Requirements - caAERS

Document Change History

Version	Date	Description
1.0	6/2006	COH completed the Release 1 SRS document
2.0	1/17/2007	Semantic Bits submits the first iteration of Release 2
2.1		Update to most recent caBIG template
2.2	4/9/07	Modify as per feedback from Mayo and WFU and Construction Phase Iteration 2
2.3	5/8/07	Update as per May F2F and Adopter feedback
2.4	6/11/07	Updated as per BAH feedback.
2.5	6/22/07	Updated as per BAH and WFU feedback
2.5.1	7/3/07	Updated as per Edmond's suggestion
2.5.3	8/27/07	Updated mods 3 and 4 plus non-functional reqt.s
2.5.4	10/5/07	Fixed date in footer
2.7	10/8/07	Updated links to external documents, updated supported environment section to reflect Browser included as part of the system Development team testing, and other edits.
2.7.1	10/15/07	Addressed BAH comments, added two requirements.
2.8	11/13/07	Import AE data, CCTS study creation
2.9	1/2/08	Address feedback from I7 and I8
2.10	2/6/2008	Address BAH and WFU feedback
3.0	4/16/2010	Updated to merge with Phase II SRS content, bring document current, and clearly separate it from Vision and Scope
3.1	4/20/2010	Added requirements from the Phase III project backlog
3.2	11/19/2010	Added links to the caAERS-AdEERS requirements and the AdEERS Web Service SRS

Document Overview

This document presents the software requirements for the caBIG® Adverse Events Reporting System (caAERS). This software requirements specification (SRS) captures the current state of the complete software requirements for the system. This document attempts to provide a complete and unambiguous definition of the software requirements as conveyed by (and traceable to) key stakeholders. This document also aims to rank in importance each requirement through the use of standard conventions.

An initial document was developed by the City of Hope National Medical Center under Statement of Work caBIG-CTMS-03-02-01. Revisions to the initial requirements document drove Phase I the system development and were a result of separate caBIG collaboration between Northwestern University, Akaza Research, SemanticBits, and other adopters of caAERs. Phase II and Phase III of the system development resulted in additional requirements changes and updates to this document, with authorship by SemanticBits and input provided by Mayo Clinic Rochester, Wake Forest Health Sciences, Cancer and Leukemia Group B (CALGB), NCI's Cancer Therapy Evaluation Program (CTEP), NCI's Division of Cancer Prevention (DCP), NCI's Center for Biomedical Informatics and Information Technology (CBIIT), along with other members of the caBIG® and cancer research community.

The initial requirements of the system was driven by input from the cancer clinical trials community to identify the key elements for a core adverse events data collection and reporting tool. Potential adopters encompass cancer centers with limited or no electronic capabilities at present as well as those with sophisticated systems who envision the caGRID modules as adjuncts to those systems. To address these varying needs, the system must be extremely flexible and configurable to allow the participant to select only those modules that provide functionality that is needed.

The SRS sections are organized as follows:

- Project Description: Provides a general description and background of the system system.
- Functional Requirements: Describes all the software requirements to a level of detail sufficient to enable designers to design a system to

satisfy those requirements, and testers to test that the system satisfies those requirements.
- Non-Functional Requirements: Provides details of requirements that do not dictate specific system functionality, but instead reflect general system behaviors and contraints.

Project Description

The objective of the the system project is to develop a comprehensive set of tools centered around the collection and reporting of information related to adverse events that occur during the course of a cancer clinical trial. Our hope is that these tools will enable use of the application to:

1. Enhance the safety of patients on cancer clinical trials by making information more readily available to those who make decisions in the patient's treatment.
2. Better support the research team collecting this information to facilitate effective identification of serious adverse events and more efficient reporting.
3. Allow researchers to answer questions related to problems with treatments and their efficacy more quickly and accurately.

caAERS is envisioned as one major component of a comprehensive system made available on the cancer Biomedical Informatics Grid (caBIG®) to facilitate cancer clinical trials data management. The main goal of the system is to be a web-based, enterprise level system, that is capable of serving as the source of record for all adverse events and adverse event reports for a clincial trial.

Modules

caAERS can be described as being comprised of several modules that represent core groupings of functional requirements. For clarity and the ease of traceability, many of the the requirements will be referred to within context of the corresponding module. The twelve (12) named the system modules are described below.

Module 1 - Adverse Event Data Capture

This module serves as a source of record for any, and potentially all, adverse events that are observed during the course of a clinical trial. Based on information entered through a web interface, the system captures the severity of the adverse event and provides instructions for further reporting. Internal reporting capabilities allow the CRA to follow submissions, Quality Assurance to review them, and the Principal Investigator(s) to monitor toxicities and address further reporting requirements.

Module 1a - Adverse Event Capture

caAERS works with cancer prevention and therapeutic trials and can accommodate a range of intervention types, including investigational and commercial agents, radiation, surgery, and medical devices. Adverse events can be coded in the system using either CTCAE or MedDRA. Users can now enter Adverse Event information, prepare and submit report, configure AE notification rules, and search adverse events in the system. Currently, multiple pieces of information can be imported from existing CTMS interfaces, such as patient and protocol-related AE information (patient information, study information, investigators, etc). However, some instances of the system require direct entry since there is not a local CTMS or it is unavailable for integration.

Module 1b - Studies

caAERS has the ability to capture study information. This information can be imported from a local CTMS, captured automatically (basic details) from C3PR when using the system as part of the CCTS, or entered manually using the the system web interface. In addition to capturing the protocol information (diseases, therapies, agents, and treatment assignments), the system also tracks what personnel (research associates, investigators, etc) are associated to the study, the study's sponsors, sites, and identifiers.

Module 1c - Subjects

Subjects that are participating in studies can be managed in the system. the system has the ability to capture general subject information, what study(s) they are involved in, and their AE history. Subject information can be imported from a local CTMS in a batch, captured automatically (basic details) from C3PR when using the system as part of the CCTS, or entered manually using the the system web interface. As a patient's involvement in a study changes, it is easy to add the association to that study.

Module 1d - Rules

The the system system features a powerful, state-of-the-art rules engine, which can capture a range of sponsor, institution, and protocol-level reporting requirements.Using these rules, the system can automatically determine if an adverse event requires expedited reporting and when and to whom the report must be submitted -- for any of an organization's trials.

The business rules used by the system can be authored within the application itself or imported from a library of approved rule sets. The rules can also be exported for use outside of the system. The rules determine appropriate notification action (reports required) based on multiple properties such as AE category, AE term, AE grade, protocol, sponsor, hospitalization/hospitalization time, expectedness, attribution, reporting time/period, and trial phase.

caAERS also includes is an easy-to-use report template generator, which allows users to build and customize reports. As part of this report generator, there's an advanced email-based alert system that can be customized along a number of dimensions (message content, recipients, delivery times) to ensure that notifications and reminders are sent out as needed. In addition, to help organizations stay in compliance with AE reporting regulations, the the system application comes loaded with a full complement of industry-standard AE reports, including the FDA MedWatch 3500A form, the CTEP AdEERS reports, the NCI-DCP SAE form, and CIOMS.

