subsystem	Description
Clinical Trials	Clinical Researchers	Patient	Provides patient-related functions.
		Registration	Provides registration-related functions.
	Community	Patient Advocate	Provides functions to manage patient advocates.
		Subject	Provides functions to manage potential trial subjects.
		TrialData	Provides functions to provide reports about trial data.

The next step is to review the subsystems and to identify any dependencies among them. A detailed description of each subsystem associated with CTS and the relationships among them is provided in [18] and is not duplicated here. The dependencies associated with the new subsystems are shown in Table 20.

Table 20. Design Model: Subsystem Dependencies.

Subsystem	Depends On	Description
Patient Advocate	none	n/a
Subject	Patient Advocate	The Patient Advocate system is used to ensure that the user is authorized to access a particular candidate's information.
	Patient	The Patient subsystem is used to enter information about a patient into the CTMS and must be completed before a subject can be referred to a trial.
	Register	The Register subsystem is used to register the subject.
Trial Data	Patient Advocate	The Patient Advocate system is used to ensure that the user is authorized to access a particular candidate's information.
	Subject	The Subject system is used to ensure that the user is authorized to access a particular candidate's information.

The final step is to identify the service components, function components, and technical components. A service that is assigned to a subsystem typically becomes a service component. Functional components provide additional business functions to the service component and are often type managers. Technical components provide functions that typically cross business domains. Table 21 identifies these components.

Upon analysis of subsystem interdependencies, it was determined that additional technical components are needed to provide function to respond to inquiries about the status of a patient advocate or subject. Confirm Subject Status and Confirm Patient

Advocate Status have been added as technical components.

Table 21. Design Model: Component Identification.

Services	Service Component			Functional Component	Technical Component		
	Patient Advocate	Subject	Trial Data		Confirm Patient Advocate Status	Confirm Subject Status	Obtain Trial Data
Recruit Patient Advocate				x			
Register Patient Advocate	x				x		
Manage Trial Candidate				x	x	x	
Obtain Trial Data							x

3) Perform Component Specification: This activity is used to specify more details about the service components. Table 22 summarizes the tasks and their inputs and outputs.

Table 22. Perform Service Specification Tasks, Inputs, and Outputs.

Task	Inputs	Outputs
Component specification	Design Subsystem Service Component (Design Model)	Service Component (Design Model)

a) Component specification (SOA): The purpose of this task is to elaborate on the service component design. This elaboration includes:

- Modeling the component flows. This is typically a Universal Markup Language (UML) sequence diagram. However, for this study, component flows are represented using Petri nets. The same Petri net can be used for Recruit Patient Advocate and Manage Trial Candidate since both require create, read, update, and delete (CRUD) processes, as shown in Figure 13. The Petri net for Register Patient Advocate is shown in Figure 14. Diagram annotations are in Table 23 and Table 24.

  These Petri nets were developed and validated using Platform Independent Petri net Editor 2.4 (PIPE2) [43].

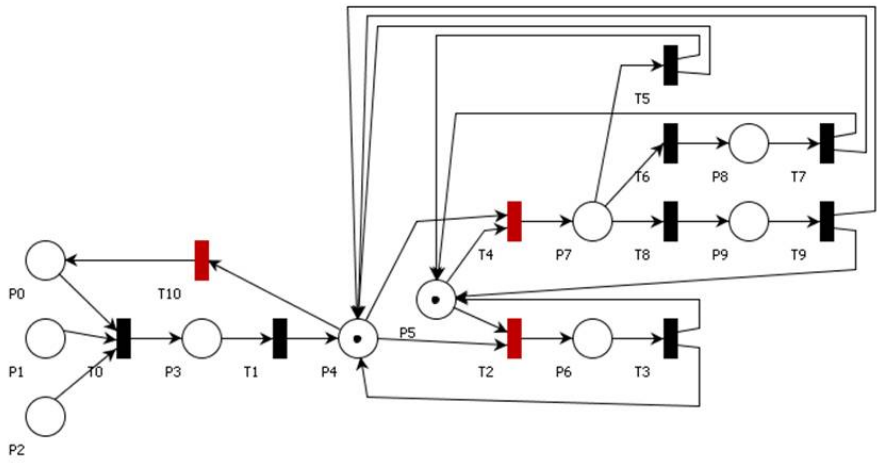

Figure 13. Design Model: Petri net for CRUD.

Table 23. Annotations for Recruit Patient Advocate and Manage Trial Candidate.

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 or Trial Candidates page (home page)
P5	Database	Connection to Advocates or Candidates database
P6	Data	Added database entry
P7	Data	Retrieved database entry
P8	Data	Updated database entry
P9	Data	Deleted database entry
T0	Task	Log in user
T1	Task	Display home page
T2	Task	Obtain database thread; add a patient advocate or trial candidate
T3	Task	Release database thread; display home page
T4	Task	Obtain database thread; retrieve database entry for patient advocate or trial candidate
T5	Task	Release database thread; display home page
T6	Task	Update database entry
T7	Task	Release database thread; display home page
T8	Task	Delete database entry
T9	Task	Release database thread; display home page
T10	Task	Log out user

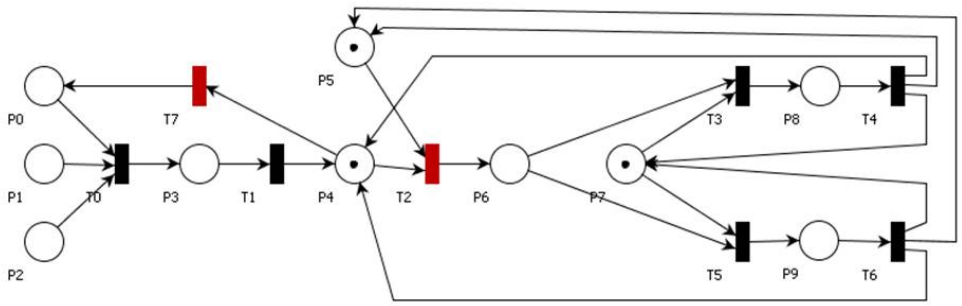

Figure 14. Design Model: Petri net for Register Patient Advocate.

Table 24. Annotations for Register Patient Advocate.

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 (home page)
T2	Task	Obtain Advocates 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

- Identifying events and messages. A high level specification was provided in the Service Model. The specification of events and messages is part of normal design activity for web services and is not unique to SOMA so this task is not covered in this study.
- Specifying component attributes. This includes: 1) component properties and attributes; 2) rules; 3) variations; 4) dependencies on other components; 5) any composition of functional or technical components; 6) a list of the services provided; and 7) a list of the services required. The attributes that are unique to SOMA have been addressed in previous steps. Refinement is not unique to SOMA, so this task is not covered in this study.

- Creating a component class diagram that shows the relationships between the functional and technical components of each service component. This will be used to conduct variability analysis. Component models are created to depict the relationships among the components. Figure 15 shows the relationship between ManageTrialCandidate and ConfirmPatientAdvocateStatus.

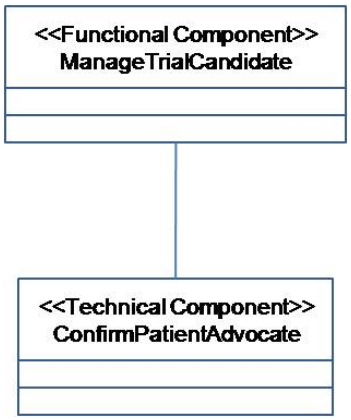

Figure 15. Design Model: relationship of components in Subject subsystem.

- Allocating components to layers. The service components have been allocated to `the Service Component layer, as illustrated in Figure 16.

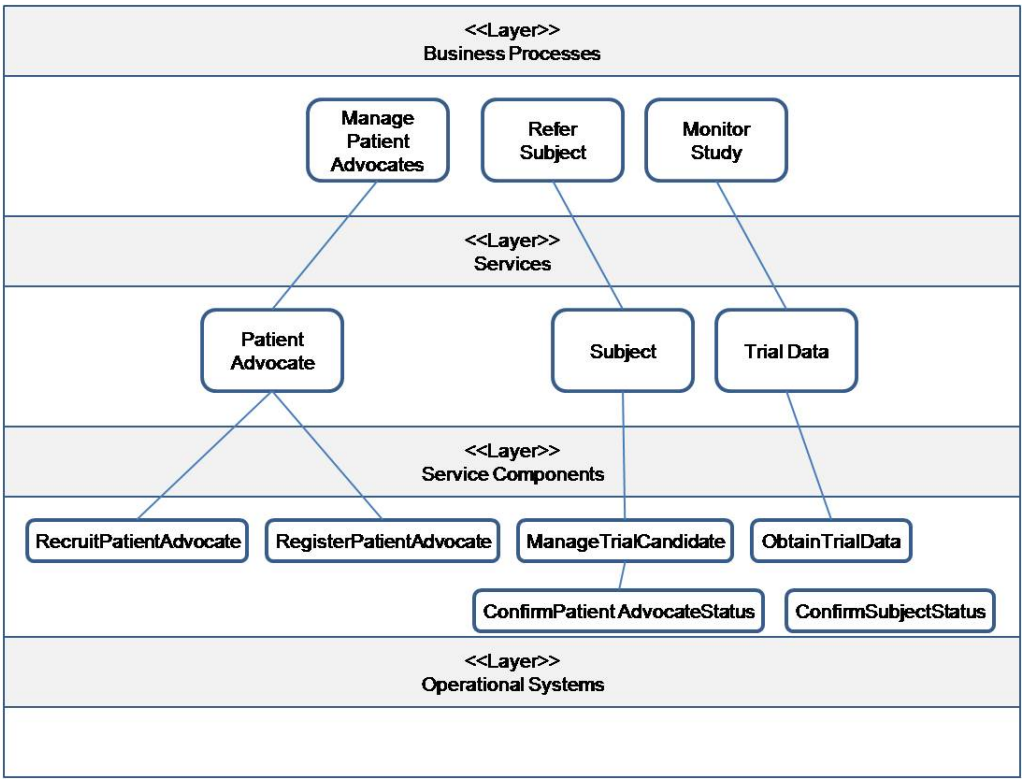

Figure 16. Design Model: architectural layers.

C. Service Realization.

This is the third phase of RUP/SOMA. During this phase, the Service Model is updated to document realization decisions; and a proof-of-concept is conducted. Service Realization consists of one activity, Realization Decisions.

1) Realization Decisions: This activity is used to evaluate various options to determine how a service will be built. Table 25 summarizes the tasks and their inputs and outputs.

Table 25. Realization Decisions Tasks, Inputs, and Outputs.

Task	Inputs	Outputs
Document service realization decisions	Reference Architecture Service Model Software Architecture Document	Design Model
Component specification	Design Subsystem Service Component (Design Model)	Service Component (Design Model)
Construct architectural proof-of-concept	Service Model	
Assess viability of architectural proof-of-concept	Architectural Proof-of-Concept Business Case Glossary Risk List Vision	Reference Architecture Review Record

a) Document service realization decisions: The purpose of this task is to determine a sourcing approach. The output is a Design Model.

RUP/SOMA describes a number of options for how to realize a service. They include: 1) developing the service in-house; 2) purchasing code for the service so it can be hosted internally; 3) extracting and transforming functionality from an existing code source; 4) subscribing to an existing publish-subscribe service; 5) creating a wrapper around legacy code; or 6) using a web service offered by an outside business. The decisions for the Community enterprise component are documented in Table 26. In all cases, the decision to build in-house was due to lack of awareness of an existing service or source code. The Patient and Registration services are realized through web services offered by a third party.

Table 26. Service Model: Service Realization Decisions.

Enterprise Component	Realized Service	Functional & Technical Components	Realization Decision
Community	Subject	ManageTrialCandidate	Build in-house
		ConfirmSubjectStatus	Build in-house
	Patient Advocate	RecruitPatientAdvocate	Build in-house
		RegisterPatientAdvocate	Build in-house
		ConfirmPatientAdvocateStatus	Build in-house
	Trial Data	ObtainTrialData	Build in-house

b) Component specification (SOA): The purpose of this task is to allocate components to layers. This is a reiteration of the step performed during Service Specification. No update is required.

c) Construct architectural proof-of-concept: This is a reiteration of the step performed during Service Identification. During this phase, additional details about the services may reveal additional issues to consider.

The proof-of-concept is focused on the high risk areas of the architecture. In this study, the proposal to use third-party services brings significant risks, such as loss of service, data loss, performance problems, unreliability of service, lack of interoperability, and format changes [44]. Because of this, the proof-of-concept will be a working prototype designed to demonstrate the feasibility of using caBIG Integration Hub to access the Patient service. The goal of the prototype is to use the Patient service to enroll a patient that has been defined in a separate application [45].

d) Assess viability of architectural proof-of-concept: The purpose of this task is to define how an Architectural Proof-of-Concept will be evaluated against Architectural Requirements and Risks. Evaluation criteria are determined based on requirements that are significant from an architectural perspective. The evaluation results are reviewed to determine if these requirements can be met. If not, the project team may want to re-evaluate the requirement priorities.

