Testing - caAERS

System Testing

caAERS will be tested on the following platforms:

Operating System	Browser	Version
Windows XP	Firefox	2.0
Windows XP	Firefox	3.0
Windows XP	IE	7.0
Windows Vista	Firefox	2.0
Windows Vista	Firefox	3.0
Windows Vista	IE	7.0
OS X	Firefox	2.0

Release Testing

Version
Test Cases created for caAERS v1.1.3
Release Testing - caAERS v1.5

CCTS inter-op testing

Results of testing hotlinking and labviewer results

The following scenarios were created from the use case document: CCTS Hotlink Windows

Details

caAERS version: 1.1.4 [CTMS:war given by srini].

Location: https://10.10.10.220:10443/caaers/

caAERS only connects to PSC. Linking to other apps [CTMS:as per use case] are not applicable

Pre-conditions:

Both caaers and PSC have the same:

- Study
- Subject
- grid ID

	Scenario	Firefox 2	IE7
1	Allow administrators to configure the URL of hotlinks.		

2	Allow administrators to configure window as • _blank: always opens into a new window • _self: always replaces the current window • NAME: opens into a specific window, replacing the contents	NA	NA
3	Clicking on the hotlink repeatedly should open application in same window	✓	✓
4	The new window should have title in the format of: FIRSTNAME LASTNAME (MRN) - SHORTTITLE (COORDINATING STUDY ID)	✓	✓

Labviewer sliding panel

		Firefox	IE7
	Labviewer visible in create AE flow?	✓	✓
	Labviewer visible in create AE flow?	✓	✓

1. Visible in create AE flow?
2. Visible in edit AE flow?

Test cases for CCTS interop

Test setup

- caAERS URL: https://ncias-c278-v.nci.nih.gov:22443/caaers/
- c3pr URL: https://ncias-c278-v.nci.nih.gov:11443/c3pr/

Username / password: dev1@nci / D3v1@NC1.gov

Test cases

Scenario 1:

1. In C3PR assign subject to study 1 at site NCI.
2. Complete registration in C3PR.
3. Study 1 should be open / released in caAERS, PSC.[Preconditon]
4. Broadcast registration from C3PR, by clicking enroll button.
5. Check caAERS to verify that the subject has been assigned to study 1 at site NCI. [Expected]
6. In C3PR assign subject to study 2 at site AR037, Ozark Cancer Clinic.
7. Complete registration in C3PR.
8. Study 2 should be open / released in caAERS, PSC.[Preconditon]
9. Broadcast registration from C3PR, by clicking enroll button.
10. Check caAERS to verify that the subject has been assigned to study 2 at site AR037. [Expected]

Scenario 2

1. In C3PR assign subject to study 1 at site NCI.
2. Complete registration in C3PR.
3. Study 1 should be open / released in caAERS, PSC.[Preconditon]
4. Broadcast registration from C3PR, by clicking enroll button.
5. Check caAERS to verify that the subject has been assigned to study 1 at site NCI. [Expected]
6. In C3PR assign subject to study 3 at site AR037, Ozark Cancer Clinic.
7. Complete registration in C3PR.
8. Study 3 should be open in caAERS, but unreleased in PSC.[Preconditon]
9. Broadcast registration from C3PR, by clicking enroll button.

10. PSC issues rollback since study 3 is not released in PSC. [Expected]
11. In caAERS to verify that the subject has NOT been assigned to study 3 at site AR037. [Expected]
12. In caAERS verify that the subject has NOT been deleted and that he is assigned to study 1 at site NCI. [Expected]

Scenario 3:

1. In C3PR assign subject to study 1 at site NCI.
2. Complete registration in C3PR.
3. Study 1 should be open / released in caAERS, PSC.[Precondition]
4. Broadcast registration from C3PR, by clicking enroll button.
5. Check caAERS to verify that the subject has been assigned to study 1 at site NCI. [Expected]
6. In C3PR assign subject to study 1 at Wake Forest University Health Sciences (NC002).
7. C3PR gives error for assigning subject to study 1 twice. [Expected]
8. Hence this registration cannot be created or broadcast from C3PR.

Scenario 4:

1. In caaers, create subject with identifier as:
    a. org: NCI
    b. type: other
    c. value: test-pt-005
2. This subject is associated to study available locally in caaers at site NCI
3. In C3PR, create a new subject with details that are identical to the one in caaers.
4. In C3PR, identifier should be as follows:
    a. org: any
    b. type: MRN
    c. value: test-pt-005
5. Assign this subject to a study in C3PR at site NCI
6. This study should already be broadcast to caaers and opened.
7. Now broadcast this registration from C3PR
8. The registration should be successfully created in caaers with the existing subject created in step 1.

Tests for COPPA integration

Test setup

1. Drop postgres DB.
2. Recreate Postgres DB.
3. Build caaers.
4. Open caaers URL, navigate to Admin>>Configure caaers.
5. Set caxchange URL.
6. Set ESB URL.
7. Import report definitions, including NCI sponsored report.
8. Import all rules, including QA only rules
9. Import orgs from docs/import/NCI -- This is for INDs
10. Restart Tomcat

Organization

	Scenario	Expected	
	Search organization by exact name "Mayo Clinic Rochester"	Search results show organization with name "Mayo Clinic Rochester" without NCI icon	
	Search organization by Identifier "NC010"	Search results show organization with name "Duke University Medical Center " without NCI icon	
	Search organization by partial name "TaKaRa"	Search results show organization with name "TaKaRa Bio Inc" with NCI icon	
	Search organization by Identifier "westat"	Search results show organization with name "WESTAT" with NCI icon	

Research Staff

	Scenario	Expected	
	Search Research staff by first name "Ramanand"	Search result shows one result for "Ramanand Achanta" from Cancer and Leukemia Group B with NCI icon	

	Search Research staff by last name "Abdelbaki"	Search result shows one result for "Ayat Abdelbaki" from Virginia Commonwealth University with NCI icon	
	Search Research staff by last name "Whitehouse"	Search result shows one result for "Jean Whitehouse" belonging to two orgs, Cancer Trials Support Unit and Abramson Cancer Center of The University of Pennsylvania with NCI icon	
	Search Research staff by org "Dixie Medical Center Regional Cancer Center"	Search result shows one result for"Veronica Brinkerhoff" from Dixie Medical Center Regional Cancer Center with NCI icon	
	Search Research staff by org "Saint Cloud Hospital", first name "Brenda" and last name "Ackerman"	Search result shows one result for"Brenda Ackerman" from Saint Cloud Hospital with NCI icon	

Investigator

	Scenario	Expected	
	Search Investigator by first name "Adilia "	Search result shows one result for "Adilia Hormigo" from Memorial Sloan Kettering Cancer Center with NCI icon	
	Search Investigator by last name "Abernathy"	Search result shows one result for "Deborah Abernathy" from Hematology and Oncology Clinic. with NCI icon	
	Search for investigator with organization "21st Century Oncology - Cape Coral"	Search result shows one result for "Constantine Mantz" from 21st Century Oncology - Cape Coral with NCI icon	

Study

	Scenario	Expected	
	Search study by identifier with partial string "nci-2009"	No results returned from COPPA	
	Search study by identifier with exact string "NCI-2009-00011"	Search shows one result for study with study ID "NCI-2009-00011" and a NCI icon	
	Search for study by short title with partial string "Evaluation of Efficacy and Mechanisms of an Antiinflammatory Intervention for Chemotherapy"	Search shows one result for study with study ID "NCI-2009-00004" and a NCI icon	

Study Mapping details

	COPPA	caAERS	
	Public Title	Short title	
	Official Title	Long title	
	Public Description	Description	
	Sponsor	Funding Sponsor	
	Lead Organization	Coordinating Center	
	Treating Site	Study Site	
	Interventions of Type Drug,Device,Other,Genetic,Biological/Vaccine,Procedure/Surgery,Radiation,Behavioral,Dietary Supplement	Therapies	
	Arms	Treatment Assignments	
	Health Care Providers	Investigators (PI,SPI,SI)	
	NCI Trial Identifier	NCI Trial Identifier	
	Lead Organization Trial ID	Coordinating Center Identifier	

Study Status Mapping details

COPPA	caAERS
Active	Active - Trial is open to accrual
Approved	Approved - Trial has official CTEP approval
Closed to Accrual	Closed to Accrual
Closed to Accrual and Intervention	Closed to Accrual & Treatment
Temporary Closed to Accrual	Temporarily Closed to Accrual
Temporary Closed to Accrual and Intervention	Temporarily Closed to Accrual & Treatment
Administratively Complete	Administratively Complete
In Review	In Review
Disapproved	Disapproved
Complete	Complete

Study Phase code mapping details

COPPA	caAERS
0	Phase 0 Trial
I	Phase I Trial
II	Phase II Trial
I/II	Phase I/II Trial
III	Phase III Trial
II/III	Phase II/III Trial
IV	Phase IV Trial
Pilot	Pilot
N/A	N/A
Other	Other

Study IND mapping details

To verify the IND's were created in caAERS. Go to Administration -> IND# -> Search IND# & click search. The IND's associated to the StudyProtocol in COPPA should be listed in search results.

COPPA Holder Type	caAERS IND holder
NCI or NIH	same as COPPA org
Industry or Organization	DUMMY organization
Investigator	Dummy Investigator

Caaers Configuration

Autocompleter Minimum Characters = 3
Autocompleter Delay = 5
caXchange URL = https://ncias-c278-v.nci.nih.gov:58445/wsrf-caxchange/services/cagrid/CaXchangeRequestProcessor
caAERS help URL = https://cabig-kc.nci.nih.gov/CTMS/KC/index.php/CaAERSv1.9.5_End_User_Guide
caAERS base URL = https://ncias-c278-v.nci.nih.gov:22443/caaers
Enable Routing and Review? = No
ESB URL = tcp://ncias-c278-v.nci.nih.gov:63618
Inactivity Duration = 15

Inactivity Grace Period = 2
LabViewer base URL = https://ncias-c278-v.nci.nih.gov:21443/ctomlabviewer
Study Calendar base URL = http://ncias-c278-v.nci.nih.gov:55081/psc
Show debugging informatio = No
SMTP server = smtp.gmail.com
SMTP port = 25
Secure SMTP? = Yes
SMTP user name = caaers.app@gmail.com
From address = caaers.app-stage@gmail.com
Unidentified Mode ? = No

Server details

username: monishd

password: Sa1222**

tomcat location: apps/caaers-webapp/apache-tomcatxxx

Host: ncias-c278-v.nci.nih.gov
Port : 5432

DB username: dev1@nci
Maintenance DB : caaers

Name : caaers
password :caaers

CCTS-DEV1 Details

https://ncias-c278-v.nci.nih.gov:22443/caaers/pages/task
https://ncias-c278-v.nci.nih.gov:11443/c3pr
http://ncias-c278-v.nci.nih.gov:55081/psc

dev1@nci
D3v1@NC1.gov

CCTS-DEV2 Details

https://ncias-d282-v.nci.nih.gov:29443/caaers
https://ncias-d282-v.nci.nih.gov:29443/c3pr
https://ncias-d282-v.nci.nih.gov:29443/psc

cctsdev1dev
An010101!!

CCTS-QA Details

https://ncias-q291-v.nci.nih.gov:18443/caaers
https://ncias-q291-v.nci.nih.gov:18443/c3pr
https://ncias-q291-v.nci.nih.gov:18443/psc

ccts_qaCcts_123!!

CTRP - Integration

https://trials-integration.nci.nih.gov/pa
abstractor
pass

https://trials-integration.nci.nih.gov/curation
curator
pass

CTRP - QA

https://trials-qa.nci.nih.gov/pa
abstractor
pass

https://trials-qa.nci.nih.gov/po-web
curator
pass

Module 1a Test Cases - Adverse Event Capture

Module 1a Test Cases - Adverse Event Data Capture

Use Case	Test Case
AE Data Collection	Tests for Capture Adverse Events Flow
Assign Subject to a Study	
Create Expedited AE Report	Test cases for amend report flow
Create Study for AE Data Entry	
Create Subject	
Enter Routine AEs	
Search AE Entry	
Study Abstraction	
1. Capture AEs	Test cases for use case 1.1
1.1 Enter Observed AEs	
1.2 Capture Solicited AE - caAERS UC	Test cases for Solicited Adverse Events
1.2.1 Associate Solicited AEs to a study	
1.2.2 Enter observed Solicited AEs into caAERS	
1.2.3 Update observed Solicited AEs into caAERS	
1.3 Enter Baseline AEs	
1.4 Modify Observed AEs (Reporting Period)	Test cases for AE locking
1.5 Streamlining Expedited Report	
1.6 Add Reporting Periods types to a study	
6. caAERS Auditing - tracking History	
6.1 caAERS Auditing - history of single routine AE	
6.2 caAERS Auditing - history of an observation period	
1.7 Creating a caAERS API for AE Queries	
???	Test cases for 'other meddra' and verbatim in study and CAE flow

Test cases for 'other meddra' and verbatim in study and CAE flow

CONTENT ON THIS PAGE HAS BEEN ENTERED INTO TESTLINK

	Scenario	Expected	Pass / Fail
	User is in Create / Edit study flow>>Evaluation Period Types. For AE term user mentions 'other specify' , chooses one AE term from the list and clicks add.	The other meddra term is add to the solicited AE list and an auto-suggest box is shown for selecting the meddra term	
	User adds an 'other meddra' AE term in Create / Edit study flow>>Evaluation Period Types. User does not specify the any meddra term in the autosuggest in the Solicited Adverse Events table and clicks continue.	Error is thrown for invalid meddra term for solicited AE	

	User adds 'Growth and Development - Other (Specify, __) ' AE term twice to the list of solicited adverse events in Create / Edit study flow>>Evaluation Period Types.	Caaers allows addition of the same 'other meddra' term twice.	✗
	User adds 'Growth and Development - Other (Specify, __) ' AE term twice to the list of solicited adverse events in Create / Edit study flow>>Evaluation Period Types. In the table showing the list of solicited AEs there are two solicited AEs that mention 'Growth and Development - Other (Specify, __) '. For both AEs , user adds '10002302 - Anemia normocytic' in the 'Other(MedDRA) ' autosuggest and clicks continue.	Caaers gives error for duplicate AE terms	??
	User adds 'Growth and Development - Other (Specify, __) ' AE term twice to the list of solicited adverse events in Create / Edit study flow>>Evaluation Period Types. In the table showing the list of solicited AEs there are two solicited AEs that mention 'Growth and Development - Other (Specify, __) '. For both AEs user mentions distinct 'Other(MedDRA) ' terms and clicks continue.	No error is thrown	??
	User add two AE terms: 1. Hemorrhage/Bleeding - Other (Specify, __) 2. Allergy/Immunology - Other (Specify, __) In the solicited AE list below, user adds the same meddra term: '10002302 - Anemia normocytic' in the 'Other(MedDRA) ' autosuggest [CTMS:for both AE terms] and clicks continue.	No error is thrown	??
	User adds 'Growth and Development - Other (Specify, __) ' AE term in list of solicited adverse events in Create / Edit study flow>>Evaluation Period Types. user assigns this AE to the treatment reporting period type. In CAE flow, user creates a new reporting period of type treatment	The 'Growth and Development - Other (Specify, __) ' AE term is listed in the solicited AE list in CAE flow	✓
	User is in CAE flow. One of the solicited AE is 'Growth and Development - Other (Specify, __) '. User tries to add an observed AE with the same term.	Caaers allows addition of an observed AE with same term	✗

Test cases for AE locking

Use case: https://wiki.nci.nih.gov/x/r6ul

	Scenario	Expected	Actual	Pass/ Fail
	User creates a new AE in CAE flow but no report is associated to it.	The 'R' icon is not shown beside the AE.		✓
	User creates a new AE in CAE flow associates a 5-day CTEP report to it. The report is not submitted. User goes back to the CAE flow.	The 'R' icon is not shown beside the AE.		✓
	User creates a new AE in CAE flow associates a 5-day CTEP report to it. The report is submitted. User goes back to the CAE flow.	The 'R' icon is shown beside the AE.		✓
	User deletes an existing observed AE. This AE is not associated to an existing report that has been submitted.	User is asked: 'are you sure you want to delete' message.		✗
	User deletes an existing observed AE. This AE is associated to an existing report that has been submitted.	User is asked "This AE is part of a submitted report. If you delete the AE, it will be removed from the report and require an amendment. Are you sure you want to continue?"		✓

	User edits an existing observed/solicited AE. This AE is associated to an existing report that has been submitted.	User is asked: 'are you sure you want to amend' message.		✓
	User edits an existing observed/solicited AE. This AE is associated to an existing report that has not been submitted.	No pop up for amend existing report is shown.		✓
	User is asked "This AE is part of a submitted report. If you delete the AE, it will be removed from the report and require an amendment. Are you sure you want to continue?". user clicks 'yes'	The existing report status is changed from 'submitted' to 'Amendment due' and user enters the edit AE report flow.		✓
	User is asked "This AE is part of a submitted report. If you delete the AE, it will be removed from the report and require an amendment. Are you sure you want to continue?". user clicks 'yes' to amend the report. User returns to the CAE>>Adverse Events page.	The AEs that are part of this AE data collection do not have the 'R' icon anymore.		✓
	User is asked "This AE is part of a submitted report. If you delete the AE, it will be removed from the report and require an amendment. Are you sure you want to continue?". user clicks 'No'	User is continues to be on the CAE>>Adverse Events page		✓
	User picks a submitted AE in CAE>>Adverse Events page. [CTMS:This has the 'R' icon]. Amends the AE and submits an Adeers 5 day report. User enters the CAE flow again and checks the AE status	The AE data collection is marked with the 'R' icon.		✓
	User takes a low grade AE which has been submitted [CTMS:This has the 'R' icon] and changes it to high grade AE. User clicks 'save and continue'	Rules are not fired on an AE that has already been submitted. No reports are suggested by caaers.		✓
	User takes a low grade AE which has not been submitted [CTMS:This does not have the 'R' icon] and changes it to high grade AE. User clicks 'save and continue'	Rules are fired by caaers which suggests appropriate reports.		✓
	An AE is included in a submitted non-amendable report (i.e. 24hr notification).	The green "R" report icon should not appear.		✗

Testing various combinations on CAE>> review and reports page

	Is AE selected?	Is report selected?	"Choose reports" pop-up shown?	User action on report pop-up	Expected	Pass/ Fail
	No	No	Yes	cancel	User will remain on 'review and report' page	✓
	No	No	Yes	edit	User is taken to edit expedited AE page to edit unsubmitted report.	✓
	No	No	Yes	amend	User is taken to edit expedited AE page to amend submitted report	✓
	Yes	No	Yes	cancel	User will remain on 'review and report' page	✓
	Yes	No	Yes	edit	User is taken to edit expedited AE page to edit unsubmitted report.	✓
	Yes	No	Yes	amend	User is taken to edit expedited AE page to amend submitted report	✓
	Yes	Yes	Yes	cancel	User will remain on 'review and report' page	✓
	Yes	Yes	Yes	edit	User is taken to edit expedited AE page to edit unsubmitted report.	✓
	Yes	Yes	Yes	amend	User is taken to edit expedited AE page to amend submitted report.	✓
	Yes	Yes	Yes	create	User is taken to edit expedited AE page to create new report.	✓
	No	Yes	No	NA [CTMS:No actions available]	javascript alert informs user that no AEs were selected	✓

Test cases for amend report flow

	Scenario	expected	actual	pass / fail
1	User chooses an existing study-subject-reporting period			
1.1	User adds a new SAE to the list of AEs associated with this RP and clicks continue.	Caaers should run rules engine only against the newly added SAE.The 24 hr and 5 day report should be selected for the new SAE only.		
1.2	User adds a new SAE to the list of AEs associated with this RP and clicks continue.There may be other SAEs that have been previously added to this RP.	Caaers should run rules engine only against the newly added SAE. Hence no new expedited reports should be required.		
1.3	User submits a 5 day ctep report which is on version 0. User clicks the amend link and submits the report again.	The newly submitted 5 day report should show version 1.		
1.4	User creates AEs that trigger a 10-day ctep report. In 'Review and submit' tab, user creates this new 10-day ctep report. User moves through expedited AE flow and in 'submit' tab sees 10-day ctep report with version 0. User does not submit this report. User goes back to Manage report flow and adds an AE that triggers 5 day report. User chooses to add this AE to the existing 10 -day report. user then continues through the expedited AE flow and goes to the 'submit' tab.	The earlier 10 day report is marked as withdrawn. The current 5 -day report is shown for submission and the version number is still 0.		

Test cases for Solicited Adverse Events

Use case context: 2.0.1 Local CTMS to caAERS - Study updates

Editing Solicited Adverse Events to study scenarios

	Scenario	result	Pass/Fail
1	User changes the AE terminology of study from CTC to meddra. In the SAE page the AE terms should reflect the changed AE terminology		
2	User changes the AE terminology of study from CTC version from v2 to v3. In the SAE page the AE terms should reflect the changed AE terminology		

3			

Notes / Issues

1. There is a gap in the use case. Currently Caaers UI allows freeform text to mention meddra version. The XSD has an ennumerated values for meddra version as one of 9,10,11,12. Hence i am not able to run this test.

Edit / Add Adverse events in Capture Adverse Event scenarios

	Scenario	result	Pass / Fail	artifact
1	User creates baseline RP which starts after a treatment RP	Error is thrown: 'Baseline Reporting Period cannot start after an existing Non-Baseline Reporting Period.'	✓	
2	User creates baseline RP which overlaps with existing treatment RP	Error is thrown: 'Reporting Period cannot overlap with an existing Reporting Period.'	✓	
3	User creates treatment RP which overlaps with existing treatment RP	Error is thrown: 'Reporting Period cannot overlap with an existing Reporting Period.'	✓	
4	User creates treatment RP with start date later than end date.	Error is thrown: 'To cannot be earlier than From'	✓	
5	User creates treatment RP with Start date as future date.	Error is thrown: 'Incorrect/future date value Start date'	✓	
6	User creates treatment RP with end date as future date.	RP is successfully created.	?	

7	User creates a valid treatment RP. The list of associated solicited AEs is shown.	The list of associated solicited AEs is shown.	✓	
8	User creates a baseline RP that starts and ends before any existing treatment RP.	Baseline RP is successfully created.	✓	
9	User creates baseline RP with invalid start date [CTMS:02/55/2008]	baseline RP is successfully created	✗	
10	User creates baseline RP with invalid end date [CTMS:02/66/2008]	baseline RP is successfully created	✗	
11	User creates a treatment RP that start and ends before an existing baseline RP	Error is thrown: 'Non-Baseline Reporting Period cannot start before an existing Baseline Reporting Period.'	✓	
12	User changes the start date of a baseline RP to another valid start date value.	Error is thrown: 'A Baseline Reporting Period already exists' [CTMS:Changing any data in the Baseline RP gives this problem.]	✗	
13	User creates a treatment RP. The list of solicited AEs appears. User goes back and edits some fields of the treatment RP. User switches to a different RP and comes back to this RP.	The list of solicited AEs is duplicated.	✗ [CTMS:error-1]	
14	User adds an observed AE that is a duplicate of a solicited AE.	The duplicate observed AE is not added.	✓	
15	User adds an observed AE by auto-suggest box. user then adds the same AE term by clicking on 'Add multiple'	The duplicate observed AE is not added.	✓	
16	User adds an Observed AE and deletes the AE.	The javascript pop up does not show correct messages.	✗ [CTMS:error-2] [CTMS:error-3]	
17	User is in Capture Adverse Event Flow: Overview, User clicks on 'Manually select reports'	No action performed.	✗	
18	User			

Notes / Issues

1. Currently System Assigned Identifier is part of XSD but not recorded in the DB.
2. There exists no way [CTMS:as per XSD] to mention the meddra version in disease coding terminology.

Test cases for use case 1.1

Use case context: 1.1 Enter Observed Adverse Events - caAERS UC https://wiki.nci.nih.gov/x/4pR8

Scenario	Expected behavior	expected	actual	pass/fail
1	User Selects a specific study / subject combination. User chooses to add new period of observation.	--	--	
1.1	User creates reporting period that overlaps with existing reporting period.	caaers should throw error/warning message for overlapping reporting period, but allow user to continue without changes	Error is thrown, but user is not allowed to continue	⚠
1.2	User creates reporting period that has a gap with the last reporting period.	Caaers should throw error/warning message for gap in reporting period, but allow user to continue without changes	Error is not thrown, but user is allowed to continue	⚠
1.3	User creates reporting period that preceeded all existing reporting periods.	Caaers should allow creation of new reporting period.		✓
1.4	User creates a reporting period with invalid date range. [CTMS:start date value is later than end date value]	Caaers gives error for invalid date range.		✓
1.5	User creates a reporting period with invalid start date [CTMS: for example MM=15]	Caaers gives error for invalid start date.	No error is thrown. Invalid month [CTMS:22/17/2008] is converted to valid date [CTMS:10/17/2009]	⚠
1.6	User creates a reporting period with invalid end date [CTMS: for example MM=15]	Caaers gives error for invalid end date.	No error is thrown. Invalid month [CTMS:22/17/2008] is converted to valid date [CTMS:10/17/2009]	⚠
1.7	User enters text [CTMS:instead of integer] for specifying cycle number for a new reporting period.	Caaers gives error for invalid cycle number.		✓
1.8	User enters -ve integer for specifying cycle number for a new reporting period.	Caaers gives error for invalid cycle number.		✓
1.9	User creates two reporting period of type "baseline".	Caaers gives error for two "baseline" type reporting periods.		✓
1.10	User creates a reporting period of type "treatment", when the only existing reporting period has the type "baseline", and doesn't mention the date of first course.	Caaers gives error for unknown date of first course.	No error is thrown	✗
1.11	User creates reporting period of type "post-treatment", when the only existing reporting period has the type "baseline", and doesn't mention the date of first course.	Caaers gives error for unknown date of first course.	No error is thrown	✗
1.12	User mentions invalid date of first course.	Caaers gives error for invalid date.		✓
1.13	User does not specify any treatment assignment for a particular reporting period and saves the reporting period.	Caaers gives error for unspecified treatment assignment code.		✓
1.14	User doesn't specify a reporting period type when creating a reporting period	caAERS gives an error for missing reporting period type		✓

2	User has chosen appropriate study / subject / reporting period with type of treatment or post treatment.			
2.1	User chooses an existing study-subject-reporting period combination. He edits one of the existing AEs and saves it.	The AE is saved without error.		
2.2	User chooses an existing study-subject-reporting period combination. He deletes one of the existing AEs and saves it.	The AE is saved without error.		
2.3	User enters information for some of the solicited AEs. Then user specifies an observed AE term that is a duplicate of one of the solicited AEs and clicks save.	Caaers throws error for duplicate AEs	caaers does not allow addition of duplicate AEs	
2.4	User does not add information to any solicited AE. In observed AEs section, user specifies an AE term that is in the solicited AEs list and clicks save.	Caaers throws error for duplicate AEs	caaers does not allow addition of duplicate AEs	
2.5	User marks one of the solicited AEs as grade 4 AE, enters info in all required fields for that AE, and clicks save.	Caaers informs user that expedited reporting is required.		
2.6	User marks one of the observed AEs as grade 4 AE, enters info in all required fields for that AE, and clicks save.	Caaers informs user that expedited reporting is required.		
2.7	User marks one of the AEs [CTMS:observed or solicited] as grade 4, and others as grade 2. User enters info in all required fields and saves.	Caaers marks only the grade 4 AE for expedited reporting, prompts user to select other AEs to include with the expedited report.		
2.7.1	User adds one of the lower grade AEs to expedited report flow.	Caaers allows user to add lower grade AEs to expedited report flow.		
2.8	User specifies the same CTC term twice when adding observed AEs and clicks save.	Caaers throws error for duplicate AEs	caaers does not allow addition of duplicate AEs	
2.9	When user specifies a grade for a solicited AE he should be able to see the following selection to choose from: • Please select • Not evaluated • Grade 0 - Evaluated, but not present (description) • grades 1-5: [CTMS:show CTC term specific grade descriptions]			
2.10	When user specifies a grade for an observed AE he should be able to see the following selection to choose from: • Please select • grades 1-5: [CTMS:show CTC term specific grade descriptions]			
2.11	Once user has filled in all information for a specific CTC term, caaers should automatically fill in expectedness information.	(this may be changing)		

2.12	User chooses 'Other - specify'. caAERS should bring up a field to enter the meddra term or AE info. The verbatim field should also still appear			
2.13	User chooses 'Other - specify' but does not enter anything into the "Other" text field	**Caaers throws error for blank 'other' field**	No error is thrown	
2.14	User specifies a solicited AE term with grade 0. He does not enter any other information and clicks save.	Caaers allows user to save AE without mentioning any attributes if CTC grade = 0. [for ex: hospitalization, verbatim etc even if marked mandatory by rules should be overidden here.]		
2.15	User creates and submits an expedited report. Then user chooses the same study-subject-reporting period combination and adds another AE with grade 4 and clicks save	Caaers prompts user that the AE is being added to the existing expedited report and gives the user the option to include additional AEs		
2.16	User creates and submits an expedited report. The user chooses the same study-subject-reporting period combination and adds other observed (non-serious) AEs to it and then clicks save	caAERS prompts user that an expedited report exists for the reporting period and prompts user to select additional AEs to the report (to amend the report)		
2.17	User enters observed AEs and then saves but doesn't answer "attribution to study"	caAERS throws error for blank attribution to study field		
2.18	User enters observed AEs and saves without entering Grade	caAERS throws error for blank grade		
2.19	User specifies a solicited AE term with grade of "Not evaluated". He does not enter any other information and clicks save.	Caaers allows user to save AE without mentioning any attributes if CTC grade = not evaluated. [for ex: hospitalization, verbatim etc even if marked mandatory by rules should be overidden here.]		
2.20	user has not entered information for all solicited AEs when he saves the changes of the reporting period	caAERS throws a warning that the solicited AEs have not all been reported on, with the option to go back and/or continue		
3	User has chosen appropriate study / subject / reporting period with type of baseline			
3.1	User chooses the existing study-subject-reporting period combination. He edits one of the existing AEs and saves it.	The information about solicited AEs and observed AEs is reflected correctly in the 'Review & Report' page	The list of observed AEs and solicited AEs is not shown on the 'Review & Report ' page	
3.2	User chooses an existing study-subject-reporting period combination. He deletes one of the existing AEs and saves it.	Information is saved without error.		
3.3	User enters information for some of the solicited AEs. Then user specifies an observed AE term that is a duplicate of one of the solicited AEs and clicks save.	Caaers throws error for duplicate AEs	caaers does not allow addition of duplicate AEs	
3.4	User does not add information to any solicited AE. In observed AEs section, user specifies an AE term that is in the solicited AEs list and clicks save.	Caaers throws error for duplicate AEs	caaers does not allow addition of duplicate AEs	
3.5	User marks one of the solicited AEs as grade 4 AE and clicks save.	caAERS allows user to save AE without mentioning any attributes/reporting since type=baseline		

3.6	User marks one of the observed AEs as grade 4 AE and clicks save.	caAERS allows user to save AE without mentioning any attributes/reporting since type=baseline	rules for attribution and hospitalization are fired although these are not applicable to reporting period type = baseline	✗
3.7	User marks one of the AEs [CTMS:observed or solicited] as grade 4, and others as grade 2 and saves	caAERS allows user to save AE without mentioning any attributes/reporting since type=baseline	For both low grade and high grade AEs caaers gives error for 'Missing Attribution to study'	✗
3.8	User specifies the same CTC term twice when adding observed AEs and clicks save.	Caaers throws error for duplicate AEs	caaers does not allow addition of duplicate AEs	✓
3.9	When user specifies a grade for a solicited AE he should be able to see the following selection to choose from: • Please select • Not evaluated • Grade 0 - Evaluated, but not present (description) • grades 1-5: [CTMS:show CTC term specific grade descriptions]			✓
3.10	When user specifies a grade for an observed AE he should be able to see the following selection to choose from: • Please select • grades 1-5: [CTMS:show CTC term specific grade descriptions]			✓
3.11	Once user has filled in all information for a specific CTC term, caaers should automatically fill in expectedness information.	(this may be changing)		?
3.12	User chooses 'Other - specify' for observed AE. caAERS should bring up a field to enter the meddra term/ AE info. The verbatim field should also still appear			✓
3.13	User chooses 'Other - specify' but does not enter anything into the "Other" text field	**Caaers throws error for blank 'other' field**	No error is thrown	✗
3.14	User specifies a solicited AE term with grade 0. He does not enter any other information and clicks save.	caAERS allows user to save AE without mentioning any attributes/reporting since type=baseline		✓
3.15	User enters observed AEs and then saves but doesn't answer "attribution to study"	caAERS allows user to save AE without mentioning any attributes since type=baseline		✗
3.16	User enters observed AEs and saves without entering Grade	caAERS throws error for blank grade		✓
3.17	User specifies a solicited AE term with grade of "Not evaluated". He does not enter any other information and clicks save.	caAERS allows user to save AE without mentioning any attributes/reporting since type=baseline		✓
3.18	user has not entered information for all solicited AEs when he saves the changes of the reporting period	caAERS throws a warning that the solicited AEs have not all been reported on, with the option to go back and/or continue		?
3.19	User chooses the existing study-subject-reporting period combination. He edits one of the existing AEs and saves it.	The rules engine should not fire for baseline reporting period types and no AEs are reportable in 'review and report' page.		✓

- Can user change existing reporting period start / end dates?

- User needs to specify start date of first course. Shouldn't this be done at the study level? It this information required for a particular study or study - subject, or study - subject - reporting period combination?

