Module 1 UC - Adverse Event Data Capture

Module 1 Use Cases - Adverse Event Data Capture

Use Case	Date Created	Date Last Modified
AE Data Collection	03/26/2008	10/14/2010
Assign Subject to a Study	03/26/2008	10/14/2010
Create Expedited AE Report	03/26/2008	10/14/2010
Create Study for AE Data Entry	03/26/2008	10/15/2010
Create Subject	03/26/2008	10/15/2010
Enter Routine AEs	03/26/2008	10/15/2010
Search AE Entry	03/27/2008	10/15/2010
Study Abstraction	03/26/2008	10/15/2010
Capture AEs	05/09/2008	10/15/2010
caAERS Auditing - tracking History	page-info: unable to locate page	page-info: unable to locate page
caAERS Auditing - history of single routine AE	05/14/2008	10/18/2010
caAERS Auditing - history of an observation period	05/15/2008	10/18/2010

1. Capture AEs - caAERS UC

Scope: Subsystem - AE module
Level: Summary

Brief Description	Users enter and modify AEs in caAERS, where they are stored in the database, available for reports, sent to different organizations for official reporting, and copied to the local CTMS.
Primary Actor	caAERS user with access to AE module
Secondary Actor	caAERS System
Steps	1. caAERS user adds Reporting Periods types to a study 2. Patient is added to a study 3. caAERS user enters baseline AEs 4. CRA observes AEs (out of scope) 5. caAERS user enters solicted AEs each observation period 6. caAERS user enters observed AEs 7. caAERS user modifies observed AEs (reporting period) 8. caAERS user creates expedited reports 9. caAERS user manages AEs
Open Issues	• Once AEs have been saved (and reviewed) should they be able to be deleted?** currently in expedited reports, they can be withdrawn, but they are still listed** There is no tracking mechanism for deleting routine AEs, any can be deleted except ones promoted to SAE

Sub-tasks	Enter Observed Adverse Events Capture Solicited AE Enter Baseline AEs Modify Observed AEs (Reporting Period) Streamline Expedited Report Add Reporting Period Types to a Study Create a caAERS API for AE Queries

1.1.2 Enter Adverse Events (Verbatim first) - caAERS UC

Primary Actor: caAERS User
Supporting/Secondary Actor: caAERS
Scope: subsystem - AE module caAERS
Level: User Goal
Trigger: Adverse Events (AEs) have been observed

Brief Description

A clinical research associate (CRA) observes adverse events (AEs) for a subject on a study over a reporting period. The caAERS user goes into caAERS into the AE flow, selects the Study/Subject combination, selects or enters the course/cycle. The caAERS user then enters the adverse events into caAERS by entering the verbatim of the AE. The caAERS user is then provided the ability to find the term for the AE.

Entering the verbatim first (i.e. prior to selecting an AE term) is the preferred method of AE entry for the FDA and is used by Industry/Pharma and CTEP.

Preconditions

1. The caAERS user has accessed the Enter Adverse Events page by entering the study, subject, and course.
2. There are adverse events on the Study/Subject to record.

Steps

Main Success Scenario

1. The caAERS user enters the verbatim of the AE into a text field (ie. no autocompleter) and clicks "Add."
    a. Upon clicking **"Add,"** an AE with the verbatim text is saved.
    b. The verbatim is now read-only.
2. The caAERS system displays a list of AE terms that match the verbatim.
    a. The matching AE terms displayed are from the MedDRA terminology version associated with the study (see Open Issue #3).
3. The user will select one of the suggested AE terms, or choose to search for additional terms which will invoke an autocompleter.
    a. If the selected AE term is a CTCAE term or a related term/synonym to a CTCAE term (see Open Issue #4), then the CTCAE term specific grading scale should be displayed.
    b. The display of related terms will only be displayed for CTCAE v4.0 (see Open Issue #6).
4. The user will finish entering any other mandatory or applicable optional data.
5. The user will save the page.

Extensions

- Editing the verbatim after "Add" *

1. After the verbatim term has been added, the user may edit the verbatim text by clicking on an edit icon adjacent to the verbatim.

- Editing the term*

1. After an AE term has been selected, the user may re-run a search to find matching terms.
2. Selecting a new AE term will replace the previous term.
    a. A confirmation will appear to the user to ensure they want to update the term.

- Deleting AEs*

1. All AEs will be able to be deleted
2. Deleted AEs that are included in a submitted report will trigger an amendment to the report, where applicable.

Sub-Flows

- Entering solicited AEs
- Entering lab-based AEs

Post Conditions

- AEs are saved in the caAERS database
- Expedited reporting is recommended as appropriate.

Data Items

Verbatim - the adverse event name or brief description as reported by the clinician, typically in the subject's medical chart.

Special\Non-Functional Requirements

- All save, edit, delete activity described in this use case will be recorded in the caAERS audit tables.
- The AdEERS Web Service currently does not support receiving verbatim. caAERS currently sends verbatim to AdEERS in the AE comments field.
- AEs must be unique per study/subject/course combination (see Open Issue #7).
- Entry of "Verbatim first" will be a configuration option for each study.

Business Rules

Open Issues

1. The "verbatim first" method of AE entry will not be applicable to solicited adverse event terms as these are predefined in the protocol as coded AE terms. Is the standard entry flow (i.e. verbatim second) acceptable for solicited AEs?
2. What should be done about lab-based AE's? Is there a verbatim?
3. When the AE terms are displayed that match the verbatim entered, should it be all of MedDRA or just from CTCAE? If just CTCAE, then when should the display of the related LLTs be triggered?
4. Need to obtain a list of synonymous MedDRA Low Level Terms (LLTs) for each CTCAE v4.0 term (and v3.0 term?) in order to display related terms.
5. For expected AEs on the ASAEL, should all synonymous LLTs also be considered expected
6. Should this method of AE entry be applied just to studies using CTCAE v4.0, or to v3.0 studies as well.
7. Assuming the scenario where each AE for a subject must be unique per course, what should determine AE uniqueness? Verbatim? CTCAE term? Verbatim + CTCAE term? For example, if a second AE is entered with a unique verbatim, but a CTCAE term common to a previously entered AE, what should happen?
8. Should the suggested AE terms that match the verbatim include only string matches to the verbatim or also include all of the synonyms to the matching terms?
9. With a verbatim first implementation, there will be the possiblity of users to enter a verbatim that represents more than one AE (i.e. patient had nausea and vomiting) - should something been done about this?

Models & User Interface Prototype

1.1 Enter Observed Adverse Events - caAERS UC

Scope: subsystem - AE module caAERS
Level: User Goal
Trigger: Adverse Events (AEs) have been observed

Brief Description	A clinical research associate (CRA) observes adverse events (AEs) for a subject on a study over a reporting period. T caAERS user goes into caAERS into the AE flow, selects the Study/Subject combination, selects or enters the reporti period. The caAERS user then enters the adverse events into caAERS. The caAERS rules engine is then run which checks t see if expedited reporting is recommended and displays any recommended reports to the user. If expedited reporting is recommended, caAERS: • Alerts the user that expedited reporting is recommended. • Identifies which expedited reports are recommended. • Identifies when the expedited reports are due. • Identifies the AEs for which expedited reporting is recommended. • Identifies the recommended method of reporting (i.e. creating a new report or amending a previous report) The caAERS user has the option to override the recommendations of the caAERS system by selecting differe reports, selecting no reports, selecting a different method of reporting (i.e. creating a new report rather than amending a report per the recommendation), and selecting the AEs which should be included in the reports. **NOTE** The caAERS rules engine is a tool for automated decision support and the results are system recommendations. It is the responsibility of the personnel who are conducting the study to ensure that the appropriate adverse event reports are completed per the instructions in the protocol. **NOTE-2** In this use case, a reporting period is a generic period defined as the period during which adverse events are being collected, reviewed, and analyzed as a set. For some studies, a reporting period by be a cou or a cycle. For other studies, a reporting period may be the period between visits to the clinic.
Primary Actor	caAERS user
Secondary Actor	caAERS system
Preconditions	1. The Study has been created. 2. The Subject has been created and assigned to the Study. 3. The caAERS user has access to the AE module 4. The caAERS user is logged in to the system 5. There are adverse events on the Study/Subject to record.

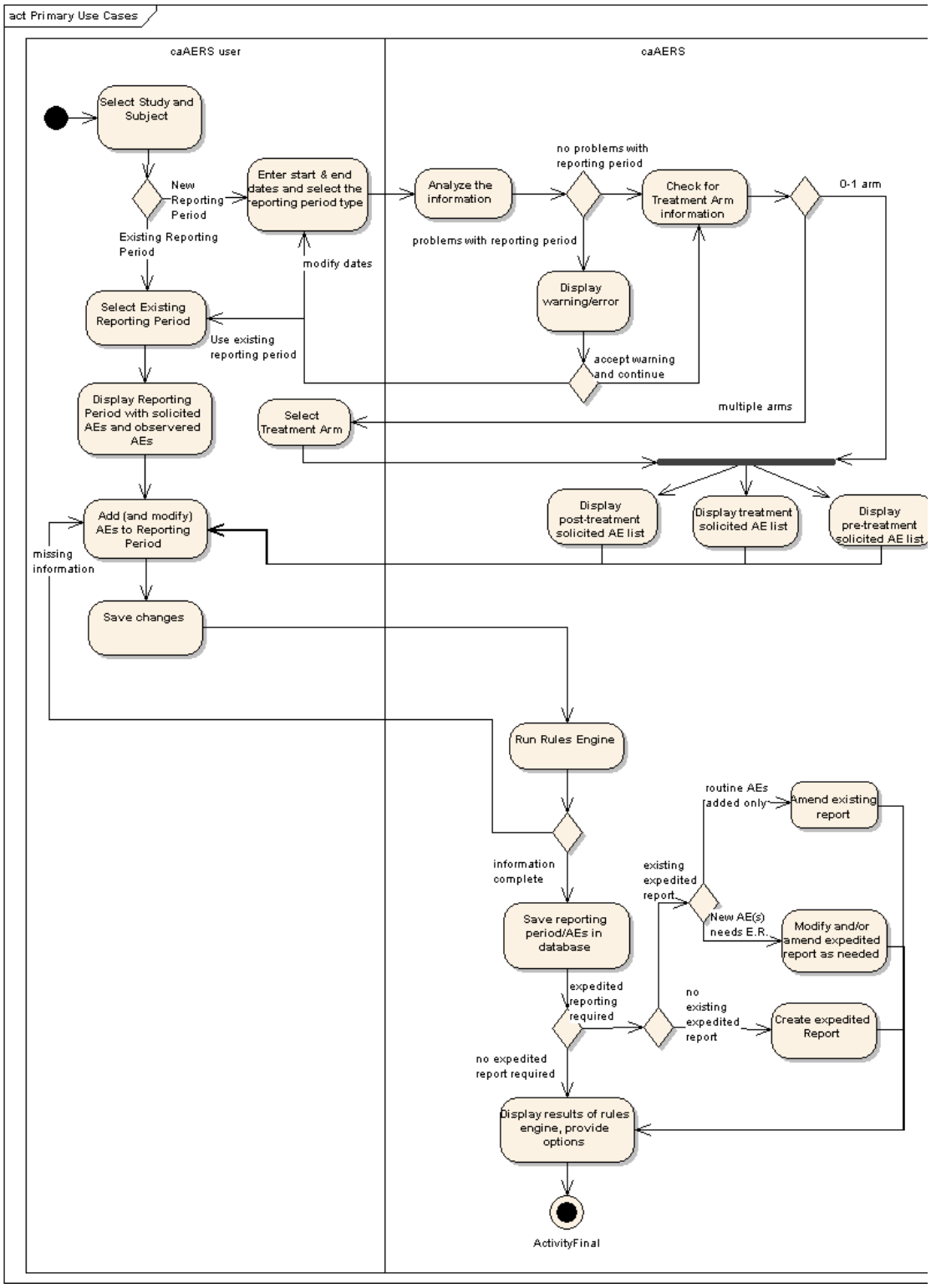
Main Success Scenario	1. caAERS user opens the Enter Adverse Event flow in caAERS
	2. caAERS user selects Subject and Study.
	  a. caAERS shows a drop-down list of reporting periods, for the study/subject that have already been ad (show all with most recent at the top), along with an option to "Create" a new reporting period.
	3. The caAERS users selects or creates the reporting period on which they wish to enter AEs.
	  a. If an existing reporting period is selected, the "Continue" button is enabled.
	  i. If the user clicks "Continue," go to step
	  b. If an existing reporting period is selected, caAERS displays an option to "Edit" the reporting period information.
	  i. If the user clicks "Edit", the reporting period create/edit window appears.
	  c. If the "Create" reporting period option is selected, the reporting period create/edit window appears.
	4. The caAERS user enters the adverse events that need to be recorded for the study/subject
	  a. The caAERS user finds and selects the adverse event term by searching the AE terminology for the study (i.e. CTCAE 3.0, MedDRA 10.0, etc) by using the auto-completer search field.
	  i. The auto-completer search field returns possible matches based upon the text entered into t field.
	  b. The caAERS user finds and selects the adverse event term(s) by browsing the nomenclature for the study (CTC and CTCAE only) by category and then selecting the terms for each category.
	  c. The caAERS user enters in the verbatim of the adverse event.
	  d. The caAERS user selects the adverse event from the displayed list of solicited AEs
	  e. The caAERS user select from the list of AEs from the previous reporting period (previous AE quick-p
	5. The caAERS user enters any applicable mandatory and/or optional data
	  a. caAERS user selects grade
	  b. selects Grade 1-5
	  c. Grade 0 (normal) and Grade -1 (not evaluated) should only appear for solicited AEs
	  d. caAERS user enters the Attribution to the study
	  e. If the user selects Possible, Probable, or Definite, caAERS prompts user to enter Attribution to the IN
	  f. caAERS user enters the additional information (optional/required fields based on study, sponsor, rule as appropriate for the solicited AEs
	  g. hospitalization
	  h. verbatim
	  i. seriousness\outcome indicators
	  j. caAERS displays the expectedness of the AE using the rules-of-expectedness for the protocol (ASAE reference and/or protocol specific configuration)
	  k. If expectedness has been abstracted into the study, the pre-populated expected value should not be editable.
	6. caAERS user clicks the "Saves and Report" button
	7. caAERS fires rules engine
	8. caAERS saves the AEs to the database
	9. caAERS provides summary of rules results and recommended actions with the following actions available
	  a. Back
	  b. Report

Extensions	3b., 3c. caAERS user selects "Edit" or "Create" Reporting Period 1. caAERS user selects to add a new report period for which to enter AEs 2. caAERS user enters the start and end dates for the reporting period, selects the reporting period type from a down list, and enters an optional descriptor regarding the reporting period (i.e. the cycle number) a. caAERS verifies the reporting period is valid (gap isn't too big, overlap isn't too big, observation perio doesn't already exist) 3. caAERS determines if the study has a treatment assignment (TAC) a. If no treatment assignment, caAERS goes to step 7 b. caAERS displays the available treatment assignment codes and descriptions for CTEP IND trials c. caAERS user selects the appropriate treatment assignment code 4. caAERS user enters the starting date of the first course a. Information would come forward for all reporting periods b. Field not required for baseline 4c. The caAERS user enters in a verbatim of the adverse event. 5. The verbatim text field shall be displayed before CTCAE data field. 6. verbatim text field shall be text-entry only - no 'Google-like' search 7. text entered into verbatim field shall be 'saved' before any additional data is entered 8. data field to follow verbatim is CTCAE Term field 9. if verbatim text entered and 'saved' is equal to CTCAE term or related term, CTCAE term shall display with CTCAE Grading Scale • CTEP, discuss: This feature will work only for CTCAE v4.0 AE terms which have associated validate related terms (one or more LLTs). • This feature will be imprecise for CTCAE v3.0 because the 'dictionary/index/Safety Profiler' is not accurate for MedDRA related terms. 10. if verbatim text entered and 'saved' is not equal to CTCAE term or related term, CTCAE data field will display 'Google-like' search for CTCAE Term list. 4d. The caAERS user selects the adverse event from the displayed list of solicited AEs. a. caAERS indicates the required fields based on the Configure AE Mandatory fields configuration b. The solicited AE terms are established in the Study set-up process 5a. Reporting period already exists 11. caAERs throws an error that the reporting period already exists with the option to open the existing reporting period 12. caAERS user goes to the existing reporting period 5b. Reporting period has a gap or overlaps too much 13. caAERS throws an error/warning that there's a gap or overlap with the reporting period and asks if the user is sure they want to continue or if they want to make changes 14. caAERS user clicks continue or modify to go back and modifies the reporting period 10a. caAERS user selects "Other - specify" 15. caAERS pops up the field to enter additional details 16. caAERS user either enters the MedDRA term or types the verbatim explanation 10.3.a. caAERS user enters CTC term that has the ASAEL in the system or protocol definition of expectedne 17. caAERS will autopopulate the expectedness field (discussed in Determining expectedness UC) 13a. caAERS user doesn't have submit permissions (discussed in Routing and Review UC) 18. caAERS throws an error and asks if the user wants to save as a draft 19. caAERS user saves as draft 20. caAERS sends notification to <role, user> that draft AEs have been reported 14a. caAERS determines information is missing 21. caAERS will throw an error detailing what information is missing (hospitalization for example) 22. caAERS user will enter required information 23. caAERS user will save the AE(s) 24. caAERS saves the AE(s) and updates the database 14b. caAERS identifies duplicate AEs 25. caAERS will throw an error 26. caAERS user will delete/modify the duplicate AE 27. caAERS user will save the AE(s) 28. caAERS saves the AE(s) and updates the database 14c. Session has expired before changes are saved 29. caAERS will return the user to the log on screen when they try to save 30. caAERS user will enter their log on information 31. caAERS will return the user to the page they were on (the solicited AE page) 32. caAERS user will repeat the entire process, reentering the information and then saves the AEs 33. caAERS saves the AE and updates the database 14d. caAERS determines expedited reporting is required for one or more AE 34. caAERS will save the AEs and update the database 35. caAERS will provide notice that expedited reporting was required for the AEs that required them 36. caAERS will prompt user to select the routine AEs that need to be included in the expedited report 37. caAERS will create the expedited report 38. caAERS will prompt the user to open the expedited report a. if yes, caAERS will open the expedited report b. if no, caAERS will show the Manage Report Page ||

Sub-Flows	Entering Solicited AEs caAERS determines user access Enter expedited report
Post-Conditions	• routine AEs are saved in the caAERS database • routine AEs are displayed in manage reports • expedited reports are started

Data Items	• New Class - Epoch, behind the scenes
	  • Each Epoch will have at least one arm
	  • Each epoch will be tied to a reporting period in the backend
	• New Class - Reporting Period Type (Epoch behind the scenes)
	  • Reporting Period Type will exist in the caAERS system statically
	  • When a study is added, a copy of the reporting period type will be added to the study, allowing the us to add additional types or remove existing types
	  • The list of values will include: Baseline, Treatment, Post-Treatment, ?
	  • Baseline can not be removed
	  • Baseline will be used to ensure rules aren't fired concerning AE entry
	  • Baseline can only be used once
	• Not Evaluated
	  • is included with the grades (0-5) for solicited AEs
	  • If selected, can not require any other fields (grade, attribution, hospitalization)
	• Observation Period gets relabeled to Reporting Period
	  • If Reporting Period Type = Baseline, must allow the start and end date to be the same
	  • If Reporting Period Type = Baseline, treatment start date must not appear
	  • There can only be unique reporting periods, not duplicates
	  • There is only one expedited report associated to each reporting period
	• Cycle
	  • A cycle can be associated to more than one reporting period
	• Notes/Verbatim for all entered AEs (not solicited)
	• If grade = 0, no other fields can be required
	• Start date of the first course
	  • Appears for all reporting period types besides baseline
	  • First time it is a date field that is required
	  • Subsequent reporting periods it will just display the date, not be modifiable

Special\Non-Functional Requirements	Baseline AEs can not require attribution
Business Rules	• Reporting Period equal to 0 or Baseline can not fire any rules for expedited reports. AEs reported only require term and grade • Each reporting period can only have one expedited report associated to it • Reporting Periods must always allow addition/modification/deletion of AEs, regardless of how much time has passed since the reporting period was started • Reporting Periods can overlap, or have a gap in between them. However, there can not be duplicates (with th same start and stop dates) and there can not be a reporting period that falls within another reporting period (1 07/01/08-08/01/08 and 2nd 07/10/08-007/25/08). All overlaps and gaps should give an error with the option to continue, modify the reporting period dates. If it's duplicate, or falls within, it should also give option to open existing reporting period. Would be good if it showed the data for the conflicting reporting periods. • If an expedited report has been created for a reporting period and more AEs are added to the reporting perioc caAERS needs to prompt the user about amending the Expedited report, allowing him/her to add AEs as necessary • There can only be one Baseline reporting period
Adverse Events	• checks for duplicate (term) AEs for the period • verifies all required information is provided
Open Issues	• What are differences between CTEP, non-CCOP requirements? • Need to review AdEERS rules to determine all rules that need to fire on this first page.

Models & User Interface Prototype	

1.2 Capture Solicited AE - caAERS UC

Scope: The system (caAERS)
Level: Summary

Brief Description	Solicited AEs are part of all protocols, and vary protocol from protocol. These are captured during each observation period and only the highest grade solicited adverse event is reported for a period.

Steps	1. Solicited AEs are identified from the protocol (out of scope) 2. caAERS user associates solicited AEs to the study in caAERS 3. CRA observes solicited AEs (out of scope) 4. caAERS user enters observed solicited AES in to caAERS 5. CRA continues to observe solicited AES during observation period (out of scope) 6. caAERS user updates observed solicited AEs in caAERS 7. caAERS pushes collected AEs to local CTMS
Open Issues	
Out of Scope Phase II - nice to haves for later	• comparing baseline AEs to the solicited AEs each reporting period • displaying baseline AE grades for the solicted AEs each reporting period
Models & User Interface Prototype	TBD
Sub-tasks	Associate Solicited AEs to a Study Enter Observed Solicited AEs Update observed Solicited AEs

1.2.1 Associate Solicited AEs to a study - caAERS UC

Primary Actor: caAERS User
Supporting/Secondary Actor: Study
Scope: subsystem, study module of caAERS
Level: User Goal
Trigger: Sites are going to use caAERS to document AEs

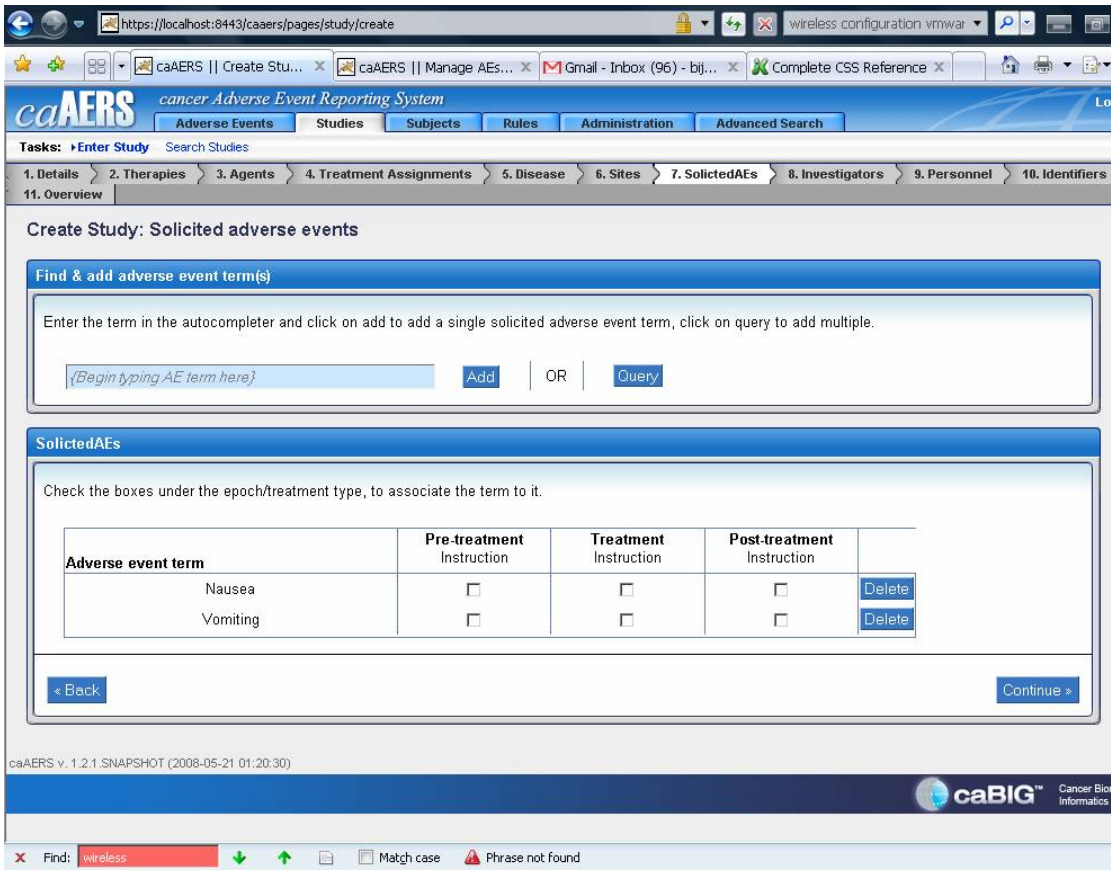
Brief Description	The primary investigator/sponsor will have noted one or more sets of Solicited AEs in the protocol for different timeframes/arms of the study. These AEs need to be associated to the study in caAERS so that caAERS users can quickly document their observations on these solicited AES during each each observation period. The term (and MedI code) should be entered, as well as any study specific instructions.
Preconditions	1. Solicited AEs must be identified from the protocol. 2. Study-specific instructions must be identified 3. Study must be in caAERS 4. caAERS user must be logged into caAERS 5. caAERS user must have right to edit studies

Main Success Scenario	1. caAERS user searches for a study in caAERS a. caAERS displays a list of studies b. The caAERS user selects the study they are interested in adding solicited AEs to 2. caAERS user goes to the solicited AE section of the study a. caAERS displays any solicited AEs that have been added to the study as well as identifiers that indic which reporting period type(s) it is associated with b. To add solicited AEs for a new reporting period type, the caAERS user continues to #3 3. caAERS user enters AE terms a. caAERS user either types in the CTC term in the autofill box and clicks Add or b. caAERS user selects Query which brings up a form that will allow the user to search for AEs and adc one or more at a time c. User can continue step 3 until all AEs are added, or continue through the flow and make changes on one to the reporting periods 4. caAERS user associates the solicited AE to (a) reporting period type: a. caAERS User can select the box above the reporting period type to select all AEs for that reporting period type b. caAERS User can individually select the boxes next to the AEs to assign the AE to the specific repor period type 5. caAERS user enters instructions (additional information) specific to solicited AEs for each Reporting Type a. Under each reporting type in the Reporting Type Area, the caAERS user clicks Instructions b. caAERS brings up a field to allow the user to enter the instructions and clicks Save c. caAERS saves the instructions 6. caAERs User has the option to save or add additional solicited AEs a. To add another solicited AE, user goes back to step #3 b. To save and exit, the caAERS user clicks save 7. caAERS fires the rules engine 8. caAERS saves the study and updates the database
Extensions	2.2.a. caAERS user changes information associated to solicited AEs for the Reporting Period Type 1. caAERS displays all solicited AEs for the study 2. caAERS User modifies the information a. modifies instructions 3. caAERS User Saves the Study 4. caAERS fires the rules engine 5. caAERS saves the study and updates the database 2.2.b. caAERS user deletes an existing solicited AE associated to the study 6. caAERS displays all solicited AEs for the study 7. caAERS User deletes a solicited AE from the list a. removes the AE completely b. removes its association to a reporting period type 8. caAERS User Saves the Study 9. caAERS fires the rules engine 10. caAERS saves the study and updates the database 2.2.c. caAERS user adds an AE to the list of solicited AEs 11. caAERS displays all solicited AEs for the study 12. caAERS User adds a solicited AE a. adds a new AE completely b. adds an association to a reporting period type 13. caAERS User Saves the Study 14. caAERS fires the rules engine 15. caAERS saves the study and updates the database 7a. caAERS determines required information is missing 16. caAERS will throw an error 17. caAERS user will enter required information 18. caAERS user will save the study 19. caAERS saves the study and updates the database 7b. Session has expired before changes are saved 20. caAERS will return the user to the log on screen when they try to save 21. caAERS user will enter their log on information 22. caAERS will return the user to the page they were on (the solicited AE page), with no information saved 23. caAERS user will re-enter the information and save the study 24. caAERS saves the study and updates the database 7c. caAERS determines there are duplicate solicited AEs entered 25. caAERS will throw an error 26. caAERS user will make changes to resolve the duplication 27. caAERS user will save the study 28. caAERS saves the study and updates the database
Sub-Flows	caAERS determines user access

Post Conditions	• A study in caAERS has solicited AEs associated to it • solicited AEs will appear when a caAERS user goes to enter AEs
Data Items	• a solicited AE should be assigned to one or more reporting period types • a reporting period type instruction field is not required
Special\Non-Functional Requirements	Solicited AEs must have a Grade '0' and not evaluated option that the user can use

Business Rules	• If solicited AEs are removed from a study
	  • The solicited AEs should remain in any user entered reporting periods
	  • Existing (old) User entered reporting period should not be corrupted/modified when the user opens th again
	• If solicited AEs are added to a study
	  • The solicited AEs should appear only on reporting periods moving forward
	  • Existing (old) User entered reporting periods should not be corrupted/modified when the user opens t again
	• If Instructions are modified for a reporting period type
	  • The new instructions should only appear on reporting periods moving forward, not those previously created
	• When checking for AE duplication, the system should check for the CTC term (so if the CTC term is listed twi one assigned to baseline the other assigned to treatment, it will still recognize it as a duplicate.
	• If caAERS user tries to select Other-Specify, caAERS needs to throw an error (other-specify is not allowed [CTMS:this iteration])

Open Issues	• Are the solicited AEs associated to the study in the local CTMS? SS: Currently they are not for CALGB. Wou be nice to have though. hint, hint ** Does this information need to be able to be synced between caAERS an the local CTMS? • Currently, if AEs are modified, added, or deleted and there are existing reporting periods, the existing reportin periods are not modified. If the change is made in the middle of a reporting period (ex: add solicited ae on 6/1 reporting period is 6/01 - 6/30) should the reporting period be modified? • how many characters is the additional info field? • use case talks about using CTC. Do we have it setup to work with meddra too?

Models & User Interface Prototype	

1.2.2 Enter observed Solicited AEs into caAERS UC - draft

Scope: sub-system, caAERS AE module
Level: User Goal
Trigger: solicited AEs have been observed and need to be reported on

Brief Description	During a trial, adverse events are observed. The PI\Sponsor often has a specific list of AEs they always want reported on, the Solicited AEs, which are documented in the protocol. There may be more than one set of solicited AEs, depending on the reporting period type.
Primary Actor	caAERS user
Secondary Actor	caAERS system
Preconditions	1. Solicited AEs have been associated to the study in caAERS 2. Observations of solicited AEs must have been collected 3. User must be logged in 4. User must have right to add observed AEs

Main Success Scenario	**Note** This is a sub use case of the main use case, Enter observed AEs, so only the basic flow is provided here. 1. caAERS user opens the AE flow in caAERS 2. caAERS user selects the study and subject 3. caAERS shows a list of reporting periods/cycles with options to modify an existing reporting period or to enter a new one a. User selects create a new reporting period 4. caAERS user enters the start and end dates for the reporting period, the cycle number, and the reporting period type (baseline, treatment, post-treatment) a. caAERS verifies the reporting period is valid (gap isn't too big, overlap isn't too big, observation period doesn't already exist) b. caAERS evaluates the reporting period type answer and brings up the appropriate solicited AEs 5. caAERS User enters additional initial information a. was hospitalization required? b. start date of first course (only on the first reporting period) c. has an investigational treatment been administered? 6. User entering required information for the solicited AEs a. selects grade (0-5) or "Not Evaluated" (see 1.1 for non-CTEP trial info) b. selects attribution (1-5), only if grade is not = 0 or "Not Evaluated" and reporting period type is not baseline. 7. caAERS user enters the optional info (Hospitalization, verbatim/notes field), as appropriate for the AEs 8. caAERS user saves the entered AEs 9. caAERS fires rules engine 10. caAERS saves the AEs to the database 11. caAERS provides summary of rules results and needed actions with actions available a. Change AEs for observation period b. Go to Manage Report c. Go to Expedited Report
Extensions	Solicited AE needs to be updated 4.1.a. Reporting period already exists 1. caAERs throws an error that the observation period already exists with the option to open the existing observation period 2. caAERS user goes to the existing observation period 4.1.b. Reporting period has a gap or overlaps too much 3. caAERS throws an error/warning that there's a gap or overlap with the reporting period and asks if the user is sure they want to continue or if they want to make changes 4. caAERS user clicks continue or modify to go back and modifies the reporting period 8a. caAERS determines required information is missing 5. caAERS will throw an error 6. caAERS user will enter required information 7. caAERS user will save the AEs 8. caAERS saves the AEs and updates the database 8b. Session has expired before changes are saved 9. caAERS will return the user to the log on screen when they try to save 10. caAERS user will enter their log on information 11. caAERS will return the user to the page they were on and have to re enter the information 12. caAERS user will save the AEs 13. caAERS saves the AEs and updates the database
Sub-Flows	caAERS determines user access Enter observed AEs
Post-Conditions	• caAERS is updated with new AE 'report' • caAERS is ready to push the collected AEs to the local CTMS
Special\Non-Functional Requirements	• Solicited AEs must a Grade '0' that the user can use • list of solicited AEs depends on answer to Reporting Period Type field
Open Issues	none
Business Rules	A solicited AE can not also be included in the Observed AE list. There needs to be a duplicate check between the two areas.
Out of Scope	Comparing grades for solicited AEs to baseline values
Models & User Interface Prototype	none

1.2.3 Update observed Solicited AEs into caAERS UC - draft

Scope: sub-system, caAERS AE module
Level: User Goal
Trigger: solicited AEs have been observed and need to be reported on

Brief Description	Solicited AE values are only reported on once during a reporting period, although they may be observed multiple times. A caAERS user enters the solicited AE values into caAERS for a reporting period. Later during that period, the solicited AE is observed with an increased grade. The caAERS user goes to caAERS, selects the study and subject, chooses the reporting period, and modifies the grade for the solicited AE.
Primary Actor	caAERS user
Secondary Actor	caAERS system
Preconditions	1. Solicited AEs have been associated to the study in caAERS 2. Observations of solicited AEs must have been collected and recorded in caAERS alread 3. caAERS User must be logged in 4. caAERS User must have right to add/modify AEs 5. Grade of observed solicited AE must have increased during the reporting period
Main Success Scenario	**Note** This is a sub use case of the main use case, 1.1 Enter observed AEs, so only the basic flow is provided here. 1. caAERS user opens the AE flow in caAERS 2. caAERS user selects the study and subject 3. caAERS shows a list of reporting periods/cycles with options to modify an existing reporting period or to enter a new one a. User selects the reporting period/cycle that needs to be modified b. caAERS displays the Solicited AEs and other AEs recorded for that period 4. caAERS User modifies a solicited AEs a. selects grade (1-5) b. selects attribution (1-5) 5. caAERS user modifies any additional fields a. was hospitalization required b. was an investigational treatment administered? c. verbatim/notes 6. caAERS user saves the changes 7. caAERS fires rules engine a. Does caAERS need to verify that the grade changed is greater than the previously saved grade? 8. caAERS saves the AEs to the database 9. caAERS provides summary of rules results and needed actions with actions available a. Change AEs for observation period b. Go to Manage Report c. Go to Expedited Report
Extensions	7a. caAERS determines required information is missing 1. caAERS will throw an error 2. caAERS user will enter required information 3. caAERS user will save the AEs 4. caAERS saves the AEs and updates the database 6b. Session has expired before changes are saved 5. caAERS will return the user to the log on screen when they try to save 6. caAERS user will enter their log on information 7. caAERS will return the user to the page they were on and reenter the changes 8. caAERS user will save the AEs 9. caAERS saves the AEs and updates the database
Sub-Flows	caAERS determines user access 1.1 Enter observed AEs Enter observed Solicited AEs
Post Conditions	• caAERS is updated with new values for the reporting period • caAERS is ready to push the collected AEs to the local CTMS

Special\Non-Functional Requirements	• Solicited AEs must a Grade '0' that the user can use • list of solicited AEs depends on answer to Reporting Period Type field
Open Issues	• Does caAERS need to verify that the grade changed is greater than the previously saved grade?
Business Rules	Attribution is only a required field if grade is equal to or greater than 1
Models & User Interface Prototype	none

1.3 Enter Baseline AEs - caAERS UC draft

Primary Actor: caAERS User
Supporting/Secondary Actor: caAERS
Scope: subsystem - caAERS AE module? caAERS subject module?
Level: User Goal
Trigger: subject is added to a study

Brief Description	Subject is added to a study. At the start of the study, grades for any AEs the subject is exhibiting are collected, possibly including some solicited AEs. caAERS user enters the baseline AEs into caAERS and the information is stored in the caAERS database.
Preconditions	1. Solicited AEs have been associated to the study in caAERS 2. Subject was recently assigned to a study 3. Baseline AEs were collected 4. caAERS User must be logged in 5. caAERS User must have right to add baseline AEs
Main Success Scenario Steps	**Note: This is a sub use case of the main use case, 1.1 Enter observed AEs, so only the basic flow is provided here.** 1. caAERS user opens the AE flow in caAERS 2. caAERS user selects the study and subject 3. caAERS opens a blank reporting period page 4. caAERS user enters the start and end dates for the reporting period, the cycle number, and selects "Baseline" for the reporting period type a. caAERS verifies the reporting period is valid (same start and end dates are valid for a Baseline reporting period type) b. caAERS evaluates the reporting period type answer and brings up the appropriate solicited AEs 5. User entering required information for the solicited AEs a. selects grade (0-5) or "Not Evaluated" 6. caAERS user enters the optional info (Hospitalization, verbatim/notes field), as appropriate for the AEs 7. caAERS user enters in other observed AE(s) 8. caAERS user can enter/select the AE term in the nomenclature for the study (i.e. CTCAE 3.0, MedDRA 10.0, etc) by using several methods of entry: • enter via the auto-completer field, or • select query and then search using category (CTC only) and/or use the show all button to list the terms, or 9. caAERS user enters the Grade + description (see 1.1 for non-CTEP trials) a. Attribution can not be required b. hospitalization can not be required c. expectedness can not be required 10. caAERS user enters the optional info (notes/verbatim), as appropriate for the AEs 11. caAERS user saves the entered AEs 12. caAERS fires rules engine a. Would we need to fire the rules engine for baseline info? 13. caAERS saves the AEs to the database and brings up the Manage Reports page

Extensions	**3a. Existing, non-Baseline reporting period** 1. caAERS shows a drop-down list of reporting periods/cycles, for the study/subject that have already been added (show all with most recent at the top) a. For a new report period/cycle, caAERS displays an option to "Add Reporting Period" (go to step 2) b. For reporting periods/cycles already created, caAERS displays an option to "Edit AEs" in the reporting period 2. caAERS user selects to Add Reporting Period 3. Continue main flow from step 4 **3b. Existing, baseline reporting period** 1. caAERS shows a drop-down list of reporting periods/cycles, for the study/subject that have already been added (show all with most recent at the top) a. For a new report period/cycle, caAERS displays an option to "Add Reporting Period" b. For reporting periods/cycles already created, caAERS displays an option to "Edit AEs" in the reporting period (go to step 2) 2. caAERS user selects the Baseline reporting period 3. continue main flow from step 4 **Sub-Flows** caAERS determines user access
Post Conditions	Baseline AEs are recorded for a subject

Data Items	• If this is the first reporting period added for a subject, it should automatically bring up the reporting period screen
	• For Baseline AE entry only, the following fields/questions are not required (should not appear?):
	  • TAC field
	  • Start date of first course
	  • Hospitalization occurred?
	  • investigation treatment administered?
	  • For solicited AEs
	  • attribution
	  • For Observed AEs
	  • attribution
	  • hospitalization
	  • expectedness

Special\Non-Functional Requirements	none
Open Issues	• Who would enter the baseline AEs? AE coordinator? Study coordinator? • Will all subjects have a set of baseline AEs? • For baseline, can we hide all fields except the grade, AE term, and notes/verbatim?