Module 1e - Administration

caAERS can be a completely self contained system. It has custom configuration to work with CTMS if desired, a separate password policy for users, and the ability to create and manage research staff (users of the system), including different levels of access. Separately, Organizations and Investigators, which are required for Study creation and AE tracking, can be imported or manually added into the system, with the majority of the organizations included in the default installation. There's also the ability to import MedDRA, to support Module 3.

Module 2 - Interfaces with Local Clinical Trials Systems

Module 2 facilitates communication between the system and the participating institution's clinical trial systems (eg. CTMS, CDMS). These interfaces will be used to integrate and share data between systems without then need for duplicative data entry. These interfaces may include data exchange for elements including (but not limited to): adverse events, adverse event reports, studies/protocols, subjects, investigators, research staff, and organizations.

Module 3 - Vocabulary Mapping Service

Module 3 defines the functional need for the system to include and support multiple vocabularies used in clinical trials.

Module 4 - External Agency Reporting

Module 4 expands the functionality of Module 1 to electronically communicate SAEs to participating entities/systems such as AdEERS and provide generic alert messages to national cooperative groups and industrial sponsors involved with NCI funded protocols.

Module 5 - Internal (institutional) Routing and Review

Module 5 will contain functionality facilitating the sending (routing) of adverse event collections and reports to other stakeholders on a study (i.e. the treating physician, the coordinating center) for review and comment. This module also supports the "Central Processing" workflow used by many cooperative groups as part of their AdEERS submission process.

Module 6 - Integrated Repository of AE Data

Module 6 establishes a data warehouse for evaluating adverse events across protocols, sites, a network, the nation, ect. This repository sets the stage for later modules that provide information for data mining and public safety communications.

Module 7 - Acquisition of Lab Data to Quantitatively Identify Adverse Events

Module 7 will assist in the grading of quantitatively identified adverse events found in lab data acquired from local laboratory systems. Grading will be based on CTEP's CTC version 2.0 and CTCAE version 3.0. An application called caLoegs is currently being developed by City of Hope that addresses this module. Once the application is completed, we will review the possibility of integrating with it.

Module 8 - Assistance in Grading Qualitative Adverse Events

Module 8 will provide assistance in the grading of adverse events found through clinical observation. It may be feasible to display the different grades available to assist the users in choosing the correct one.

Module 9 - Study Participant Self-Reporting of Adverse Events

Module 9 facilitates the reporting of adverse events by the study participant and their family caregivers. Data will be collected via web-entry or via a telephone.

Module 10 - Data Mining for Risk Patterns

Module 10 enables authorized individuals to gain access to the Adverse Events Data Warehouse for data mining across protocols. Information collected for the current CDUS system is also accessible. Statistical analysis of risk patterns should provide opportunities for improved clinical trials and knowledge acquisition.

Module 11 - Public Safety Website

Module 11 addresses dissemination of information about adverse events and drug and procedural safety alerts to the public. It uses the information collected in the data warehouse and evaluated via the functionality in the previous module.

Module 12 - Automated Decision Support for Expectedness of AEs

This module refines the capture of adverse events data by providing protocol-specific information against which the event is compared. This enables the system to determine whether an adverse event is expected or unexpected at the initial point of entry. The Developers will work with the adopters and elaborators (including CTEP) to identify the specific use cases around expectedness of AEs to determine what information needs to be collected and how the system will handle the information (or the absence of that information).

Module 13 - Security

caAERS has been set up to work with an institutions existing security framework. If an institution already has user accounts in place, the system can be integrated into the existing system so users only have one user name and password.

Access to the information in the system is also controlled. The different Research Staff roles limits the information that can be accessed by each user. These controls are handled in the Administration Module (Module 1e).

User Characteristics

Users of the system may fall into one or more of the following categories:

1. Cancer Center participants who collect and report information on clinical trials patients. These users will have access to only their institution's information. These may be Principal Investigators, Clinical Research Associates, Protocol Nurses, and other cancer center staff as designated. This group is able to enter and edit data for their institution. Some Cancer Center institutions may collect data from treatment centers in which case, the treatment center staff would only have access to their own information but the coordinating Cancer Center would have access to information from each of its affiliates.
2. Cancer Center Administrative personnel who are responsible for entering information about when an AE must be reported to the local regulatory entities (IRB, DSMB). This group may view data entered but may not change it.
3. Protocol Administrators would include the Study Chair, Study Statistician, and possibly staff from a centralized data coordinating center. This group might have access to information from more than one institution as in the case of a cooperative group or a consortium. This group would have the ability to enter protocol specific triggers for AE reporting.
4. Sponsors would include government agencies and other entities (such as a pharmaceutical) that would have access to data from a number of cancer centers. Sponsor staff would not have the ability to change any of the data but might be able to add comments, generate reports or views, and send requests for additional information or corrections to the initiating center. Sponsors would also have access to functions that enable them to enter information that facilitates sponsor-reporting triggers.

Functional Requirements

Conventions

The following terminology was used when writing the requirements:

- MUST - This word means that the definition is an absolute requirement of the specification.
- MUST NOT - This phrase means that the definition is an absolute prohibition of the specification.
- WILL - This word means that the definition is an absolute future requirement of the specification.
- WILL NOT - This phrase mean that the definition is an absolute future prohibition of the specification.
- SHOULD - This word means that there may exist valid reasons in particular circumstances to ignore a particular item, but the full implications must be understood and carefully weighed before choosing a different course.
- SHOULD NOT - This phrase means that there may exist valid reasons in particular circumstances when the particular behavior is acceptable or even useful, but the full implications should be understood and the case carefully weighed before implementing any behavior described with this label.
- MAY - This word means that a requirement is truly optional. The developer may choose to include the item based on the needs of their design.

Qualification Provisions

The Functional Requirements each describe an aspect of the software that is directly observable by an end user. No special tests or equipment will be required in order to ensure that the requirements are being met.
The Non-Functional Requirements, however, may require software-based tests, inspection of code, or the examination of database query results. These requirements may also require observation of user interaction with the software.