Tests for Capture Adverse Events Flow

	Scenario	expected	result
1	User enters valid study and subject in manage AEs tab and clicks continue. User clicks on the AE for a specific reporting period. For the list of solicited AEs, user chooses various values of grade and other attributes. User clicks continue.	User is taken to the overview page without any errors.	
2	User enters valid study and subject in manage AEs tab and clicks continue. User clicks on the AE for a specific reporting period. For the list of solicited AEs, user chooses a grade of 'Please select' or 'not evaluated'. User adds valid values to other attributes.	Error is thrown since other attribute values do not apply for 'Please select' or 'not evaluated' grades	
3	User adds an observed AE that is grade 2 or less [CTMS:not serious] and clicks continue. In the CAE>> overview page , user chooses this AE as the primary AE. User clicks 'back' and in the CAE>>Enter AEs page deletes the observed AE. User then clicks continue.	User is in CAE>> overview page without any errors	
4	User adds an observed AE that is grade 2 or less [CTMS:not serious] and clicks continue. In the CAE>> overview page , user selects this AE for reporting and clicks back.	User is in CAE>> Enter AEs page without errors	[http://10.10.10.220:8060/browse/CAAERS-530]
5	User adds some High grade AEs in the CAE>> Enter AEs page and clicks continue. This triggers some CTEP report as mandatory. In the CAE>>Review & Report page user unselects all AEs for reporting and clicks continue.	Error is thrown for report with no AEs	
6	User adds a high grade solicited AE and a low grade observed AE in CAE>> Enter AEs page and clicks continue. In the next page user makes the [CTMS:low grade] observed AE as primary [CTMS:it is unchecked] and clicks continue.	Error is thrown for primary AE not being checked for reporting	

Module 1b Test Cases - Study

Module 1b Test Cases - Study

Use Case	Test Case
???	Study soft delete test cases
???	Test cases for excel study import
Create Study for AE Data Entry	Test cases for use case 2.1 - Study create and-or update
???	Testing multi-modality studies

Study soft delete test cases

Source: http://jira.semanticbits.com/browse/CAAERS-2322

Scenario	Expected	Actual	Pass/fail
Study is in "data incomplete" status.	The user should not be able to see the study in the Manage reports study auto-completer.		✓
Study is in "data incomplete" status.	The user should not be able to see the study in the Report AEs study auto-completer.		✓
Study is in "data incomplete" status.	User should not be able to assign subject to the study.	http://jira.semanticbits.com/browse/CAAERS-2330	✓ Issue is fixed
Study is in "data complete" status.User adds a course for a particular study-subject combo which used a TAC from the study. User then deletes the TAC from study. User edits this course in the Report AEs page	The option for this TAC should not be shown	The option for the TAC is shown.	http://jira.semanticbits.com/browse/CAAERS-2331 ✓ Issue is fixed
Study is in "data complete" status.User adds a course for a particular study-subject combo which used a TAC from the study. User then deletes the TAC from study. User edits this course in the Report AEs page	User should not be able to save this course anymore. Caaers gives an error	User is able to save this course without issues.	http://jira.semanticbits.com/browse/CAAERS-2332 ✓ Issue is fixed
New Study Treatment information (TAC) is keyed in and saved.	The TAC should change to a label, so that one cannot edit it.		✓
Study Agent is associated to a report. User deletes the study agent in the study.	Caaers allows deletion of study agent.		✓
Study Agent is associated to a report. User deletes the study agent in the study.	The report still reflects the deleted study agent. However user cannot save the agent anymore after visiting the Study Interventions tab.		✓

User adds new agent to study and saves it.	The study agent information is no longer editable once saved.		✅
Study disease is associated to a report. User deletes the study agent in the study.	Caaers allows deletion of study disease.		✅
Study disease is associated to a report. User deletes the study agent in the study.	The report still reflects the deleted study disease. However user cannot save the disease anymore after visiting the subject details tab.	User is able to save the study disease after visiting the subject details tab, even though it has been deleted from study	✅ Issue is fixed
User is still processing a report that has not been submitted. The study TAC that is part of the report is deleted. User attempts to submit the report.	The report is not submittable although deleted TAC information is still associated to the report.		✅
User submits an expedited report to Adeers. The study TAC that is part of the report is deleted. User exports report to PDF	The deleted TAC that is part of the report is shown in the PDF.		✅

Test cases for "Adding DCP Conditions to a Study"

	Scenario	Expected	Actual	Pass / Fail
	In create / edit study flow, user chooses disease terminology as 'Other conditions' [CTMS:not CTEP or meddra]. User goes to 'Diseases and Conditions' page.	In the 'Diseases and Conditions' page user should see the auto-suggest box for 'add another condition'		✅
	In study>>Diseases and Conditions, user types 'add another condition' in the auto-suggest.	A pop up is shown for adding a new condition term		✅
	User defines a new condition and adds the condition. User then searches for the condition in the auto-suggest.	The newly added condition is shown in the auto-suggest		✅
	User defines a new condition and adds the condition. User clicks 'show all' link.	The newly added condition is a shown in the 'show all' list	There is no show all link	❌
	User adds the same condition twice	Caeers does not allows addition of duplicate conditions.	duplicate conditions are allowed	❌
	User adds a condition to the study. In the expedited AEs flow, the user goes to the 'subject medical history' tab.	The added study conditions should be reflected in the 'subject medical history' tab.		✅

	User deletes a condition to the study. In the expedited AEs flow, the user goes to the 'subject medical history' tab.	The deleted study conditions should be reflected in the 'subject medical history' tab.		
	User adds a condition to the study. In the assign subject to study flow, the user goes to the 'subject medical history' tab.	The added study conditions should be reflected in the 'subject medical history' tab.		
	User deletes a condition to the study. In the assign subject to study flow, the user goes to the 'subject medical history' tab.	The deleted study conditions should be reflected in the 'subject medical history' tab.		
	User creates a DCP report with the conditions added to the study.	The report reflects the conditions added.		

link to use case: https://wiki.nci.nih.gov/x/Jqul

Test cases for ASAEL

Use Case: http://jira.semanticbits.com/browse/CAAERS-3877

Add Expected AE to Agent.

1. User navigates to Admin>>Agents>>Search Agent.
2. User searches for agent by identifier '723227'
3. In the search results user is shown agent with name: (161-180)ESO-1 Peptide
4. User clicks on this agent name and is taken to Edit agent flow.
5. User specifies the Expected Adverse Events AE terminology as CTCAE.
6. User specifies CTC version as v3.0
7. The autosuggest box for adding AEs is shown.
8. User adds AE with term 'Adrenal insufficiency' and clicks save.
9. User gets confirmation: 'Information saved successfully '

Confirm Expected AE addition is persisted.

1. User again searches for same agent and pulls up the agent record.
2. User should be able to see the recently added AE 'Adrenal insufficiency'

Add Agent to Study.

1. User navigates to Studies>>Search Studies
2. User searches for study by identifier 6882.
3. In the study search results user clicks on study 6882.
4. User is taken to edit study flow.
5. User navigates to study >> agents tab.
6. User clicks add study agent button.
7. In the autosuggest user types '723227'
8. User enters ind information as CTEP IND.
9. Lead IND information is set to yes.
10. User clicks save and navigates to Expected AEs tab.
11. In the expected AEs tab, user should see 'Adrenal insufficiency' added as an expected AE automatically

Delete Agent from Study.

1. User navigates to Study>>Agents tab and deletes Agent with identifier '723227'
2. User clicks save and navigates to Expected AEs tab.
3. In the expected AEs tab, user should see 'Adrenal insufficiency' deleted automatically.

Add Expected ASAEL AE to course

Pre-conditions

Study 6882 has study agent 723227 with Expected AE 'Adrenal insufficiency'

Scenario

1. user navigates to Adverse Events>>Report Adverse Events
2. User selects the study as 6882 and an appropriate subject and course.
3. User clicks continue and is in the Adverse Events tab.
4. User type 'Adrenal insufficiency' in the auto-suggest and adds the resultant AE term.
5. User verifies that the expected value is defaulted to 'Yes'

Add Expected non-ASAEL AE to course

Pre-conditions

Study 6882 does not have study agent 723227 with Expected AE 'Adrenal insufficiency'

Scenario

1. user navigates to Adverse Events>>Report Adverse Events
2. User selects the study as 6882 and an appropriate subject and course.
3. User clicks continue and is in the Adverse Events tab.
4. User type 'Adrenal insufficiency' in the auto-suggest and adds the resultant AE term.
5. User verifies that the expected value is defaulted to 'Please select'

Import ASAEL

1. User navigates to Administration>>Import.
2. User selects 'Type of import file' as Agent specific expected AEs
3. User selects the attachedfile.
4. User clicks continue.
5. In the review and submit tab, user clicks import.
6. In the import summary tab, user is shown the list of agents which are successfully imported.
7. User clicks done.
8. User navigates to Administration>>Agents tab.
9. User searches for agent by identifier '726190'
10. User clicks on the search result.
11. In the edit agent flow, user is shown the list of AEs imported from the excel sheet.

Test cases for excel study import

	Scenario	Expected	Actual	Pass/fail
	User imports a study which does not exist in caaers	Study is successfully created	site investigators were not loaded	
	User imports a study which already exists in caaers	Study is not imported from excel sheet		
	User imports study with duplicate study agents	Error is thrown for duplicate study agents		
	Save excel sheet in excel 95 format and load			
	Save excel sheet in excel 97-2003 format and load.			
	User imports study with duplicate study diseases	Error is thrown for duplicate study diseases		
	User imports study with duplicate TACs	Error is thrown for duplicate study TACs		
	User imports study with duplicate Coordinating centers	Error is thrown for duplicate study coordinating centers		
	User imports study with duplicate study sites	Error is thrown for duplicate study sites		
	User imports study investigators with duplicate CTEP_INVESTIGATOR_IDs [CTMS:other details like first name etc are distinct]			
	User imports study investigators with all details identical, but distinct CTEP_INVESTIGATOR_IDs.			

	User imports study investigators with null values for PI_EMAIL PI_FAX PI_PHONE			
	User imports the same study investigator twice.	Error thrown for duplicate study investigators.		
	User imports study with duplicate Study therapies	Error is thrown for duplicate study study therapies		

Test cases for use case 1.2.1

Use case context: 1.2.1 Associate Solicited AEs to a study - caAERS UC

	Scenario	Expected behavior	result	Pass / Fail
1	User adds a duplicate AE term to the list of solicited AEs	Caaers throws error for duplicate solicited AEs.	Duplicate terms are not added to the list of solicited AEs	
2	User adds too much text in the additional information field	caAERS throws an error that the field can have x characters only ***how many characters did we make that field?***		
3	User adds additional information for the baseline reporting period type and saves the study. User then creates a reporting period with a reporting period type of treatment	the baseline Additional information should not appear		
4	User adds additional information for the baseline reporting period type and saves the study. User then creates a reporting period with a reporting period type of post-treatment	the baseline Additional information should not appear		
5	User adds additional information for the baseline reporting period type and saves the study. User then creates a reporting period with a reporting period type of baseline	the baseline Additional information should appear		
6	User adds additional information for the treatment reporting period type and saves the study. User then creates a reporting period with a reporting period type of treatment	the treatment Additional information should appear		
7	User adds additional information for the treatment reporting period type and saves the study. User then creates a reporting period with a reporting period type of post-treatment	the treatment Additional information should not appear		
8	User adds additional information for the treatment reporting period type and saves the study. User then creates a reporting period with a reporting period type of baseline	the treatment Additional information should not appear		
9	User adds additional information for the post-treatment reporting period type and saves the study. User then creates a reporting period with a reporting period type of treatment	the post-treatment Additional information should not appear		
10	User adds additional information for the post-treatment reporting period type and saves the study. User then creates a reporting period with a reporting period type of post-treatment	the post-treatment Additional information should appear		

11	User adds additional information for the post-treatment reporting period type and saves the study. User then creates a reporting period with a reporting period type of baseline	the post-treatment Additional information should not appear		
	~~User is editing a study for which an expedited report or reporting period has been created. He changes the term and/or medDRA code for this study.~~ Not in scope for this use case	~~This should not be allowed as these solicited AEs have already been reported for some study participant assignment.~~		
	~~User is editing a study. The session times out. User clicks 'save'. User is taken to logon screen. After logging in user is able to save the entered information.~~ To be covered in later use case, details still coming			
12	User adds a solicited AE to a study, but does not associate it to any of the three reporting period types.	Caaers throws error for not selecting a reporting period type for the AE.		
13	User adds a ctc term that contains "other - specify"	caAERS throws an error saying "other - specify is not allowed"	Currently other specify is not selectable	
14	User creates a study with MedDRA as its vocabulary and then goes to add solicited AEs	solicited AE selection should also be in MedDRA, not CTC		
15	User creates a study with CTC v 2 as its vocabulary and then goes to add solicited AEs	solicited AE selection should also be in CTC v2, not CTCAE v3		
16	User adds solicited AEs to the study and checks the box above the Baseline reporting period type	the checkbox in the Baseline reporting period type column should be checked and all solicited AEs should show up when a new reporting period with baseline as the type is created		
17	User goes to the solicited AE section of the study and removes the check from the box above the Baseline reporting period type	the checkbox in the Baseline reporting period type column shouldn't be checked and no solicited AEs should show up when a new reporting period with baseline as the type is created		
18	User adds a new solicited AE to a study, associate it to a EPT (Evaluation Period Type) and save it. For a specific study-subject user opens an existing reporting period. (This step should be performed for all existing EPT.)	The list of solicited AEs should **not** show the newly added AE and should not be corrupted or become corrupted when saving/editing the AEs for the reporting period		
19	User adds a solicited AE to a study and clicks save. For a specific study-subject user pulls up an existing expedited report. (don't test for a 'new' expedited report, since that is/will be created from the reporting period)	Existing expedited report entries should not be modified to include the new solicited AE and should not be corrupted or become corrupted when saving/editing the AEs for the reporting period		
20	User adds a new solicited AE to a study and clicks save. For a specific study-subject user adds a new reporting period.[CTMS:The new evaluation period type should be the same as selected in the study]	The list of solicited AEs should show the newly added AE.		
21	User deletes an existing solicited AE on a study. For a specific study-subject user adds a new reporting period.	The list of solicited AEs should not show the deleted AE.		
22	User deletes an existing solicited AE on a study. For a specific study-subject user pulls up an existing expedited report.	The reporting period should included the deleted AE and should not be corrupted or become corrupted when saving/editing the AEs for the reporting period		

23	User deletes a solicited AE to a study and clicks save. For a specific study-subject user opens an existing reporting period.	Existing expedited report should still contain the deleted solicited AEs and should not be corrupted or become corrupted when saving/editing the AEs for the reporting period		
24	User modifies the instructions for a specific reporting period type and saves. For a specific study-subject user adds a new reporting period.	Reporting period should show the new instructions		
25	User modifies the instructions for a specific reporting period type and saves. For a specific study-subject user pulls up an existing expedited report.	Expedited report should show the old instructions and should not be corrupted or become corrupted when saving/editing the AEs for the reporting period		
26	User modifies the instructions for a specific reporting period type and saves. For a specific study-subject user opens an existing reporting period.	Reporting period should show the old instructions and should not be corrupted or become corrupted when saving/editing the AEs for the reporting period		
27	User deletes the instructions for a specific reporting period type and saves. For a specific study-subject user adds a new reporting period.	Reporting period shouldn't show instructions		
28	User deletes the instructions for a specific reporting period type and saves. For a specific study-subject user pulls up an existing expedited report.	Expedited report should show the old instructions and should not be corrupted or become corrupted when saving/editing the AEs for the reporting period		
29	User deletes the instructions for a specific reporting period type and saves. For a specific study-subject user opens an existing reporting period.	Reporting period should show the old instructions and should not be corrupted or become corrupted when saving/editing the AEs for the reporting period		
30	User adds a solicited AE and associates it to all 3 reporting period types and saves. Then user creates a new reporting period for each reporting period type	solicited AE should show up in all 3 reporting periods		
31	User adds a solicited AE and associates it to 2 reporting period types and saves. Then user creates a new reporting period for each reporting period type *(three tests: associated with baseline and treatment, baseline and post-treatment, & treatment and post-treatment)*	solicited AE should show up only in the 2 reporting periods it is associated to • shows up for baseline and treatment, not in post-treatment • baseline and post-treatment, not in treatment • treatment and post-treatment, not in baseline		
32	User adds a solicited AE and associates it to 1 reporting period types and saves. Then user creates a new reporting period for each reporting period type (*(three tests: associated with baseline, treatment, and post-treatment)*	solicited AE should show up in only the reporting periods it is associated to. Shows up for • baseline, not treatment or post-treatment • treatment, not baseline and post-treatment • post-treatment, not baseline and treatment		

33	User is in Edit study flow> Solicited AEs tab. user adds some solicited AEs and then selects one of the reporting period types as applicable to the AEs. Then the reporting period type is deleted.	The list of AEs that are associated with said reporting period type are not removed		✗
34	User is in Edit study flow> Solicited AEs tab. user adds some solicited AEs. User has not associated these AEs to any reporting period type. One of the reporting period is deleted.	The list of AEs that are not associated with any reporting period type are not removed.		✗
35	User should not be able to delete Baseline reporting period type			✓
36	User adds CTC term 'Vasculitis' and assigns to a reporting period type. User then again attempts to add the term 'Vasculitis'. This term is not added to the list of solicited AEs again. User then clicks save.		Although the term is not added again, when the user clicks save, the term 'Vasculitis' is listed twice after the page has finished loading.	✗

In use case 1.2.1 >> Extensions >> 2.2.a >> step 4 , the firing of rules engine is mentioned. What role does the rules engine play in edit study flow? ***answer: when talking about the 'rules engine' here, directly referring to it checking to ensure all solicited AEs are associated to a reporting period type, there are no duplicates, there are no "other - specify", that sort of thing.**

Test cases for use case 2.1 - Study create and-or update

Use case context: 2.0.1 Local CTMS to caAERS - Study updates

Update study scenarios

	Scenario	pre-req	result	Pass/Fail
1	User updates study with non existent study identifier.	--	Error is thrown: "Study with Short Title "Study PCS_4" does not exist in caAERS"	✓
2	User changes the study short title for an existing study with an empty string for title.	study with valid short title exists	Message returned: "Study with Short Title "NA" updated in caAERS"	?
3	User changes the study long title for an existing study with empty string.	study with valid long title exists	Study is updated with empty long title.	✗
4	User changes existing study phase from I to II.	study exists with phase of I	Study phase is updated with as phase II study	✓
5	User changes AE terminology from CTC to meddra.	study exists with AE terminology of CTC	Error is thrown: "AeTerminology is either Empty or Not Valid". See footnote 1.	?
6	User changes disease terminology from CTEP to meddra.	study exists with disease terminology of CTEP	Error is thrown: "Selected terminology is not CTEP"	✗
7	User adds device and removes radiation from therapy	study exists with radiation [CTMS:and not device therapy]	Study is updated with device therapy and no radiation therapy.	✓

8	User changes funding sponsor from CTEP to WAKE	study exists with CTEP as funding sponsor	Study funding sponsor is not changed from CTEP to WAKE	✗
9	User changes funding sponsor identifier.	study exists with given funding sponsor identifier.	funding sponsor identifier is updated in study	✗
10	User adds one study site and removes another.	study exists with given study site.	Study is updated with old study site deleted and new study site added.	✓
11	User adds one study investigator and removes another.	study exists with given study investigator.	Study is updated correctly.	✓
12	User changes the role of a study investigator.	study exists with given investigator in given role.	Study is updated correctly.	✓
13	User changes description of given TAC code	Study with given TAC code exists.	Study is updated correctly.	✓
14	User adds TAC with same code as in DB but the comments, description etc are different	Study with given TAC code exists.	Study is updated correctly.	✓
15	User changes the IND type of existing study agent.	Study exists with given study agent.	Study does not get updated with specified IND type	✗
16	User adds a new study agent.	Study exists.	Study does not reflect the specified IND types	✗
17	User changes a study agent from lead agent to non lead agent.	Study exists with given study agent.	Study does not reflect change from lead to non lead agent	✗
18	User mentions meddra disease codes when disease terminology is set to CTEP.	Study exists with disease terminology set to CTEP.	No error is thrown. Study is created without study diseases	✗
19	User modifies CTEP study disease from lead to non lead.	Study exists with given study disease as lead.	Study diseases correctly updated.	✗
20	User adds a CTEP disease and removes another.	Study exists with given CTEP study disease	Study diseases correctly updated	✓
21	User mentions <fundingSponsor> identifier of CTEP004a and <identifiers> of <type>Protocol Authority Identifier</type> and <value>CTEP004b</value> [CTMS:the two identifiers should be the same]	Study exists with identifier of CTEP004	Study is updated with the following identifiers: Cancer Therapy Evaluation Program Protocol Authority Identifier CTEP004a Cancer Therapy Evaluation Program Protocol Authority Identifier CTEP004b [CTMS:Two protocol authority identifiers are allowed]	✗
22	User mentions TAC with empty string for TAC code	Study exists.	Study with empty TAC code created.	✗

Notes / Issues

1. There is a gap in the use case. Currently Caaers UI allows freeform text to mention meddra version. The XSD has an ennumerated values for meddra version as one of 9,10,11,12. Hence i am not able to run this test.

Create study scenarios

	Scenario	result	Pass / Fail	artifact
1	User creates study. None of the identifiers are indicated as primary.	Study is created with no primary identifiers.	✗	
2	User creates study. Two of the identifiers are indicated as primary.	Study is created with two primary identifiers	✗	
3	User creates study with an empty string for study short title.	Study is created with "NA" as short title	✗	
4	User creates study with an empty string for study long title.	Study is created with empty string as long title	✗	
5	User creates study with an empty string for phase.	Error is thrown: "StudyDto to StudyDomain Conversion Failed"	⚠	
6	User creates study with an empty string for status.	Error is thrown: "StudyDto to StudyDomain Conversion Failed"	⚠	
7	User creates study with value "YES" [CTMS:All caps] for multi-institution indicator. [XSD only expects one of [true | CTMS:false]	Study is created with multi-institution indicator set to "No"	✗	
8	User creates study with value "TRUE" [CTMS:All caps] for AdEERS reporting required field.	Study is created with AdEERS reporting required indicator set to "No"	✗	
9	User creates study with AE terminology CTC version 10. [CTMS:non existent]	Error is thrown: "CTC is either Empty or Not Valid"	✓	
10	User creates study with AE terminology meddra version 20. [CTMS:non existent]	Error is thrown: "AeTerminology is either Empty or Not Valid"	⚠	
11	User creates study with disease coding terminology "PPP". [CTMS:non existent]	Error is thrown: "Disease Code Term is either Empty or Not Valid" "Selected terminology is not CTEP"	✓	
12	User creates study with study design value of "blind". [CTMS:all lowercase]	Study is created with a study design set to 'Please select'	✗	
13	User creates study with a funding sponsor identifier of "CTEP0 015" [CTMS:Space in the identifier]	Study is created with a funding sponsor identifier of "CTEP0 015"	✓	this is allowed
14	User creates a study with funding sponsor organization name of "xxxxx" [CTMS:non existent]	Error is thrown: "The organization specified in fundingSponsor is invalid"	✓	
15	User creates study with funding sponsor organization nci institute code of "xxx" [CTMS:non existent]	Error is thrown: "The organization specified in fundingSponsor is invalid"	✓	
16	User creates study with duplicate study agents.	Study is created with duplicate study agents.	✓	
17	User creates study with name for "other agent" as "1-Aminocyclopentane"	Error is thrown: "Provdided Agent is not Valid"	✗	
18	User enters study with study agent that is CTEP IND and also mentions the IND# [CTMS:IND# is not mentioned in UI]	Study is created with given study agent. IND# is ignored	✓	
19	User creates study with two CTEP IND agents. Both are set as "Lead IND"	Study is created with two CTEP IND agents. Both are set as lead IND	✗	this is not allowed
20	User creates study with duplicate TAC codes.	Study is created with duplicate TAC codes	✗	

21	User creates study with blank string for TAC code.	Study is created with blank string for TAC code	✖	
22	User creates study with blank string for TAC description	Study is created with blank string for TAC description	✖	
23	User mentions disease coding terminology as CTEP and then specifes diseases with meddra terms [CTMS:uses <meddraStudyDisease> tag instead of <ctepStudyDisease> tag]	Study is created with disease terminology of CTEP . No disease information is specified.	✖	
24	User mentions meddra disease with non existent meddra disease code. [CTMS:102200045]	Study is created with disease terminology of MEDDRA and when user goes to diseases tab, NULLPOINTER exception is thrown.	✖	
25	User mentioned CTEP disease with non existent term.	Error is thrown: "The selected disease Term Chondrosarcomaaaa is not Valid"	✔	
26	User mentions duplicate CTEP disease terms.	Study is created with duplicate CTEP disease terms.	✖	
27	User mentions two CTEP disease terms as primary.	Study is created with two primary CTEP diseases	?	
28	User creates study with duplicate study sites.	Study is created with duplicate study sites.	✖	
29	User creates study with duplicate study site investigators	Study is created with duplicate study site investigators	✖	
30	User creates study with invalid role for study site investigator [CTMS:"xyz"]	Error is thrown: "StudyDto to StudyDomain Conversion Failed"	✔	
31	User creates study with duplicate study site personnel	Study is created with duplicate study site personnel	✖	
32	User creates study with invalid role for study site investigator [CTMS:"xyz"]	Error is thrown: "StudyDto to StudyDomain Conversion Failed"	✔	
33	User creates study with duplicate identifiers.	Study with duplicate identifiers is created.	✖	
34	User creates study with two primary identifiers.	Study is created with two primary identifiers	✖	
35	User creates study with two protocol authority identifiers	Study is created with two protocol authority identifiers	✖	

Notes / Issues

1. Currently System Assigned Identifier is part of XSD but not recorded in the DB.
2. There exists no way [CTMS:as per XSD] to mention the meddra version in disease coding terminology.

Testing multi-modality studies

Agent only studies

Study: Judy Freeman (11-95-10-7)

Participant: Ronak James

	Scenario	caAERS	AdEERS
1	No Agent information in 'Course and Agent' tab + No prior therapy + No radiation + No surgery	⚠ Protocol agents must be not be provided if Course Information has not been provided.	NA

2	Agent Information + No prior therapy + No radiation + No surgery	No error	: EXCEPTIONS --------- PRIOR_THERAPY: SEC_MAN_ERR - Required Section for pathway is not provided
4	Agent Information + Prior therapy + No radiation + No surgery	No error	No error
5	Agent Information + Prior therapy + Radiation + No surgery	Radiation intervention must not be provided when the pathway does not include RADIATION.	NA
6	Agent Information + Prior therapy + No Radiation + surgery	Surgery intervention must not be provided when the pathway does not include SURGERY.	NA
7	Agent Information + Prior therapy + Radiation + surgery	* Radiation intervention must not be provided when the pathway does not include RADIATION. * Surgery intervention must not be provided when the pathway does not include SURGERY.	NA

Agent + Radiation studies

Study: N027D

Participant: Catherine Jones

	Scenario	caAERS	AdEERS
1	No Agent information in 'Course and Agent' tab + No prior therapy + No radiation + No surgery	Protocol agents must be not be provided if Course Information has not been provided.	NA
2	Agent Information + No prior therapy + No radiation + No surgery	No error	: EXCEPTIONS --------- PRIOR_THERAPY: SEC_MAN_ERR - Required Section for pathway is not provided
4	Agent Information + Prior therapy + No radiation + No surgery	No error	No error
5	Agent Information + Prior therapy + Radiation + No surgery	Radiation intervention must not be provided when the pathway does not include RADIATION.	NA
6	Agent Information + Prior therapy + No Radiation + surgery	Surgery intervention must not be provided when the pathway does not include SURGERY.	NA
7	Agent Information + Prior therapy + Radiation + surgery	* Radiation intervention must not be provided when the pathway does not include RADIATION. * Surgery intervention must not be provided when the pathway does not include SURGERY.	NA

Agent + Radiation + Surgery studies

Study: RTOG-0330

Participant:

	Scenario	caAERS	AdEERS

1	No Agent information in 'Course and Agent' tab + No prior therapy + No radiation + No surgery	Protocol agents must be not be provided if Course Information has not been provided.	NA
2	Agent Information + No prior therapy + No radiation + No surgery	No error	: EXCEPTIONS --------- PRIOR_THERAPY: SEC_MAN_ERR - Required Section for pathway is not provided
4	Agent Information + Prior therapy + No radiation + No surgery	No error	No error
5	Agent Information + Prior therapy + Radiation + No surgery	Radiation intervention must not be provided when the pathway does not include RADIATION.	NA
6	Agent Information + Prior therapy + No Radiation + surgery	Surgery intervention must not be provided when the pathway does not include SURGERY.	NA
7	Agent Information + Prior therapy + Radiation + surgery	* Radiation intervention must not be provided when the pathway does not include RADIATION. * Surgery intervention must not be provided when the pathway does not include SURGERY.	NA

10-day ctep report was used for all studies

Module 1c Test Cases - Subjects

Module 1c Test Cases - Subjects

Use Case	Test Case
???	Test cases for assign subject to study flow
???	Test cases for Subject Identifiers
Create Subject (caAERS UC)	Test cases for use case 2.2 - Subject create and-or update

Test cases for assign subject to study flow

Assign subject to study flow

	Scenario	Expected	Actual	Pass / Fail
	User is in create subject flow. User enters Month of birth as 20 and year of birth as 0000.	Error is thrown for incorrect month and year of birth	An error is thrown but the messages are unclear: • Incorrect date value Date of birth • Incorrect Date Of Birth	
	User is in create subject flow. User enters duplicate Organization assigned identifiers.	Caaers throws error for duplicate organization assigned identifiers	No error is thrown	
	User is in create subject flow>>Choose study. User uses wild card '%' to search for the list of study sites	Only study sites that apply to the participant are shown.	--	

	User is in create subject flow>>Choose study. User uses partial string '%N0' to search for the list of study sites based on identifier.	Only applicable studies [CTMS:N0177, N027D] are shown.		✅
	User is in create subject flow>>Choose study. After choosing a study site, user does not mention 'Study subject identifier ' and clicks continue.	An error is thrown for missing Study subject identifier		✅
	User is in Enter subject>> Subject Medical History. User mentions duplicate metastatic disease siites	An error is thrown for duplicate metastatic disease sites.	An error message is thrown but it is incorrect: Duplicate Concomitant Medication: Bone Marrow.	❌
	User is in Enter subject>> Subject Medical History. User attempts to delete existing Metastatic Disease Site	The metastatic disease site is deleted.	The metastatic disease site is not deleted. [CTMS:caaers1.png]	❌
	User adds a study site to study [CTMS:'Alexander Fleming Cancer Center']. User then goes to Enter subject>>Details.	The added site should be part of the sites dropdown menu		✅
	User is in Enter subject>> Subject Medical History. For Disease Information>>Date of initial diagnosis, user feeds in alphanumeric characters.	Error is thrown for invalid format		✅
	User is in Enter subject>> Subject Medical History. For Disease Information>>Date of initial diagnosis, user enters 14 as value of month. The day and year are entered correctly.	Error is thrown for invalid month	No error is thrown for invlaid month	❌
	User is in Enter subject>> Subject Medical History. User adds a prior therapy and exits the flow. User now enters the edit CAE flow for the same study and subject. User selects an existing report and edits it.	The newly added prior therapy should not be shown in this expedited report flow.		✅
	User is in Enter subject>> Subject Medical History. User adds a prior therapy and exits the flow. User now enters the edit CAE flow for the same study and subject. User creates a new report.	The newly added prior therapy should be shown in this expedited report flow.		✅
	User is in edit expedited AE flow for a specific study and subject. User adds a new prior therapy, saves and exits. User is in Enter subject>> Subject Medical History for the same study and subject.	The newly added prior therapy should be shown in edit study subject assignment flow.		✅
	User is in Subjects>> Assign subjects to study flow. User searches for subjects. A list of results are shown. User does not select any participant radio button and clicks continue.	Error is thrown for not selecting participant		✅
	User is in create subject flow. User is a subject manager and registrar at organization Mayo clinic rochester. Wake and Duke are Study sites for study 5876. Mayo clinic rochester is a Coordinating Center at 5876.	In the enter subject>>details tab, the organization drop down shows Mayo, Wake and Duke as the list of potential study sites.		

Search subject

	Scenario	Expected	Actual	Pass / Fail
	User is in Subjects>> Search subject. User enters wild card '%' to search for all subject identifiers.	All subjects in the caaers DB are returned.		✅
	User is in Subjects>> Search subject. User enters wild card '%mrn' to search for all subject identifiers.	All subjects with 'mrn' as part of the identifier string should be returned		✅

	User is in Subjects>> Search subject. User enters wild card '%jo' to search for all subject firstnames.	All subjects with 'jo' as part of the first name should be returned.		✓

Test cases for Subject Identifiers

Tested by Karthik and Gowri

	Scenario	Expected	Pass / Fail
1	Create a subject with org = mayo clinic rochester, SI = mrn-pt-9876 Create another subject with org = mayo clinic rochester, SI = mrn-pt-9876	Caaers should throw error for duplicate subject identifier	✓
2	Create a subject with org = mayo clinic rochester, SI = mrn-pt-9876 Search for existing subject and edit it. change the subject identifier to mrn-pt-9876 and save.	Caaers should throw error for duplicate subject identifier	✓
3	Create a subject with org = mayo clinic rochester, SI = mrn-pt-9876 Assign to study 5876 with SSI=ssi-5544 save the assignment. Create a subject with org = mayo clinic rochester, SI = mrn-pt-5432 Assign to study 5876 with SSI=ssi-5544 save the assignment.	Caaers should throw error for duplicate study subject identifier	✓
4	Create a subject with org = mayo clinic rochester, SI = mrn-pt-9876 Assign to study 5876 with SSI=ssi-5544 save the assignment. Create a subject with org = mayo clinic rochester, SI = mrn-pt-5432 Assign to study 7208 with SSI=ssi-5544 save the assignment.	Caaers should not throw error for duplicate study subject identifier	✓
5	Create a subject with org = mayo clinic rochester, SI = mrn-pt-9876 Assign to study 5876 with SSI=ssi-5544 save the assignment. Create a subject with org = mayo clinic rochester, SI = mrn-pt-5432 Assign to study 7208 with SSI=ssi-2233 save the assignment. Assign above subject to study 5876 with SSI=ssi-5544 save the assignment	Caaers should throw error for duplicate study subject identifier	✓
6	Create a subject with org = mayo clinic rochester, SI = mrn-pt-9876 Assign to study 5876 with SSI=ssi-5544 save the assignment. Create a subject with org = mayo clinic rochester, SI = mrn-pt-5432 Assign to study 7208 with SSI=ssi-2233 Assign the above subject to study 7848 with SSI=ssi-5544	Caaers should not throw error for duplicate study subject identifier	

Test cases for use case 2.2 - Subject create and-or update

Use case context: 2.0.2 Local CTMS to caAERS - Subject updates

Update subject scenarios

	Scenario	pre-req	result	Pass/Fail
1	User updates non existing participant first name [CTMS:participant identifier does not exist in the system]	Participant does not exist.	Error is thrown: "Participant fn0000 ln0000 Does not exist in caAERS"	✓
2	User assigns participant to non existing study	Participant exists but study does not exist	Error is thrown: "The Study with Identifier " xyz " is either nonexistant or does not match the provided Site"	✓
3	User assigns participant to the two different study sites of the same study	Participant and study exist.	Participant is assigned both study sites belonging to same study. [CTMS:There is no way to verify this from the UI. I verified it through DB]	?
4	User updates first name of participant.	Participant exists.	Participant first name is correctly updated.	✓
5	User updates birth date of participant.	Participant exists.	Participant birth date is correctly updated.	✓
6	User adds identifier to participant.	Participant exists.	Identifier added to participant.	✓
7	User removes existing identifier of participant	Participant identifier exists.	Identifier removed from participant	✓
8	User adds identifier which is duplicate of existing participant identifier	Participant identifier exists.	Participant identifier is added only once	✓
9	User adds a primary identifier when there an existing identifier is already primary	Participant identifier exists.	Both identifers are marked as primary.	✗
10	User adds organization assigned identifier for participant with the same organization name as existing organization assigned identifier.	Participant with given identifier exists.	Organization assigned identifier is added to study.	?
11	User assigns study site to participant where the site is not part of the given study.	Participant and study exist.	Error is thrown: "The Study with Identifier " RTOG-0330 " is either nonexistant or does not match the provided Site"	✓
12	User assigns valid study site to participant. [CTMS:sites belong to two different studies]	Participant and study exist.	Study site is correctly assigned to the participant.	✓
13	User assigns participant two different study sites.	Participant and study exist.	Study sites are correctly assigned to the participant.	✓

Notes / Issues

Create subject scenarios

	Scenario	result	Pass / Fail	artifact
1	User creates participant with empty string for first name	Participant created with empty first name	✗	