Business Rules	• Baseline AEs only require
	  • the term
	  • the grade
	• Baseline AEs are exempt from expedited reporting rules

1.4 Modify Observed AEs (Reporting Period) - caAERS UC draft

Primary Actor: caAERS User
Supporting/Secondary Actor: caAERS
Scope: subsystem - AE module caAERS
Level: User Goal
Trigger: Additional Adverse Events (AEs) have been observed or the grade has increased

Brief Description	The CRA observes an increase of grade for an AE or observes additional AEs for a subject on a study over a reporting period. The caAERS user goes in to caAERS into the AE flow, selects the Study/Subject combination, and selects the reporting period. The caAERS user then modifies any existing information and adds other observed AEs, and then saves the AEs. The caAERS system runs the rules engine which: • checks for duplicate (term) AEs for the period • verifies all required information is provided • checks to see if expedited reporting is required • saves the AEs to the system • brings up a rules engine results page If expedited reporting is required, caAERS • identifies the AEs that required expedited reporting • informs the user that expedited reporting is required • copies all routine AEs into the expedited report
Preconditions	1. The Study has been created. 2. The Subject has been created and assigned to the Study. 3. The caAERS user has access to the AE module 4. The caAERS user is logged in to the system 5. The caAERS user has already added AEs to a reporting period 6. The CRA observed additional AEs or increases in grade for AEs already reported
Main Success Scenario Steps	1. caAERS user opens the AE flow in caAERS 2. caAERS user selects Subject and Study. 3. caAERS shows a list of reporting periods/cycles, for the study/subject that have already been added (show most recent 10, recent at the top) 4. caAERS user selects a reporting period to modify 5. caAERS pulls up the reporting period with the solicited AEs and other observed AEs listed. 6. caAERS user modifies AEs, as necessary a. Enters increases in grade b. Enters/modifies the Attributions c. Enters information in the notes/verbatim field d. Can the user delete an AE from this reporting period? e. caAERS displays the expectedness of the AE using the rules-of-expectedness for the protocol (ASAEL reference and/or protocol specific configuration f. Changes the answer to "investigational treatment been administered" g. ~~Changes the answer to "did hospitalization occur"~~###* ~~If answer is changed to yes, one or more AEs have to have the answer to "hospitalization or prolonged hospitalization" be Yes~~ 7. caAERS user enters additional observed AE(s) a. caAERS user can enter/select the AE term in the nomenclature for the study (i.e. CTCAE 3.0, MedDRA 10.0, etc) by using several methods of entry: • enter via the auto-completer field, or • query and select category (CTC only) and/or use the show all button to list the terms, or • select from the list of AEs from the previous reporting period (previous AE quick-pick) b. caAERS user enters the required information (Grade + description, Attribution) c. caAERS user enters the optional info (Hospitalization, Expected, verbatim/notes field), as appropriate for the AEs d. caAERS displays the expectedness of the AE using the rules-of-expectedness for the protocol (ASAEL reference and/or protocol specific configuration) 8. caAERS user clicks "Saves and Continue" button 9. caAERS fires rules engine a. check that if a grade was changed it increased, not decreased? 10. caAERS saves the AEs to the database 11. caAERS provides summary of rules results and needed actions with actions available a. If routine AEs were added and there's an existing Expedited Report, caAERS prompts user to select AEs to amend the expedited report b. If an AE requires expedited reporting, and there's an existing Expedited Report, caAERS prompts user to amend the expedited report c. If an AE was entered that requires expedited reporting and there's not an existing expedited report, caAERS prompts user that expedited report is needed, and has user select which routine AEs are included d. Change AEs for observation period e. Go to Manage Report f. Go to Expedited Report

Extensions	**7a. caAERS user selects "Other - specify"** 1. caAERS pops up the field to enter additional details 2. caAERS user either enters the MedDRA term or types the verbatim explanation **7.4.a. caAERS user enters CTC term that has the ASAEL in the system or protocol definition of expectedness** 1. caAERS will autopopulate the expectedness field (discussed in Determining expectedness UC) **8a. caAERS user doesn't have submit permissions (discussed in Routing and Review UC)** 1. caAERS throws an error and asks if the user wants to save as a draft 2. caAERS user saves as draft 3. caAERS sends notification to <role, user> that draft AEs have been reported **9a. caAERS determines information is missing** 1. caAERS will throw an error detailing what information is missing (hospitalization for example) 2. caAERS user will enter required information 3. caAERS user will save the AE(s) 4. caAERS saves the AE(s) and updates the database **9b. caAERS identifies duplicate AEs** 1. caAERS will throw an error 2. caAERS user will delete/modify the duplicate AE 3. caAERS user will save the AE(s) 4. caAERS saves the AE(s) and updates the database **9c. Session has expired before changes are saved** 1. caAERS will return the user to the log on screen when they try to save 2. caAERS user will enter their log on information 3. caAERS will return the user to the page they were on and reenter the information 4. caAERS user will save the AEs 5. caAERS saves the AE and updates the database **9d. caAERS determines expedited reporting is required for one or more AE** 1. caAERS will save the AEs and update the database 2. caAERS will create the expedited report 3. caAERS will provide notice that expedited reporting was required for the AEs that required them 4. caAERS will prompt the user to select which AEs need to be associated to the expedited report 5. caAERS will prompt the user to open the expedited report a. if yes, caAERS will open the expedited report b. if no, caAERS will show the Manage Report Page
Sub-Flows	Entering Solicited AEs caAERS determines user access Enter expedited report
Post Conditions	• routine AEs are saved in the caAERS database • routine AEs are displayed in manage reports • expedited reports are started
Data Items	• If the user enters yes to "Was hospitalization required during this reporting period", caAERS needs to verify that one or more AEs has Yes answered for "hospitalization or prolonged hospitalization"
Special\Non-Functional Requirements	none
Open Issues	• Can the user delete an AE from this reporting period? • Should we check that if a grade was changed it increased, not decreased?
Models & User Interface Prototype	none

1.5b Manage AEs page

Primary Actor: caAERS
Supporting/Secondary Actor: caAERS

Scope: sub-system
Level: User Goal
Trigger: User wants to see all the AEs for a specific study/subject combo & selects Manage AEs (manage Reporting Periods, Review AEs?)

Brief Description

The Manage AEs and Reporting Periods page is a summary page that displays the Reporting Periods, AEs in those reporting periods, and reports that are required.

All information will be displayed in a table with the different levels expandable/collapsable. When items are expanded, the items will shift down and the details will appear in a nested table.

Details for the REporting Periods and AEs will be read-only. The status fields will autopopulate based on data entered in the reports or options selected.

Data Items

- Data Entry Status (Data Complete field on current manage report, w changes)
    - In process
        - Data Entry Status for Reporting period type has business rules associated to it
    - Complete
- Options [CTMS:for Reporting Period row] (only display if there are actions available)
    - Send to PSC (only if PSC is available)
    - Export Reporting Period Info
    - Change Data Entry Status to Complete (only appears if a - no reports, b - all reports have been submitted)
- Options [CTMS:for specific report row] (only display when the option is valid for first 4)
    - Submit
    - Withdraw
    - Amend
    - Resubmit? (create without for now, may need it in the future to support when submissions to AdEERS fails)
    - ------ (spacer line - not actually selectable - if selected automatically gives error
    - Create XML of Expedited Report (only if expedited report exists)
    - create AdEERS PDF (only if AdEERS report was created)
    - Create MedWatch PDF
    - Create DCP SAE PDF (only for DCP studies)
- Report Status
    - Report(s) Due
    - Report(s) Submitted
- Submission Status - use list from the "Status" field on the existing Manage Reports

Special\Non-Functional Requirements

- Any special items of interest or non-functional requirements to be addressed

Business Rules

- The Data Entry Status for the reporting period defaults to in process
    - The user will be able to change that field to complete by selecting "Change Data Entry Status to complete" from the Options list
    - The option will only be available when the criteria is met
        - All required fields in the solicited AE table and Observed AE tables are complete
            - includes all solicited AEs have a grade assigned to them
        - Report Status (either of the two)
            - There are no reports
            - Any reports have the submission status of Submitted
    -
-

6.1 caAERS Auditing - history of single routine AE (POC) UC draft

Scope: system - caAERS
Level: User Goal
Trigger: User wants to see the history of a routine AE in caAERS

Brief Description	A caAERS User wants to see what changes have been made to a routine AE for a particular user/study in caAERS. He/she logs into caAERS and goes to Manage Reports, searches for the user and study, and sees all the AEs displayed. Next to the routine AE, he/she clicks on history, which displays a history for that AE. The report shows when the AE was added and modified. The user can then export the history to excel if desired.

Primary Actor	caAERS user
Secondary Actor	caAERS system
Preconditions	• AE must currently exist in the manage report for the user/study combination • caAERS user must be logged in to caAERS • caAERS user must have access to the user/study combination they are trying to view (is this true?)
Main Success Scenario Steps	1. caAERS user selects Manage Reports 2. caAERS user enters participant and study a. caAERS pulls up the manage Report page displaying all the AEs for the user/study 3. caAERS user clicks History next to an AE listed in the Routine AE area a. caAERS brings up a history window that displays the history of that AE. It includes the following fields: Date & time stamp User Name Treatment code AE Term, AE description field (for, "Other, Specify field" Grade Attribution Hospitalization Expected Operation (Created and Modified only [CTMS:Deleted is out of scope for the POC, but will be included when history is available for observation period]) 4. Only the fields whose values have changed will have information in them 5. caAERS user has the option to export the information to .xls or close the history
Extensions	Enter any alternative flows, failure flows, and exceptions
Sub-Flows	Enter any paths that are used by multiple paths within the use case (could just be a link to another use case)
Post Conditions	What items hold true after the use case is enacted?
Data Items	none
Special\Non-Functional Requirements	none
Open Issues	• Who needs to have access to the auditing feature? Who should not have access? Will those who need access have caAERS login ids? • What does a user need to be able to do with that data besides export it to xls?
Models & User Interface Prototype	• Provide an optional UI mockup, if useful. • Provide an optional UML diagram

6.2 caAERS Auditing - history of an observation period UC draft

Scope: system - caAERS
Level: User Goal
Trigger: User wants to see the history of a routine AE in caAERS

Brief Description	A caAERS User wants to see what changes have been made to the AEs provided for an observation period for a particular user/study in caAERS. He/she logs into caAERS and goes to Manage Reports, searches for the user and study, and sees the AEs and expedited reports displayed. Next to the observation period, he/she clicks on "history", which displays a history for that observation period. The report shows when the AEs were added, modified, and deleted. The user can then export the history to excel if desired.
Primary Actor	caAERS user
Secondary Actor	caAERS system

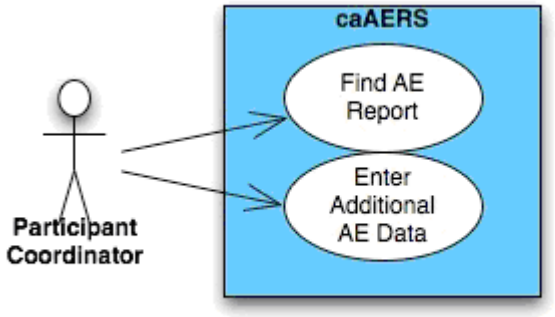
Preconditions	• The observation period must currently exist in the manage report for the user/study combination • caAERS user must be logged in to caAERS • caAERS user must have access to the user/study combination they are trying to view (is this true?)

Main Success Scenario Steps	1. caAERS user selects Manage Reports
	2. caAERS user enters participant and study
	  a. caAERS pulls up the manage Report page displaying all the AEs for the user/study
	3. caAERS user clicks History next to the observation period listed in the Routine AE area (not next to a specific AE)
	  a. caAERS brings up a history window that displays the history of the AEs for that observation period. It includes the following fields:
	  Date & time stamp
	  Treatment code
	  AE Term
	  AE description field (for, "Other, Specify field")
	  Grade
	  Attribution
	  Hospitalization
	  Expected
	  Operation (Created, Modified, and Deleted)

Notes:	• Only the fields whose values have changed will have information in them
	• If an AE was deleted, all fields will have the information in them, with operation being "deleted"
	• caAERS user has the option to export the information to .xls or close the history
	• Data will be sorted by
	  • date, oldest to newest?
	  • AEs grouped together by date, oldest to newest?

Extensions	3a. caAERS user wants to sort the data differently# caAERS allows the data to be sorted by other fields
Post Conditions	• No changes were made to caAERS • caAERS user may have a printed history report.
Data Items	none
Special\Non-Functional Requirements	none
Open Issues	• Who needs to have access to the auditing feature? Who should not have access? Will those who need access have caAERS login ids? • What does a user need to be able to do with that data besides export it to xls?
Models & User Interface Prototype	• Provide an optional UI mockup, if useful. • Provide an optional UML diagram

AE Data Collection (caAERS UC)

Brief Description	A Participant Coordinator (PC) enters additional data about an AE which already exists in the system. whether or not a data element is required is dynamically determined based upon configured triggers and reporting needs. 
Primary Actor	Participant Coordinator (PC)
Preconditions	1. The AE Report already exists in the system. 2. Notification triggers have been setup.
Basic Flow of Events	1. The PC selects option to search for AE Report entries by Study Participant and Protocol. (Use Case 1.7). Protocol-specific codes should show up first. 2. The PC selects the desired AE Report. 3. caAERS displays the AE Report data entry screen with current data. 4. The PC completes dynamically generated data collection (Use Case 4.2) form which comprises the core data elements required for the indicated reporting agencies as determined by the triggers. PLEASE SEE SAE Form Elements spreadsheet for the identification of elements comprising the core data set as determined by requirements from all external reporting agencies 5. The PC submits data.
Postconditions	1. After successful completion of this use case, the SC will have saved edits to an existing AE for a Study Participant linked to an existing protocol. 2. Time stamp of last saved edits with User ID are readily viewable. An audit log of updates is available. 3. Reporting triggers and notifications are invoked and updated as data collection occurs. 4. The report can be saved and edited any number of times. Once all of the required fields have been completed, the AE report is considered to be complete.
Special Requirements	See Data form

Create Study for AE Data Entry (caAERS UC)

Brief Description	Before AE data can be captured for a given Subject and Study, the Study must exist within the caAERS system. In this Use Case, a Study Coordinator (SC) creates an entry in the caAERS system for an existing Study in order to capture AE data. (Note: Module 2 Use Case 2.1 represents the caAERS function for abstracting Study AE data from an existing CTMS system.)
Primary Actor	Study Coordinator (SC)
Secondary Actor	Admin
Preconditions	The Study does not already exist in the system.

Basic Flow of Events	1. The SC has logged into the system and indicates he/she wants to create a new Study. 2. The system displays a page that allows the SC to create a Study. 3. The SC enters and saves the data (see Data Item below). 4. The system checks for duplicate Study (*e.g.*, match on Site PI, Sponsor name and Sponsor Study ID). • If duplicate is found: a. Alert SC of a possible duplicate study and display details of the duplicate. b. SC views a page with the possible duplicate study information. c. SC may choose the following actions: i. **Change study data** to modify entered data and continue. (Note: Site PI, Sponsor Name or Sponsor Study ID must be changed or a duplicate warning with occur again) ii. **Cancel** to the main menu page without creating the new study. • If no duplicate is found, continue. 5. The system assigns a unique identifier to the Study, not visible to the user. 6. The system displays a confirmation to the SC upon successful Study creation.
Postconditions	1. Study information is stored in the system and is editable. 2. Unique system Study ID assigned. 3. Confirmation of Study creation is displayed.
Notes	1. The actor is able to exit the function at any time. 2. The system will store the following information for audit purposes: a. User information related to the registered study. b. The caAERS institution that registered the study. c. Date and time of activity. 3. The combination of data items that trigger a duplicate warning are: a. Site Principal Investigator name b. Primary sponsor name c. Primary sponsor Study ID number

Special Requirements

Data Item	Notes/Validation Rule
Site Principal Investigator	Coded element. Required
Long study title	Required
Short study title	Optional
Primary sponsor name	From LOV Required
Primary sponsor study version date	mm/dd/yyyy- forced format upon typing or calendar
Agents and Devices	Not Required capture any number of these as well asINDor IDE #.and holder of this number
Study IDs	User must enter one, but may enter any number of Study IDs as well as the institution that assigned the ID.
Study Diseases	Not required, capture any number of these.
Phase of Study	Required Added to facilitate triggers, Coded, Required
Sites	In multi-site trials, this describes which sites are involved in performing the trial.

1.5c - Streamlining Study Interventions

Primary Actor: caAERS User - AE entry
Supporting/Secondary Actor: caAERS User - Study definition entry
Scope: Adverse event reporting
Level: User Goal

Brief Description

This is a usability use case with the main purpose being to simplify the entry of study intervention data required for submission of an expedited report. Currently, the intervention data entered into the expedited report flow does not leverage intervention data entered as as part of the study

defintion. This use case will leverage the use of intervention data previously entered into the system to both reduce the amount of data requiring entry and to guide the user through the expedited flow in an intelligent manner.

Preconditions

1. A study must be entered into the caAERS system.
2. An Expedited AE report must be initiated.

Steps

Main Success Scenario

1. An expedited report is initiated.
2. The study interventions that are appropriate (based on the study definition) are shown and available for data entry
    - For the interventions available for entry, there will be a reuse of data (i.e. agent name, device name, etc) entered into the study definition.
3. Interventions that are not applicable for the study will NOT be available for entry (e.g. if a study doesn't have radiation, radiation will not be available for entry as a study intervention).

Extensions

If a study defintion is updated to add/remove interventions after a report is initiated, the updates should be reflected in the report.

Sub-Flows

Enter any paths that are used by multiple paths within the use case (could just be a link to another use case)

Post Conditions

- What items hold true after the use case is enacted?

Data Items

- Study interventions:
    - Course
    - Agent
    - Radiation
    - Device
    - Surgery
    - Behavioral Therapy (new)
    - Other Interventions (new)

Special\Non-Functional Requirements

-

Business Rules

- If an intervention is defined for a study, entry of data for that intervention will be allowed, otherwise entry of data for that intervention will not be allowed.

Open Issues

- Should "Other Causes" be included on the interventions tab.

Models & User Interface Prototype

See tab "Study Interventions -r"

1.6 Add Reporting Periods types to a study - caAERS UC

Scope: sub-system, Study module
Level: User Goal
Trigger: User is entering a study into caAERS

Brief Description	caAERS user creates a new study in caAERS. During the creation, caAERS user verifies/modifies, deletes pre-substantiated reporting period types and/or adds additional reporting period types.
Primary Actor	caAERS user
Secondary Actor	caAERS system
Preconditions	User has access to the Study Module
Main Success Scenario Steps	1. caAERS user creates a study and goes to tab **9. AE Reporting Information** 2. caAERS user goes to the **Reporting Period Type and Solicited AE section** 3. caAERS user views the three pre-populated reporting period types a. Baseline - first reporting period type, cannot be changed or deleted b. Treatment - can be deleted or renamed i. to delete, click the X in the upper-right corner ii. to modify, click on treatment and type something new c. Post-Treatment - can be deleted or renamed i. to delete, click the X in the upper-right corner ii. to modify, click on Post-Treatment and type something new 4. caAERS user adds new reporting period type a. clicks Add b. types a reporting period type name in and hits enter 5. caAERS user saves the study 6. caAERS verifies the information and saves the study to the database
Extensions	**caAERS user modifies an existing study** 1. caAERS user opens an existing study and goes to tab **9. AE Reporting Information** 2. caAERS user goes to the **Reporting Period Type and Solicited AE section** 3. caAERS user views the existing reporting period types a. Baseline - first reporting period type, can not be changed or deleted b. Any reporting period type which has been used in the AE flow **cannot** be changed or deleted, so shouldn't have the X available c. Any reporting period type which hasn't been used in the AE flow can be deleted or renamed i. to delete, click the X in the upper right corner ii. to modify, click on <the reporting period type name> and type something new 4. caAERS user adds a new reporting period type a. clicks Add b. types a reporting period type name in and hits enter 5. caAERS user Saves the study 6. caAERS verifies the information and Saves the study to the database **6a. caAERS finds two reporting period types with the same name** 1. caAERS returns an error: "There is a duplicate reporting period type. Modify or delete the reporting period types so they are all unique." 2. caAERS user makes changes to the reporting period type 3. caAERS user Saves the study 4. caAERS verifies the information and Saves the study to the database **4a. caAERS user doesn't type a title for the reporting period type (no change to what's populated when the user clicks add)** 1. caAERS returns an error: "Each reporting period type must have a valid title. Type the title or delete the reporting period type" 2. caAERS user types the reporting period type title 3. caAERS user Saves the study 4. caAERS verifies the information and Saves the study to the database
Sub-Flows	Create Study
Post Conditions	• reporting period types are added to the study • are available to have solicited AEs assigned to them in the study module • are available for selection when creating a reporting period
Data Items	• Reporting period type • always has three values pre-created - Baseline, Treatment, Post-treatment • there will be a relationship between the following items: • reporting period type & reporting period • reporting period type & solicited AEs • reporting period type & study

Special\Non-Functional Requirements	• When the user clicks Add, the reporting period type should be added with the title pre-populated with "enter title here", which automatically deletes when the user starts typing
Business Rules	• the baseline reporting period type cannot be deleted or modified • once a reporting period type has been used in creating a reporting period it can not be modified or deleted • reporting period types are associated to a study • two reporting periods can not have the same name
Open Issues	none
Models & User Interface Prototype	none

Consolidate Interventions UC

Primary Actor: caAERS
Supporting/Secondary Actor:
Scope:
Level: User Goal
Trigger:

Brief Description

1. Combine all study interventions into one page
2. Only show study interventions which are valid for the study

Preconditions

1. Study is in caAERS
2. AE requiring expedited reporting is entered

Steps

Main Success Scenario

1. The following interventions can be part of a study:
    - Agent
    - Radiation
    - Surgery
    - Device
    - Behavioral
2. The first four currently have their own pages in the expedited report and should be combined into one page
3. The only interventions that will appear will be the ones that are included in the study
    a. For agent only studies, one study agent will pre-instantiate
    b. For radiation only studies, one radiation record will pre-instantiate
    c. For surgery only studies, one surgery record will pre-instantiate
    d. For device only studies, on device record will pre-instantiate
4.

Extensions

- The Course & Agent page will need to be reworked
- The Attribution page would need to pull from the various sections of the Intervention page
- The Mandatory Sections of Rules will need to be reworked since it'll be section based and not page based
- The business rules may need to be adjusted to address the new layout

Post Conditions

- Course page should no longer include Agent information
- Interventions will be combined into one page
- Mandatory Sections of Rules (for interventions) will be mapped to sections of a page, not to separate pages)

Data Items

- There are new fields in Agent:
  - How did the treatment differ from the TAC. Options - Dose increased, Dose not changed, Dose reduced, Dose withdrawn, Not applicable
  - Delayed. Options - Yes, No
  - Duration Delay (text field)
  - Units. Options - seconds, minutes, hours, days.
- There are fields to remove from Agent:
  - Dose modified checkbox
  - Modified dose
  - Modified does units

Special\Non-Functional Requirements

-

Business Rules

- Only therapies entered in the study will appear on the page
- Existing rules about required fields still hold true
-

Open Issues

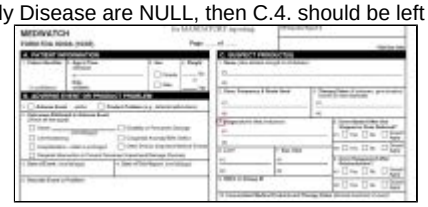
- How do we address behavioral studies?
- We may want to make the Comments field conditionally required based on response to "How did the treatment differ from the TAC" since AdEERS says the details should be included in the Comments field (https://capps-ctep.nci.nih.gov/ctep-html/adr_protagnt.htm).

Models & User Interface Prototype

See attached html mockup. Possible differences would include using a two-column layout. Tables should be avoided where possible. Agent list should continue to be a dropdown (mockup uses various methods).

Entering the Study Purpose (caAERS UC)

Brief Description	A Study Coordinator enters information about the study purpose. The study disease is subsequently entered. Based on the value entered as study purpose, the expedited reporting flow may have different behavior with respect to the study disease.
Primary Actor	Study Coordinator
Secondary Actors	Supplemental Study Information Manager / AE Reporter
Preconditions	1. The users have the appropriate permissions.

Basic Flow of Events	1. The Study Coordinator the Study Purpose from one of the following values: • Treatment, Prevention, Supportive Care, Screening, Early Detection, Diagnostic, Epidemiologic, Outcome, Observational, Ancillary, Correlative, Health Service Research, Other, Basic Science 2. The Study is "Saved" 3. The Supplemental Study Information Manager logs into the system, searches for the study, selects the study to edit it, and enters the study "diseases". 4. The Study is again, "Saved". 5. The AE Reporter is in the expedited flow for a patient on this study. 6. If the Study Purpose is "Treatment" or NULL then the Study Disease appears on the Attribution tab. • If the Study Purpose is anything besides "Treatment" then the Study Disease does NOT appear on the Attribution tab. 7. On the MedWatch 3500A form, the indication (Field C.4.) should read as"For *StudyPurpose* of *StudyDisease*" (e.g. "For *Treatment* of *Breast Cancer*). • If Study Purpose is NULL, then just the Study Disease should be displayed. • If Study Disease is NULL, but Study Purpose is not NULL, then just the Study Purpose should be displayed. • If both Study Purpose and Study Disease are NULL, then C.4. should be left blank. 
Postconditions	
Special Requirements	• If Study Purpose is "Treatment" or NULL then the Disease Information section is available in the Subject Medical History page. • If Study Purpose is NOT "Treatment" then the Disease Information section is NOT available in the Subject Medical History page. • This applies to the Subject Medical History page in assign subject to study, enter subject, edit subject, and the expedited reporting flow.  • Study Purpose should be an optional field on the Study Details page. • Study Purpose should be included in the Study Export feature. • Study Purpose should be included in the Study Import feature. • The Study Import feature should be backwards compatible to support importing earlier study XMLs that have no Study Purpose tag.

Study Abstraction (caAERS UC)

Study Abstraction - Sponsors, Committees and Organizations

Brief Description	This use case links sponsors, committees and organizations (entered as "Organizations" into caAERS) that are important to the management of the Study as they relate to the recording and reporting of AEs. The Study Coordinator will be able to enter/update information about these entities. The basic course of action is to link an Organization to the protocol by adding the Organization to a collection associated with the protocol. The SC will then decide whether the organization is concerned with all AE Reports entered into the system or only for those Reports which involve a particular Agent or Device.
Primary Actor	Study Coordinator (SC)
Preconditions	1. The Study exists in the system. 2. SC has entered all appropriate institutional values for the coded elements: Sponsor, Committees and Organizations into the system. 3. SC has found the desired Study.

Basic Flow of Events	1. The SC navigates to the Study abstraction screen - Sponsors, Committees, and Organizations. 2. The SC searches for the desired protocol (Use Case 1.13). 3. The SC selects a Sponsor, Committee, or Organization and associates it with the Study. 4. The SC enters the appropriate data regarding this association. (See Data table) 5. The system stores the information.
Postconditions	Sponsors, committees and/or organizations have been associated with the Study.
Notes	Detailed information about the Sponsor, Committee, or Organization will be entered and edited through an administrative interface. To facilitate study-specific changes in this information, the Study Coordinator may need to have access to this interface, but it will not be reentered here. The Actions taken with respect to these entities will be described by the Rulesets.

Special Requirements

Data Item	caAERS Class (Types)
Entity	Sponsor, Committee, Funding Agency, External Regulatory Agency, Multi-Center Consortium
Entity Name	
EntityID (e.g. sponsor ID)	

Create Subject (caAERS UC)

Brief Description	Before AE data can be captured for a given Subject and Study, the Subject must exist within the caAERS system. In this Use Case, a Participant Coordinator (PC) creates an entry in the caAERS system for an existing subject in order to enable AE data capture.
Primary Actor	Participant Coordinator (PC)
Preconditions	1. The Subject is qualified and enrolled in the study. (caAERS does not manage eligibility or enrollment workflow.) 2. The Subject does not already exist in the system.
Basic Flow of Events	1. The PC selects Create Subject. 2. The PC enters data about the Subject and submits it (see Data table below). 3. The system checks for duplicate Subject using Subject Identifiers, First and Last Name, DOB, and Gender. 4. If duplicate is found: a. System displays duplicate data b. PC decides to: i. Modify data ii. Cancel Subject creation 5. If no duplicate is found, continue. a. The system displays a confirmation to the PC of successfully creating a Subject.
Postconditions	1. Subject data is stored in the system. 2. The PC is presented with a confirmation of Subject creation. 3. The PC must now assign the Subject to a study (see Use Case 1.3).

Special Requirements

Data Item	Notes/Validation Rule
Subject Identifier	At least one is required. The system will allow for any number of these to be specified and will capture the type of the identifier, the issuer of the identifier, and its value. This ID is unique to the Subject independent of the Subject's participation in a clinical trial.
First Name/Initial	Required
Middle Initial	Not Required
Last Name/Initial	Required

Date of Birth	Mm/dd/yyyy, forced format or calendar, Required
Gender	Coded, Required
Race	Coded, Required (Valid values include "unknown" and "unreported")
Ethnicity	Coded, Required

1.5a Setting up Patient Medical History

Primary Actor: caAERS
Supporting/Secondary Actor:
Scope: subsystem
Level: system
Trigger: Patient is assigned to a study, medical history is added to an expedited report

Brief Description

A patient's medical history can be gathered during their registration to a study, so it will be added to each expedited report for the patient. However, not everyone will add the information during registration, so we need to allow updates to the information in both the expedited report and in the patient/study registration area.