Module 1 - Adverse Event Data Capture

Module 1a - Adverse Event Capture

Req ID	Requirement	Requested by
M1.4	The system must only allow one grade 5 submission per subject	AE SIG
M1.5	The system should have a configuration setting that allows an organization to say how many "other - specifies" can be added as AEs for a given subject during a reporting period	CALGB
M1.6	The system must not allow a user to add the same AE multiple times for a given subject during a reporting period	adopters
M1.7	Users should be able to capture a patient's medical history once and have the information available when reporting Aes	adopters
M1.8	Users must be able to add, modify, delete any data that is capture before reporting an AE and brought in to the flow	adopters
M1.9	The system should provide a "cycle number" field	adopters
M1.10	The system may have the ability to add custom fields at the study level	CALGB
M1.11	The system may have the ability to print a blank AE data capture page	CALGB
M1.12	The system must provide a way to document three types of AEs, baseline, AES that occur during treatment, and Late AEs	adopters
M1.13	The system should have the ability to handle commercial agent only trials	CTEP
M1.14	The system must provide notification when an AE requires (is promoted) an expedited report	adopters
M1.15	The system should provide a way to link the AE that required an expedited report to that expedited report (if there are multiple serious Aes, which one goes to which report, are they all to the same report, etc)	adopters
M1.16	AEs should be grouped by reporting period	adopters
M1.17	The system must provide a warning if reporting periods overlap by more than 1 day	adopters
M1.18	The system must provide a warning if reporting periods have a gap larger than 1 day in between them	adopters
M1.19	The system should allow one user to enter the AE information but still document who provided the information originally	adopters
M1.20	There must be a way to turn off the requirement for start and stop dates for routine Aes	Mayo
M1.21	AEs in an expedited report must be associated to a reporting period	adopters
M1.22	The system must support solicited AE configuration at the Study level	adopters
M1.23	Solicited AEs must be displayed during the AE flow	adopters
M1.24	"Hospitalization" must not be required except when the business rules require it	Mayo
M1.25	"hospitalization" should be a yes/no question	adopters, CTEP
M1.26	The system should include instructions when the CTC category and term is used in the routine AE flow to explain to users what they should do	adopters
M1.27	The system must allow users to save AEs for a reporting period without having entered all the information (partially completing the data)	adopters
M1.28	If a protocol has an agent, Agent 1 should be expanded automatically, but still be delete-able	adopters
M1.29	The system must include a dropdown list for Physicians in the AE flow	adopters
M1.30	There may be a way to copy an existing report	adopters
M1.31	The system must turn off all attributions & reporting requirements except Grade for AEs reported as Baseline	adopters
M1.32	AEs should not have an arrow to promote them to Primary, there should be a button that says "make primary AE" that appears on all AEs except the primary AE	adopters

M1.33	Users must have the ability to add all AEs from a reporting period to an expedited report	adopters
M1.34	The system should provide a query API	Wake
M1.35	The expedited report path should be streamlined to make it more user friendly	CTEP, Adopters, DCP
M1.36	The system may provide advanced analytic features (to be expanded)	CBIIT, CCTS
M1.37	The system must provide DCP with a way to enter conditions instead of diseases during study definition	DCP
M1.38	The system will use EVS for specifying Agents for DCP	DCP
M1.39	The system may provide a features to allow the creation of custom tex for AE Grades for use with studies	CTEP
M1.40	The system may allow the attachment of photos and documents to be included with the submission of reports	adopters
M1.41	Grades must always have descriptions, either the grade specific to the term or the default values if there isn't a specific one given	adopters
M1.42	users should have the ability to export search results as text	Wake
M1.43	users should be able to search for routine AES	adopters
M1.44	users should be able to search for expedited reports	adopters
M1.45	users should be able to search for AES by reporting periods	adopters
M1.46	multiple users must not be able to open the same object at the same time (caAERS must prevent overlapping access)	adopters
M1.47	When submitting expedited reports, the system should show roles and email addresses that will receive the report	adopters
M1.48	When reporting on solicited AEs, "-1 Not evaluated" and "0 Not observed" must be grade options	adopters
M1.49	The system should list all error messages on all AEs that have errors (if attribution to disease was not included on both)	adopters
M1.50	The system should provide errors on the submission page and manage reports so the user can see if there is an error before they exit	adopters
M1.51	The system must allow the submission of just mm/yyyy for many date fields	adopters
M1.52	When "Other - specify" is selected as the term, the system must require "other" field to be populated with medDRA term (if no medDRA installed, should require verbatim)	adopters
M1.53	Verbatim field must be included for all Aes	DCP, FDA
M1.54	The system must include the field "has the patient ever received the investigational drug" (if yes, uses IND agent rules for reporting purposes, if no, uses commericial agent rules)	CTEP, DCP
M1.55	The system must be able to handle a name change for a subject without the data becoming corrupt	adopters
M1.56	Need to be able to identify the subject id as internal/all transmission - some ids are only for internal use while others can be viewed by all (oct 11, 2007)	adopters
M1.57	The system should prompt users for addition information when specific Aes are entered (standard requests from IDB, Paul has hard copy list)	CBIIT
M1.58	The system may provide a way to show customized instructions on the enter AE page to go with the solicited AEs, study	CALGB
M1.59	The system should assign and display a report # to all expedited reports, making refering to the AE easier (show the AdEERS report # for example)	adopters
M1.60	The system should provide list of 6 serious indicators to support EORTC, ICH, and EMEA rules	CBIIT
M1.61	expectedness should not be required all the time	Mayo
M1.62	If commercial agent only study, when documenting Aes, must provide messages about what is required & disable the "additional information" page	FDA/Medwatch
M1.63	The system must be configurable to handle differences with commercial agent only trials	adopters
M1.64	The system may include a way to caputre secondary malignancies that occur long term (AML)	CALGB

M1.65	The system should provide a way to identify AEs that continue from reporting period to reporting period (no end date)	adopters
M1.66	The system may have a copy feature for AE information	adopters
M1.67	The system should provide notification if there's an increase of frequency of an AE across patients in a study	CALGB
M1.68	The system must be able to document DLT Toxicity for Phase I studies	CDUS, CALGB
M1.69	AEs should be listed most recent first	adopters
M1.70	all information on the "manage report" page must be collapsible	adopters
M1.71	The status of an expedited report must be at the top level	adopters
M1.72	There should be a way to combine multiple AdEERS reports into one report	adopters
M1.73	There should be a way to print AE information for site records and audit use	adopters
M1.74	Users should be able to sort the AE information multiple ways	adopters
M1.75	Must be able to select and export AEs by reporting period, including expedited report	adopters
CAAERS-198	The system should support grading solicited adverse events	Adopters
CAAERS-339	Treatment assignment description should not be editable from the edit reporting period pop-up	Adopters
CAAERS-1161	The system should support need to be able to capture partial adverse event data for an evaluation period	Adopters
CAAERS-1956	The system should support a configuration where an adverse event term can only exist once per course	Adopters
CAAERS-2363	The system should support printing blank adverse event forms	Adopters
CAAERS-3129	The system will support support multiple distinct aes of the same term within a single course	Adopters
CAAERS-3130	The system will support support entry of verbatim first	Adopters
CAAERS-3141	The system should support if changes are made to course they are not shared between the expedited and capture ae flows	Adopters
CAAERS-3156	The system should support when an "other" tac is used in one course, copy the description to subsequent courses created for that subject	Mayo
CAAERS-3162	The system should support need to add an indicator showing that an ae has been reported	Adopters
CAAERS-3204	The system should support add "no" as a rule value option for hospitalization	Adopters
CAAERS-3282	The system will support add a scroll bar to the autocompleter results display and increase number of results returned	Mayo
CAAERS-3461	The system will support allow configuration of mandatory, optional, and n/a fields on capture ae screen	Adopters
CAAERS-3680	The system should support allow multiple "other, specify" ae terms of the same type in cae, expedited flow, solicited, and expected ae pages	Adopters
CAAERS-3755	The system will support allow configuration of mandatory, optional, and n/a fields on course pop-up	Adopters
CAAERS-3869	Custom instructions for course type should be highlighted when shown in CAE>>Adverse events	CALGB