As indicated earlier, the highest risk aspects of the architecture are associated with use of third-party services. Evaluation criteria involve the answers to these questions:

- Can authentication and authorization be implemented to ensure secure access to information?
- Do the services provide the capability necessary to implement the complete solution?
- Will the performance characteristics allow the solution to scale?
- Are the called services sufficiently stable from a capability, interface, and quality perspective?

VIII Evaluation of Proposed Solution

After the Service Model and Design Model are created and technically validated via an architectural proof-of-concept, it is appropriate to evaluate the proposed solution against the original project goals, requirements, and expected benefits.

Figure 17 shows the overall architecture of the proposed solution. It includes service components, web application components, and the relationships among the components. Refer to Appendix I for a model of the Monitor Subject application using a Petri net.

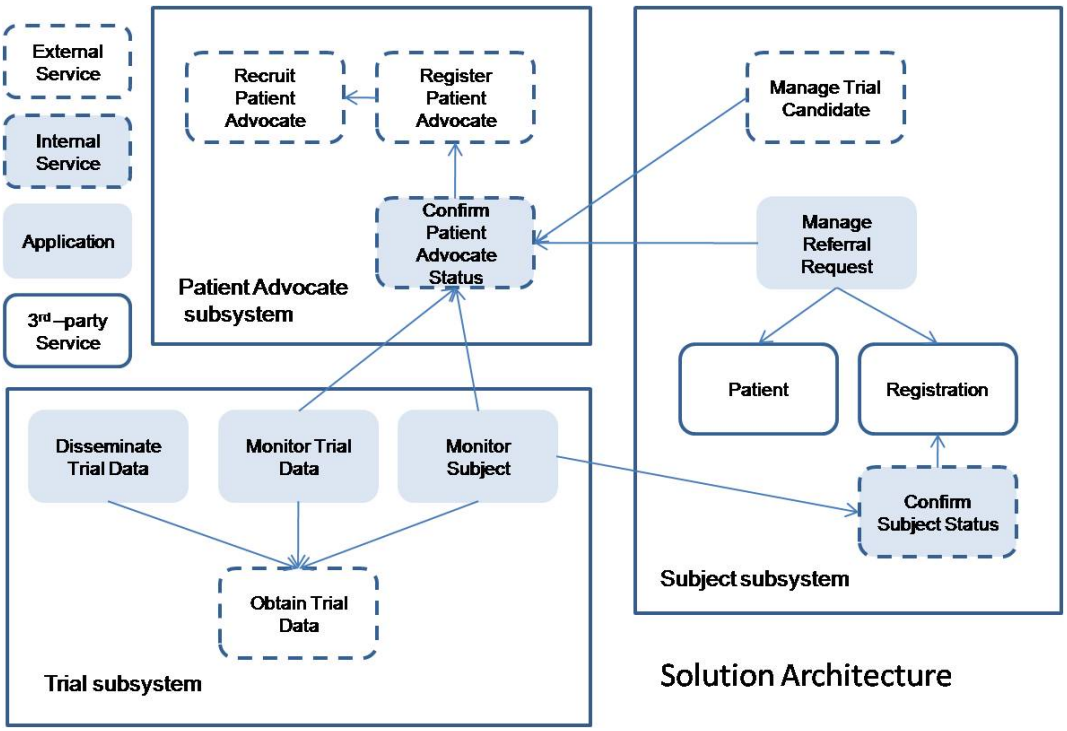

Figure 17. Solution architecture.

A. Evaluation Against Goals.

Because SOMA includes the Goal-Service Modeling step, there is a clear relationship between business goals and the services being proposed, as shown in Table 27. As the metrics identified in Table 16 are collected and analyzed, there will be objective evidence to show that these services are effective in meeting business goals.

Table 27. Goal-Service Summary.

Goal or Sub-Goal	Services
1: Reduce clinical trial costs.	
1.1: Improve trial subject recruitment rates.	Manage Trial Candidate Confirm Subject Status
1.1.1: Increase trust between clinical researchers and the communities where they operate.	Recruit Patient Advocate Register Patient Advocate Confirm Patient Advocate Status
1.2: Improve trial subject retention rates.	Obtain Trial Data
1.2.1: Increase trust between clinical researchers and the communities where they operate.	Obtain Trial Data
2: Improve quality of trial data.	
2.1: Improve quality of data submitted by trial subjects.	Recruit Patient Advocate Register Patient Advocate
2.1.1: Increase trust between clinical researchers and the communities where they operate.	Obtain Trial Data
3: Receive effective treatment for a health concern.	Recruit Patient Advocate Register Patient Advocate Manage Trial Candidate Obtain Trial Data

B. Evaluation Against Requirements.

Some of the business requirements identified in Section VI will be addressed through implementation of business processes that do not require an IT solution. Table 28 shows the mapping between the business requirements and the new services that are part of the solution. Note that the design and architecture meet requirement A-13, even though there

is no specific service associated with it.

Table 28. Business Requirements Mapped to Services.

Business Requirement	Business Process	New Business Use Case	Service
A-1. Increase awareness	Perform Outreach	none	n/a
A-2. Educate physicians	Perform Outreach	none	n/a
A-3. Incorporate community perspective	All existing business processes, where appropriate	none	n/a
A-4. Provide culturally appropriate education	Perform Outreach	none	n/a
A-5. Provide culturally appropriate informed consent	All informed consent processes	none	n/a
A-6. Incorporate community needs and priorities	All existing business processes, where appropriate	none	n/a
A-7. Include members of the community in all stages of the clinical trials process	All existing business processes, where appropriate	none	n/a
A-8. Engage and train research advocates	Manage Patient Advocates Refer Patient Advocate Refer Subject	Recruit Patient Advocate Train Patient Advocate Manage Trial Candidate Request Subject Referral Manage Referral Request	RecruitPatientAdvocate RegisterPatientAdvocate ManageTrialCandidate ConfirmPatientAdvocateStatus ConfirmSubjectStatus
A-9. Engage community physicians and healthcare providers	All existing business processes, where appropriate	none	n/a

A-10. Ensure follow-through on commitments to trial subjects	not applicable	none	n/a
A-11. Ensure ongoing one-on-one communication	Monitor Study	Monitor Subject Monitor Trial Data Obtain Trial Data	ObtainTrialData
A-12. Provide health education to trial subjects	Provide Health Education	none	n/a
A-13. Provide a single, consistent interface	not applicable	none	n/a
A-14. Disseminate project outcomes	Disseminate Trial Results	Disseminate Trial Results Obtain Trial Data	ObtainTrialData

In addition to business requirements, some architectural requirements were identified in Section V.C:

- Requirement: The solution must be integrated with existing systems.

  Assessment: This is largely possible because CTS is services-based. If different systems had been chosen as the basis for this study, it might have been more difficult to achieve integration.

- Requirement: The system must accommodate multiple CTMS and CDMS back-ends.

  Assessment: Because CTMSs and CDMSs are accessed via services, the architecture is not limited to specific back-end systems. However, there may be limitations based on the ability to create a service wrapper around a system.

- Requirement: The solution must be sufficiently flexible to accommodate the specific requirements of each supported clinical trial.

  Assessment: Because reusable services will be created and made public, solution developers can mix and match them to accommodate their specific needs. It is easier for them to fill in the missing functionality because the services have well-defined interfaces.
- Requirement: The solution must support rapid deployment and be cost-effective.

  Assessment: The expectation is that there will be less need to build functionality from scratch. Solution developers should be able to spend less time implementing core capabilities to support their trust-building activities so they can focus on issues that are unique to a particular trial, such as translation of user interfaces.

C. Evaluation Against the Case Study.

As stated in Section III, trust in the Hispanic community is influenced by common cultural characteristics. Table 29 shows the linkage between these cultural characteristics and business processes or services.

In support of the case study, patient advocates recruited from the San Jose Hispanic community would be managed using Recruit Patient Advocate and Register Patient Advocate. This would include family members, community-based healthcare providers, or primary care physicians.

Table 29. Linkage between Trust Issues and Services.

Characteristic	Business Process Support	Supporting Service Support
Language	Develop Informed Consent Form Obtain Informed Consent	none
Family	Perform Outreach Manage Patient Advocates Disseminate Trial Results	Recruit Patient Advocate Register Patient Advocate Obtain Trial Data
Respect	Monitor Study Disseminate Trial Results	Obtain Trial Data
Personal Relationships	Refer Subject Monitor Study	Manage Trial Candidate Obtain Trial Data

Healthcare providers would be trained about the benefits of participating in clinical trials and encouraged to refer patients using Manage Trial Candidate. Because the eligibility requirements of the case study can be stated as rules that can be verified electronically, a custom-built service to automatically verify eligibility could be developed and incorporated into the solution. Because the solution is an SOA, incorporating this change should be straight-forward.

Once the trial started, the trial subject would be able to view all trial data collected to date and perhaps view trend data, such as changes in BMI over time, using Obtain Trial Data. The subject's healthcare provider would also be able to use the service to view the patient's progress and, perhaps, to order lab tests to monitor the effects of better diet and improved BMI on other health indicators, such as blood sugar, cholesterol levels, and blood pressure.

D. Summary.

Table 30 contains a summary of the evaluation. The primary business goals can be met if trust is improved through use of the proposed solution. Most of the architectural requirements have been realized. Linkages between these services and increased trust in the San Jose Hispanic community were demonstrated.

Table 30. Summary of Solution Evaluation.

Project Goal Requirement	Goal Met or Requirement Met
Goal	
1. Reduce clinical trial costs.	Yes, due to improved trust
2. Improve quality of trial data.	Yes, due to improved trust
3. Receive effective treatment for a health concern.	Will depend on effectiveness of treatments under study
Requirement	
The solution must be integrated with existing systems.	Yes
The solution must be sufficiently flexible to accommodate the specific requirements of each supported clinical trial.	Yes
The solution must support rapid deployment and be cost-effective.	Too early to determine

IX Summary and Conclusions

The technical solution conceived at the beginning of this study to address trust-building between clinical researchers and the San Jose Hispanic community was fairly straightforward. 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 providers access to trial data; and 3) provide a means for community members and clinical researchers to interact with each other.

As a stand-alone application for a single trial, this would have been simple and quick to implement. However, that would have been a short-sighted solution. There might be duplicate or overlapping efforts by different IT staff; the community might experience a lack of continuity from trial to trial due to lack of data sharing; or relationships established during one trial might have to be rebuilt in the next. Managing each clinical trial in the community differently would not encourage trust.

A better approach was to find a way to implement a solution that could provide a consistent interface to the community while accommodating the various CTMSs used by different researchers. An SOA approach was explored using the RUP/SOMA methodology.

Because RUP/SOMA assumes that requirements analysis has been completed, a methodology was developed to translate non-functional wants and needs to technical requirements. The resulting requirements specification became input to the RUP/SOMA methodology.

RUP/SOMA focuses on the architecture and design of external web services, using SOMA notations and Unified Modeling Language (UML) to model them.
Petri nets were used to simulate flows among web services and validate the architecture.

The solution was evaluated against the original business goals and requirements. The methodology for deriving the requirements provided linkage from the non-functional wants and needs to business processes to technical requirements. RUP/SOMA provided linkage from the business goals to service components. Because these two methodologies maintained traceability throughout the definition of the architecture, the result addressed all goals and requirements.

A. Next Steps.

The next steps for this study are to plan and execute the architectural proof-of-concept. The functional requirements and use case for the proof-of-concept have been defined [45]. Initial investigation of the service messages associated with Patient and the protocols for using Integration Hub has been completed. Additional details must be added to the component specification, to provide greater details about how to invoke the

Patient service and deal with any errors from the service.

A number of issues arose that require consideration: First, the services being provided by caBIG are being defined and prototyped concurrently with this study. Because of this, service capabilities, interfaces, and protocols have been subject to change. Second, to test this system, the entire caBIG infrastructure, including caGRID, must be installed. Further work on the proof-of-concept should be delayed until the required third-party services are implemented and stable and a test harness is in place.

After completion of the proof-of-concept, implementation, deployment, and management should follow. The solution should be re-evaluated at key checkpoints during the service life cycle to ensure it continues to meet original intents.

It should be noted that the methodology defined in Section VI is not domain-specific so it may be sufficiently general and complete to be used for transforming any non-functional requirements into implementable technical requirements. Further work is needed to confirm this.