Preconditions

- patient exists in caAERS
- study exists in caAERS
- caAERS user has access to the patient/study registration module
  and/or
  caAERS user has access to the expedited report module

Steps

New Patient/Study Registration - collect medical history

1. caAERS user goes into patient/study registration area
    a. NOTE: This needs to be available in both the "Enter Subject" and "Assign Subject to Study" flows
2. caAERS user selects patient
3. caAERS user selects study
4. caAERS presents user with screen to enter patient's medical history
    - screen will initially show collapsed with just the section name and status, with the option to expand each section individually
        - statuses are: info added, no info added
        - sections are: general, disease information, metastatic disease site, pre-existing conditions, conmeds, prior therapies
5. caAERS user adds informations for the sections
    - none of these sections are mandatory. however, if they add information, ~~the existing rules remain true~~#** F~~or example, if Disease Name is added, primary site of disease is required~~
        - ~~For example, the priory therapy rules are true~~
    - to add information for the section, you need to expand it
        - General and Baseline will automatically show the fields when the area is expanded & information will be added/changed directly in those fields
        - Metastatic Disease Site, Pre-existing Conditions, and ConMeds will show any items that have been added, with a way to delete them. There will be an "add" button which when clicked will add a line to the table where the user can type in the information
        - Prior Therapies will show the title of the therapy as a link, with a way to delete it. There will be an "add" button which will bring up a pop-up that allows the user to add a prior therapy. To get the full details on the prior therapy, the user will click on the therapy name (which is a link), this will bring up the same pop-up with the information already populated.
    - information for all sections except prior therapies will be added in line by clicking 'add'
6. caAERS user saves the patient/study registration

Expedited Report for patient/study combo - pull medical history

1. caAERS user access AE flow
2. caAERS user enters AEs & additional information
3. caAERS determines a report is required
4. caAERS user goes to expedited report
5. caAERS creates a copy of the information from the patient/study registration information
6. caAERS user accesses medical history page
7. caAERS presents information from the patient/study registration page, with all sections expanded
    a. information is brought in as read only
    b. information that is brought in can be deleted

c. information that is brought in can not be edited in the report
d. fields that are blank that aren't part of a grouping can be added/modified
    - baseline performance can be added
    - primary site of disease can not be added if disease name already exists
    - date of initial diagnosis can not be added if disease name exists
8. caAERS user adds additional information to any of the sections
9. caAERS user deletes information from the section
10. caAERS user clicks Save, Save and Continue, or clicks to another page
11. caAERS updates the patient/study registration area
    - caAERS takes any information that was added and adds it to the patient/study registration area
    - caAERS does not modify the patient/study registration area if anything was Deleted
12.

Extensions

Edit Medical History for Patient/study combination

1. caAERS user goes to Subject Module
2. caAERS user searches for subject
3. caAERS displays subject and study assignments
4. caAERS user clicks on "Modify Medical History" next to the study
5. caAERS displays the user's medical history for that study in expanded mode
6. caAERS user makes changes
    - can modify fields
    - can add fields/sections
    - can delete information
7. caAERS user saves
8. caAERS updates the record for the patient study
    - caAERS does not update any existing reports, regardless of the status of that report (submitted, in process, etc)
9.

Enter any alternative flows, failure flows, and exceptions

Sub-Flows

- UC 1.1

Post Conditions

- caAERS

Data Items

- Separating Metastatic Disease Site from Disease
- Adding a Status to each section
    - two values: Info added and No info added
    - defaults to "no info added" until something is actually populated for that section. if all information is removed from the section, it'll go back to "no info added"
-

Special\Non-Functional Requirements

- The same "Relevant Medical History" page will be used in the patient/study registration, expedited report, and modify relevant medical history
    - It will be called "Patient Details in the expedited report flow and will need to include the Height, weight, and body Surface Area
- Expand/Collapse do not have to be separate buttons if there's a good visual representation for it - work with David to determine
-

Business Rules

- Once an expedited report is created for a patient/study combination, caAERS makes a copy of the medical history & does not modify it even if the history is updated at the patient/study level
- There can not be duplicates information added to any of these areas
    - When they click Save it should verify it is not a duplication
    - When information is being pushed to this area from the expedited report, if it a duplicate item, caAERS should leave it in the expedited report but not add it to the patient/study level (no error to the user, just don't copy it to the database)
-

Open Issues

- There is a slim possibility that there will be a problem with Disease Information. If the disease information isn't added during registration, and 2 reports are created at the same time, it may try to populate that information to the database twice, which isn't currently supported. The best workaround for this is to have the disease information required during registration. Should ask the adopters this
- If the AE coordinator doesn't have rights to the assign subject role, it will throw errors. Need to address this
- What does the baseline performance field specifically reference? see if can find that on ctep's site -
- Should we capture the height & weight at the study/subject registration time? would leave it editable
- What rules can we have fire during the collection? Biju will document the rules that could be an issue
- By creating a copy of the data when an expedited report is created, there are some disadvantages
    - anything added at the patient/study level will not be added to that report, potentially causing double entry
    - the expedited report may try to push duplicate data to the patient/study level, as discussed in the business rule
    - On the plus side though, the copy means if we delete anything and don't finish the report, those deletions will stay
    - If this becomes an issue after implementation, we can revisit. possibly add another field called status, although that also has problems

Models & User Interface Prototype

Provide an optional UI mockup, if useful.
Provide an optional UML diagram

Assign Subject to a Study (caAERS UC)

Brief Description	Subjects must be assigned to a Study before AE data can be abstracted. in this Use Case, the Participant Coordinator (PC) assigns a Subject to a Study. Unless the Subject has already been created and assigned to another Study, this action will immediately follow Subject creation within the UI.
Primary Actor	Participant Coordinator (PC)
Preconditions	1. Subject must exist in caAERS system. 2. Study must exist in caAERS system.
Basic Flow of Events: Option 1	1. PC creates a Subject or selects an existing Subject. 2. PC selects a Study and Site. 3. PC saves the assignment of the Subject to the Study.
Basic Flow of Events: Option 2	1. PC selects a Study and Site. 2. PC selects an existing Subject. 3. PC enters StudySubject ID and submits the assignment of the Subject to the Study. 4. The System will generate an alert if a duplicate assignment is found. a. PC will be able to: i. Cancel assignment ii. Select a different Study iii. Select a different Subject
Postconditions	Subject assignment to a study is recorded in the caAERS system.
Special Requirements	Data **Data Element** : StudySubjectID **Notes/Validation** : Should support multiple institutional and sponsor-assigned identifiers

Enter Routine AEs (caAERS UC)

Brief Description	The Participant Coordinator enters routine AEs for a given Subject over a certain time period and for a certain Study. The data is manually entered into caAERS so that the system can verify that an expedited report is not required. If an AE qualifies as expedited, the system will begin an expedited report and give the PC the option to move to the Expedited AE Report workflow.
Primary Actor	Participant Coordinator (PC)

Preconditions	1. The Study has been created. 2. The Subject has been created and assigned to the Study.
Basic Flow of Events	1. PC chooses to enter routine AEs. 2. PC selects Subject and Study. 3. PC chooses start and end dates for the time period being covered by this collection. 4. PC chooses the appropriate AE Categories and Terms. 5. PC fills in the Grade, Attribution, Expectedness, and Hospitalization for each term. 6. Upon saving, caAERS determines if an expedited report is required for any of the AEs. a. If not required, the AEs are simply saved to the database and the flow ends. b. If Expedited is required, PC will be given the option to move to the Expedited workflow (Use Case 1.5).
Postconditions	Routine AEs exist in the database.
Special Requirements	none

Recording a Continuing Adverse Event

Scenario	A clinical research associate (CRA) observes that an adverse event that had previously been observed on a patient is still occurring. She enters this adverse event observation into the adverse event management system.
Name	UC-#: Entering Continuing Adverse Events
Summary	A new occurrence of a previously resolved adverse event is observed and entered into the system.
Rationale	
Users	All AE Reporter users
Preconditions	1. A patient or study subject exists. 2. A adverse event had already been observed on the patient or study subject and entered into the system. 3. Another observation of the adverse event is made.
Basic Course of Events	
Alternative Paths	• The adverse event improves (decreases in grade or severity) within a reporting period (i.e. cycle). • The adverse event improves (decreases in grade or severity) between reporting periods. • The adverse event worsens (increases in grade or severity) within a reporting period (i.e. cycle). • The adverse event worsens (increases in grade or severity) between reporting periods. • There is no change in the adverse event severity within a reporting period (i.e. cycle). • There is no change in the adverse event severity between reporting periods.
Postconditions	The reporting rules run.

Recording a Recurring Adverse Event

Scenario	A clinical research associate (CRA) observes a new occurrence of an adverse event that had previously been observed on the same patient and later resolved. She enters this adverse event into the adverse event management system.
Name	UC-#: Entering Recurring Adverse Events
Summary	A new occurrence of a previously resolved adverse event is observed and entered into the system.
Rationale	
Users	All AE Reporter users

Preconditions	1. A patient or study subject exists. 2. An adverse event had already been observed on the patient or study subject and entered into the system. 3. The previously observed adverse event had resolved (i.e. gone away). 4. A new occurrence of the adverse event is observed.
Basic Course of Events	
Alternative Paths	
Postconditions	The reporting rules run appropriately for the recurring AE.

Search AE Entry (caAERS UC)

Brief Description	Participant Coordinator searches through existing AE Reports to find one of interest.
Primary Actor	Participant Coordinator (PC)
Preconditions	The AE Report must already exist. The PC should know the Study and Participant for whom he or she is seeking the AE Report.
Basic Flow of Events	1. PC selects the Study and Participant for whom he or she is seeking the AE Report. 2. caAERS presents the PC with a chronological list of AE Reports for the Participant on the Study. 3. PC selects a report and views the data.
Postconditions	AE Report is displayed

Module 2 UC - Interfaces for System Integration

Module 2 Use Cases - Interfaces for System Integration

Use Case	Date Created	Date Last Modified
Import Current AE Data	03/27/2008	10/18/2010
Import Legacy AE Data	03/27/2008	10/18/2010
caAERS to Local CTMS Integration	05/08/2008	03/01/2011
2.1 Importing data into caAERS		
2.1.1 Import research staff into caAERS - UC	07/11/2008	03/01/2011
2.1.2 Import Investigators - caAERS UC	07/11/2008	10/19/2010
2.1.3 Import Study Data - caAERS UC	03/27/2008	10/19/2010
2.1.4 Import Patient Data - caAERS UC	03/27/2008	10/19/2010
2.2 Interfaces with caBIG Clinical Trial Suite applications		
2.2.1 Receive Study Data from C3PR	03/27/2008	10/19/2010
2.2.2 Receive Registration Data from C3PR	03/27/2008	10/19/2010
2.2.3 Receive Lab Data from LabViewer	07/02/2008	10/19/2010
2.2.4 Send AE notifications to PSC	03/27/2008	10/19/2010
2.3 Interfaces with the NCI Enterprise Services		
2.3.1 Search Person Service		

2.3.2 Search Organization Service		
2.3.3 Search Protocol Abstraction Service	08/11/2009	10/19/2010

1.7 Creating a caAERS API for AE Queries - UC

Primary Actor: caAERS User
Supporting/Secondary Actor: caAERS
Scope: system
Level: User Goal
Trigger: caAERS user wants to create a list of AEs based on a specific query

Brief Description

Using an API, a caAERS User will be able to perform multiple queries to capture AE information. The caAERS team will create the API, an AE schema, and a usable interface. The end users will access the API via browser, perform their queries, and receive the output in XML format?

Preconditions

- query service is enabled
- API is added to a grid node
- has client that can access API (probably browser)
-

Steps

Main Success Scenario

1.

Extensions

Sub-Flows

Post Conditions

- user is able to receive query results in XML format

Data Items

-

Special\Non-Functional Requirements

- Methods should be domain objects with java docs
- It's a grid service with parameters loaded in gme
-

Business Rules

- User should not be able to access data they don't have rights to (central caAERS for multi-sites for example)

Open Issues

- Will the results only be in XML format or will there be other formats that lay users could understand/use?

Possible Queries

- All AEs for a patient\study
- All AEs for a study
- All AEs for a participant
- Particular AE for a study
- Particular AE for all studies
- Particular AE with grade x
- All AEs with a grade x for a particular study
- All AEs with a grade x for a particular patient
- All AES that are expected for a study
- AES that required reporting
-

2.0 Local CTMS Integration with caAERS - UC

Primary Actor: caAERS
Secondary Actors: Local CTMS
Scope: System, caAERS to Local CTMS
Level: Summary

Brief Description	Organizations want to integrate their local CTMS systems with caAERS. Many changes will be made in the local CTMS that they want to sync with caAERS, such as subject, study, and staff information. They also want to add AEs entered in caAERS into their local CTMS.
Initial Setup	1. Institution installs caAERS 2. Institution exports study, subject, routine AE data from their local CTMS 3. Institution 2.1.1 Import research staff into caAERS - UC 4. Institution 2.1.2 Import Investigators - caAERS UC 5. Institution 2.1.3 Import Study Data - caAERS UC 6. Institution 2.1.4 Import Patient Data - caAERS UC
Syncing Study Data	1. local CTMS user changes (adds, modifies, or deletes) study in their local CTMS 2. 2.0.1 Local CTMS to caAERS - Study updates • will not support changes to a study in caAERS being pushed to the local CTMS
Syncing Subject Data	1. local CTMS user changes (adds, modifies, or deletes) subject in their local CTMS 2. 2.2 Local CTMS to caAERS - Subject updates • will not support changes to a subject in caAERS being pushed to the local CTMS
Syncing Staff (research staff, investigators, physicians) Data	1. local CTMS user changes (adds, modifies, or deletes) staff in their local CTMS 2. 2.3 Local CTMS to caAERS - Staff updates • will not support changes to a staff in caAERS being pushed to the local CTMS
Syncing AE Data	1. caAERS user creates new AE in caAERS 2. 2.0.4 caAERS to local CTMS - AE updates • will not support changes to a AEs in local CTMS being pushed to caAERS
Blocking access to fields in caAERS	All fields that are imported into caAERS from the local CTMS must be blocked from modification within caAERS. The fields that are locked down may vary site to site. 1. 2.5 caAERS locks down subject fields 2. 2.6 caAERS locks down study fields 3. 2.7 caAERS locks down staff fields 4. 2.12 caAERS locks down investigator fields
Open Issues	na
Models & User Interface Prototype	na

Sub-tasks	Local CTMS to caAERS - Study updates Local CTMS to caAERS - Subject updates Local CTMS to caAERS - Staff & Investigator updates caAERS to local CTMS - AE updates Lock fields in caAERS - UC

Data Input and Output
When information is coming from a local CTMS, should it also be editable in caAERS? What about if it's coming from C3PR? How do we lock down what can be modified in caAERS, if the local CTMS doesn't include all the information that's needed (for example, CALGB doesn't currently include solicited AEs with their study definitions).

The following table shows the data flow we're enabling in caAERS. caAERS will either be receiving data, or pushing data. At this time, we do not have two-way data flow being developed.

	Staff	Study	Subject	AEs	Expedited Report	Participant to Study
C3PR						x
caAERS to AdEERS					x	
caAERS to local CTMS				x		
local CTMS to caAERS	x	x	x			

Ideally, if you only have one-way data flow, you should only be able to modify the data in the source application (modify a subject in the local CTMS and push it to caAERS). This feature is not in scope for this phase due to the variety of CTMS being used by the different organizations.

The following table shows where we believe the data will be able to be modified.

	Staff	Study	Subject	AEs	Expedited Report	Participant to Study
C3PR						x
AdEERS					x	
caAERS	x	x	x	x	x	x
local CTMS	x	x	x	x		x

2.0.1 Local CTMS to caAERS - Study updates

Scope: system level - caAERS
Level: User Goal
Triggers: 1- Fresh install of caAERS, needs to add the studies. **2-** studies updated/added/deleted in local CTMS

Brief Description	There are two scenarios: 1. caAERs user goes to the admin module and manually imports study(s) 2. local CTMS user makes a change (adds, modifies, or deletes) to a study, the local ctms creates an xml, calls a web service, and sends the update to caAERS
Primary Actor	caAERS User, caAERS System, Local CTMS system
Secondary Actor	local CTMS user

Preconditions	**General** 1. SemanticBits has published the xml schema 2. Elements exist in caAERS a. staff b. organizations c. agents **Admin module** 1. xml file has been created (by the adopter) 2. caAERS user has access to the Admin module **Web Service** 1. SemanticBits has published the wsdl 2. Local CTMS (manager) has configured the generation of the xml to include response information - required only when a response is requested
Success Scenario 1 - Admin area	1. Local CTMS user creates an xml 2. caAERS user logs in to caAERS and access the Admin module 3. caAERS user goes to the import area and selects the XML file 4. caAERS validates the file • caAERS returns a message if there are problems with the file • caAERS prompts the user to continue 5. caAERS imports the file 6. caAERS generates a report • Shows what records were updated (displaying identifier only) • Shows what records were added (displaying identifier only) • Shows what failed, if the xml is formatted correctly
Success Scenario 2 - web service	1. CTMS user makes a change (addition, modification, deletion) to a study in the local CTMS and saves the change 2. CTMS recognizes a change was made and 'packages' the change • Generates the xml (xsd) • Includes info on how caAERS should respond if a response is requested 3. CTMS calls the wsdl (web service, basically url to be called) 4. caAERS processes the information and persists the data • Uses synchronous method 5. If information was included in the xml, caAERS will send a response to the local CTMS
Extensions	**web Service 3a. connection to caAERS can not be established** 1. ? **web Service 3b. problem with xml (xsd file)** 2. ? **Admin 6a- Required Information is missing in caAERS** 3. caAERs does not import studies 4. caAERS provides information about error • Missing Staff • Missing Organizations • Missing Agent **web service4a- Required Information is missing in caAERS** 5. caAERs does not import studies 6. caAERS provides information about error (if information on how to respond is included in the xml) • Missing Staff • Missing Organizations • Missing Agent
Sub-Flows	none
Post-Conditions	Study data in the caAERS database has been updated
Data Items	Need to develop a way to keep the agent list up-to-date (see open issues)
Special\Non-Functional Requirements	• Generated XML files should contain multiple records • XML files cannot be partial files - all fields must be included. If a field is not included, caAERS will read it as a 'delete' and will either delete the information for the field, or will throw an error if the field can not be deleted. • Deletions will result in a "soft delete" where the information is marked as inactive

Open Issues	• For future release, need to determine how to handle locking down changes in caAERS based on fields/information the CTMS will push to caAERS
	• For identification of Staff to the study, caAERS currently uses the investigator's first & last name plus organization id
	• are there security issues to resolve, since studies can only be modifief by specific roles (site coordinators, study coordinators, and admin)
	• Have to determine the alternative flow/exception handling (ctms needs to know info wasn't updated in caAERS, needs to be able to resync)
	• How to we maintain/update the Agents list in caAERS?
	• What is the Source of Truth for agents?** CTEP agents = http://ctep.cancer.gov/guidelines/codes.html
	  ◦ DCP agents = ?
	  ◦ Commercial agents = ?
	  ◦ Device = ?
	  ◦ Other = ?
	• createStudy : Creates Study Data
	• updateStudy : updateStudy updates the study data .
	Assumption 1 (current implementation): Local CTMS always sends full list of study sites. (this applies to all associated objects)
	
	1. If create study xml has 3 study sites A,B,C , all the 3 study sites are saved in database.
	2. If two more study sites D and E are added from caAERS UI , total 5 study sites are saved in database
	3. If update xml has 3 study sites B,C and F, updateStudy deletes study site A,D and E , updates study sites B , C and adds study site F. So, after processing update xml , study would have only 3 study sites B , C and F .
	Assumption 2 : Local CTMS always sends deltas
	4. If update xml has 3 study sites B,C and F, updateStudy updates study sites B and C and adds study site F. So, after processing update xml , study would have all 6 study sites A, B , C , D, E, F .
	5. If any of the above study sites are deleted from Study definition , caller needs to keep track of deleted Study sites and call new "deleteStudySites" method with list of deleted study sites.

Business Rules	• When updates occur, if there is a record in the xml file that is exactly the same in the caAERS database, caAERS will show that record as updated, since there's no character checks
	• XML file should only include study information (not subject or staff)
	• changes to Staff data fields in the study will not be updated when importing the data
	  ◦ (example: jane brown's name changes to jane smith) The Staff change would have to be made in the Staff section of the local ctms and imported to caAERS that way.
	  ◦ The import would succeed, but the change would not appear (would still show jane brown)
	  ◦ Do all local ctms manage separate 'staff' areas, or would it be common practice to update a name, phone #, etc, when updating/adding a study?
	• When caAERS does a search, only 'active' subjects, should be included, unless in audit mode
	• The following groups/fields can not be delete. New fields can be added, statuses can be modified, descriptions can be modified, but the existing data must stay in the database to avoid corruption of Adverse Events
	  ◦ shortTitle
	  ◦ longTitle
	  ◦ phaseCode
	  ◦ treatmentAssigment code
	  ◦ studyAgent name
	  ◦ studySite
	  ◦ studyInvestigator - all fields can be modified, but the investigator can't be removed from the study
	  ◦ studyPersonnel - all fields can be modified, but the personnel can't be removed from the study
	• aeTerminology and diseaseTerminology can be changed. However, changing these fields results in:
	  ◦ possible problems submitting to AdEERS - the terminology must match the information in AdEERS or submitting a report fails
	  ◦ if you open an existing reporting period/expedited report, the AE and disease information will exist as originally entered. However, if you make any changes, you will be required to also change the AE and disease information
	• changing or deleting the remaining fields may affect existing reporting periods/expedited reports. When you open an existing reporting period or expedited report, the previous information should appear. However, if you make any changes, you may be required to change other fields (disease for example).

Models & User Interface Prototype	na

2.0.2 Local CTMS to caAERS - Subject updates

Primary Actor: caAERS User, caAERS System, Local CTMS system
Supporting/Secondary Actor: local CTMS user

Scope: system level - caAERS
Level: User Goal
Triggers: 1- Fresh install of caAERS, needs to add the subjects. **2-** subjects updated/added/deleted in local CTMS

Brief Description	There are two scenarios: 1. caAERs user goes to the admin module and manually imports subjects 2. local CTMS user makes a change (adds, modifies, or deletes) to a subject, the local ctms creates an xml, calls a web service, and sends the update to caAERS **Note**: Subject updates do not include associations to studies. This will be addressed during a later iteration.
Preconditions	**General** 1. SemanticBits has published the xml schema 2. Studies have been added to caAERS 3. caAERS is installed at adopter site 4. Business rules governing the management of subject data are in place in caAERS **Admin module** 1. xml file has been created (by the adopter) 2. caAERS user has access to the Admin module **Web Service** 1. SemanticBits has published the wsdl 2. Local CTMS (manager) has configured the generation of the xml to include response information - required only when a response is requested
Success Scenario 1 - Admin area	1. Local CTMS user creates an xml 2. caAERS user logs in to caAERS and access the Admin module 3. caAERS user goes to the import area and selects the XML file 4. caAERS validates the file • caAERS returns a message if there are problems with the file • caAERS prompts the user to continue 5. caAERS imports the file 6. caAERS generates a report • Shows what records were updated (displaying identifier only) • Shows what records were added (displaying identifier only) • Shows what failed, if the xml is formatted correctly
Success Scenario 2 - web service	1. CTMS user makes a change (addition, modification, deletion) to a subject in the local CTMS and saves the change 2. CTMS recognizes a change was made and 'packages' the change • Generates the xml (xsd) • Includes info on how caAERS should respond if a response is requested 3. CTMS calls the wsdl (web service, basically url to be called) 4. caAERS processes the information and persists the data • Uses synchronous method 5. If information was included in the xml, caAERS will send a response to the local CTMS
Extensions	**web Service 3a. connection to caAERS can not be established** 1. ? **web Service 3b. problem with xml (xsd file)** 1. ?
Sub-Flows	none
Post Conditions	• Subject data in the caAERS database has been updated • **Admin import** - Report has been generated

Data Items	**Subject** *Currently has the following required fields in caAERS:* Site First Name Last Name Date of birth Gender Ethnicity Race Identifier/Identifier type/Organization (can add multiple - one is required, rest are optional *Currently has the following optional fields in caAERS:* Maiden Name Middle Name *Identifier/Identifier type/Organization (can add multiple - one is required, rest are optional* Changes needed? Unique identifier should be?
Special\Non-Functional Requirements	• Generated XML files should contain multiple records • Deletions will result in a "soft delete" where the information is marked as inactive
Open Issues	• What is a subject's unique identifier? • Currently only the participant coordinator role can create/edit a subject, so how do we handle the security issues? • Have to determine the alternative flow/exception handling (ctms needs to know info wasn't updated in caAERS, needs to be able to resync) • For future release, need to determine how to handle locking down changes in caAERS based on fields/information the CTMS will push to caAERS
Business Rules	• When updates occur, if there is a record in the xml file that is exactly the same in the caAERS database, caAERS will show that record as updated, since there's no character checks • XML file should only include subject and associated study information (not study or staff) • When caAERS does a search, only 'active' subjects should be included, unless in audit mode?
Models & User Interface Prototype	na

Early Subject Use Case work - reference only

[CTMS:UC#1] Import subject data from CTMS-local into caAERS

Brief Description

caAERS is newly installed at the adopters site. Initially the caAERS schema is empty. It needs to be bootstrapped with existing subject data already present in the local CTMS system before normal usage of caAERS can begin.

Primary Actor

caAERS User

Secondary Actor

None

Preconditions

1. Subject data in CTMS-local has already been exported to XML formatted files as per caAERS specifications
2. caAERS has already installed on adopter's site
3. The business rules governing management of subject data is available.
4. caAERS provides a utility program [CTMS:in the form of an ANT file or java program] to enable import of subject XMLs

Basic Flow of Events

1. caAERS user generates XML files as per caAERS specifications. [CTMS:more details about specifications here]
2. caAERS user uses utility program to import data into caAERS schema.
3. Utility program creates log of events occured when processing subject XMLs.

Postconditions

1. caAERS is successfully populated with subject data from CTMS-local.
2. Error log of utility program shows any errors encountered during import.

Special Requirements

1. Privileges to run utility program at adopter's site.

[CTMS:UC#2] Update subject data in caAERS

Brief Description

Subject data that is updated in CTMS-local should be propogated to caAERS.

Primary Actor

caAERS User

Secondary Actor

None

Preconditions

1. caAERS is running normally at adopter's site.
2. caAERS has been bootstrapped with subject data from CTMS-local.
3. The business rules governing subject data is already available.
4. Data in caAERS and CTMS-local is synchronized.

Basic Flow of Events

1. Subject data has been updated in CTMS-local.
2. CTMS-local calls a caaers web service to update the subject data in caAERS.
3. One of two scenarios can occur:
    a. caAERS updates participant data and sends confirmation message to CTMS.
    b. Error occurs [CTMS:for example, due to violation of a business rule] and caAERS sends error message to CTMS

Postconditions

1. caAERS is successfully updated with subject data from CTMS-local.
2. Data in caAERS and CTMS-local is synchronized.

Special Requirements

None

[CTMS:UC#3] Delete subject data in caAERS

Brief Description

Subject data that is deleted in CTMS-local should be propogated to caAERS.

Primary Actor

caAERS User

Secondary Actor

None

Preconditions

1. caAERS is running normally at adopter's site.
2. caAERS has been bootstrapped with subject data from CTMS-local.
3. The business rules governing subject data is already available.
4. Data in caAERS and CTMS-local is synchronized.

Basic Flow of Events

1. Subject data has been deleted in CTMS-local.
2. CTMS-local calls a caaers web service to delete the subject data in caAERS.
3. One of two scenarios can occur:
    a. caAERS deletes participant data and sends confirmation message to CTMS.
    b. Error occurs [CTMS:for example, due to violation of a business rule] and caAERS sends error message to CTMS

Postconditions

1. caAERS is successfully deleted subject data from CTMS-local.
2. Data in caAERS and CTMS-local is synchronized.

Special Requirements

None

UC - Creating & Syncing Participant demographics from local CTMS to caAERS

Use Case Model

Provide a formal UML use case model with stick-figure actors associated with use cases and sub-use cases.

Brief Description

This document describe the use cases related to creating and syncing the participant demographic information from local CTMS to caAERS. This includes:

	local CTMS	caAERS
1	a new participant get created	it should also create a new participant
2	participant information got updated	it should update the information of ***same*** participant
~~3~~	~~participant got deleted~~	~~it should also delete the participant~~

This **DOES NOT COVER** following scenarios

	local CTMS	caAERS
1	Participant is assigned to a study on a site	TBD
2	participant assignment is removed from a study on a site	TBD

Primary Actor(s)

What individual or component is the primary actor? What is their role in the use case?

TBD

Secondary Actor(s)

What individual or component is the primary actor? What is their role in the use case?

TBD

Preconditions

caAERS need following condition to met before Creating a new Participant (in caAERS database):

1. Participant must follow the constraints defined in participant.xsd
2. Participant must not already existing in the caAERS database

Issues

1. How is the participant uniquely identified? Is it combination of first name and last name or something else?

caAERS need following condition to met before Updating a Participant (in caAERS database):

1. Participant must follow the constraints defined in participant.xsd
2. Participant must not already existing in the caAERS database

Issues

1. How is the participant uniquely identified? Is it combination of first name and last name or something else?

Exception Handling

caAERS will throw validation exception if any of the criteria mentioned in pre-conditions does not satisfy. We need to decide how the local CTMS will handle these exceptions. caAERS needs to define the interface related to exceptions.

Security

Only participant coordinator (a role in caAERS) can create/edit a participant. So we need to finalize the security issues also.

Basic Flow of Events

Provide an outline of the flow of use case. Provide a sequence diagram if it is helpful.

TBD

Post Conditions

What items hold true after the use case is enacted?

TBD

Data Items

What data items are of interest and should be modeled?

Special Requirements

Any special items of interest.

User Interface Prototype

Provide an optional UI mockup if useful.

2.0.3 Local CTMS to caAERS - Staff & Investigator updates

Primary Actor: caAERS User, caAERS System, Local CTMS system
Supporting/Secondary Actor: local CTMS user
Scope: system level - caAERS
Level: User Goal
Triggers: 1- Fresh install of caAERS, needs to add the research staff. **2-** research staff updated/added/deleted in local CTMS

Brief Description	There are two scenarios: 1. caAERs user goes to the admin module and manually imports Staff (research staff, physicians, and investigators) with their associated Organization(s) 2. local CTMS user makes a change (adds, modifies, or deletes) to Staff (research staff, physicians, and investigators), the local ctms creates an xml, calls a web service, and sends the update to caAERS

Preconditions	**General** 1. Organization must exist in caAERS (primary key is the NCI ID, so all organizations have to have some sort of identifier) **Admin module** 1. SemanticBits has published the xml schema 2. xml file has been created (by the adopter) 3. caAERS user has access to the Admin module **Web Service** 1. SemanticBits has published the xml schema 2. SemanticBits has published the wsdl 3. Local CTMS (manager) has configured the generation of the xml to include response information - required only when a response is requested

Success Scenario 1 - Admin area	1. Local CTMS user creates an xml
	2. caAERS user logs in to caAERS and access the Admin module
	3. caAERS user goes to the import area and selects the XML file
	4. caAERS validates the file
	  • caAERS returns a message if there are problems with the file
	  • caAERS prompts the user to continue
	5. caAERS imports the file
	6. caAERS generates a report
	  • Shows what records were updated (displaying identifier only)
	  • Shows what records were added (displaying identifier only)
	  • Shows what failed, if the xml is formatted correctly

Success Scenario 2 - web service	1. CTMS user makes a change (addition, modification, deletion) to Staff in the local CTMS and saves the change
	2. CTMS recognizes a change was made and 'packages' the change
	  • Generates the xml (xsd)
	  • Includes info on how caAERS should respond if a response is requested
	3. CTMS calls the wsdl (web service, basically url to be called)
	4. caAERS processes the information and persists the data
	  • Uses synchronous method
	5. If information was included in the xml, caAERS will send a response to the local CTMS

Extensions	**web Service 3a. connection to caAERS can not be established** 1. ? **web Service 3b. problem with xml (xsd file)** 1. ?
Sub-Flows	na
Post Conditions	Staff data in the caAERS database has been updated

Data Items	**Investigator** *Currently has the following required fields in caAERS:* First Name Last Name Email Address Phone Organization and Status (can add multiple - one is required, rest are optional *Currently has the following optional fields in caAERS:* Middle Name Investigator number Fax Organization and Status (can add multiple - one is required, rest are optional) Changes needed? Unique identifier should be? **Research Staff** *Currently has the following required fields in caAERS:* First Name Last Name Email Address Phone Organization *Currently has the following optional fields in caAERS:* Middle Name Research id Fax Changes needed? Unique identifier should be? Should you be able to assign research staff to multiple organizations? **Physician Info** *Should have the following required fields in caAERS:* First Name Last Name Email Address Phone Organization and Status (can add multiple - one is required, rest are optional *Should have the following optional fields in caAERS:* Middle Name Fax Organization and Status (can add multiple - one is required, rest are optional) Changes needed? Unique identifier should be? Is there some id that organizations use for physicians?
Special\Non-Functional Requirements	• Generated XML files should contain multiple records • Deletions will result in a "soft delete" where the information is marked as inactive

Open Issues	• For future release, need to determine how to handle locking down changes in caAERS based on fields/information the CTMS will push to caAERS
	• Are there security issues to resolve, since currently site coordinators and admin are the only users that can modify Staff
	• Have to determine the alternative flow/exception handling (ctms needs to know info wasn't updated in caAERS, needs to be able to resync)
	• The Unique identifier for investigator has to be determined.** Currently, the first & last names + organization id are used
	  • Investigator can be assigned to multiple organizations, but only has one email address/phone
	  • NCI Identifier is not required in caAERS at this time.*** Defined as "the identifier assigned in the NCI investigator registry to a physician approved for conducting a clinical trial"
	  • Based on definition, it should be unique to the investigator, not to the investigator/study combination.

Business Rules	• When updates occur, if there is a record in the xml file that is exactly the same in the caAERS database, caAERS will show that record as updated, since there's no character checks • XML file should only include Staff information (not study or participant) • When caAERS pulls up a study, only 'active' staff should be included, unless in audit mode

Models & User Interface Prototype	none

2.0.4 caAERS to local CTMS - AE updates

Primary Actor: caAERS
Supporting/Secondary Actor: local ctms
Scope: system level - caAERS
Level: User Goal
Trigger: AEs have been added or updated in caAERS

Brief Description	A cancer center uses caAERS to managed and maintains the AE collection for their studies, but they use a local ctms for maintain the subject and study information and for auditing and reporting purposes. So, when users add AEs to caAERS, caAERS needs to send that information to the local CTMS.
Preconditions	• Adopters have developed a way to receive AE information • Service is set up to send information from caAERS

Main Success Scenario	1. caAERS user makes a change (adds, modifies, or deletes) an AE in caAERS and saves the change
	2. caAERS saves the change and updates the database
	3. caAERS 'packages' the change in an xml (xsd)
	  a. Generates the xml (xsd)
	  b. Includes info on how the local CTMS should respond if a response is requested
	4. caAERS calls the WSDL (web service, basically url to be called)
	5. local CTMS processes the information and persists the data
	6. If information was included in the xml, local CTMS will send a response to caAERS

Extensions	**3a. The connection between the two systems is down** ? **3b. problem with xml (xsd file)** ?
Post-Conditions	The local ctms is in sync with caAERS concerning AE data
Data Items	?
Special\Non-Functional Requirements	?
Open Issues	• Different sites have different CTMS. May need to develop different methods to send the AEs • Each site has to provide information about how they would receive information (their schemas) • Would this need to include the expedite report fields, or just the general fields (reporting period) • How are we supporting the bi-directional communication? First supporting pushing data out, then 2nd phase focus on accepting data?
Models & User Interface Prototype	none

2.0.5 Lock fields in caAERS - UC

Primary Actor: caAERS
Supporting/Secondary Actor: caAERS user, CTMS
Scope: subsystem
Level: User Goal
Trigger: setting up caAERS

Brief Description	When caAERS is not used as the source of data creation, Organizations want the ability to lock down fields to prevent them from being edited . However, they also need to be able to bypass those lockdowns on a case-by-case basis. Fields that only exist within caAERS will always be editable in caAERS.