Module 1b - Studies

Req ID	Requirement	Requested by
CAAERS-195	The system should support association of solicited adverse events to a study	Adopters
CAAERS-1096	Add validation that if study should be reported to CTEP, then disease coding must be CTEP	Adopters
CAAERS-1766	The system should support adding ability for a study definition to be provisional until approved	Adopters
CAAERS-3058	The system should support study set up complete	Adopters
CAAERS-3280	Study - Research Staff buttons should not refresh the page	Adopters
CAAERS-3866	Specific and helpful error messages should be shown in the import study module	Adopters

CAAERS-3916	The system must support the modification and deletion of a TAC from a study	RPCI

Module 1c - Subjects

Req ID	Requirement	Requested by
CAAERS-681	The system should support add validation for participant medical history tab	Adopters
CAAERS-3727	Must allow for deletion of subjects and deletion of study subject assignments	RPCI

Module 1d - Rules

Req ID	Requirement	Requested by
CAAERS-706	DCP expedited flow should fire CTEP rules , if AdEERS reporting is selected	Adopters
CAAERS-1279	The system should support rules and admin tabs: link from user guide to appropriate sections of admin or install guide	Adopters
CAAERS-1911	The system will support create api for rules (rules evaluation service)	Adopters
CAAERS-1921	The system should support support for surgery, bone marrow transplant trials - add duration and time since intervention as variables in the sae reporting rules	Adopters
CAAERS-1932	The system should support re-run rules when there are changes to the ae	Adopters
CAAERS-2096	The system will support notification when rules are re-run	Adopters
CAAERS-2238	More than one amendable report should be able to be returned by the rules	Adopters
CAAERS-2779	The system should support provide confirmation to user regarding which rules were fired and which resulted in the recommended action	WFU
CAAERS-3013	Due date should be added to the report definition's email notifications as a parameter	Adopters
CAAERS-3205	The system should support adding "does not equal" to rule criteria for expected	Adopters
CAAERS-3508	The system should support allow authoring of a new rule set by using an existing ruleset as a template	Adopters
CAAERS-3521	The system should support device operator business rules and conditional ui behavior	Adopters
CAAERS-3611	The system should support it would be nice if existing rules could be copied and used as a starting point for other rules	RPCI
CAAERS-3712	The system will support need to suppress the "re-run rules" message in the expedited flow when there are no sae reporting rules for the study	Adopters
CAAERS-3713	The system should support update business rules to remove the study agent name (and others) as a system mandatory field - use mandatory fields instead	Adopters
CAAERS-3787	The system should support provide a means for users to automatically check a rule set for conflicting rules	Adopters
CAAERS-3809	The system should support need a user account that allows access to rules but not to administration	Adopters
CAAERS-3829	The system will support field level mandatory rules	Adopters
CAAERS-3844	The system should support add ability to configure (on the report definition) the role / person who can submit a report	CALGB
CAAERS-3893	The system must provide the ability to prevent overriding the recommendations of specific rule sets	CTEP
CAAERS-3899	The system should display sponsor specific rules for a study with the sponsor's protocol ID	CALGB
CAAERS-3917	The system should have human readable names for exported rule XML files	RPCI

Module 1e - Administration

Req ID	Requirement	Requested by

CAAERS-3085	The system should support need to add additional address fields	Adopters
CAAERS-3274	The system will support need to be able to delete organization on admin > research staff	Adopters

Module 2 - Interfaces with Local Clincial Trials The systems

Req ID	Requirement	Requested by
M2.1	The system must be able to receive (real-time) study information from an organizations existing system	Adopters
M2.2	The system must be able to receive (real-time) subject information from an organizations existing system	Adopters
M2.3	The system must be able to receive (real-time) staff information from an organizations existing system	Adopters
M2.4	The system must be able to receive (real-time) investigator information from an organizations existing system	Adopters
M2.5	If a subject's death is reported in the local CTMS, the system should know to expect a Grade 5 SAE	Adopters
M2.6	The system must be able to receive an import of subject data	Adopters
M2.7	The system must be able to receive an import of study data	Adopters
M2.8	The system must be able to receive an import of staff data	Adopters
M2.9	The system must be able to receive an import of investigator data	adopters
M2.10	Should be able to disable study additions and updates within the system	Adopters
M2.11	Should be able to disable subject additions and updates within the system	Adopters
M2.12	Should be able to disable staff additions and updates within the system	Adopters
M2.13	Should be able to disable investigator additions and updates within the system	Adopters
M2.14	The system must be able to export AE information into local CT databases and other CTMS application components for aggregation and analysis	Adopters
M2.15	The system must only create a study once when it has multiple identifiers	Adopters
M2.16	The system must not required hospitalization or expectedness when importing AE data	Adopters
CAAERS-223	The system should support import staff with associated organizations	Adopters
CAAERS-1052	Excel import should map Long Title to Short Title	Adopters
CAAERS-1320	The system should support meddra disease terminology version issues	Adopters
CAAERS-1909	The system will support add security to web services	Adopters
CAAERS-1916	The system should support allow addition of study site through the particpant message	Adopters
CAAERS-1934	The system should support re-evaluate method of updating/deleting data via web services	Adopters
CAAERS-1974	The system should support update web services to support device information	Adopters
CAAERS-2264	The system will support a API/service to programatically enter adverse events into the system	Adopters
CAAERS-2544	The system should support add organization to the investigator and research staff sections in the study overview / review pages	Adopters
CAAERS-2867	Study research staff and study investigator should show as pending until successfully saved	Adopters
CAAERS-3084	The system should support create a study export feature	Adopters
CAAERS-3139	The system will support need to support programmatically editing the security header in a soap message	RPCI
CAAERS-3376	COPPA search limits should be configurable	Adopters
CAAERS-3672	The system should support add ability to create a 'system' account for webservices	CALGB
CAAERS-3832	The system should support allow adding an ind in the study ui and the study apis	Adopters