2	User creates participant with empty string for last name	Participant created with empty last name	✖	
3	User creates participant with birth date in invalid date format [CTMS:expected format is yyyy-mm-dd]	Error is thrown: "could not insert: [CTMS:gov.nih.nci.cabig.caaers.domain.Participant]; nested exception is org.hibernate.exception.ConstraintViolationException: could not insert: [CTMS:gov.nih.nci.cabig.caaers.domain.Participant]"	?	
4	User creates participant with birth date as future date.	Participant created with future birth date	✖	
5	User creates participant with gender as 'xyz' [CTMS:invalid gender value].	Participant created with no gender information	✖	
6	User creates participant with race as 'xyz' [CTMS:invalid race value].	Participant created with no race information	✖	
7	User creates participant with race as 'More than one race' .	Participant created with no race information	✖	
8	User creates participant with ethnicity as 'xyz' [CTMS:invalid race value].	Participant created with no ethnicity information	✖	
9	User omits gender element when creating participant.	Participant created with no gender information	✖	
10	User omits race element when creating participant.	Participant created with no race information	✖	
11	User omits ethnicity element when creating participant.	Participant created with no ethnicity information	✖	
12	user creates participant with duplicate organization assigned identifiers.	Participant with organization assigned identifiers is created	✖	
13	User creates participant with invalid organization assigned identifier type [ex: 'xyz' instead of 'MRN'] .	Error is thrown: "ParticipantDto to ParticipantDomain Conversion Failed"	⚠	
14	User creates participant with two primary organization assigned identifiers.	Participant created with two primary identifiers. Also given following XML: <p:organizationAssignedIdentifier> <type>MRN</type> <value>mrn0014</value> <primaryIndicator>true</primaryIndicator> <p:organization> <name>Cancer Therapy Evaluation Program</name> <nciInstituteCode/> </p:organization> </p:organizationAssignedIdentifier> <p:organizationAssignedIdentifier> <type>MRN</type> <value>duke0014</value> <primaryIndicator>true</primaryIndicator> <p:organization> <name>Duke University Comprehensive Cancer Center</name> <nciInstituteCode/> </p:organization> </p:organizationAssignedIdentifier> The following identifiers are created: Duke University Comprehensive Cancer Center MRN mrn0014 Duke University Comprehensive Cancer Center MRN duke0014	✖	
15	User creates participant assigned to duplicate study sites.	Error is thrown: "<description>Participant John0015 Doe0015 could not be created in caAERS</description> <message>Participant identifier already exists.</message>"	⚠	
16	User creates participant assigned to study site which is not part of given study.	Error is thrown: The Study with Identifier " WFCCC004 " is either nonexistant or does not match the provided Site	⚠	
17	User creates participant with with study site organization as 'xyz' [CTMS:invalid organization]	Error is thrown: "The Study with Identifier " CTEP004 " is either nonexistant or does not match the provided Site"	⚠	
18	User creates participant with non existent study site identifer.	Error is thrown: "he Study with Identifier " xyz " is either nonexistant or does not match the provided Site`"	⚠	

19	User creates particpant with organization assigned identifier that has already been assigned to another participant	Error is thrown: "<description>Participant John0019 Doe0019 could not be created in caAERS</description> <message>Participant identifier already exists.</message>"		

Notes / Issues

Module 1d Test Cases - Rules and Reports

Module 1d Test Cases - Rules and Reports

Use Case	Test Case
???	Rules re-firing test case
???	Test Case - Commercial Agent Only Reporting
???	Test cases for 'Disallow submission if mandatory section items are not created'
???	Test cases for - Addition of field "Does this place participant at increased risk?" to expedited flow
???	Test cases for generic caAERS template
???	Test cases for Review and report functionality
???	Testing CTEP rules
???	Testing report definition XML import and export

Rules re-firing test case

		Alert	Other	Page Button		Button
New Report	Expected	actual			Expected	Actual
Add AE	yes	yes		"Create Report"	none	none
In-process Report						
No changes made	no	no	Hide 1st box; 2nd box "Reports"; 3rd box "Adverse Events in Report"; add grayed out check box.	"Access Report"	edit	edit
Add AE - no report required	no	no	Hide 1st box; 2nd box "Reports"; 3rd box "Adverse Events in Report"; add "in report" icon for earlier AEs.	"Update Report"	edit	edit
Add AE - same report required	yes	yes	Hide 1st box; 2nd box shows alert, update alert text, remove radio button but keep text.	"Update Report"	edit	edit
Add AE - new report required	yes	yes			replace	**edit**
Edit AE only - same report required	no	no			edit	edit
Edit AE only - new report required	yes	yes			replace	**edit**

Edit AE only - no reports required	tbd	**no**			withdraw	**edit**
Submitted Report						
No changes made	no				amend	
Add AE - no report required	no				amend	
Add AE - same report required	yes				amend	
Add AE - new report required	yes				amend	
Edit AE only - same report required	no				locking - edit	
Edit AE only - new report required	yes				locking - edit	
Edit AE only - no reports required	yes				locking - withdraw	

Karthik's test scripts

AE1 and AE2 trigger 10 day ctep report. Report is in edit mode. AE 3 is newly added

	Expected	Pass / Fail
AE 3 grade 1	No report alert	✓
AE 3 grade 2	10 day CTEP alert	✓
AE 3 grade 5	5 day CTEP alert	✓
AE 3 grade 1, AE 1 grade 2	No report alert	✓
AE 3 grade 1, AE 1 grade 5	5 day CTEP alert	✓
AE 3 grade 2, AE 1 grade 5	5 day CTEP alert	✓
AE 3 grade 5, AE 1 grade 5	5 day CTEP alert	✓

AE1 and AE2 trigger 10 day ctep report. Report is in amend mode. AE 3 is newly added

	Expected	Pass / Fail
AE 3 grade 1	No report alert	✓
AE 3 grade 2	10 day CTEP alert	✓
AE 3 grade 5	5 day CTEP alert	✓
AE 3 grade 1, AE 1 grade 2	No report alert	✓
AE 3 grade 1, AE 1 grade 5 [CTMS:amended]	5 day CTEP alert	✓
AE 3 grade 2, AE 1 grade 5 [CTMS:amended]	5 day CTEP alert	✓

AE 3 grade 5, AE 1 grade 5 [CTMS:amended]	5 day CTEP alert	

Test Case - Commercial Agent Only Reporting

Description

This is the test case for the Commercial Agent Only reporting pathway supporting the use case for SAE reporting from caAERS to the AdEERS system.

This test case will test the performance of the system regarding the following elements:

- Testing to ensure the SAE reporting rules fire only when required
- Testing to ensure that the report correctly identifies the mandatory, conditional, optional, and not applicable sections.
- Testing to ensure that the report correctly identifies the mandatory, conditional, optional, and not applicable fields.
- Testing to ensure that the report enforces the correct business rules.
- Testing to ensure that the submission of the report is successful through the AdEERS web service.

Testing Materials / Methods

Test Study: CALGB-10501

(KR;04.15.09) Test Participant: Kandie Barr (100000)

Report Definition: CTMS:CTEP Commercial Agent Only Report

(KR;04.15.09) Link to report: https://oracle.qa.semanticbits.com/caaers/pages/ae/edit?aeReport=1181&study=81&participant=141

Rules Sets:
CTMS:SAE Reporting Rules
CTMS:Mandatory Section Rules

Supporting Materials:
AdEERS web service business rules
CTMS:CTEP AE reporting requirements
AdEERS Beta System: https://capps-ctep.nci.nih.gov/openapps_10gbeta/gadeers_main$.startup

Test Scripts and Results

Reporting Rules Testing

Severity Grade	Attribution	Expectedness	Hospitalization	CTEP commercial agents report expected?	Actual	Pass / Fail
4	Definite	Yes	Yes	Yes	Yes	Pass
4	Probable	Yes	Yes	Yes	Yes	Pass
4	Possible	Yes	Yes	Yes	Yes	Pass
4	Definite	No	Yes	No	No	Pass
4	Probable	No	Yes	No	No	Pass
4	Possible	No	Yes	No	No	Pass
5	Definite	Yes	Yes	Yes	Yes	Pass
5	Probable	Yes	Yes	Yes	Yes	Pass
5	Possible	Yes	Yes	Yes	Yes	Pass
5	Definite	No	Yes	No	No	Pass
5	Probable	No	Yes	No	No	Pass
5	Possible	No	Yes	No	No	Pass

Mandatory Sections and Fields Testing

Category	Field Level	XML (Parent Tag)	XML(Tag)	Field Type Actual	Field Type Test (Pass / Fail)	T
General	Field	AE_REPORT	AE_REPORT			
General	Field	AE_REPORT	DEATH_UNRELATED_TO_AE			
General	Field	AE_REPORT	TICKET_NUMBER			
General	Field	AE_REPORT	AMENDMENT_NUMBER			
General	Section	AE_REPORT	PROTOCOL_INFORMATION			
General	Field	PROTOCOL_INFORMATION	NCI_PROTOCOL_NUMBER			
Treatment Assignment	Section	AE_REPORT	TREATMENT_ASSIGNMENT_INFORMATION			
Treatment Assignment	Field	TREATMENT_ASSIGNMENT_INFORMATION	TREATMENT_ASSIGNMENT_CODE	restricted value		
Treatment Assignment	Field	TREATMENT_ASSIGNMENT_INFORMATION	OTHER_TREATMENT_ASSIGNMENT			
Study Site	Section	AE_REPORT	INSTITUTION_INFORMATION			
Category	**Field Level**	**XML (Parent Tag)**	**XML(Tag)**	**Field Type Actual**	**Field Type Test (Pass / Fail)**	**T**
Study Site	Field	INSTITUTION_INFORMATION	INSTITUTION_NAME	restricted value		
Study Site	Field	INSTITUTION_INFORMATION	CTEP_ID	restricted value		
Reporter	Section	AE_REPORT	REPORTER_INFORMATION	M	Pass	
Reporter	Field	REPORTER_INFORMATION	FIRST_NAME	M	Pass	
Reporter	Field	REPORTER_INFORMATION	LAST_NAME	M	Pass	
Reporter	Field	REPORTER_INFORMATION	MIDDLE_NAME	O	Pass	
Reporter	Field	REPORTER_INFORMATION	PHONE	M	Pass	
Reporter	Field	REPORTER_INFORMATION	EMAIL	M	Pass	
Reporter	Field	REPORTER_INFORMATION	FAX	M	Pass	
Submitter	Section	AE_REPORT	SUBMITTER_INFORMATION	M	Pass	

Category	Field Level	XML (Parent Tag)	XML(Tag)	Field Type Actual	Field Type Test (Pass / Fail)	T
Submitter	Field	SUBMITTER_INFORMATION	FIRST_NAME	M	Pass	(
Submitter	Field	SUBMITTER_INFORMATION	LAST_NAME	M	Pass	(
Submitter	Field	SUBMITTER_INFORMATION	MIDDLE_NAME	O	Pass	(
Submitter	Field	SUBMITTER_INFORMATION	PHONE	M	Pass	(
Submitter	Field	SUBMITTER_INFORMATION	EMAIL	M	Pass	(
Submitter	Field	SUBMITTER_INFORMATION	FAX	M	Pass	(
Physician	Section	AE_REPORT	PHYSICIAN INFORMATION	M	Pass	(
Physician	Field	PHYSICIAN INFORMATION	FIRST_NAME	M	Pass	(
Physician	Field	PHYSICIAN INFORMATION	LAST_NAME	M	Pass	(
Physician	Field	PHYSICIAN INFORMATION	MIDDLE_NAME	O	Pass	(
Category	**Field Level**	**XML (Parent Tag)**	**XML(Tag)**	**Field Type Actual**	**Field Type Test (Pass / Fail)**	**T**
Physician	Field	PHYSICIAN INFORMATION	PHONE	M	Pass	(
Physician	Field	PHYSICIAN INFORMATION	EMAIL	M	Pass	(
Patient	Section	AE_REPORT	PATIENT_INFORMATION	M	Pass	(
Patient	Field	PATIENT_INFORMATION	PATIENT_ID	M	Pass	(
Patient	Field	PATIENT_INFORMATION	BIRTH_DATE	M	Pass	(
Patient	Field	PATIENT_INFORMATION	RACE	restricted value M	Pass	(
Patient	Field	PATIENT_INFORMATION	ETHNICITY	restricted value M	Pass	(
Patient	Field	PATIENT_INFORMATION	GENDER	restricted value M	Pass	(
Patient	Field	PATIENT_INFORMATION	HEIGHT	M	Pass	(
Patient	Field	PATIENT_INFORMATION	WEIGHT	M	Pass	(

Category	Field Level	XML (Parent Tag)	XML(Tag)	Field Type Actual	Field Type Test (Pass / Fail)	T
Patient	Field	PATIENT_INFORMATION	BASELINE_PERFORMANCE_STATUS	restricted value O	Pass	(
Patient	Field	PATIENT_INFORMATION	DISEASE_NAME	restricted value M	Pass	(
Patient	Field	PATIENT_INFORMATION	DISEASE_NAME_NOT_LISTED	N/A	Fail	(
Patient	Field	PATIENT_INFORMATION	PRIMARY_SITE_OF_DISEASE	restricted value N/A	Pass	(
Patient	Field	PATIENT_INFORMATION	PRIMARY_ANATOMIC_SITE	restricted value N/A	Pass	(
Patient	Field	PATIENT_INFORMATION	OTHER_PRIMARY_SITE_OF_DISEASE	N/A	Pass	(
Patient	Field	PATIENT_INFORMATION	DATE_OF_INITIAL_DIAGNOSIS	N/A	Pass	(
Prior Therapy	Section	AE_REPORT	PRIOR_THERAPY	O	Pass	(
Prior Therapy	Field	PRIOR_THERAPY	THERAPY_NAME	restricted value M	Pass	(
Prior Therapy	Field	PRIOR_THERAPY	THERAPY_COMMENTS	O	Pass	(
Category	**Field Level**	**XML (Parent Tag)**	**XML(Tag)**	**Field Type Actual**	**Field Type Test (Pass / Fail)**	**T**
Prior Therapy	Field	PRIOR_THERAPY	THERAPY_START_DATE	O	Fail	(
Prior Therapy	Field	PRIOR_THERAPY	THERAPY_END_DATE	O	Fail	(
Prior Therapy	Field	PRIOR_THERAPY	CHEMO_AGENT_NAME	restricted value O	Fail	(
Con Meds	Section	AE_REPORT	CONCOMITANT_MEDICATION	O	Pass	(
Con Meds	Field	CONCOMITANT_MEDICATION	CONCOMITANT_MEDICATION_NAME	M	Pass	(
Pre-Existing Condition	Section	AE_REPORT	PRE_EXISTING_CONDITION	O	Pass	(
Pre-Existing Condition	Field	PRE_EXISTING_CONDITION	CONDITION_NAME	restricted value C	Pass	(
Pre-Existing Condition	Field	PRE_EXISTING_CONDITION	OTHER_CONDITION_NAME	C	Pass	(
Metastatic Disease	Section	AE_REPORT	SITE_OF_METASTATIC_DISEASE	O	Pass	(
Metastatic Disease	Field	SITE_OF_METASTATIC_DISEASE	SITE_NAME	restricted value O	Fail	(

Metastatic Disease	Field	SITE_OF_METASTATIC_DISEASE	OTHER_SITE_NAME	N/A	Fail	
Category	**Field Level**	**XML (Parent Tag)**	**XML(Tag)**	**Field Type Actual**	**Field Type Test (Pass / Fail)**	
Adverse Event	Section	AE_REPORT	ADVERSE_EVENT_CTC	M	Pass	
Adverse Event	Field	ADVERSE_EVENT_CTC	CATEGORY	restricted value M	Pass	
Adverse Event	Field	ADVERSE_EVENT_CTC	AE_TERM	restricted value M	Pass	
Adverse Event	Field	ADVERSE_EVENT_CTC	SELECT_AE	restricted value O	Pass	
Adverse Event	Field	ADVERSE_EVENT_CTC	OTHER_ADVERSE_EVENT	O	Pass	
Adverse Event	Field	ADVERSE_EVENT_CTC	GRADE	restricted value M	Pass	
Adverse Event	Field	ADVERSE_EVENT_CTC	HOSPITALIZATION	restricted value C	Pass	
Adverse Event	Field	ADVERSE_EVENT_CTC	IS_PRIMARY_AE	restricted value M	Pass	
Adverse Event	Field	ADVERSE_EVENT_CTC	AE_START_DATE	C	Pass	
Adverse Event	Field	ADVERSE_EVENT_CTC	AE_END_DATE	O	Pass	
Category	**Field Level**	**XML (Parent Tag)**	**XML(Tag)**	**Field Type Actual**	**Field Type Test (Pass / Fail)**	
Adverse Event	Field	ADVERSE_EVENT_CTC	AE_COMMENTS	O	Pass	
Adverse Event	Field	ADVERSE_EVENT_CTC	ATTRIBUTION_FOR_AE	M	Pass	
Adverse Event	Field	ATTRIBUTION_FOR_AE	TYPE_OF_CAUSE	restricted value M	Pass	
Adverse Event	Field	ATTRIBUTION_FOR_AE	CAUSE_NAME	restricted value M	Pass	
Adverse Event	Field	ATTRIBUTION_FOR_AE	ATTRIBUTION	restricted value M	Pass	
Event Description	Section	AE_REPORT	DESCRIPTION_OF_EVENT	M	Pass	
Event Description	Field	DESCRIPTION_OF_EVENT	EVENT_DESCRIPTION	M	Pass	

Event Description	Field	DESCRIPTION_OF_EVENT	PRESENT_STATUS	restricted value M	Pass	
Event Description	Field	DESCRIPTION_OF_EVENT	DATE_OF_RECOVERY_OR_DEATH	N/A	Pass	
Category	**Field Level**	**XML (Parent Tag)**	**XML(Tag)**	**Field Type Actual**	**Field Type Test (Pass / Fail)**	
Event Description	Field	DESCRIPTION_OF_EVENT	RETREATED	restricted value N/A	Pass	
Event Description	Field	DESCRIPTION_OF_EVENT	REMOVED_FROM_PROTOCOL_TRT	restricted value N/A	Pass	
Event Description	Field	DESCRIPTION_OF_EVENT	REMOVED_FROM_PROTOCOL_TRT_DATE	N/A	Pass	
Event Description	Field	DESCRIPTION_OF_EVENT	CAUSE_OF_DEATH	restricted value n/a	Fail	
Event Description	Field	DESCRIPTION_OF_EVENT	PROGRESSIVE_DISEASE	restricted value n/a	Fail	
Event Description	Field	DESCRIPTION_OF_EVENT	DEATH_DATE	n/a	Fail	
Event Description	Field	DESCRIPTION_OF_EVENT	AUTOPSY_PERFORMED	restricted value O	Fail	
Course	Section	AE_REPORT	COURSE_INFORMATION	M	Pass	
Course	Field	COURSE_INFORMATION	START_DATE_OF_FIRST_COURSE	M	Pass	
Course	Field	COURSE_INFORMATION	START_DATE_OF_AE_COURSE	M	Pass	
Category	**Field Level**	**XML (Parent Tag)**	**XML(Tag)**	**Field Type Actual**	**Field Type Test (Pass / Fail)**	

Course	Field	COURSE_INFORMATION	COURSE_NUMBER_OF_AE	O	Pass	
Course	Field	COURSE_INFORMATION	TOTAL_NUMBER_OF_COURSES	O	Pass	
Course	Field	COURSE_INFORMATION	INV_AGENT_ADMIN	restricted value N/A	Pass	
Course	Field	COURSE_INFORMATION	INV_DEVICE_ADMIN	restricted value N/A	Pass	
Protocol Agent	Section	AE_REPORT	PROTOCOL_AGENT	M	Pass	
Protocol Agent	Field	PROTOCOL_AGENT	AGENT_NAME	restricted value M	Pass	
Protocol Agent	Field	PROTOCOL_AGENT	NSC_NUMBER	restricted value M	Pass	
Protocol Agent	Field	PROTOCOL_AGENT	DOSE_UOM	restricted value M	Pass	
Protocol Agent	Field	PROTOCOL_AGENT	TOTAL_DOSE_ADMINISTERED	M	Pass	
Protocol Agent	Field	PROTOCOL_AGENT	LAST_ADMINISTERED_DATE	N/A	Pass	
Category	**Field Level**	**XML (Parent Tag)**	**XML(Tag)**	**Field Type Actual**	**Field Type Test (Pass / Fail)**	
Protocol Agent	Field	PROTOCOL_AGENT	PROTOCOL_AGENT_COMMENTS	O	Pass	
Protocol Agent	Field	PROTOCOL_AGENT	AGENT_ADJUSTMENT	restricted value N/A	Pass	
Protocol Agent	Field	PROTOCOL_AGENT	AGENT_DELAYED	restricted value N/A	Pass	
Protocol Agent	Field	PROTOCOL_AGENT	DELAY	N/A	Pass	
Protocol Agent	Field	PROTOCOL_AGENT	DELAY_UOM	restricted value N/A	Pass	
Protocol Agent	Field	PROTOCOL_AGENT	AGENT_START_DATE	N/A	Fail	
Protocol Agent	Field	PROTOCOL_AGENT	AGENT_END_DATE	N/A	Fail	
Protocol Agent	Field	PROTOCOL_AGENT	LOT_NUMBER	O	Pass	
Radiation Intervention	Section	AE_REPORT	RADIATION_INTERVENTION	N/A	Pass	
Radiation Intervention	Field	RADIATION_INTERVENTION	TYPE_OF_RADIATION_ADMINISTRATION	restricted value N/A	Pass	

Category	Field Level	XML (Parent Tag)	XML(Tag)	Field Type Actual	Field Type Test (Pass / Fail)	T
Radiation Intervention	Field	RADIATION_INTERVENTION	TOTAL_DOSE_TO_DATE	N/A	Pass	(
Radiation Intervention	Field	RADIATION_INTERVENTION	UNIT_OF_MEASURE	restricted value N/A	Pass	(
Radiation Intervention	Field	RADIATION_INTERVENTION	DATE_OF_LAST_TREATMENT	N/A	Pass	(
Radiation Intervention	Field	RADIATION_INTERVENTION	SCHEDULE_NUMBER_OF_FRACTIONS	N/A	Pass	(
Radiation Intervention	Field	RADIATION_INTERVENTION	SCHEDULE_NUMBER_OF_ELAPSED_DAYS	N/A	Pass	(
Radiation Intervention	Field	RADIATION_INTERVENTION	ADJUSTMENT	restricted value N/A	Pass	(
Surgery Intervention	Section	AE_REPORT	SURGERY_INTERVENTION	N/A	Pass	(
Surgery Intervention	Field	SURGERY_INTERVENTION	SITE_OF_INTERVENTION	restricted value N/A	Pass	(
Surgery Intervention	Field	SURGERY_INTERVENTION	DATE_OF_INTERVENTION	N/A	Pass	(
Protocol Device	Section	AE_REPORT	SUSPECT_MEDICAL_DEVICE	N/A	Pass	(
Protocol Device	Field	SUSPECT_MEDICAL_DEVICE	BRAND_NAME	N/A	Pass	(
Protocol Device	Field	SUSPECT_MEDICAL_DEVICE	COMMON_NAME	restricted value N/A	Pass	(
Category	**Field Level**	**XML (Parent Tag)**	**XML(Tag)**	**Field Type Actual**	**Field Type Test (Pass / Fail)**	**T**
Protocol Device	Field	SUSPECT_MEDICAL_DEVICE	TYPE_OF_DEVICE	N/A	Pass	(
Protocol Device	Field	SUSPECT_MEDICAL_DEVICE	MANUFACTURER_NAME	N/A	Pass	(
Protocol Device	Field	SUSPECT_MEDICAL_DEVICE	MANUFACTURER_CITY	N/A	Pass	(
Protocol Device	Field	SUSPECT_MEDICAL_DEVICE	MANUFACTURER_STATE	restricted value N/A	Pass	(
Protocol Device	Field	SUSPECT_MEDICAL_DEVICE	MODEL_NUMBER	N/A	Pass	(
Protocol Device	Field	SUSPECT_MEDICAL_DEVICE	CATALOG_NUMBER	N/A	Pass	(
Protocol Device	Field	SUSPECT_MEDICAL_DEVICE	EXPIRATION_DATE	N/A	Pass	(

Protocol Device	Field	SUSPECT_MEDICAL_DEVICE	SERIAL_NUMBER	N/A	Pass	
Protocol Device	Field	SUSPECT_MEDICAL_DEVICE	LOT_NUMBER	N/A	Pass	
Protocol Device	Field	SUSPECT_MEDICAL_DEVICE	OTHER_NUMBER	N/A	Pass	
Protocol Device	Field	SUSPECT_MEDICAL_DEVICE	IMPLANTED_DATE	N/A	Pass	
Category	**Field Level**	**XML (Parent Tag)**	**XML(Tag)**	**Field Type Actual**	**Field Type Test (Pass / Fail)**	
Protocol Device	Field	SUSPECT_MEDICAL_DEVICE	AE_DEVICE_OPERATOR	N/A	Pass	
Protocol Device	Field	AE_DEVICE_OPERATOR	DEVICE_OPERATOR	restricted value N/A	Pass	
Protocol Device	Field	AE_DEVICE_OPERATOR	DEVICE_OPERATOR_OTHER	N/A	Pass	
Protocol Device	Field	SUSPECT_MEDICAL_DEVICE	EXPLANTED_DATE	N/A	Pass	
Protocol Device	Field	SUSPECT_MEDICAL_DEVICE	IS_SINGLE_USE_DEVICE	restricted value N/A	Pass	
Protocol Device	Field	SUSPECT_MEDICAL_DEVICE	REPROCESSOR_NAME	N/A	Pass	
Protocol Device	Field	SUSPECT_MEDICAL_DEVICE	REPROCESSOR_ADDRESS	N/A	Pass	
Protocol Device	Field	SUSPECT_MEDICAL_DEVICE	EVAL_DEVICE	restricted value N/A	Pass	
Protocol Device	Field	SUSPECT_MEDICAL_DEVICE	RETURNED_DATE	N/A	Pass	
Other Cause	Section	AE_REPORT	OTHER_CONTRIBUTING_CAUSE	O	Pass	
Category	**Field Level**	**XML (Parent Tag)**	**XML(Tag)**	**Field Type Actual**	**Field Type Test (Pass / Fail)**	
Other Cause	Field	OTHER_CONTRIBUTING_CAUSE	OTHER_CAUSE	M	Pass	
Labs	Section	AE_REPORT	LAB_RESULT	O	Fail	
Labs	Field	LAB_RESULT	LAB_CATEGORY	restricted value O	Fail	
Labs	Field	LAB_RESULT	LAB_NAME	restricted value C	Pass	
Labs	Field	LAB_RESULT	OTHER_LAB	C	Pass	
Labs	Field	LAB_RESULT	BASELINE_DATE	C	Pass	

Labs	Field	LAB_RESULT	BASELINE_VALUE	C	Pass	
Labs	Field	LAB_RESULT	BASELINE_UOM	restricted value C	Pass	
Labs	Field	LAB_RESULT	WORST_DATE	C	Pass	
Labs	Field	LAB_RESULT	WORST_VALUE	C	Pass	
Labs	Field	LAB_RESULT	WORST_UOM	restricted value C	Pass	
Category	**Field Level**	**XML (Parent Tag)**	**XML(Tag)**	**Field Type Actual**	**Field Type Test (Pass / Fail)**	
Labs	Field	LAB_RESULT	RECOVERY_LATEST_DATE	C	Pass	
Labs	Field	LAB_RESULT	RECOVERY_LATEST_VALUE	C	Pass	
Labs	Field	LAB_RESULT	RECOVERY_LATEST_UOM	restricted value C	Pass	
Labs	Field	LAB_RESULT	MICROBIOLOGY_SITE	C	Pass	
Labs	Field	LAB_RESULT	MICROBIOLOGY_DATE	C	Pass	
Labs	Field	LAB_RESULT	INFECTIOUS_AGENT	C	Pass	
Additional Info	Section	AE_REPORT	ADDITIONAL_INFORMATION	O	Pass	
Additional Info	Field	ADDITIONAL_INFORMATION	ADDITIONAL_INFO_NAME	restricted value O	Fail	
Additional Info	Field	ADDITIONAL_INFORMATION	ADDITIONAL_INFO_OTHER	O	Pass	

Business Rules Testing

Report Submission Testing

Test cases for 'Disallow submission if mandatory section items are not created'

Source: http://jira.semanticbits.com/browse/CAAERS-3397

	Scenario	Expected		Pass / Fail
T1	1. Prior therapy is a mandatory section. 2. Prior therapy should be pre-initialized. 3. User deletes the pre-initialized Prior therapy.	The Subject Details tab should not show a green check.		

T2	1. Prior therapy is a mandatory section. 2. Prior therapy should be pre-initialized. 3. User deletes the pre-initialized Prior therapy.	On the "Review and Submit" page, the report should not be ready to submit and there should be a message indicating that "at least one Prior Therapy must be provided."		✓
T3	1. Prior therapy is a mandatory section. 2. Prior therapy should be pre-initialized 3. User deletes the pre-initialized Prior therapy. 4. The user returns to the Prior Therapy section, clicks Add, and adds a prior therapy.	If all other information is entered on the Subject Details tab, that tab should now show a green check.		✓
T4	1. Prior therapy is a mandatory section. 2. Prior therapy should be pre-initialized 3. User deletes the pre-initialized Prior therapy. 4. The user returns to the Prior Therapy section, clicks Add, and adds a prior therapy.	On the "Review and Submit" page, there should no longer be an error indicating that "at least one Prior Therapy must be provided."		✓
T5	1. Study is agent-only. 2. Study Intervention and Agents are both mandatory sections.	In expedited AE flow>>Study interventions, Agent should be pre-initialized.		✓
T6	1. Study is agent-only. 2. Study Intervention and Agents are both mandatory sections. 3. Agent should be pre-initialized. 4. User deletes the pre-initialized Agent	The Study Intervention tab should show a red * and no green check.		✓
T7	1. Study is agent-only. 2. Study Intervention is a mandatory section. 3. User does not add agent.	On the "Review and Submit" page, the report should not be ready to submit and there should be a message indicating that "at least one Study Intervention must be provided."		✓
T8	1. Study is agent-only. 2. Study Intervention and Agents are both mandatory sections. 3. Agent should be pre-initialized. 4. User deletes the pre-initialized Agent 5. The user returns to the Agents section, clicks Add, and enters all mandatory fields for Agent.	The Study Intervention tab should now show a red * and a green check		✓

T9	1. Study is agent-only. 2. Study Intervention and Agents are both mandatory sections. 3. Agent should be pre-initialized. 4. User deletes the pre-initialized Agent 5. The user returns to the Agents section, clicks Add, and enters all mandatory fields for Agent.	On the "Review and Submit" page, there should no longer be an error indicating that "at least one Study Intervention must be provided."		✅
T10	1. Study is Multi-modality (Agent and Radiation) 2. Study Intervention, Agents, and Radiation are all mandatory sections	In Exp AE flow>> Study Intervention, Agent and Radiation should be pre-initialized.		✅
T11	1. Study is Multi-modality (Agent and Radiation) 2. Study Intervention, Agents, and Radiation are all mandatory sections 3. User deletes the pre-initialized Agent and Radiation	The Study Intervention tab should show a red * and no green check.		✅
T12	1. Study is Multi-modality (Agent and Radiation) 2. Study Intervention, Agents, and Radiation are all mandatory sections 3. User deletes the pre-initialized Agent and Radiation 4. The user returns to the Radiation section section, clicks Add, and enters all mandatory fields for radiation.	On the "Review and Submit" page, the report should not be ready to submit and there should be a message indicating that "at least one Study Intervention must be provided." Error should be shown for missing agent		✅
T13	1. Study is Multi-modality (Agent and Radiation) 2. Study Intervention, Agents, and Radiation are all mandatory sections 3. User deletes the pre-initialized Agent and Radiation 4. The user returns to the Agents section, clicks Add, and enters all mandatory fields for Agent.	The Study Intervention tab should now show a red * and a green check		✅
T14	1. Study is Multi-modality (Agent and Radiation) 2. Study Intervention, Agents, and Radiation are all mandatory sections 3. User deletes the pre-initialized Agent and Radiation 4. The user returns to the Agents section, clicks Add, and enters all mandatory fields for Agent.	On the "Review and Submit" page, there should be no error indicating that "at least one Study Intervention must be provided."Error should be shown for missing radiation.		✅

T15	1. Study Intervention is NOT a mandatory section. 2. Agent is a mandatory section 3. Study Intervention is NOT a mandatory section 4. User deletes the pre-initialized Agent	The Study Intervention tab should show a red * and a green check.		✅
T16	1. Study Intervention is NOT a mandatory section. 2. Agent is a mandatory section 3. User deletes the pre-initialized Agent	On the "Review and Submit" page, there should NOT be an error indicating that "at least one Study Intervention must be provided."		✅
T17	1. Study Intervention is NOT a mandatory section. 2. Agent is a mandatory section 3. User deletes the pre-initialized Agent	On the "Review and Submit" page, there should be an error indicating that "at least one Agent must be provided."		✅
T18	Pre-existing condition is a mandatory section.	In Exp AEs>>Subject details, the pre-existing condition field is pre-intiallized.		✅
T19	1. Pre-existing condition is a mandatory section. 2. In Exp AEs>>Subject details, the pre-existing condition field is deleted by user.	On the "Review and Submit" page, there should be an error indicating that "at least one pre-existing condition must be provided."		✅

Impact on routing and review

1. Turn on Routing and Review in Admin Page
2. In edit study, Add AE coordinator at coordinating center.
3. Add investigator [CTMS:physician] at study site.
4. Add Participant coordinator at study site.
5. Participant coordinator is the site CRA in workflow.
6. In rules, study has agent section marked as mandatory.
7. Login as site CRA.
8. Create a new reporting period for a study and subject.
9. Create a new report.
10. Remove any agent information
11. In the review and submit tab, report should not be ready for submission, since mandatory sections are not filled.
12. User should see validation error for agent mandatory sections not being unfilled.
13. In pull-out panel user should not see transition to "Send to SAE coordinator"
14. Add an agent.
15. In review and report, the report should be "ready to submit."
16. In pull-out panel user should see transition to "Send to SAE coordinator" as an option.
17. User clicks on the option.

18. User logs out and logs in as AE coordinator.
19. User chooses this specific report.
20. In the review and report tab, user is allowed to submit the report.
21. User submit report successfully

Study:7848

Coordinating center: Mayo Clinic Rochester

AE coordinator at CC: Username: test

study site: Mayo Clinic Rochester

Investigator at study site: Charles Erlichman

Participant coordinator at study site: username: iyerk

Subject(MV-23) Mark Vane
Study(7848) A Phase II Trial of Intravenous Administration of Reovirus Serotype 3 - Dearing Strain (Reolysin) in Patients with Metastatic MelanomaCourseCycle #: 11; Start Date: 01/01/10

Test cases for -- Addition of field "Does this place participant at increased risk?" to expedited flow

Source: http://jira.semanticbits.com/browse/CAAERS-3281

	Test case	Pass / Fail
	The field "Does this place participant at increased risk?" is available in Rules>>Report definition>>mandatory fields.	✓
	The field "Does this place participant at increased risk?" is in Rules>>Report definition>>mandatory fields. It is set to optional. User is in expedited AE flow>>Adverse Events. User does not specify value for this field and clicks continue. Caaers does not give error for 'required' field	✓
	The field "Does this place participant at increased risk?" is in Rules>>Report definition>>mandatory fields. It is set to mandatory. User is in expedited AE flow>>Adverse Events. User does not specify value for this field and clicks continue. Caaers gives error for 'required' field	✓
	The field "Does this place participant at increased risk?" is in edit Rules>>with Adverse event drop down.	✓
	User sets rule in edit rules page where if value of "increased risk"=yes then action=ctep 5 day report. In CAE flow>>Adverse events, user sets "Does this place participant at increased risk?"=yes and clicks continue. caaers suggests CTEP 5 day report.	✓

Test cases for generic caAERS template

Use case: http://jira.semanticbits.com/browse/CAAERS-2438

	Scenario	Expected	Actual	Pass / Fail

	User is in create report definition >> Details	In the Report format drop down, user has option for "caAERS custom template"		✅
	All fields in Medical devices section are set as Not applicable in Report definition>> Mandatory fields.	In the PDF report, user does not see the Medical devices section.		✅
	'Pre-existing condition' is set to optional in Report definition>> Mandatory fields.	In PDF report, user can see the 'Pre-existing conditions' section and 'Pre-existing condition' field.		✅
	'Medication' is set as mandatory in Report definition>> Mandatory fields >> Concommitant Medications. The other fields in conmeds are set as not applicable	In PDF report, user can see, Concomitant medication section and the medication field. Other fields of concomittant medication are not shown.		✅
	'Description and treatment of event(s). ' is set to optional in Report definition>> Mandatory fields. User does not specify value for Description and treatment of event(s) in expedited report flow.	In the PDF report, user can see the 'Description and treatment of event(s).' field with blank space for unspecified value.		✅
	Generate custom PDF using the respective report definition.	The following fields should be included in summary section of the PDF: 1. Study ID, 2. Title, 3. Study Subject ID, 4. Subject Organization, 5. Report ID, 6. Amendment #, 7. and Date Submitted	1. Study ID, ✅ 2. Title, ✅ 3. Study Subject ID, ✅ 4. Subject Organization, ✅ 5. Report ID, ✅ 6. Amendment # ✅ 7. and Date Submitted	
	User sets the display name in Report definition>>Details.	In the PDF report, the title of the report is set to the display name.	Report name is set to 'Custom name'	❌
	User is in Report definition>>Details.	User should be able to set the following subsitution variables for header and footer • "Organization Name," • "Page # of #'s", • "CONFIDENTIAL", • "Date generated"	No facility exists to add these variables	❌
	User creates a new caaers custom report format belonging to organization CTEP.	User is in CAE>>review report for a CTEP sponsored study. User clicks override and the caaers custom report is shown in the list of reports to be chosen from.		✅
	User has entered expedited AE flow after choosing a custom template as the applicable report definition. User is in exp AE flow>>Review and submit.	In the export drop down the current report should be one of the PDF formats offered for export.		✅
	User is filling a CTEP 5 day report. User is in exp AE flow>>Review and submit.	In the export drop down the current report should NOT be one of the PDF formats offered for export.		✅

Questions

1. What is the relevance of Delivery details tab when a new custom template is being created?
2. If a particular field is optional in report definition and it is not filled in the expedited report flow, the should the value for that field be blank or shown as 'NA' in the PDF report?
3. Where will header and footer information be recorded in the UI?