Preconditions	• information is maintained outside of caAERS • caAERS is set up to receive data • caAERS User has access to the admin module • caAERS User has access to the study module
Study Scenario Scenario	1. caAERS receives study information 2. study is imported using the caAERS Admin Import function as XML 3. study is imported using the caAERS Admin Import function as XLS 4. study is sent via message from adopter's CTMS 5. study is sent via message from C3PR 6. caAERS identifies where the study information came from 7. caAERS XML 8. caAERS XLS 9. CTMS message 10. C3PR message 11. caAERS locks down fields associated to the study source of truth type
Scenario Two	1. Organization assigns roles based on access requirements 2. Users with access to the modules have the ability to make changes to the area
Scenario Three	1. Organization installs caAERS 2. caAERS user goes to the 'lock down fields' page of the Admin module 3. caAERS user selects all fields that will be read-only within caAERS
Scenario Four	1. Organization installs caAERS 2. caAERS user goes to the 'lock down fields' page of the Admin module 3. caAERS user selects all fields that will be read-only within caAERS 4. User imports data from their CTMS 5. caAERS recognizes the data was not manually created and automatically selects "use lock down field configurations for this item" 6. caAERS user goes to enter info (staff, investigator, study, etc) 7. caAERS allows user to enter the info and asks user if they want to "use lock down field configurations for this item" 8. caAERS user saves the changes a. if user says Yes, the info will be saved and then locked down (per configuration) b. if user says No, the information will remain open to editing
Post-Conditions	• Study is added to caAERS • caAERS user is prevented from modifying certain study fields in caAERS • caAERS edit study module displays some fields as read-only
Data Items	• How Study was entered - manually, from C3PR, from adopter CTMS (file), ?** Do we need to lock the fields down if they come from C3PR, or is there a 2-way communication there? • Will there be a difference between receiving via message and importing using caAERS?*** How would you differentiate between the 1-time import of studies at the beginning of caAERS and continuing imports? • Will there be a difference between receiving via message and receiving via XLS? • Should fields be locked down question, w Yes/No • necessary for import using caAERS import functionality to help differentiate between 1-time & continuing imports
Special\Non-Functional Requirements	Fields that are locked down will appear as read-only in the edit study flow
Business Rules	• The create/edit study functionality cannot be completely locked down because some fields do not come through an import • solicited AEs • expedited report format • Once a study is added to caAERS it can not be removed

Open Issues	• adopters need to agree on which fields will always be included with the import/locked down in caAERS** very difficult to customize locking down based on organization
Models & User Interface Prototype	

Import research staff into caAERS - UC

Primary Actor: caAERS User
Supporting/Secondary Actor: caAERS, CTMS user who creates the XML
Scope: subsystem - Admin module, import section
Level: User Goal
Trigger: Initial caAERS setup, update to research staff data

Brief Description	• caAERS user is setting up caAERS for the first time and imports an XML files containing information about Research Staff, including their role(s) and which organizations they belong to • caAERS user is updating the Research Staff data in caAERS and imports an XML files containing updates and additions of Research Staff, including their role(s) and which organizations they belong to *Note: Deletions are not part of this release*
Preconditions	1. Properly formatted XML file exists and is available 2. the caAERS user must have access to the admin module
Initial Import	1. caAERS user goes to the Admin module, selects Import, and clicks "Import Research Staff" 2. caAERS user either enters the location of the XML file or clicks browse to locate the location of the XML file, then clicks **Save & Continue** 3. caAERS validates that the file is formatted properly. 4. caAERS displays a Review and Submit page a. section for invalid entries b. section for records that will be loaded 5. caAERS user decides to continue or quit • If continue click Import (save?) • If quit to fix the xml, can close out of caAERS 6. caAERS imports the records
Update Records Import	1. caAERS user goes to the Admin module, selects Import, and clicks "Import Research Staff" 2. caAERS user either enters the location of the XML file or clicks browse to locate the location of the XML file, then clicks **Save & Continue** 3. caAERS validates that the file is formatted properly 4. caAERS displays a Review and Submit page a. section for invalid entries b. section for records that will be loaded 5. caAERS user decides to continue or quit • If continue click Import (save?) • If quit to fix the xml, can close out of caAERS 6. caAERS imports the records • If the record exists in the database, caAERS compares what is in the database to the xml and updates the field that have changed • If the record doesn't exist in the database, caAERS adds it to the database
Extensions	none
Sub-Flows	none
Post-conditions	1. Research Staff data has been loaded into the caAERS database. 2. Research Staff data has been updated in the caAERS database 3. Research Staff data may now be edited in the caAERS interface.
Data Items	The following fields can be added/updated using this feature: none

Special\Non-Functional Requirements	none
Business Rules	Research staff data can not be deleted from the database
Open Issues	none
Models & User Interface Prototype	see attached xml files

2.1.2 Import Investigators - caAERS UC

Primary Actor: caAERS User
Supporting/Secondary Actor: caAERS, CTMS user who creates the XML
Scope: subsystem - Admin module, import section
Level: User Goal
Trigger: Initial caAERS setup, update to investigator data

Brief Description	• caAERS user is setting up caAERS for the first time and imports an XML files containing information about investigators, including which organizations they belong to • caAERS user is updating the investigator data in caAERS and imports an XML files containing updates and additions of investigators, including which organizations they belong to *Note: Deletions are not part of this release*
Preconditions	1. Properly formatted XML file exists and is available 2. the caAERS user must have access to the admin module
Initial Import	1. caAERS user goes to the Admin module, selects Import, and clicks "Import Investigator" 2. caAERS user either enters the location of the XML file or clicks browse to locate the location of the XML file, then clicks **Save & Continue** 3. caAERS validates that the file is formatted properly. 4. caAERS displays a Review and Submit page a. section for invalid entries b. section for records that will be loaded 5. caAERS user decides to continue or quit • If continue click Import (save?) • If quit to fix the xml, can close out of caAERS 6. caAERS imports the records
Update Records Import	1. caAERS user goes to the Admin module, selects Import, and clicks "Import Investigator" 2. caAERS user either enters the location of the XML file or clicks browse to locate the location of the XML file, then clicks **Save & Continue** 3. caAERS validates that the file is formatted properly 4. caAERS displays a Review and Submit page a. section for invalid entries b. section for records that will be loaded 5. caAERS user decides to continue or quit • If continue click Import (save?) • If quit to fix the xml, can close out of caAERS 6. caAERS imports the records • If the record exists in the database, caAERS compares what is in the database to the xml and updates the field that have changed • If the record doesn't exist in the database, caAERS adds it to the database
Extensions	none
Sub-Flows	none
Post-conditions	1. Investigator data has been loaded into the caAERS database. 2. Investigator data has been updated in the caAERS database 3. Investigator data may now be edited in the caAERS interface.

Special\Non-Functional Requirements	none
Business Rules	Investigator data can not be deleted from the database
Open Issues	none
Models & User Interface Prototype	see attached xml files

2.1.3 Import Study Data - caAERS UC

Primary Actor: caAERS User
Supporting/Secondary Actor: caAERS, CTMS user who creates the XML
Scope: subsystem - Admin module, import section
Level: User Goal
Trigger: Initial caAERS setup, update to study data

Brief Description	• caAERS user is setting up caAERS for the first time and imports an XML files containing information about Studies, including agent information, assigned staff and investigators, etc • caAERS user is updating the study data in caAERS and imports an XML files containing updates and additions of Research Staff, including agent information, assigned staff and investigators, etc *Note: Deletions are not part of this release*
Preconditions	1. Properly formatted XML file exists and is available 2. the caAERS user must have access to the admin module
Initial Import	1. caAERS user goes to the Admin module, selects Import, and clicks "Import Study / Protocol" 2. caAERS user either enters the location of the XML file or clicks browse to locate the location of the XML file, then clicks **Save & Continue** 3. caAERS validates that the file is formatted properly. 4. caAERS displays a Review and Submit page a. section for invalid entries b. section for records that will be loaded 5. caAERS user decides to continue or quit • If continue click Import (save?) • If quit to fix the xml, can close out of caAERS 6. caAERS imports the records
Update Records Import	1. caAERS user goes to the Admin module, selects Import, and clicks "Import Study / Protocol" 2. caAERS user either enters the location of the XML file or clicks browse to locate the location of the XML file, then clicks **Save & Continue** 3. caAERS validates that the file is formatted properly 4. caAERS displays a Review and Submit page a. section for invalid entries b. section for records that will be loaded 5. caAERS user decides to continue or quit • If continue click Import (save?) • If quit to fix the xml, can close out of caAERS 6. caAERS imports the records • If the record exists in the database, caAERS compares what is in the database to the xml and updates the field that have changed • If the record doesn't exist in the database, caAERS adds it to the database
Extensions	none
Sub-Flows	none

Post-conditions	1. Study has been loaded into the caAERS database. 2. Study data has been updated in the caAERS database 3. Study abstraction data may be edited in the caAERS interface. 4. Rule sets can be associated with the Study and Subjects can be assigned to it.
Special\Non-Functional Requirements	none
Business Rules	• research staff must be imported before Studies (can't assign research staff to a study if they doesn't exist in caAERS) • Investigators must be imported before Studies (can't assign investigators to a study if they doesn't exist in caAERS) • research staff data can not be deleted from the database
Open Issues	none
Models & User Interface Prototype	• see attached xml files • XML Schema • XML Example

2.1.4 Import Patient Data - caAERS UC

Scope: subsystem - Admin module, import section
Level: User Goal
Trigger: Initial caAERS setup, update to Patient data

Brief Description	• caAERS user is setting up caAERS for the first time and imports an XML files containing information about Patients/subjects, including on which study or studies they are enrolled. • caAERS user is updating the patient/subject data in caAERS and imports an XML files containing updates and additions of Patients/subjects, including on which study or studies they are enrolled. *Note: Deletions are not part of this release*
Primary Actor	caAERS user
Secondary Actor	caAERS, CTMS user who creates the XML
Preconditions	1. Properly formatted XML file exists and is available 2. The studies on which patients are enrolled must already exist in caAERS 3. the caAERS user must have access to the admin module

Initial Import	1. caAERS user goes to the Admin module, selects Import, and clicks "Import Subject"
	2. caAERS user either enters the location of the XML file or clicks browse to locate the location of the XML file, then clicks **Save & Continue**
	3. caAERS validates that the file is formatted properly.
	4. caAERS displays a Review and Submit page
	  a. section for invalid entries
	  b. section for records that will be loaded
	5. caAERS user decides to continue or quit
	  • If continue click Import (save?)
	  • If quit to fix the xml, can close out of caAERS
	6. caAERS imports the records

Update Records Import	1. caAERS user goes to the Admin module, selects Import, and clicks "Import Subject" 2. caAERS user either enters the location of the XML file or clicks browse to locate the location of the XML file, then clicks **Save & Continue** 3. caAERS validates that the file is formatted properly. 4. caAERS displays a Review and Submit page a. section for invalid entries b. section for records that will be loaded 5. caAERS user decides to continue or quit • If continue click Import (save?) • If quit to fix the xml, can close out of caAERS 6. caAERS imports the records • If the record exists in the database, caAERS compares what is in the database to the xml and updates the field that have changed • If the record doesn't exist in the database, caAERS adds it to the database
Extensions	none
Sub-Flows	none
Postconditions	1. Patient/subject data has been loaded into the caAERS database. 2. Patient/subject data has been updated in the caAERS database 3. Patient/subject data may now be edited in the caAERS interface. 4. AE reports may now be entered for the Patients.
Data Items	The following fields can be added/updated using this feature: none
Special\Non-Functional Requirements	• see the following links for the schema and an xml example • XML Schema • XML Example
Business Rules	Studies must be imported before patients/subjects (can't assign a patient to a study that doesn't exist in caAERS)
Open Issues	none
Models & User Interface Prototype	see attached xml files

Adverse Event Management Service API

Primary Actor: caAERS User
Supporting/Secondary Actor: caAERS
Scope: system

Level: User Goal
Trigger: caAERS user wants to send list of AEs to caAERS system

Brief Description

- API to import adverse events to caAERS System.

Preconditions

- Study exists in caAERS
- Participant exists in caAERS.

Requirements

- Adverse Events for a given Course , Participant and Study.
- Create,Update,Delete Adverse Events.
- Invoke System and SAE rules while create and update.
- Create course if course doesn't exist in caAERS.
- If an AE is a SAE , send notification to study personnel.

Technical Details

- CTMS:AdverseEvent Management Schema
- CTMS:AdverseEventManagementService
- CTMS:Service WSDL

Sample SOAP messages :

CTMS:1. Create Adverse Events.

CTMS:2. Create/Update Adverse Events

CTMS:3. Delete Adverse Events

2.3.3 Search Protocol Abstraction Service

Primary Actor: caAERS User
Supporting/Secondary Actor: caAERS System, NCI Protocol Abstraction (PA) service
Scope:
Level: User Goal
Trigger:

Brief Description	This use case describes the process by which a caAERS user can search for and access study definitions using the P
Preconditions	• The caAERS user has valid access and credentials to perform the necessary activities within caAERS • There is an internet connection available • The PA service is available
Main Success Scenario	1. The caAERS user logs into caAERS 2. The caAERS user goes to the Study >> Search Studies tab 3. The caAERS user enters some search criteria and presses "Search" 4. The caAERS System executes a search of studies that match the search criteria. a. The local caAERS database is searched b. The PA service is searched 5. The results of the search are displayed  # The caAERS user can select a study and will enter the Edi
Extensions	Enter any alternative flows, failure flows, and exceptions
Sub-Flows	Loading INDs/IDEs
Post-Conditions	What items hold true after the use case is enacted?
Data Items	What data items are of interest and should be modeled?
Special\Non-Functional Requirements	Any special items of interest or non-functional requirements to be addressed
Business Rules	Enter rules here
Open Issues	**Any questions about the flow that need to be answered before the flow can be finalized.**

Models & User Interface Prototype	Provide an optional UI mockup, if useful. Provide an optional UML diagram As per our discussion last week in regards to when would CTMS Suite apps call the PA service based on the Process here is the link for the Update and Amendment spreadsheet that I had mentioned on the call. https://gforge.nci.nih.gov/plugins/scmsvn/viewcvs.php/trunk/documents/analysis_and_design/data/CTRP_Update_Ele https://gforge.nci.nih.gov/plugins/scmsvn/viewcvs.php/trunk/documents/analysis_and_design/data/CTRP_Update_Ele Some explanation on this spreadsheet -- – It is a working document for the COPPA/CTRP project and will be modified as the CTRP stakeholders finalize this in – It groups the list of COPPA/CTRP elements into 2 groups from "subject to change" perspective – Grouped as "Upda – The sheets on this spreadsheet also distinguish which application in CTRP collects a particular Protocol element. – Relation of Protocol Processing State to the overall Application workflow — At end of Trial Registration (registration Processing State of "Accepted" AND at end of Trial Abstraction (Abstraction elements) the Trial gets a Processing Sta Evaluation for CTMS Suite of Apps -- Please review the list of elements in both the CTRP Registration App and Protocol Abstraction (PA) list of elements ar Suite apps needs a Protocol with a state of "Accepted" or "Abstracted". Please know that these Protocols/Trials will ge and Updates. We are still working out the details on Update elements. Please let me know if you have questions. This spreadsheet is a COPPA/CTRP artifact and not customized to be cons it helps, we can review this spreadsheet on one of the scrum calls this week.

2.3.3.1 Load Regulatory Applications from Protocol Abstraction Service

Primary Actor: caAERS User
Supporting/Secondary Actor: caAERS System, NCI Protocol Abstraction (PA) service
Scope:
Level: User Goal
Trigger: The caAERS user successfully executes the search study in PA use case

Brief Description

This use case describes the process by which a caAERS user can search for and access study definitions using the PA service.

Preconditions

- The caAERS user has valid access and credentials to perform the necessary activities within caAERS
- The PA service is available

Steps

Main Success Scenario

1. The caAERS user successfully executes the search study in PA use case
2. The regulatory application information (i.e. INDs and IDEs) is saved to the caAERS system
    a. The regulatory application information is not associated to the study
    b. If the regulatory application information already exists in the caAERS system as identified by the application number and application type, then the data is updated in caAERS

Extensions

1. A caAERS user enters the Create or Edit Study flow
2. The user goes to the Agents tab
3. The user adds or edits an Agent
    a. In the IND box all regulatory applications of that type will be available.

1. A caAERS user enters the Administration >> INDs tab
2. The user searches for regulatory applications and finds those obtained from the PA service.

Sub-Flows

Post Conditions

- What items hold true after the use case is enacted?

Data Items

Several changes to the model are required. Here is a summary:

1. The class "InvestigationalNewDrug" is being renamed to "RegulatoryApplication."
    a. RegulatoryApplication roughly maps to "StudyIndIde" from the PAv3.1 model and
    b. Several attributes are being added, renamed, or having the datatypes changed.
2. An new class "RegulatoryAuthority" is being created, with associations to "Organization" and to "RegulatoryApplication"
    a. Groovy scripts may be needed to ensure all RegulatoryAuthories are in Organization.

Class: RegulatoryApplication

Attribute	Value	Description
expandedAccessStatusCode	Available Expanded	access is currently available for this treatment
	No longer available	Expanded access was available for this treatment previously but is not currently available and will not be available in the future
	Temporarily not available	Expanded access is not currently available for this treatment, but is expected to be available in the future
	Approved for marketing	This treatment has been approved for sale to the public
grantorCode	CDER	Center for Drug Evaluation and Research
	CBER	Center for Biologics Evaluation and Research
	CDRH	Center for Devices and Radiological Health
holderTypeCode	Organization	
	Industry	
	Investigator	
	NIH	National Health Institute
	NCI	National Cancer Institute
indIdeTypeCode	IND	Investigational new drug
	IDE	Investigational device exemption
nciDivProgHolderCode	CCR	Center for Cancer Research
	CTEP	Cancer Therapy Evaluation Program
	DCB	Division of Cancer Biology
	DCCPS	Division of Cancer Control and Population Sciences
	DCEG	Division of Cancer Epidemiology and Genetics
	DTP	Developmental Therapeutics Program
	DCP	Division of Cancer Prevention
	DEA	Division of Extramural Activities
	OD	Office of the Director, NCI, NIH
	OSB/SPOREs	Organ Systems Branch (OSB) /Specialized Programs of Research Excellence (SPOREs)
	CIP	Cancer Imaging Program
	CDP	Cancer Diagnosis Program
	TRP	Translational Research Program
	RRP	Radiation Research Program
	N/A	Not applicable
nihInstholderCode	NEI	National Eye Institute
	NHLBI	National Heart, Lung, and Blood Institute

	NHGRI	National Human Genome Research Institute
	NIA	National Institute on Aging
	NIAAA	National Institute on Alcohol Abuse and Alcoholism
	NIAID	National Institute of Allergy and Infectious Diseases
	NIAMS	National Institute of Arthritis and Musculoskeletal and Skin Diseases
	NIBIB	National Institute of Biomedical Imaging and Bioengineering
	NICHD	Eunice Kennedy Shriver National Institute of Child Health and Human Development
	NIDCD	National Institute on Deafness and Other Communication Disorders
	NIDCR	National Institute of Dental and Craniofacial Research
	NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
	NIDA	National Institute on Drug Abuse
	NIEHS	National Institute of Environmental Health Sciences
	NIGMS	National Institute of General Medical Sciences
	NIMH	National Institute of Mental Health
	NINDS	National Institute of Neurological Disorders and Stroke
	NINR	National Institute of Nursing Research
	NLM	National Library of Medicine
	CIT	Center for Information Technology
	CSR	Center for Scientific Review
	FIC	John E. Fogarty International Center for Advanced Study in the Health Sciences
	NCCAM	National Center for Complementary and Alternative Medicine
	NCMHD	National Center on Minority Health and Health Disparities
	NCRR	National Center for Research Resources (NCRR
	CC	NIH Clinical Center
	OD	Office of the Director

The COPPA Valid Values file was referenced for the above attributes and values.

Special\Non-Functional Requirements

- Any special items of interest or non-functional requirements to be addressed

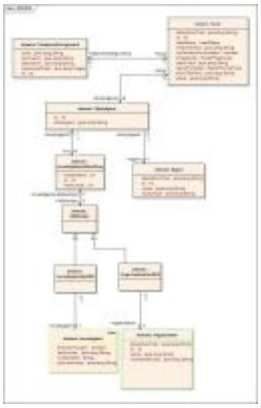
Business Rules

- enter rules here

Open Issues

- Need to confirm nihInstholderCode format (is it the acronym or the acronym-name?).
- nihInstholderCode does not contain NCI-National Cancer Institue. Is this correct?
- Are there business rules with respect of when we will get a nihInstholderCode or a NCIDivisionProgramCode?
- Any questions about the flow that need to be answered before the flow can be finalized.

Models & User Interface Prototype

Previous model:  New model: 

https://gforge.nci.nih.gov/plugins/scmsvn/viewcvs.php/trunk/documents/analysis_and_design/data/?root=coppa

Protocol Abstraction Search - Design

PA DESIGN DOC

Introduction:

The modes of fetching the Protocol details can be split into two categories, Update and Amendment.

Update:

The parts of the study that can change without requiring a formal amendment qualify as Updates. These attributes can be updated at any point without warning and thus require to be fetched every time the corresponding object is displayed, irrespective of whether it's a read or a write operation.

In the C3PR domain model various attributes of the Study domain object fall under this category. These "updateable attributes" are the ones that will be annotated with @RemoteProperty. This will ensure that every time the Study object is loaded, fresh data will be fetched from COPPA and inserted into these attributes by the Hibernate Interceptor and displayed to the user.

One of the critical details in this approach is the transferring of data between collections while intercepting and populating the Hibernate Objects. There are two approaches being discussed and investigated right now.

Approach 1: Custom Collection Wrapper with Lazy Loading

In this approach, a custom Collection will be used which will have the Hibernate Collection, known as PersistentBag, as an attribute. The Hibernate bag in the Session is replaced with this custom collection by the interceptor. At this point the lists aren't initialized. Whenever the collection is requested the custom wrapper will fetch all the remote attributes and update the PersistentBag. This is when the lists are initialized. This ensures that the collection associated with the Hibernate session is updated with the latest remote objects.

Approach 2: Eager Loading

In this approach all the associated lists of the object being loaded are eagerly initialized in the interceptor itself. This is done so that the interceptor can fetch the remote data and update the PersistentBag with the latest data. This means that when the study is loaded the associated study sites, eligibility criteria etc are all updated and loaded eagerly. This may not be very efficient, but it ensures latest data at all times.

The following table lists the attributes which fall under the Update category. Please note that this list is a work in progress and can be updated going forward.

Study Site Name

Study Site Target Accrual

Study Site IRB Approval Date

Study Site Start Date

Study Target Accrual

Study Personnel

Study Investigators

Amendment:

The parts of the Study which cannot change unless there is a formal amendment qualify as amendment details. This basic nature of amendment

details encourages the employment of a different strategy; the checking for Amendment Version before fetching fresh data.

In C3PR every Study has a list of StudyVersion objects each of which correspond to an amendment version. They are sorted by the Amendment Date and the current Study Version is the one with the latest Amendment Date. C3PR does not update the current Study Version every time it is loaded, instead, at strategic points in the application (listed below) an Amendment version check is performed by making a COPPA call which tells C3PR if it has the latest version. If so the values in the local database are used. If not then the latest version is fetched from COPPA and a new Study Version with these values is created and inserted into the Study. This strategy ensures that the application only fetches amendment based data when they are updated and avoids unnecessary calls to COPPA services.

One of the critical decisions in this approach is determining when to check for the AmendmentVersion. The two workflows in C3PR that demand this check are as follows:

When the user clicks on a study in the study search results to enter Manage Study from where he can go into Amend or Edit flow.
When the Create Registration Service picks up a study for accrual.

The following table lists the attributes which fall under this category. Please note that this list is a work in progress and can be updated going forward.

Phone Call Randomization Number

Stratification

Blinded Indicator

Multi Institution Indicator

Randomization Indicator

Stratification Indicator

Coordinating center

Coordinating center assigned Identifier

Funding Sponsor

PI

Short title

Phase

Type

Study Disease

Long Title

Module 2 Interface Local Trial Databases Use Cases (caAERS)

Module 2 - Interface Local Trial Databases

This component will provide a standards-based API for integrating the Adverse Event Data Capture tool with an adopting institution's clinical trials management database. This may include a webservices or caGrid interface, depending on the touch points required.

- Import Legacy AE Data (caAERS UC)
- Import Current AE Data (caAERS UC)

Import Current AE Data (caAERS UC)

Brief Description	Study Coordinator imports XML files containing current AE data. This data will be stored in the caAERS database and will be evaluated for expedited reporting and completeness.
Primary Actor	Study Coordinator (SC)
Secondary Actors	A data manager or other IT personnel will first have to create the XML files, most likely from data within the existing CTMS.

Preconditions	1. Properly formatted XML file exists and is available to the SC. 2. The studies and patient enrollment information must already exist in caAERS. 3. Within the XML, the "status" element should set to "CURRENT."
Basic Flow of Events	1. SC chooses to "Import AE Data." 2. A wizard is launched, prompting SC for the location of the XML file. 3. caAERS verifies that the file is formatted properly. The file is rejected if it is not formatted properly. 4. caAERS verifies that each AE in the file is using a valid term and grade, and that "Other specify" values have been included. Any AE with an invalid term or grade or that is missing an "Other specify" value will be rejected. 5. SC is presented with a screen that lists all of the AEs that will be imported and a list that will be rejected. 6. SC decides to either accept the import or cancel it to fix the invalid data. 7. If the import is accepted, the AEs will be evaluated for expedited reporting requirements.
Postconditions	Expedited Reports will be created for AEs that have been evaluated as requiring expedited reporting. The SC will then be able to fill in the additional required data and submit the report.
Special Requirements	XML Schema XML Example

Import Legacy AE Data (caAERS UC)

Brief Description	Study Coordinator imports XML files containing legacy AE data. This data will be stored in the caAERS database but will not be evaluated for reporting or required fields.
Primary Actor	Study Coordinator (SC)
Secondary Actors	A data manager or other IT personnel will first have to create the XML files, most likely from data within the existing CTMS.
Preconditions	1. Properly formatted XML file exists and is available to the SC. 2. The studies and patient enrollment information must already exist in caAERS. 3. Within the XML, the "status" element should set to "LEGACY."
Basic Flow of Events	1. SC chooses to "Import AE Data." 2. A wizard is launched, prompting SC for the location of the XML file. 3. caAERS verifies that the file is formatted properly. The file is rejected if it is not formatted properly. 4. caAERS verifies that each AE in the file is using a valid term and grade, and that "Other specify" values have been included. Any AE with an invalid term or grade or that is missing an "Other specify" value will be rejected. 5. SC is presented with a screen that lists all of the AEs that will be imported and a list that will be rejected. 6. SC decides to either accept the import or cancel it to fix the invalid data.
Postconditions	AE data has been loaded into the caAERS database.
Special Requirements	XML Schema XML Example

Push AE notifications to PSC (caAERS UC)

Brief Description	While viewing an AE Report for a Subject, the Participant Coordinator will be able to click a button to send information about the primary AE in the report to the Patient Study Calendar (PSC). This will alert the next person who views the Subject's schedule that an AE has occurred and modifications to the Subject's treatment may be necessary.
Primary Actor	Participant Coordinators (PC)
Secondary Actors	User of PSC
Preconditions	1. Subject's schedule has been generated in PSC. 2. AE report has been created for the Subject.

Basic Flow of Events	1. PC is viewing AE data for a Subject. 2. PC decides to send an alert to the Subject's calendar. 3. PC clicks a button on the list AE page to send data about a particular AE to PSC. 4. PC receives a confirmation that PSC received the data.
Post-conditions	An alert will show in the Subject's calendar within PSC.
Special Requirements	Both caAERS and PSC must be configured as per CCTS specifications.

Receive Lab Data from LabViewer

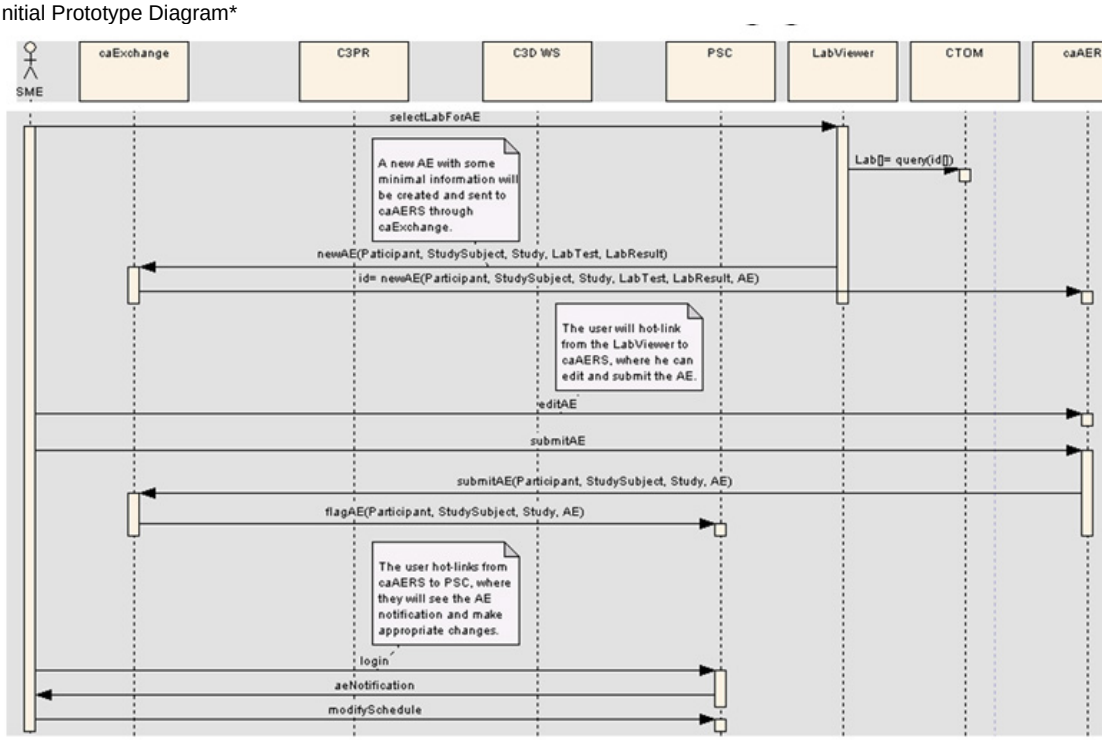
Scope: system
Level: User Goal
Trigger: user enters lab values in lab viewer

Brief Description	User selects lab values in LabViewer based upon the date range in which they are interested. LabViewer highlights va that are out of range (potential AEs). The user clicks on the out of range lab values that they wish to send to caAERS. LabViewer sends a message to caAERS. For the specific patient (subject) - study combo, caAERS creates an alert th will be available in the manage report page, expedited report flow, and routine AE flow stating that labs have been adc
Primary Actor	LabViewer, caAERS
Secondary Actor	CTMS user
Preconditions	• User must have the CTMS suite installed, or at least the LabViewer, caAERS, and caXchange. • Study must exist in caAERS • Patient must exist in caAERS
Main Success Scenario	1. Lab is selected in LabViewer and user clicks a button to send it to caAERS 2. Lab information is sent from Lab Viewer to caAERS via a message sent through caXchange hub a. message includes, at minimum, the following information: • patient/subject id • Study ID • date/time • Lab test name • Test results • numeric results • unit of measure • lower limit • upper limit 3. caAERS receives the message. For the subject-study combo, caAERS a. adds alert information in the following locations • manage report page • expedited report flow • routine AE flow b. 4. User accesses caAERS a. clicks the caAERS link from labviewer, which will automatically log the user in to caAERS and open t patient-study combo's manage report page b. manually logs in to caAERS, searches for the patient-study combo, and opens the manage report pa
Extensions	none
Sub-Flows	none
Post-Conditions	• Message about Labs from LabViewer is in the Manage Reports in caAERS • Labs/values are available in Lab section of new expedited reports

Data Items	• caAERS microbology lab fields:** lab category
	  • lab test name
	  • site
	  • date
	  • infectious agent
	• caAERS other lab fields:** lab category
	  • lab test name
	  • units
	  • baseline value & date
	  • worst value & date
	  • recovery value & date
	• labviewer fields:** patient id
	  • date/time
	  • Lab test
	  • Test results
	  • numeric results
	  • unit of measure
	  • lower limit
	  • upper limit

Special\Non-Functional Requirements	• Use the side-mounted window as found in C3PR for the alerts in the two AE flows • Add "Alerts" section at the top of the manage Reports page • Each alert must be able to be dismissed (removed completely from the list) and printed • There must be a link to the lab viewer search page from the caAERS Alert sections
Business Rules	caAERS can only receive messages for study-subject combinations already in caAERS

Open Issues	• The pre-existing message is attached to the wiki. There are many fields in the message that aren't important f caAERS. The fields that are important are:** participant?
	  • studysite
	  • studysubject
	  • activity? An abstract class that defines actions that can, in the context of a study, be planned, schedu or performed. An activity may be related to other activities in arbitrarily complex ways using instance ActivityRelationship. For example, a surgical procedure, a laboratory test, or the administration of the drug would all be considered activities.
	  • LabResult
	  • numericResult
	  • numericUnit
	  • referenceRangeHigh
	  • referenceRangeLow
	  • referenceTextList
	  • name?
	• What fields are not collected in the message that are necessary to populate the labs tab of the expedited repo There are two messages, one that was sent to caAERS and one that was sent to C3D
	  • The one with C3D is more current, works with grid service, bridge, etc
	  • Patrick Conrad to provide the service already implemented
	  •
	• caAERS uses a defined vocabulary, LabViewer uses an uncontrolled vocabulary - causes problems with tryin pre-populate info in an expedited reports labs page

Models & User Interface Prototype	Initial Prototype Diagram* 

Receive Registration Data from C3PR (caAERS UC)

Brief Description	When a patient is registered to a Study in C3PR, that registration can be sent to caAERS. The Study must already be in the caAERS database, but the patient will be added if he or she does not already exist.
Primary Actor	C3PR (CancerCenter Clinical Participant Registry) User
Secondary Actor	caAERS
Preconditions	The Study must already exist within both caAERS and C3PR.

Basic Flow of Events	1. C3PR User registers a patient to a Study
	2. C3PR sends registration message to caAERS
	3. If patient already exists in caAERS database:
	  a. Patient is registered to Study.
	4. If patient does not already exist in caAERS database:
	  a. Patient is added to caAERS database.
	  b. Patient is registered to Study.

Post-conditions	1. Patient is registered to Study in caAERS. 2. AEs may now be entered for the Patient on the Study.
Special Requirements	Both caAERS and C3PR must be configured as per CCTS specifications.

Receive Study Data from C3PR (caAERS UC)

Brief Description	When a Study is created in C3PR, the data will also be sent to caAERS. caAERS will add the Study to its own database.
Primary Actor	C3PR (CancerCenter Clinical Participant Registry) User

Secondary Actor	caAERS
Preconditions	caAERS and C3PR have been configured to exchange messages.
Basic Flow of Events	1. C3PR User creates a Study 2. C3PR sends creation message to caAERS 3. caAERS verifies completeness and uniqueness of message. 4. caAERS creates the Study within the caAERS database.
Post-conditions	Study is now available in caAERS to finish abstraction, ruleset creation, and patient registration.
Special Requirements	Both caAERS and C3PR must be configured as per CCTS specifications.

Whiteboard - caAERS Web Services Security

> This page is a white board for discussing authorization use cases and a place to draft the authorization use cases.

A use case has been created for authorization. Please review and be ready to discuss. 13.1 Using an Organization's system for Authorization - caAERS UC draft

Approach

The OASIS WS-Security specification is the open standard for Web services security.