B. Recommendations.

This paper concludes with some observations about the RUP/SOMA methodology, along with recommendations for projects contemplating its use.

1) Project Selection: If a project is small and limited in scope, the additional effort expended to follow the RUP/SOMA methodology may not yield any measurable benefit. The SOA governance process should have criteria for determining which projects are in the scope of the SOA and which are not. This lets the enterprise focus resources and efforts on the solutions most likely to yield high-value services.

This study also demonstrated that use of the RUP/SOMA methodology does not have to be restricted to an individual business. It can also be used to architect a solution for a well-defined business process that is shared by an industry.

2) Consideration for the Existing IT Environment: RUP/SOMA can be used to architect services in both SOA and non-SOA environments. However, it is a much more difficult task to use the methodology if the enterprise has not already adopted some kind of formal IT architecture or if it has not documented an inventory of its software.

The operation-first approach suggests a comprehensive search for reuse opportunities throughout the entire enterprise. This can be very time-consuming in an environment where needed information is not available. When architecting a relatively small solution of limited scope such as the trust-building application, starting the service identification at the sub-function level may be more cost-effective, as the opportunities for reuse are more likely within that sub-function or the immediate function enclosing it.

3) Business Goals: RUP/SOMA focuses on business goals; but many times the effect a small project has on the top business goals can be minimal. When performing goal-service modeling, it is important to start with goals at an appropriate level within the business where the positive impacts of the services can actually be discerned.

4) RUP/SOMA and the Software Development Life Cycle: To perform service identification adequately, the software architect must have a clear understanding of the requirements and some idea of how those requirements will be met from a functional perspective. Also, during the services realization phase, the decisions there can significantly impact the software development schedules, test plans, and resource allocations.

To be effective, the RUP/SOMA methodology must be tightly integrated with the normal software development life cycle (SDLC) so external services design and architecture are performed in parallel with activities for the other components of the project. Buy-versus-make decisions should be made as early as possible to enable better project planning.

5) SOA Metrics: Even though a service is perfectly aligned with business goals, its maintenance and upkeep as a service may not be cost-effective if that service has only a few internal consumers. Metrics should be identified to measure the effectiveness of service selection as part of SOA governance.

6) SOA Governance: During the service identification phase of RUP/SOMA, the mapping from business processes, as understood by the business process analyst, to services, as understood by the software architect, is performed. To ensure the mapping across these two disciplines is correct, it is highly recommended that SOA governance include policies regarding model reviews and approvals. Similarly, goal-service models should be reviewed by a cross-functional team.

All models should be retained and be accessible for use by other projects in the enterprise to minimize duplicate efforts. These models should be reviewed periodically to ensure they still reflect current business goals and practices.

In conclusion, even though the RUP/SOMA methodology focuses on an enterprise-wide SOA, it is possible to use the methodology within a single business function or sub-function as the starting point for an SOA. By narrowing the scope, the architect can identify reusable components in a more cost-effective way. Other strategies for success are tighter integration with the SDLC, identification of metrics to measure the effectiveness of service selection, and model review.

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Appendix A Sample Questions to Elicit Domain Solutions

Prior to architecting a solution, it is important to understand what the solution requirements are. One way to determine solution requirements is by interviewing clinical trial participants to understand the underlying causes for lack of trust. Figure 18, Figure 19, Figure 20, and Figure 21 are samples of questions an architect can ask to get a better understanding of the requirements. For this study, solution requirements were determined by [4]-[9], [11], [12].

Questions for Clinical Researchers

1. Research history
    a. Have you conducted any clinical research targeted at the Hispanic community within the last 5 years? If no, skip to 1c.
    b. What was the purpose of the most recent one? Skip to 2.
    c. Have you conducted any clinical research within the last 5 years that may have included members of the Hispanic community? If no, skip to 8.
    d. What was the purpose of the most recent one?

These questions are for the most recent study.

2. Participants - data
    a. How many participants did you plan to include in the study?
    b. How did you go about finding participants? (Examples: advertising in papers, direct mail, through community clinics)
    c. Was any study information translated in Spanish? If so, what?
    d. What was the actual number of participants?
    e. What tools did you use to manage recruitment? Patient data? Were you satisfied with them? Why/why not?
3. Participants - observations
    a. What techniques were most successful in recruiting participants?
    b. Were there any issues associated with informed consent?
    c. Are there any things you would do differently in the recruitment process?
    d. What techniques or tools, if any, would improve your recruiting process?
4. Managing participation - data

a. How long was each participant expected to participate?
b. What were participants required to do?
c. How were study requirements communicated to each participant? Were they in Spanish?
d. How did you monitor patient participation?
e. How often did you contact them directly?
f. If a participant had questions or concerns, how did they contact you?
g. What tools did you use to manage participation? Patient data? Were you satisfied with them? Why/why not?

5. Managing participation – observations
   a. Were you satisfied with the quality of input from participants? Why/why not?
   b. Are there any actions you would recommend for improving the quality of input in future studies?
   c. What techniques or tools, if any, would help you manage participation better?
   d. What would help you manage patient data better?
6. Interaction with primary care physicians
   a. Were participants' primary care physicians informed of their participation in the study? If so, how?
   b. Was there a way for physician to communicate directly with the researchers during the study? If so, how?
   c. Was participant data made available to physicians during the study? If so, how?
   d. Do you think greater involvement by patient primary care physicians would have resulted in better participation or higher quality results?
   e. If primary care physicians involved: What tools did you use to communicate with physicians? Were you satisfied with them? Why/why not?
7. Interaction with community leaders
   a. Were any community leaders involved in your study? If yes, what was their role?
   b. How did you communicate with them?
   c. What tools did you use? Were you satisfied with them? Why/why not?
8. Thank researcher for his/her time.

Figure 18. Sample questions for clinical researchers.

Questions for Community Leaders

1. Local issues and concerns
   a. What are the most important health issues in the Hispanic community?
2. Encouraging participation in clinical research
   a. Do you think it's important for the local Hispanic community to participate in clinical research focused on these issues? Why or why not?

b. Are you aware of any clinical research in the last 5 years that has been focused on these issues?
c. If yes, how did you hear about it?
d. If yes, did you actively promote participation in that research? Why or why not? If yes, how?

3. Engaging leaders
   a. Were you included in the planning of the study? If so, how?
   b. Were you kept informed of progress? If so, how?
   c. How important was it to you to be included in study planning and execution?
   d. What information would be most useful to you?

Figure 19. Sample questions for community leaders.

Questions for Healthcare Professionals

1. Encouraging participation in clinical research
   a. Are you aware of any clinical research in the last 5 years that would be beneficial to your Hispanic patients?
   b. If yes, how did you hear about it?
   c. If yes, did you actively promote participation in that research? Why or why not? If yes, how?
2. Engaging healthcare professionals
   a. Were you included in the planning of the study? If so, how?
   b. Were you kept informed of progress? If so, how?
   c. How important was it to you to be included in study planning and execution?
   d. What information would be most useful to you?

Figure 20. Sample questions for healthcare professionals.

Questions for Participants

(To ensure privacy, will not ask about the specifics of the study; focus on the process.)

1. Informed consent
   a. How was the purpose of the study and the risks explained to you?
   b. Did you feel the researchers communicated this clearly to you?
2. Study process
   a. How did researchers explain what was required from you?
   b. How did you communicate with researchers during the study? How often?
   c. If you had questions or concerns during the study, how could you contact a researcher? Did you have to do that during the study? If so, were you happy with the answer/resolution?

d. Did you participate for the full planned period? If not, why not?

3. Follow-up
   a. When did your participation in the study end?
   b. Did researchers contact you any time after the end of your participation? If so, why? If not, would you want them do?
   c. Were you informed of the overall results of the study? If so, how?
4. Satisfaction
   a. Were you satisfied with your communications with researchers?
   b. If you had the opportunity to participate in another study, would you? Why/why not?
   c. Would you personally recommend participation to others? If not, why not?

Figure 21. Sample questions for participants.

Appendix B General Trust-Building Model

Merriam-Webster Online Dictionary defines trustworthiness as “worthy of confidence” [46]. Lewicki and Tomlinson [47] further assert that assessment of an individual’s trustworthiness is based on three dimensions of trustworthy behavior. These dimensions are ability, integrity, and benevolence. The more an individual exhibits these behaviors, the more that person is deemed trustworthy. Evaluation is based on questions such as: Is this individual competent? Based on past actions, is this individual truthful, does the individual follow through on commitments, and has the individual acted fairly? Is this individual concerned about my welfare?

Although these dimensions were defined for individual trustworthiness, they were used as part of this study to evaluate whether or not the solutions proposed in Section II could improve trustworthiness of researchers from the perspective of members of the San Jose Hispanic community. Figure 22 maps the problem themes identified in Section II to the trust dimensions defined by Lewicki and Tomlinson [47]. 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 Figure 22.

Based on this mapping, this study concludes that a solution addressing these problem themes will increase community trust in clinical research and will positively impact a

community's assessment of clinical research trustworthiness.

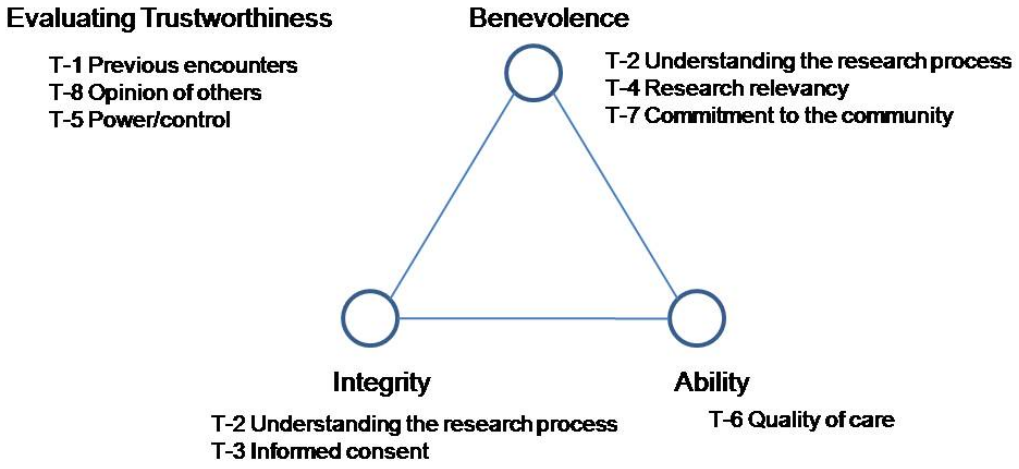

Figure 22. Mapping problem themes to dimensions of trust.

Appendix C Final Report Summary from NIH Roadmap Projects

Table 31 summarizes the information technology aspects of the NIH projects and impacts, if any, on underserved communities.

Table 31. Summary of Broad Agency Announcement (BAA) Report.

Researcher	Information Technology	Features	Technologies Used	Impacts of research on community interactions and reaching underserved populations
MCRC Univ of Michigan	Honest Broker	Registry Messaging Data transformation and filtering Security and privacy Administrative control	International standards-based protocol stack for biomedical data encoding 3-tier Java P2P with authorized external applications	Delivery of enriched clinical data to the PCP; extensions to the prompt and reminder system
	ClinfoTracker	Networking capability for data exchange		
AGNIS National Marrow Donor Program	AGNIS	Platform-independent messaging system	Data dictionary containing Common Data Elements (CDEs) Java Globus security model Grouper group management Open source applications	No direct interaction with patients or underserved populations
TB Trials Network Duke Univ Med Center	Query Tracking System	Query identification and tracking	TB data standards Web service evaluated but not used due to cost	Not available
	AE/SAE Tracking	Reporting Trial management		
	Web portal	Forum for team member collaboration		

	ALCHEMIST	Decision analysis model (economic)		
CTN Best Practices Med Center	CTN Best Practices web site www.ctnbestpractices.org	Resources related to institutional review boards, clinical sites new to research, regulatory requirements, etc.	Acute Coronary Syndrome (ACS) data standards Open source	Not available
	Clinical Trial Management System (CTMS)	Manage information about a clinical research study, including individuals and organizations		
	Investigator Profile Library	Repository of information on clinical site investigators and staff		
	Data Standards Inventory	Identifies organizations creating or promoting standards		
InterTrial Columbia Univ	WorkWeb	Project management Individuals connected through various relationships to other entities	Wiki and other social software	Sites for this study were chosen due to existing good relationships with local communities
CNICS UCSF	FASTA	Data transfer system de-identifies, reformats, and aggregates		Not applicable
	HL7-HLC	Translates HL7 data to format required by CNICS sites		
	MIRTH	Translates HL7 to XML		
	Website tools	For importing, validating, and posting data on public website		
	Data Entry tool for non-electronic phenotypic data	Consistent and reliable structure for manual entry		
	Data analysis tools	Interpret HIV treatment choices and medication categories		
CRN Harmony	Clinical Research	Supports clinical and	Oracle Clinical	Re-use of common data elements

Univ of Pennsylvania	Informatics Platform	translational research products	Pharmaceutical Application (OPA)	in collecting study elements enables researchers to consider characteristics of the underserved
HMORN CCSN Group Health Cooperative	Virtual Data Warehouse	Stores laboratory data		Greater interest and willingness to participate in clinical research by selected cardiologists with access to program PRISM readability toolkit makes content more accessible
Critical Care Decisions LDS Hospital	eProtocol-insulin	Protocol to calculate changes in IV insulin drip rate		Not available
ePCRN Univ of Minnesota	ePCRN Gateway	Registration of clinical practices Security Locally controlled filters Imports Continuity of Care Record XML strings (CCR) Local identification of patients matching eligibility criteria Print, email, text messaging Specific disease management software	Standardized multiple-disease registry Globus Server	ePCRN is suited for involvement of practices located in underserved areas Promotes better communication and collaboration at remote sites Being considered at Hispanic clinics in Los Angeles.
	ePCRN Research Portals	Single access site for queries		
COG Children's Oncology Group	None specified		CDEs for pediatric blood and marrow transplantation	Enhanced ability to perform pilots
RIOS Net University of New Mexico	RIOS Net IT infrastructure	Centralized data and processes Data collection: web, commercial software, scanned, PDAs	SQL Server	All research is centered on underserved populations. Community outreach staff expanded communications into these communities.