Test cases for Review and report functionality

	Scenario	Expected	
	User adds a grade 1 AE to a Course	No reports are suggested by the rules engine	
	AE 1 [CTMS:grade 5] is part of submitted report. AE 2 [CTMS:grade 1] is newly added.	No reports are suggested by the rules engine	
	AE 1 [CTMS:grade 5] is part of submitted report. AE 2 [CTMS:grade 5] is newly added.		
	The due date for AE report is calculated from the earliest graded date of the AEs		✅
	User sets a high grade AE that requires a CTEP 5 day report. User then goes to CAE>>review and report page	Rules engine recommends CTEP 5 day report	✅
	In review and report page, user unchecks an AE that requires CTEP 5 day report.	Recommendation for CTEP 5 day report is removed	✅
	In review and report page, user unchecks and then re-checks an AE that requires CTEP 5 day report.	Recommendation for CTEP 5 day report should be restored.	❌ http://jira.semanticbits.com/browse/CAAERS-2445
	AE 1 has graded date that is earlier than graded date of AE 2. AE 1 and and AE 2 are of grade 4. The CTEP 10 day report recommended by caaers is due based on AE 1 graded date. User then sets AE 1 grade to 1. This AE is no longer required for CTEP 10 day report. Only AE 2 is needed for CTEP 10 day report.	The due date for the CTEP 10 day report should be based on AE 2 graded date only.	❌ http://jira.semanticbits.com/browse/CAAERS-2446
	User is in review and report page. The CTEP 5 day report is recommended for AE 1 and AE 2. User unchecks both AEs. Caaers removes recommendations. User then manually over-rides and 'restores recommendation'. Now caaers again recommends CTEP 5 day report. However no AEs are selected. User clicks continue.	Caaers should not allow user in expedited AE flow.	❌ http://jira.semanticbits.com/browse/CAAERS-2447
	User has AE 1 with grade 4 which is part of a CTEP 10 day report. In CAE>>Review and report, user unchecks the AE and is informed that the report will be withdrawn. The user clicks report button.	The report is withdrawn and user is taken back to review and report page.	❌ http://jira.semanticbits.com/browse/CAAERS-2448
	User has AE 1 with grade 5 in CAE >> Adverse Events. This AE is not yet part of any report.	The rules engine recommends creation of CTEP 24 hr report.	✅
	User has AE 1 with grade 5 in CAE >> Adverse Events. This AE is added to CTEP 10 day report by manually overriding the caaers recommendation for a 24 hr CTEP report. User now adds AE 2 with grade 5 which requires a CTEP 24 hr report. The 10 day CTEP report is in edit mode.	caaers will not suggest a 24 hr CTEP report since user has overriden with an active 10 day report	✅
	User has AE 1 with grade 5 in CAE >> Adverse Events. This AE is added to CTEP 10 day report by manually overriding the caaers recommendation for a 24 hr CTEP report.User now adds AE 2 with grade 5 which requires a 24 hr day report. The 10 day CTEP report has been submitted.	caaers will suggest a 24 hr CTEP report since the overriden report is inactive	✅
	User has AE 1 with grade 5 in CAE >> Adverse Events. This AE is added to CTEP 10 day report by manually overriding the caaers recommendation for a 24 hr CTEP report.User now adds AE 2 with grade 5 which requires a CTEP 24 hr report. The 10 day CTEP report has been withdrawn.	caaers will suggest a 24 hr CTEP report since the overriden report is inactive	✅

	User has AE 1 with grade 4 in CAE >> Adverse Events. caaers recommends a CTEP 10 day report. User now changes the grade of AE 1 to 5 which requires a CTEP24 hr report. The 10 day CTEP report is in edit mode.	caaers will suggest replacing 10 day CTEP report with 24 hr CTEP report.	
	User has AE 1 with grade 5 in CAE >> Adverse Events. caaers recommends a CTEP 24 hr report. User submits 24 hr CTEP report. The 24 hr CTEP report is in submitted mode. The child CTEP 5 day report is also submitted. User adds AE 2 with grade 4 which requires a CTEP 10 day report.	Caaers will suggest amending the CTEP 5 day with CTEP 10 day report.	
	User has AE 1 with grade 5 in CAE >> Adverse Events. caaers recommends a CTEP 5 day report. User submits 5 day CTEP report.The 5 day CTEP report is in submitted mode. User modifies AE 1 with grade 4 which requires a CTEP 10 day report.	Caaers will suggest amending the CTEP 5 day with CTEP 10 day report.	
	User has AE 1 with grade 5 and AE 2 with grade 4 in CAE >> Adverse Events. caaers recommends a CTEP 5 day report. User submits 5 day CTEP report.The 5 day CTEP report is in submitted mode. User deletes AE 1 with grade 5.	Caaers will suggest amending the CTEP 5 day with CTEP 10 day report.	
	User submits a 5 day CTEP report and notes the ticket number. He then amends it with a 10 day CTEP report and submits it.	The 10 day CTEP report has the same ticket number as the 5 day	
	The 5 day report is set up as a child of the 24 hr. User submits a 24 hr report.	When user returns to Review and report page, A CTEP 5 day report is created for him	
	User is editing a 5 day CTEP report recommended by caaers. user adds AE 2 with grade 5 to this data collection. This should trigger a 24 hr report normally. User goes to review and report.	caaers still recommends CTEP 5 day report. [CTMS:If a child report is active, if rules engine suggest parent report, it should be ignored]	
	AE 1 [CTMS:grade 5] triggers both 24 hr and 5 day report [CTMS:as set up in rules page].	caaers only recommends 24 hr report. [CTMS:report with earliest due date is picked]	
	The 5 day report is set up as a child of the 24 hr. User submits a 24 hr report and notes the ticket number. User submits the child 5 day CTEP report.	The ticket number for the child 5 day should be the same as the parent 24 hr report.	
	User adds AE 1 and AE 2 to a 5 day report and submits it. In review and report , user unchecks AE 1.	Caaers recommends amending the CTEP 5 day report.	
	User adds AE 1 and AE 2 [CTMS:grade 4] to a 5 day report and submits it. In review and report, user unchecks AE 1. User amends 5 day report and submits it. User is in review and report page.	Caaers recommends a CTEP 10 day report.	
	User adds AE 1 which is graded yesterday. AE 2 is graded today. CTEP 5 day report is chosen.	caaers shows report due in 4 days [CTMS:earliest graded date]	
	User adds AE 1 which is graded yesterday. CTEP 5 day report is chosen and submitted. User modifies AE 1 and amends the 5 day report.	caaers shows report due in 5 days. [CTMS:earliest post submission modified date]	
	User adds AE 1 with grade 5 and submits a CTEP 5 day report. user modifies AE 1 with grade 5 and amends the 5 day CTEP report into 10 day CTEP report.		

	DC 1 has AE 1[CTMS:grade 3] which is part of CTEP 10 day report[CTMS:edit mode]. DC 2 has AE 2[CTMS:grade =1, expectedness=yes] which requires no report. AE 3 is added [CTMS:grade=5, expectedness=no]. User is in review and report page.	DC1: caaers recommends withdraw 10 day and create 24 hr and create IRB. DC2: caaers recommends create 24 hr and create IRB.	

Test cases for Sponsor auto-suggest in create rule flow

Pre-conditions

1. User is logged with the role of AE Rule and report manager.
2. User navigates to Rules>>Create Rules tab.
3. User chooses type as SAE reporting rules.
4. User chooses level as Sponsor rules.

Scenario #1

1. User types NCI.

Expected

1. Orgs matching NCI in the name are shown first
2. Orgs matching NCI in the identifier are shown next
3. Orgs matching NCI in the in the middle or end of the name are shown last

Scenario #2

1. User types MD.

Expected

Testing CTEP rules

Study

N027D

Short title

A Phase I Study of CCI-779 and Temozolomide in Combination with Radiation Therapy in Glioblastoma Multiforme

Rule #	Study Phase	IND holder	severity	Hospitalization	Expected	Attribution	Expected behavior	Result
1,3	Phase I Trial	CTEP IND	Grade 3	yes	No	Definite	5 Calendar Day SAE Report	
1,3	Phase I Trial	CTEP IND	Grade 3	yes	No	Definite	24 Hour SAE Notification	
2	Phase I Trial	CTEP IND	Grade 3	yes	No	Unlikely	CTEP 10 Calendar Day SAE Report	
1	Phase I Trial	CTEP IND	Grade 3	no	No	Definite	24 Hour SAE Notification	

1	Phase I Trial	CTEP IND	Grade 3	no	No	Probable	5 Calendar Day SAE Report	Error[CTMS:CAAERS-754]
3	Phase I Trial	CTEP IND	Grade 3	Yes	no	Possible	5 Calendar Day SAE Report	✓
3	Phase I Trial	CTEP IND	Grade 3	Yes	no	Possible	24 Hour SAE Notification	✓
4	Phase I Trial	CTEP IND	Grade 3	Yes	yes	Possible	CTEP 10 Calendar Day SAE Report	✓
4	Phase I Trial	CTEP IND	Grade 3	Yes	yes	Definite	CTEP 10 Calendar Day SAE Report	✓
5	Phase I Trial	CTEP IND	Grade 4	Yes	YES	Possible	5 Calendar Day SAE Report	✓
5	Phase I Trial	CTEP IND	Grade 4	Yes	YES	Possible	24 Hour SAE Notification	✓
5	Phase I Trial	CTEP IND	Grade 5	Yes	YES	Possible	5 Calendar Day SAE Report	✓
5	Phase I Trial	CTEP IND	Grade 5	Yes	YES	Possible	24 Hour SAE Notification	✓
6	Phase I Trial	CTEP IND	Grade 2	Yes	No	Definite	CTEP 10 Calendar Day SAE Report	Error[CTMS:CAAERS-756]
6	Phase I Trial	CTEP IND	Grade 2	Yes	No	Possible	CTEP 10 Calendar Day SAE Report	Error[CTMS:CAAERS-757]

Study
C80405
Short title
A Phase III Trial of Irinotecan/5-FU/Leucovorin or Oxaliplatin/5-FU/Leucovorin

Rule #	Study Phase	IND holder	severity	Hospitalization	Expected	Attribution	Action	Result
7	Phase III Trial	CTEP IND	Grade 2	NA	no	definite	CTEP 10 Calendar Day SAE Report	✓
7	Phase III Trial	CTEP IND	Grade 2	yes	no	Possible	CTEP 10 Calendar Day SAE Report	✓
8	Phase III Trial	CTEP IND	Grade 3	yes	no	unrelated	CTEP 10 Calendar Day SAE Report	✓
8	Phase III Trial	CTEP IND	Grade 3	yes	no	Possible	CTEP 10 Calendar Day SAE Report	✓
9	Phase III Trial	CTEP IND	Grade 3	yes	no	definite	CTEP 10 Calendar Day SAE Report	✓
9	Phase III Trial	CTEP IND	Grade 3	no	no	definite	CTEP 10 Calendar Day SAE Report	Error[CTMS:CAAERS-758]
10	Phase III Trial	CTEP IND	Grade 3	yes	yes	definite	CTEP 10 Calendar Day SAE Report	✓
10	Phase III Trial	CTEP IND	Grade 3	yes	yes	Unlikely	CTEP 10 Calendar Day SAE Report	✓
11	Phase III Trial	CTEP IND	Grade 4	NA	yes	definite	CTEP 10 Calendar Day SAE Report	Error[CTMS:CAAERS-759]
11	Phase III Trial	CTEP IND	Grade 5	yes	yes	definite	CTEP 10 Calendar Day SAE Report	✓

12	Phase III Trial	CTEP IND	Grade 4	NA	no	unlikely	CTEP 10 Calendar Day SAE Report	Error[CTMS:CAAERS-760]
12	Phase III Trial	CTEP IND	Grade 5	no	no	unrelated	CTEP 10 Calendar Day SAE Report	Error[CTMS:CAAERS-761]
13	Phase III Trial	CTEP IND	Grade 4	NA	no	definite	CTEP 10 Calendar Day SAE Report	Error[CTMS:CAAERS-762]
13	Phase III Trial	CTEP IND	Grade 5	yes	no	probable	5 Calendar Day SAE Report	
13	Phase III Trial	CTEP IND	Grade 5	yes	no	probable	24 Hour SAE Notification	

Testing field rules

Scenario #1

1. The following field rule is set:
   Rule-1: If Study Agent IND Holder is 'Cancer Therapy Evaluation Program' null Actions Mandatory
2. In Wayne State University 10 day report>>mandatory fields>>Subject details,Rule-1 is applied to Weight value field.
3. Study 5876 has study site Wayne State University.
4. User is Report AEs tab and chooses study as 5876 subject as wayne-pt2 and Cycle #: 11; Start Date: 11/03/10
5. User adds AE with grade=1, attribution=unrelated.
6. User clicks save and continue.
7. In the review and report page, no reports are recommended by caaers.
8. User clicks override and sees the list of reports
9. User chooses Wayne State University 10 day report and clicks report.[create/edit]
10. User moves through report flow and is in Study interventions tab.
11. User adds agent Alvocidib which is a Study Agent with IND Holder 'Cancer Therapy Evaluation Program'
12. User clicks save and continue and is in subject details tab

Expected

Weight is marked as a mandatory field 

Scenario #2

1. The following field rule is set:
   Rule-1: If Study Agent IND Holderis 'Cancer Therapy Evaluation Program' null Actions Mandatory
2. In Wayne State University 10 day report>>mandatory fields>>Subject details,Rule-1 is applied to Weight value field.
3. Study 5876 has study site Wayne State University.
4. User is Report AEs tab and chooses study as 5876 subject as wayne-pt2 and Cycle #: 11; Start Date: 11/03/10
5. User adds AE with grade=1, attribution=unrelated.
6. User clicks save and continue.
7. In the review and report page, no reports are recommended by caaers.
8. User clicks override and sees the list of reports
9. User chooses Wayne State University 10 day report and clicks report.[create/edit]
10. User moves through report flow and is in Study interventions tab.
11. User adds agent CISplatin which is not a Study Agent with IND Holder 'Cancer Therapy Evaluation Program'
12. User clicks save and continue and is in subject details tab

Expected

Weight is not marked as a mandatory field 

[Weight is not marked as a mandatory field]

Scenario #3

1. The following field rule is set: If Study is 'Phase I Trial' . Actions Mandatory

2. In Wayne State University 10 day report>>mandatory fields>>Subject details,Rule-7 is applied to Height value field.
3. Study 5876 has study site Wayne State University and phase Phase II Trial.
4. User is Report AEs tab and chooses study as 5876 subject as wayne-pt2 and Cycle #: 11; Start Date: 11/03/10
5. User adds AE with grade=1, attribution=unrelated.
6. User clicks save and continue.
7. In the review and report page, no reports are recommended by caaers.
8. User clicks override and sees the list of reports
9. User chooses Wayne State University 10 day report and clicks report.[create/edit]
10. User moves through report flow and is in subject details tab.

Expected

Height is not marked as a mandatory field

Scenario #4

1. The following field rule is set: If Study is 'Phase I Trial' . Actions Mandatory
2. In Wayne State University 10 day report>>mandatory fields>>Subject details,Rule-7 is applied to Height value field.
3. Study 5876 has study site Wayne State University and phase Phase I Trial.
4. User is Report AEs tab and chooses study as 5876 subject as wayne-pt2 and Cycle #: 11; Start Date: 11/03/10
5. User adds AE Vasculitis with grade=1, attribution=unrelated.
6. User clicks save and continue.
7. In the review and report page, no reports are recommended by caaers.
8. User clicks override and sees the list of reports
9. User chooses Wayne State University 10 day report and clicks report.[create/edit]
10. User moves through report flow and is in subject details tab.

Expected

Height is marked as a mandatory field

Scenario #5

1. The following field rule is set: If Severityis 'Grade 1' . Actions Mandatory
2. In Wayne State University 10 day report>>mandatory fields>>Adverse events, Rule-5 is applied to Did this place the subject at increased risk?. value field.
3. Study 5876 has study site Wayne State University and phase Phase I Trial.
4. User is Report AEs tab and chooses study as 5876 subject as wayne-pt2 and Cycle #: 11; Start Date: 11/03/10
5. User adds AE with grade=1, attribution=unrelated.
6. User clicks save and continue.
7. In the review and report page, no reports are recommended by caaers.
8. User clicks override and sees the list of reports
9. User chooses Wayne State University 10 day report and clicks report.[create/edit]
10. User moves through report flow and is in adverse events tab.

Expected

Did this place the subject at increased risk? is marked as a mandatory field

Scenario #6

1. The following field rule is set: If Severityis 'Grade 1' . Actions Mandatory
2. In Wayne State University 10 day report>>mandatory fields>>Other contributing causes, Rule-5 is applied to Cause. value field.
3. Study 5876 has study site Wayne State University and phase Phase I Trial.
4. User is Report AEs tab and chooses study as 5876 subject as wayne-pt2 and Cycle #: 11; Start Date: 11/03/10
5. User adds AE with grade=1, attribution=unrelated.
6. User clicks save and continue.
7. In the review and report page, no reports are recommended by caaers.
8. User clicks override and sees the list of reports
9. User chooses Wayne State University 10 day report and clicks report.[create/edit]
10. User moves through report flow and is in Other contributing causes tab.

Expected

Cause is marked as a mandatory field

Scenario #7

1. The following field rule is set: If Study is 'Phase I Trial' . Actions Mandatory

2. In Wayne State University 10 day report>>Adverse Event,Rule-7 is applied to Comments field.
3. Study 5876 has study site Wayne State University and phase Phase I Trial.
4. User is Report AEs tab and chooses study as 5876 subject as wayne-pt2 and Cycle #: 11; Start Date: 11/03/10
5. User adds AE with grade=1, attribution=unrelated.
6. User clicks save and continue.
7. In the review and report page, no reports are recommended by caaers.
8. User clicks override and sees the list of reports
9. User chooses Wayne State University 10 day report and clicks report.[create/edit]
10. User moves through report flow and is in Adverse Event tab.

Expected

Comments is marked as a mandatory field 

Scenario #8

1. The following field rule is set: If Study Therapyis 'Device' . Then Mandatory
2. In Wayne State University 10 day report>>Devices>>Brand name above rule is applied.
3. Study N027D has study site Wayne State University and study intervention device.
4. User is Report AEs tab and chooses study as N027D, subject as wayne-pt5 and Cycle #: 11; Start Date: 12/01/10
5. User adds AE with grade=1, attribution=unrelated.
6. User clicks save and continue.
7. In the review and report page, no reports are recommended by caaers.
8. User clicks override and sees the list of reports
9. User chooses Wayne State University 10 day report and clicks report.[create/edit]
10. User moves through report flow and is in Study Interventions tab.
11. User adds a device.

Expected

Brand name is marked as a mandatory field

https://oracle.qa.semanticbits.com/caaers/pages/ae/edit?aeReport=821&report=1121

Scenario #9

1. The following field rule is set: If Severity is 'Grade 1' . Actions Mandatory
2. In Wayne State University 10 day report>>Devices>>Common name above rule is applied.
3. Study N027D has study site Wayne State University and study intervention device.
4. User is Report AEs tab and chooses study as N027D, subject as wayne-pt5 and Cycle #: 11; Start Date: 12/01/10
5. User adds AE with grade=1, attribution=unrelated.
6. User clicks save and continue.
7. In the review and report page, no reports are recommended by caaers.
8. User clicks override and sees the list of reports
9. User chooses Wayne State University 10 day report and clicks report.[create/edit]
10. User moves through report flow and is in Study Interventions tab.
11. User adds a device.

Expected

Common name is marked as a mandatory field

Scenario #10

1. The following field rule is set: If Study Therapy is 'Device' . Then Mandatory
2. In Wayne State University 10 day report>>mandatory fields>>Did this place the subject at increased risk? above rule is applied.
3. Study N027D has study site Wayne State University and study intervention device.
4. User is Report AEs tab and chooses study as N027D, subject as wayne-pt5 and Cycle #: 11; Start Date: 12/01/10
5. User adds AE with grade=1, attribution=unrelated.
6. User clicks save and continue.
7. In the review and report page, no reports are recommended by caaers.
8. User clicks override and sees the list of reports
9. User chooses Wayne State University 10 day report and clicks report.[create/edit]
10. User moves through report flow and is in Study Interventions tab.
11. User adds a device.
12. User goes back to adverse events page.

Expected

Did this place the subject at increased risk? is marked as a mandatory field

Scenario #11

1. The following field rule is set: If Study Therapy is not 'Device' .Actions Mandatory
2. In Wayne State University 10 day report>>mandatory fields>>Adverse events>>Where was the subject when the event occurred?.above rule is applied.
3. Study 5876 has study site Wayne State University and no device intervention.

1. User is Report AEs tab and chooses study as 5876 subject as wayne-pt2 and Cycle #: 11; Start Date: 11/03/10
2. User adds AE Vasculitis with grade=1, attribution=unrelated.
3. User clicks save and continue.
4. In the review and report page, no reports are recommended by caaers.
5. User clicks override and sees the list of reports
6. User chooses Wayne State University 10 day report and clicks report.[create/edit]
7. User moves through report flow and is in Adverse events tab.

Expected

Where was the subject when the event occurred? is marked as a mandatory field

Scenario #12

1. The following field rule is set: If Severityis 'Grade 3' . Actions Mandatory
2. In Wayne State University 10 day report>>mandatory fields>>Adverse events, Rule-5 is applied to Did this place the subject at increased risk?. value field.
3. Study 5876 has study site Wayne State University and phase Phase I Trial.
4. User is Report AEs tab and chooses study as 5876 subject as wayne-pt2 and Cycle #: 11; Start Date: 11/03/10
5. User adds AE with grade=1, attribution=unrelated.
6. User clicks save and continue.
7. In the review and report page, no reports are recommended by caaers.
8. User clicks override and sees the list of reports
9. User chooses Wayne State University 10 day report and clicks report.[create/edit]
10. User moves through report flow and is in adverse events tab.

Expected

Did this place the subject at increased risk? is NOT marked as a mandatory field for this **particular** AE.

Scenario #13

1. The following field rule is set: If Severityis 'Grade 3' . Actions Mandatory
2. In Wayne State University 10 day report>>mandatory fields>>Adverse events, Rule-5 is applied to Did this place the subject at increased risk?. value field.
3. Study 5876 has study site Wayne State University and phase Phase I Trial.
4. User is Report AEs tab and chooses study as 5876 subject as wayne-pt2 and Cycle #: 11; Start Date: 11/03/10
5. User adds AE with grade=3, attribution=unrelated.
6. User clicks save and continue.
7. In the review and report page, no reports are recommended by caaers.
8. User clicks override and sees the list of reports
9. User chooses Wayne State University 10 day report and clicks report.[create/edit]
10. User moves through report flow and is in adverse events tab.

Expected

Did this place the subject at increased risk? is marked as a mandatory field for this **particular** AE.

Scenario #14

1. The following field rule is set: If Severityis 'Grade 3' . Actions Mandatory
2. In Wayne State University 10 day report>>mandatory fields>>Subject details,Rule-5 is applied to Weight value field.
3. Study 5876 has study site Wayne State University and phase Phase I Trial.
4. User is Report AEs tab and chooses study as 5876 subject as wayne-pt2 and Cycle #: 11; Start Date: 11/03/10
5. User adds AE with grade=1, attribution=unrelated.
6. User clicks save and continue.
7. In the review and report page, no reports are recommended by caaers.
8. User clicks override and sees the list of reports
9. User chooses Wayne State University 10 day report and clicks report.[create/edit]
10. User moves through report flow and is in adverse events tab.

Expected

Weight is NOT marked as a mandatory field. 

Scenario #15

1. The following field rule is set: If Severityis 'Grade 3' . Actions Mandatory
2. In Wayne State University 10 day report>>mandatory fields>>Subject details,Rule-5 is applied to Weight value field.
3. Study 5876 has study site Wayne State University and phase Phase I Trial.
4. User is Report AEs tab and chooses study as 5876 subject as wayne-pt2 and Cycle #: 11; Start Date: 11/03/10
5. User adds AE with grade=3, attribution=unrelated.
6. User clicks save and continue.
7. In the review and report page, no reports are recommended by caaers.
8. User clicks override and sees the list of reports
9. User chooses Wayne State University 10 day report and clicks report.[create/edit]
10. User moves through report flow and is in adverse events tab.

Expected

Weight is marked as a mandatory field. 

Scenario #16

1. The following field rule is set:
   Rule-1: If Study Agent IND Holderis 'Cancer Therapy Evaluation Program' null Actions Mandatory
2. In Wayne State University 10 day report>>Adverse Event,Rule is applied to Event time field.
3. Study 5876 has study site Wayne State University and phase Phase I Trial.
4. User is Report AEs tab and chooses study as 5876 subject as wayne-pt2 and Cycle #: 11; Start Date: 11/03/10
5. User adds AE with grade=1, attribution=unrelated.
6. User clicks save and continue.
7. In the review and report page, no reports are recommended by caaers.
8. User clicks override and sees the list of reports
9. User chooses Wayne State University 10 day report and clicks report.[create/edit]
10. User moves through report flow and is in Study interventions tab.
11. User adds agent Alvocidib which is a Study Agent with IND Holder 'Cancer Therapy Evaluation Program'
12. User clicks save and continue and navigates to Adverse events tab

Expected

Event time is marked as a mandatory field 

CAAERS-4613

Scenario #17

1. The following field rule is set:
   Rule-1: If Study Agent IND Holderis 'Cancer Therapy Evaluation Program' null Actions Mandatory
2. In Wayne State University 10 day report>>Adverse Event,Rule is applied to Event time field.
3. Study 5876 has study site Wayne State University and phase Phase I Trial.
4. User is Report AEs tab and chooses study as 5876 subject as wayne-pt2 and Cycle #: 11; Start Date: 11/03/10
5. User adds AE with grade=1, attribution=unrelated.
6. User clicks save and continue.
7. In the review and report page, no reports are recommended by caaers.
8. User clicks override and sees the list of reports
9. User chooses Wayne State University 10 day report and clicks report.[create/edit]
10. User moves through report flow and is in Study interventions tab.
11. User adds agent Cisplatin which is a not a Study Agent with IND Holder 'Cancer Therapy Evaluation Program'
12. User clicks save and continue and navigates to Adverse events tab

Expected

Event time is NOT marked as a mandatory field

CAAERS-4613

Scenario #18

1. The following field rule is set:
   Rule-1: If Study Agent IND Holderis 'Cancer Therapy Evaluation Program' null Actions Mandatory
2. In Wayne State University 10 day report>>mandatory fields>>Subject details,Rule is applied to Height value field.
3. Study 5876 has study site Wayne State University and phase Phase I Trial.
4. User is Report AEs tab and chooses study as 5876 subject as wayne-pt2 and Cycle #: 11; Start Date: 11/03/10
5. User adds AE with grade=1, attribution=unrelated.
6. User clicks save and continue.
7. In the review and report page, no reports are recommended by caaers.
8. User clicks override and sees the list of reports
9. User chooses Wayne State University 10 day report and clicks report.[create/edit]
10. User moves through report flow and is in Study interventions tab.
11. User adds agent Alvocidib which is a Study Agent with IND Holder 'Cancer Therapy Evaluation Program'
12. User clicks save and continue and is in subject details tab

Expected

Height is marked as a mandatory field

Scenario #19

1. The following field rule is set:
   Rule-1: If Study Agent IND Holderis 'Cancer Therapy Evaluation Program' null Actions Mandatory
2. In Wayne State University 10 day report>>mandatory fields>>Subject details,Rule is applied to Height value field.
3. Study 5876 has study site Wayne State University and phase Phase I Trial.
4. User is Report AEs tab and chooses study as 5876 subject as wayne-pt2 and Cycle #: 11; Start Date: 11/03/10
5. User adds AE with grade=1, attribution=unrelated.
6. User clicks save and continue.
7. In the review and report page, no reports are recommended by caaers.
8. User clicks override and sees the list of reports
9. User chooses Wayne State University 10 day report and clicks report.[create/edit]
10. User moves through report flow and is in Study interventions tab.
11. User adds agent Cisplatin which is a not a Study Agent with IND Holder 'Cancer Therapy Evaluation Program'
12. User clicks save and continue and is in subject details tab

Expected

Height is NOT marked as a mandatory field

Rule-5

If
Adverse Event “Severity” is 'Grade 3' .
Actions
Mandatory

Rule-6

If
Adverse Event “Expectedness” is 'is' expected
Actions
Mandatory

Testing report definition XML import and export

	Scenario	Expected	Pass / Fail
	User exports a report definition XML from caaers UI. On a fresh DB, user imports the report definition through caaers UI.	All the details in the report definition are reproduced correctly.	
	User imports a report definition whose name matches an existing report definition.	Caaers gives error for duplicate report definition	
	User imports CTEP rules, then imports the CTEP report definition	For CTEP report definition, caaers throws error for duplicate report definition.	
	User imports report definition and then imports rules	On the rules review page, the reports are correctly picked up as Actions.	

	After importing rules and report definitions, user tries to submit a report to adeers	user is able to successfully submit a report.	

Module 1e Test Cases - Administration

Module 1e Test Cases - Administration

Use Case	Test Case
???	Test cases for medDRA import functionality
???	Test cases for use case 2.3 - Investigator create and-or update
???	Test cases for use case 2.3 - Staff create and-or update

Test cases for "Allow configuration of Mandatory, Optional, and NA fields on capture AE screen"

Source: http://jira.semanticbits.com/browse/CAAERS-3461

	Scenario	Expected	Actual	Pass / Fail
	User is in Administration >> configure caaers	There is a new tab labeled: "Mandatory Fields"		

	User is in Administration >> configure caaers >> mandatory fields	The following fields are available for configuration with the following default values: • term -- Mandatory • grade -- Mandatory • verbatim -- Optional • start date -- Optional • end date -- Optional • attribution -- Optional • hospitalization -- Optional • expected -- Optional • Where was the patient when the event occurred?. -- Not Applicable • comments -- Not Applicable		
	There exists one study in the system where adeers reporting is false.	Outcome is set as optional for all studies.		
	There exists no study in the system where adeers reporting is false	Outcome is set as NA for all studies.	Unable to test since it requires DB to be in a certain state. Will need to be checked with DB with single study which has adeers reporting as false and bering script version is less than release 16, migration 44 as per sameer	
	~~User opens an old existing study. User is in edit flow. Adeers reporting as true.~~	~~Outcome is set as NA for study.~~		
	~~User opens an old existing study. User is in edit flow. Adeers reporting as false.~~	~~Outcome is set as optional for study.~~		
	~~User imports study using study xml with Adeers reporting as true.User edits study in UI.~~	~~Outcome is set as NA for study.~~		
	~~User imports study using study xml with Adeers reporting as false.User edits study in UI.~~	~~Outcome is set as optional for study.~~		
	User is in Administration >> configure caaers >> mandatory fields. User set term and grade to NA.	In CAE>>Adverse event, the term and grade fields will not be shown for observed AEs		

	User is in Administration >> configure caaers >> mandatory fields. User set term and grade to NA.	In CAE>>Adverse event, the term and grade fields will not be shown for solicited AEs		✅
	User is in Administration >> configure caaers >> mandatory fields. User set verbatim and event location to mandatory. In CAE>>Adverse event, user leaves the fields blank for observed AE and clicks save and continue.	User is not allowed to continue until verbatim and event location are filled.		✅
	User is in Administration >> configure caaers >> mandatory fields. User set verbatim and event location to mandatory. In CAE>>Adverse event, user leaves the fields blank for solicited AE and clicks save and continue.	User is allowed to continue although verbatim and event location are unfilled.		✅
	User is in Administration >> configure caaers >> mandatory fields. hospitalization is set to NA. In CAE>>Adverse events, Create an AE that obeys the following rule: If Study is 'Phase I/II Trial' or 'Phase I Trial' And Study Agent IND Holder is 'Cancer Therapy Evaluation Program' And Severity is 'Grade 3' And Hospitalization or Prolonged Hospitalization is not 'No ' And Adverse Event is not 'is ' expected And Attribution is 'Unlikely' or 'Unrelated' Actions CTEP 10 Calendar Day SAE Report Hospitalization field cannot be set.	In CAE>>Review and report, caaers should recommend the CTEP 10 day report.	If new AE is added then rule for hospitalization still fires. http://jira.semanticbits.com/browse/CAAERS-3663	❌
	User is in Administration >> configure caaers >> mandatory fields. hospitalization is set to NA. In CAE>>Adverse events, user fills in grade as 4 and the required details and clicks continue.	caaers will not fire rule for hospitalization required if grade>2	If new AE is added then rule for hospitalization still fires. For existing AEs the rule does not fire http://jira.semanticbits.com/browse/CAAERS-3663	❌
	User is in Study>> Mandatory fields. hospitalization is set to optional. In CAE>>Adverse events, user fills in grade as 4 and the required details. Hospitalization is left at please select. User clicks continue.	caaers fires rule for hospitalization required if grade>2		✅
	User is in Administration >> configure caaers >> mandatory fields. hospitalization is set to mandatory. In CAE>>Adverse events, user fills in grade as 2 and the required details. Hospitalization is left at please select. User clicks continue.	caaers gives error for not filling mandatory hospitalization		✅
	User is in Administration >> configure caaers >> mandatory fields.	The field 'Does this place participant at increased risk?' is available for configuration		✅
	User is in Administration >> configure caaers >> mandatory fields. The field 'Does this place participant at increased risk?' is set to mandatory. In CAE>>Adverse events, user does not specify value for 'Does this place participant at increased risk?' and clicks continue.	Caaers gives error for not filling mandatory 'Does this place participant at increased risk?'		✅
	User is in Administration >> configure caaers >> mandatory fields. The field 'Does this place participant at increased risk?' is set to optional. In CAE>>Adverse events, user does not specify value for 'Does this place participant at increased risk?' and clicks continue.	Caaers does not give error for not filling mandatory 'Does this place participant at increased risk?'		✅

Questions:

1. How will rules fire if term and grade as set as NA?

Test cases for medDRA import functionality

Use case context: JIRA task CAAERS-224 https://wiki.nci.nih.gov/x/4pR8

	Scenario	Pass / Fail
1	Import medDRA version 9. In create study flow>>disease tab, check if the list of terms is available.	✓
2	Import medDRA version 10. In create study flow>>disease tab, check if the list of terms is available.	✓
3	caAERS already has a particular version of medDRA. User tries to import the same medDRA version again. Error message should be thrown for duplicate import.	✓
4	Import a medDRA file whose format is corrupted. caAERS should recover gracefully from the error.	✓
5	User import medDRA file and creates a study with disease and adverse event coding terminology as medDRA. A participant is assigned to this study. An AE is created for this particular study and participant. An expedited AE report is successfully submitted to AdEERS.	✓
6	User deletes an existing medDRA version and re-imports the same version.	✓
7	User specifies invalid URI for location of meddra files on the server. caAERS should throw an error and recover gracefully.	✓
8	Delete is a long running process [CTMS:approx 20 secs]. So user clicks 'delete' to delete a medDRA version. In the middle of the delete, he moves on to some other tab and comes back. The meddra version is still visible. User clicks delete again to delete the version. The version should be deleted without any error.	✓
9	User inputs a large amount of text in the 'version' text box when importing medDRA.	✓
10	User attempts to delete an existing meddra version [CTMS:say v9] when a study for a said meddra version is existing. Caaers should not delete meddra version since study for that meddra version exists.	✓
11	User attempts to delete an existing meddra version [CTMS:say v9] when a study for a said meddra version is existing. User changes the study AE terminology to CTC v3.0. Currently there are no more meddra studies. Caaers should delete meddra version since there are no meddra studies.	✗

Test cases for use case 2.3 - Investigator create and-or update

Use case context: CTMS:2.3 Local CTMS to caAERS - Staff updates

Update investigator scenarios

	Scenario	pre-req	result	Pass/Fail
1	User adds investigator that is duplicate of existing investigator			

	User modifies investigator first name.			
	User modifies investigator last name			
	User modifies investigator last email.			
	User modifies investigator phone.			
	User modifies investigator fax.			
	User modifies investigator role.			
	User modifies investigator organization.			