We use UsernameToken Profile for caAERS web services. UsernameToken Profile describes how a Web service client can supply a UsernameToken as a way to identify the requestor by a username and password. The following XML snippet shows a sample WS-Security UsernameToken:

```
    <wsse:Security>
      <wsse:UsernameToken>
        <wsse:Username>user@domain.com</wsse:Username>
        <wsse:Password>password</wsse:Password>
      </wsse:UsernameToken>
    </wsse:Security>
```

To authenticate using WS-Security, you'd need to add a SOAP header to the SOAP envelope. This header would contain the WS-Security information, as follows:

```
<soapenv:Envelope xmlns:soapenv="http://schemas.xmlsoap.org/soap/envelope/"
         xmlns:adv="http://webservice.caaers.cabig.nci.nih.gov/adverseevent"
         xmlns:wsse="http://docs.oasis-open.org/wss/2004/01/oasis-200401-wss-wssecurity-secext-1.0.xsd">
  <soapenv:Header>
    <wsse:Security>
      <wsse:UsernameToken>
        <wsse:Username>user@domain.com</wsse:Username>
        <wsse:Password>password</wsse:Password>
      </wsse:UsernameToken>
    </wsse:Security>
  </soapenv:Header>
  <soapenv:Body>
    <adv:createAdverseEvent>
      .....
      </adv:AdverseEventsInputMessage>
    </adv:createAdverseEvent>
  </soapenv:Body>
</soapenv:Envelope>
```

Implementation

- caAERS web services are implemented using Codehaus XFire java SOAP framework. http://xfire.codehaus.org/
- Implemented a handler (validateUserTokenHandler) on service side to process the WS-Security informantion in SOAP header
- validateUserTokenHandler parses the header information and authenticates the user using caAERS Authentication manager.

Handler Configuration :

```
<bean id="adverseEventManagementService" class="org.codehaus.xfire.spring.ServiceBean">
      ........
      <property name="inHandlers">
        <list>
          <ref bean="domInHandler"/>
          <ref bean="validateUserTokenHandler"/>
          <ref bean="xFireSchemaValidationHandler"/>
        </list>
      </property>
      ...........
  </bean>
<bean id="validateUserTokenHandler" autowire="byType"  class="gov.nih.nci.cabig.caaers.web.utils.ValidateUserTokenHandler" />
```

Questions & Discussion

Whiteboard - Local CTMS to caAERS Integration

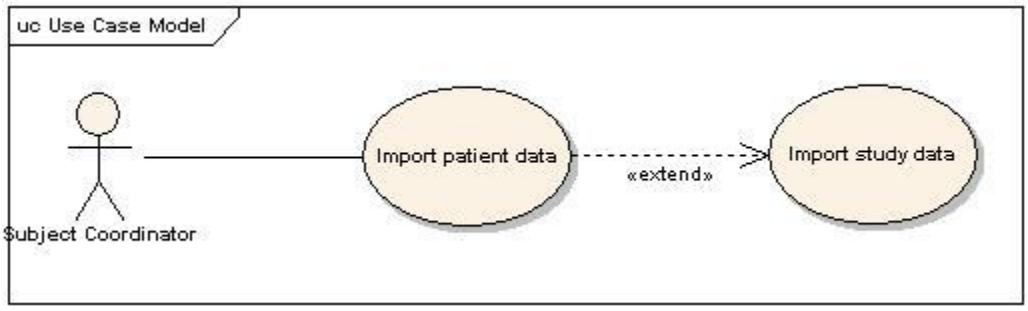
> This page is intended to be a White board for Local-CTMS to caAERS Integration Discussion.

04/29/2008 :: caAERS team met to discuss local-ctms to caAERS integration use cases (Level -1 Use Cases)
05/05/08: Action items: SemanticBits to provide schema report and xml samples

Topic of Discussion

The Study and Participant information available in the Local-CTMS should be available in caAERS for use.
Srini had inputs from the conf call with the technical team of CALGB and MAYO.

Members : Vinay Kumar,Srini Akkala, Saurabh Agarwal,Monish Dombla, Karthik Iyer.



Participant Use Cases

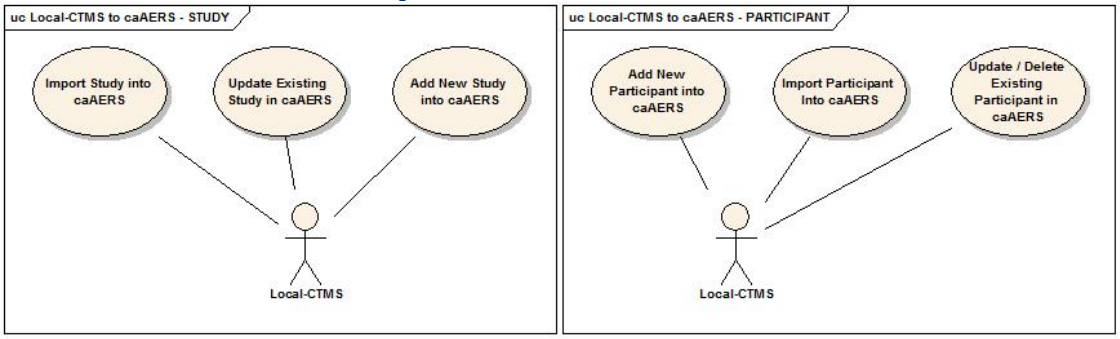
1. Existing participant information in Local-CTMS should be made available in caAERS (Depends on Study Information) - already done via import at initial setup
2. New participant/s created in Local-CTMS should propogate to caAERS.
3. Updates to existing participant/s in Local-CTMS should propogate to caAERS
    - Withdrawn consent, removing patients from studies, should these be addressed in caAERS? - issue to be raised during functional meeting.

Study Use Cases

1. Existing study information in Local-CTMS should be made available in caAERS - already done via import at initial setup
2. New Study created in Local-CTMS should propogate to caAERS.
3. Updates to existing Study / Studies in Local-CTMS should propogate to caAERS.

Use Case Diagrams

Whiteboard - Local CTMS to caAERS Integration



Technical Points

caAERS system should provide fine grained services for Local-CTMS to use for the above mentioned.

There are 2 xml schemas related to the discussion.

- CTMS:studyXSD.xsd
- CTMS:participantXSD.xsd

Existing Functionality in caAERS

1: Study Import.
2: Participant Import.

Participant

Constraints and Validations

Xml should match with CTMS:participantXSD.xsd. Following are some constraints and validations

Participant

attribute name	attribute type	conditions or occurance
firstName	String	
lastName	String	
maidenName	String	minOccurs="0"
middleName		minOccurs="0"
birthDate	date	
birthYear	customDateType	
gender	String	minOccurs="0" or values could only be "Male", "Female","Not Reported", "Unknown"
race	String	minOccurs="0" or value can only be one of "Asian", "White", "Black or African American", "American Indian or Alaska Native", "Native Hawaiian or other Pacific Islander", "Not Reported", "Unknown",
ethnicity	String	minOccurs="0" or value can only be one of "Hispanic or Latino", "Non Hispanic or Latino", "Not Reported", "Unknown"
identifiers	Identifier	
assignments	Assignment	minOccurs="1"

Assignment

attribute name	attribute type	conditions
studySite	StudySite	

StudySite

attribute name	attribute type	conditions
study	Study	minOccurs="1", maxOccurs="1"
organization	Organization	minOccurs="1", maxOccurs="1"

Organization

attribute name	attribute type	conditions
name	String	minOccurs="1"

Study

attribute name	attribute type	conditions
identifiers	StudyIdentifierType	

Open Issues

We need to get clarifications from the adopters for the following issues:

1. Can subject data exist independent of assignment to study? Currently caaers forces user to assign every subject to a study.
    - Response:
2. What are the business rules for subject? Should caaers be a dumb system and assume that only valid participant data will be pushed to it? Or should caaers enforce business rules when data is fed to it from local CTMS? For example: Is the subject assigned an identifier that is unique to the organization or unique to the study? Can each subject have more than one identifier? Can subject be deleted?
    - Response:
3. Similar questions are there regarding business rules for study.
    - Response:
4. How are organizations uniquely identified?
    - Response: Will use NCI Code, and store adopters' primary ids.
5. How are participants uniquely identified?
    - Response: CALGB uses the patient id, Mayo uses a combo of subject ref id (which could be duplicated from diff orgs) and the referring or identifier. Should create a primary key that will be passed back and forth during all data transfers, so always insync

Implementation of Create or Sync Participant info from local CTMS to caAERS

Contents

Introduction

This describe the implementation details on how to create or synchronize the participant info from local CTMS to caAERS. This document explains various approaches considered to implement this functionality. For detailed requirement see Creating and Syncing Participant demographic information from local CTMS to caAERS

Implementation details

We can use either
grid service
web services

However functionality of creating participant in caAERS by external system already exists. There are 2 ways we can push participant/study into caAERS.

- Via xml imports
- Via a grid service

Both has different input structure (schema) associated to it

- Import uses XStream.
- Grid uses Castor objects (supplied by C3PR)

Can we combine these two existing approaches and/or write some generic interface/classes to abstract out the logic?

No.

Module 3 UC - Vocabulary Mapping Services

Module 3 - Vocabulary Mapping Service

Use Case	Phase it was created	Status
Select Appropriate Vocabulary for Study	I	

Module 3 Vocabulary Mapping Service Use Cases (caAERS)

Module 3 - Vocabulary Mapping Service

The reference architecture and data services will utilize the mappings created in other projects and available through the caDSR to facilitate customized reports and forms based on the user's vocabulary preferences.

- Select Appropriate Vocabulary for Study (caAERS UC)

Select Appropriate Vocabulary for Study (caAERS UC)

Select Appropriate Vocabulary for Study

Brief Description

During Study Abstraction, the Study Coordinator will be able to select one ofthree Adverse Event vocabularies to be used for the study: CTC v2, CTCAE v3,and MedDRA v9.

Primary Actor

Study Coordinator (SC)

Preconditions

1. Study information is being abstracted.
2. Adverse event vocabulary is known.

Basic Flow of Events

1. During study abstraction, SC selects dropdown box labeled AE Vocabulary.
2. SC chooses the appropriate vocabulary: CTC v2, CTCAE v3, or MedDRA 9.0.

3. SC saves this abstraction.

Postconditions

The proper vocabulary will be available for routine AE and expedited reporting for this particular study.

Special Requirements

1. In order to support MedDRA licensing requirements, users will have to upload MedDRA into the caAERS database.
2. Only one vocabulary will be used for each study.

Module 4 UC - External Agency AE Reporting

Module 4 - External Agency Reporting

Use Case	Date Created	Date Last Modified
External Agency Reporting Use Case Overview	03/26/2008	10/20/2010
Expedited AE Reporting to AdEERS via caAERS	03/25/2009	10/21/2010
Prepare an AE Notification for Submission to the Food and Drug Administration (FDA)	01/13/2010	10/21/2010
Expedited Reporting with a CTEP Hosted caAERS System	01/14/2010	10/21/2010
Log Report Submissions	06/23/2009	10/21/2010
Review and Report page	05/12/2009	05/20/2009

1.5 Streamlining Expedited Report - caAERS UC

Scope: subsystem - AE module
Level: User Goal
Trigger: entered AE requires expedited report

Brief Description	Someone needs to enter an AE that requires expedited reporting. This attached spreadsheet shows the redesigned screens for the process.
Primary Actor	caAERS user
Secondary Actor	caAERS system
Preconditions	• caAERS user has access to the AE module of caAERS • patient has been assigned to the study in caAERS • patient details have been added to the patient in the patient module

Scenarios	**10-day expedited report is required, report is not submitted, report is unselect** 1. user unselects 10-day report with status of "due..." 2. caAERS unselects AE on the reports required page 3. caAERS removes the status from the report 4. caAERS removes the AE from the report **10-day expedited report is required, report is submitted, report is unselect** 1. user unselects 10-day report with status of "submitted" 2. caAERS unselects AE on the reports required page 3. caAERS changes the status of the report to "amendment due" - would this be amendment due or withdraw required? 4. caAERS removes the AE from the report **10-day expedited report is not required, report is not submitted, report is unselect** 1. user unselects 10-day report with status of "due..." 2. caAERS unselects AE on the reports required page 3. caAERS removes the status from the report 4. caAERS removes the AE from the report **10-day expedited report is not required, report is submitted, report is unselected** 1. user unselects 10-day report with status of "submitted" 2. caAERS unselects AE on the reports required page 3. caAERS changes the status of the report to "amendment due" - would this be amendment due or withdraw required? 4. caAERS removes the AE from the report **10-day expedited report is required, report is not submitted, AE detail (grade, attribution, etc) is changed** 1. user changes a detail on an AE that's on the report (that doesn't change reporting requirements) 2. caAERS updates the information **10-day expedited report is required, report is submitted, AE detail (grade, attribution, etc) is changed** 1. user changes a detail on an AE that's on the report (that doesn't change reporting requirements) 2. caAERS updates the information in the database 3. caAERS changes status to "amendment due" - can caAERS make this change without actually hitting the "Report required" page?
Post Conditions	• Expedited report is created • Reporting period is created and all AEs are saved in the reporting period

Data Items	**New fields required for DCP**
	AE Details
	• Event approximate time, including am/pm
	• Event occurred at (location of patient)
	• Primary treatment Approximate time, including am/pm
	AE Details - Study Agent
	• Formulation (tablet, solution, etc)
	• Lot # (if known)
	• Date reduced
	Personnel
	• Reporter - Title
	• Physician - address
	Patient Details - conmeds
	• start date
	• stop date
	• continuing indication
	Submission - select who to send to
	• Investigator wants to send the report to additional areas (IRB, Manufacturer/Distributor, Other Investigators participating in this study (with a textbox for names) - select boxes above the "enter additional email addresses" field
	New fields required for all
	AE Details
	• Autopsy performed? (y/n)
	• Cause of death (text field)
	
	Additional Info - Attachments
	• Option for Death Certificate
	
	Reports Required
	• Reports
	  • Status (copy status from manage report)
	  • Required indicator - field, visual cue (change the color of the report if it's required?)
	• AEs
	  • Required indicator - field, separate table, visual cue (change the color of the report if it's required?)?
	  Rename fields
	
	  Personnel
	• Physician changes to Physician/Investigator
	
	Enter AE

- Start date of first course changes to Start date of intervention or Start date of first course/intervention

Reports
- Change the name of the DCP 48-hr report definitions to "**48-Hour SAE Report to NCI Medical Monitor and Regulatory Contractor"** (done in demo)

AE Details
- Description to Describe event and Treatment
  New functionality required:
- If a (DCP) study is blind, there must be an "unknown-blind" option in study agents, since study agent is required when a TAC is entered
- For 24- & 48- hr DCP SAE reports, for lab values, recovery value can not be required
- DCP studies don't have diseases. Need to be able to put in "target organ" and free-text field;
  - may eventually be able to populate a "condition" list.
  - I don't know if this needs to be added to both vocabulary terminology lists, or if we need to add a 'DCP' vocabulary terminology for diseases
- Need to import/include DCP agents with EVS codes
  Remove from DCP SAE report
- IND no
  Move to Patient Module
  This information would be collected in the patient module. If something needed to be modified, there would be a modify option that would bring up a 'pop-up' of the patient module to allow the changes to be made.

Patient Details
- baseline performance
- birth date
- gender
- race
- ethnicity

Disease
- Name
- Primary Site
- Date of Initial diagnosis
- Metastatic Site

Pre-existing conditions
- condition

Prior Therapies
- Prior Therapy
- Start Date
- End Date
- Agent
- Comments

Con Meds
- Conmed
- Start Date
- End Date

	• Continued? **Verbiage for Overview screen** *Over the AE Table area* All AEs included in the reporting period are listed in the tables below. AEs that are determined to be serious have been moved to a separate table and are automatically selected for inclusion in reports. AEs that are selected will be included in the expedited reports. You can unselect a serious AE so that it is not included in the report, but it will remain in the table to show that it was identified as serious. *First time to page, no reports required* Based on reporting requirements and the information you've provided, caAERS has determined that reports (and notifications) are not required. Click Save to save the information and continue to the Manage Report page. If you would like to submit a report, click Manually Select, make your report selections, associate AEs to the report by selecting them from the Observed AEs and Solicited AEs tables, and then click Save. *First time to page, reports required* Based on reporting requirements and the information you've provided, caAERS has identified the serious AES and determined the following notifications and reports are required. Select any additional AEs from the Solicited AEs and Observed AEs tables that you want to add to the report and then click Save. Report list You can bypass the caAERS-based selection and manually select the reports you want to send. Click Manually Select, make your report selections, and then associate AEs to the report by selecting them from the Serious AEs, Observed AEs, and Solicited AEs tables. When you save, caAERS will continue to identify which reports it identified as required, but will only create the reports you've selected. *Revisit page - changed, report selected but not submitted* You've made changes to the AEs included in the reporting period. Verify your AE selections in the AE tables below and then click Save. Report list You can bypass the caAERS-based reporting selection and manually select the reports you want to send. Click Manually Select, make your report selections, and then associate AEs to the report by selecting them from the Serious AEs, Observed AEs, and Solicited AEs tables. When you save, caAERS will continue to identify which reports it identified as required, but will only create the reports you've selected. *Revisit page - changed AE included in submitted report* You've made changes to an AE included in a submitted report. Click Save to verify an amendment is due, or click Back to make changes. *Revisit page - changed AE information not included in submitted report* You've made changes to the AEs included in the reporting period. To include additional AEs in the submitted report, select them from the Serious AEs, Observed AEs, and Solicited AEs tables, click Save, and then go to the expedited report to submit an amendment. *Revisit page - new AE requires expedited report* An AE you've added to the reporting period requires expedited reporting and has been selected. Verify your AE selections in the AE tables below, click Save, and then continue to the expedited report. You can override the selection and not add the AE to the report by unselecting it. When you click Save it will continue to be identified as a serious AE but will not be included in the report.
Business Rules	• Expected field can not be required for DCP studies
Open Issues	• Unknown how the 'expected' field is being handled across the system. • If the information under patient details is not pertinent to the AE, should there be a way to remove it? For example, a conmed is old, a prior therapy is old and no way related, etc.
Models & User Interface Prototype	See attached mock-ups in the xls sheet.

Report Selection

Primary Actor: caAERS User
Supporting/Secondary Actor:

Scope:
Level: User Goal
Trigger:

Brief Description

Need to display:

- Suggested Reports
- Suggested AEs per report
- Changes (in the AE list) since the last visit
- Changes (in the suggested reports) since the last visit

Preconditions

Enter any factors that must be met before the use case starts

Steps

Main Success Scenario

1. Enter the main steps

Extensions

Enter any alternative flows, failure flows, and exceptions

Sub-Flows

Enter any paths that are used by multiple paths within the use case (could just be a link to another use case)

Post Conditions

- What items hold true after the use case is enacted?

Data Items

Special\Non-Functional Requirements

- Reports should be sorted by required, then due date, then alphabetical
- AEs should be sorted by required, grade, then alphabetical
- Only suggested reports should be displayed. There will be a button that says "More Reports" that when clicked will show other reports
- Suggested AEs will be indicated by a red box around a regular checkbox.
- AE category (solicited and observed) should be collapsible
- First time caAERS suggests a report, the suggested AEs are autoselected
- Subsequent visits, no additional selections/deselections will be made, only displays existing selections
- Subsequent visit, If a new report is required, the suggested AEs are autoselected

Business Rules

- 1st visit
    - suggested Report will be shown by appearing in the list
    - suggested report will be selected by selecting 1 or more AEs for the report
    - suggested AEs will be shown by grouping, checkbox color/background= red
    - suggested AEs selected for suggested reports by check
    - other AEs not selected but selectable
    - other reports not displayed but displayable (by clicking a button) and selectable by selecting an AE
    - status field is not populated
- subsequent visits - suggested & selected AE. Grade/attribution has change but still present, no longer a suggested AE require reporting. report started, not submitted
    - AE Term no longer grouped with suggested AE
    - AE Term checkbox no longer identified as suggested (no red background)
    - AE Term checked
    - status field would show when the report is due
- subsequent visit - added an AE that has a suggested report. report started, but not submitted
    - Suggested AEs will be shown by grouping
    - Suggested AE checkbox color/background= red
    - Suggested AE will not be checked

        - status field for new report would be blank
        - status field for other reports would show when the report is due
- subsequent visit - AE updated, from suggested to not suggested, report already submitted
    - ?
- subsequent visit - AE added, user selects AE, report already submitted
    - status shows as submitted
    - confirmation page shows amendment due
    - next visit status shows as amendment due
- subsequent visit - user unselects AE, report already submitted
    - status shows as submitted
    - confirmation page shows amendment due
    - next visit status shows as amendment due
- subsequent visit - AE deleted, report already submitted
    - status shows as submitted
    - AE term shows as greyed out
    - AE term shows as selected (greyed out)
    - confirmation page shows amendment due
    - next visit status shows as amendment due
-

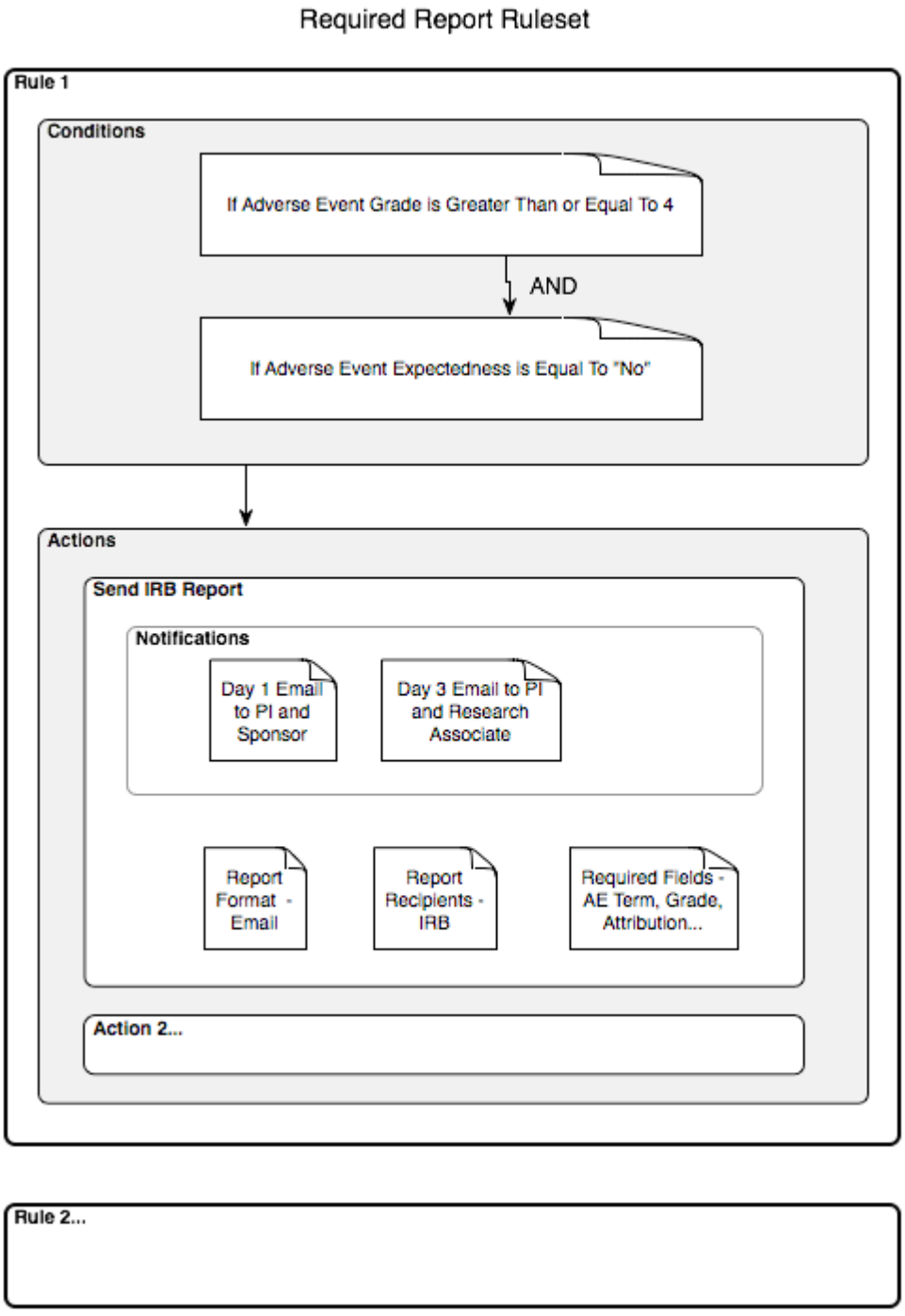
Open Issues

- When selecting AEs for the reports, does the user need to be able to tell the difference between observed & solicited AEs?
- When we show the grade, does it need to be the full definition or can it be just the number?
- How difficult would it be to highlight what has changed for a submitted report that is amended?
- How d

Scenarios

- Required AE has a grade change is no longer required
- AEs have been added to the reporting period
- AE included on a report has been changed
- Report submitted. New AE added that requires reporting
- AE on a report is deleted (both a submitted report & not submitted report)

4.0 External Agency Reporting Use Case Overview

External Agency Reporting Use Case Overview	caAERS will provide interfaces and methods for the messaging of AEs to systems external to the local adopter. We anticipate that this will include two-way communication of adverse events with cooperative groups, national studies, study sponsors, the NCI and the FDA. The following diagram shows the relationship between Rulesets, Notifications, and Report definitions: 
Sub-Pages	Configure Messages, Timing, and Escalation Rules Create AE Ruleset Create Report Definition Export Rulesets Import Rulesets Submit Report to AdEERS

Configure Messages, Timing, and Escalation Rules (caAERS UC)

Brief Description	The Study Coordinator configures the notifications that should occur if the conditions of a certain ruleset are met at the time an AE Report is saved. The timing of the notifications relative to the save action will be specified as well as the message format and content.
Primary Actor	Study Coordinator (SC)
Preconditions	None for creation, but notification recipients must be defined and the notifications must be associated with a ruleset before any notifications can actually be sent.
Basic Flow of Events	1. SC chooses to "Create Notifications." 2. SC names the particular sequence of notifications that is being created. 3. SC selects when the notifications will occur relative to the report save. 4. SC selects the format and creates the content of the notifications. 5. SC selects the recipients for the notifications. These may be the predefined roles within the caAERS system (see Section 2) or actual contact information.
Post-conditions	Notification exists and is ready to be associated with a ruleset.

Special Requirements

Data Item	Description
Notification name	Name of this particular series of Notifications
Notification calendar	Collection of timings that tell when notifications should be sent
Notification type	Format of the notification: email, page, SMS,etc...
Notification content	The body (content) of the notification
Notification recipient	Who receives the notification. This could be a variable or a constant.

Create AE Ruleset (caAERS UC)

Brief Description	This use case will describe the creation of AE Rulesets. A Study Coordinator (SC) will create a Ruleset in the administrative interface and designate a Ruleset as being a Study, Sponsor, or Site Ruleset. The Rulesets are evaluated when an AE Report is created.
Primary Actor	Study Coordinator (SC)
Preconditions	The appropriate Study, Sponsor, and Site have already been created.
Basic Flow of Events	1. SC selects option to create a new Ruleset. 2. SC chooses a title for the Ruleset. 3. SC chooses from drop-down list whether the Ruleset is a Study, Sponsor, or Site level Ruleset. 4. SC creates a new rule. 5. SC creates a condition consisting of an attribute from an AE Report, an operator, and a value. (See chart below for possible attributes of a condition.) 6. SC repeats step 5 as necessary to complete the rule. Each condition has an AND relationship to the other conditions within the rule. The rules have an OR condition with each other. (See chart below for conditions.) 7. SC selects the agenda that will be executed if the conditions of the rule are satisfied. 8. SC repeats steps 4 thru 7 for each rule in the Ruleset. 9. If Ruleset is a Study-level Ruleset,SC will select the appropriate Study with which to associate the Ruleset. 10. If Ruleset is a Sponsor-level Ruleset,SC will select the appropriate Sponsor with which to associate the Ruleset. 11. Ruleset is a Site-level Ruleset,SC will select the appropriate Site with which to associate the Ruleset.
Post-conditions	1. The SC has created a Ruleset that will be run after initial AE data is entered and saved. 2. The SC will be able to run a set of test data to verify that the rules function properly.

Special Requirements

Data Item	Type
Ruleset Name	Required

Ruleset Type	Required, Study, Organization, or Site
Report Attributes	One selected for each condition of a rule
Grade	Not Required
Hospitalization	Not Required
Expectedness	Not Required
Phase	Not Required
Attribution	Not Required. Must be selectable in terms of particular agents or devices being used on the trial.
AE Term	Not Required. (CTC or MedDRA)
Operators	Required, =, <, >, <=, >=, <>
Actions	Required. Defined in Administrative Interface

Create Report Definition (caAERS UC)

Brief Description	Study Coordinator will be able to define a report and determine which fields will be included in it. The sending of this report will then be available as an action to the Rulesets.
Primary Actor	Study Coordinator (SC)
Basic Flow of Events	1. SC selects the "Reports" tab. 2. SC selects "Create Report" option. 3. SC enters a unique name and maximum time from initial creation to submission of report. 4. SC creates as many notifications as needed and enters recipients as either role names or actual email addresses. (See Use Case 4.3 below) 5. SC selects which fields will be mandatory for this report. 6. SC saves the report definition.
Post-conditions	1. When creating Rulesets, the Report Definition will be available as a possible action if the conditions of the Rule are met. 2. When a Ruleset fires and determines that the Report is required, mandatory fields will be designated and verified. Note: For creation of Ruleset, please see Use Case 1.9 above.

Export Rulesets (caAERS UC)

Brief Description	The Study Coordinator exports a Ruleset to a file.
Primary Actor	Study Coordinator (SC)
Preconditions	The Ruleset already exists within caAERS.
Basic Flow of Events	1. SC chooses to export the Ruleset. 2. SC tells caAERS the name of the file and the location to which it should be exported. 3. caAERS exports the Ruleset.
Post-conditions	A file containing the Ruleset exists which can then be imported into another caAERS instance.

Import Rulesets (caAERS UC)

Brief Description	The Study Coordinator imports a Ruleset into caAERS.
Primary Actor	Study Coordinator (SC)

Preconditions	1. The Sponsor or Organization to which the Ruleset refers must already exist within caAERS. 2. The Ruleset must be properly formatted.
Basic Flow of Events	1. SC obtains a file containing the Ruleset. 2. SC chooses to import the Ruleset. 3. SC tells caAERS the location of the file to be imported. 4. caAERS imports the Ruleset. 5. SC associates the Ruleset with a Study, Sponsor, or Institution.
Post-conditions	Ruleset exists within the system and has been associated with the Study, Sponsor, or Institution.

Submit Report to AdEERS (caAERS UC)

Brief Description	When a Study is configured for AdEERS reporting, Expedited Reports will be submitted to AdEERS.
Primary Actor	Participant Coordinator (PC)
Secondary Actor	Study Coordinator (SC)
Preconditions	1. During Study abstraction, the option for submitting Expedited Reports to AdEERS was selected. 2. An AE requiring Expedited Reporting has occurred for a Subject on this Study.
Basic Flow of Events	1. PC creates and **completes** an Expedited Report. 2. PC submits the report. 3. caAERS sends the report to AdEERS.
Post-conditions	1. If the report was sent successfully, AdEERS receives the Expedited AE Report and the user receives an email from AdEERS with the ticket number of the report. 2. If the report was not sent successfully, the user will receive a failure notice by email that describes the cause of the failure. 3. AdEERS now has a copy of the AE data as it appears in caAERS.

4.1.2 Expedited Reporting with a CTEP Hosted caAERS System

Primary Actor: caAERS User
Supporting/Secondary Actor: The AdEERS Web Service
Scope:
Level: User Goal
Trigger: An adverse event which requires expedited reporting via AdEERS occurs on a study subject

Brief Description	The following describes the sequence of actions required to begin, complete, and submit an expedited report to the AdEERS system, via caAERS hosted at CTEP.
Preconditions	• System is hosted at CTEP • System will not support local reports (i.e. IRB reports)

Main Success Scenario	1. Select Reporting Context a. Select Study b. Select Subject i. Search Subject ii. Edit Subject iii. Create Subject c. Select Course i. Create Course ii. Edit Course d. Enter AEs (See Extension 1.d below) e. Run Adverse Event Expedited Reporting Rules (See Extension 1.e below) f. Select Report i. Start New Report ii. Edit Existing Report iii. Withdraw Existing Report iv. Amend Submitted Report 2. Complete Expedited Report a. Enter Reporter b. Enter Aes i. Enter Aes ii. Delete AEs iii. Edit Aes iv. Change Primary AE c. Describe Event d. Review Course i. Edit Course e. Study Interventions f. Subject Details g. Labs h. Other Causes i. Attribution j. Additional Info k. Review and Submit 3. Submit Report a. Submitter Info b. Recipients c. Submission Status
Extensions	**1.d. Enter Aes** 1.Enter Aes 2. Delete Aes 3. Edit Aes **1.e. Run Adverse Event Expedited Reporting Rules** 1. Action Recommended 2. No Action Recommended 3. Override Recommended Action 4. Restore Recommended Action
Sub-Flows	Enter any paths that are used by multiple paths within the use case (could just be a link to another use case)
Post-Conditions	What items hold true after the use case is enacted?
Data Items	What data items are of interest and should be modeled?
Special\Non-Functional Requirements	• The system shall support reporting to AdEERS in the absence of AE Reporting Rules • The system shall not include fields which are not part of the AdEERS system (Attribution to Study; Expected; Outcome; End date of course/cycle; Treatment type) • The system shall allow a user to only select between a CTEP Notification due in 24hrs or a CTEP Expedited Report due in 10 days (post-AE entry) • A report that is due in 5-days should not be selectable by the user. • A report due in 5-days shall be initiated after a 24hr notification has been submitted. • The system shall support entering and saving verbatim AEs prior to selecting a CTCAE term • The system shall support a mechanism for a reporter to quickly and easily set up a user account.
Business Rules	See AdEERS business rules

Open Issues	• Will there be the possibility that there are some reports with rules and some without rules on the same study in the same system? * Will CTEP want the option to turn rules on for certain studies? (If yes, then Option 2 may be needed) * What should the access be for a user? Only their subjects? All subjects from their site?.
Models & User Interface Prototype	See expedited flow

4.1 Expedited AE Reporting to AdEERS via caAERS

Goal: Completion and submission of a report to AdEERS.
Primary Actor: caAERS User at study site (domain titles: CRA, Research Nurse, Physician; caAERS Roles: AE Coordinator, Subject Coordinator)
Supporting/Secondary Actor: caAERS User at coordinating center; AdEERS system
Scope: This use case applies to all expedited AE reporting to AdEERS via the caAERS system.
Level: User Goal
Trigger: An adverse event has been entered that requires expedited reporting to the AdEERS system.