Appendix D Mapping between SOMA and RUP/SOMA

Table 32 identifies the differences between SOMA and RUP/SOMA [36], [48]. Both methodologies consist of three major steps: 1) identification; 2) specification; and 3) realization. Each step is further decomposed into activities, shown in the SOMA Activity column. In the SOMA Task column, the specific tasks to be completed for an activity as defined by SOMA are listed. In the RUP/SOMA Content column, the equivalent task or guideline is identified.

Table 32. Mapping between SOMA and RUP/SOMA.

SOMA Activity	SOMA Task	RUP/SOMA Content
Service Identification		
Domain Decomposition	Functional Area Analysis	Functional Area Analysis
	Process Decomposition	Refine a Business Use-Case
	Variation-Oriented Analysis	Variability Analysis
Goal-Service Modeling	Identify Goals and Sub-goals	Identify Business Goals and KPIs
	Identify Services for Sub-goals	Identify and Associate Services to Goals
	Identify KPIs and Metrics for Sub-goals and Services	Identify Business Goals and KPIs
Existing Asset Analysis	Existing Asset Analysis	Existing Asset Analysis
		Data Model Analysis
		Business Rule Analysis
Service Specification		
Service Specification	Apply Service Litmus Tests	Apply Services Litmus Tests
	Model Service Dependencies	Service Specification
	Model Service Composition and Flow	
	Document Service Non-Functional Requirements	
	Specify Service Messages	Service Specification Message Design
	Document State Management Decisions	Service Specification
Subsystem Analysis	Identify Subsystem Dependencies	Subsystem Design (SOA)

	Identify Service Component	
	Identify Functional Components	Component Specification (SOA)
	Identify Technical Components	
Component Specification	Specify Component Attributes	
	Identify Events and Messages	
	Model Component Internal Flow	
	Create Component Class Diagram	
	Variation-Oriented Design	Variability Analysis
Service Realization		
Realization Decisions		Document Service Realization Decisions
	Service Allocation	Component Specification (SOA)
	Component Allocation to Layers	
	Technical Feasibility Exploration	Construct Architectural Proof-of-Concept (SOA)

Appendix E Service Model and Design Model

The Service Model is updated throughout all phases of the RUP/SOMA methodology, and the Design Model is updated during the Specification phase. Table 33 and Table 34 contain outlines of the two models and provide indexes to sections in the main document where content has been defined.

Table 33. Index to Service Model Content.

RUP/SOMA Step Where Created	Service Model Section	Table or Figure
Identification	Service Portfolio	Table 15
	Service Hierarchy	Figure 8
Specification	Service Exposure	Table 14
	Service Dependencies	Figure 12
	Service Composition & Flow	n/a
	Service Messages	Table 17
	Service Non-Functional Requirements State Management Decisions	n/a
Realization	Realization Decisions	Table 26

Table 34. Index to Design Model Content.

RUP/SOMA Step Where Created	Service Model Section	Table or Figure
Specification	Functional Area Analysis	Table 19
	Subsystem Dependencies	Table 20
	Component Identification	Table 21
	Component Internal Flow	Figure 13, Figure 14
	Component Class Diagrams	Figure 15
	Allocation to Architecture Layers	Figure 16
	Events and Messages Component Attributes	n/a

Appendix F Business Process Flows

Implementing RUP/SOMA requires understanding of the business process flows. Figure 23 shows the as-is business process flow for the clinical trials process, and Figure 24 shows the to-be business process flow. Manage Community is a new process that includes sub-processes to manage activities associated with members of the community. A decomposition of Manage Community business process flows is shown in Figure 25.

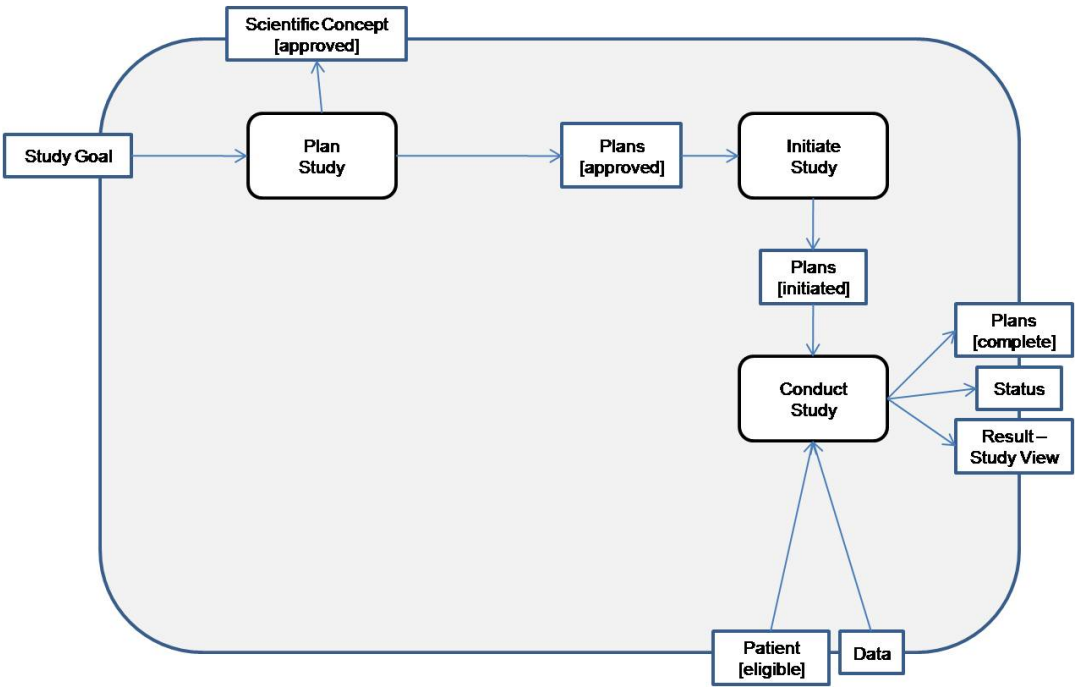

Figure 23. As-is clinical trials business process.

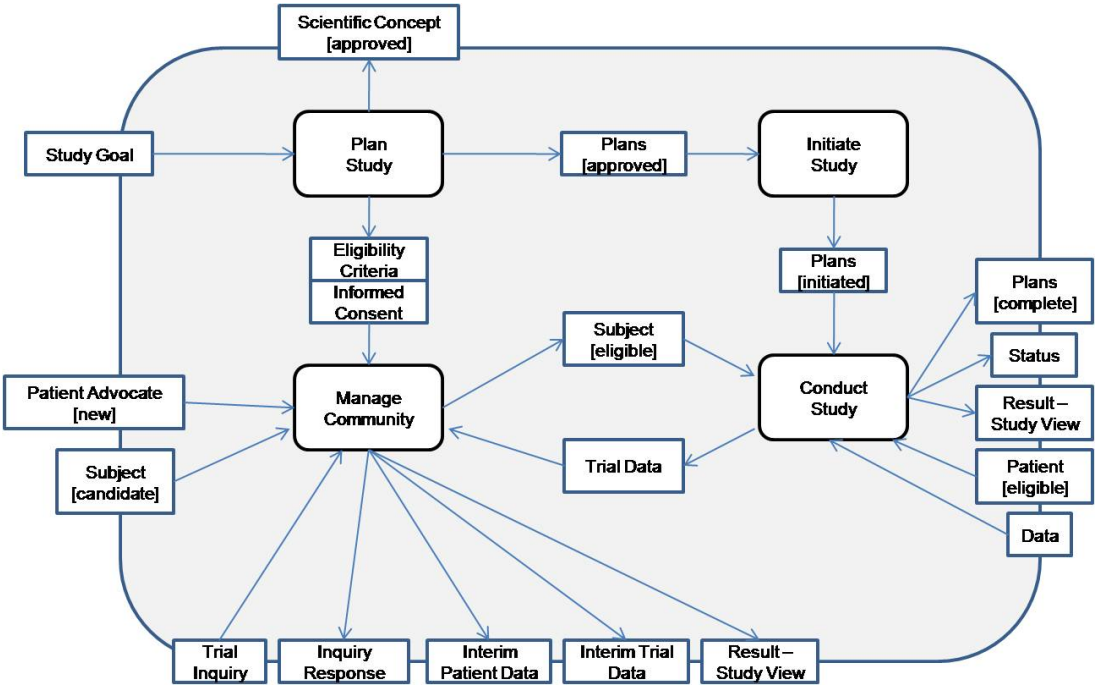

Figure 24. To-be clinical trials process.

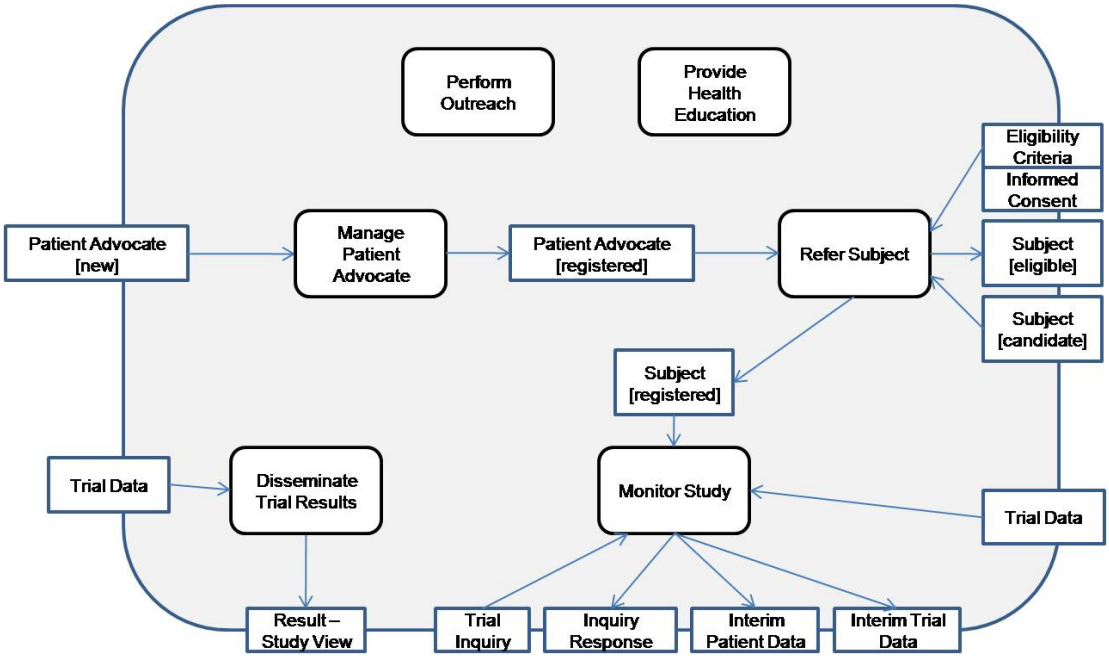

Figure 25. Decomposition of Manage Community.

Appendix G Business Actors and Business Use Case Model

To identify an appropriate set of use Business Actors and Business Use Cases to review for refinement, an earlier version of the SOMA methodology was used [34]. In that version of SOMA, two business process models are developed. The as-is model describes the current business; and to-be model describes the desired future business. A comparison of the two models yields the business use cases that will require review.