Module 3 - Vocabulary Mapping Service

Req ID	Requirement	Requested by
M3.1	The system must support MedDRA 10.0	Adopters
M3.2	The system must support MedDRA 11.0	Adopters
M3.3	The system should have the ability to define, use, and map multiple sets of vocabulary (MedDRA, WHO, CTC, CTCAE, SWOG, CALGB) [CALGB uses a derivative of SWOG with no primary identifier, just identifier mappings.	CALGB
M3.4	The system will support the FDA Drug List	AE SIG
M3.5	The system will support the WHO Drug list	AE SIG
M3.6	The system will support LOINC vocabulary	AE SIG
M3.7	The system will support SNOMED vocabulary	AE SIG
M3.8	The system must allow only valid AE grading options when using CTCv2.0	CTEP, DCP
M3.9	The system must not display the medDRA code (ICH/FDA doesn't want clinicians user it)	CBIIT
M3.10	The system may support the use of a custom code book (Use of SWOG for reporting routine AEs)	CALGB
M3.11	The system must keep organization list up-to-date (CTEP updates daily)	Adopters
M3.12	Institutions must be able to import organizations 7000+ already exist, organization must have CTEP code to be able to send AdEERS so this should be handled by keeping Organization list up-to-date	CALGB
M3.13	The system must keep study agent list up to date (CTEP may update daily)	Adopters
CAAERS-139	The system should support support multiple versions of meddra	Adopters
CAAERS-321	The system will support associating grades with ctcv20	Adopters
CAAERS-2888	The system must support the CTCAE v4.0 vocabulary	Adopters
CAAERS-3128	The system should support advance search functionality for the CTCAE v4.0	CTEP
CAAERS-3231	The system will support allow import of organization lists	Adopters
CAAERS-3232	The system should support allow import of agent list	Adopters

Module 4 - External Agency Reporting

Req ID	Requirement	Requested by
M4.1	Will have the ability to export anonymous data sets	CBIIT
M4.2	Must have the ability to send an amendment to an AdEERS report	CTEP, adopters
M4.3	Must have the ability to handle 24-hour notifications to the system	CTEP, adopters
M4.4	Must have the ability to send AdEERS partially completed reports	CTEP, adopters
M4.5	Must provide an accurate mapping from the system to MedWatch PDF	FDA, CBIIT
M4.6	Must provide an accurate mapping from the system to DCP 48-hr SAE report	DCP, CBIIT
M4.7	will support electronic submission to FDA	CBIIT, adopters
M4.8	The system should support ICH guidelines & definitions for SAE Reporting	EORTC

M4.9	The system may have a report that provides specific line-listing of all supsected SAEs that were reported for a trial from all sites within a period	EORTC
M4.10	The system should be able to share data with the FDA repository	CBIIT
M4.11	The system must allow separate definition of required sections for commercial agent only trials	FDA
M4.12	The system should be able to pull data from AdEERS/access reports created in AdEERS	CALGB
M4.13	The system will support integration with the IG-RDC	AE SIG
M4.14	The system should provide an accurate mapping from the system to the CIOMS form (can be used in place of the MedWatch 3500a form) (http://www.fda.gov/medwatch/report/instruc_3500A.htm#facsimile)	AE SIG
M4.15	The system may support online reporting of MedWatch 3500 (https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm)	AE SIG
M4.16	The system must support capturing the elements included in the caBIG® adverse event (AE) case report form (CRF)	CBIIT
M4.17	The system must support SAE reporting for the NCI-Division of Cancer Prevention (DCP)	DCP
M4.18	The system must support the collection and reporting of data elements required by other domestic and international agencies.	AE SIG
M4.19	The system must allow the submission of a (DCP) report without requiring the addition of an agent if an agent hasn't been given. Scenario holds true for AdEERS reports as well (Pre-treatment AEs)	DCP
CAAERS-190	The system should support indication on adeers report if it was generated via the system	Adopters
CAAERS-273	The system should support removing Describe Event - Details field for CTEP sponsored trials	CTEP
CAAERS-1304	The system should support expectedness	Adopters
CAAERS-1322	The system should support support export and import of report definitions	Adopters
CAAERS-1407	The system will support add ability to update report definitions via import	Adopters
CAAERS-1450	The system should support preventing user modification of a submitted report without first amending the report	Adopters
CAAERS-1708	The system will support update the system-adeers message to send ticket # and amendment # when amending a report	Adopters
CAAERS-1917	The system should support move system mandatory fields to report definition	Adopters
CAAERS-1918	If Attribution is not a mandatory section, the requirement for attributing each AE to a cause should be removed	Adopters
CAAERS-1919	The system should support move system conditional fields to report definition	Adopters
CAAERS-1920	The system should support add "not applicable" as selectable option for certain fields in the ae report	Adopters
CAAERS-1922	The system should support add a "study focus" field	Adopters
CAAERS-1958	The system should support allow agents to be assigned to a tac at the study definition level	Adopters
CAAERS-1959	The system should support need a method of logging report submission in-progress, submitted, failed, etc	Adopters
CAAERS-1968	The system should support add "disease name not listed" text box if patient disease is selected as "solid tumor, nos" or "hematopoietic malignancy, nos"	Adopters
CAAERS-1972	The system should support add device to study definition	Adopters
CAAERS-1973	The system should support display study devices in expedited flow	Adopters
CAAERS-1975	The system should support medwatch support: add "not applicable" selection to a couple data fields	Adopters
CAAERS-2063	The system should support assigning a ticket# and/or report id	Adopters
CAAERS-2094	The system should support indicating when an adverse event is included in a report	Adopters
CAAERS-2114	The system should support add validation to "was investigational agent administered?"	Adopters
CAAERS-2153	In the expedited flow, the Reporter and Submitter should be defaulted to the logged in user	Adopters
CAAERS-2220	The system should support allow 2 decimal places for subject height and weight fields	Adopters
CAAERS-2240	The system should support handling of unanticipated problems in the system	Adopters