Notes / Issues

Create investigator scenarios

	Scenario	result	Pass / Fail	artifact
1	User enters empty string for investigator first name.	Error is thrown: 'Line : 0 - cvc-minLength-valid: Value '' with length = '0' is not facet-valid with respect to minLength '1' for type 'CustomStringType'.'		
2	User enters empty string for investigator last name.	Error is thrown: 'Line : 0 - cvc-minLength-valid: Value '' with length = '0' is not facet-valid with respect to minLength '1' for type 'CustomStringType'.'		
3	User enters empty string for investigator email.	Line : 0 - cvc-minLength-valid: Value '' with length = '0' is not facet-valid with respect to minLength '1' for type 'CustomStringType'.		
4	User enters invalid string for investigator email. [CTMS:jd0004nci.org]	Investigator is successfully created.		
5	User enters empty string for investigator phone.	Error is thrown: 'Line : 0 - cvc-minLength-valid: Value '' with length = '0' is not facet-valid with respect to minLength '1' for type 'CustomStringType'.'		
6	User enters -ve number for investigator phone.	Investigator is successfully created.		
7	User enters empty string for investigator fax.	Error is thrown: 'Line : 0 - cvc-minLength-valid: Value '' with length = '0' is not facet-valid with respect to minLength '1' for type 'CustomStringType'.'		
8	User enters -ve number for investigator phone.	Investigator is successfully created.		
9	User mentions invalid value for investigator role [CTMS:xyz].	???		
10	User mentions invalid value for organization [CTMS:xyz].	Error is thrown: ' color="red">- No organization exist with nciCode :xyz'		
11	User creates investigator with two identical site investigators.	Investigator is created with duplicate site identifiers.		

Notes / Issues

Test cases for use case 2.3 - Staff create and-or update

Use case context: 2.0.3 Local CTMS to caAERS - Staff & Investigator updates

Update staff scenarios

	Scenario	pre-req	result	Pass/Fail
1				

Notes / Issues

Create staff scenarios

	Scenario	result	Pass / Fail	artifact
1	User enters empty string for Research staff first name.			
2	User enters empty string for Research staff middle name.			
3	User enters empty string for Research staff last name.			
4	User enters empty string for Research staff first name.			

Notes / Issues

Module 2 Test Cases - Interfaces for System Integration

Module 2 Test Cases - Interfaces for System Integration

Use Case	Test Case
???	Testing Adverse Event Management Service API (Create AEs)
???	Testing Adverse Event Management Service API (Create-Update AEs)
???	Testing Adverse Event Management Service API (Delete AEs)

Testing Adverse Event Management Service API (Create AEs)

Use case reference: https://wiki.nci.nih.gov/x/ggHj

Study 5876)

Subject: (mrn-pt-0004) Edmund Randolph

Create Adverse Events

Sample XML

	Scenario	Expected	Actual
	User specifies a course with start date earlier than start date of first course/cycle	<message>Start date of this course/cycle cannot be earlier than the Start date of first course/cycle</message>	
	User specifies a course with start date and end date that matches start and end date of existing course but not the treatment type		http://jira.semanticbits.com/browse/CAAERS-2299
	User specifies course with start date later than end date		http://jira.semanticbits.com/browse/CAAERS-2300
	For a non baseline type course user specifies a start date which is same as end date.	<message>For Non-Baseline treatment type Start date cannot be equal to End date.</message>	
	User specifies a course which partially overlaps with existing course.	<message>Course/cycle cannot overlap with an existing course/cycle.</message>	
	User specifies a Non-Baseline course that starts before a baseline course.	<message>Non-Baseline treatment type cannot start before an existing Baseline treatment type.</message>	
	User specifies a Baseline course that starts after a Non-Baseline course.	<message>Baseline treatment type cannot start after an existing Non-Baseline treatment type.</message>	
	For existing course user specifies AEs which are not part of the course	The AEs are added successfully as observed AEs	
	For existing course user specifies AEs which are already part of the Observed AEs of the course	<message>This AE Term(Burn) already exists for given course.</message>	
	For existing course user specifies AEs which are already part of the Solicited AEs of the course	The AEs are not added to the course	http://jira.semanticbits.com/browse/CAAERS-2316
	For existing course user specified AE of grade 3 but does not include hospitalization.	<message>'Hospitalization' must be provided if 'Grade' greater than 2 (Cardiac ischemia/infarction)</message>	
	For existing course user specifies two AEs with identical terms.	The AE is created successfully only once	
	For existing course user specifies an AE with grade -1	Course with grade -1 cannot be created	http://jira.semanticbits.com/browse/CAAERS-2318
	For existing course user provides verbatim details for an AE	The verbatim for the AE is shown in the UI	

	For existing course user gives an AE start date that is later than AE end date.	<message>'End date' must be greater than or equal to 'Start date' for adverse event (Acute vascular leak syndrome)</message>	
	For existing course user gives an AE with no start and end date.	AE is created successfully	
	For existing course user gives an AE with invalid CTEP term	AE with invalid term is not created	
	For existing course user gives an AE with CTEP term 'Allergy/Immunology - Other (Specify, __)' but does not specify 'otherMeddra'	<message>gov.nih.nci.cabig.caaers.CaaersSystemException: gov.nih.nci.cabig.caaers.CaaersSystemException: Other(MedDRA) missing.</message>	
	For existing course user gives an AE with CTEP term 'Allergic reaction/hypersensitivity (including drug fever)' and specifies an 'otherMeddra'	<message>gov.nih.nci.cabig.caaers.CaaersSystemException: gov.nih.nci.cabig.caaers.CaaersSystemException: Other MedDRA is not allowed for this term(Allergic reaction/hypersensitivity (including drug fever)).</message>	

Testing Adverse Event Management Service API (Create-Update AEs)

Use case reference: https://wiki.nci.nih.gov/x/ggHj

Study:

Subject:

Create Adverse Events

Sample XML

	Scenario	Expected	Actual
	User specifies a course with start date earlier than start date of first course/cycle	<message>Start date of this course/cycle cannot be earlier than the Start date of first course/cycle</message>	
	User specifies a course with start date and end date that matches start and end date of existing course but not the treatment type		http://jira.semanticbits.com/browse/CAAERS-2299
	User specifies course with start date later than end date	<message>Course End date cannot be earlier than Start date.</message>	
	For a non baseline type course user specifies a start date which is same as end date.	<message>For Non-Baseline treatment type Start date cannot be equal to End date.</message>	

	User specifies a course which partially overlaps with existing course.	<message>Course/cycle cannot overlap with an existing course/cycle.</message>	
	User specifies a Non-Baseline course that starts before a baseline course.	<message>Non-Baseline treatment type cannot start before an existing Baseline treatment type.</message>	
	User specifies a Baseline course that starts after a Non-Baseline course.	<message>Baseline treatment type cannot start after an existing Non-Baseline treatment type.</message>	
	For existing course user specifies AEs which are not part of the course	The AEs are added successfully as observed AEs	
	For existing course user specifies AEs which are already part of the Observed AEs of the course	The AEs in the course are updated	
	For existing course user specifies AEs which are already part of the Solicited AEs of the course	The AEs in the course are updated	http://jira.semanticbits.com/browse/CAAERS-2316
	For existing course user specified AE of grade 3 but does not include hospitalization.	<message>'Hospitalization' must be provided if 'Grade' greater than 2 (Acute vascular leak syndrome)</message>	
	For existing course user specifies two AEs with identical terms.	Duplicate AEs are are treated as two consecutive updates.	
	For existing course user specifies an AE with grade -1	If AE is an observed AE then an error message should be shown	http://jira.semanticbits.com/browse/CAAERS-2318
	For existing course user provides verbatim details for an AE	The verbatim for the AE is shown in the UI	
	For existing course user gives an AE start date that is later than AE end date.	<message>'End date' must be greater than or equal to 'Start date' for adverse event (Cognitive disturbance)</message>	
	For existing course user gives an AE with no start and end date.	AE is created successfully	
	For existing course user gives an AE with invalid CTEP term	<message>gov.nih.nci.cabig.caaers.CaaersSystemException: gov.nih.nci.cabig.caaers.CaaersSystemException: CTC term(xxxCognitive disturbance not found.</message>	
	For existing course user gives an AE with CTEP term 'Allergy/Immunology - Other (Specify, __)' but does not specify 'otherMeddra'	<message>gov.nih.nci.cabig.caaers.CaaersSystemException: gov.nih.nci.cabig.caaers.CaaersSystemException: Other(MedDRA) missing.</message>	
	For existing course user gives an AE with CTEP term 'Allergic reaction/hypersensitivity (including drug fever)' and specified an 'otherMeddra'	<message>gov.nih.nci.cabig.caaers.CaaersSystemException: gov.nih.nci.cabig.caaers.CaaersSystemException: Other MedDRA is not allowed for this term(Allergic reaction/hypersensitivity (including drug fever)).</message>	

Testing Adverse Event Management Service API (Delete AEs)

Use case reference: https://wiki.nci.nih.gov/x/ggHj

Study:5876

Subject: (mrn-pt-0003) Margaret Campbell

Delete Adverse Events

Sample XML

	Scenario	Expected	Actual	Pass / Fail
	User specifies a course with start date earlier than start date of first course/cycle	<message>Course/ Cycle doesn't exist.</message>		✓
	User specifies a course with start date and end date that matches start and end date of existing course but not the treatment type	✗	http://jira.semanticbits.com/browse/CAAERS-2299	✗
	User specifies course with start date later than end date	✗	<message>Course/ Cycle doesn't exist.</message>	??
	For a non baseline type course user specifies a start date which is same as end date.	✗	<message>Course/ Cycle doesn't exist.</message>	??
	User specifies a course which partially overlaps with existing course.	✗	<message>Course/ Cycle doesn't exist.</message>	??
	User specifies a Non-Baseline course that starts before a baseline course.	✗	<message>Course/ Cycle doesn't exist.</message>	??
	User specifies a Baseline course that starts after a Non-Baseline course.	✗	<message>Course/ Cycle doesn't exist.</message>	
	For existing course User specifies an AE term for deletion which is observed AE for the course.	The AE is deleted from course		✓
	For existing course User specifies an AE term for deletion which is solicited AE for the course.	The AE is not deleted from course	http://jira.semanticbits.com/browse/CAAERS-2316	✗
	For existing course User specifies an AE term for deletion which is not part of the course.		<faultstring>Fault: java.lang.NullPointerException</faultstring>	??
	For existing course User specifies two identical AE terms for deletion	??	The AE term is deleted, however the response is: <soap:Fault> <faultcode>soap:Client</faultcode> <faultstring>Fault: java.lang.NullPointerException</faultstring> </soap:Fault>	
??				

	For existing course User specifies an AE term for deletion which is not part of the course.		<soap:Fault> <faultcode>soap:Client</faultcode> <faultstring>Fault: java.lang.NullPointerException</faultstring> </soap:Fault>	??

Module 4 Test Cases - External Agency Reporting

Module 4 Test Cases - External Agency Reporting

Use Case	Test Case
Submit Report to AdEERS (caAERS UC)	Testing Submissions to AdEERS

AdEERS business rules in caAERS

Expedited AE flow

	Rule code	Location	Description
1	AER_BR3_ERR	Enter AEs	An answer to 'Hospitalization' must be provided if 'Grade' is greater than 2.
2	AER_BR4_ERR		The 'Start Date' must be provided for the primary AE.
3	AER_BR5_ERR		The 'End date' can not be before the 'Start Date', it should be either be the same day or later'.
4	AER_UK_ERR		You have added two adverse events with the same CTC term. Delete or modify one of the adverse events.
		Course and Agent	
5	SEC_BR5A_ERR		Protocol Agents must be provided if Course Information has been provided.
6	SEC_BR5A_ERR		Protocol agents must be not be provided if Course Information has not been provided. **[CTMS:Wrongly tagged as SEC_BR5A_ERR in help.properties]**
7	TAI_BR2_ERR		'Treatment Assignment Code' or 'Describe Treatment Assignment' must be provided.
8	CIN_BR1_ERR		'Course number on which event occurred' must not be greater than 'Total number of courses'.
9	PAG_BR1A_ERR		'Administration delay' must be provided if 'Dose modified' is checked.
10	PAG_BR1B_ERR		'Administration delay' must not be provided if 'Dose modified' is not checked.
11	PAG_BR3_ERR		'Date last administered' must be provided for an investigational agent.
12	PAG_UK_ERR		You've entered two identical study agents. Modify or delete one one of the study agents.
13	PAG_BR2B_ERR		'Unit of measure' must be provided if 'Total dose administered this course' is provided.
		Describe Event	
14	DSC_BR1A_ERR		'Date of Recovery or Death' must be provided if 'Present Status' has one of following values:'Fatal/Died', 'Recovered/Resolved without Sequelae', or 'Recovered/Resolved with Sequelae'.

15	DSC_BR1B_ERR		'Date of Recovery or Death' must not be provided if 'Present Status' has one of following values: 'Intervention for AE continues' or 'Recovering/Resolving' or 'Not Required/Not Resolved'.
16	DSC_BR2_ERR		'Has the participant been re-treated?' must be 'No' if 'Present Status' is 'Fatal/Died'.
17	DSC_BR3_ERR		'Date Removed from Protocol Treatment' must be provided if 'Present Status' is 'Fatal/Died'
18	DSC_BR5_ERR		'Date Removed from Protocol Treatment' can not be after 'Date of Recovery or Death', it should be either the same day or earlier.
		Patient Details	
19	PAT_BR2A_ERR		Disease Name Not Listed must not be null if Disease Name is 'Solid tumor, NOS' or 'Hematopoietic malignancy, NOS'.
20	PAT_BR2B_ERR		Disease Name Not Listed must not be provided where Disease Name is not 'Solid tumor, NOS' or 'Hematopoietic malignancy, NOS'.
21	PAT_BR3B_ERR		'Other (site of primary disease)' must be provided if 'Primary site of disease' is 'Other'.
22	SMD_BR1_ERR		'Other (site of metastatic disease)' must be provided if 'Site Name' is 'Other'.
		Pre-existing conditions	
23	PEC_BR1_ERR		A value must be provided for 'Pre-Existing condition'. Provide a value or delete the Pre-existing condition. If you select 'Other - specify', you must also enter information for 'Other'.
		Prior Therapies	
24	PTY_BR3_ERR		'Therapy End Date' must only be provided when 'Therapy Start Date'is provided.
25	PTY_BR2_ERR		'Therapy End Date' can not be before 'Therapy Start Date', it should be the same date or later.
26	PTY_BR4A_ERR		Prior Therapy Agents' is required when 'Prior_Therapy' has one of the following values: 'Bone Marrow Transplant', 'Chemotherapy (NOS)', 'Chemotherapy multiple agents systemic', 'Chemotherapy single agent systemic','Immunotherapy', or 'Hormonal Therapy'.
27	PTY_BR4B_ERR		'Prior Therapy Agents' must not be provided when "Prior_Therapy" has one of the following values: 'Anti-retroviral Therapy', 'Antisense', 'No prior therapy', 'Oncolytic Virotherapy', 'Prior Therapy NOS', 'Radiation Therapy', 'Surgery', 'Therapy (NOS)', or 'Vaccine'.
28	PTY_UK_ERR		You have added two identical prior therapies. Delete or modify one of them.
29	PTA_UK_ERR		You have added two identical prior therapy agents. Delete or modify one of them.
		Medical device	
30	SME_BR1_ERR		Either 'Brand name' or 'Common name' must be provided.
31	SME_BR2_ERR		One of the following must be entered: 'Model number', 'Serial number', 'Lot number', or 'Catalog number'.
32	ADO_BR1_ERR		'Other device operator' must is required when 'Device operator' is 'Other'. It should not be provided at any other time.
		Labs	
33	LAB_BR1_ERR		'Lab Category' and 'Other' must be provided when the 'Lab Test Name' is 'Other - Specify'.
34	LAB_BR2A_ERR		'Baseline Value', 'Worst value', and 'Recovery Values' must not be provided if 'Lab Category' is 'Microbiology'.
35	LAB_BR2B_ERR		'Baseline Value', 'Worst value', and 'Recovery Values'must be provided when the 'Lab Category' has the follwoing values: 'Bone Marrow Biopsy', 'Chemistry', 'Coagulation', 'Hematologic' and 'Respiratory'.
36	LAB_BR3_ERR		The 'Date' of the 'Baseline Value' can not be later than the 'Date' of the 'Worst Value'.
37	LAB_BR4_ERR		The 'Date' of the 'Worst Value' can not be later than the 'Date' of the 'Recovery Value'.
38	LAB_BR5A_ERR		'Site','Date', and 'Infectious Agent' must be provided if 'Lab Category' is 'Microbiology'.
39	LAB_BR5B_ERR		'Site','Date', and 'Infectious Agent' must not be provided if 'Lab Category' is 'Microbiology'.

40	LAB_UK_ERR		You have added two labs with the same information. Delete or modify one of the labs.
		Attributions	
41	AER_BR7_ERR		Each Adverse Event needs one or more attributions of 'Possible', 'Probable' or 'Definite'. An adverse event that resulted in death is considered exempt from this requirement.
42	ATT_BR1_ERR		attribution_for_ae to all possible causes not provided.
		Submit report	
43	SEC_BR1_ERR		Course Information and/or Radiation Intervention must be provided for AGENTS + RADIATION pathways.
44	SEC_BR2_ERR		Course Information and/or Surgery Intervention must be provided for AGENTS + SURGERY pathways.
45	SEC_BR3_ERR		Surgery Intervention and/or Radiation Intervention must be provided for SURGERY + RADIATION pathways.
46	SEC_BR4_ERR		A combination of Course Information, Surgery Intervention, and Radiation Intervention must be provided for AGENTS + SURGERY + RADIATION pathways.
47	SEC_BR50_ERR		Surgery intervention must not be provided when the pathway does not include SURGERY.
48	SEC_BR51_ERR		Radiation intervention must not be provided when the pathway does not include RADIATION.
49	SEC_BR52_ERR		Course information must not be provided when the pathway does not include AGENTS.
50	SEC_BR53_ERR		Medical Device information must not be provided when the pathway does not include DEVICEs.

List of business rules that are in code which need to be moved into the rules engine.

Template

method Qname:

rule:

1> gov.nih.nci.cabig.caaers.web.ae.CtcBasicsTab.validateAdverseEvent(AdverseEvent, int, Map<String, InputFieldGroup>, Errors)
If CTC term is of type 'Other specify' then the '# Missing Other (MedDRA)' or 'Missing Other (verbatim)' fields must be specified

2> gov.nih.nci.cabig.caaers.web.ae.BasicsTab.validate(ExpeditedAdverseEventInputCommand, BeanWrapper, Map<String, InputFieldGroup>, Errors)
Start date required for primary AE **2**

3> gov.nih.nci.cabig.caaers.web.ae.CheckpointTab.validate(ExpeditedAdverseEventInputCommand, BeanWrapper, Map<String, InputFieldGroup>, Errors)
At least one expedited report must be selected to proceed

4> gov.nih.nci.cabig.caaers.web.ae.PreExistingConditionsTab.validateSaeReportPreExistingCondition(SAEReportPreExistingCondition, int, Errors)
Either a known pre Existing Condition or other is required **23**

5> gov.nih.nci.cabig.caaers.web.ae.PriorTherapyTab.validatePriorTherapy(SAEReportPriorTherapy, int, Errors)
Prior Therapy is required

6> gov.nih.nci.cabig.caaers.web.ae.PriorTherapyTab.validatePriorTherapy(SAEReportPriorTherapy, int, Errors)
Prior Therapy can not have agents : Delete Agents and then proceed **26 & 27**

7> gov.nih.nci.cabig.caaers.web.ae.TreatmentTab.validate(ExpeditedAdverseEventInputCommand, BeanWrapper, Map<String, InputFieldGroup>, Errors)
Missing description of treatment assignment or dose level **7**

8> gov.nih.nci.cabig.caaers.domain.repository.ReportRepositoryImpl.validate(Report, Collection<ExpeditedReportSection>)
The mandatory sections collection must not contain nulls
"The adverse event, '%s, ' is not attributed to a cause. " + "An attribution of possible or higher must be selected for at least one of the causes." **41 & 42**

9> gov.nih.nci.cabig.caaers.domain.repository.ReportRepositoryImpl.validate(ExpeditedAdverseEventReport, List<String>, ExpeditedReportSection, ReportSubmittability)
"There is no section node in the report tree for " + section.name() + ". This shouldn't be possible."

Submit to Adeers with Routing and Review

Pre-conditions

- Study 5876 exists with Coordinating center Mayo clinic rochester
- mayo AE Expedited Report Reviewer is a RS associated to site Mayo clinic rochester
- mayo AE Expedited Report Reviewer is associated to study 5876 at Coordinating center Mayo clinic rochester
- subject wayne pt2 is associated to study 5876 at site Wayne State University
- mayo AE reporter is a RS associated to site Mayo clinic rochester.
- mayo AE reporter is associated to study 5876 at Coordinating center Mayo clinic rochester
- Routing and review is on for CTEP 10 day report.
- CTEP rules and report definitions are set up correctly.

Scenario

- User logs in as mayo AE reporter
- User clicks on Adverse events tab
- User clicks on Report Adverse events
- User chooses study 5876 in the study auto-suggest
- User chooses wayne pt2 as subject in subject auto-suggest
- In the course drop down user chooses to create course
- User creates a new course
- User clicks continue
- In the Adverse events tab, user adds a new AE term 'vasculitis'
- The following CTC term attributes are added: grade =3, hospitalization=yes, expected=No
- User clicks save and continue
- In the review and report page, caaers recommends CTEP 10 report
- User clicks report
- User begin completing CTEP 10 report
- User is in Review and Submit tab
- In the actions drop down, user clicks on Submit to central office report reviewer
- User gets acknowledgment of successful submit in a pop up
- User logs off caaers
- User logs in as mayo AE Expedited Report Reviewer
- User navigates to Adverse events>>Routing and review tab.
- In the study auto-suggest user picks study 5876
- User clicks continue
- User is shown all courses for which routing and review is enabled
- User chooses appropriate course and report
- User clicks on the report and is shown a PDF version of the report
- user clicks on the actions button

- In the drop down user clicks submit report
- User is taken to the report submission flow
- User completes report submission successfully

Pre-conditions

AE report reviewer is able to submit report to adeers successfully.

Test cases for "Save copies of submitted reports"

Link to use case: https://wiki.nci.nih.gov/x/LKul

	Scenario	Expected	Actual	Pass / Fail
	User submits a 24 hrs and 5 day CTEP report successfully	User is able to view the caaers XML, 24 hr report and 5 day report		
	User submits a DCP report successfully.	User is able to view the caaers XML and the DCP PDF report.		
	User amends a submitted report and submits the report again	User is able to view the reports for all report versions.		

Testing for commercial agents

To Do List

1. Create study calgb-10501 from caaers demo.
2. make study agent as N/A commercial in the study.
3.

Testing Submissions to AdEERS

Below is a summary of the various AdEERS pathways that have been exercised via the pilot. The numbers in each cell indicate the report number which was used to validate the test

Legend	Meaning
✓	Passed
✗	Failed
⊖	Not tested

Study Phase	Study Interventions	IND/IDE holder	CTEP Protocol ID	24hr Notification	Completed Report (5-day)	24hr Amendment	Complete Amendme (5-day)
I	Agent	NCI	8231	✓ 201	✓ 221	✓ 222	✓ 241

I	**Agent**	**Non-NCI**					
I	**Agent**	**Commercial**					
II-IV	**Agent**	**NCI**	5876	✅ 141	✅ 142	✅ 143	✅ 144
II-IV	**Agent**	**Non-NCI**	N0735				
II-IV	**Agent**	**Commercial**	N0543				
I	**Device**	**NCI**					
I	**Device**	**Non-NCI**					
I	**Device**	**Commercial**					
II-IV	**Device**	**NCI**					
II-IV	**Device**	**Non-NCI**					
II-IV	**Device**	**Commercial**					
I	**Surgery**						
II-IV	**Surgery**						
I	**Radiation**						
II-IV	**Radiation**						
I	**Multi-modality**	**NCI**	N027D	✅ 301	✅ 321	✅ 341	✅ 342
I	**Multi-modality**	**Non-NCI**					
I	**Multi-modality**	**Commercial**					
II-IV	**Multi-modality**	**NCI**					
II-IV	**Multi-modality**	**Non-NCI**					
II-IV	**Multi-modality**	**Commercial**					
II-IV	**Agent + Stem Cell Transplantation**	**non-NCI**	CALGB-50403	setup complete			
N/A	**Device (Imaging)**	**Commercial**	ACRIN-6678	❌ (N/A, but required in prototol)			
N/A	**Device**	**Commercial**	ACRIN-6668	❌ 	❌	❌	❌
II	**Agent (CIP)**	**Non-NCI**	8052	❌ 1	**N/A**	❌ 1	**N/A**
II	**Agent + Radiation + Surgery (CIP)**	**Non-NCI**	7958	❌ 1	**N/A**	❌ 1	**N/A**
	DCP-CCOPS						

Foot notes

1.

```
AE_REPORT: REP_24HRAPPL_ERR 24-Hr Notifications are not applicable for this study.
```

2.

```
Error  -  NCI_PROTOCOL_NUMBER is a required field. Enter in the format String,maxLength 35,
Error  -  cvc-type.3.1.3: The value '' of element 'NCI_PROTOCOL_NUMBER' is not valid.
```

Set up investigator

1. Navigate to Administration>>Import tab
2. In "Type of import file" drop down, choose 'Investigator'
3. In "File to import " click browse and choose file mayo-inv1.xml
4. Click continue.
5. If there are no errors then the valid records will be shown in green.
6. Click import.
7. You will get a "Data imported successfully" message.

Set up research staff

1. Navigate to Administration>>Import tab
2. In "Type of import file" drop down, choose 'research staff.
3. In "File to import " click browse and choose file mayo-rs1.xml
4. Click continue.
5. If there are no errors then the valid records will be shown in green.
6. Click import.
7. You will get a "Data imported successfully" message.

Setup study

1. Navigate to Administration>>Import tab
2. In "Type of import file" drop down, choose 'Study/protocol'
3. In "File to import " click browse and choose file exportedstudy_5876.xml
4. Click continue.
5. If there are no errors then the valid records will be shown in green.
6. Click import.
7. You will get a "Data imported successfully" message.
8. Navigate to the Studies>>Search studies tab.
9. Search by "Identifier", type 5876 in the text box and click search
10. In the results table, you should see the recently imported study.
11. Click on the study to edit it.
12. Ensure that "Data Entry Status" is set to complete by clicking "Study setup complete" button.
13. Click on the personnel tab, click on "Mayo Clinic Rochester-site"
14. Verify that the research staff "mayo rs1" is shown in the list of research staff

Setup participant

1. Navigate to Administration>>Import tab
2. In "Type of import file" drop down, choose 'Subject'
3. In "File to import " click browse and choose file pt_5876.xml
4. Click continue.
5. If there are no errors then the valid records will be shown in green.
6. Click import.
7. You will get a "Data imported successfully" message.
8. Navigate to the Subjects>>Search subjects tab.
9. Search by "Identifier", type 'pt_5876' in the text box and click search.
10. In the results table, you should see the recently imported subject.
11. Click on the subject to edit it.
12. Complete the subject flow and update additional info.

Create course

1. Navigate to Adverse events>>Report Adverse events
2. IN the study text box type 5876 and click on the suggestion to choose the study
3. IN the subject text box type pt_5876 and click on the suggestion to choose the subject
4. In Course/Cycle drop down, choose create new
5. In the pop up for course cycle specify the necessary details and click save

6. After the pop up closes, you will see the message: "Course/Cycle created successfully"

Add AEs to course

1. Click continue
2. You will be taken to Adverse events page.
3. Click the "Add multiple" button. Choose the appropriate AE Category and AE terms and click "Add terms" in the pop up
4. The terms you added will be shown on the Adverse events page.
5. For each AE fill in all the necessary details.
6. ake sure for at least one of the AEs, the values are set as follows
    a. Grade: 5: Death
    b. Start date: current date
    c. Attribution to study intervention: probable
    d. Did AE cause hospitalization?: Yes
    e. Expected?: Yes
7. Click "save and report"
8. Based up the rules set up in caaers, a recommendation for creating 24 hr report will be shown in the Review and Report page.
9. Click "Report"

Tests for Commercial Agent Reporting

Notes

- Items underlined are expected scenarios.

Pre-conditions

1. There should exist a report definition CTEP Commercial Intervention SAE Report. A copy can be imported into caaers from here
2. Study N0543 should be available in caaers. A copy can be imported from here
3. Assign a subject to the study. A copy can be imported into caaers from here
4. There should exist an appropriate reporting period for this study and subject.