A. As-Is Business Use Case Model.

caBIG created a business architecture model for clinical trials [37] that was used to represent the as-is business use case model in this study. The business use case model is represented using Unified Modeling Language (UML). Only that subset of use cases that are relevant to trust-building activities will be shown.

caBIG identifies four categories of business use cases for Manage Clinical Research, shown in Figure 26. These categories are a way of partitioning the use cases and are not intended to represent the business processes.

Figure 26. Business use case categories for as-is Manage Clinical Research.

The use cases for Plan Study, shown in Figure 27, represent preparatory activities covering scientific aspects, logistics, regulatory and legal issues, and finance. This includes activities such as identification of the study team, trial design, recruitment plans, and trial monitoring.

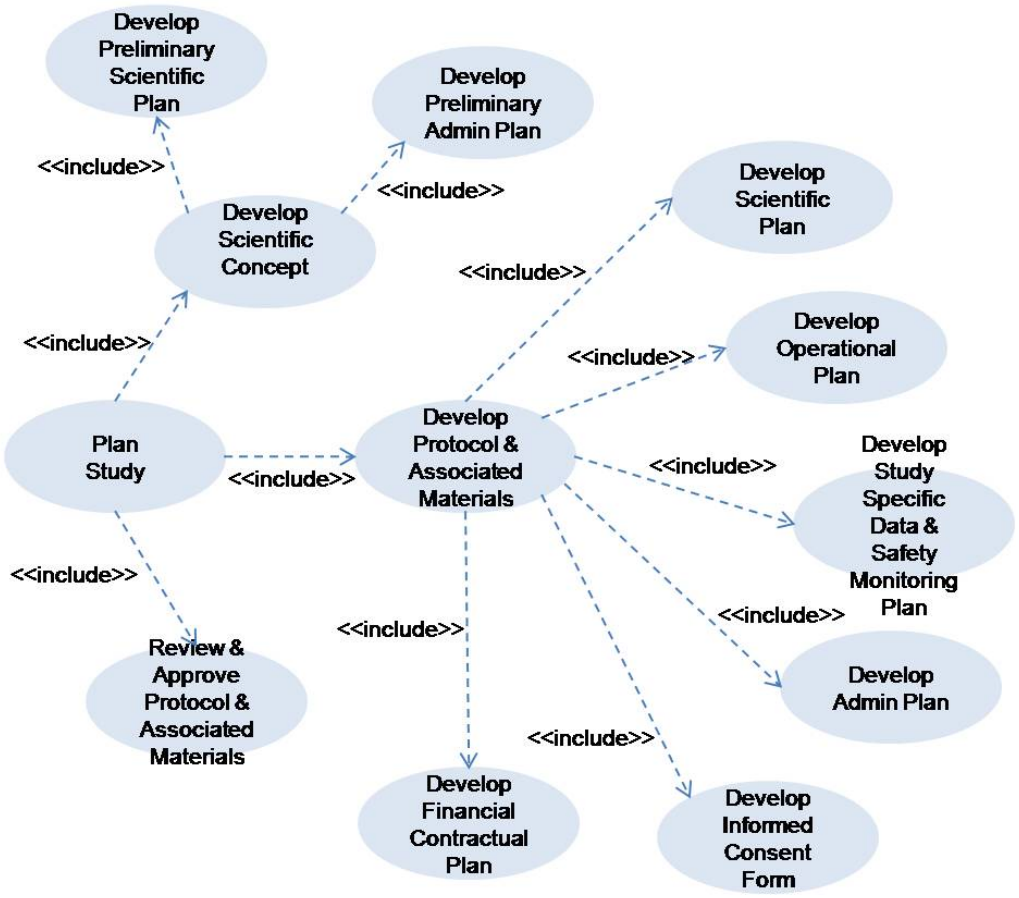

Figure 27. Business use cases for as-is Plan Study.

The use cases for Initiate Study, shown in Figure 28, cover study activation activities. This includes recording and maintaining participant information and training for trial

personnel.

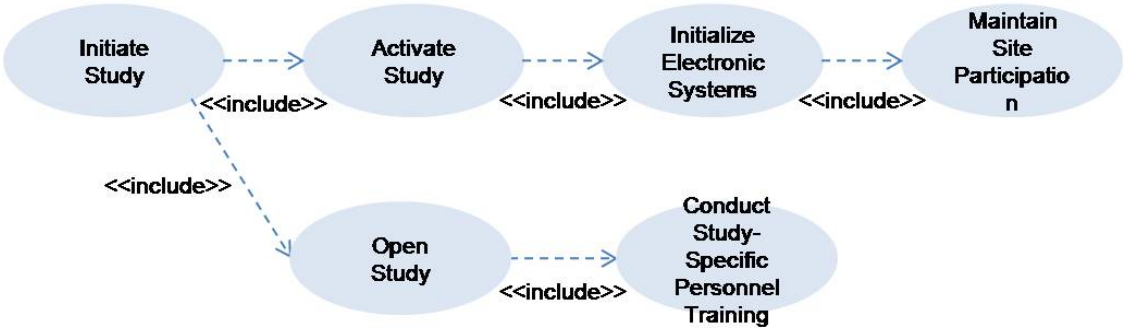

Figure 28. Business use cases for as-is Initiate Study.

Conduct Study contains a number of relevant use cases, including one to grant access to data, several to manage trial subject registration, and others to manage trial subject schedules. These are shown in Figure 29.

The Report and Analyze Study use cases focus on regulatory and scientific reports and data. Sharing Data for Collaborative purposes focuses on ad hoc reporting, as shown in Figure 30.

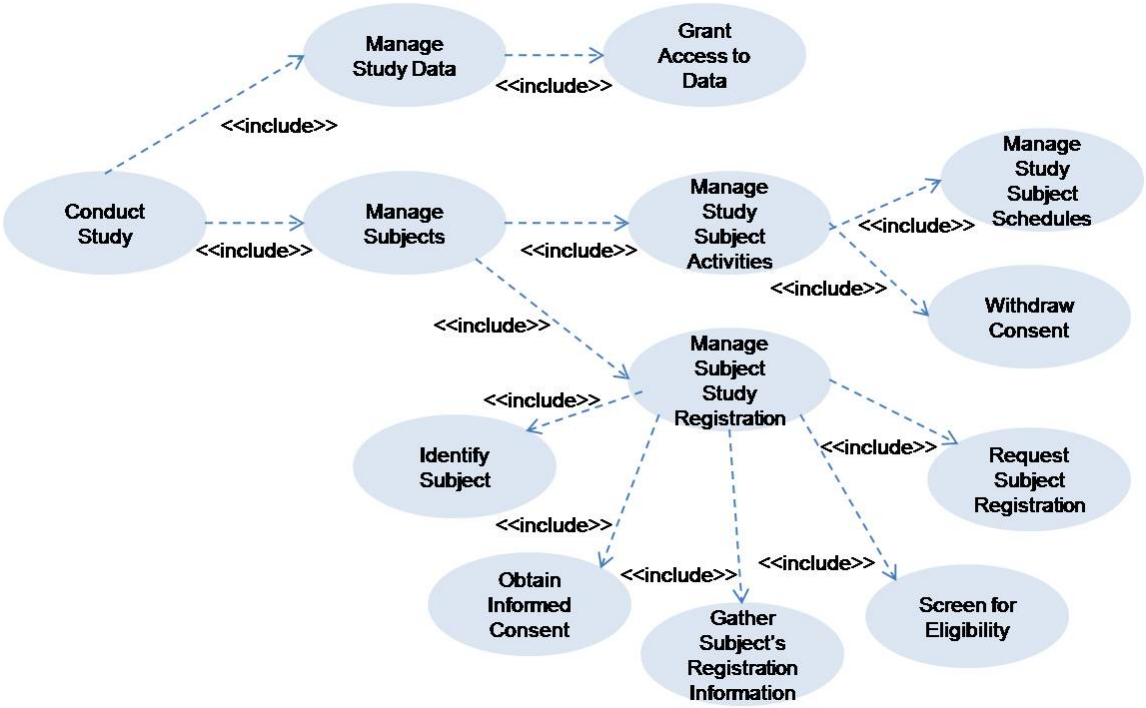

Figure 29. Business use cases for as-is Conduct Study.

Figure 30. Business use cases for as-is Report and Analyze Study.

B. To-Be Business Use Case Model.

To determine which business uses cases require update and what new business use cases may be required, the as-is use cases are mapped against business requirements. Table 35 shows the business requirements derived in Section VI mapped to appropriate as-is business use cases.

Table 35. Mapping Business Requirements to As-Is Business Use Cases.

Business Requirement	As-Is Business Use Case	Use Case Category	To-Be Updates
A-1. Increase awareness about clinical research and the clinical trials process through education, outreach, and advocacy.	none	none	Add category: Manage Pre-Study Add use case: Perform Outreach
A-2. Educate physicians on the benefits to their patients and to themselves of participating in clinical trials.	none	none	See A-1.
A-3. Incorporate a community perspective in the clinical trials process.	none	none	Incorporated in other business use cases
A-4. Build community awareness of researcher presence; provide clinical trials education that is culturally appropriate.	none	none	See A-1.
A-5. Use culturally appropriate questions and translations to ensure comprehension and accessibility of informed consent.	Develop Informed Consent Form	Plan Study	none
	Conduct Study-Specific Personnel Training	Initiate Study	Add actor: Patient Advocate to provide input to training and optionally to provide training
A-6. Incorporate community needs, patient perspectives, priorities, issues, and concerns in trial design.	Determine Logistical Feasibility of Study/Trial Completion	Plan Study	Add actor: Patient Advocate to provide input
	Determine Patient Care Funding	Plan Study	Add actor: Patient Advocate to provide input
A-7. Include members of the community in all stages of the clinical trials process for input, monitoring, and decision-making. This includes participation on review boards and on data safety monitoring boards.	Define Objectives	Plan Study	none
	Develop Eligibility Criteria	Plan Study	none
	Define Ancillary Studies	Plan Study	none
	Describe Study Design and Schema	Plan Study	none
	Develop Accrual Plan	Plan Study	none
	Describe Patient Recruitment Plan	Plan Study	none
A-8. Engage and train research advocates to participate in all stages of the clinical trials process,	none	none	**Add use case: Manage Patient Advocates to**

including subject recruitment.			**Manage Pre-Study**
	none	Initiate Study	**Add use case: Register Patient Advocate**
	none	Conduct Study	**Add use case: Refer Subject**
A-9. Engage community physicians and healthcare providers as study investigators or by utilizing their facilities.	Define Professional Qualifications of an Investigator Needed for Study Trial	Plan Study	none
	Identify and Contact Study/Trial Team	Plan Study	Add step: Primary Investigator includes community members on the team as patient advocates
	Identify Participating Sites (Site Identification)	Plan Study	Add step: Contact physicians in the community to elicit input
A-10. Ensure follow-through on commitments to trial subjects.	none	none	not applicable
A-11. Ensure ongoing one-on-one communication with trial participants throughout the trial and be responsive to concerns.	Develop Study Specific Data and Safety Monitoring Plan	Plan Study	none
	Develop Study Specific Plan for the Safety, Monitoring, and Evaluation of Participants	Plan Study	none
	none	Conduct Study	**Add use cases: Monitor Subject, Monitor Trial Data**
	Report and Analyze Study	Report and Analyze Study	**Add use case: Obtain Trial Data**
A-12. Provide health education to trial subjects that is sensitive to cultural values and beliefs.	none	Conduct Study	Add use case: Provide Health Education
A-13. Provide a single, consistent interface between the community and different researchers.	none	none	n/a

A-14. Disseminate project outcomes.	none	none	**Add category: Manage Post-Study Add use case: Disseminate Trial Results**

The Business Requirement column contains the suggested actions identified previously; the As-Is Use Case column identifies an existing use case that is relevant to the business requirement; the Use Case Category column identifies the applicable category; and the To-Be Updates column identifies the changes or additions to be made to use cases or to use case categories.

Candidates for implementation via software systems are highlighted in bold. They are Manage Patient Advocates, Refer Subject, Monitor Subject, Monitor Trial Data, Obtain Trial Data, and Disseminate Trial Results. Perform Outreach is focused on general awareness and is most likely the responsibility of functions such as marketing communications, so it is outside the scope of the clinical trials process. Business use cases associated with training, such as Provide Health Education, may be supported via software systems, but will most likely be conducted in a face-to-face manner.

If the to-be update is specified as "none," the as-is use case already addresses the business requirement, usually through incorporation of a patient advocate in the process. If the to-be update is specified as "not applicable," the business requirement describes an action that must be implemented through some means other than by a business process.