CAAERS-2267	The system should support the system-adeers: allow agents for all prior therapies except "no prior therapy", "radiation therapy", and "surgery"	Adopters
CAAERS-2269	The system should support report definition flow - need to show report name and organization in header	Adopters
CAAERS-2276	The system should support implement configurable notifications for submission failures	Adopters
CAAERS-2338	The system should support move DCP dose reduced/modified fields under agent	Adopters
CAAERS-2368	The system will support update the system to support new adeers submission schemas, specifically 24hr notification	Adopters
CAAERS-2379	The system should support support additional lab values	Adopters
CAAERS-2382	When submitting a report, the user should be kept on the submit page until the submission attempt is complete	Adopters
CAAERS-2383	The system should support update the prior therapy chemo agent list	Adopters
CAAERS-2387	The system should support when saving a change to an enabled rule set, automatically enable the change	Adopters
CAAERS-2411	The system should support alphabetize research staff and investigator lists in reporter drow down	Adopters
CAAERS-2417	The system should support supress display of dose modification fields if dose modification is set to no	Adopters
CAAERS-2438	The system will support develop a generic the system report template	Adopters
CAAERS-2483	The system should support the business rule where an expedited report can only contain one grade 5 adverse event	CTEP
CAAERS-2484	New AdEERS business rule - The present status of "Fatal/Died" on the report can only be selected (and must be selected) if there is a Grade 5 AE on the report	Adopters
CAAERS-2710	In Exp AE>>Study Intervention>>agent , an IND agent should be indicated by an icon	Adopters
CAAERS-2781	The system will support show ind # field with DCP ind, CTEP ind, other ind, ind-exempt	Adopters
CAAERS-3046	The system should support indentifying an investigational agent while creating an expedited adverse event report	Adopters
CAAERS-3103	The system should support allow pre-existing conditions to be attributed to the ae	Adopters
CAAERS-3116	The system should support if physician or reporter is not available in the dropdown, have an option in the dropdown to "add below"	Adopters
CAAERS-3157	The system should support allow an "other" tac description to be entered in study and available for each study subject	Mayo
CAAERS-3171	The system will support include parent report support for report definition export and import	Adopters
CAAERS-3173	The system should support allow deactivation of report definitions	Adopters
CAAERS-3206	The system will support need to support sending a notification upon report withdrawl	Adopters
CAAERS-3207	The system will support need to support configuration of delivery notification message	Adopters
CAAERS-3241	The system should support need to allow configurable notifications for a report based on the study	Mayo
CAAERS-3242	The system should support allow rule base notifications	Mayo
CAAERS-3281	The system will support addition of field "does this place participant at increased risk?" to expedited flow	Adopters
CAAERS-3285	The system should support update total dose administerd to allow for 14 digits prior to the decimal	Mayo
CAAERS-3447	The system should support only allow an agent to be on a report once	Adopters
CAAERS-3452	The system will support support electronic submission to the fda	Adopters
CAAERS-3453	The system should support allow users to add new fields to the expedited report flow	Adopters
CAAERS-3458	The system should support in report definition, indicate which fields are mapped to the particular report template	Adopters
CAAERS-3518	The system should support add validation to device reprocessed field	Adopters
CAAERS-3520	The system will support support investigational devices (ides)	Adopters
CAAERS-3524	The system should support add business rule to device returned	Adopters

CAAERS-3642	The system will support need to add "is" as an operator and yes as a condition for the rule : study - investigational new drug?	RPCI
CAAERS-3698	The system will support suppress option to select a child report	Adopters
CAAERS-3699	The system must support of ACRIN/CIP trials	Adopters
CAAERS-3806	The system will support need to add the ability to withdraw a submitted report	RPCI

Module 5 - Internal (Institutional) Routing and Review

Req ID	Requirement	Requested by
M5.1	Should enable communication/data sharing between multiple sites (local installations across sites supporting the same study; cooperative groups)	adopters
M5.2	Should have the ability to integrated with the IG-RDC (when adopted)	adopters
M5.3	The system should provide a user the ability to accept, reject, or request changes to a routine AE	adopters
M5.4	The system should provide a way for different level of users to communicate about an AE when the data needs changes or is questionable	adopters
M5.5	The system may have an email notification system that can report requested changes or newly submited Aes	CALGB
M5.6	The system must provide a status for all documented AEs (list still being defined)	coops
M5.7	The system must support ad-hoc notification of AEs to specific roles	adopters
M5.8	The system should support rule-based notifications of AEs to specific roles	CBIIT
M5.9	The system must support a review and approval workflow for AEs	adopters
M5.10	The system should provide support for multi-site (hierarchal) access	adopters
M5.11	The system may provide a hosted the system instance for multi-site access	adopters
M5.12	The system should have a configurable notification system based on roles, AE status, AE creation, etc (needs more clarification, all options)	adopters
CAAERS-2271	The system should support add generic name to prior therapy agents and allow querying by the generic name	Adopters
CAAERS-2490	The system will support workflow refactoring needed to account for multiple reports in data collection	Adopters
CAAERS-3460	The system will support allow configuration of routing and review workflows	Adopters
CAAERS-3722	The system should support when workflow is transitioned, the user needs to see a confirmation that the transition occurred	CALGB
CAAERS-3752	The system should support add submission status as a searchable attribute in routing and review	Adopters
CAAERS-3753	The system should support filter the routing and review status drop-down to only contain statuses appropriate for the user role(s)	Adopters
CAAERS-3872	Report reviewer should have export options in a single "Action": drop down	CALGB

Module 7 - Acquisition of Lab Data to Quantitatively Identify Adverse Events

Req ID	Requirement	Requested by
M7.1	Must have ability to receive lab data from the LabViewer	CBIIT, CCTS
M7.2	Must be able to display lab data within the AE flow	CBIIT, CCTS
M7.3	User should be able to automatically add lab values to the labs Tab of the expedited report flow	CBIIT, CCTS
M7.4	User should be able to stop displaying labs received from LabViewer	CBIIT, CCTS
M7.5	LabViewer data must only appear on the patient/study combinition	CBIIT, CCTS

Module 10 - Data Mining for Risk Patterns

Req ID	Requirement	Requested by
CAAERS-2251	The system should support advanced search UI	Adopters
CAAERS-3456	The system will support add some basic graphical analytics to the advanced search results	Adopters

Module 12 - Automated Decision Support for Expectedness of AEs

Req ID	Requirement	Requested by
M12.1	The "Expected" field must not be required	AE SIG, CTEP, Adopters
M12.2	"Expected" should autopopulate based on information from the protocol	AE SIG, CTEP, Adopters
M12.3	The system should implement ASAEL for automating determination of expectedness	CTEP
M12.4	The system must support protocol-based configuration of expectedness	Adopters
M12.5	The system should disable user entry of expectedness for IND treatment	CBIIT
M12.6	The system may develop rulesets to automatically determine expectedness	CBIIT
M12.7	for DCP SAE report (non CCOPS studies), expected should not appear	DCP
CAAERS-263	The system will support preventing user modification of "expectedness" for CTEP IND studies when entering adverse events	CTEP
CAAERS-3877	The system must support the import and usage of the Agent Specific Adverse Event List (ASAEL)	CTEP