Test case 1 

1. Navigate to Rules>>Manage Report Definitions.
2. Choose edit on 'CTEP Commercial Intervention SAE Report'
3. In the edit report definition flow, click on mandatory fields tab.
4. For the chosen study, subject and course, navigate to Capture Adverse Events>>Adverse Events screen.
5. Scroll down to 'Additional information' sections and set all fields to Not Applicable.
6. Click save and continue and exit the flow.
7. Navigate to Adverse Events>>report AEs tab.
8. Choose study N0543and appropriate subject
9. Choose appropriate course.
10. Click continue.
11. Add an appropriate AE and set the grade as 4.
12. Add other details related to AE:
    a. Start date,
    b. Attribution to study intervention=Unlikely,
    c. Hospitalization=yes,
    d. Expectedness=No
13. Click save and report.
14. In the Review and report page, caaers should recommend the following report: CTEP Expedited Report - Commercial Intervention
15. Click on report button
16. You will now be taken to the report flow.
17. Move through each tab in the flow and add information for all required fields.
18. In the additional info tab, no fields will be shown and the following information will be shown: Additional information is not applicable for this report.
19. In the review and submit tab, check off on the Physician signoff checkbox.
20. Your report is now data complete and is submittable to Adeers.
21. Click on Actions and in the drop down Click on 'Submit'
22. Complete the report submission flow.
23. Navigate to Adverse Events>>Manage reports.
24. Choose the appropriate subject and study.
25. IN the list of courses, expand the appropriate course.
26. The Commercial Intervention report will be listed here.
27. Verify the 'Report Submission Status' as Successfully submitted

Test case 2 

1. Navigate to Rules>>Manage Report Definitions.
2. Choose edit on 'CTEP Commercial Intervention SAE Report'
3. In the edit report definition flow, click on mandatory fields tab.
4. For the chosen study, subject and course, navigate to Capture Adverse Events>>Adverse Events screen.
5. Scroll down to 'Additional information' sections and set all fields to Not Applicable.
6. Click save and continue and exit the flow.
7. Navigate to Adverse Events>>report AEs tab.
8. Choose study N0543and appropriate subject
9. Choose appropriate course.
10. Click continue.
11. Add an appropriate AE and set the grade as 4.
12. Add other details related to AE:
    a. Start date,
    b. Attribution to study intervention=Unlikely,
    c. Hospitalization=yes,
    d. Expectedness=No
13. Click save and report.
14. In the Review and report page, caaers should recommend the following report: CTEP Expedited Report - Commercial Intervention
15. Click on report button
16. You will now be taken to the report flow.
17. Move through each tab in the flow and add information for all required fields.
18. In the additional info tab, no fields will be shown and the following information will be shown: Additional information is not applicable for this report.
19. In the review and submit tab, check off on the Physician signoff checkbox.
20. Your report is now data complete and is submittable to Adeers.
21. Click on Actions and in the drop down Click on 'Export Caaers XML'
22. Save the exported file in the local drive and open it with an editor.
23. +You should not be able to see the following tags:+

```
<AdditionalInformation>
...
</AdditionalInformation>
```

Test case 3 

1. Navigate to Rules>>Manage Report Definitions.
2. Choose edit on 'CTEP Commercial Intervention SAE Report'
3. In the edit report definition flow, click on mandatory fields tab.
4. For the chosen study, subject and course, navigate to Capture Adverse Events>>Adverse Events screen.
5. Scroll down to 'Additional information' sections and set all fields to Not Applicable.
6. Click save and continue and exit the flow.
7. Navigate to Adverse Events>>report AEs tab.
8. Choose study N0543and appropriate subject
9. Choose appropriate course.
10. Click continue.
11. Add an appropriate AE and set the grade as 4.
12. Add other details related to AE:
    a. Start date,
    b. Attribution to study intervention=Unlikely,
    c. Hospitalization=yes,
    d. Expectedness=No
13. Click save and report.
14. In the Review and report page, caaers should recommend the following report: CTEP Expedited Report - Commercial Intervention
15. Click on report button
16. You will now be taken to the report flow.
17. Move through each tab in the flow and add information for all required fields.
18. In the additional info tab, no fields will be shown and the following information will be shown: Additional information is not applicable for this report.
19. In the review and submit tab, check off on the Physician signoff checkbox.
20. Your report is now data complete and is submittable to Adeers.
21. Click on Actions and in the drop down Click on 'Export Adeers PDF'
22. Save the exported file in the local drive and open it the file.
23. You should not be able to see the 'Additional Information' section in the pdf document

Module 5 Test Cases - Internal Routing and Review

Module 5 Test Cases - Internal Routing and Review

Use Case	Test Case
5.1a Routing and Reviewing - caAERS UC draft	Routing and Review (workflow) - Data coordinator
5.1a Routing and Reviewing - caAERS UC draft	Routing and Review (workflow) - SAE coordinator
5.1a Routing and Reviewing - caAERS UC draft	Routing and Review (workflow) - site CRA
5.1a Routing and Reviewing - caAERS UC draft	Routing and Review (workflow) - site Physician
5.2 Routing and Reviewing an Expedited Report	Routing and Review test cases - Expedited Report
5.2 Routing and Reviewing an Expedited Report	Routing and Review test cases - Expedited Report - caAERS v. 2.1-RC2
5.1 Routing and Reviewing a Reporting Period	Routing and Review test cases - Reporting period
5.1 Routing and Reviewing a Reporting Period	Routing and Review test cases - Reporting period - caAERS v. 2.1-RC2
5. Internal Routing and Review	Routing and Review Testing 04-15-2010

Routing and Review (workflow) -- Data coordinator

Test data

Research Staff Details

Organization North Central Cancer Treatment Group (NCCTG)
First name ncctg-data
Last name coordinator
Email address caaers.app3@gmail.com
Phone 0000000000
Login Id ncctg.data.coordinator
User Roles Data coordinator

Pre-conditions:

1. Routing and Review is disabled.
2. User is logged in as Data coordinator.
3. Study Primary identifier N027D
4. Subject (mrn-bw-01) brian waugh

Test Case	Scenario	Expected	Actual	Pass / Fail
1	User selects "Routing and Review" tab.	The search criteria (Study, Subject, etc) is not displayed. Instead there is a message saying that the Routing and Review feature has been disabled.		✓
4	User clicks on Manage Reports Tab. User enters subject and study information and clicks 'Continue'. The User then selects the option of "Edit Adverse Events" for one of the courses	User is taken to the read only page for a course. There is no routing and review slider displayed on that page.	User is taken to read only page, however the slider is shown. http://jira.semanticbits.com/browse/CAAERS-2245	✗
5	User clicks on Manage Reports Tab. User enters study and subject information and clicks continue. User then clicks on one of the reports on the page.	The user is taken to the read-only page (PDF applet) page. There is no Routing And Review related section. Only the pdf report and the Report Validation sections are displayed.		✓

Pre-conditions:

1. Routing and Review is enabled.
2. User is logged in as Data coordinator.

Test Case	Scenario	Expected	Actual	Pass / Fail
8	User selects "Routing and Review" tab.	The search criteria (Study, Subject, etc) are displayed.		✓
8	User selects "Routing and Review" tab.	The user can see the results only if he has any actions to be taken on the results (means the course or the expedited report is in a workflow state where the user should take an action).		✓
9	The user reaches the pdf page for a report	The user is able to successfully add a routing and review comment.		✓
9	The user reaches the pdf page for a report	The user is able to successfully advance the workflow to next state.		NA
17	User enters caAERS. User reaches the read only pdf page for the report .	The data Coordinator is not allowed to submit the report from the page.		✓
17	User enters caAERS. User reaches the Manage Reports page for this report.	The data Coordinator is not allowed to submit the report from the page.		✓
22	Routing and Review is enabled. CRA creates a course and initiates a report for that course. The report is completed but still not submitted. The system admin enters caAERS and disables routing and review. Any User (user with any role) enters caAERS and reaches the submit page of the edit report flow.	The user can see both 'Submit' and 'Withdraw' options.		NA
22	Routing and Review is enabled. User creates a course and initiates a report for that course. The report is completed but still not submitted. The system admin enters caAERS and disables routing and review. Any User (user with any role) enters caAERS and reaches the manage reports page.	The user can see both 'Submit' and 'Withdraw' options.		✓

Routing and Review (workflow) -- SAE coordinator

Pre-conditions:

1. Routing and Review is disabled.
2. User is logged in as SAE coordinator.
3. Study Primary identifier N027D
4. Subject (mrn-bw-01) brian waugh

Test Data

- Research Staff Details
- Organization North Central Cancer Treatment Group (NCCTG)
- First name ncctg-sae
- Last name coordinator
- Email address caaers.app15@gmail.com
- Phone0000000000
- Login Id ncctg.sae.coordinator
- User Roles Central Office Report Reviewer

Test Case	Scenario	Expected	Actual	Pass / Fail
1	User selects "Routing and Review" tab.	The search criteria (Study, Subject, etc) is not displayed. Instead there is a message saying that the Routing and Review feature has been disabled.		✓

4	User clicks on Manage Reports Tab. User enters subject and study information and clicks 'Continue'. The User then selects the option of "Edit Adverse Events" for one of the courses	User is taken to the read only page for a course. There is no routing and review slider displayed on that page.	Routing and review slider is displayed on read only page for N027D - Brian Waugh - 04/14/09 http://jira.semanticbits.com/browse/CAAERS-2246	✗
5	User clicks on Manage Reports Tab. User enters study and subject information and clicks continue. User then clicks on one of the reports on the page.	The user is taken to the read-only page (PDF applet) page. There is no Routing And Review related section. Only the pdf report and the Report Validation sections are displayed.		✓
6	User enters and reaches the Manage Reports page. The report is incomplete.	The User reaches the static PDF page. There are no options available.		✓
7	User enters and reaches the Manage Reports page. The report is complete.	The user reaches the static PDF page. Submit option is available there.		✓

Pre-conditions:

1. Routing and Review is enabled.
2. User is logged in as SAE coordinator.

Test Case	Scenario	Expected	Actual	Pass / Fail
8	User selects "Routing and Review" tab.	The search criteria (Study, Subject, etc) are displayed.		✓
8	User selects "Routing and Review" tab.	The user can see the results only if he has any actions to be taken on the results (means the course or the expedited report is in a workflow state where the user should take an action).		✓
9	User reaches the Routing and Review search result page.	The user is able to successfully add a routing and review comment.		✓
9	User reaches the Routing and Review search result page.	The user is able to successfully advance the workflow to next state.		✓
9	The user reaches the pdf page for a report	The user is able to successfully add a routing and review comment.		✓
9	The user reaches the pdf page for a report	The user is able to successfully advance the workflow to next state.		✓
16	User enters caAERS. User reaches the read only pdf page for the report .	The SAE Coordinator is allowed to submit the report from the page.		✓
16	User enters caAERS. User reaches the Manage Reports page for this report.	The SAE Coordinator is allowed to submit the report from the page.		✓
18	User enters caAERS. User clicks on an incomplete report on the Manage Reports page.	The User is taken to the read only page (pdf). In the "Report Validation" section, the incomplete fields of the fields are mentioned and the user cannot submit the report.		✓

22	Routing and Review is enabled. CRA creates a course and initiates a report for that course. The report is completed but still not submitted. The system admin enters caAERS and disables routing and review. Any User (user with any role) enters caAERS and reaches the submit page of the edit report flow.	The user can see both 'Submit' and 'Withdraw' options.	User can see PDF page where 'submit' option is available. User cannot enter edit flow for report. http://jira.semanticbits.com/browse/CAAERS-2247	✗
22	Routing and Review is enabled. User creates a course and initiates a report for that course. The report is completed but still not submitted. The system admin enters caAERS and disables routing and review. Any User (user with any role) enters caAERS and reaches the manage reports page.	The user can see both 'Submit' and 'Withdraw' options.	User can see PDF page where 'submit' option is available. http://jira.semanticbits.com/browse/CAAERS-2248	✗

Routing and Review (workflow) -- site CRA

Pre-conditions:

1. Routing and Review is disabled.
2. User is logged in as site CRA.

Test data

- Study Primary identifier N027D
- Subject (mrn-bw-01) brian waugh
- Research Staff Details
  - Organization University of Alabama at Birmingham (AL002)
  - First name site3
  - Last name cra3
  - Email address anotknown1@gmail.com
  - Phone 0000000000 Fax 0000000000
  - Login Id anotknown1@gmail.com
  - User Roles Subject coordinator

Test Case	Scenario	Expected	Actual	Pass / Fail
1	User selects "Routing and Review" tab.	The search criteria (Study, Subject, etc) is not displayed. Instead there is a message saying that the Routing and Review feature has been disabled.		✓
2	User enters the Capture Adverse Events flow. There is no lab data available for the assignment.	The slider is not displayed on capture adverse events page		✓
2	User enters the expedited Report flow. There is no lab data available for the assignment.	There is no "Actions" section on the Submit Report page (final Tab of the expedited report flow)		✓
3	User enters the Capture Adverse Events flow. There is lab data available for the assignment.	Only the labs tab should be displayed in the slider.	http://jira.semanticbits.com/browse/CAAERS-2229	✗
3	User enters the expedited Report flow. There is lab data available for the assignment.	Only the labs tab should be displayed in the slider.		✓
6	User enters and reaches the submit tab (final tab in the expedited report flow). The report is incomplete.	The user can see 'Withdraw' option.		✓

6	User enters and reaches the Manage Reports page. The report is incomplete.	The user can see 'Withdraw' option.		✅
7	User enters and reaches the submit tab (final tab in the expedited report flow).The report is complete.	The user can see both 'Submit' and 'Withdraw' options.		✅
7	User enters and reaches the Manage Reports page. The report is complete.	The user can see both 'Submit' and 'Withdraw' options.		✅

Pre-conditions:

1. Routing and Review is enabled.
2. User is logged in as site CRA.

Test Case	Scenario	Expected	Actual	Pass / Fail
8	User selects "Routing and Review" tab.	The search criteria (Study, Subject, etc) are displayed.		✅
8	User selects "Routing and Review" tab.	The user can see the results only if he has any actions to be taken on the results (means the course or the expedited report is in a workflow state where the user should take an action).	http://jira.semanticbits.com/browse/CAAERS-2230\\	✅
9	User reaches the Routing and Review search result page.	The user is able to successfully add a routing and review comment.	http://jira.semanticbits.com/browse/CAAERS-2230	✅
9	User reaches the Routing and Review search result page.	The user is able to successfully advance the workflow to next state.	http://jira.semanticbits.com/browse/CAAERS-2230	✅
9	User reaches the capture adverse events page.	The user is able to successfully add a routing and review comment.		✅
9	User reaches the capture adverse events page.	The user is able to successfully advance the workflow to next state.		✅
9	User reaches the edit report flow .	The user is able to successfully add a routing and review comment in the slider.		✅
9	User reaches the submit page(final tab in the edit report flow) .	User is able to successfully advance the workflow to the next state if there is an action possible.		✅
10	User creates a new course and clicks Continue	A slider is shown with next possible transitions.		✅
11	User creates an expedited report. User clicks 'Continue' on the Reporter Tab. User eventually reaches the submit page (the final tab in the edit report flow) with the report is in incomplete state (all the mandatory fields are not completed).	User sees a slider on all the tabs.	Slider is not seen on Study interventions tab	❌

11	User creates an expedited report. User clicks 'Continue' on the Reporter Tab. User eventually reaches the submit page (the final tab in the edit report flow) with the report is in incomplete state (all the mandatory fields are not completed).	On the submit page user can only see the transition 'Send to Physician for Review'.		✓
11	User creates an expedited report. User clicks 'Continue' on the Reporter Tab. User eventually reaches the submit page (the final tab in the edit report flow) with the report is in incomplete state (all the mandatory fields are not completed).	On the submit page user has an option to withdraw the report under the 'Options' column in the submit page.		✓
11	User creates an expedited report. User clicks 'Continue' on the Reporter Tab. User eventually reaches the submit page (the final tab in the edit report flow) with the report is in complete state (all the mandatory fields are completed).	On the submit page user has an option to submit the report to SAE coordinatoe under the 'Options' column in the submit page.	http://jira.semanticbits.com/browse/CAAERS-2233	✗
11	User creates an expedited report. The report is in incomplete state (all the mandatory fields are not completed).User locates the report in the Manage reports tab.	User has an option to withdraw the report under the 'Options' column.		✓
12	User creates an expedited report and completely fills the report. User reaches the submit page (the final tab of the edit report flow)	User can withdraw the report from the submit page. User is not allowed to submit the report.		✓
12	User creates an expedited report and completely fills the report. User reaches the Manage Reports page for this report.	User can withdraw the report from the Manage Reports page. User is not allowed to submit the report.		✓
12	User creates an expedited report and completely fills the report. User reaches the submit page (the final tab of the edit report flow)	User can see the transition 'Send to SAE Coordinator for Review' as the report is complete.	http://jira.semanticbits.com/browse/CAAERS-2233	✗
19	Routing and Review is disabled. A new course and a new report is created. --Routing and review is enabled. Subject (mrn-bw-01) brian waugh Study (N027D) A Phase I Study of CCI-779 and Temozolomide in Combination with Radiation Therapy in Glioblastoma Multiforme Course Start Date: 02/19/09	The Routing and Review slider is not shown there is no workflow associated to the course.	The slider is shown after workflow is enabled	✗
19	As above	When the user reaches the edit report flow, still there is no slider as there is no workflow associated to the report too.	The slider is shown after workflow is enabled	✗
19	As above	In the routing and review tab, this course doesn't show up in the results.		✓
19	As above	The user cannot submit this report from the submit page.		✓
19	As above	The user cannot submit this report from the manage reports page.		✓

20	Routing and Review is disabled. A new course and a new report is created and submitted. Routing and review is enabled. User amends the report	user now sees a routing and review slider in the edit report flow.	http://jira.semanticbits.com/browse/CAAERS-2234	
21	Routing and Review is enabled. User creates a course and initiates a report for that course. The report is still incomplete. The system admin enters caAERS and disables routing and review. User enters caAERS and reaches the edit report flow.	The user can see 'Withdraw' option even though the report is incomplete.		
21	Routing and Review is enabled. User creates a course and initiates a report for that course. The report is still incomplete. The system admin enters caAERS and disables routing and review. User enters caAERS and reaches the manage reports page.	The user can see 'Withdraw' option even though the report is incomplete.		
22	Routing and Review is enabled. User creates a course and initiates a report for that course. The report is completed but still not submitted. The system admin enters caAERS and disables routing and review. Any User (user with any role) enters caAERS and reaches the submit page of the edit report flow.	The user can see both 'Submit' and 'Withdraw' options.		
22	Routing and Review is enabled. User creates a course and initiates a report for that course. The report is completed but still not submitted. The system admin enters caAERS and disables routing and review. Any User (user with any role) enters caAERS and reaches the manage reports page.	The user can see both 'Submit' and 'Withdraw' options.		

Routing and Review (workflow) -- site Physician

Pre-conditions:

1. Routing and Review is disabled.
2. User is logged in as site physician.

Investigator Details

- First Name site
- Last Name physician
- Middle Name
- Investigator number
- Email address site.physician@gmail.com
- Phone 0000000000
- Fax 0000000000
- Login Id site.physician@gmail.com
- Associate Sites
- Site University of Alabama at Birmingham (AL002) Active

Test Case	Scenario	Expected	Actual	Pass / Fail
1	User selects "Routing and Review" tab.	The search criteria (Study, Subject, etc) is not displayed. Instead there is a message saying that the Routing and Review feature has been disabled.		
2	User enters the Capture Adverse Events flow. There is no lab data available for the assignment.	The slider is not displayed on capture adverse events page		

2	User enters the expedited Report flow. There is no lab data available for the assignment.	There is no "Actions" section on the Submit Report page (final Tab of the expedited report flow)		✓
3	User enters the Capture Adverse Events flow. There is lab data available for the assignment.	Only the labs tab should be displayed in the slider.	The slider is not displayed in CAE flow	✗
3	User enters the expedited Report flow. There is lab data available for the assignment.	Only the labs tab should be displayed in the slider.		✓
6	User enters and reaches the submit tab (final tab in the expedited report flow). The report is incomplete.	The user can see 'Withdraw' option.		✓
6	User enters and reaches the Manage Reports page. The report is incomplete.	The user can see 'Withdraw' option.		✓
7	User enters and reaches the submit tab (final tab in the expedited report flow).The report is complete.	The user can see both 'Submit' and 'Withdraw' options.		✓
7	User enters and reaches the Manage Reports page. The report is complete.	The user can see both 'Submit' and 'Withdraw' options.		✓

Pre-conditions:

1. Routing and Review is enabled.
2. User is logged in as site physcian.

Test Case	Scenario	Expected	Actual	Pass / Fail
8	User selects "Routing and Review" tab.	The search criteria (Study, Subject, etc) are displayed.		✓
8	User selects "Routing and Review" tab.	The user can see the results only if he has any actions to be taken on the results (means the course or the expedited report is in a workflow state where the user should take an action).		✓
9	User reaches the Routing and Review search result page.	The user is able to successfully add a routing and review comment.		✓
9	User reaches the Routing and Review search result page.	The user is able to successfully advance the workflow to next state.		✓
9	User reaches the capture adverse events page.	The user is able to successfully add a routing and review comment.		✓
9	User reaches the edit report flow .	The user is able to successfully add a routing and review comment in the slider.		✓
9	User reaches the submit page(final tab in the edit report flow) .	User is able to successfully advance the workflow to the next state if there is an action possible.		✓
13	User enters caAERS. User opens the expedited report and reaches the submit page (final tab in the edit report flow).	User has option to withdraw report but not to submit it.		✓
13	User enters caAERS. User opens the expedited report and reaches the Manage Reports page.	User has option to withdraw report but to submit it.		✓
22	Routing and Review is enabled. User creates a course and initiates a report for that course. The report is completed but still not submitted. The system admin enters caAERS and disables routing and review. Any User (user with any role) enters caAERS and reaches the submit page of the edit report flow.	The user can see both 'Submit' and 'Withdraw' options.		✓

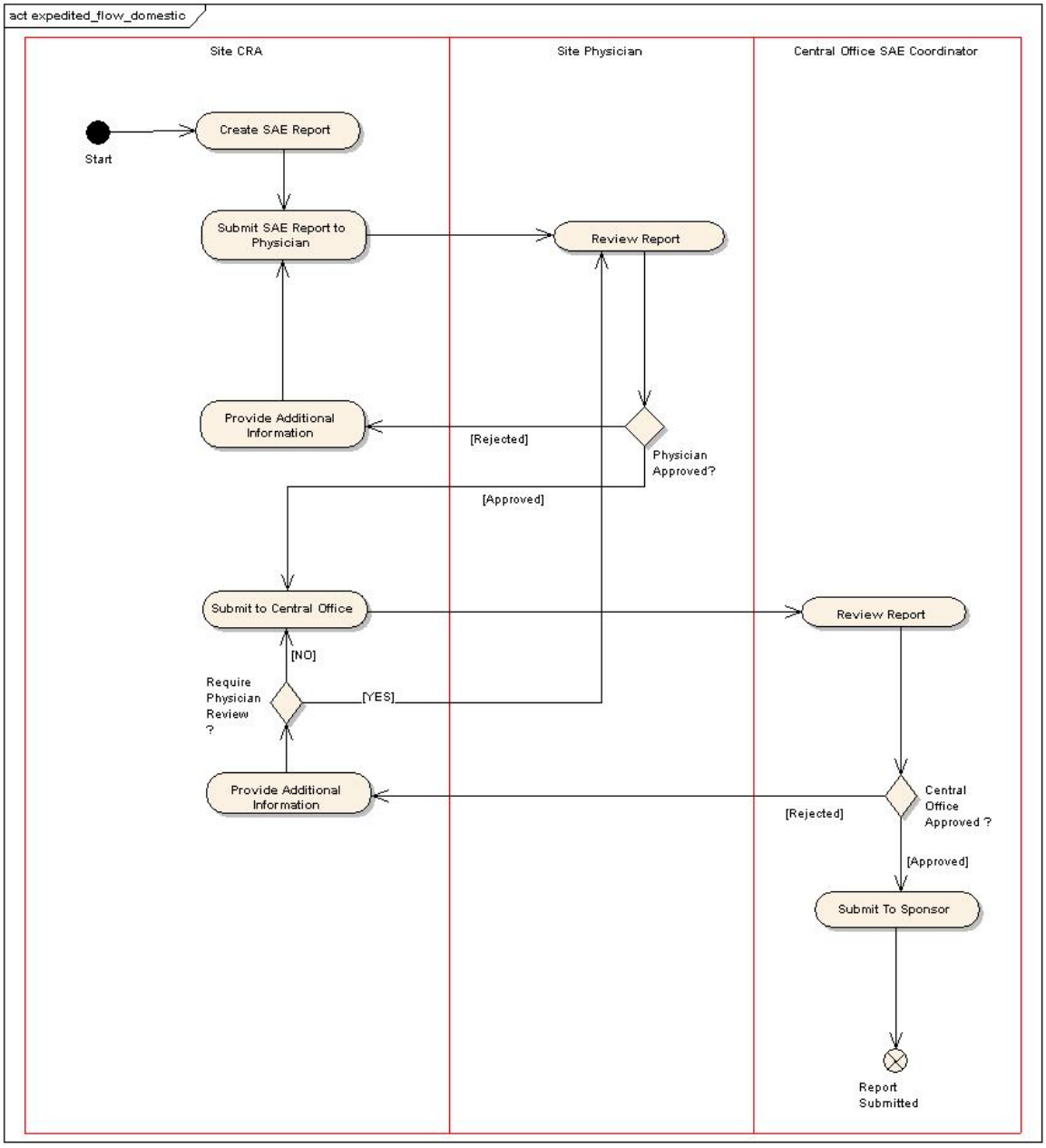
22	Routing and Review is enabled. User creates a course and initiates a report for that course. The report is completed but still not submitted. The system admin enters caAERS and disables routing and review. Any User (user with any role) enters caAERS and reaches the manage reports page.	The user can see both 'Submit' and 'Withdraw' options.		

Routing and Review test cases -- Expedited Report

These test cases are sourced from Design Document - Routing and Review

Informal state diagram is available CTMS:here

Activity diagram for expedited report workflow



Data used

	Use Case Role	Caaers Role	Site type	Site name	login ID	caaers password	gmail password
	Site CRA	subject coordinator	study site	University of Alabama at Birmingham	site.cra@gmail.com	passwordcra1!	passwordcra
	Site Physician	Investigator	study site	University of Alabama at Birmingham	site.physician@gmail.com	passwordphy1!	passwordphy
	Data Coordinator	AE coordinator	study coordinating center	NCCTG	coordinating.center@gmail.com	passwordcc1!	passwordcc

Study used: N027D

URL for caaers: https://dev.semanticbits.com/caaers/

Test Cases for site CRA

Pre-conditions:

1. site CRA is assigned to study N027D
2. User is logged in as site CRA
3. Workflow is enabled in Admin tab.
4. caAERS base URL is set in Admin tab.
5. Subject is Kristopher Cane (id-1).

	Scenario	Expected	Actual	Pass / Fail
	site CRA creates a new expedited report.	The report is assigned to the site CRA with review status 'Draft/Incomplete'		✓
	site CRA creates a new expedited report.	Email is sent to site CRA with link to newly created report		✓
	site CRA adds some comments and saves them. The workflow status is 'Draft/Incomplete'. user clicks edit in the slider to edit an existing comment	Comment is edited and saved.	Unable to save changed comment	✗ http://jira.semanticbits.com/browse/CAAERS-1778
	site CRA triggers the action of 'Submit to physician' on a report with workflow status of 'Draft/Incomplete'	The status is changed to 'Physician Review' and no other actions are available to the user.		✓
	site CRA triggers the action of 'Submit to physician' on a report with workflow status of 'Draft/Incomplete'	The comments added by the site CRA are uneditable		✓
	SP has a report with status of 'Physician Review' and triggers the action of 'Request Additional Information'	site CRA receives email about report task with status of 'Additional Info Requested by Physician'		✓
	site CRA has a report task with workflow status of 'Additional Info Requested by Physician'	The actions available for this task are: 'Submit to physician'		✓
	site CRA has a report task with workflow status of 'Additional Info Requested by Physician'. site CRA triggers action of 'Submit to physician'	The status of the report workflow is changed to 'Physician Review' and no other actions are available to the user.		✓
	SP has a report with status of 'Physician Review' and triggers the action of 'Approve report'	Email is received by site CRA for report with status 'Approved by Physician '		✓

	site CRA has a report with workflow status of 'Approved by Physician '	The only action available for the site CRA is 'submit to central office SAE coordinator'		✓
	site CRA has a report with workflow status of 'Approved by Physician ' and triggers action of 'submit to central office SAE coordinator'	Report workflow status is changed to 'Central Office SAE Coordinator Review'		✓
	site CRA has a report with workflow status of 'Approved by Physician ' and triggers action of 'submit to central office SAE coordinator'	No other report workflow actions are available.		✓
	DC has report with workflow status of 'Central Office SAE Coordinator Review' and triggers the action of 'Request Additional information'	Email is received by site CRA for report with status 'Additional Info Request by Central Office'		✓
	site CRA has a report with workflow status of 'Additional Info Request by Central Office'	The actions available for site CRA are: 'Submit for physician review' and 'Submit to central office'		✓
	site CRA has a report with workflow status of 'Additional Info Request by Central Office' and triggers the action 'Submit for physician review'	The report workflow status is changed to 'Physician Review' and no other actions are available to user		✓
	site CRA has a report with workflow status of 'Additional Info Request by Central Office' and triggers the action 'Submit for physician review'	The task is no longer available in 'Routing and review' page.		✓

Test Cases for site physician

Pre-conditions:

1. site physician is assigned to study N027D
2. User is logged in as site physician
3. Workflow is enabled in Admin tab.
4. caAERS base URL is set in Admin tab.
5. Subject is Kristopher Cane (id-1).

	Scenario	Expected	Actual	Pass / Fail
	site CRA triggers the action of 'Submit to physician' on a report with workflow status of 'Draft/Incomplete'	site physician receives email for the report task with status 'Physician Review'		✓
	site physician receives email for the report task with status 'Physician Review'. SP clicks on link for task in the email.	SP is taken to the Reporter tab of the report		✓
	SP opens the slider bar to review the comments of site CRA.	SP can view but not edit the comments of site CRA		✓

	SP has a report with status of 'Physician Review'.	The only actions available for the SP are 'Request Additional Information' and 'Approve Report'		✓
	SP has a report with status of 'Physician Review' and triggers the action of 'Request Additional Information'	The status of the report is changed to 'Additional Info Requested by Physician'		✓
	SP has a report with status of 'Physician Review' and triggers the action of 'Request Additional Information'	No actions are available for this report workflow to the SP anymore.		✓
	SP has a report with status of 'Physician Review' and triggers the action of 'Approve report'	The status of the report is changed to 'Approved by Physician'		✓
	SP has a report with status of 'Physician Review' and triggers the action of 'Approve report'	No actions are available for this report workflow to the SP anymore.		✓
	site CRA has a report with workflow status of 'Additional Info Request by Central Office' and triggers the action 'Submit for physician review'	site physician receives email for the report task with status 'Physician Review'		✓

Test Cases for data Coordinator

Pre-condition:

1. Data coordinator is assigned to study N027D
2. Data coordinator is logged in as data coordinator.
3. Workflow is enabled in Admin tab.
4. caAERS base URL is set in Admin tab.
5. Subject is Kristopher Cane (id-1).

	Scenario	**Expected**	**Actual**	**Pass / Fail**
	site CRA has a report with workflow status of 'Approved by Physician ' and triggers action of 'submit to central office SAE coordinator'	Email is sent to DC for report with workflow with status 'Central Office SAE Coordinator Review'		✓
	DC has report with workflow status of 'Central Office SAE Coordinator Review'	The actions available to the DC are: 'Request Additional information' and 'Approve report'		✓
	DC adds some comments to a report with workflow status of 'Central Office SAE Coordinator Review'	The comments added by DC are editable.		✓
	DC is viewing the comments on the slider for a report with workflow status of 'Central Office SAE Coordinator Review'	The comments added by site CRA and site Physician are not editable.		✓
	DC has report with workflow status of 'Central Office SAE Coordinator Review' and triggers the action of 'Request Additional information'	Report workflow status is changed to 'Additional Info Request by Central Office'		✓
	DC has report with workflow status of 'Central Office SAE Coordinator Review' and triggers the action of 'Request Additional information'	No other actions are available to DC after change of report workflow status.		✓
	DC has report with workflow status of 'Central Office SAE Coordinator Review' and triggers the action of 'Request Additional information'	The report task is no longer visible in 'Routing and review' tab.		✓
	DC has report with workflow status of 'Central Office SAE Coordinator Review' and triggers the action of 'Approve report'	Report workflow status is changed to 'Ready for Submission to Sponsor '		✓
	DC has report with workflow status of 'Central Office SAE Coordinator Review' and triggers the action of 'Approve report'	DC receives email for report with status 'Ready for Submission to Sponsor '		✓
	DC has report with workflow status of 'Ready for Submission to Sponsor '	The actions available to the DC are: 'Submit report to sponsor'		✓
	DC has report with workflow status of 'Ready for Submission to Sponsor ' and triggers the action of 'Submit report to sponsor'	The report workflow status is changed to 'Submitted to Sponsor' and no more actions are available to DC		✓

Questions

1. Currently once site CRA has added comments and changed the report workflow status from 'Draft/Incomplete' to 'Physician Review'. Now all comments of site CRA are uneditable. However site CRA can add new comments and they are editable. What is the desirable behavior?
   If this is allowed then site CRA has the flexibility of adding and editing new comments even after the task is not in his inbox. However the disadvantage is that locking implementation is incomplete and other actors may not be notified of the updates in time.
2. current data coordinator can add comments when report workflow is in 'Approved by Physician'. These comments are viewable [CTMS:but not editable] by others. But when DC is adding comments in this situation and some one changes the status and the DC refreshes the page, his comments are locked out. Thus DC comments can be locked out by events outside of his control.

Routing and Review Validation - Expedited Report

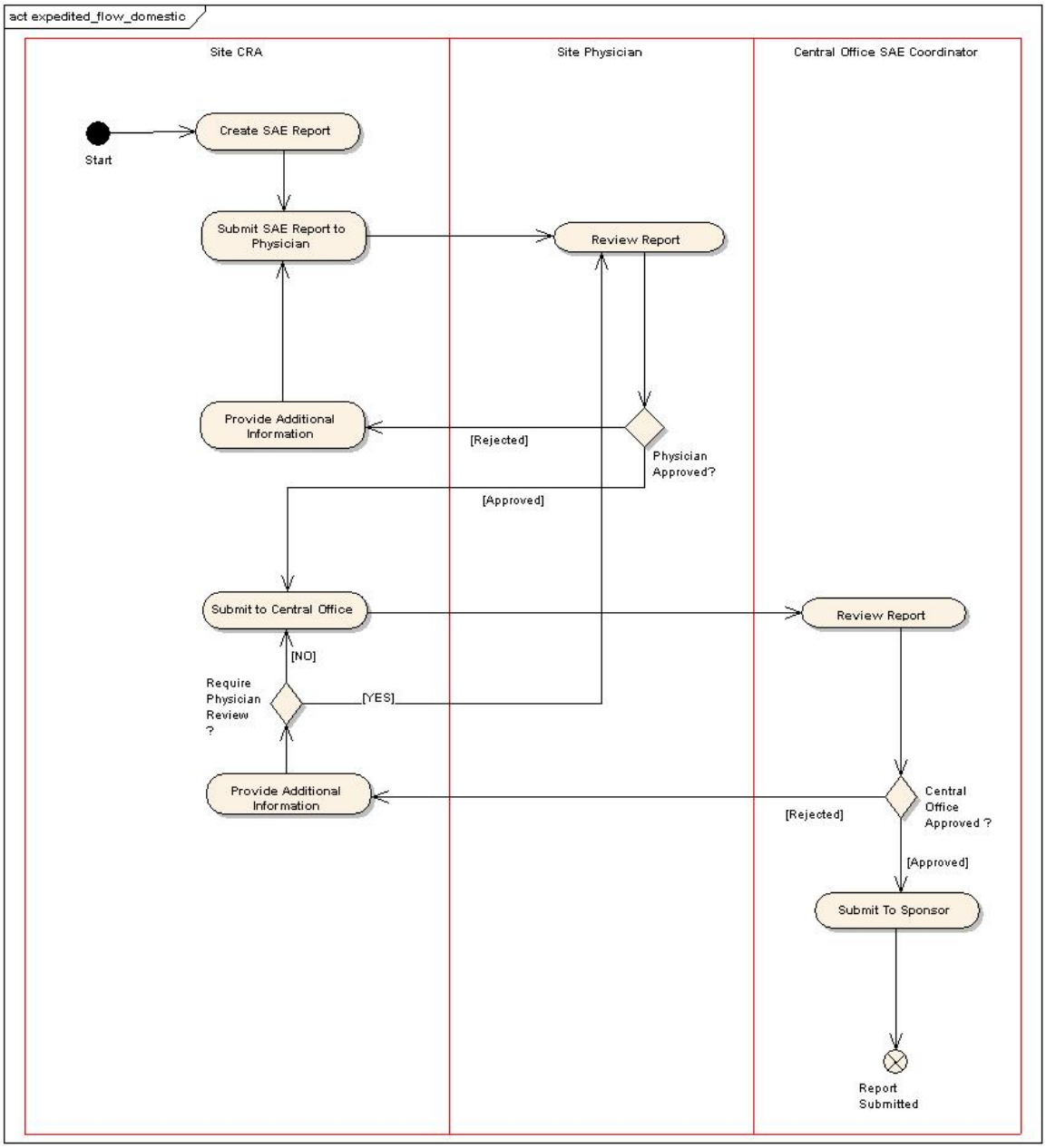
1. Create Expedited Report
2. Select Study
3. Select Subject
4. Select Course
    a. Create Course if needed
5. Click "Continue"
   On Enter Adverse Events Page
6. Enter an AE term
    a. Type "Nausea", select the term

Routing and Review test cases -- Expedited Report -- caAERS v. 2.1-RC2

These test cases are sourced from Design Document - Routing and Review

Informal state diagram is available CTMS:here

Activity diagram for expedited report workflow



Data used

	Use Case Role	Caaers Role	Site type	Site name	login ID	email
	Site CRA	subject coordinator / site coordinator	study site	Wayne State University	wayne-rs1 / Hello-12	caaers.qa@gmail.com
	Site Physician	Investigator	study site	Wayne State University	wayne-inv1 / Hello-12	caaers.app7@gmail.com
	Data Coordinator	Data coordinator	study coordinating center	Mayo clinic rochester	mayo-dc / Hello-12	caaers.app8@gmail.com
	Central office report reviewer [CORR]	Central office report reviewer	study coordinating center	Mayo clinic rochester	mayo-rs44 / Hello-12	caaers.app6@gmail.com

Study used: 7082

URL for caaers: https://dev.semanticbits.com/caaers/

Test Cases for site CRA

Pre-conditions:

1. site CRA is assigned to study 7082
2. User is logged in as site CRA
3. Workflow is enabled in Admin tab.
4. caAERS base URL is set in Admin tab.
5. Subject is John Gleese.