In the following figures, new or modified business use cases are highlighted with bold outline based on the mapping shown in Table 35. Figure 31 shows two new categories of business use cases, Manage Pre-Study and Manage Post-Study. These business use cases will describe activities to be conducted before or after a clinical trial. Preliminary activities would include awareness activities and patient advocate and healthcare provider recruitment and training. Follow-on activities would include disseminating trial results.

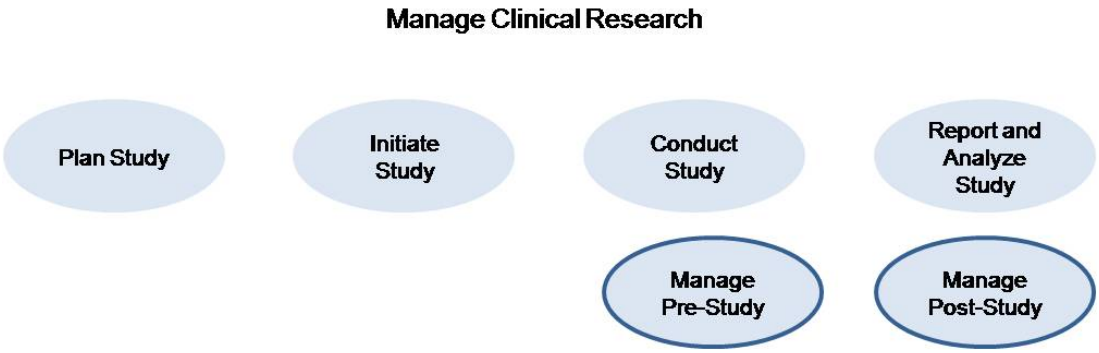

Figure 31. Business use cases for to-be Manage Clinical Research.

The Manage Pre-Study is a new classification of business use cases that will address activities that are performed to establish trust prior to a study. Perform Outreach targets media, policy makers, communities, and healthcare providers. Manage Patient Advocates includes activities for maintaining relationships with patient advocates, such as recruitment and training. These are shown in Figure 32.

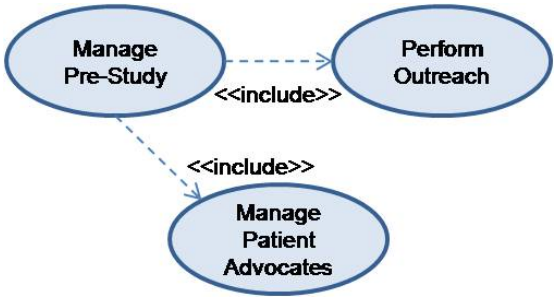

Figure 32. Business use cases for Manage Pre-Study.

No new use cases need to be created for Plan Study. In many cases, the as-is business use case already included a patient advocate as one of the actors. Because the patient advocates are there to represent the patient view, many of these business use cases may already be capable of improving trust.

Some business use cases require some modification to include participation by patient advocates or by physicians in the community. These are Determine Logistical Feasibility of Study/Trial Completion, Determine Patient Care Funding, Identify and Contact Study/Trial Team, and Identify Participating Sites (Site Identification). These business use cases are further details of Develop Preliminary Scientific Plan, Develop Financial Contractual Plan, Develop Preliminary Admin Plan, and Develop Admin Plan business use cases, respectively, as shown in Figure 33.

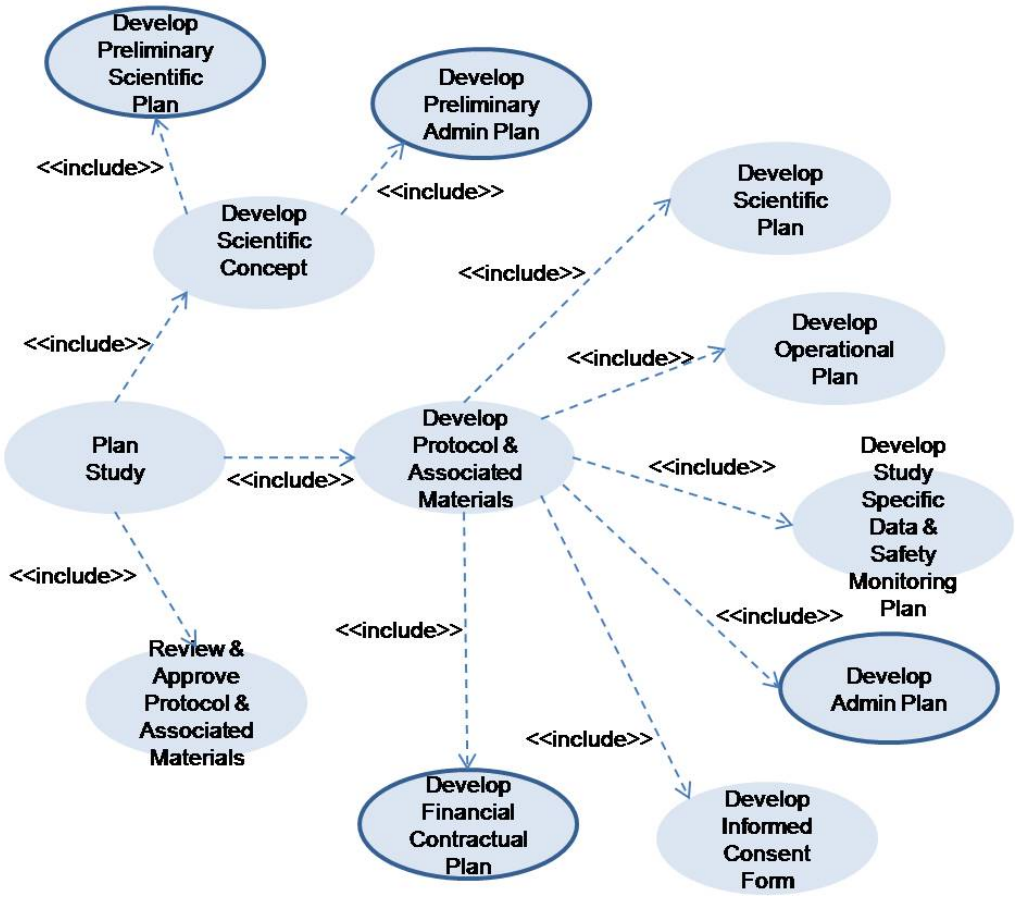

Figure 33. Business use cases for to-be Plan Study.

Register Patient Advocate is a new business use case in the Initiate Study category. Patient advocates will need to be identified to the electronic systems since they will require authorization to access trial data. Conduct Study-Specific Personnel Training must be modified to include patient advocate input. A summary of additions and changes are shown in Figure 34.

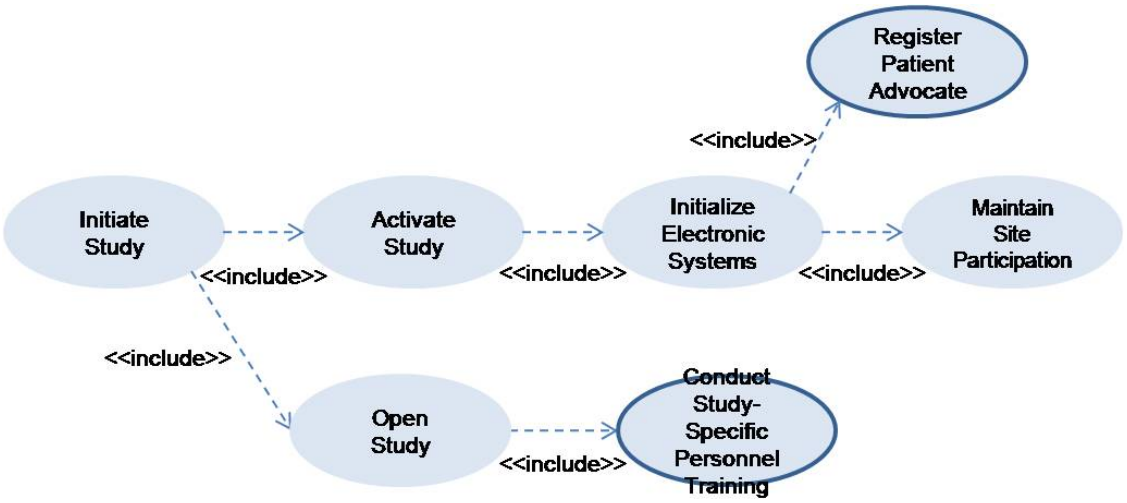

Figure 34. Business use cases for to-be Initiate Study.

Four new business use cases need to be created for Conduct Study. They are Refer Subject, Monitor Subject, Monitor Trial Data, and Provide Health Education. A fifth business use case, Monitor Study has been created, as a convenience, to aggregate the monitoring use cases. A summary of additions and changes are shown in Figure 35.

One new use case, Obtain Trial Data, needs to be created for Report and Analyze Study, as shown in Figure 36. This use case will generate patient and trial views of data in response to ad hoc requests from trial subjects and patient advocates and for general reports to the community.

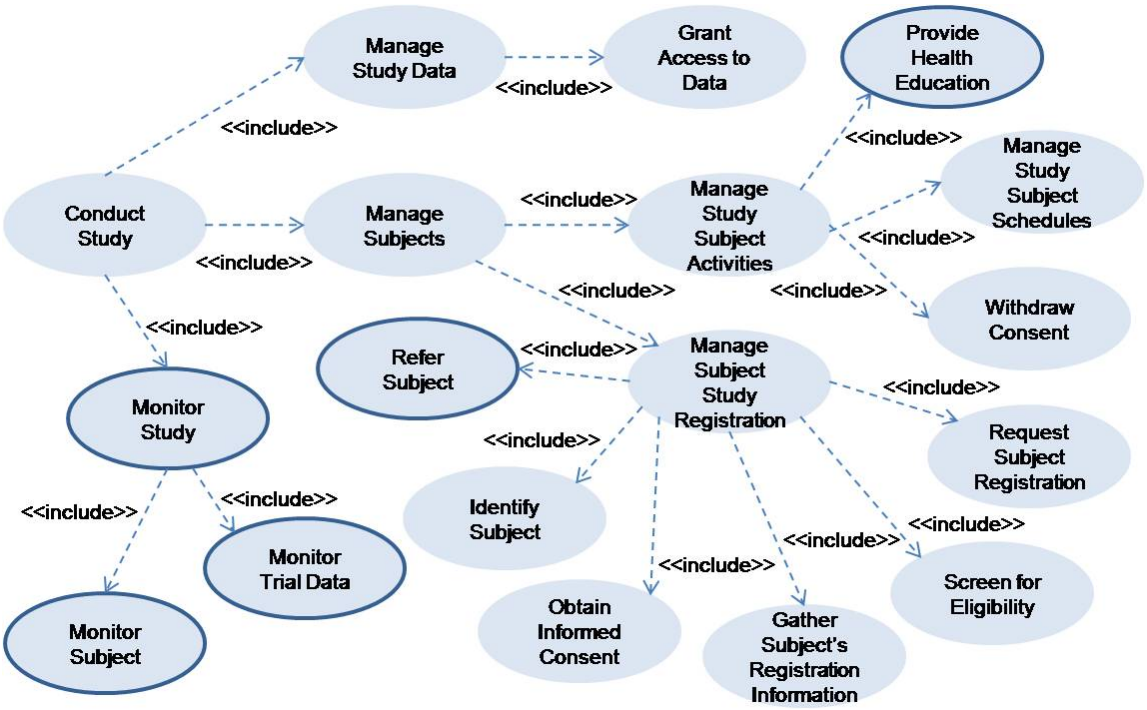

Figure 35. Business use cases for to-be Conduct Study.

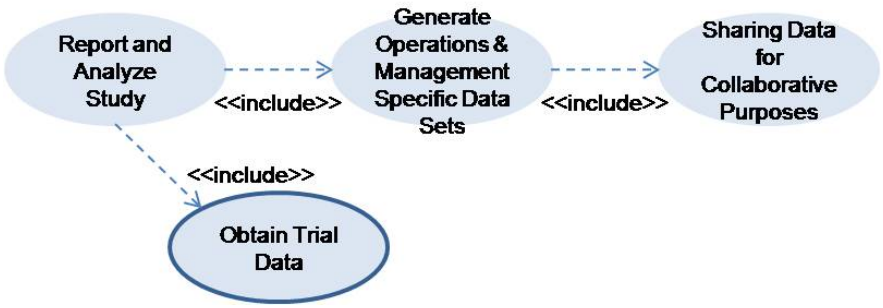

Figure 36. Business use cases for to-be Report and Analyze Study.