Module 13 - Security

Req ID	Requirement	Requested by
M13.1	Must be able to integrate with an organization's authorization system	Adopters
M13.2	Must be able to integrate with an organization's authentication system	Adopters
M13.3	Research staff must be able to be assigned to more than one site	Adopters
M13.4	Must have the ability to define an organization hierarchy (this site is the main organization, these are affiliates)	CALGB
M13.5	Members of the main organization must have access to the affiliates' data	CALGB
M13.6	There must be a role that allows a user to access all studies at all sites that fall under a coop group	CALGB
M13.7	The system should provide the ability to control access to the field level, not just module	CALGB
M13.8	The system should provide a more fine-grained method for controling rights/privileges for users	Adopters
M13.9	The system must support access rights of new institutional roles (IRB, Safety Review Board, etc)	Adopters
M13.10	The system should have the ability to assign staff by institution, not study (someone at a different institution shouldn't have access to the study information at another institution)	CALGB
M13.11	The system should not allow inactive sites to submit AEs	CALGB
M13.12	The system should not allow AEs to be reported against closed studies	CALGB
M13.13	The system should support three levels of security/access: Global, Study, and Institution/site	CALGB
CAAERS-49	The system should support adding new ADMIN role with READ/WRITE privedges on each module	Adopters
CAAERS-1540	The system will support integration with a third party authorization system	Adopters
CAAERS-1895	The system should support deactivatition a user account	Adopters

CAAERS-2122	The system should support a Login ID for each user	Adopters
CAAERS-2367	The system should support create / change password token expiration	Adopters
CAAERS-2407	The system should support making Login ID uneditable after it has been saved	Adopters
CAAERS-2416	The system should include a flag in investigator screen that will enable/disable investigator user account creation	Adopters
CAAERS-2441	The system should support study sponsor user access with the same filtering as a coordinating center	Adopters
CAAERS-2658	Must provide mechanism for changing the SYSTEM_ADMIN password	Adopters
CAAERS-2773	The system will support an "unlock account" feature	Adopters
CAAERS-2820	The system should support preventing the same user from logging-in twice at the same time	Adopters
CAAERS-2928	The system should support a message to appear warning user that the will be logged out due to inactivity	Adopters
CAAERS-2934	The system should support informing user of password requirements	Adopters
CAAERS-3082	The system should support an inactivity grace period, after which expires, the system will log the user out and return to the login screen	Adopters
CAAERS-3810	The system should support need to support creating groups / departments for authorization	Adopters
CAAERS-3879	The system must be able to maintain acceptable search performance when searching a large number of records and filtering the results according to user permissions	CALGB
CAAERS-3880	The system will support common security framework for the Suite applications	CBIIT

General

Req ID	Requirement	Requested by
Gen.1	Should be able to apply edit checks on a group	Adopters
Gen.2	Should be able to apply edit checks on a study-type	Adopters
Gen.3	Should be able to apply edit checks on a study level	Adopters
Gen.4	The system should autoformat dates when they're entered in the same field (4-4-08 automatically becomes 04/04/2008)	Adopters
Gen.5	The system should only show tabs that are pertinent to the study protocol when entering AEs (don't show radiation when it can't be entered for example)	Adopters
Gen.6	enhancements to business rules management engine should be made.	Adopters
Gen.7	Users should be able to export rulesets	Adopters
Gen.8	Users should be able to import rulesets	Adopters
Gen.9	caAERs must provide updated schemas	Adopters
Gen.10	columns in the system must be visually separated	Adopters
Gen.11	Must provide specific, detailed instructions for each section in each module.	Adopters
Gen.12	The system should support NCI's standardization of routine AE documentation (as put together by City of Hope & being reviewed)	CBIIT
Gen.13	The system should provide a way to enable sharing of data between the system installations at different sites	Adopters

Non-Functional Requirements

Compatibility

Req ID	Requirement Description	Requested by
NFR32101	The system will be developed using a DAM that will be harmonized with BRIDG	CBIIT
NFR32102	All the system modules will be developed with at least Silver level Compatibility	CBIIT

Data Exchange

Req ID	Requirement Description	Requested by
NFR32201	The standard mechanism for exchanging data with a the system instance will be XML.	CBIIT
NFR32202	The system will expose APIs for data import.	CBIIT
NFR32203	Separate the system installations will be able to exchange data with each other via XML.	CBIIT
NFR32204	Adopters will be able to exchange Rulesets so that all users under a certain sponsor can use the same Rulesets. These will be sent in XML format.	CBIIT
CAAERS-140	The the system data service should be periodically updated with the domain model extract from cadsr	Adopters
CAAERS-1910	The system will support usage / implementation of an adverse event enterprise service	Adopters
CAAERS-2882	The system will support upgrading grid services to support grid v13	Adopters
CAAERS-2886	The system will support use of an enterprise service bus	Adopters
CAAERS-2887	The system will support using "getbyplayerid" calls in PO service	Adopters
CAAERS-3457	The system will support support the usage of caxchange and coppa in a stand-alone mode	Adopters
CAAERS-3536	The system should support pa services to support: disease	Adopters
CAAERS-3543	The system should support pa services to support: agents	Adopters
CAAERS-3553	The system will support person and org services v31	Adopters
CAAERS-2168	The system should support multiple formats of phone numbers	CBIIT
CAAERS-2766	The system will support change nci id label to CTEP id	CBIIT
CAAERS-3322	The system should support pa services to support: arm	CBIIT
CAAERS-3533	The system should support pa services to support: ind	CBIIT
CAAERS-3548	The system will support pa services to support: ind	CBIIT
CAAERS-3637	The system will support support consuming C3PR create study messages when the study organization(s) don't exist in the system	CBIIT
CAAERS-3638	The system will support support consuming C3PR create study messages when the study investigator(s) don't exist in the system	CBIIT
CAAERS-3715	The system should support importing a large number of records	CBIIT

GUI Specifications

Req ID	Requirement Description	Requested by
NFR323001	The system will be tested for Section 508 compliance	CBIIT
CAAERS-3	The system should support add show all for labs	Adopters
CAAERS-4	The system should support add show all disease sites in the patient details tab	Adopters
CAAERS-5	The system should support add show all agents in the prior therapy tab	Adopters
CAAERS-7	The system should support add "show all" for metastatic disease site also	Adopters
CAAERS-9	User should be able to Go to the system Home page from any page in the system	Adopters