Brief Description	A participant on a study has experienced a AE. A caAERS user a study site, typically a clinical research associate (CRA) at has previous
Preconditions	• The caAERS system has been configured with the appropriate AdEERS reports. • The caAERS "Basic Report Rules" and "Mandatory Section Rules" have been configured appropriately for each report. • The caAERS "SAE Reporting Rules" have been configured appropriately for the study NOTE: A NO SAE Reporting Rules configuration is a valid configuration for a study. • An AE has been experienced by a study participant that needs to be reported in an expedited fashion to CTEP. • The caAERS system has been configured with the study on which an AE occured and requires reporting.
Main Success Scenario	1. The caAERS system displayes to the user the optional and required information for completion of the selected report. NOTE: Reports can have different optional and required information 2. The user completes the required and optional information a. Missing required information is reported to the user as an error message. 3. The caAERS user initiates the the report submission a. Routing and review is required - see extension 3.a. below 4. The caAERS system electronically sends the report to AdEERS 5. The AdEERS system receives the report a. AdEERS does not receive the report - see extension 6. The AdEERS system sends a response to caAERS 7. The caAERS system receives the response from AdEERS a. caAERS does not receive the response from AdEERS - see extension 8. The caAERS system displays the response from AdEERS 9. The caAERS user corrects any issues and resubmits
Extensions	3.a. 1. The caAERS user (CRA) routes the report to the treating physician for review and approval 2. After approval, the caAERS user (CRA) routes the report to the caAERS user (SAE coordinator) at the coordinating center. 3. The caAERS user (SAE coordinator) at the coordinating center initiates the the report submission

Sub-Flows	24hr notification 5-Day Report 10-Day Report Amending a report Withdrawing a report Editing an in-process report Adding an AE to an in-process report Commercial intervention reporting Non-NCI IND reporting Multimodality reporting ACRIN/CIP reporting
Post-Conditions	caAERS has successfully communicated to AdEERS the appropriate reporting transaction and the AdEERS system has responded in confirmation

Data Items	• AdEERS WS v3.1.0 message schemas
	  • 24hr notifications
	  • Other report transactions

Special\Non-Functional Requirements	caAERS-AdEERS SRS
Business Rules	AdEERS Business Rules
Open Issues	Any questions about the flow that need to be answered before the flow can be finalized.
Models & User Interface Prototype	Provide an optional UI mockup, if useful. Provide an optional UML diagram

4.2 Prepare an AE Notification for Submission to the Food and Drug Administration (FDA)

Brief Description	The caAERS system sends an adverse event notification to the Food and Drug Administration (FDA). This notification occurs after the user enters all relevant information into caAERS for the report. The user may have several options for submitting the report to the FDA.
Primary Actor	caAERS User (User)
Secondary Actor	• FDA Electronic Submission Gateway (FDA-ESG) • Enterprise Service Bus (ESB)
Preconditions	• All information for an AE has been entered into caAERS • Report to submit has been configured in caAERS
Basic Flow of Events	1. User enters AE information entered in caAERS 2. User selects FDA report to complete 3. User selects mode of form submission 4. User is guided through submission preparation process
Post-Conditions	• FDA receives the report via the FDA-ESG • User is shown confirmation that they have completed all submission preparation steps within caAERS
Special Requirements	Use MedDRA terminology

Extensions

- Export form as PDF
- Export form and supportive files for E2B-compliant XML submission
- Export form and supportive files in eCTD format

FDA Submission Options

If Agent: CDER
If Biologic (i.e. vaccine, etc): CBER
If Device or diagnostic: CDRH

Type	Medium	Method	Address	Format	Reference
Non-Investigational (i.e. commercial/post-marketing)	paper	Fax		MedWatch3500	
Non-Investigational (i.e. commercial/post-marketing)	paper	Mail		MedWatch3500	
Non-Investigational (i.e. commercial/post-marketing)	electronic (.pdf)	email		MedWatch3500	FDA post-marketing guidance
Non-Investigational (i.e. commercial/post-marketing)	electronic (.pdf)	ESG		MedWatch3500	FDA post-marketing guidance
Non-Investigational (i.e. commercial/post-marketing)	electronic (xml)	ESG		E2B	FDA post-marketing guidance
Non-Investigational (i.e. commercial/post-marketing)	electronic (xml)	Database to database / webservices		E2B	FDA post-marketing guidance
Investigational	paper	Fax		MedWatch3500A + 1571	
Investigational	paper	Mail		MedWatch3500A + 1571	
Investigational	electronic	ESG (https://esgtest.fda.gov/)		eCTD	FDA Guidance
Investigational	electronic	ESG (https://esgtest.fda.gov/)		pdf	FDA Guidance
Investigational	electronic	webservice		eCTD	FDA Guidance

Currently, CDRH does not use eCTD
Electronic submissions for INDs should use eCTD

- The 1571 must be included
- The serial number of the submission MUST be provided by the submitter - it is NOT provided by the FDA receipient
- caAERS will need to be able to generate a 1571 with the appropriate serial # for the IND submission

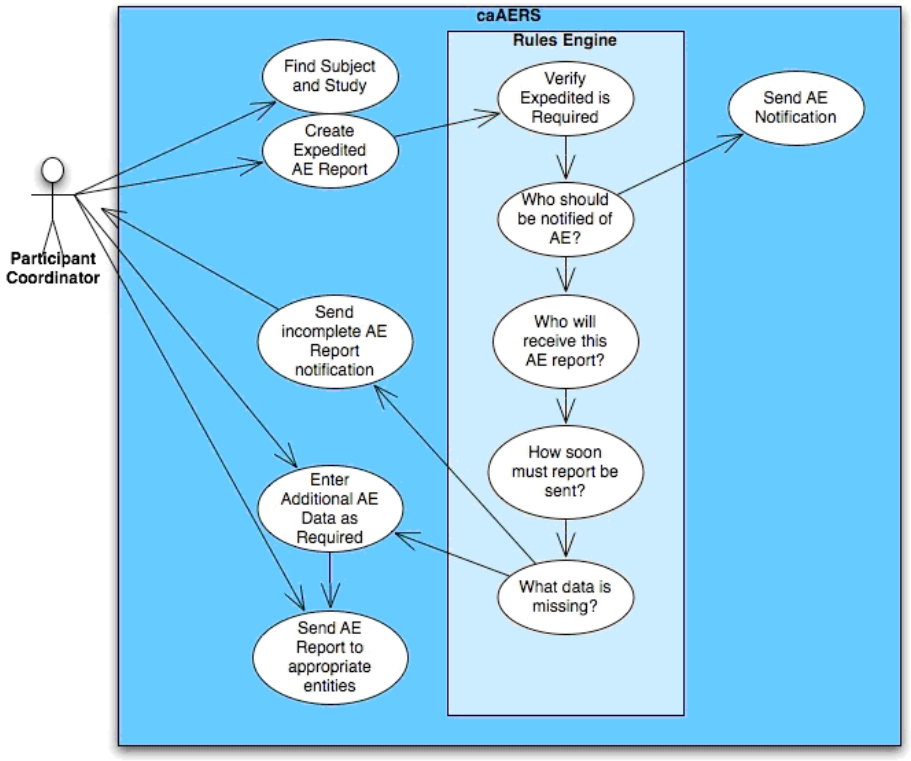
Is there a webservice that can be called for electronic submissions? Alternative: Is there a programmatic method to use the ESG?

Old format of IND specified by 21 CFR 312.23
Old format of NDA specified by 21 CFR 314.50
eCTD is the new format for IND and NDA combined

- Problem was significant effort to move from paper IND format to paper NDA format
- International Committee on Harmonization (ICH; US, Japan, northern Europe) came up with eCTD as solution as a common electronic document format that could be used for IND applications and the subsequent NDA applications, and as a common submission document to US, Japan, and European regulators
- Currently, eCTD used by CDER and CBER

Noteworthy example: Aricept submission consisted of 770 volumes at 350 pages per volume. FDA required 3 copies. Submission delivered on two (2)- 18 wheelers.

Create Expedited AE Report (caAERS UC)

Brief Description	The Participant Coordinator (PC) creates a new Expedited AE Report for a given Subject assigned to a Study. This report is manually entered into caAERS so that the system can verify that the report should be treated as expedited and determine which entities should receive copies of the report. If caAERS determines that the report does not require expedited reporting, the PC will decide to either submit it as expedited anyway or move to the Routine Report. 
Primary Actor	Participant Coordinator (PC)
Preconditions	1. The Study has been created. 2. The Subject has been created and assigned to the Study.
Basic Flow of Events	1. The PC searches for and selects a Subject on which to begin an Expedited AE Report. If the Subject is linked to multiple Studies, the applicable Study must also be selected. 2. The PC selects option to create a new Expedited AE Report. 3. The initial data screen is presented with Study and Subject identified. 4. PC prompted to input the required data to create an Expedited AE Report. a. If Report is a duplicate (based upon AE terms and Report Date as well as Study and Subject IDs): 5. PC may continue to submit duplicate report. 6. PC may change values and submit again. 7. PC may cancel report. a. If Report is not a duplicate, data is submitted to system. 8. caAERS determines if the AEs entered actually require Expedited Reporting. a. If yes, move to Step 6. b. If no, PC may either submit an Expedited report anyway as per Step 6, or may move to the Routine AE workflow (Use Case 1.6) to enter additional Routine AEs. The data that has already been entered will appear in the Routine flow. 9. PC receives a confirmation screen and may now continue AE data collection (see Use Case 1.7) or can navigate away from this screen and return later to enter the additional data.
Postconditions	1. PC will have created an Expedited AE Report for a Subject assigned to a Study. 2. Rulesets for determining which reports should be sent and which fields are required are invoked. 3. System prepared for subsequent AE data collection. 4. The AE Report is in state "pending."

Special Requirements

Data Item	Type	Notes/Validation Rules
Start Date of Primary AE	Required	
End Date	Not required, only entered if applicable	
MedDRA Code	Required if AE category and term not provided.	
Category	Required for CTEP studies and if MedDRA Code not provided.	CTCAE
MedDRA Version	Required if MedDRA codes are used.	caAERS will use the whole-number, annual releases of MedDRA.
CTC Version	Required for CTEP studies and if MedDRA Code not provided.	CTCAE v2.0/3.0 Should be collected during study abstraction.
Term	Required for CTEP studies and if MedDRA Code not provided.	Also provide an "Other, Specify ____" text box
Grade	Required	If CTC is used, only appropriate grades for each term should be available for selection.
Expectedness	"Requiredness" dictated by configured institution, sponsor and study triggers	Timing of reporting dictated by configured institution, sponsor and study triggers
Attribution	"Requiredness" dictated by configured institution, sponsor and study triggers	Timing of reporting dictated by configured institution, sponsor and study triggers
Hospitalization	"Requiredness" dictated by configured institution, sponsor and study triggers	DCP or CTEP definitions may be utilized
Treating Physician	Required	Coded using CTEP identifiers when possible

CTEP Reports generated by caAERS

24 hour notification

Attachments

- Current PDF/Report
- New Report Format

Changes to the fields in the current PDF

Fields not currently in caAERS

Business Rules

- What to report (what triggers reports)
- When to report
- What fields are required in the report

Field mapping

5-Day Report

Attachments

- Current PDF/Report
- New Report Format

Changes to the fields in the current PDF

Fields not currently in caAERS

Business Rules

- What to report (what triggers reports)
- When to report
- What fields are required in the report

Field mapping

10-day report

Attachments

- Current PDF/Report
- New Report Format

Changes to the fields in the current PDF

Fields not currently in caAERS

Business Rules

- What to report (what triggers reports)
- When to report
- What fields are required in the report

Field mapping

DCP Reports generated by caAERS

48 SAE Report

Attachments

- Current PDF/Report? (The attached is a 15 day, and is not identical to the other DCP SAE form I have. I created that report from a CTEP report. Does that mean we need to update/change that?)
- New Report Format

Changes to the fields in the current PDF

Current Field	New Value
IND No	NCI Study #
Study (Indication)	Study Title

In section A3 & A4: avialable	available
Primary Event	Verbatim AE Term (make field smaller)
Study Drug	Study Agent
	Physician e-mail (section B)
	CTCAE category, CTCAE Term (under Verbatim AE Term)
Initial Event Report Follow-up	Initial Event Report Follow-up Amendment
Study Drug	Study Agent (pg 2, Section D)

Fields not currently in caAERS

AE Details

- Event approximate Time, including am/pm
- event occurred at (location of patient)
- primary treatment Approximate time, including am/pm
- Autopsy performed? (y/n)
- Cause of death (text field)

AE Details - Study Agent

- formulation (tablet, solution, etc)
- Lot # (if known)
- Date reduced

Personnel

- Reporter - Title
- Physician
    - address
    - e-mail address
    - telephone #?
- Attending Physician (completely new)
    - Name
    - Phone #
    - Fax #
    - Hospital/Clinic
    - Address

Patient Details - conmeds

- start date
- stop date
- continuing indication

Labs

- Normal Range
- Normal Range Units

Additional Info - Attachments

- Option for Death Certificate

Submit page

- The Investigator also wants it sent here:
- IRB
- Manufacturer/Distributor
- Other Investigators participating in this study

Create Study Flow

- NCI Contract/Grant #
- IRB Protocol #

Business Rules

- What to report (what triggers reports)
- When to report
- What fields are required in the report

Field mapping

24 hour notification

Attachments

- Current PDF/Report
- New Report Format

Changes to the fields in the current PDF

Fields not currently in caAERS

Business Rules

- What to report (what triggers reports)
- When to report
- What fields are required in the report

Field mapping

FDA Reports generated by caAERS

MedWatch Report

Attachments

- Current PDF/Report
- New Report Format

Changes to the fields in the current PDF

Fields not currently in caAERS

Business Rules

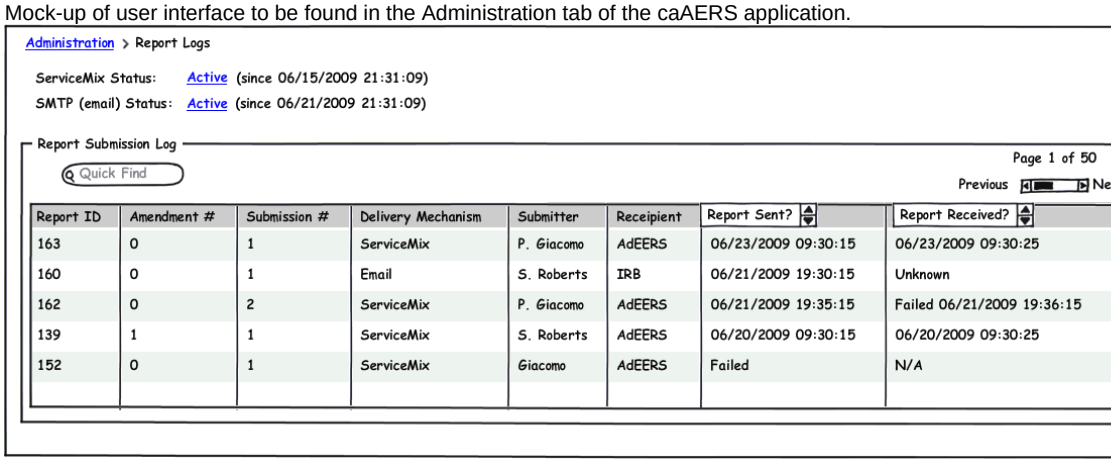
- What to report (what triggers reports)
- When to report
- What fields are required in the report

Field mapping

Log Report Submissions (caAERS Use Case)

Primary Actor: caAERS User (superuser or Admin)
Supporting/Secondary Actors: report submitter; ServiceMix; SMTP server; report receipient
Scope:
Level: User Goal
Trigger: A report submission is attempted by a caAERS user

Brief Description	Upon submission of a report from the caAERS system, there needs to be a clear and detailed log of the submission activities and their corresponding statuses, such that a superuser or administrator could review these logs and identify reports failing submission.
Preconditions	Enter any factors that must be met before the use case starts
Main Success Scenario	Enter the main steps
Extensions	Enter any alternative flows, failure flows, and exceptions
Sub-Flows	Enter any paths that are used by multiple paths within the use case (could just be a link to another use case)
Post-Conditions	What items hold true after the use case is enacted?
Data Items	What data items are of interest and should be modeled?
Special\Non-Functional Requirements	Any special items of interest or non-functional requirements to be addressed
Business Rules	Enter rules here
Open Issues	Any questions about the flow that need to be answered before the flow can be finalized.
Tracking steps	1. Submission Initiated. 2. PDF/XML generated. 3. Notification (email). 4. Submission to ESB system initiated - Connecting ESB - Transformation - Connecting external system (eg AdEERS) - Submitted to external system (eg AdEERS) - Response received. 5. Notification to Submitter
Models & User Interface Prototype	Mock-up of user interface to be found in the Administration tab of the caAERS application.



Review and Report page

The purpose of this page is to allow the user to review the results of the rules engine and initiate any reporting actions.

Use Case Requirements

The requirements of this page are as follows:

1. The page must tell the user if a report is recommended by the caAERS rules engine.
2. If the report recommend has changed from a report already in progress (but not subitted), the page must convey this information to the user.
3. The user must be allowed to override the recommendations of the caAERS system.
    - The user must be allowed to override the reports recommended.
    - The user must be allowed to override the AE's to be included on the report.
    - The user must be allowed to override the recommended action
4. This page must support the following general scenarios:
    a. one data collection per course and one report per data collection
    b. one data collection per course and multiple reports per data collection
    c. multiple data collections per course and multiple reports per data collection

Basic Flow

The basic flow of the page is as follows:

1. Based on the AEs you entered, the following action is recommended based on the Rules Engine
    - When there is a recommended action, an alert will be shown on the page for emphasis
    - When there is no recommended action, the available optional actions will be displayed and no alert will appear
2. Now perform the recommended action, or pick an alternative action.

Available Actions include:

Action	Button Text	Description
CREATE new reports "x"	Create Report	• Creates a new report with a new data collection • Recommended when a report is required for the first time • Option available to change report(s) to be created • An optional action anytime there are AEs
ADD REPORT "y"	Add Report	• Recommended when report "x" is in process, there are no unreported AEs, but report "y" is now required. • An optional action anytime there is a report in process and there are no unreported AEs.
UPDATE (continue/edit/access) in-process reports "x"	Update Report	• Recommended when report "x" is in process and there are AEs requiring report "x" (or a report with a longer due date) that are not yet part of a report. • An optional action anytime there is a report in process
AMEND submitted report "x" with report "y"	Amend Report	• Recommended when "y" is required and "x" has been submitted • Option available to change "y" to a different report • An optional action anytime there is a submitted report
REPLACE in-process reports "x" with reports "y"	Replace Report	• Recommended when "y" is required and "x" has not been submitted • Option to change "y" to a different report (cannot pick "x" again)
WITHDRAW in-process report "x"	Withdraw Report	• Recommended when reporting is no longer required for any AEs and report "x" has not yet been submitted. • An optional action whenever report "x" has not yet been submitted.
TAKE NO ACTION	Button grayed out	• An optional action at all times.

Display

- The page header will specify the Study, Subject, and Course
- If there is a recommended action, the alert will be displayed prominently at the top of the page

- If there is a recommended action, that action will be selected by default.
- The recommended action will have a clear icon adjacent to the action stating "Recommended"
- When an action is selected via radio button, that action will expand to show a table below the action displaying the reports included or selectable for the action.
- Below the table containing the reports will be an expanded table displaying the AEs included or selectable for inclusion in the reports.
- Upon selecting an action, the "Continue" button will be refreshed with text appropriate for the action (i.e. if CREATE report is selected, the continue button will say "CREATE REPORT").

Scenarios

Starting State Reports	Starting State Data Collections	Description	AEs Added?	AEs Modified?	Alert Displayed	Action Recommended	Optional Actions
None	None	*AEs are added that do NOT require reports	YES	no	no	none	1. CREATE 2. TAKE NO ACTION
None	None	AEs are added that DO require reports	YES	no	ALERT!	CREATE	1. TAKE NO ACTION
Single Report - in progress	Single Data Collection	*No AEs added *No changes made to AEs	no	no	no	none	1. UPDATE 2. ADD REPORT 3. REPLACE 4. WITHDRAW 5. TAKE NO ACTION
Single Report - in progress	Single Data Collection	*No AEs added *Changes made to AEs that don't change the report	no	YES	no	none	1. UPDATE 2. ADD REPORT 3. REPLACE 4. WITHDRAW 5. TAKE NO ACTION
Single Report - in progress	Single Data Collection	*AEs are added that don't require reports *Changes may have been made to AEs that don't change the report	YES	yes or no	no	none	1. UPDATE 2. ADD REPORT 3. CREATE (new data collection with new AEs) 4. REPLACE 5. WITHDRAW 6. TAKE NO ACTION
Single Report - in progress	Single Data Collection	*AEs are added that require the exact report currently in progress *Changes may have been made to AEs that don't change the report	YES	yes or no	ALERT!	UPDATE	1. ADD REPORT 2. CREATE (new data collection with new AEs) 3. REPLACE 4. WITHDRAW 5. TAKE NO ACTION

Single Report - in progress	Single Data Collection	*AEs are added that require a completely different type of report not currently in progress (eg. one from a different organization) *Changes may have been made to AEs that don't change the report	YES	yes or no	ALERT!	1. ADD REPORT	1. UPDATE 2. CREATE (new report, new data collection, and new AEs) 3. REPLACE (the current report with a new report) 4. WITHDRAW 5. TAKE NO ACTION
Single Report - in progress	Single Data Collection	*AEs are added requiring a similar report currently in progress but with a different due date *Changes may have been made to AEs that don't change the report	YES	yes or no	ALERT!	REPLACE	1. UPDATE 2. ADD REPORT 3. CREATE (new report, new data collection, and new AEs) 4. WITHDRAW 5. TAKE NO ACTION
Single Report - in progress	Single Data Collection	*AEs are added requiring a similar report currently in progress but with a different due date (eg. 10-day in progress, 5-day required) *Changes have been made to AEs that change the report • • Scenario could warrant need to do one thing with new AEs and something else with updated AEs (eg. Replace report and Create new date collection)	YES	YES	ALERT!	REPLACE	1. UPDATE 2. ADD REPORT (without adding new AEs) 3. CREATE (new report, new data collection, and new AEs) 4. WITHDRAW 5. TAKE NO ACTION

Module 5 UC - Internal Routing and Review

Module 5 - Internal (institutional) Routing and Reviewing

Use Case	Date Created	Date Last Modified
5. Internal Routing and Review	06/13/2008	05/24/2010
5.1 Routing and Reviewing a Reporting Period	05/15/2008	03/25/2009
5.2 Routing and Reviewing an Expedited Report	06/13/2008	03/25/2009
5.3 Routing and Review Setup	06/11/2008	03/25/2009
5.4 Central Processing	05/15/2008	03/25/2009

5. Internal Routing and Review

Scope: system - caAERS
Level: User Goal
Trigger:

Brief Description

This use case documents the different routing and reviewing requests from the adopters. In general, routing and reviewing is a QA of the information. central processing is specifically for CTEP studies that have lead organizations which review all expedited reports before they are turned over to CTEP.

Primary Actor

caAERS system, AdEERS system

Secondary Actor

caAERS user

Preconditions

none

Steps

- Setup routing and reviewing preferences in caAERS
- Reviewing of Reporting Periods and AEs
- Reviewing of Expedited Reports - non central processing
- Central Processing

Extensions

none

Sub-Flows

Determining user rights

Post Conditions

- routing and reviewing is set up in caAERS
- the adopters can do their individual routing and review processes
- central processing is set up in caAERS

Data Items

-

Special\Non-Functional Requirements

-

Open Issues

-

5.1a Routing and Reviewing - caAERS UC draft

Primary Actor: caAERS Users
Supporting/Secondary Actor: caAERS

Scope: sub-system, AE module
Level: User Goal
Trigger: Expedited Report is created, evaluation period is created, user changes the status to say it's ready for reviewer

Brief Description

After AEs are entered into caAERS, some organizations have a review process in place. This may be for routine AEs (evaluation periods), expedited reports, or both. Reviewers will review the data reported and then ask for additional information/clarification by leaving comments and changing the status, or just change the status to indicate review is complete.

Preconditions

- user has access to the AE module
- AEs have been entered and are marked ready for review

Requirements

- Must have the ability to query a study and return all sites
- Need to add pagination to the search results page for display of large number of results.
- Should allow for a collapse/expand functionality on each result container.
- Must ensure that the search functionality for routing and review has the appropriate security calls
- Need to determine how routing will work for CALGB given they don't use roles for security - they will likely need to support study functional roles (i.e. PI, Site investigator, Reporter, etc).
- Each study will have two different workflows for each study site: one workflow for expedited reports, one for routine AEs
- Expedited report flow:
    1. (domestic) Site CRA (entry) -> Physician (review) -> Site CRA (submit) -> CALGB Central Office (review) -> Submit to AdEERS
    2. (international) Site CRA (entry) -> Physician (review) -> Monitor (review) -> CALGB Central Office (review) -> Submit to AdEERS
- Routine AE flow:
    1. Site CRA -> CALGB Data Coordinator -> Finalize
    2. Site CRA -> Main Member Data Coordinator -> CALGB Data Coordinator -> Finalize
- Need ability to see who (or what role) a review is going to. Will help folks pick the correct review.
- Need to be able to have different review flows for different sites and for different things being reviewd (Routine vs Expedited).
- Possibly could use ability to have different review flows for different studies as well.
  UAT scenarios need to test the different scenarios.
- Comments must have date AND time stamp.
- Have new comment window below the most recently added comment.
- Have a show all / show none collapse ability for the comments.
- A link to the item needing review must be included in the report.
- Notifications for review need to have configurable substitution variables.
- Editing of the report or evaluation period by the reviewer (rather than just leaving comments) should be restricted to reviews being done by the same site where data entry occurred. The reason for this is that the information included in caAERS must match the source documentation.
- When reviewing data entered by another site, only comments back to the site regarding needed changes should be included to ensure that source documentation is appropriately updated prior to making changes in caAERS.
- Physician sign-off should be a status.
- Submit should be a status.
- Need the ability for reviewer to go into the report and make changes, with log of changes included in the comments panel. Ideally this would be something that a physician could do.
- In order for physicians to use this functionality, there must be a link in the notification email that takes them to the exact record requiring review. For report reviews, a pdf of the the report included in the email would be beneficial.
- Within a flow (capture AE or reporting), there should be the ability to change the review status (i.e. "Save and Send to Review").

Steps

Main Success Scenario

1. caAERS user searches for items to be reviewed; Search can be any of the following:
    a. Patient
    b. Study + Site (if only one site available, then it's defaulted to that site)
    c. Patient + Study (doesn't need Site since patient is only on Study at one site)
    d. Patient + Review status
    e. Study + Site + Review status
2. caAERS brings up review page; page always be organized by Subject and Study:
    a. Page Header will include the Search criteria selected by the user
    b. Each Subject/Study result will be organized in a separate box
        i. The header for the Subject/Study result will contain the Study Title, Protocol Authority ID, and Coordinating Center ID if the search is restricted by Subject
        ii. The header for the Subject/Study result will contain the Subject first and last name, Primary ID, and Study-Subject ID if the search is restricted by Study.
    c. The column headers for the results should look similar to the snapshot

   d. ~~Patient~~ ### ~~Organized by Study, then Evaluation Period (which expands to show AEs and Reports)~~
   e. ~~Study~~ ### ~~Organized by Patient, then Evaluation Period (which expands to show AEs and Reports)~~
   f. ~~Patient + Study~~ ### ~~Looks like current manage report page~~
   g. ~~Patient + Review status~~ ### ~~Two tables, one for evaluation period, one for Reports~~
      i. ~~Report table will have the following columns, non-expandable: Report Name, Study, Report Format (current options dropdown) Comments, and Status~~
      ii. ~~Evaluation period table will have the following columns: Evaluation Period, Study, Comments, Status. Each row will expand to show reports and AEs, similar to current manage reports.~~
   h. ~~Study + Review status~~ ### ~~Two tables, one for evaluation period, one for Reports~~
      i. ~~Report table will have the following columns, non-expandable: Report Name, Patient ID, Report Format (current options dropdown) Comments, and Status~~
      ii. ~~Evaluation period table will have the following columns: Evaluation Period, Patient ID, Comments, Status. Each row will expand to show reports and AEs, similar to current manage reports.~~
3. caAERS user reviews the information
   a. expands the different areas to see full details
   b. uses the Report format dropdown to chose a view to view the expedited report
4. Reviewer adds comments and/or changes the status
   a. Each evaluation period and expedited report has a comments field associated to it
   b. Each evaluation period and expedited report has a status field associated to it
5. *Question: Does this page need a "Save" button, or will changing the Status and adding the comments automatically save the changes?*
6. caAERS sends out notifications for items that have changed
   a. e-mail notifications, based on roles and specific research staff in the system
   b. inbox notifications, built into the caAERS application
7.

Extensions

?

Post Conditions

- Reporting periods will be in various review statuses
- Expedited reports will be in various review statuses
- Users may receive notifications
- Comments may be associated to various reporting periods
- Comments may be associated to various expedited reports

Data Items

Statuses

Statuses are discussed in detail on the following two pages:

- Routing & Review Statuses for caAERS
- 5.3 Routing and Review Setup

When a new expedited report or evaluation period is created, the status automatically goes to draft/incomplete

Attributions

The following attributions need to show for each AE in the evaluation period
Note: * means it's only needed for DCP studies, ** means it's only needed if there's data in it (AE term, verbatim, and other may be combined together, as is done in the review & report page)

- ae term
- verbatim field **
- Other field **
- grade
- attribution
- Seriousness *

- Hospitalization

Special/Non-Functional Requirements

Business Rules

- Viewing/accessing certain statuses should be locked down by user roles (*For future iterations?)*
- *Information on this page is Read-only, except the comments field*
- *All Users should have access to this page*

Open Issues

- While reviewing is in place for expedited reports, it does not replace the central processing currently in place in AdEERS
-

Models & User Interface Prototype

5.1 Routing and Reviewing a Reporting Period

Goal: A completed adverse event reporting period is submitted for review by a clinical research associate at a study site and reviewed by a data coordinator at the coordinating center.
Source: CALGB (a cooperative group)
Primary Actors: caAERS user at study site requiring review of AEs (domain title: CRA, Study Coordinator); caAERS role: AE Coordinator or Subject Coordinator)
Secondary Actors: caAERS user at Coordinating Center performing the review of AEs (domain title: Data Coordinator; caAERS role: SAE Coordinator)
Scope: sub-system, AE module
Level: User Goal
Trigger:

Brief Description

Some centers have one user enter the AEs and another review them before they can be 'submitted'. The standard rules for AE submission are still valid, but not 100% represented here.

Preconditions

- user has access to the AE module

Steps

Main Success Scenario

1. caAERS User 1 logs into caAERS and accesses the AE module
2. caAERS User 1 enters/modifies AEs
3. caAERS User 1 saves the AEs
    a. caAERS evaluates the permissions
    b. caAERS saves the changes (see data items)
    c. caAERS checks for notification rules
        i. caAERS sends appropriate notifications
        ii. Notification will be role based
4. caAERS User 2 logs in to caAERS and accesses the AE module
5. caAERS evaluates the permissions
    a. If the user has review permissions, caAERS will allow access to a reviewer notes field
        - button for user to press next to each reporting period that will pop up a field to enter notes
    b. caAERS will allow the user to change the status of the reporting period
6. caAERS User 2 opens the "Manage Reporting Periods and AEs"
7. caAERS User 2 reviews Reporting Period & AE info
    a. if necessary, caAERS User drills down further and opens the reporting period
    b. if user has permission, can make modifications
8. caAERS User 2 enters any notes they feel are necessary
9. caAERS User 2 changes the status
    a. based on status selected, different things need to happen
10. caAERS saves the AEs

Extensions

7a. caAERS User 2 determines more information is needed before submitting

1. caAERS User 2 adds notes
2. caAERS user 2 changes status to "Reviewed needs updates"
3. caAERS analyzes the status and notification rules
    a. caAERS sends notification, as required
4. caAERS user 1 receives notification/reviews reporting period
5. caAERS user 1 reviews notes
6. caAERS user 1 opens the reporting period and makes necessary modifications
7. process repeats at step 3

Sub-Flows

- caAERS determines user access
- 1.1 Enter Observed AEs

Post Conditions

- some reporting periods are incomplete
- some reporting periods are ready for review
- some reporting periods have been reviewed and need updates made
- some reporting periods have been completed and are ready to be finalized
- some reporting periods are finalized

Data Items

Statuses

If the date the user is in the system is before the end date of the reporting period, the status will go to draft/incomplete.
If the date the user is in the system is after the end date of the reporting period, the status will go to complete ready for review
If the status is "changes requested" and the reporting period is modified, caAERS changes the status to complete ready for review?
An expedited report can be created for all statuses

- Draft/Incomplete
- Complete ready for review
- Changes Requested
- Complete
- Finalized
- Locked

Special\Non-Functional Requirements

Roles & Rights

- Need a role that has review rights only (PI, Study Coordinator, statisticians)
- Need a role (for Wake) that can Finalize the reporting period (limited access)
- Need a role (for Wake) that can Lock the reporting period (no additional changes can be made)
- Roles for CALGB - Data Coordinator and Data Entry. what are the permissions here?

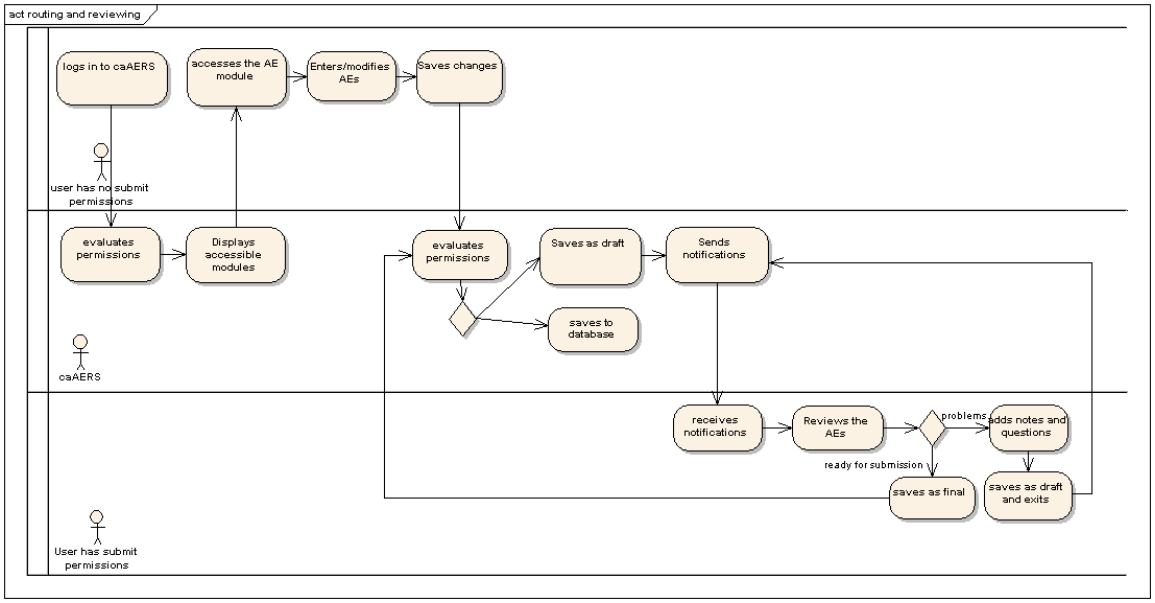
Business Rules

- Need to be able to have ability to have multiple levels of review (side-by-side and hierarchical)

Open Issues

- When would the review take place? at the end of the reporting period? anytime the reporting period info has been modified?
- How does this differ from central processing?
- How will we handle the display of all reporting periods for a study? Should that even be in this use case?