Manage Post-Study business use cases will address activities that are performed to maintain community trust after a study has completed. Disseminate Trial Results targets community members, such as community-based research partners, trial subjects and their

physicians, patient advocates, and community leaders. This is shown in Figure 37.

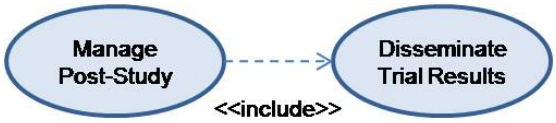

Figure 37. Business use cases for Manage Pre-/Post-Study.

Appendix H New Business Actors, Business Models, and Business Use Cases

Although not part of RUP/SOMA, the Service Identification task to refine a business use case should be applied to new use cases. New business actors should be defined, business models should be refined, and business use cases defined in sufficient detail to be realized.

A. Business Actors.

Business use case analysis yielded new actors, Patient Advocate Coordinator, Community Member, and Community Outreach Coordinator. Brief descriptions of each actor are provided below:

- The Patient Advocate Coordinator is responsible for recruiting, training, and managing patient advocates and community healthcare providers.
- A Community Member can be a community leader, a community-based healthcare provider, community healthcare providers, or potential trial subjects and their families.
- The Community Outreach Coordinator is responsible for general outreach activities to media, policy makers, community leaders and members, and healthcare providers-in-training.

B. Business Model Refinement.

The business models for Manage Patient Advocates and Refer Subject have been further

refined, as shown in Figure 38 and Figure 39.

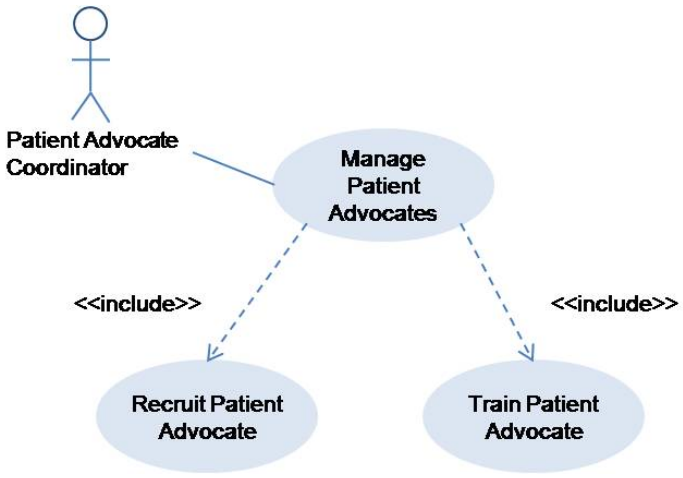

Figure 38. Refinement of Manage Patient Advocates business use case.

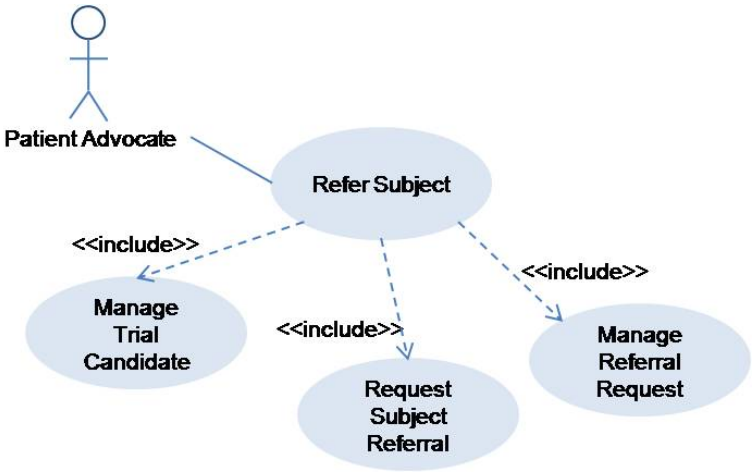

Figure 39. Refinement of Refer Subject business use case.

C. Detailed Business Use Cases.

Details for each business use case to be implemented follow.

UC0001: Recruit Patient Advocate

Participating Actors: Patient Advocate Coordinator

Description: Maintain contact information for a healthcare provider (e.g., enrolling physician) or a patient advocate. Information can be added, changed, displayed, or deleted.

Preconditions:

1. User is authorized to perform read, create, update, and delete participants.
2. User has accessed the application logon page.

Postconditions: An entry for an advocate has been read, created, updated, or deleted.

Main Success Scenario

Actor	System	Resource
1 The user requests to log into the system.		
	2 The system requests user authorization / authentication.	
		3 Return authorization / authentication status.
	4 The system displays the Patient Advocates page showing a list of processing options.	
5 If the user chooses to add an advocate		
	5.1 The system displays a form to collect information.	
5.2 The user enters the required information and submits a request.		
	5.3 The system verifies that the form fields contain valid data.	
	5.4 The system requests to create an entry in the Advocates repository.	
		5.5 The database creates an entry.
	5.6 The system displays a message to indicate the entry was created successfully.	
6 If the user chooses to review, update, or delete		
	6.1 The system displays options to process a single entry or multiple entries.	
6.2 If the user chooses to process from a list of advocates from the repository		
	6.2.1 The system requests to retrieve all entries in the Advocates repository.	
		6.2.2 The database

		retrieves all entries.
	6.2.3 The system displays the results, sorted in alphabetical order by last name.	
6.2.4 The user selects one of advocates to process and submits a request to review, update or delete.		
6.3 If the user chooses to process a single entry		
	6.3.1 The system displays a form to enter the name of the advocate.	
6.3.2 The user updates the form and submits a request to update or delete.		
	6.3.3 The system verifies that the form fields contain valid data.	
	6.4 The system requests to retrieve the entry in the Advocates repository for the requested advocate.	
		6.4.1 The database retrieves the entry.
	6.4.2 The system displays the current data for the advocate.	
6.5 If the user chooses to change information about an advocate		
6.5.1 The user updates the form and submits a request.		
	6.5.2 The system verifies that the form fields contain valid data.	
	6.5.3 The system requests to update the entry in the Advocates repository.	
		6.5.4 The database updates the entry
	6.5.5 The system displays a message to indicate the entry was updated successfully.	
6.6 If the user chooses to delete an advocate from the repository		
6.6.1 If the user confirms delete		
	6.6.2 The system requests to delete the entry from the Advocates repository.	
		6.6.3 The database deletes the entry.
	6.6.4 The system displays a message to indicate the entry was deleted successfully.	
6.6.5 If the user cancels delete		
	7 The system displays the Patient Advocates page.	

UC0002: Register Patient Advocate

Participating Actors: Patient Advocate Coordinator

Description: Assign a patient advocate to an active trial. Information can be added, changed, displayed, or deleted.

Preconditions:

1. User is authorized to perform read, create, update, and delete participants.
2. User has accessed the application logon page.

Postconditions: Advocate has been added or dropped from a clinical trial.

Main Success Scenario

Actor	System	Resource
1 The user requests to log into the system.		
	2 The system requests user authorization / authentication.	
		3 Return authorization / authentication status.
	4 The system displays the Patient Advocates page with options to process a single entry or multiple entries.	
5 If the user chooses to process from a list of advocates from the repository		
	5.1 The system requests to retrieve all entries in the Advocates repository.	
		5.2 The database retrieves all entries.
	5.3 The system displays the results, sorted in alphabetical order by last name.	
5.4 The user selects one of advocates to process and submits a request to register or drop.		
6 If the user chooses to process a single entry		
	6.1 The system displays a form to enter the name of the advocate.	
6.2 The user updates the form and submits a request to register or drop.		
	6.3 The system verifies that the form fields contain valid data.	
	7 The system requests to retrieve the entry in the Advocates repository for the requested advocate.	

		8 The database retrieves the entry.
	9 If the request is to register, the system requests to retrieve a list of active trials from the Trials repository.	
	10 If the request is to drop, the system requests to retrieve a list of trials associated with the advocate from the Trials repository.	
		11 The database retrieves the list.
	12 The system displays the current data for the advocate.	
13 If the user chooses to register the advocate for one or more trials		
	13.1 The system requests to update the entry in the Advocates repository.	
		13.2 The database updates the entry
	13.3 The system displays a message to indicate the entry was updated successfully.	
14 If the user chooses to drop an advocate from an active trial		
	14.1 The system requests to update the entry in the Advocates repository.	
		14.2 The database updates the entry
	14.3 The system displays a message to indicate the entry was updated successfully.	
	15 The system displays the Patient Advocates page.	

UC1001: Manage Trial Candidate

Participating Actors: Patient Advocate

Description: Maintain information required to refer a subject for a clinical trial. A trial candidate and information associated with that subject can be added, changed, displayed, or deleted. Once all required information is completed, a request can be submitted

Preconditions:

1. User is authorized to perform read, create, update, and delete information about trial candidates.
2. User has accessed the application logon page.

Postconditions: An entry for a trial candidate has been read, created, updated, or deleted.

Main Success Scenario

Actor	System	Resource
1 The user requests to log into the system.		
	2 The system requests user authorization / authentication.	
		3 Return authorization / authentication status.
	4 The system displays the Trial Candidates page showing a list of processing options.	
5 If the user chooses to add a candidate		
	5.1 The system displays a form to collect information.	
5.2 The user enters the required information and submits a request.		
	5.3 The system verifies that the form fields contain valid data.	
	5.4 The system requests to create an entry in the Candidates repository.	
		5.5 The database creates an entry.
	5.6 The system displays a message to indicate the entry was created successfully.	
6 If the user chooses to review, update, or delete		
	6.1 The system displays options to process a single entry or multiple entries.	
6.2. If the user chooses to process from a list of candidates from the repository		
	6.2.1 The system requests to retrieve all entries in the Candidates repository associated with the advocate.	
		6.2.2 The database retrieves all entries.
	6.2.3 The system displays the results, sorted in alphabetical order by last name.	
6.2.4 The user selects one of candidates to process and submits a request to refer or drop.		
6.3 If the user chooses to process a single entry		
	6.3.1 The system displays a form to enter the name of the candidate.	
6.3.2 The user updates the form and submits a request to update or delete.		
	6.3.3 The system verifies that the form fields contain valid data.	

	6.4 The system requests to retrieve the entry in the Candidates repository for the requested candidate.	
		6.4.1 The database retrieves the entry.
	6.4.2 The system displays the current data for the candidate.	
6.5 If the user chooses to change information about a candidate		
6.5.1 The user updates the form and submits a request.		
	6.5.2 The system verifies that the form fields contain valid data.	
	6.5.3 The system requests to update the entry in the Candidates repository.	
		6.5.4 The database updates the entry
	6.5.5 The system displays a message to indicate the entry was updated successfully.	
6.6 If the user chooses to delete a candidate from the repository		
6.6.1 If the user confirms delete		
	6.6.2 The system requests to delete the entry from the Candidates repository.	
		6.6.3 The database deletes the entry.
	6.6.4 The system displays a message to indicate the entry was deleted successfully.	
6.6.5 If the user cancels delete		
	7 The system displays the Trial Candidates page.	

UC1002: Request Subject Referral

Participating Actors: Patient Advocate

Description: Request to refer a subject to an active trial. Information can be added or changed.

Preconditions:

1. User is authorized to perform read, create, update, and delete participants.
2. User has accessed the application logon page.

Postconditions: Advocate has been added or dropped from a clinical trial.

Main Success Scenario

Actor	System	Resource
1 The user requests to log into the system.		
	2 The system requests user authorization / authentication.	
		3 Return authorization / authentication status.
	4 The system displays the Trial Candidates page with options to process a single entry or multiple entries.	
5 If the user chooses to process from a list of candidates from the repository		
	5.1 The system requests to retrieve all entries in the Candidates repository associated with the advocate.	
		5.2 The database retrieves all entries.
	5.3 The system displays the results, sorted in alphabetical order by last name.	
5.4 The user selects one of candidates to process and submits the request.		
6 If the user chooses to process a single entry		
	6.1 The system displays a form to enter the name of the candidate.	
6.2 The user updates the form and submits a request to retrieve.		
	6.3 The system verifies that the form fields contain valid data.	
	7 The system requests to retrieve the entry in the Candidate repository for the requested candidate.	
		8 The database retrieves the entry.
	9 The system requests to retrieve a list of active trials from the Trials repository associated with the advocate.	
		10 The database retrieves the list.
	11 The system displays the current data for the candidate and processing options	
12 If the user chooses to view trial information		
	12.1 The system requests to retrieve trial information from the Trials repository.	
		12.2 The database retrieves the information.

	12.3 The system displays trial information and processing options.	
13 The user chooses to refer the candidate for the trial or to drop the candidate.		
	13.1 The system requests to update the entry in the Candidates repository.	
		13.2 The database updates the entry.
	13.3 The system displays a message to indicate the entry was updated successfully.	
	14 The system displays the Trial Candidates page.	