CAAERS-13	The system should support change site drop down to show site name (nci code) in create/edit subjet page	Adopters
CAAERS-14	The system should support add the studysubjectidentifier for create/edit and assign subject to study	Adopters
CAAERS-18	User should be able to delete the study subject identifier	Adopters
CAAERS-141	The system should support show red asterisk for start date of the primary ae	Adopters
CAAERS-177	The system should support show roles and email address on submit page	Adopters
CAAERS-719	The system should support inform user when login session times out	Adopters
CAAERS-1537	The system should support alerting user if there are unsaved changes prior to leaving a page	Adopters
CAAERS-1609	The system should support displaying username / role of the user logged into the system	Adopters
CAAERS-1768	The system should support provide a visual indicator that highlights fields that are mandatory but do not have a valid value entered	Adopters
CAAERS-1905	The system will support showing the user when information is missing	Adopters
CAAERS-1962	The system should support improve method of sorting autocompleter results	Adopters
CAAERS-2045	Autocompleters of study, patient should prefix identifers	Adopters
CAAERS-2046	The system should support maintain the state of subject/study, so that if we go back from expedited flow, to manage report or capture ae flow this need not be re-entered	Adopters
CAAERS-2048	The system should support manage reports , report status highlighting	Adopters
CAAERS-2099	All UI fields should have field level help tag exposed in helpproperties	Adopters
CAAERS-2223	All autocompleters should have a "in process" spinning symbol	Adopters
CAAERS-2586	The system should support add a confirmation message after an ae is deleted from the capture ae page	Adopters
CAAERS-2648	The system should support replace subject with participant	Adopters
CAAERS-2731	When leaving all flows, the user should be prompted to save any unsaved data	Adopters
CAAERS-2788	In create study, there should be a summary header displayed on each page	Adopters
CAAERS-2789	In create study, there should be the ability to save on all pages	Adopters
CAAERS-2790	The system should support improve message when subject is assigned to the same study twice	Adopters
CAAERS-3003	Investigator Fax and Phone should allow more formats	Adopters
CAAERS-3006	The system will support need to improve the handling of concurrent access to reduce chance of exceptions	Adopters
CAAERS-3018	The system should support pa integration	Adopters
CAAERS-3104	The system should support tab preview upon mouse over	Adopters
CAAERS-3143	The system should support advanced search - add study subject id as a searchable and viewable attribute	Adopters
CAAERS-3159	The system should support need to tweak method of alerting user that the page is still loading	Adopters
CAAERS-3454	The system should support allow users to relabel fields	Adopters
CAAERS-3456	The system will support add some basic graphical analytics to the advanced search results	Adopters
CAAERS-3588	The system should support for lab values - need to accept decimals without a leading zero	Adopters
CAAERS-3628	The system will support allow addition of custom fields into the user interface	Adopters
CAAERS-3843	The system should support support the configuration of date fields formats	Adopters
CAAERS-3876	The system should support user / role centric dashboards	Adopters

Security (Module 13)

Req ID	Requirement Description	Requested by

NFR324001	The system Administrator will create user accounts.	CBIIT
NFR324002	The system Administrator will assign one or more roles to each user account.	CBIIT
NFR324003	The application must ensure that users are only able to access data and functionality that has been granted to their roles and/or account.	CBIIT
NFR324004	If a user forgets his or her password, the system will be able to create a new password for that user.	CBIIT
NFR324005	The system must implement authentication using caGrid 1.0 security infrastructure. This will facilitate the use of existing institutional identity providers.	CBIIT
NFR324005	The system must implement authorization/access control using caGrid 1.0 security infrastructure.	CBIIT

Audit

Req ID	Requirement Description	Requested by
CAAERS-1896	Records will be marked as deleted, but data will never be deleted once it has been entered into the system.	CBIIT
CAAERS-225	Audit logs will record create, update, and delete actions to data items as well as when the modification occurred and who performed it.	CBIIT

Database Schema

Req ID	Requirement Description	Requested By
NFR326001	The system will leverage Bering to automatically create the proper database schema during the installation process.	CBIIT

Performance Criteria

Req ID	Requirement Description	Requested By
NFR327001	The system should respond to user requests at a pace deemed acceptable by the adopters.	CBIIT

Availability

Req ID	Requirement Description	Requested By
NFR328001	The system will be able to be made available at all times other than during software updates. Regularly scheduled downtime will not be needed.	CBIIT

caBIG Compatibility

Req ID	Requirement	Requested by
caBIG.1	Ability to query PSC regarding Patient's treatment to make reporting AE more streamlined.	CCTS
caBIG.2	The system must only show CTMS features when the system is part of the CTMS (notify PSC, view details in Lab Viewer)	CCTS
caBIG.3	The system must have interoperability with C3PR	CCTS

Completeness

Req ID	Requirement	Requested by
NFR329001	The system will be verify that all expedited reports are complete before they are sent to report recipients. Incomplete fields will be brought to the user's attention.	Adopters, CTEP

Correctness

Req ID	Requirement	Requested by
NFR3210001	The system is being evaluated by domain experts to verify correctness of design.	CBIIT
NFR3210001	The system will be able to accurately display all data entered into the system.	CBIIT

Cost of Ownership

Req ID	Requirement Description	Requested By
NFR3211001	The system is Open Source Software and may be freely downloaded and installed by any user	CBIIT

Extensibility

Req ID	Requirement Description	Requested By
NFR3212001	As an open source project, the system will be extendable by another software development team.	CBIIT

Installation Complexity

Req ID	Requirement Description	Requested By
NFR3213001	The the system Team is working to simplify the installation and configuration of the system. The final product will be easily installable by a system administrator who is familiar with Tomcat and serving web-based Java applications. the system will be able to be served from a server that also hosts other applications with non-conflicting dependencies.	CBIIT
CAAERS-53	The system should support collecting SYSTEM_ADMIN password upon installation	Adopters
CAAERS-180	Installer should support upgrades	Adopters
CAAERS-2279	The system should provide a method of alerting administrators when there is a system component outage	Adopters
CAAERS-3918	The system should support upgrades without having to export, delete, and re-import rules	RPCI

Portability

Req ID	Requirement Description	Requested By
NFR3214001	The system will be installable in any environment that supports the proper JVM.	CBIIT

Regulatory

Req ID	Requirement Description	Requested By
NFR3215001	The system will enable HIPAA and 21 CFR Part 11 compliance.	CBIIT

Reusability

Req ID	Requirement Description	Requested By
NFR3216001	The system should be able to function as an Adverse Event Reporting system at any cancer clinical research institution.	CBIIT
NFR3216002	Portions of the the system source code will be abstracted into the CTMS Commons project for use by other applications.	CBIIT

Scalability

Req ID	Requirement Description	Requested By
NFR3217001	The system will be able to accommodate as many studies and patients as required by modern cancer centers.	CBIIT

Time to Market

Req ID	Requirement Description	Requested By
NFR3218001	The system is currently available for testing and will have its production release during the fourth quarter of 2007.	CBIIT

Training Complexity

Req ID	Requirement Description	Requested By
NFR3219001	Clinical trial professionals should find the system intuitive and easy to learn with the assistance of the the system documentation.	CBIIT

Usability

Req ID	Requirement Description	Requested By
NFR3220001	Must be user-friendly and intuitive for clinical trial professionals to use as determined by adopters of the system.	CBIIT

Reference Documents

For additional the system information, refer to the following documents:

Document Name	Version	Location
Vision & Scope Document	1	caAERS Vision and scope
Use Case Document	2.7	Use Case Document
Acronym List		caAERS Acronyms
caAERS-to-CTEP Requirements	1.0	caAERS-CTEP_Software_Requirement_Specifications_v1.0.doc
AdEERS Web Service Requirements	2.2	caAERS-AdEERS - SRS_v2.2.DOC