	Scenario	Expected	Actual	Pass / Fail
	site CRA creates a new expedited report.	The report is assigned to the site CRA with review status 'Draft/Incomplete'		
	site CRA creates a new expedited report.	Email is sent to site CRA with link to newly created report		
	site CRA adds some comments and saves them. The workflow status is 'Draft/Incomplete'. user clicks edit in the slider to edit an existing comment	Comment is edited and saved.		
	Report workflow status is 'Draft/Incomplete'. The report is data incomplete. site CRA pulls up available workflow actions for report in routing and review page	The option 'Submit to central office report reviewer ' is not available since, report is data incomplete		
	Report workflow status is 'Draft/Incomplete'. The report is data complete. site CRA pulls up available workflow actions for report in routing and review page.	The option 'Submit to central office report reviewer ' is available since, report is data complete.		
	site CRA triggers the action of 'Submit to central office report reviewer ' on a report with workflow status of 'Draft/Incomplete'	The status is changed to Central Office Report Review and no other actions are available to the user.		
	site CRA triggers the action of 'Submit to physician' on a report with workflow status of 'Draft/Incomplete'	The status is changed to 'Physician Review' and no other actions are available to the user.		
	site CRA triggers the action of 'Submit to physician' on a report with workflow status of 'Draft/Incomplete'	The comments added by the site CRA are uneditable		
	SP has a report with status of 'Physician Review' and triggers the action of 'Request Additional Information'	site CRA receives email about report task with status of 'Additional Info Requested by Physician'		
	site CRA has a report task with workflow status of 'Additional Info Requested by Physician'	The actions available for this task are: 'Submit to physician'		
	site CRA has a report task with workflow status of 'Additional Info Requested by Physician'. site CRA triggers action of 'Submit to physician'	The status of the report workflow is changed to 'Physician Review' and no other actions are available to the user.		
	SP has a report with status of 'Physician Review' and triggers the action of 'Approve report'	Email is received by site CRA for report with status 'Approved by Physician '		
	site CRA has a report with workflow status of 'Approved by Physician '	The only action available for the site CRA is 'Submit to central office report reviewer '		
	site CRA has a report with workflow status of 'Approved by Physician ' and triggers action of 'Submit to central office report reviewer '	Report workflow status is changed to 'Central Office SAE Coordinator Review'		
	site CRA has a report with workflow status of 'Approved by Physician ' and triggers action of 'Submit to central office report reviewer '	No other report workflow actions are available.		
	CORR has report with workflow status of 'Central Office Report Review' and triggers the action of 'Request Additional information'	Email is received by site CRA for report with status 'Additional Info Request by Central Office'		
	site CRA has a report with workflow status of 'Additional Info Request by Central Office'	The actions available for site CRA are: 'Submit for physician review' and 'Submit to central office'		
	site CRA has a report with workflow status of 'Additional Info Request by Central Office' and triggers the action 'Submit for physician review'	The report workflow status is changed to 'Physician Review' and no other actions are available to user		

	site CRA has a report with workflow status of 'Additional Info Request by Central Office' and triggers the action 'Submit for physician review'	The task is no longer available in 'Routing and review' page.		✓

Test Cases for site physician

Pre-conditions:

1. site physician is assigned to study 7082
2. User is logged in as site physician
3. Workflow is enabled in Admin tab.
4. caAERS base URL is set in Admin tab.
5. Subject is John Gleese.

	Scenario	Expected	Actual	Pass / Fail
	site CRA triggers the action of 'Submit to physician' on a report with workflow status of 'Draft/Incomplete'	site physician receives email for the report task with status 'Physician Review'		✓
	site physician receives email for the report task with status 'Physician Review'. SP clicks on link for task in the email.	SP is taken to the report		✓
	SP opens the slider bar to review the comments of site CRA.	SP can view but not edit the comments of site CRA		✓
	SP has a report with status of 'Physician Review'.	The only actions available for the SP are 'Request Additional Information' and 'Approve Report'		✓
	SP has a report with status of 'Physician Review' and triggers the action of 'Request Additional Information'	The status of the report is changed to 'Additional Info Requested by Physician'		✓
	SP has a report with status of 'Physician Review' and triggers the action of 'Request Additional Information'	No actions are available for this report workflow to the SP anymore.		✓
	SP has a report with status of 'Physician Review' and triggers the action of 'Approve report'	The status of the report is changed to 'Approved by Physician'		✓
	SP has a report with status of 'Physician Review' and triggers the action of 'Approve report'	No actions are available for this report workflow to the SP anymore.		✓
	site CRA has a report with workflow status of 'Additional Info Request by Central Office' and triggers the action 'Submit for physician review'	site physician receives email for the report task with status 'Physician Review'		✓

Test Cases for Central office report reviewer

Pre-condition:

1. CORR is assigned to study 7082
2. CORR is logged in as Central office report reviewer.
3. Workflow is enabled in Admin tab.

4. caAERS base URL is set in Admin tab.
5. Subject is John Gleese.

	Scenario	Expected	Actual	Pass / Fail
	site CRA has a report with workflow status of 'Approved by Physician ' and triggers action of 'submit to Central office report reviewer'	Email is sent to CORR for report with workflow with status 'Central Office Report Review'		
	CORR has report with workflow status of 'Central Office Report Review'	The actions available to the CORR are: 'Request Additional information' and 'Approve report'		
	CORR adds some comments to a report with workflow status of 'Central Office Report Review'	The comments added by CORR are editable.		
	CORR is viewing the comments on the slider for a report with workflow status of 'Central Office Report Review'	The comments added by site CRA and site Physician are not editable.		
	CORR has report with workflow status of 'Central Office Report Review' and triggers the action of 'Request Additional information'	Report workflow status is changed to 'Additional Info Request by Central Office'		
	CORR has report with workflow status of 'Central Office Report Review' and triggers the action of 'Request Additional information'	No other actions are available to CORR after change of report workflow status.		
	CORR has report with workflow status of 'Central Office Report Review' and triggers the action of 'Request Additional information'	The report task is no longer visible in 'Routing and review' tab.		
	CORR has report with workflow status of 'Central Office Report Review' and triggers the action of 'Approve report'	Report workflow status is changed to 'Ready for Submission to Sponsor '		
	CORR has report with workflow status of 'Central Office SAE Coordinator Review' and triggers the action of 'Approve report'	The report workflow ends and it is no longer shown in routing and review tab.		
	~~CORR has report with workflow status of 'Ready for Submission to Sponsor '~~	~~The actions available to the CORR are: 'Submit report to sponsor'~~		
	~~CORR has report with workflow status of 'Ready for Submission to Sponsor ' and triggers the action of 'Submit report to sponsor'~~	~~The report workflow status is changed to 'Submitted to Sponsor' and no more actions are available to CORR.~~		

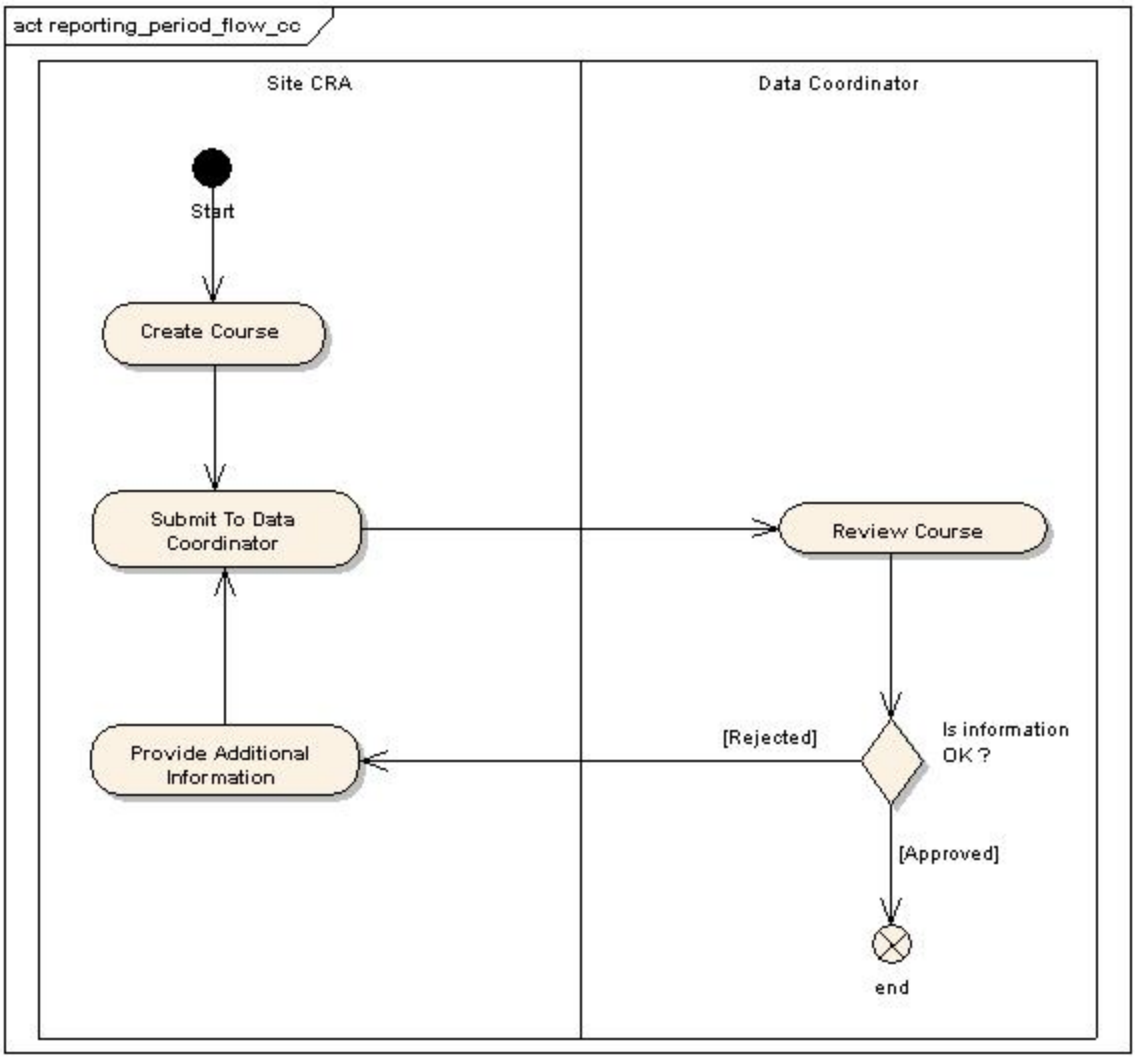
Questions

1. Currently once site CRA has added comments and changed the report workflow status from 'Draft/Incomplete' to 'Physician Review'. Now all comments of site CRA are uneditable. However site CRA can add new comments and they are editable. What is the desirable behavior?
   If this is allowed then site CRA has the flexibility of adding and editing new comments even after the task is not in his inbox. However the disadvantage is that locking implementation is incomplete and other actors may not be notified of the updates in time.
2. current data coordinator can add comments when report workflow is in 'Approved by Physician'. These comments are viewable [CTMS:but not editable] by others. But when DC is adding comments in this situation and some one changes the status and the DC refreshes the page, his comments are locked out. Thus DC comments can be locked out by events outside of his control.

Routing and Review test cases -- Reporting period

These test cases are sourced from Design Document - Routing and Review

Activity diagram for Reporting period workflow



Study used: N027D

URL for caaers: https://oracle.qa.semanticbits.com/caaers

Data used

	Use Case Role	Caaers Role	Site type	Site name	login ID	caaers password	gmail password
	Site CRA	subject coordinator	study site	University of Alabama at Birmingham	site.cra@gmail.com	passwordcra1!	passwordcra
	Site Physician	Investigator	study site	University of Alabama at Birmingham	site.physician@gmail.com	passwordphy1!	passwordphy
	Data Coordinator	AE coordinator	study coordinating center	NCCTG	coordinating.center@gmail.com	passwordcc1!	passwordcc

Study used: N027D

Test Cases for site CRA

Pre-conditions:

1. site CRA is assigned to study N027D
2. User is logged in as site CRA
3. Workflow is enabled in Admin tab.
4. caAERS base URL is set in Admin tab.
5. Subject is catherine jones.

	Scenario	Expected	Actual	Pass / Fail
	User is in Report Adverse Events and searches for study in 'Select study' textbox	Only the studies for which the user is assigned to are shown	Only n027D is shown	✓
	User is in Report Adverse Events and creates a new course.	An email is sent to user with task "Submit Reporting Period for Data Coordinator Review" for the course.	--	✓
	User clicks on link in email sent for creation of new course	User is taken to the newly created course.	--	✓
	User adds comments for the reporting period to the slider and clicks add.	The comment of this user is added and is editable.		✓
	User changes the workflow of the course to 'Submit to Data Coordinator' in the slider.	Status of workflow is changed and no more workflow actions are available to the user.		✓
	User changes the workflow of the course to 'Submit to Data Coordinator' in the slider.	Comments added by this user are no longer editable.		✓
	User adds comments for a particular course. User switches to a different course.	Comments added in the earlier course should not be shown in the currently selected course.		
	dc changes the status of a course to 'Provide additional info'	site CRA receives mail about the change of status of a course to 'Additional Info Requested By Data Coordinator'		✓
	site CRA receives mail about the change of status of a course to 'Additional Info Requested By Data Coordinator' and clicks on the link.	site CRA is taken to the Report AES>>AEs tab of the course.		✓
	site CRA pulls up comments created by dc.	Comments from the dc are not editable.		✓
	site CRA is editing a course with status of 'Additional Info Requested By Data Coordinator'	The only action available for site CRA is 'Submit to Data Coordinator'		✓
	site CRA pulls up a course with 'Approved' status.	The only action available is 'Submit to Data coordinator review'		✓
	site CRA pulls up a course with 'Approved' status. User triggers action 'Submit to Data coordinator review'	The status of the course is changed to 'Data Coordinator Review'		✓

Test Cases for data Coordinator

Pre-condition:

1. Data coordinator is assigned to study N027D
2. Data coordinator is logged in as data coordinator.
3. Workflow is enabled in Admin tab.
4. caAERS base URL is set in Admin tab.
5. Subject is catherine jones.

	Scenario	Expected	Actual	Pass / Fail
	site CRA has changed the workflow status of a course to 'Data Coordinator Review'	Email is sent to the dc with a link to the course		✓
	dc clicks on link for reporting period with status 'Data Coordinator Review'	dc is taken to read only page of the course		✓

	dc is in 'Routing and Review' page and selects study and subject for the specific course received in the email	dc should be able to see the course with status 'Data Coordinator Review'		
	dc is looking at comments for the reporting period in 'Routing and Review' page.	dc should be able to see comments for the course added by the site CRA, but they are not editable.		✓
	dc is adding comments for the reporting period in 'Routing and Review' page.	dc should be able to add comments for the course , and they are editable.		✓
	dc clicks on the '+' sign to view all AEs added by site CRA in 'Routing and Review' page.	All AEs added by site CRA should be visible	The AEs added by the site CRA are not shown to the dc	✗ http://jira.semanticbits.com/browse/CAAERS-1767
	dc is in 'Report Adverse Events' creates a new course.	??	Email is sent to site CRA with task "Submit Reporting Period for Data Coordinator Review"	??
	dc triggers the 'Provide additional info' action on a particular course	The status of the course is changed to 'Additional Info Requested By Data Coordinator' and no other actions are available.		✓
	dc is viewing a course with 'Data Coordinator Review' status.	The only actions available are: 'Additional Info Requested By Data Coordinator' and 'Approve reporting period'		✓
	dc triggers the action 'Approve reporting period' on a course.	The course status is changed to 'Approved'		✓
	site CRA pulls up a course with 'Approved' status. site CRA triggers action 'Submit to Data coordinator review'	dc receives email for the course assigned to him with 'Data Coordinator Review' status		✓

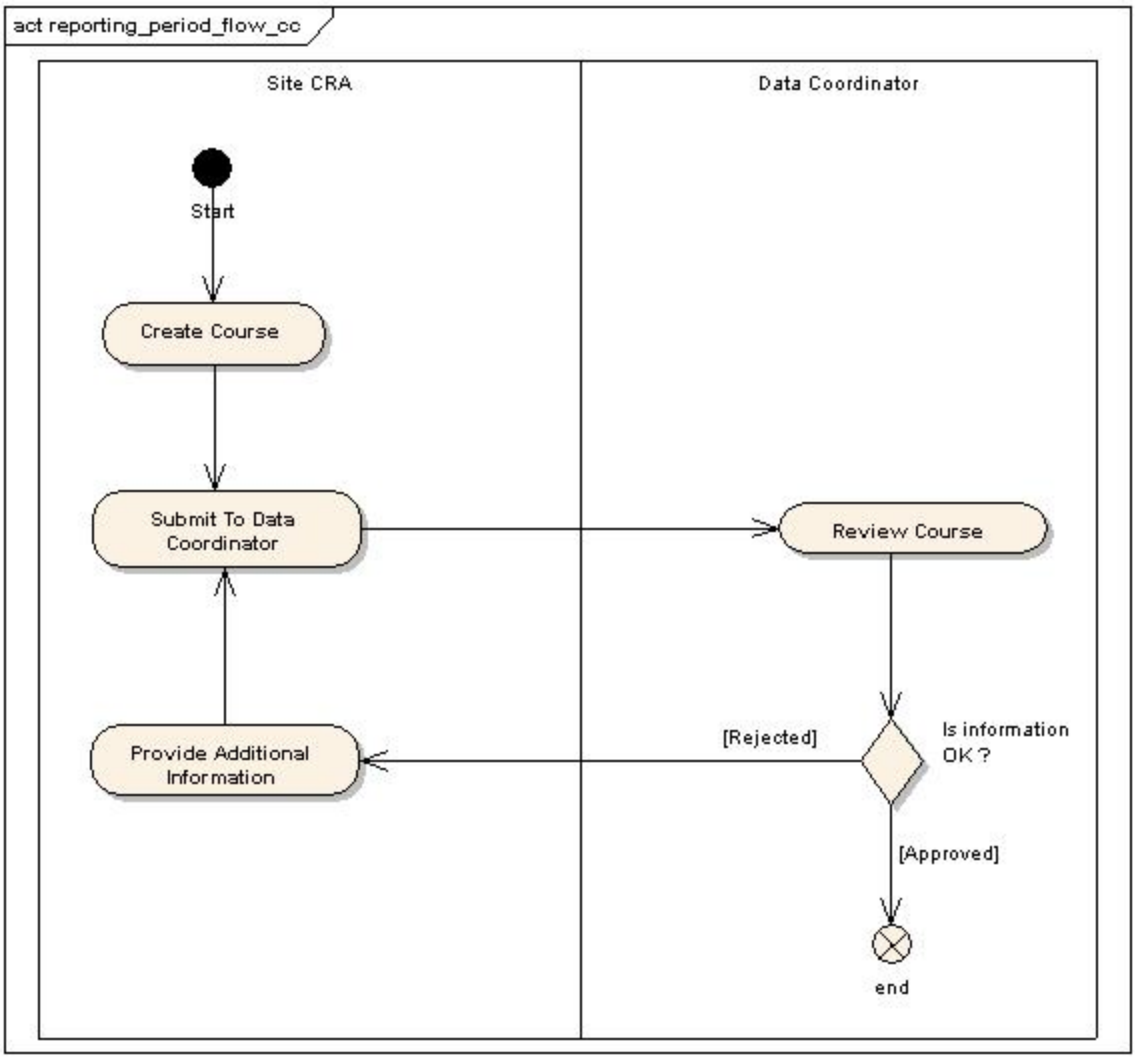
Questions

1. In routing and review page, user can filter by review status. But if a user is logged in as data coordinator, he can never see 'Provide additional Information' for a course. But in the drop down this choice is offered to him. Only statuses that are viewable by a role should be shown in the drop down.
2. The list of statuses in routing and review>>review status is a mix of course status and AE report status. These should be shown as separate lists for clarity.
3. When the dc creates a new course, the same workflow is triggered as by the site CRA. In this case too the site CRA receives the email. What is the scenario for workflow when dc creates a new course?

Routing and Review test cases -- Reporting period -- caAERS v. 2.1-RC2

These test cases are sourced from Design Document - Routing and Review

Activity diagram for Reporting period workflow



Study used: 7082

URL for caaers: https://oracle.qa.semanticbits.com/caaers

Data used

	Use Case Role	Caaers Role	Site type	Site name	login ID	email
	Site CRA	subject coordinator / site coordinator	study site	Wayne State University	wayne-rs1 / Hello-12	caaers.qa@gmail.com
	Site Physician	Investigator	study site	Wayne State University	wayne-inv1 / Hello-12	caaers.app7@gmail.com
	Data Coordinator	Data coordinator	study coordinating center	Mayo clinic rochester	mayo-dc / Hello-12	caaers.app8@gmail.com

Study used: 7082

Test Cases for site CRA

Pre-conditions:

1. site CRA is assigned to study 7082

2. User is logged in as site CRA
3. Workflow is enabled in Admin tab.
4. caAERS base URL is set in Admin tab.
5. Subject is John Gleese.

	Scenario	Expected	Actual	Pass / Fail
	User is in Report Adverse Events and searches for study in 'Select study' textbox	Only the studies for which the user is assigned to are shown	All studies belonging to the study site are shown	?
	User is in Report Adverse Events and creates a new course.	An email is sent to user with task "Submit Reporting Period for Data Coordinator Review" for the course.		✓
	User clicks on link in email sent for creation of new course	User is taken to the newly created course.	--	✓
	User adds comments for the reporting period to the slider and clicks add.	The comment of this user is added and is editable.		✓
	User changes the workflow of the course to 'Submit to Data Coordinator' in the slider.	Status of workflow is changed and no more workflow actions are available to the user.		✓
	~~User changes the workflow of the course to 'Submit to Data Coordinator' in the slider.~~	~~Comments added by this user are no longer editable.~~		
	User adds comments for a particular course. User switches to a different course.	Comments added in the earlier course should not be shown in the currently selected course.		✓
	dc changes the status of a course to 'Provide additional info'	site CRA receives mail about the change of status of a course to 'Additional Info Requested By Data Coordinator'		✓
	site CRA receives mail about the change of status of a course to 'Additional Info Requested By Data Coordinator' and clicks on the link.	site CRA is taken to the Report AES>>AEs tab of the course.		✓
	site CRA pulls up comments created by dc.	Comments from the dc are not editable.		✓
	site CRA is editing a course with status of 'Additional Info Requested By Data Coordinator'	The only action available for site CRA is 'Submit to Data Coordinator'		✓
	site CRA pulls up a course with 'Reviewed' status.	The only action available is 'Submit to Data coordinator review'		✓
	site CRA pulls up a course with 'Reviewed' status. User triggers action 'Submit to Data coordinator review'	The status of the course is changed to 'Data Coordinator Review'		✓
	User creates a course which has a solicited AE. In CAE>>Adverse events user does not add grade information to the course. In Routing and review page, user selects the action 'Submit to Data Coordinator'.	Error is thrown for missing AE grade information		✓
	User creates a course which has a solicited AE. In CAE>>Adverse events user does not add grade information to the course. In Routing and review page, user selects the action 'Submit to Data Coordinator'.	Transition is not allowed since AE information is missing		✓

Test Cases for data Coordinator

Pre-condition:

1. Data coordinator is assigned to study 7082
2. Data coordinator is logged in as data coordinator.
3. Workflow is enabled in Admin tab.
4. caAERS base URL is set in Admin tab.
5. Subject is catherine jones.

	Scenario	Expected	Actual	Pass / Fail
	site CRA has changed the workflow status of a course to 'Data Coordinator Review'	Email is sent to the dc with a link to the course		✓
	dc clicks on link for reporting period with status 'Data Coordinator Review'	dc is taken to read only page of the course		✓
	dc is in 'Routing and Review' page and selects study and subject for the specific course received in the email	dc should be able to see the course with status 'Data Coordinator Review'		✓
	dc is looking at comments for the reporting period in 'Routing and Review' page.	dc should be able to see comments for the course added by the site CRA, but they are not editable.		✓
	dc is adding comments for the reporting period in 'Routing and Review' page.	dc should be able to add comments for the course , and they are editable.		✓
	dc clicks on the '+' sign to view all AEs added by site CRA in 'Routing and Review' page.	All AEs added by site CRA should be visible		✓
	dc triggers the 'Provide additional info' action on a particular course	The status of the course is changed to 'Additional Info Requested By Data Coordinator' and no other actions are available.		✓
	dc is viewing a course with 'Data Coordinator Review' status.	The only actions available are: 'Additional Info Requested By Data Coordinator' and 'Approve reporting period'		✓
	dc triggers the action 'Approve reporting period' on a course.	The course status is changed to 'Approved'		✓
	site CRA pulls up a course with 'Reviewed' status. site CRA triggers action 'Submit to Data coordinator review'	dc receives email for the course assigned to him with 'Data Coordinator Review' status		✓

Questions

1. ~~In routing and review page, user can filter by review status. But if a user is logged in as data coordinator, he can never see 'Provide additional Information' for a course. But in the drop down this choice is offered to him. Only statuses that are viewable by a role should be shown in the drop down.~~
2. The list of statuses in routing and review>>review status is a mix of course status and AE report status. These should be shown as separate lists for clarity.
3. When the dc creates a new course, the same workflow is triggered as by the site CRA. In this case too the site CRA receives the email. What is the scenario for workflow when dc creates a new course?

Routing and Review Testing 04-15-2010

System used:

SB DEV: caAERS v. 2.1.2-SNAPSHOT (2010-04-15 11:13:06)
URL: https://dev.semanticbits.com/caaers/

Tester	Browser	Role	Site	Site Role	Subject(s)
Sameer	IE7	AE Coordinator	John's Hopkins	Study Site	Richard2
John	FF 3.6.3	AE Coordinator	John's Hopkins	Study Site	Mark Jansen
Ben	IE7	AE Coordinator	John's Hopkins	Study Site	Test User
Karthik	FF 3.6	AE Coordinator	John's Hopkins	Study Site	Test Two
Paul	IE8	Central Office Reviewer	Mayo Clinic Rochester	Coord Center	

Role	caAERS Username	caAERS Password	Email address	Email Password
AE Coord at Study Site (JHU)	Dutts1	passwordcra1!	site.cra1@gmail.com	passwordcra

	Dixitm	passwordcc1!	coordinating.center@gmail.com	passwordcc

Test procedure

Tester account setup

1. Login as SYSTEM // system_admin
2. Go to Administration >> Research Staff >> Create Research Staff
3. Enter yourself as a Research Staff
    a. Select "Johns Hopkins University" as the organizatino
    b. Select "AE Coordinator" as your role
    c. Check the "Associate to all studies" box
    d. Enter a second email address as the Organization email
    e. Enter any Address / phone info
4. Click Save and logout of caAERS
5. Check your email for instructions to create your password
6. Create your password and login

Create Adverse Events

1. Click on Adverse Events tab and then click Report Adverse Events
2. In the 'Study' text field, type and choose 6882 as the study
3. In the 'Subject' text field, type and choose the subject assigned to you
4. In the 'Course/cycle' drop-down menu, choose the 'Create New' option
5. You will be shown a pop up to enter the course/cycle details
6. Enter all appropriate details and click Save
7. The pop up will disappear and you will see 'Course/Cycle created successfully' message
8. Click Continue
9. In the Adverse events sub-tab, type "vasculitis" in the text box and choose the term from the drop down list. Click '+ Add'
10. The term will be added below.
11. Add the appropriate details such as 'Grade' 5, 'Start date', 'Attribution to study intervention' Possible, 'Expected' Yes, and 'Hospitalization' No.
12. Click Save & Report.
13. In the 'Review and Report' page, caAERS should recommend creation of a CTEP 24 Hour Notification.
14. Click the Report button
    You will now be taken to expedited AE report flow.

Create Adverse Event Report

Test Scripts for Routing and Review enhancements

Preconditions

- Switch off routing and review for course
- Switch on routing and review for 10 day
- Switch off routing and review for ctep commercial agent
- Create new subject jh-subject-005
- assign to study site 5876@Johns Hopkins University

Test Scenario: Test for report with workflow enabled

1. Login as site CRA **md017.cra**
2. Create new course
3. Pick 10 day report.
4. In create flow comments slider should appear.
5. add few comments to the reporting flow slider
6. make sure report is data complete.
7. Send to report reviewer [ws-rs2 @mn026]
8. report reviewer sends back report to site CRA with comments
9. Site CRA sends back with report to report reviewer with updates
10. Report reviewer approves report
11. Report reviewer submits report

Test Scenario: Test for report with workflow disabled

1. Login as site CRA **md017.cra**
2. Pick ctep commercial agent.
3. In create flow no slider should appear.

4. make sure report is data complete.
5. Check in routing and review.
6. This course and report should not be shown
7. Login as Report reviewer.
8. Check in routing and review.
9. This course and report should not be shown.

Module 12.1 Test Cases for Setting up Expectedness in AEs

Module 12.1 Test Cases for Setting up Expectedness in AEs

Use Case	Test Case
12.1 Setting up Expectedness in AEs - caAERS UC draft	Test cases for Expected AEs
12.1 Setting up Expectedness in AEs - caAERS UC draft	Test cases for use case 12.1

Test cases for Expected AEs

	Scenario	Expected	Actual	Pass/Fail
	User is in create/edit study and in details tab chooses AE terminology as CTC	In the study>>expected AEs tab, the auto-suggest should display only CTC terms		
	User is in create/edit study and in details tab chooses AE terminology as CTC. In the study>>expected AEs tab,user should be allowed to add 'other MedDRA' term as an Expected AE.	An 'other MedDRA' term is added to the list of expected AEs with an autosuggest to add a MedDRA term.		
	User is in create/edit study and in details tab chooses AE terminology as MedDRA.	In the study>>expected AEs tab, the auto-suggest should display only MedDRA terms		
	In CAE flow, for a particular reporting period-study-subject combination, user adds an observed AE. This observed AE is set as an expected AE in the study.	The expected field of the AE is set to 'Yes' by caaers		
	In CAE flow, for a particular reporting period-study-subject combination, user adds an observed AE. This observed AE is NOT set as an expected AE in the study.	The expected field of the AE is set to 'Please select' by caaers		
[CTMS:deprecated]	In CAE flow, for a particular reporting period-study-subject combination, a solicited AE term is set as an expected AE in the study. User sets grade <=0 for this AE.	The expected field is left at 'Please select'.		
[CTMS:deprecated]	In CAE flow, for a particular reporting period-study-subject combination, a solicited AE term is set as an expected AE in the study. User sets grade >=1 for this AE.	The expected field is set to 'Yes' by caaers.		
	User is in Edit Study>>Expected AE. User adds the same AE terms twice.	Caaers should not allow addition of the same AE terms twice		
	In CAE flow, for a particular reporting period-study-subject combination, a solicited AE term is set as an expected AE in the study. The expectedness is automatically marked as 'Yes' while the AE grade is still 'Please select'. User clicks save.	No Error is thrown for setting expectedness as 'Yes' when grade is not selected.		

Test cases for use case 12.1

Link to use case: https://wiki.nci.nih.gov/x/tJI8

	Scenario	expected	actual	Pass / Fail

	User is in edit / create study flow and sets the AE terminology to be CTC. User goes to 'Expected AE' page.	The AE lists should only show CTC disease terms and categories		
	User is in edit / create study flow and sets the AE terminology to be meddra. User goes to 'Expected AE' page.	The AE lists should only show meddra disease terms.		
	User is in edit / create study flow and sets the AE terminology to be CTC. User selects a CTC term in the 'Expected AE page'	The CTC category box should auto-populate		
	User adds an expected AE and saves the study. User re-enters the flow and checks the overview page	The newly added expected AE should be shown in the overview page		
	User removes an existing expected AE in a study and saves the study. He exits the study and re-enters the flow	The deleted AE should not be shown in the overview page.		
	User is in CAE flow and adds an AE which has been set as an expected AE in the study.	The expectedness value is automatically chosen to yes.		
	User is in CAE flow and adds an AE which has NOT been set as an expected AE in the study.	The expectedness value is automatically chosen to no.		

Notes

1. What is the difference between expected AEs and solicited AEs?
2. Is the use case for expectedness applicable only to specific sponsor [CTMS:for ex. only CTEP sponsored studies will use the expectedness feature] or a application wide feature available to all types of studies?
3. Will there be an option to add multiple expected AEs in edit study flow?
4.

Module 13 Test Cases - Security

Module 13 Test Cases - Security

Use Case	Test Case
caAERS - User Roles and Rights	Testing User Roles and Rights (NCI)-- AE coordinator - Coordinating Center
caAERS - User Roles and Rights	Testing User Roles and Rights (NCI) - Site coordinator - Coordinating center
caAERS - User Roles and Rights	Testing User Roles and Rights (NCI) - Study coordinator - Coordinating Center
caAERS - User Roles and Rights	Testing User Roles and Rights (NCI) - Subject coordinator - Coordinating Center
caAERS - User Roles and Rights	Testing User Roles and Rights - AE coordinator

caAERS - User Roles and Rights	Testing User Roles and Rights - AE coordinator - Coordinating Center
caAERS - User Roles and Rights	Testing User Roles and Rights - Site coordinator
caAERS - User Roles and Rights	Testing User Roles and Rights - Site coordinator - Coordinating center
caAERS - User Roles and Rights	Testing User Roles and Rights - Study coordinator
caAERS - User Roles and Rights	Testing User Roles and Rights - Study coordinator - Coordinating Center
caAERS - User Roles and Rights	Testing User Roles and Rights - Subject coordinator
caAERS - User Roles and Rights	Testing User Roles and Rights - Subject coordinator - Coordinating Center

Authentication Test Cases

Inactivity Test Cases

Password Policy Test Cases

Reset Password Test Cases

Authorization Test Cases

- **Global** scoping does not limit the data to which the user has access. The user can view, for example, all sites, all subjects.
- **Site** scoping limits data access to sites to which a user is assigned.
- **Site and Study** scoping limits data access to all studies to which a user is assigned at the sites to which the user is assigned.

There are also two types of user roles, global and organization-level. A global role enables a user to perform the role at all sites across an application. Within the caBIG Clinical Trials Suite, the global role enables a user to perform the role across any Suite application (C3PR, caAERS, caBIG Patient Study Calendar, caBIG Lab Viewer, caBIG Integration Hub, and caBIG Clinical Connector). An organization-level role provides access to information within a specified organization only.

Note
caBIG® Clinical Trials Suite users only need only to log on to the Suite once to access all Suite products installed on their system. To launch the Suite, open one of the component applications. To exit the Suite, users must log out of each application or close each window individually.