UC1003: Manage Referral Request

Participating Actors: Site Registrar

Description: Review trial candidate referrals and approves or rejects for registration.

Preconditions:

1. User is authorized to review trial candidate referrals.
2. User has accessed the application logon page.

Postconditions: A trial candidate has been reviewed, accepted, or rejected for a clinical trial.

Main Success Scenario

Actor	System	Resource
1 The user requests to log into the system.		
	2 The system requests user authorization / authentication.	
		3 Return authorization / authentication status.
	4 The system displays the Trial Candidates page with options to process a single entry or multiple entries.	
5 If the user chooses to process from a list of candidates from the repository		
	5.1 The system requests to retrieve all entries in the Candidates repository associated with the advocate.	
		5.2 The database retrieves all entries.
	5.3 The system displays the results, sorted in alphabetical order by last name.	

5.4 The user selects one of candidates to process and submits the request.		
6 If the user chooses to process a single entry		
	6.1 The system displays a form to enter the name of the candidate.	
6.2 The user updates the form and submits a request to retrieve.		
	6.3 The system verifies that the form fields contain valid data.	
	7 The system requests to retrieve the entry in the Candidate repository for the requested candidate.	
		8 The database retrieves the entry.
	9 The system requests to retrieve a list of active trials from the Trials repository associated with the advocate.	
		10 The database retrieves the list.
	11 The system displays the current data for the candidate and processing options	
12 If the user chooses to view trial information		
	12.1 The system requests to retrieve trial information from the Trials repository.	
		12.2 The database retrieves the information.
	12.3 The system displays trial information and processing options.	
13 The user chooses to accept the candidate for the trial or to accept the candidate.		
	13.1 The system requests to add the patient to the trial.	
		13.2 The Patient service adds the candidate.
	13.3 The system requests to register the patient in the trial	
		13.4 The Registration service registers the candidate.
	13.5 The system displays a message to indicate the entry was updated successfully.	
	14 The system displays the Trial Candidates page.	

UC2001: Monitor Subject – Study Subject

Participating Actors: Study Subject

Description: Review trial data for the study subject and submit questions to researchers.

Preconditions:

1. User is authorized to the system.
2. User has accessed the application logon page.

Postconditions: Trial data has been viewed, a question has been submitted, or a response has been viewed.

Main Success Scenario

Actor	System	Resource
1 The user requests to log into the system.		
	2 The system requests user authorization / authentication.	
		3 Return authorization / authentication status.
	4 The system displays a list of processing options.	
5 If the user chooses to retrieve data		
	5.1 The system requests to retrieve trial data for the user from the Trial Data database.	
		5.2 The database retrieves the trial data.
	5.3 The system displays the trial data.	
6 If the user chooses to submit a question		
	6.1 The system displays a form for the question.	
6.2 The user enters the question on the form and submits it.		
	6.3 The system requests the question to be posted in the Communications database.	
		6.4 The database creates an entry.
	6.5 The system displays a message indicating the question has been posted.	
7 If the user chooses to retrieve communications		
	7.1 The system requests to retrieve all communications for the user.	

		7.2 The database retrieves all communications.
	7.3 The system displays communications and a menu of options.	
7.4 If the user chooses to view a selected communication		
	7.4.1 The system displays the communication in a pop-up window.	
7.4.2 The user closes the window.		
	8 The system displays the Trial Monitoring page.	

UC2002: Monitor Subject – Enrolling Physician

Participating Actors: Enrolling Physician

Description: Review trial data for the patients who are participating in a study and submit questions to researchers.

Preconditions:

1. User is authorized to the system.
2. User has accessed the application logon page.

Postconditions: Trial data has been viewed, a question has been submitted, or a response has been viewed.

Main Success Scenario

Actor	System	Resource
1 The user requests to log into the system.		
	2 The system requests user authorization / authentication.	
		3 Return authorization / authentication status.
	4 The system displays the Trial Monitoring page with options to process a single entry or multiple entries.	
5 If the user chooses to process from a list of patients from the repository		
	5.1 The system requests to retrieve all entries in the Candidates repository that are registered for one or more trials and are associated with the enrolling physician.	
		5.2 The database retrieves all entries.
	5.3 The system displays the results, sorted in alphabetical order by last name.	

5.4 The user selects one of patients to process and submits the request.		
6 If the user chooses to process a single entry		
	6.1 The system displays a form to enter the name of the patient.	
6.2 The user updates the form and submits a request to retrieve.		
	6.3 The system verifies that the form fields contain valid data.	
	7 The system requests to retrieve the entry in the Candidate repository for the requested candidate.	
		8 The database retrieves the entry.
	9 The system requests to retrieve a list of trials from the Trials repository associated with the patient.	
		10 The database retrieves the list.
	11 The system displays the current trials for the patient and processing options	
12 If the user chooses to retrieve trial data		
	12.1 The system requests to retrieve trial data for the patient from the Trial Data database.	
		12.2 The database retrieves the trial data.
	12.3 The system displays the trial data.	
13 If the user chooses to submit a question		
	13.1 The system displays a form for the question.	
13.2 The user enters the question on the form and submits it.		
	13.3 The system requests the question to be posted in the Communications database.	
		13.4 The database creates an entry.
	13.5 The system displays a message indicating the question has been posted.	
14 If the user chooses to retrieve communications		
	14.1 The system requests to retrieve all communications for the user.	
		14.2 The database retrieves all communications.

	14.3 The system displays communications and a menu of options.	
14.4 If the user chooses to view a selected communication		
	14.4.1 The system displays the communication in a pop-up window.	
14.4.2 The user closes the window.		
	15 The system displays the Trial Monitoring page.	

UC2003: Monitor Trial Data

Participating Actors: Enrolling Physician, Community Member

Description: Review summary trial data and submit questions to researchers.

Preconditions:

1. User is authorized to the system.
2. User has accessed the application logon page.

Postconditions: Summary trial data has been viewed, a question has been submitted, or a response has been viewed.

Main Success Scenario

Actor	System	Resource
1 The user requests to log into the system.		
	2 The system requests user authorization / authentication.	
		3 Return authorization / authentication status.
	4 The system displays a list of processing options.	
5 If the user chooses to retrieve data		
	5.1 The system requests to retrieve trial data from the Trial Data database for the associated user.	
		5.2 The database retrieves the trial data.
	5.3 The system displays the trial data.	
6 If the user chooses to submit a question		
	6.1 The system displays a form for the question.	

6.2 The user enters the question on the form and submits it.		
	6.3 The system requests the question to be posted in the Communications database.	
		6.4 The database creates an entry.
	6.5 The system displays a message indicating the question has been posted.	
7 If the user chooses to retrieve communications		
	7.1 The system requests to retrieve all communications for the user.	
		7.2 The database retrieves all communications.
	7.3 The system displays communications and a menu of options.	
7.4 If the user chooses to view a selected communication		
	7.4.1 The system displays the communication in a pop-up window.	
7.4.2 The user closes the window.		
	8 The system displays the Trial Monitoring page.	

UC2004: Obtain Trial Data

Participating Actors: Enrolling Physician, Community Member

Description: Reports for members of the community, including interim reports on trial subjects, interim reports on the overall trial, and final reports on trial outcomes. The reports allow trial subjects to monitor their progress and make decisions about their participation; they allow enrolling physicians to monitor their patient's progress; and they keep members of the community engaged.

Preconditions:

1. User is authorized to the system.
2. Reports have been pre-defined.

Postconditions: The report has been provided.

UC3001: Disseminate Trial Results

Participating Actors: Community Outreach Coordinator

Description: This process describes the steps for obtaining trial outcome reports and distributing them to members of the community.

Preconditions:

1. User is authorized to the system.

Postconditions: A report has been distributed.

Appendix I Petri Net for Monitor Subject Application

Figure 40 shows a Petri net representing the flow of the Monitor Subject application. Annotations are noted in Table 36. This application is complex in that it requires invocation of several internal and external web services. A Petri net can be used to validate this part of the solution.

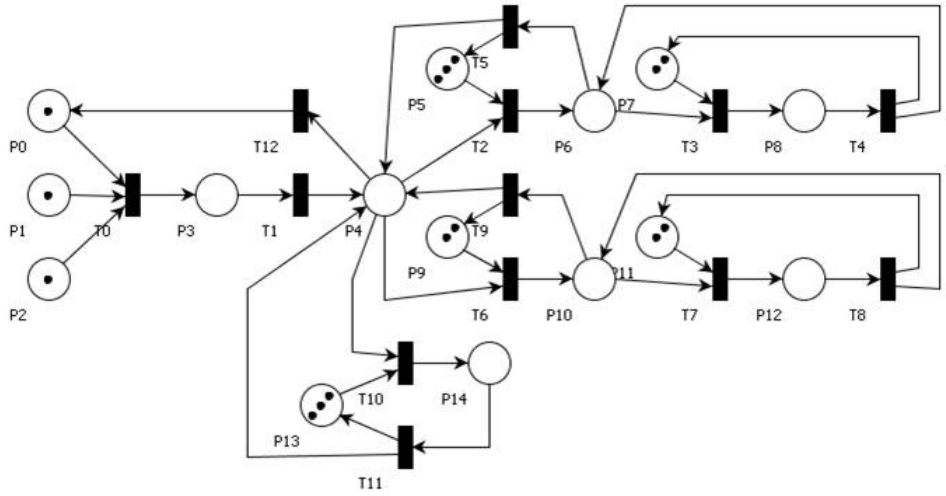

Figure 40. Petri net for Monitor Subject.

Table 36. Annotations for Monitor Subject.

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	Monitor Subject page
P5	Service	Connection to Confirm Patient Advocate Status

P6	Data	Request to Register Patient Advocate
P7	Service	Connection to Register Patient Advocate
P8	Data	Patient Advocate Status
P9	Service	Connection to Confirm Subject Status
P10	Data	Request to Confirm Subject Status
P11	Service	Connection to Registration
P12	Data	Subject Status
P13	Service	Connection to Obtain Trial Data
P14	Data	Trial Data
T0	Task	Log in user
T1	Task	Display Monitor Subject page (home page)
T2	Task	Obtain connection to Confirm Patient Advocate Status service; submit request to service
T3	Task	Obtain connection to Register Patient Advocate; submit request to service
T4	Task	Release connection to Register Patient Advocate; return patient advocate status
T5	Task	Release connection to Confirm Patient Advocate Status; return patient advocate status
T6	Task	Obtain connection to Confirm Subject Status; submit request to service
T7	Task	Obtain connection to Registration; submit request to service
T8	Task	Release connection to Confirm Subject Status; return subject status
T9	Task	Release connection to Registration; return subject status
T10	Task	Obtain connection to Obtain Trial Data
T11	Task	Release connection to Obtain Trial Data; return data
T12	Task	Log out user

Appendix J Glossary of Terms

caBIG	Cancer Biomedical Informatics Grid. This platform and infrastructure is used by the National Cancer Institute to integrate and ensure interoperability among various systems designed to manage cancer research.
CDMS	Clinical Data Management System. This system is used by clinical researchers to manage data associated with one or more clinical trials.
COTS	Commercial Off-the-Shelf Software.
CRO	Contract Research Organization. This organization performs research activities on behalf of a client.
CRUD	Create, Read, Update, Delete. This acronym is used to describe basic functions typically associated with software data.
CTMS	Clinical Trial Management System. This system is used by clinical researchers to manage the clinical trials process.
CTS	Clinical Trial Suite. This is a CTMS that is developed by the National Cancer Institute.
Design Model	This is a document used during the Specification phase of the RUP/SOMA methodology to model the high-level design of a web service. Refer to Appendix E for more details about its content.
KPI	Key Performance Indicator. This is a metric that is used to measure the performance of a process or tool.
NIH	National Institute of Health.
Petri net	This is a modeling notation that can be used to represent asynchronous and concurrent processes.
RUP	Rational Unified Process. This is a software development process that describes how requirements are transformed into software.
Service Model	This is a document that is used throughout all phases of the RUP/SOMA methodology to model a web service. Refer to

	Appendix E for more details about its content.
SOA	Service-Oriented Architecture. This is an architectural style that focuses on building discrete, reusable services.
SOMA	Service-Oriented Modeling and Architecture. This is a methodology developed by IBM for defining and implementing an SOA.
Type 1 dependency	SOMA defines a Type 1 dependency as a functional dependency. When Service A is composed of Service B and Service C, it has Type 1 dependencies on both Service B and Service C.
Type 2 dependency	SOMA defines a Type 2 dependency as a temporal dependency. When Service A can only be invoked after Service B has been executed, it has a Type 2 dependency on Service B.
UML	Unified Modeling Language. This is a visual modeling language that can be used to describe software systems.