Models & User Interface Prototype



5.2 Routing and Reviewing an Expedited Report

Primary Actor: caAERS User - no AE submit permissions
Supporting/Secondary Actor: caAERs, caAERS user with submit permissions
Scope: sub-system, AE module
Level: User Goal
Trigger:

Brief Description

Some centers have special routing and reviewing processes for expedited reports. This use case documents those

Preconditions

- user has access to the AE module

Steps

Main Success Scenario

1. caAERS User 1 logs into caAERS and accesses the AE module
2. caAERS User 1 enters/modifies AEs
3. caAERS User 1 saves the AEs
    a. caAERS evaluates the permissions
    b. caAERS saves the changes (see data items)
    c. caAERS checks for notification rules
        i. caAERS sends appropriate notifications
        ii. Notification will be role based
    d. caAERS prompts for expedited report
4. caAERS User 1 creates the expedited report
5. caAERS User 1 sets the status (to?)
6. caAERS User 1 saves the report

    a. caAERS saves the changes
    b. caAERS checks for notification rules
        i. caAERS sends appropriate notifications
        ii. Notification will be role based
7. caAERS User 2 logs in to caAERS and accesses the AE module
8. caAERS evaluates the permissions
    a. If the user has review permissions, caAERS will allow access to a reviewer notes field
        - button for user to press next to each reporting period that will pop up a field to enter notes
        - reviewers note field on personnel page of expedited report?
    b. caAERS will allow the user to change the status of the reporting period
9. caAERS User 2 opens the "Manage Reporting Periods and AEs"
10. caAERS User 2 reviews Reporting Period & AE info
11. caAERS User 2 locates expedite reports and opens it
12. caAERS User 2 reviews the expedited report
13. caAERS User 2 enters any notes they feel are necessary
14. caAERS User 2 changes the status & saves the expedited report
    a. based on status selected, different things need to happen
15. caAERS saves the expedited report and updates the status

Extensions

12a. caAERS User 2 determines more information is needed before submitting

1. caAERS User 2 adds notes
2. caAERS user 2 changes status to "Changes requested"
3. caAERS analyzes the status and notification rules
    a. caAERS sends notification, as required
4. caAERS user 1 receives notification/reviews expedited report
5. caAERS user 1 reviews notes
6. caAERS user 1 opens the expedited report and makes necessary modifications
7. process repeats at step 7

Sub-Flows

- caAERS determines user access
- 1.1 Enter Observed AEs

Post Conditions

- some reporting periods are incomplete
- some reporting periods are ready for review
- some reporting periods have been reviewed and need updates made
- some reporting periods have been completed and are ready to be finalized
- some reporting periods are finalized

Data Items

Statuses

If the date the user is in the system is before the end date of the reporting period, the status will go to incomplete.
If the date the user is in the system is after the end date of the reporting period, the status will go to complete ready for review
If the status is reviewed - needs updates and the reporting period is modified, caAERS changes the status to complete ready for review
An expedited report can be created for all statuses

- Incomplete
- Complete ready for review
- Reviewed - needs updates
- Complete
- Finalized
- Locked

-

Special\Non-Functional Requirements

Roles & Rights

- Need a role that has review rights only (PI, Study Coordinator, statisticians)
- Need a role (for Wake) that can Finalize the reporting period (limited access)
- Need a role (for Wake) that can Lock the reporting period (no additional changes can be made)
- Roles for CALGB - Data Coordinator and Data Entry. what are the permissions here?

Business Rules

- Need to be able to have ability to have multiple levels of review (side-by-side and hierarchical)

Open Issues

- When would the review take place? at the end of the reporting period? anytime the reporting period info has been modified?
- How does this differ from central processing?
- How will we handle the display of all reporting periods for a study? Should that even be in this use case?

Models & User Interface Prototype

5.3 Routing and Review Setup

Primary Actor: caAERS User
Supporting/Secondary Actor: caAERS
Scope:
Level: User Goal
Trigger: caAERS is installed

Brief Description

- Institutions set up routing and reviewing for a caAERS instance, either enabling it or disabling it.
  - *Can we set it per site if multiple sites are using the same instance?*
- If routing & review is enabled, institutions can disable it on a per study basis
  - *What if it's not enabled for the site? can they still enable it for the study?*

Preconditions

- cancer center has caAERS installed
- caAERs user has admin rights

Steps

First Setup Screen - Details

1. User has a way to turn Routing & Review on or off for the caAERS instance
2. User has a way to select Review Status from a list, ~~and order the way they appear to the end users~~. Current list is available here:Routing & Review Statuses for caAERS
   a. ~~Draft/incomplete~~
   b. ~~Ready for review~~
   c. ~~Additional info needed~~
   d. ~~Complete~~
   e. ~~In 2nd level review~~
   f. ~~Finalized~~
   g. ~~Locked~~
3. *Do the statuses have business meanings and if they do, how are they set up?## Workflow?*
   a. *backend?*
   b. *Don't allow business meaning?*

Second Setup Page - Workflow

1. User has a way to setup notification based on each status selected on the first page
   a. Send to role
   b. Send to email address in the system (autocompleter, similar to gmail pulling up matches from your address book)
2. User has a way to setup what status is available
   a. could be based on current status
   b. could be based on role/rights (Not current iteration)
3. ~~From Ram - use the rules module - bring Ram into developer discussion~~

Sub-Flow - modify Study Details

New field: "Routing and Review enabled for this study?"

- If Routing & Review is not enabled for the caAERS instance, this defaults to no and is read only
- If Routing & Review is enabled for the caAERS instance, this defaults to yes, but can be changed to no
    - If they change it to no, Routing & Review fields should not be associated to the AE flow for that study

Post Conditions

- ~~*If reviewing is set up, status field will be used and may need controls*~~
- ~~*If reviewing is set up, a Reviewer's notes field will be added to the Enter AE page*~~
- ~~*If expedited report is required, Reviewer field(s) will be added to personnel page*~~

Data Items

- ~~Will need new roles~~** ~~two level of reviewing~~
    - ~~roles only appear if reviewing is set up?~~
    - ~~make sure this works for authorization~~

Special\Non-Functional Requirements

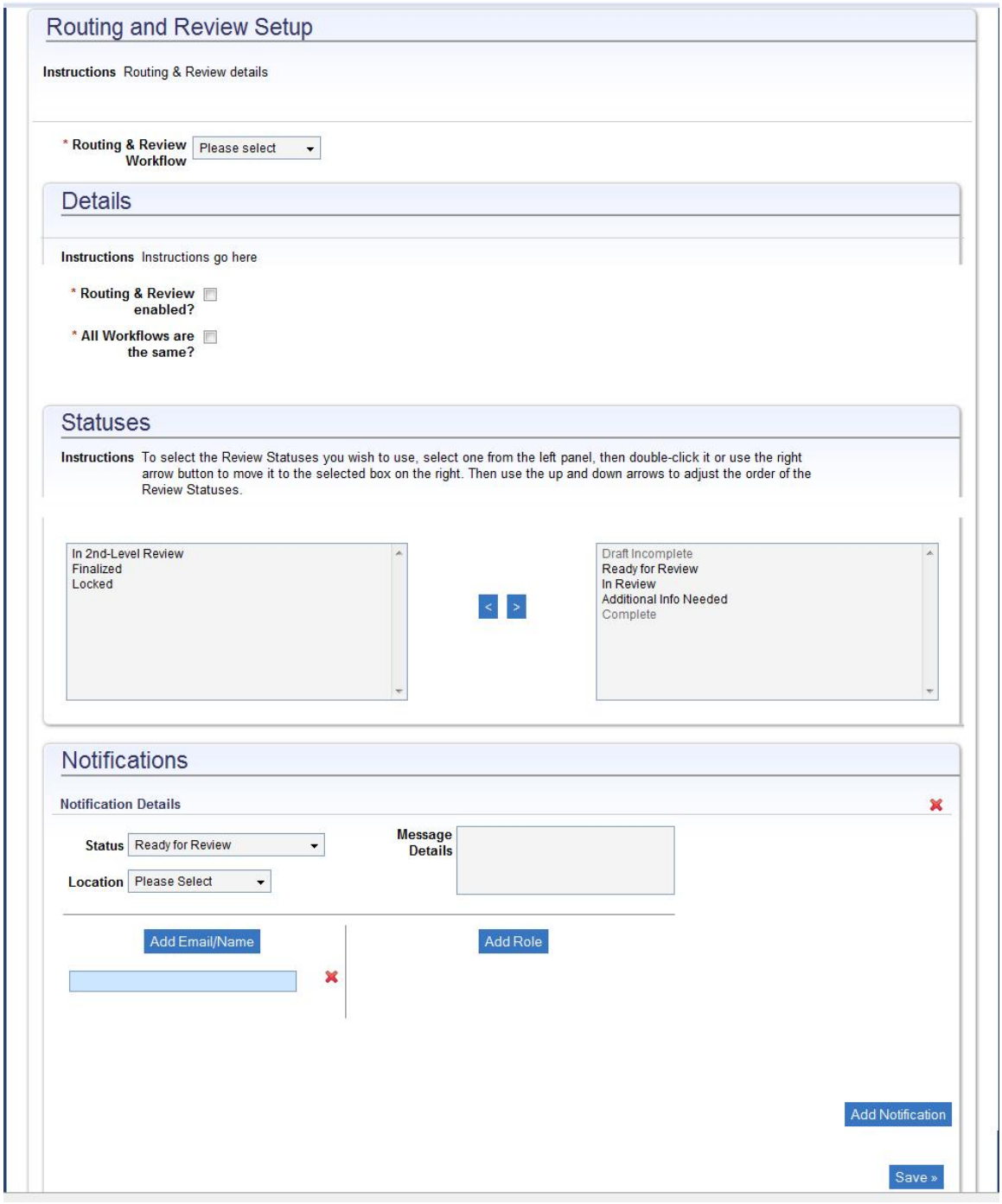
- ?

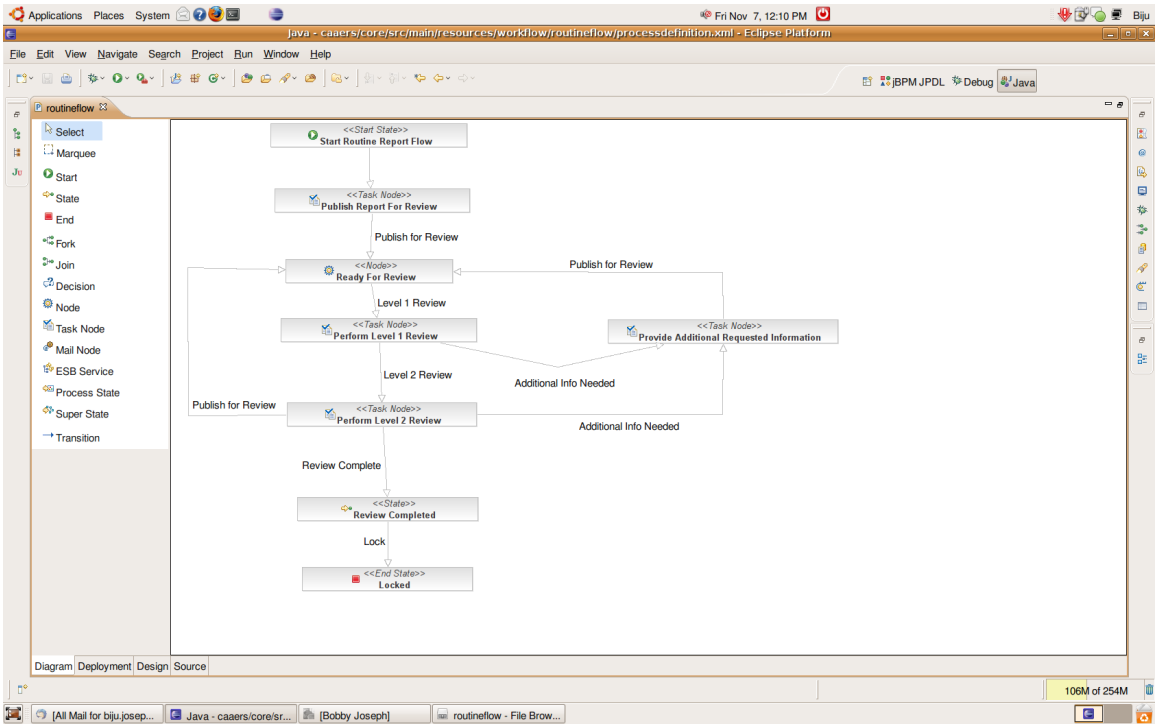
Open Issues

- ~~Need to be careful when setting up new roles, since authentication and authorization will be used.~~

Models & User Interface Prototype

You need flash player installed to preview ppt and pdf files


Routing and Review Setup
Instructions Routing & Review details
* Routing & Review Workflow
Please select
Details
Instructions Instructions go here
* Routing & Review enabled?
* All Workflows are the same?
Statuses
Instructions To select the Review Statuses you wish to use, select one from the left panel, then double-click it or use the right arrow button to move it to the selected box on the right. Then use the up and down arrows to adjust the order of the Review Statuses.
In 2nd-Level Review
Finalized
Locked
Draft Incomplete
Ready for Review
In Review
Additional Info Needed
Complete
Notifications
Notification Details
Status
Ready for Review
Location
Please Select
Message Details
Add Email/Name
Add Role
Add Notification
Save »



5.4 Central Processing

Primary Actor: caAERS
Supporting/Secondary Actor: AdEERS
Scope: system level
Level: User Goal
Trigger: caAERS user submits an expedited report through caAERS that requires central processing

Brief Description

Some multi-institutional studies sponsored by CTEP have all expedited reports go to the lead organization before they're handed off to CTEP and NCI. AdEERS tracks certain time triggers during the process

Preconditions

- caAERS User must have permissions to submit an expedited report
- It must be one of the institutes that still send expedited reports to the lead organization before they go to CTEP/NCI
- caAERS is programmed to know which organizations go through central processing

Steps

AdEERS to AdEERS Central Processing - current process

1. AdEERS user submits expedited report
2. AdEERS checks to see if central processing is in place
    a. AdEERS sends report to central office? How? notification how?
    b. AdEERS records a timestamp on when it was sent to the central office
    c. AdEERS keeps the report in the front end as "pending"
    d. AdEERS prevents original submitter from making any changes
3. Central Processor reviews report
    a. Makes any required changes
    b. Contacts site with any questions
4. Central Processor submits report
5. AdEERS submits the report to CTEP, NCI
    a. AdEERS records a timestamp on when it was sent to CTEP

caAERS to AdEERS Central Processing

1. caAERS user submits an expedited report
2. caAERS submits report to AdEERS
    a. caAERS includes indication of central process requirement
        - What indications? Lead org from study abstraction?
3. AdEERS receives expedited report from caAERS
    a. Checks to see if central processing is in place
    b. AdEERS sends report to central office? How? notifications? physical?
    c. AdEERS (caAERS?) records a timestamp on when it was sent to the central office
    d. AdEERS keeps the report in the front end as "pending"
    e. AdEERS prevents original submitter from making any changes
4. Central Processor reviews report
    a. Makes any required changes
    b. Contacts site with any questions
5. Central Processor submits report
6. AdEERS submits the report to CTEP, NCI
    a. AdEERS records a timestamp on when it was sent to CTEP

caAERS to caAERS Central Processing - out of scope?

1. caAERS user submits an expedited report
2. caAERS checks to see if central processing is required

1.
    - What indications? Lead org from study abstraction?

1.
    a. caAERS marks status as pending - central processing
    b. caAERS sends report notification to central processor?
    c. caAERS records a timestamp on when it was sent to the central office
    d. caAERS locks out all users except those at central processing
2. Central Processor reviews report in caAERS
    a. Makes any required changes
    b. Contacts site with any questions
    c. records comments in reviewer notes?
3. Central Processor submits report
4. caAERS submits report to AdEERS
    a. caAERS records a timestamp on when it was sent to CTEP
    b. includes indication that it has been through central processing
        - how? need to prevent AdEERS from trying to send it to central processing. Would AdEERS have the protocol abstraction to do this if they are using caAERS?
    c. includes the two recorded timestamps
5. AdEERS finalizes the report and makes it available to CTEP/NCI

AdEERS to caAERS Central Processing - out of scope

Extensions

Report requires central processing but wasn't flagged as such

Sub-Flows

caAERS determines user access
Enter expedited report

Post Conditions

- central processor has reviewed the report
- expedited report is sent to CTEP/NCI

Data Items

- Need new 'central processing in place?' field that is associated to organization.
    - need to pass it to AdEERS since AdEERS generally pulls it from CTEP protocol abstraction, which may not be in the AdEERS system anymore
    - AdEERS handles this with a flag for "lead Org". If there is a Lead organization listed in the protocol abstraction, it goes to central processing.

Special\Non-Functional Requirements

- Any special items of interest or non-functional requirements to be addressed

Business Rules

- CTEP must be able to track timestamps
    - when it was sent to central processor
    - when it was finalized in AdEERS (central processor completely)
-

Open Issues

- Would we need to prevent a user from sending an amended report until the report had completely gone through central processing?
- Since central processing is tied to the organization, not the study, need to figure out how to set that up
- If the central processor makes changes to the report in AdEERS, how do the changes get back into caAERS?
- If we allow caAERS to caAERS to AdEERS reviewing, need a way to indicate the report has been reviewed by Lead Org/Central Processing so it doesn't go down the same path in AdEERS

Models & User Interface Prototype

Provide an optional UI mockup, if useful.
Provide an optional UML diagram

Assigning Permissions - UC draft

Primary Actor: caAERS User
Supporting/Secondary Actor:
Scope:
Level: User Goal
Trigger:

Brief Description

Enter a brief description

Preconditions

Enter any factors that must be met before the use case starts

Steps

Main Success Scenario

1. Enter the main steps

Extensions

Enter any alternative flows, failure flows, and exceptions

Sub-Flows

Enter any paths that are used by multiple paths within the use case (could just be a link to another use case)

Post Conditions

- What items hold true after the use case is enacted?

Data Items

- What data items are of interest and should be modeled?

Special\Non-Functional Requirements

- Any special items of interest or non-functional requirements to be addressed

Open Issues

- Any questions about the flow that need to be answered before the flow can be finalized.

Models & User Interface Prototype

Provide an optional UI mockup, if useful.
Provide an optional UML diagram

caAERS R&R Reqt

Routing & Reviewing
Items to consider

- Configurations
    - Single site
    - caAERS - caAERS reviewing
    - caAERS - AdEERS reviewing
- Types of Reviews
    - Reviewing by subject/study combination
    - Reviewing by subject
    - Reviewing by study
    - Reviewing evaluation period
    - Reviewing single AEs
    - Reviewing expedited reports
        - Central Processing
        - No central processing
- Two review processes
    - Verify data entry is complete
    - Verify data is valid (data entry personnel does not see status)
    - Once data entry review is complete, that level of reviewer does not see the other statuses
- Levels of review
    - side-by-side
    - hierarchical
- Access rights
    - Access data for a study regardless of location
    - Some Reviewers will have read-only rights
- Separate module?
- Routing & Review Setup
    - Per site?
    - Per study?
    - Levels of review
- Communication required between reviewer and data entry
- Search by review status
- What data needs to be viewable for the review?
- Review reports (printable)
- Notifications based on review status
    - notification ready to review
    - notification of action required
    - Should it include list of actions?
- Review Statuses
    - Customizable by site

caAERS Routing & Reviewing Brainstorming

Add a Routing and Reviewing task in the Admin Module

1. First setting: Is Routing and Reviewing on? yes/no
    a. If Yes, New fields on Research Staff page and new task viewable under AE module
2. Second setting: What review statuses do you want to add?
    a. autocompleter, pre-populated with statuses, with a show all button
    b. If not in the list, when they hit enter or add, it asks if you want to add the status
3. Third setting: Studies this shouldn't be applied to?: autocompleter (next phase?)
4. Fourth setting: Send email notifications? yes/no
    a. If Yes, link on Routing & Reviewing task that allows email to be sent
    b. (next phase), allow setup of auto-notifications?
5.

Modifying the Research Staff page

1. When adding research staff, assign Review statuses that are viewable
    a. Column for Review status listing all statuses with checkboxes
    b. User selects the statuses the user would be able to view
2.

?

Routing and Review Task

1. Add Routing & Review as a task under AE module
2. Provide Search parameters - user must select one or more - provide warning if just use wildcard
    a. Study (auto-completer)
    b. Patient (auto-completer)
    c. Date range (mm/dd/yyyy fields plus calendar icons)
    d. Review status (multi-select dropdown)
    e. AE term (auto-completer)
3. Provide fields to show
    a. evaluation period
    b. patient id (name?)
    c. study
    d. ae term
    e. verbatim field
    f. grade
    g. attribution
    h. link to expedited report (pdf)
    i. other?
4. Search results come up on the next page
    a. table format, two rows per
    b. organized chronologically by patient, but can sort by columns
    c. Review status is right-most column
    d. Notes field icon next to status
    e. Notify button that allows user to send notification to other user?
    f. click on evaluation period to bring up evaluation period to make changes?
    g. make fields editable on this page?
5. User's possible actions
    a. Change Review status
    b. Add notes/question for other users
    c. send notifications?
    d. Must click Save to save the changes made on this page
6.

Routing & Review Statuses for caAERS

	Status	Definition	Required?	Comments
1	Draft/Incomplete	Status given to any newly created evaluation period or expedited report	Yes	
2	Ready for Review	Status used when data entry is complete for the evaluation period or expedited report	no	
3	In Review	Status to indicate the information is being reviewed	no	
4	In Second Review	Status to indicate the information is going through a second level review	no	After discussions with Amish, need to clarify this name to clearly indicate that it's another level of review, not a second look at the data
5	Additional Info Needed	Status used by the reviewer when more info is needed or changes are requested	no	Amish - Is there any distinction between "Additional Info Needed" and "Rejected"? Obviously Rejected sounds more negative, but it also conveys the point, whereas Additional Info Needed sounds more optional
6	Review Complete	Status used to indicate the review has been complete	Yes	
7	Locked	Status to indicate the data can not be changed **Note**: locking the data will not be implemented in the first release	no	

Routing and Review Whiteboard

Will reviewers be making changes to the data they review, or will they just be commenting on it?

Wake

I believe reviewers should only be able to comment on data they review. Changes should be made by the person who entered information.

Mayo

- Will not be using this more than likely.
- Doesn't believe reviewers should be able to make changes.
- Only review of report is physician review which is paper-based.
- Pat reviews after it's been submitted, but doesn't make changes, only sends feedback.

CALGB

- Will be using this.
- Will be reviewing data entered from a site
- Central office will update the patient ids for on expedited reports
- Monitors aren't allowed to make changes, but they provide comments
- Not sure what lead cras do
- Reviewers (Lead CRAs, staff at CALGB, otherwise) should have read-access only, with a comments field
- If changes are possible, it should only be for things like typos, not clinical info

CTEP

IT IS IMPORTANT TO DEFINE 'REVIEWER' -- DEPENDING ON USER/SPONSOR, 'REVIEWER' MIGHT ALSO BE REPORTER, SUBMITTER. FOR HISTORICAL/CURRENT USE OF ADEERS, REVIEWER HAS THE ROLE AS BOTH REVIEW-ONLY, AND/OR MODIFY DATA. SEE ADEERS SUBMISSION SCREEN:"I CERTIFY THAT THIS REPORT HAS BEEN REVIEWED AND APPROVED BY.....RESPONSIBLE FOR....PATIENT....ETC"

If they can make changes, what information should they be able to change?

- What specific fields?
- Can they delete AEs?
- Can they add AEs?
- Can they modify expedited reports?

Wake

1. Attribution mainly, grade and expectedness to some degree, but that is constrained by the protocol or the grading scale
2. They should not be able to delete them entirely unless they are found to be completely in error; I believe the only person who should delete is the person who entered the information.
3. Yes, but again, that would be because of an error (missed from flow chart)
4. Can they modify expedited reports? Expectedness, attribution mainly

Mayo

na

CALGB

- no changes, just comments
- can't delete or add AEs
    - DELETING AN AE IS SAYING THE EVENT DIDN'T HAPPEN. IF THEY THINK IT IS AN INCORRECT TERM, OR IT DOESN'T MEET THE DEFINITION OF THE PARTICULAR AE, THEY SHOULD COMMUNICATE WITH THE REPORTER. I THINK I'M MAKING WORK FOR US. BUT THERE ARE A LOT OF REPORTS THAT DON'T SEEM TO MAKE SENSE, BUT THE REVIEWER DOESN'T KNOW THE PATIENT. IF THE COMMUNICATION IS ALL ELECTRONIC, SPEAKING FOR MYSELF I COULD PROBABLY MAKE COMMENTS MORE PROMPTLY. I CAN'T BELIEVE I'M SAYING THAT BUT ALL OF THE PILES IN MY OFFICE ARE PAPER COPIES OF AEs FROM COMPANIES. I REVIEW THE ELECTRONIC ONES SOONER.
- can't modify expedited reports
    - COMMENTS ARE PROBABLY MORE RELEVANT TO EXPEDITED REPORTS THAN TO ROUTINE REPORTS, BUT MY THINKING IS QUALITATIVELY THE SAME.

CTEP

DEPENDING ON CAAERS DEFINITION OF REVIEWER. IN ADEERS, THE REVIEWER IS THE MEDICAL INDIVIDUAL RESPONSIBLE FOR THE ACCURACY OF THE ADEERS REPORT DATA. THEREFORE, IN ADEERS THE REVIEWER MAY CHANGE ANY DATA ELEMENT, Delete AEs, Add AEs, and modify the expedited report.

If they can make changes, are the changes real-time, or do they have to viewed and accepted by the person (role) who originally entered the information?

Wake

I believe they are passed back to the person who entered them, though in some systems the sign off is in electronic and immediate; Agree - should be passed back to the person who entered the information.

Mayo

na

CALGB

Comments are made, but no actual changes (beyond typos, minor changes) THE SUGGESTIONS TO ADD OR DELETE AN EVENT, CHANGE A GRADE OR AN ASSESSMENT OF ATTRIBUTION SHOULD BE VIEWED BY THE REPORTER. MAYBE NOT EXACTLY REAL TIME, BUT SEE COMMENTS ABOVE REGARDING TIMELINESS

CTEP

IN THE ADEERS SYSTEM, ANY CHANGE MADE TO THE REPORT IS, OF COURSE, REAL-TIME. THE INDIVIDUAL ENTERING ORIGINAL DATA NEED NOT 'ACCEPT' OR APPROVE / REJECT DATA CHANGES. IN ADEERS THE REVIEWER (SOMETIMES ALSO THE SUBMITTER) IS INTENDED TO BE THE MEDICAL PERSON MOST KNOWLEDGEABLE ABOUT THE PATIENT AND AE DATA ON REPORT.

If reviewers do make changes, should they have the ability to start reports (should the rules fire when they click Save & Continue on the Enter AE page?)

Wake

yes, if they up a grade and it triggers a report, they need to be able to very very quickly start an SAE and or pass on the need to the person responsible for entry.

Mayo

na

CALGB

na

CTEP

IN ADEERS, NO. IN ADEERS THE CLOCK SET STARTS WHEN THE REPORT IS ORIGINATED - REGARDLESS WHO THAT MAY BE. REMEMBER, IT IS ASSUMED THAT WHEN SOMEONE STARTS AN EXPEDITED REPORT, SOME HUMAN HAS KNOWLEDGE THAT AN AE OCCURRED THAT REQUIRES EXPEDITED REPORTING. THEREFORE IT IS THAT TIMEFRAME UPON WHICH TIMELINES FOR SUBMISSION TO SPONSOR/REGULATOR ARE BASED.

What are the different reviews you are doing & what is the information you need to be able to do that review

- For example: checking to see if an evaluation period has more than 5 "other specify" AEs, would need to view all AEs in the evaluation period and what other data?
    - Actually is a check done when CALGB submits the CDUS reports, and it's 5%, not 5
- Second example: verifying Evaluation Periods don't overlap too much, don't have gaps between them
    - CALGB is under the impression that the system will not allow CRAs to submit reports with overlapping dates and that having a gap between forms would generate an warning error. If we will do this check internally we will basically need to see a list of the evaluation periods submitted for a pt.
- Third example: verifying all solicited AEs have been commented on, requires evaluation period, AE, verbatim field, grade, attribution fields
    - CALGB thought this was built into the system

Wake

1. For example: checking to see if an evaluation period has more than 5 "other specify" AEs, would need to view all AEs in the evaluation period and what other data? Yes, that would be a valid review, also review for missing data, template data that has been deleted, and AE's graded higher than baseline that attributed to the protocol.

2. Second example: verifying Evaluation Periods don't overlap too much, don't have gaps between them Yes.
3. Third example: verifying all solicited AEs have been commented on (no), requires evaluation period , AE, verbatim field, grade, attribution fields (yes, we have a PI review of attribution report.

Mayo

na

CALGB

For routine reports we are reviewing:

- the correct pt ID was used (this should be done by the system for the most part since Pt IDs will be loaded into the system and the system should not let sites pick Pts that are not registered by them or Pt IDs that are not registered to the correct study.)
- Correct evaluation period
- All solicited events have a grade (system should check for this too)
- All events graded > 0 have an attribution code (and hospitalization and expectedness if required) (system should check for this too)
- Routine reports match AdEERS reports (system will ensure this happens as well)

Do you need to be able to comment on individual AEs or just on the overall evaluation period?

Wake

Both

Mayo

na

CALGB

Individual AEs would be nice but with the system doing all of these checks, I can't imagine we will commenting on too many individual AEs

Do you need to be able to provide statuses on each AE in an evaluation period, or just a status for the evaluation period as a whole, and a status for each report that is part of the evaluation period?

Wake

I think for the entire evaluation period (done not done, pending or not pending queries) should be sufficient

Mayo

na

CALGB

We do not need statuses for each AE. I guess I am confused- I thought we could only have one report per evaluation period. Either way, we need to have a status for each report whether there is more than one per evaluation period or not.
To do our review we will need a view that is similar to the Manage Reports page, but we would like to be able to query for forms submitted for a certain study (not just a single pt), for a single pt.and for a review status. The query return page should return a list of pt IDs meeting the search criteria and then clicking on a pt ID will open a page with a list of reports submitted for that pt. function like the manage reports page: A list of forms shows up and clicking on the arrows expands the list of AEs included in that report, etc.

Module 5 Internal Routing Use Cases (caAERS)

Module 5 - Internal (Institutional) Routing and Review

Module 6 UC - Integrated Repository of AE Data

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 UC - Automated AE Grading from Lab Data

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 caLAEGS 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 UC - Assistance with Grading Qualitative AEs

Module 8 - Assistance with Grading Qualitative Adverse Events

Module 8 will provide assistance in the grading of adverse events found through clinical observation. Grading will be based on CTEP's CTC version 2.0 and CTCAE version 3.0. It may be feasible to display the different grades available to assist the users in choosing the correct one.

Module 9 UC - Patient Reported Adverse Events

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 UC - 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.

Use Case	PDate Created	Date Last Modified
10.1 Analyze Adverse Events	02/10/2010	02/25/2011

10.1 Analyze Adverse Events - Use Case

Scope: system - caAERS
Level: User Goal
Trigger:

Brief Description

This use case documents the steps to determine the observed frequency of adverse events.

Primary Actor

cAERS system, caAERS user

Preconditions

- The caAERS user has access to the Advanced Search tab
- There are adverse events to which the caAERS user has search access in the Advanced Search tab

Steps

1. The user selects the criteria for the study they want to search on
2. The user selects any subject criteria they want to search on
3. The user selects any adverse event criteria they want to search on
4. The results of the search are returned to the user
5. The user selects the type of statistic report they would like to see (eg. frequency, severity)
6. The results of the statistic are displayed
    a. A tabular display is available
    b. A graphical display is available
7. The user can click on the returned results and drill-down into the records corresponding to that result
8. The user can adjust the filter criteria on-the-fly and regenerate the results (i.e. further filter by subjects of a certain age, filter AEs by term or category).

Extensions

Sub-Flows

Determining user rights

Post Conditions

Data Items

Special\Non-Functional Requirements

Patient safety
Study toxicity

Analyses that should be able to be performed include:

1. The occurance frequency of an AE on a study
2. The severity of an AE on a study
3. The distribution of AE severity on a study
4. The % of subjects having experienced a "serious" AE
5. # of AEs that resolved
6. # of AEs that didn't resolve
7. Summary of AEs by type and by grade (patient safety)
8. Summary of SAEs by type and by grade
9. Hospitalization events
10. Trend analysis on a patient for an AE or a selected set of AEs
11. Trend analysis on the study for a particular AE or selected set/category of AEs

Open Issues

- Which roles should be allowed to run these analyses?

Module 11 UC - Public Safety Website

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 UC - Decision Support for AE Expectedness

Module 12 - Automated Decision Support for Expectedness

Use Case	Date Created	Date Last Modified
12.1 Setting up Expectedness in AEs	05/15/2008	10/22/2010

12.1 Setting up Expectedness in AEs - caAERS UC draft

Primary Actor: caAERS User
Supporting/Secondary Actor: caAERS; TRI, PI (Sponsor)
Scope: sub-system
Level: User Goal
Trigger: a new study is being added to caAERS

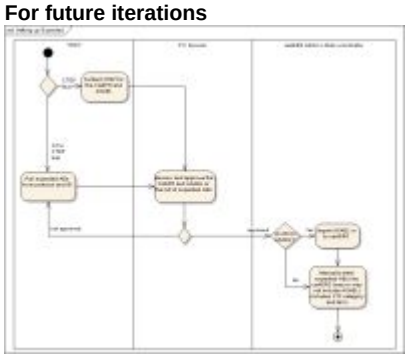
Brief Description	At the beginning of a CTEP IND trial, someone at CTEP reviews the Investigation Brochure and Protocol and compiles a CAEPR (Comprehensive Adverse Event and Potential Risk List) and ASAEL (Agent Specific Adverse Event List), with the ASAEL being a subset of the CAEPR, used for expedited purposes only.
	The Wake Forest Research Base only does Cancer Controlled Prevention Studies. The AE list is taken directly from information in the protocol, and a Toxicity Assessment Sheet is created and added as an appendice.
	
	Expectedness of an AE can also be found in the following locations:
	
	• the protocol related documents (though the specificity and completeness of their description may vary)
	  • in more technical terms in the AE section of the protocol document. (these may require some explosion from general categories to specific terms)
	  • any applicable investigator brochure, (this would be a duplicate of what is in the protocol document most likely
	  • the informed consent document (the use of lay terms in the consent may require some educated translation to medra terms)
	• other relevant sources of information
	  • product labeling and package inserts
	  • electronic databases (for commercial agents)
	  • First Databank (http://www.firstdatabank.com/)
	  • Lexi-Comp(http://www.lexi.com/web/partlexi.jsp)
	  • Micromedex(http://www.micromedex.com/). Micromedex is available via the NIH Library.
	
	Once a list of expected AEs is compiled, they are reviewed by the Principal Investigator (PI) and/or the Sponsor to validate them. (this should be done before IRB approval and may be an appendix to the protocol or part of the protocol)
	Setting up expectedness in caAERS is a multi-phased process. For the first phase of implementation, caAERS users will be able to add a list of expected AEs during the study set up to determine the expectedness as they document . If a user enters an expected AE during a reporting period, the expected field will autopopulate.
	In future phases, we will work to have the ability to replicate or import the ASAEL in to caAERS, and possibly a way to import the expected AE list.

Things to consider	??do disease expected AE's figure into this process? for rules that do not use relatedness, only expectedness, this could be problematic. The ability to add expected AE's from similar trials would be expedient as well Currently, expectedness is an all or nothing thing. For example, a PI/consent may say that mild nausea is expected, but if severe nausea occurred it would still be listed as expected. However, nurses say that really bad nausea would trigger other AEs, like electrolytes etc that would be reported. So, nurses understand that it is unexpected based on grade, even though it'd be reported as expected. Perhaps this is why we have managed to go this long without having to address this, that is, nothing mentioned as expected in mild form can happen in severe form without triggering something else. So, future version may need to address this.

Preconditions	• caAERS user has access to the Studies module • caAERS user has knowledge of medical terms and AE terminology • Study has been/is being added to caAERS • caAERS User is logged in to caAERS
First phase Implementation	**Enter expected AEs in Study Flow** 1. caAERS user has a list of expected AEs (*receives the list of expected AEs from the Investigator)* 2. caAERS user logs in to caAERS and opens the study/adds the study 3. caAERS user goes to the Expected AE page of the study definition 4. caAERS user adds expected AEs, based on the list provided a. Uses CTC terminology i. both category and ctc term need to be included ii. user can select the category and then select the term iii. user can type in the term and have the category autopopulate iv. user has ability to add multiple terms at once (same "Add Multiple as the AE flow and solicted AEs) v. user has the ability to add multiple "Other specify", as long as the "other field is different b. Uses MedDRA terminology i. enters term 5. caAERS user saves the study 6. caAERS verifies the information is valid and saves the information to the database **Enter AEs** 1. caAERS user enters AEs in an evaluation period OR Evaluation period has a solicted AE 2. User adds a grade for the AE 3. If there are expected AEs tied to the study, caAERS does the following: a. Expected field selection is driven by expected AEs 4. If the AE is listed in the study, the response becomes "Yes" 5. If the AE is not listed in the study, the response becomes "No" a. *Expected field becomes read-only* - implement next iteration, with an override option b. Expected field is still optional 6. If there are not expected AEs tied to the study, caAERS does the following: a. Expected field is left at "Please select" b. Expected field remains optional 7. If the expected field is left blank (Please select), the rule value will be read as "No" **So, the expected field will only autopopulate if there are expected AEs associated to the study, and if a Grade is associated to the AE** **Extensions** **5a. caAERS encounters an error when saving expected AEs** 1. caAERS displays an error stating what the problem is 2. caAERS user adds/modifies/deletes information 3. caAERS user saves the study 4. caAERS verifies the information is valid and saves the information to the database **Sub-Flows** caAERS determines user access

Possible next phase implementations	**Associate expected AEs to specific therapies, Agents, TACs** Similar to associating solicited AEs to Evaluation periods, we need to associate expected AEs to the Therapy, Agent, TACs. We need to research how it's provided in the protocol before moving forward, but we know ASAEL is based on agent. **Add ASAEL** Working with CTIS, we'll determine a way to receive the ASAEL (*via message?*) and integrate it into the study definition. Until that is possible, we could integrate it via the following method (or something similar). *Enter ASAEL Manually* 1. caAERS user receives the ASAEL from CTEP 2. caAERS user logs in to caAERS and opens the study/adds the study 3. caAERS user goes to the Expected AE page of the study definition 4. caAERS user selects from dropdown Expected AE format a. Enter List b. Enter ASAEL 5. caAERS user adds the ASAEL a. AE term b. Grade c. Hospitalization 6. caAERS user clicks Continue, Save, or Save&Continue (depending on if they're adding or editing a study) 7. caAERS evaluates the information to see if there are errors 8. If there are errors, caAERS displays the errors and does not continue 9. User makes changes to fix the errors & saves again 10. caAERS saves the Study **Import Electronic ASAEL; (electronic expected AE list for non-CTEP IND studies?)** What format would you want the information to be provide to be able to import it, if we don't get it from AdEERS? The Wake Forest Research Base does not get any information from AdEERS, or the CTEP agent list. 1. caAERS user opens Import area of Admin module 2. caAERS user selects ASAEL to import 3. caAERS evaluates the information to see if there are errors a. If there are errors, caAERS displays the errors and does not continue 4. caAERS imports the ASAEL 5. caAERS user opens the study to verify the expected AEs are listed **Import Electronic expected AE list for non-CTEP IND studies** Need to determine if we want to allow this and what format it should be provided in. For example, Wake Forest Research Base does not get any information from AdEERS, or the CTEP agent list. 1. caAERS user opens Import area of Admin module 2. caAERS user selects ASAEL to import 3. caAERS evaluates the information to see if there are errors a. If there are errors, caAERS displays the errors and does not continue 4. caAERS imports the ASAEL 5. caAERS user opens the study to verify the expected AEs are listed
Post Conditions	Expected AEs have been associated with the study in caAERS
Special\Non-Functional Requirements	Expected will be populated when grade is entered, since it is not pertinent if the grade is not entered or is 0 (in the case of solicited AEs)

Open Issues	• The expected AEs can change over the length of a study, correct? (yes)
	  • When an AE is added to the expected list, should this affect AEs reported in past reporting periods, or only ones included in new/modified reporting periods?
	  • When an AE is removed from the expected list, should this affect AEs reported in past reporting periods, or only ones included in new/modified reporting periods?

Models & User Interface Prototype	**The proposed mockup**  **For future iterations** 

Module 13 UC - Security

Module 13 - Security

Use Case	Date Created	Date Last Modified
13.1 Using an Organization's system for Authorization	05/23/2008	10/22/2010
13.2 Adding a user to caAERS	07/07/2009	02/24/2011
13.3 Updating user information	02/24/2011	02/24/2011
13.4 Resetting a user's password	02/24/2011	02/24/2011

13.1 Using an Organization's system for Authorization - caAERS UC draft

Scope: System
Level: User Goal
Trigger: User tries to log in to caAERS

Brief Description	caAERS needs to work with an organization's existing credential provider (repository of user names and passwords) and authorization system (authorization scheme and policies). A user logs in to caAERS using their standard user name and password. caAERS contacts the organization's credential provider to verify the user name and password, and their authorization system to check for roles and permissions. The credential provider and authorization system provide user object(s) that caAERS uses for the session only.
Primary Actor	caAERS system
Secondary Actor	CTMS Authorization System, CTMS credential provider

Preconditions	• Organization's credential provider and authorization system should expose well-defined APIs
	  • APIs should be java-based
	  • If APIs are not java-based, the organization needs to expose the web/grid services for the APIs

Success Scenario - inside firewall, centralized authentication/authorization	1. User logs into the local domain
	2. User opens caAERS
	  a. caAERS determines if domain authentication is required or not
	3. caAERS queries the local domain for authentication and authentication information (separate calls)
	  a. The credential provider returns a user object after successful authentication
	  b. The credential provider returns a user object after successful user id validation
	  c. The authorization system provides information about the user's role(s) and permissions
	4. caAERS makes a call to their authorization system asking if the role has permissions or not
	  a. Their authorization checks, returns true/false if the user has permissions (field, page, module)
	  i. pending on local requirements, caAERS can cache's the user's roles and rights for the session only
	  ii. caAERS keeps the user object for the user session only
	5. caAERS displays only those modules which the user is authorized to access
	6. caAERS will release user object and cache info when user logs out or the session times out (15-20 min)

Success Scenario - outside firewall, centralized authentication/authorization	1. NOTE: This is written to be specific for the CALGB.
	2. User logs into caAERS with their organization provided user id and password## If userid and password are correct and the account is active then the credential provider returns a UserAccount object (i.e., Prinicipal) after successful authentication. At this point the user is considered to be authenticated and no more authentication calls are required. [CTMS:Although we can consider that there is some time-to-die for any authenticated user which should require a re-authentication of some kind.]
	  a. If userid and password are not correct or the account is not active, then a Null is returned.
	  b. NOTE: We may handle this via SSO in which case no call would need to be made, rather the authentication would take place via a redirect to and back from the SSO ***(out of SemanticBits' scope)***##* caAERS keeps the UserAccount object (i.e., Prinicipal) for the user session only
	3. Given a valid UserAccount (i.e., Prinicpal) object, caAERS will query the credential provider whether a specific username has a specific permission to perform a specific user action. This includes not only "executeApplication" permissions for caAERS itself, but also for any screen, dropdown, button press, etc. as well as reading, writing, etc, of any object in the system. [CTMS:The granularity here depends on how caAERS allows users to do certain actions. If it is large grained and assumes that a single permission covers many things or if it is fine-grained and wants to check each field, button, etc.]## The credential provider returns an Answer which may have any of four statuses: PERMIT, DENY, INDETERMINATE, or NOT_APPLICABLE. These mean Allow, Deny, exception occurred inside authorization (treat as DENY), and the values passed in do not exists e.g., the permission asked about doesn't exist. ***(what is the indeterminate for? if you can't determine, you should be denied)***
	  a. It is crucial to note that calls must also be made here to determine if a specific user has Create, Read, Update or Delete permissions for various instances of Studies, Subjects, Staff and Sites. caAERS may ask if a specific user has 'ReadStudy' for CALGB Id '40401'. caAERS may ask for a list of all Subjects that a specific user can update ('UpdatePatient').
	4. caAERS will respect the Answer to make all authorization decisions## No database objects (i.e., Study, Subject, Staff, Site and perhaps others) should ever be shown to a user without first checking for permission.
	  a. caAERS may cache the user's permissions for the user session only.
	5. caAERS display only those modules which the user is authorized to access
	6. caAERS display only those objects which the user is authorized to access
	7. caAERS allow only those actions which the user is authorized to perform
	8. caAERS will release user object and cache info when user logs out or the session times out (15-20 min)

Success Scenario - inside firewall, not centrally managed	1. User logs into the local domain
	2. User opens caAERS
	3. caAERS queries the local domain for authentication information
	  • The credential provider returns a user object after successful authentication
	4. caAERS uses the user object to checks internal roles for authorization
	  • caAERS keeps the user object for the user session only
	5. caAERS logs the user in and displays only those modules which the user is authorized to access
	6. caAERS will release user object and cache info when user logs out or the session times out (15-20 min)

Success Scenario - outside a firewall, not centrally managed	1. User logs into caAERS with their organization provided user id and password
	2. caAERS queries the local domain for authentication information
	  • The credential provider returns a user object after successful authentication
	3. caAERS uses the user object to checks internal roles for authorization
	  • caAERS keeps the user object for the user session only
	4. caAERS logs the user in and displays only those modules which the user is authorized to access
	5. caAERS will release user object and cache info when user logs out or the session times out (15-20 min)

Extensions	2a. user name/password is invalid • linking password policy use case (out of scope) 1. caAERS returns an error message and brings up the sign on screen again 2. caAERS user signs on again • Note: SSO will handle both of these automatically

Data Items	• user object** password
	  • name
	  • user name
	  • roles
	  • permissions
	• CALGB case: UserAccount which implements Principal** username
	  • participantId
	  • fullName
	  • primaryEmailAddress
	  • status ***what does this mean?***
	  • statusDate
	  • lastLoginDate
	  • creationDate
	  • CALGB doesn't pass back a reference to the actual password that was used to get the UserAccount object.
	  • CALGB doesn't attach roles or permissions to the UserAccount. Callers are expected to ask at the time of need.
	  • CALGB doesn't expose any of our Role information. Our system only deals with Permissions. Our centralized Authorization system uses Roles internally to help manage Permissions. We do not expose the Roles so that developers cannot overload them with their own idiosyncratic permissions. In other words, we want callers to ask for permissions like 'CreatePatient' and not assumes that the Role "Clinical Research Associate" can just do this. We want to be able to change and modify our security policies without fear of introducing funky behavior in production apps.
	• Need to set up authentication chaining mechanism

Mayo specifics - based on 6/6 meeting	Process: request to server -> miniserver on DMZ -> server behind firewall gives yes/no -> back to mini server ->back to user Need further discussions with Randy (handles security and authorization) **Authentication** perl script sends pass/fail on login or transaction Can be course-grain (module level vs field level) HT access files through Apache Server CGI bin and perl files are used has a java pugin for working with java-based apps **Authorization** only thing exposed is CGI/perl bin When searching for all studies, would have to pass each study individually to verify Network links are generally secured via SSL (https for SemanticBits)

Special\Non-Functional Requirements	When authorization is set up, the following things have to happen: • Access to the research staff area of caAERS needs to be disabled (no creating research staff w/i caAERS) • The caAERS password policy can not be enabled • The reset password button either needs to be hidden or set to redirect to the organizations reset password area • the caAERS Admin (login name) must be not call back to the organization's authorization (hard coded/set up during caAERS installation)* CALGB: I think we may want the Admin (superuser) to call back into our system as well. This depends on what specifically such an account is for. If it is just for a developer or IT Admin to tweak the system then it may be ok as is. However, if this to be used by a real user (and certainly if by more than one user) then we would want it to operate with teh callback into our own Authorization system.
Open Issues	• How does caAERS determine what role(s)/permissions the user has based on the authorization system? What would be passed to the caAERS?** CALGB: We would need to add caAERS-specific Permissions into our own Authorization system so that caAERS could ask about them. • How will you handle new users/requests for access?** CALGB: New user requests would be added to our own Authentication and Authorization system. • Are roles application specific, or the same across the suite? For example, if someone is a study coordinator in c3pr, would they also be a study coordinator in caAERS?** CALGB: We have a centrally managed Authorization system (currently ~150 roles). We would need to match existing Permissions where possible and add new ones where necessary. WRT the role "StudyCoordinator" we simply don't expose this. We require that apps ask for specific Permissions like 'ReadStudy'. There are no exposed Roles that a calling app can overload with their own security interpretation. • Wake Forest does not manage roles centrally • If something new is added to caAERS (new module, new object, etc), how will you be able to provision access to that? ? For example, a Grid service for data mining** CALGB: Any new Permissions would be added to our Authorization system so that caAERS could ask about them. • Should everyone except the super admin be blocked when something new is added?** CALGB: Yes. Permissions must be in place before anyone can access anything. This may apply to the superuser as well. • Will you have more than one user that needs admin rights (should it be a role that users can be configured to have the rights)? Currently caAERS only allows one admin, which is set up during the installation** CALGB: Yes. We should add specific admin permissions and these should be checked by caAERS before allowing any access.

13.2 Adding a user to caAERS - Use Case

Primary Actor: caAERS Admin (user with Administrator or Site Coordinator roles)
Supporting/Secondary Actor: CSM; Email system
Scope: Addition of a user
Level: User Goal
Trigger: A new user for caAERS is identified who needs to be added to the system

Brief Description

caAERS is a secure system and all users of the system require a user name and password. This use case describes the process for adding a user to the caAERS system. The new user is added to the system by a caAERS user with an administrative role (referred to here as the caAERS Admin). The caAERS Admin can interact with the caAERS system to add the user either via a user creating interface, XML import

Preconditions

- caAERS must be installed and configured with email server (SMTP) access
- There must be a caAERS user with system admin or site coordinator permissions (referred to here as caAERS Admin)
- There is a user who is not in the system that requires access to caAERS

Steps

Main Success Scenario

1. The caAERS Admin accesses the user interface for adding/managing research staff and/or investigators
2. Basic info is entered (first name, last name, user ID)
3. An organization is selected

4. Organization specific contact info is entered (phone, fax, email, mailing address)
5. An active date (current or future) for the user at the organization is selected
6. The roles of the user at the organization are selected.
7. The active date for each selected role is assigned
    a. The role active date must be greater than or equal to the active date for the user active date at the organization.
    b. The system will default the active date of each selected role to the same date as the organization active date.
8. The studies to which the user should be assigned to (for the given organization) are selected
    a. There will be an "all-studies" option which will associate the user to all current and future studies for the organization.
    b. The study assignments set here will cascade to the study for all roles associated with the user for that organization.
    c. Changes made to the user-study association at the study level will cascade back to the user entry/managment screen.
    d. The one limitation for this assignment compared to the assignments available at the study level is that the study level assignments will allow specific user roles to be selected/unselected.
9. An additional organization can be selected and steps 3-8 then repeat.
10. The caAERS Admin clicks on the "Create User" button
    a. The caAERS system confirms that the information has been saved and the new user created.
11. The caAERS system sends an email to the new user instructing them how to change their password and login.

Extensions

1. The caAERS Admin accesses the user interface for importing research staff and/or investigators
2. The caAERS Admin selects an XML file containing data for items 2-8 in the main success scenario
3. The caAERS system parses the XML file and adds users if the user ID is new to the system
4. The caAERS system parses the XML file and updates user info if the user ID is already in the system

1. The caAERS Admin accesses the programatic interface (Web Service, JMS messaging) for importing research staff and/or investigators
2. The caAERS Admin sends to the caAERS system an XML file containing data for items 2-8 in the main success scenario
3. The caAERS system parses the XML file and adds users if the user ID is new to the system
4. The caAERS system parses the XML file and updates user info if the user ID is already in the system

Sub-Flows

Enter any paths that are used by multiple paths within the use case (could just be a link to another use case)

Post Conditions

- The caAERS system sends an email to the new user instructing them how to change their password and login.
- The user is added in CSM
- The user's study associations cascade to the appropriate studies
    - If the "All-studies" option was selected in step 8a., then each time a study is associated to the user's organization, the user and all of their active roles are also associated to the study.

Data Items

- Research Staff and Investigator

Special\Non-Functional Requirements

- Any special items of interest or non-functional requirements to be addressed

Business Rules

- enter rules here

Open Issues

- Any questions about the flow that need to be answered before the flow can be finalized.

Models & User Interface Prototype

Provide an optional UI mockup, if useful.
Provide an optional UML diagram

13.3 Updating user information - Use Case

Primary Actor: caAERS Admin (user with Administrator or Site Coordinator roles)
Supporting/Secondary Actor: CSM; Email system
Scope: Updating a user's record
Level: User Goal
Trigger: A user's provisioning details need to be updated

Brief Description

This use case describes the process for updating a user in the caAERS system. An existing user's record is accessed by a caAERS user with an administrative role (referred to here as the caAERS Admin) and makes changes as needed. Changes may include updating authorization details such as role, organization and study associations, as well as updating basic details such as first and last name.

Preconditions

- caAERS must be installed and configured with email server (SMTP) access
- There must be a caAERS user with system admin or site coordinator permissions (referred to here as caAERS Admin)
- There is a user who exists in the system that requires some authorization changes

Steps

Main Success Scenario

1. caAERS Admin accesses the user interface for adding/managing research staff and/or investigators
2. caAERS Admin searches for and identifies the user record to be updated
3. caAERS Admin identifies changes to be made
4. caAERS Admin makes necessary updates to authorization and/or basic details
5. caAERS Admin saves the updated record

Extensions

1. The caAERS system parses the XML file and updates user info if the user ID is already in the system
2. The caAERS Admin accesses the programatic interface (Web Service, JMS messaging) for updating user

Sub-Flows

Post Conditions

- The caAERS system sends an email to the new user alerting him that his user account has been updated
- The user record is updated in CSM
- If applicable, the user's study associations cascade to the appropriate studies

Data Items

Special\Non-Functional Requirements

Business Rules

Open Issues

Models & User Interface Prototype

13.4 Resetting a user's password - Use Case

Primary Actor: caAERS user
Supporting/Secondary Actor: CSM; Email system

Scope: A user resets his password.
Level: User Goal
Trigger: A user needs to reset his password

Brief Description

This use case describes the process of a user resetting his password. This might be necessary if a user forgets his password.

Preconditions

- caAERS must be installed and configured with email server (SMTP) access
- The user must have a valid caAERS account

Steps

Main Success Scenario

1. caAERS user accesses the caAERS log in page
2. caAERS user clicks link to reset password
3. caAERS user is taken to a screen where he enters his username
4. System sends an email message with link to change password
5. caAERS user clicks the link in the email
6. On the resulting caAERS screen, caAERS user enters his username and new password twice for confirmation
7. caAERS user clicks save
8. System displays a confirmation message

Extensions

Sub-Flows

Post Conditions

- The user record is updated in CSM with the new password

Data Items

Special\Non-Functional Requirements

Business Rules

Open Issues

Models & User Interface Prototype

caAERS - User Roles and Rights

Roles and Rights for the v1.5 and prior versions of caAERS are available on the CTMS Knowledge Center Wiki Roles and Rights for the v1.6 and later versions of caAERS are described below.

Role Definitions

- **System Administrator (super user)** - Responsible for maintaining the caAERS hardware and software; has access to all modules in caAERS; resolves user issues
- **Site Coordinator** - Responsible for maintaining information about the site
- **Subject Coordinator** - Responsible for adding subjects and reporting adverse events
- **Study Coordinator** - Responsible for setting up the study in the system, creating the protocols, defining adverse events, and setting the general parameters of a study

- **Adverse Event (AE) Coordinator** - Responsible for reviewing adverse events as they are defined by the study or sponsor
- **Investigator** - Responsible for reviewing and possibly creating adverse event reports
- **Central Office Report Reviewer** - A person who can review, and submits Expedited report to external agency (if workflow is enabled).
- **Central Office Data Coordinator** - A person who reviews the Reporting Period/Course (if workflow is enabled)

Following are different user's roles and modules with the details of operation that user having the selected role can perform.

Content Filtering

Organization based filtering:

- **Coordinating Center** - Typically a Co-op group or a Lead organization. The Coordinating Center for a study can see all of the data for all of the Study Sites on that study.
- **Study Sponsor** - The sponsor for a study can see all of the data for all of the Study Sites on that study (i.e. filtering is identical to coordinating center filtering).
- **Study Site** - A study site user can only see data for the site to which they belong. They cannot see any data for any other sites on the study.

Study assignment filtering:

- **System Administrator (super user) -** No content filtering is applied based on Site or Study assignment.
- **Site Coordinator** - No Study assignment filtering applies, however, the Organization based filtering does apply (e.g. A Site Coordinator at a Study Site can only see data for the study site, where as a Site Coordinator at a Coordinating Center can see data for all study sites on the given study).
- **Study Coordinator -** No Study assignment filter applies for Study queries and on the Study module. Site filtering only should apply on these components. The reason for this is that a Study Coordinator will be creating studies and assigning personnel to studies and thus need access to Study information at an organization level. Study assignment filtering should apply to this role for all other application privledges.
- **AE Coordinator** - Study level filter applies to all application privileges.
- **Subject Coordinator** - Study level filter applies to all application privileges.
- **Investigator -** Study level filter applies to all application privileges.
- **Central Office Report Reviewer** - Study level filter applies to all application privileges.
- **Central Office Data Coordinator** - Study level filter applies to all application privileges.

Modules

✅ = rights/access

❌ = no rights, no access, does not show. **Note:** if can't hide the links, task, or information, need to change the error message that says they don't have access to that feature/information and provide a back button which returns them to the previous screen

Note: As discussed in meeting, view rights only would enable user to view the "Details" step of the study, subject, etc, but not the other steps that are involved in editing/creating. Possible implementation was a 'view' url

caAERS Module	AE Coordinator	Investigator	Study Coordinator	Subject Coordinator	Site Coordinator	System Admin	Central Office Report Reviewer	Data Coordinator
Adverse Event tab	✅	✅	✅	✅	✅	✅	✅	✅
Enter Adverse Events	✅ (for assigned studies)	✅ (for assigned studies)	❌	✅ (for assigned studies)	❌	✅	❌	❌
Create Adverse Event Reports	✅ (for assigned studies)	✅ (for assigned studies)	❌	✅ (for assigned studies)	❌	✅	❌	❌
Manage Reports (View AE's and AE Reports)	✅ (for assigned studies)	✅ (for assigned studies)	✅ (for assigned studies)	✅ (for assigned studies)	✅	✅	✅ (for assigned studies)	✅ (for assigned studies)

Submit AE Reports	✓ (for assigned studies when Workflow is disabled) ✗ (when workflow is enabled)	✓ (for assigned studies when Workflow is disabled) ✗ (when workflow is enabled)	✗	✓ (for assigned studies when Workflow is disabled) ✗ (when workflow is enabled)	✗	✓	✓ (for assigned studies)	✗
Studies tab	✗	✗	✓	✓	✓	✓	✗	✗
Create Study	✗	✗	✓	✗	✓	✓	✗	✗
Edit Study	✗	✗	✓	✗	✓	✓	✗	✗
View Study	✗	✓ (for assigned studies)	✓	✓ (for assigned studies)	✓	✓	✗	✗
Search Studies	✗	✓ (for assigned studies)	✓	✓ (for assigned studies)	✓	✓	✗	✗
Subjects tab	✗	✗	✓	✓	✓	✓	✗	✗
Create Subject	✗	✗	✗	✓ (for assigned studies)	✓	✓	✗	✗
Assign a Subject to a Study (Subject already created)	✗	✓ (for assigned studies)	✓ (for assigned studies)	✓ (for assigned studies)	✓	✓	✗	✗
View Subject	✗	✓ (for assigned studies)	✓ (for assigned studies)	✓ (for assigned studies)	✓	✓	✗	✗
Search Subject	✗	✓ (for assigned studies)	✓ (for assigned studies)	✓ (for assigned studies)	✓	✓	✗	✗
Advanced Search tab	✓	✓	✓	✓	✓	✓	✓	✓
Study Search	✓ (for assigned studies)	✓ (for assigned studies)	✓ (for assigned studies)	✓ (for assigned studies)	✓	✓	✓ (for assigned studies)	✓ (for assigned studies)
Subject Search	✓ (for assigned studies)	✓ (for assigned studies)	✓ (for assigned studies)	✓ (for assigned studies)	✓	✓	✓ (for assigned studies)	✓ (for assigned studies)
Adverse Event Search	✓ (for assigned studies)	✓ (for assigned studies)	✓ (for assigned studies)	✓ (for assigned studies)	✓	✓	✓ (for assigned studies)	✓ (for assigned studies)
Rules tab	✗	✗	✗	✗	✓	✓	✗	✗
Create Rule	✗	✗	✗	✗	✓	✓	✗	✗
Edit Rule	✗	✗	✗	✗	✓	✓	✗	✗

Create Report Definition	✗	✗	✗	✗	✓	✓	✗	✗
Edit Report Definition	✗	✗	✗	✗	✓	✓	✗	✗
View Report Definition	✗	✗	✗	✗	✓	✓	✗	✗
Admin module tab	✗	✗	✗	✗	✓	✓	✗	✗
create/edit/search Organization	✗	✗	✗	✗	✓	✓	✗	✗
create/edit/search Research Staff	✗	✗	✗	✗	✓	✓	✗	✗
configure caAERS	✗	✗	✗	✗	✓	✓	✗	✗
create/edit/search Investigator	✗	✗	✗	✗	✓	✓	✗	✗
Import	✗	✗	✗	✗	✓	✓	✗	✗
IND	✗	✗	✗	✗	✓	✓	✗	✗
password policy	✗	✗	✗	✗	✓	✓	✗	✗

Additional caAERS Roles & Module info

Note
This page is an archive.

Adverse Events

Business Rules related to security

Following are important security business rules that applied while handling adverse events

1. User can search only those studies which are performed on the site of logged in user.

2. User can see all the subject irrespective of any site. User may still get access defined exception if user selects any subject that belongs to a study which is not performed on the site of logged in user

All Operations that user can perform

Create Adverse event:

user can create adverse events. Following are all important links that are used in this operation

- Document routine AEs
- Enter expedited report

Edit Adverse event

user can edit adverse events. Following are all important links that are used in this operation

- Edit AEs

Manage Adverse Event

user can manage adverse events. Following are all important links that are used in this operation

- Manage reports

List Adverse Event

user can list adverse events. Following are all important links that are used in this operation

- Manage reports

Admin module

Business Rules related to security

none

All Operations that user can perform

create/edit/search Organization

create/edit/search Research Staff

Studies module

Business Rules related to security

none

All Operations that user can perform

Create Study:

user can create Study. Following are all important links that are used in this operation

Edit Study

user can edit study. Following are all important links that are used in this operation

Search and list Study

user can search and list. Following are all important links that are used in this operation

Delete Study

user can delete study. Following are all important links that are used in this operation

Second and last level one text.

User Roles and Rights - draft for unified security

Roles and Rights for the v1.5 and prior versions of caAERS are available on the CTMS Knowledge Center Wiki Roles and Rights for the v1.6 and later versions of caAERS are described below.

Role Definitions

- **System Administrator** -
- **Business Administrator** -
- **Person and Organization Information Manager** -
- **Data Importer** -
- **User Administrator** -
- **Study Creator** -
- **Supplemental Study Information Manager** -
- **Study Team Administrator** -
- **Study Site Participation Administrator** -
- **AE Rule and Report Manager** -

- **Study Calendar Template Builder** -
- **Study QA Manager** -
- **Registration QA Manager** -
- **Subject Manager** -
- **Study Subject Calendar Manager** -
- **Registrar** -
- **AE Reporter** -
- **Expedited Report Reviewer** -
- **Adverse Event Study Data Reviewer** -
- **Lab Impact Calendar Notifier** -
- **Lab Data User** -
- **Data Reader** -
- **Data Analyst** -

Following are different user's roles and modules with the details of operation that user having the selected role can perform.

Content Filtering

Organization based filtering:

- **Coordinating Center** - Typically a Co-op group or a Lead organization. The Coordinating Center for a study can see all of the data for all of the Study Sites on that study.
- **Study Sponsor** - The sponsor for a study can see all of the data for all of the Study Sites on that study (i.e. filtering is identical to coordinating center filtering).
- **Study Site** - A study site user can only see data for the site to which they belong. They cannot see any data for any other sites on the study.

Study assignment filtering:

- **System Administrator** -
- **Business Administrator** -
- **Person and Organization Information Manager** -
- **Data Importer** -
- **User Administrator** -
- **Study Creator** -
- **Supplemental Study Information Manager** -
- **Study Team Administrator** -
- **Study Site Participation Administrator** -
- **AE Rule and Report Manager** -
- **Study Calendar Template Builder** -
- **Study QA Manager** -
- **Registration QA Manager** -
- **Subject Manager** -
- **Study Subject Calendar Manager** -
- **Registrar** -
- **AE Reporter** -
- **Expedited Report Reviewer** -
- **Adverse Event Study Data Reviewer** -
- **Lab Impact Calendar Notifier** -
- **Lab Data User** -
- **Data Reader** -
- **Data Analyst** -

Modules

= rights/access

= no rights, no access, does not show. **Note:** if can't hide the links, task, or information, need to change the error message that says they don't have access to that feature/information and provide a back button which returns them to the previous screen

Note: As discussed in meeting, view rights only would enable user to view the "Details" step of the study, subject, etc, but not the other steps that are involved in editing/creating. Possible implementation was a 'view' url

caAERS Module	System Administrator	Business Administrator	Person and Organization Information Manager	Data Importer	User Administrator	Study QA Manager	Study Creator	Supplemental Study Information Manager	Study Tea Administ
Adverse Event tab									

Enter Adverse Events	✗		✗	✗	✗	✗	✗	✗	✗
Create Adverse Event Reports	✗		✗	✗	✗	✗	✗	✗	✗
Manage Reports (View AE's and AE Reports)	✗		✗	✗	✗	✗	✗	✗	✗
Submit AE Reports	✗		✗	✗	✗	✗	✗	✗	✗
Studies tab	✗		✗	✗	✗	✓	✓	✗	✗
Create Study	✗		✗	✗	✗	✓	✓	✗	✗
Edit Study	✗		✗	✗	✗	✓	✗	✗	✗
View Study	✗		✗	✗	✗	✓	✗	✗	✗
Search Studies	✗		✗	✗	✗	✓	✓	✗	✗
Associate site to study									
Subjects tab	✗		✗	✗	✗	✗	✗	✗	✗
Create Subject	✗		✗	✗	✗	✗	✗	✗	✗
Assign a Subject to a Study (Subject already created)	✗		✗	✗	✗	✗	✗	✗	✗
View Subject	✗		✗	✗	✗	✗	✗	✗	✗
Search Subject	✗		✗	✗	✗	✗	✗	✗	✗
Advanced Search tab	✗		✗	✗	✗	✓	✓	✗	✗
Study Search	✗		✗	✗	✗	✓	✓	✗	✗
Subject Search	✗		✗	✗	✗	✗	✗	✗	✗
Adverse Event Search			✗	✗	✗	✗	✗	✗	✗
Rules tab	✗		✗	✗	✗	✗	✗	✗	✗
Create Rule	✗		✗	✗	✗	✗	✗	✗	✗
Edit Rule	✗		✗	✗	✗	✗	✗	✗	✗
Create Report Definition	✗		✗	✗	✗	✗	✗	✗	✗
Edit Report Definition	✗		✗	✗	✗	✗	✗	✗	✗
View Report Definition	✗		✗	✗	✗	✗	✗	✗	✗

Admin module tab	✓		✗	✓	✗	✗	✗	✗	✓
Create Organization	✗		✓	✗	✗	✗	✗	✗	✗
Edit Organization	✗		✓	✗	✗	✗	✗	✗	✗
Search Organization	✗		✓	✗	✗	✗	✗	✗	✗
Create Research Staff			✓	✗	✗	✗	✗	✗	✗
Create Investigator	✗		✓	✗	✗	✗	✗	✗	✗
Provision Research Staff Member as User	✗		✗	✗	✓	✗	✗	✗	✗
Provision Investigator as User	✗		✗	✗	✓	✗	✗	✗	✗
Edit Investigator	✗		✓	✗	✗	✗	✗	✗	✓
Edit Research Staff Member	✗		✓	✗	✗	✗	✗	✗	✓
Configure caAERS	✓	✗	✗	✗	✗	✗	✗	✗	✗
Import	✗	✓	✗	✓	✗	✗	✗	✗	✗
IND	✗	✓	✗	✗	✗	✗	✗	✓	✗
password policy	✓	✗	✗	✗	✗	✗	✗	✗	✗
Reload labels	✗	✓	✗	✗	✗	✗	✗	✗	✗

Enter Personnel

Brief Description	A user with the Person and Organization Information Manager user privledges creates a record of a person (personnel) in caAERS.
Primary Actor	A user with the Person and Organization Information Manager user privledges.
Preconditions	1. The AE Report already exists in the system. 2. Notification triggers have been setup.
Basic Flow of Events	1. The PC selects option to search for AE Report entries by Study Participant and Protocol. (Use Case 1.7). Protocol-specific codes should show up first. 2. The PC selects the desired AE Report. 3. caAERS displays the AE Report data entry screen with current data. 4. The PC completes dynamically generated data collection (Use Case 4.2) form which comprises the core data elements required for the indicated reporting agencies as determined by the triggers. PLEASE SEE SAE Form Elements spreadsheet for the identification of elements comprising the core data set as determined by requirements from all external reporting agencies 5. The PC submits data.

Postconditions	1. After successful completion of this use case, the SC will have saved edits to an existing AE for a Study Participant linked to an existing protocol. 2. Time stamp of last saved edits with User ID are readily viewable. An audit log of updates is available. 3. Reporting triggers and notifications are invoked and updated as data collection occurs. 4. The report can be saved and edited any number of times. Once all of the required fields have been completed, the AE report is considered to be complete.
Special Requirements	See Data form

handling caAERS timeouts - UC

Primary Actor: caAERS
Supporting/Secondary Actor: caAERS User
Scope: subsystem - AE module
Level: User Goal
Trigger: caAERS user is using the system but becomes inactive

Brief Description

caAERS automatically logs out of the system after a short period of inactivity (15 min?). This use case explorers the different ways SemanticBits can handle this.

Preconditions

- caAERS user is logged into caAERS
- caAERS user is accessing the AE module

Steps

caAERS provides a warning 5 minutes before timeout

1. Enter the main steps

caAERS takes the user to the log on screen when the system times out

1. Enter the main steps

caAERS saves the information in 'soft memory'

1. Enter the main steps

caAERS saves the information in draft mode

1. Enter the main steps

Post Conditions

- What items hold true after the use case is enacted?

Data Items

- What data items are of interest and should be modeled?

Special\Non-Functional Requirements

- Any special items of interest or non-functional requirements to be addressed

Open Issues

- Any questions about the flow that need to be answered before the flow can be finalized.

Models & User Interface Prototype

Provide an optional UI mockup, if useful.
Provide an optional UML diagram

User and Person

		Person and Org Info Manager	
		NO	YES
User Admin	NO		Enter Person
			Edit Person
			Deactivate Person
			Add Person Details to a User
			Search Persons and Users
	YES	Search Persons and Users	Search Persons and Users
		Create User	Enter Person and Create User
		Edit user	Edit Person and Edit User
		Deactivate User	Deactivate Person and Deactivate User
		Add User Details to a Person	