Role	Scoping	Description
System Administrator	Global	Configures the technical system level properties and behavior of the applications (i.e. the password policy, email setup, ESB, etc).
Business Administrator	Global	Manages the domain related application wide properties and behavior (i.e. label names, reference data lists, etc)
Person and Organization Information Manager	Site	Manages organizations and rosters. Creates and updates person info including contact info, degrees/certifications, rosters they are associated with
Data Importer	Global	Identifies studies defined by Coordinating Center and imports as a consumer that data defined elsewhere
User Administrator	Site	Ability to read system personnel (research staff and investigators) and create/manage user accounts/application roles, defines Custom Combination Roles

Study QA Manager	Site	Updates the core study info (e.g. PI, title, description, phase, epochs/arms & basic study design, etc.) after saving and opening the study. does read-only review of study calendar template data and releases templates for use at participating sites. does read-only review of released study calendar templates, indicating when they have been approved for use at a participating site. Performs read-only review of study calendar template data and releases templates for use at participating sites. Performs read-only review of released study calendar templates, indicating when they have been approved for use at a participating site.
Study Creator	Site	Creates the core study info (e.g. PI, title, description, phase, epochs/arms & basic study design, etc.) NOTE: some sites may want to combine the supplemental study info roles into this role
Supplemental Study Information Manager	Site	Adds treatment assignment codes, drugs, adEERS-specific diseases?, whether study requires adEERs reporting, CTC/MedDRA version to use, etc. Update and manage registration metadata (e.g. stratifications, eligibility criteria, notifications, target accrual, multi-institutional indicator, consent form version, study randomized indicator, etc.)
Study Team Administrator	Site	Connects study level people to the study and internal staff to the study; Assigns internal staff to a protocol, determines which study artifacts (e.g. study calendar templates, CRFs, etc.) are accessible by each particular staff member
Study Site Participation Administrator	Site	Connects participating sites to a protocol
AE Rule and Report Manager	Global	Creates, manages, imports AE rules. Creates, manages, imports AE report definitions
Study Calendar Template Builder	Site & Study	Creates and updates study calendar templates
Registration QA Manager	Site	Updates registration information (study subject ID, Date of consent) after enrollment. Can waive the eligibility criteria for certain study subjects.
Subject Manager	Site	defines patient to system (remaining subject data managed by other roles which are not defined)
Study Subject Calendar Manager	Site & Study	creates and updates a subject-specific study calendar based on a study calendar template
Registrar	Site & Study	accepts and approves/denies subject registration requests; requests subject registration on a particular study
AE Reporter	Site & Study	creates and updates information about an AE that needs to be reported and submits report to appropriate parties per the report definition. Enters set of required AEs that have to be assessed and any additional AEs that the patient experienced.
AE Expedited Report Reviewer	Site & Study	Read-only: reviews, provides comments, and routes expedited reports through the review workflow
Adverse Event Study Data Reviewer	Site & Study	Read-only: reviews, provides comments, and adverse event data through a review workflow
Lab Impact Calendar Notifier	Site & Study	creates a calendar notification for a potential lab-based treatment modification
Lab Data User	Site & Study	Enters, edits, and imports labs from LIMS, viewing labs, selecting and sending labs to CDMS and caAERS
Data Reader	Site & Study	Read only role: typically not part of the org that they are auditing, but granted temporary read-only access to a particular study (no modifications allowed), access might be to whole study or specific subjects on the study, any data entered by the site for that subject on that study, crosses all apps (i.e. registration-, AE- and possibly calendar-related data)
Data Analyst	Site & Study	Read only - searches for data, uses built-in analysis tools, exports data to third party tools

Content Filtering Test Cases

Use case supported: Coordinating Center Study Management

1. Create a new user (user 1) from an organization (org 1) not currently used in the system.
2. Create user 1 with the following roles:
    a. Study QA Manager
    b. Study Creator
    c. Supplemental Study Information Manager
    d. Study Team Administrator
    e. Study Site Participation Administrator
3. Login to the system as user 1
4. Create a Study (Study A) where org 1 is the Coordinating Center, but is not the Sponsor. Only complete the details page, Save, and click on the Search Study tab.
5. Search for the Study (expected result: study found)
6. Click on the Study to edit (expected result: Study Overview and all study tabs are displayed)
7. Add 3 study sites (org 2, org 3, org 4)

Use case supported: Study Sponsor Study Management

1. Login to the system as user 1
2. Create a Study (Study B) where org 1 is the Sponsor, but is not the Coordinating Center. Only complete the details page, Save, and click on the Search Study tab.
3. Search for the Study (expected result: study found)
4. Click on the Study to edit (expected result: Study Overview and all study tabs are displayed)
5. Do not add any study sites

Use case supported: Study Site Management

1. Create a new user (user 2) from org 2 (Study A study site).
2. Create this userwith the following role:
    a. Study Site Participation Administrator
3. Login to the system as user 2
4. Search for Study B (expected result: study not found)
5. Search for the Study A (expected result: study found)
6. Click on the Study to edit (expected result: Study Overview and Sites tabs are displayed)
7. Click on the Sites tab
    a. Enter the wildcard "%" search in the sites autocompleter (expected result: only org 2 appears).

Use case supported: Study Site Study Investigator Management

1. Login to the system as a User Administrator and Person and Org Information Manager
2. Create an investigator (invest 2) from org 2 (login to the system NOT needed).
3. Search for user (user 2) from org 2 (Study A study site).
4. Update this user's roles as follows:
    a. Deactivate Study Site Participation Administrator
    b. Add Study Team Administrator
5. Login to the system as user 2
6. Search for the Study A (expected result: study found)
7. Click on the Study to edit (expected result: Study Overview, Investigator, and Personnel tabs are displayed)
8. Click on the Investigator tab (expected result: tab renders with only links to org 2 displayed)
    a. Click on org 2 in the right panel or select org 2 from the drop down
    b. Click "Add Investigator"
    c. Enter the wildcard "%" search in the autocompleter (expected result: only invest 2 appears).
    d. Select invest 2
    e. Click on the roles dropdown (expected result: Principal Investigator, Site Principal Investigator, Site Investigator are options)
    f. Select Site Principle Investigator as the role.
    g. Click Save

Use case supported: Study Site Study Personnel Management

1. Login to the system as a User Administrator and Person and Org Information Manager
2. Create a second user from org 2 (user 2b)
3. Provision user 2b with the following roles:
    a. Registration QA Manager
    b. Subject Manager
    c. Registrar
4. Login to the system as user 2
5. Search for the Study A (expected result: study found)
6. Click on the Study to edit (expected result: Study Overview, Investigator, and Personnel tabs are displayed)
7. Click on the Personnel tab (expected result: tab renders with only links to org 2 displayed)

    a. Click on org 2 in the right panel or select org 2 from the drop down
    b. Click "Add Personnel"
    c. Enter the wildcard "%" search in the autocompleter (expected result: user 2 and user 2b appears).
    d. Select user 2b.
    e. Click on the roles dropdown (expected result: Registration QA Manager, Subject Manager, Registrar are options)
    f. Select Subject Manager.
    g. Click Save

Use case supported: Study Site Registration (Negative)

1. Login to the system as user 2b (expected result: Subject tab appears with Enter, Search, and Assign sub tabs)
2. Select Subjects >> Enter Subject
    a. In the drop down, only org 2 should be available
    b. Enter the required information on the screen
    c. click "Continue"
3. On the next tab (Select Study), enter Study A in the search box
    a. Expected result: no results found.

Use case supported: Study Site Registration (Positive)

1. Login to the system as user 2
2. Search for the Study A (expected result: study found)
3. Click on the Study to edit (expected result: Study Overview, Investigator, and Personnel tabs are displayed)
4. Click on the Personnel tab (expected result: tab renders with only links to org 2 displayed)
    a. Click on org 2 in the right panel or select org 2 from the drop down
    b. Click "Add Personnel"
    c. Enter the wildcard "%" search in the autocompleter (expected result: user 2 and user 2b appears).
    d. Select user 2b.
    e. Click on the roles dropdown (expected result: Registration QA Manager, Subject Manager, Registrar are options)
    f. Select Registrar.
    g. Click Save
5. Logout and Login to the system as user 2b (expected result: Subject tab appears with Enter, Search, and Assign sub tabs)
6. Select Subjects >> Enter Subject
    a. In the drop down, only org 2 should be available
    b. Enter the required information on the screen
    c. click "Continue"
7. On the next tab (Select Study), enter Study A in the search box
    a. Expected result: Study A found
    b. Select Study A
    c. Enter Study Subject ID
    d. Click Continue
8. On Subject Medical History, Click Continue
9. On Review, Click Save
    a. Expected Result: Subject successfully saved.

Use case supported: Coordinating Center Subject Registration

1. Login to the system as a User Administrator and Person and Org Information Manager
2. Create a second user from org 1 (user 1b)
3. Provision user 1b with the following roles:
    a. Registration QA Manager
    b. Subject Manager
    c. Registrar
4. Login to the system as user 1
5. Search for the Study A (expected result: study found)
6. Click on the Study to edit (expected result: Study Overview and all study tabs are displayed)
7. Click on the Personnel tab (expected result: tab renders with links to org 1, org 2, org 3, and org 4 displayed, along with the Study Sponsor)
    a. Click on org 1 in the right panel or select org 1 from the drop down
    b. Click "Add Personnel"
    c. Enter the wildcard "%" search in the autocompleter (expected result: user 1 and user 1b appears).
    d. Select user 1b.
    e. Click on the roles dropdown (expected result: Registration QA Manager, Subject Manager, Registrar are options)
    f. Select Registrar.
    g. Click Save
8. Logout and Login to the system as user 1b (expected result: Subject tab appears with Enter, Search, and Assign sub tabs)
9. Select Subjects >> Enter Subject
    a. In the drop down, only org 2, org 3, and org 4 should be available (org 1 should not be available)
    b. Select org 2
    c. Enter the required information on the screen
    d. click "Continue"
10. On the next tab (Select Study), enter Study A in the search box
    a. Expected result: Study A found

    b. Select Study A
    c. Enter Study Subject ID
    d. Click Continue
11. On Subject Medical History, Click Continue
12. On Review, Click Save
    a. Expected Result: Subject successfully saved.

Role	Scoping	Description
AE Reporter	Site & Study	

Role	Scoping	Description
AE Expedited Report Reviewer	Site & Study	

Role	Scoping	Description
Data Reader	Site & Study	

Role	Scoping	Description
Data Analyst	Site & Study	

Organization Filtering Test Cases

Study Filtering Test Cases

Multi-Role Test Cases

https://spreadsheets.google.com/ccc?key=0Am2rxzjJDiq0dFNLZUV6SzJxVzExOUVjWjhUMFpwclE&hl=en&authkey=CNPDhsgC

https://spreadsheets.google.com/ccc?key=0Am2rxzjJDiq0dEs3TENjaTVDQUxWNjBsWEgwenpPUnc&hl=en

Single Role Test Cases

Use Case: https://spreadsheets.google.com/ccc?key=0Am2rxzjJDiq0dF9VUnd6MVJremxOa3RvbmZURXBBcFE&hl=en

Postgres Testing:
https://spreadsheets.google.com/ccc?key=0AnC1Vm2dZKUNdHczQm45azdjdUVOdzJjVEdsTWZERlE&hl=en&authkey=CNK2o4YJ

Oracle Testing:
https://spreadsheets.google.com/ccc?key=0AuDYVOSkK1W7dDU4UUVQd3FTNy1oNWVDUGM1N3p3VlE&hl=en&authkey=CJbt5roB

Testing of Index refresh optimization

Scenario: Org Index is not refreshed for every login session of user 

1. mayo-super-user is initially logged out
2. Check ID range of mayo-super-user in org index
3. mayo-super-user logs in to caaers
4. Check ID range of mayo-super-user in org index

Expected: ID range is the same before and after logging in

```
SQL statements:
select min(id), max(id), count(*) from organization_index where login_id ='mayo-super-user'  order by
id
```

Before login:

MIN(ID) MAX(ID) COUNT(*)
---------- ---------- ----------

29544401 29563005 18605

After login: wait for 20+ secs

MIN(ID) MAX(ID) COUNT(*)
---------- ---------- ----------
29544401 29563005 18605

Scenario: Study Index is not refreshed for every login session of user

1. mayo-super-user is initially logged out
2. Check ID range of mayo-super-user in Study index
3. mayo-super-user logs in to caaers
4. Check ID range of mayo-super-user in Study index

Expected:
ID range is the same before and after logging in

```
SQL statements:
select min(id), max(id), count\(*) from study_index where login_id ='mayo-super-user'  order by id
```

Before login:

MIN(ID) MAX(ID) COUNT(*)
---------- ---------- ----------
1612141 1613778 1638

After login: wait for 20+ secs

MIN(ID) MAX(ID) COUNT(*)
---------- ---------- ----------
1612141 1613778 1638

Scenario: Subject Index is not refreshed for every login session of user

1. mayo-super-user is initially logged out
2. Check ID range of mayo-super-user in Subject index
3. mayo-super-user logs in to caaers
4. Check ID range of mayo-super-user in Subject index

Expected:
ID range is the same before and after logging in

```
SQL statements:
select min(id), max(id), count(*) from PARTICIPANT_INDEX where login_id ='mayo-super-user'  order by
id
```

Before login:

MIN(ID) MAX(ID) COUNT
---------- ---------- ----------
3893461 3993503 5003

After login: wait for 20+ secs

MIN(ID) MAX(ID) COUNT
---------- ---------- ----------
3893461 3993503 5003

Scenario: Adverse Event Index is not refreshed for every login session of user

1. mayo-super-user is initially logged out

2. Check ID range of mayo-super-user in Adverse Event index
3. mayo-super-user logs in to caaers
4. Check ID range of mayo-super-user in Adverse Event index

Expected:ID range is the same before and after logging in

```
SQL statements:
select min(id), max(id), count(*) from ADVERSEEVENT_INDEX where login_id='mayo-super-user'  order by
id
```

Before login:

MIN(ID) MAX(ID) COUNT

426461 427530 1070

After login: wait for 20+ secs

MIN(ID) MAX(ID) COUNT

426461 427530 1070

Scenario: Org Index is refreshed when org is added to user

1. User is logged in as SYSTEM_ADMIN
2. User adds org to mayo-super-user Hospital Militar Central (02002)
3. All roles are selected
4. Check ID range of mayo-super-user in org index
5. SYSTEM_ADMIN logs out of caaers
6. mayo-super-user logs in to caaers
7. Check ID range of mayo-super-user in org index

Expected:ID range after login is different from before login. count of the records increases.

```
SQL statements:
select min(id), max(id), count(*) from organization_index where login_id ='mayo-super-user'  order by
id
```

Before login:

MIN(ID) MAX(ID) COUNT

29544401 29563005 18605

After login: wait for 20+ secs

MIN(ID) MAX(ID) COUNT

29544401 30389467 18612

Scenario: Study Index is refreshed when user is de-activated from study

1. User is logged in as SYSTEM_ADMIN
2. User edits study N027D
3. wayne AE reporter is associated to the study as AE Reporter at Wayne State University.
4. This study personnel is de-activated
5. Check ID range of wayne-ae-reporter in Study index
6. SYSTEM_ADMIN logs out of caaers
7. wayne-ae-reporter logs in to caaers
8. Check ID range of wayne-ae-reporter in Study index

Expected: ID range after login is different from before login. count of the records decreases.

```
SQL statements:
select min(id), max(id), count(*) from study_index where login_id ='wayne-ae-reporter'
```

Before login:

MIN(ID) MAX(ID) COUNT
---------- ---------- ----------
1502441 1502442 2

After login: wait for 20+ secs

MIN(ID) MAX(ID) COUNT
---------- ---------- ----------
1502442 1502442 1

Scenario: Subject Index is refreshed when user is de-activated from study

1. User is logged in as SYSTEM_ADMIN
2. User edits study N027D
3. wayne AE reporter is associated to the study as AE Reporter at Wayne State University.
4. This study personnel is de-activated
5. Check ID range of wayne-ae-reporter in Subject index
6. SYSTEM_ADMIN logs out of caaers
7. wayne-ae-reporter logs in to caaers
8. Check ID range of wayne-ae-reporter in Subject index

Expected: ID range after login is different from before login. count of the records decreases.

```
SQL statements:
select min(id), max(id), count(*) from PARTICIPANT_INDEX where login_id ='wayne-ae-reporter '  order
by id
```

Before login:

MIN(ID) MAX(ID) COUNT
---------- ---------- ----------
3341021 3341022 2

After login: wait for 20+ secsMIN(ID) MAX(ID) COUNT

---------- ---------- ----------
3341022 3341022 1

Scenario: Adverse Event Index is refreshed when user is de-activated from study

1. User is logged in as SYSTEM_ADMIN
2. User edits study N027D
3. wayne AE reporter is associated to the study as AE Reporter at Wayne State University.
4. This study personnel is de-activated
5. Check ID range of wayne-ae-reporter in Adverse Event index
6. SYSTEM_ADMIN logs out of caaers
7. wayne-ae-reporter logs in to caaers
8. Check ID range of wayne-ae-reporter in Adverse Event index

Expected: ID range after login is different from before login. count of the records decreases.

```
SQL statements:
select min(id), max(id), count(*) from ADVERSEEVENT_INDEX where login_id='wayne-ae-reporter'  order by
id
```

Before login:

MIN(ID) MAX(ID) COUNT

355761 355826 66

After login: wait for 20+ secs

MIN(ID) MAX(ID) COUNT

355762 355826 63

Before login:

After login: wait for 20+ secs

Testing User Roles and Rights (NCI)-- AE coordinator -- Coordinating Center

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

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 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 privledges.
- **Subject Coordinator** - Study level filter applies to all application privledges.

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

Data used:

Research Staff Details

Organization type: Study Site

Research Staff Details
Organization:
Mayo Clinic Rochester (MN026)
First Name:
ae-coord-fn-1-cc
Last Name:
ae-coord-ln-1-cc
Middle Name:
Researcher ID:
Email address:
caaers.app9@gmail.com
Phone:
0000000000
Fax:
User Roles

1. Adverse event coordinator

password: asdfg123!

Assigned to study: 7848

Study N027D is used for negative scenarios
Coordinating center
North Central Cancer Treatment Group

AE module	**AE Coordinator**				
	7848 Expected	**7848 Actual**	**N027D Expected**	**N027D Actual**	**Comments**
AE module tab	✓	✓	✗	✗	
Enter AEs • enter routine AE's • enter SAEs and create expedited reports	✓ (for assigned studies)	✗	✗	✗	http://jira.semanticbits.com/browse/CAAERS-2226\\ http://jira.semanticbits.com/browse/CAAERS-2227
View AE's and manage reports • view details of evaluation periods, expedited reports, and routine AEs • Print / view PDFs of expedited reports • View expedited report in AdEERS • Links from Manage reports (Submit, Amend, Withdraw, and report to PSC; hyperlink of expedited report and evaluation period) - not site or study coordinator	✓ (for assigned studies)	✓	✗	✗	
Submit AE reports	✗ (when workflow is enabled)	✗	✗	✗	
Studies module	**AE Coordinator**				
Studies module tab	✗	✗	✗	✗	

Create Study	✗	✗	✗	✗	
Edit Study	✗	✗	✗	✗	
View Study	✗	✗	✗	✗	
Search Studies	✗	✗	✗	✗	
Subjects module	**AE Coordinator**				
Subjects Module tab	✗	✗	✗	✗	
Create and Assign Subject	✗	✗	✗	✗	
Assign a Subject to a Study (Subject already created)	✗	✗	✗	✗	
View Subject	✗	✗	✗	✗	
Search Subject	✗	✗	✗	✗	
Advanced Search module	**AE Coordinator**				
Advanced Search module tab	✓	✓	✗	✗	**The tab is not shown**
Study Search	✗	✗	✗	✗	
Subject Search	✗	✗	✗	✗	
Expedited Report Search	✓ (for assigned studies)	✓	✗	✗	
Rules module	**AE Coordinator**				
Rules module tab	✗	✗	✗	✗	
Create Rule	✗	✗	✗	✗	
Edit Rule	✗	✗	✗	✗	
Create Report Definition	✗	✗	✗	✗	
Edit Report Definition	✗	✗	✗	✗	
View Report Definition	✗	✗	✗	✗	
Admin module	**AE Coordinator**				
Admin module tab	✗	✗	✗	✗	
create/edit/search Organization	✗	✗	✗	✗	
create/edit/search Research Staff	✗	✗	✗	✗	

configure caAERS	✖	✖	✖	✖	
create/edit/search Investigator	✖	✖	✖	✖	
Import Medra	✖	✖	✖	✖	
IND	✖	✖	✖	✖	
password policy	✖	✖	✖	✖	
Import Study, Subject, ~~Routine AE~~, Research Staff, Investigator	✖	✖	✖	✖	

Testing User Roles and Rights (NCI) -- Site coordinator -- Coordinating center

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

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 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 privledges.
- **Subject Coordinator** - Study level filter applies to all application privledges.

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

Data used:

Research Staff Details

Organization type: Study Site

Research Staff Details
Organization:

Mayo Clinic Rochester (MN026)
First Name:
ae-coord-fn-4-cc
Last Name:
ae-coord-ln-4-cc
Middle Name:
Researcher ID:
Email address:
caaers.app6@gmail.com
Phone:
0000000000
Fax:
User Roles

1. Site coordinator

password: asdfg123!

Assigned to study: 7848

Study N027D is used for negative scenarios

Coordinating center
North Central Cancer Treatment Group

AE module	**Site Coordinator**				
	7848 Expected	**7848 Actual**	**N027D Expected**	**N027D Expected**	**Comments**
AE module tab	✓				
Enter AEs • enter routine AE's • enter SAEs and create expedited reports	✗	✗	✗	✗	
View AE's and manage reports • view details of evaluation periods, expedited reports, and routine AEs • Print / view PDFs of expedited reports • View expedited report in AdEERS • Links from Manage reports (Submit, Amend, Withdraw, and report to PSC; hyperlink of expedited report and evaluation period) - not site or study coordinator	✓	✗	✗	✗	http://jira.semanticbits.com/browse/CAAERS-2213
Submit AE reports	✗	✗	✗	✗	
Studies module	**Site Coordinator**				
Studies module tab	✓				
Create Study	✓	✓	✗	✗	http://jira.semanticbits.com/browse/CAAERS-2214
Edit Study	✓	✓	✗	✗	

View Study	✓	✓	✗	✗	
Search Studies	✓	✓	✗	✗	
Subjects module	**Site Coordinator**				
Subjects Module tab	✓				
Create and Assign Subject	✓	✓	✗	✗	
Assign a Subject to a Study (Subject already created)	✓	✓	✗	✗	
View Subject	✓	✓	✗	✗	
Search Subject	✓	✓	✗	✗	
Advanced Search module	**Site Coordinator**				
Advanced Search module tab	✓	✓	✗	✗	
Study Search	✓	✗	✗	✗	http://jira.semanticbits.com/browse/CAAERS-2215
Subject Search	✓	✓	✗	✗	
Expedited Report Search	✓	✓	✗	✗	
Rules module	**Site Coordinator**				
Rules module tab	✓				
Create Rule	✓	✓	✗	✓	
Edit Rule	✓	✓	✗	✓	http://jira.semanticbits.com/browse/CAAERS-2218
Create Report Definition	✓	✗		✓	http://jira.semanticbits.com/browse/CAAERS-2216
Edit Report Definition	✓	✓	✗	✓	http://jira.semanticbits.com/browse/CAAERS-2217
View Report Definition	✓	✓	✗	✓	
Admin module	**Site Coordinator**				
Admin module tab	✓				
create/edit/search Organization	✓	✓	✗	✓	http://jira.semanticbits.com/browse/CAAERS-2218
create/edit/search Research Staff	✓	✓	✗	✓	http://jira.semanticbits.com/browse/CAAERS-2224
configure caAERS	✓	✓	NA		
create/edit/search Investigator	✓	✓	✗	✓	
Import Medra	✓				http://jira.semanticbits.com/browse/CAAERS-2225
IND	✓	✓	✗	✓	

password policy	✓	✓	NA		
Import Study, Subject, ~~Routine AE~~, Research Staff, Investigator	✓		✗		

Testing User Roles and Rights (NCI) -- Study coordinator -- Coordinating Center

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

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 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 privledges.
- **Subject Coordinator** - Study level filter applies to all application privledges.

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

Data used:

Research Staff Details

Organization type: Study Site

Research Staff Details
Organization:
Mayo Clinic Rochester (MN026)
First Name:
ae-coord-fn-2-cc
Last Name:
ae-coord-ln-2-cc
Middle Name:
Researcher ID:
Email address:
caaers.app8@gmail.com

Phone:
0000000000
Fax:
User Roles

1. Study coordinator

password: asdfg123!

Assigned to study: 7848

Organization type: Study Site

Study N027D is used for negative scenarios

Coordinating center
North Central Cancer Treatment Group

AE module	**Study Coordinator**				
	7848 Expected	**7848 Actual**	**N027D Expected**	**N027D Actual**	**Comments**
AE module tab	✓	✓			
Enter AEs • enter routine AE's • enter SAEs and create expedited reports	✗	✗	✗	✗	
View AE's and manage reports • view details of evaluation periods, expedited reports, and routine AEs • Print / view PDFs of expedited reports • View expedited report in AdEERS • Links from Manage reports (Submit, Amend, Withdraw, and report to PSC; hyperlink of expedited report and evaluation period) - not site or study coordinator	✓	✗	✗	✗	http://jira.semanticbits.com/browse/CAAERS-2209
Submit AE report	✗	✗	✗	✗	
Studies module	**Study Coordinator**				
Studies module tab	✓	✓			
Create Study	✓	✓	✗	✓	http://jira.semanticbits.com/browse/CAAERS-2211
Edit Study	✓	✓	✗	✗	
View Study	✓	✓	✗	✗	
Search Studies	✓	✓	✗	✗	
Subjects module	**Study Coordinator**				

Subjects Module tab	✅				
Create and Assign Subject	❌	❌	❌	❌	
Assign a Subject to a Study (Subject already created)	✅ (for assigned studies)	✅	❌	❌	
View Subject	✅ (for assigned studies)	✅	❌	❌	
Search Subject	✅ (for assigned studies)	✅	❌	❌	
Advanced Search module	**Study Coordinator**				
Advanced Search module tab	✅	✅			
Study Search	✅	❌	❌	❌	http://jira.semanticbits.com/browse/CAAERS-2212
Subject Search	✅ (for assigned studies)	✅	❌	❌	
Expedited Report Search	✅ (for assigned studies)	✅	❌	❌	
Rules module	**Study Coordinator**				
Rules module tab	❌	❌			
Create Rule	❌	❌	❌	❌	
Edit Rule	❌	❌	❌	❌	
Create Report Definition	❌	❌	❌	❌	
Edit Report Definition	❌	❌	❌	❌	
View Report Definition	❌	❌	❌	❌	
Admin module	**Study Coordinator**				
Admin module tab	❌	❌			
create/edit/search Organization	❌	❌	❌	❌	
create/edit/search Research Staff	❌	❌	❌	❌	
configure caAERS	❌	❌	❌	❌	
create/edit/search Investigator	❌	❌	❌	❌	
Import Medra	❌	❌	❌	❌	
IND	❌	❌	❌	❌	

password policy	✖	✖	✖	✖	
Import Study, Subject, ~~Routine AE~~, Research Staff, Investigator	✖	✖	✖	✖	

Testing User Roles and Rights (NCI) -- Subject coordinator -- Coordinating Center

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

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 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 privledges.
- **Subject Coordinator** - Study level filter applies to all application privledges.

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

Data used:

Research Staff Details

Organization type: Study Site

Research Staff Details

Organization:
Mayo Clinic Rochester (MN026)
First Name:
ae-coord-fn-3-cc
Last Name:
ae-coord-ln-3-cc
Middle Name:

Researcher ID:
Email address:
caaers.app7@gmail.com
Phone:
0000000000
Fax:

User Roles

Subject coordinator

password: asdfg123!

Assigned to study: 7848

Study N027D is used for negative scenarios

Coordinating center
North Central Cancer Treatment Group

AE module	**Subject Coordinator**				
	7848 Expected	**7848 Actual**	**N027D Expected**	**N027D Actual**	**Comments**
AE module tab	✓	✓	--	--	
Enter AEs • enter routine AE's • enter SAEs and create expedited reports	✓ (for assigned studies)		✗	✗	http://jira.semanticbits.com/browse/CAAERS-2203\\ http://jira.semanticbits.com/browse/CAAERS-2204
View AE's and manage reports • view details of evaluation periods, expedited reports, and routine AEs • Print / view PDFs of expedited reports • View expedited report in AdEERS • Links from Manage reports (Submit, Amend, Withdraw, and report to PSC; hyperlink of expedited report and evaluation period) - not site or study coordinator	✓ (for assigned studies)	✓	✗	✗	
Submit AE reports	✗ (when workflow is enabled)	✗	✗	✗	
Studies module	**Subject Coordinator**				
Studies module tab	✓	✓			
Create Study	✗	✗	✗	✗	
Edit Study	✗	✗	✗	✗	
View Study	✓ (for assigned studies)	✓	✗	✗	

Search Studies	✓ (for assigned studies)	✓	✗	✗	
Subjects module	**Subject Coordinator**				
Subjects Module tab	✓	✓			
Create and Assign Subject	✓ (for assigned studies)	✓	✗	✗	http://jira.semanticbits.com/browse/CAAERS-2205
Assign a Subject to a Study (Subject already created)	✓ (for assigned studies)	✓	✗	✗	
View Subject	✓ (for assigned studies)	✓	✗	✗	
Search Subject	✓ (for assigned studies)	✓	✗	✗	
Advanced Search module	**Subject Coordinator**				
Advanced Search module tab	✓	✓			
Study Search	✓ (for assigned studies)	✗	✗	✗	http://jira.semanticbits.com/browse/CAAERS-2207
Subject Search	✓ (for assigned studies)	✓	✗	✗	
Expedited Report Search	✓ (for assigned studies)	✓	✗	✗	
Rules module	**Subject Coordinator**				
Rules module tab	✗	✗	✗	✗	
Create Rule	✗	✗	✗	✗	
Edit Rule	✗	✗	✗	✗	
Create Report Definition	✗	✗	✗	✗	
Edit Report Definition	✗	✗	✗	✗	
View Report Definition	✗	✗	✗	✗	
Admin module	**Subject Coordinator**				
Admin module tab	✗	✗	✗	✗	

create/edit/search Organization	✖	✖	✖	✖	
create/edit/search Research Staff	✖	✖	✖	✖	
configure caAERS	✖	✖	✖	✖	
create/edit/search Investigator	✖	✖	✖	✖	
Import Medra	✖	✖	✖	✖	
IND	✖	✖	✖	✖	
password policy	✖	✖	✖	✖	
Import Study, Subject, ~~Routine AE~~, Research Staff, Investigator	✖	✖	✖	✖	

Testing User Roles and Rights -- AE coordinator

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

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 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 privledges.
- **Subject Coordinator** - Study level filter applies to all application privledges.

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

Data used:

Research Staff Details

Organization type: Study Site

Organization:Johns Hopkins University (MD017)
First Name:ae-coord-fn-1
Last Name:ae-coord-ln-1
Middle Name:
Researcher ID:ae-coord1
Email address:caaers.app2@gmail.com
Phone:0000000000
Fax:
User Roles
Adverse event coordinator

password: asdfg123!

Assigned to study: 7848

Participant details #1

First name
jim
Last name
baker
Maiden name
Middle name
Date of birth
09/15/2008
Ethnicity
Hispanic or Latino
Race
Asian
Gender
Male
Identifiers
Assigning Authority Identifier Type Identifier
Cancer Therapy Evaluation Program MRN mrn-pt1

Study Subject Assignments
Study Primary ID Study Short Title Site Study Subject Identifier
7848 A Phase II Trial of Intravenous Administration of Reovirus Serotype 3 - Dearing Strain (Reolysin®) in Patients with Metastatic Melanoma
Washington University School of Medicine
ssi1

Participant details #2

First name
dean
Last name
white
Maiden name
Middle name

Date of birth
08/04/2008
Ethnicity
Hispanic or Latino
Race
Asian
Gender
Male
Identifiers
Assigning Authority Identifier Type Identifier
Cancer Therapy Evaluation Program MRN mrn-pt2

Study Subject Assignments
Study Primary ID Study Short Title Site Study Subject Identifier
7848 A Phase II Trial of Intravenous Administration of Reovirus Serotype 3 - Dearing Strain (Reolysin®) in Patients with Metastatic Melanoma
Johns Hopkins University
ssi2

AE module	**AE Coordinator**		
	Expected	**Actual**	**Comments**
AE module tab	✅	✅	
document AEs • evaluation periods • expedited reports • Link from Manage report (when no AEs have been documented yet)	✅ (for assigned studies)	❌	Access is denied error http://jira.semanticbits.com/browse/CAAERS-1449
edit AEs • evaluation periods • expedited report • Links from Manage reports (Submit, Amend, Withdraw, and report to PSC; hyperlink of expedited report and evaluation period)	✅ (for assigned studies)	❌	Access is denied error
View manage reports • view details of evaluation periods, expedited reports, and routine AEs • Print PDFs of expedited reports • View expedited report in AdEERS	✅ (for assigned studies)	❌	Access is denied error
Studies module	**AE Coordinator**		
Studies module tab	❌	❌	
Create Study	❌	❌	
Edit Study	❌	❌	
View Study	❌	❌	
Search Studies	❌	❌	
Subjects module	**AE Coordinator**		
Subjects Module tab	❌	❌	
Create and Assign Subject	❌	❌	
Assign a Subject to a Study (Subject already created)	❌	❌	
View Subject	❌	❌	
Search Subject	❌	❌	
Advanced Search module	**AE Coordinator**		
Advanced Search module tab	✅	❌	**The tab is not shown.** **http://jira.semanticbits.com/browse/CAAERS-1452**
Study Search	❌	❌	

Subject Search	✗	✗	
Expedited Report Search	✓ (for assigned studies)	✗	http://jira.semanticbits.com/browse/CAAERS-1452
Rules module	**AE Coordinator**		
Rules module tab	✗	✗	
Create Rule	✗	✗	
Edit Rule	✗	✗	
Create Report Definition	✗	✗	
Edit Report Definition	✗	✗	
View Report Definition	✗	✗	
Admin module	**AE Coordinator**		
Admin module tab	✗	✗	
create/edit/search Organization	✗	✗	
create/edit/search Research Staff	✗	✗	
configure caAERS	✗	✗	
create/edit/search Investigator	✗	✗	
Import Medra	✗	✗	
IND	✗	✗	
password policy	✗	✗	
Import Study, Subject, ~~Routine AE~~, Research Staff, Investigator	✗	✗	

Testing User Roles and Rights -- AE coordinator -- Coordinating Center

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

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 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 privledges.
- **Subject Coordinator** - Study level filter applies to all application privledges.

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

Data used:

Research Staff Details

Organization type: Study Site

Research Staff Details
Organization:
Mayo Clinic Rochester (MN026)
First Name:
ae-coord-fn-1-cc
Last Name:
ae-coord-ln-1-cc
Middle Name:
Researcher ID:
Email address:
caaers.app9@gmail.com
Phone:
0000000000
Fax:
User Roles

1. Adverse event coordinator

password: asdfg123!

Assigned to study: 7848

Participant details #1

First name
jim
Last name
baker
Maiden name
Middle name
Date of birth
09/15/2008
Ethnicity
Hispanic or Latino
Race
Asian
Gender
Male

Identifiers
Assigning Authority Identifier Type Identifier
Cancer Therapy Evaluation Program MRN mrn-pt1

Study Subject Assignments
Study Primary ID Study Short Title Site Study Subject Identifier
7848 A Phase II Trial of Intravenous Administration of Reovirus Serotype 3 - Dearing Strain (Reolysin®) in Patients with Metastatic Melanoma Washington University School of Medicine
ssi1

Participant details #2

First name
dean
Last name
white
Maiden name
Middle name

Date of birth
08/04/2008
Ethnicity
Hispanic or Latino
Race
Asian
Gender
Male
Identifiers
Assigning Authority Identifier Type Identifier
Cancer Therapy Evaluation Program MRN mrn-pt2

Study Subject Assignments
Study Primary ID Study Short Title Site Study Subject Identifier
7848 A Phase II Trial of Intravenous Administration of Reovirus Serotype 3 - Dearing Strain (Reolysin®) in Patients with Metastatic Melanoma Johns Hopkins University
ssi2

AE module	**AE Coordinator**		
	Expected	**Actual**	**Comments**
AE module tab	✓	✗	**"Access is denied" pop up**
document AEs • evaluation periods • expedited reports • Link from Manage report (when no AEs have been documented yet)	✓ (for assigned studies)	✗	http://jira.semanticbits.com/browse/CAAERS-1469
edit AEs • evaluation periods • expedited report • Links from Manage reports (Submit, Amend, Withdraw, and report to PSC; hyperlink of expedited report and evaluation period)	✓ (for assigned studies)	✗	http://jira.semanticbits.com/browse/CAAERS-1469
View manage reports • view details of evaluation periods, expedited reports, and routine AEs • Print PDFs of expedited reports • View expedited report in AdEERS	✓ (for assigned studies)	✗	http://jira.semanticbits.com/browse/CAAERS-1469
Studies module	**AE Coordinator**		

Studies module tab	✗	✗	
Create Study	✗	✗	
Edit Study	✗	✗	
View Study	✗	✗	
Search Studies	✗	✗	
Subjects module	**AE Coordinator**		
Subjects Module tab	✗	✗	
Create and Assign Subject	✗	✗	
Assign a Subject to a Study (Subject already created)	✗	✗	
View Subject	✗	✗	
Search Subject	✗	✗	
Advanced Search module	**AE Coordinator**		
Advanced Search module tab	✓	✗	**The tab is not shown**
Study Search	✗	✗	http://jira.semanticbits.com/browse/CAAERS-1470
Subject Search	✗	✗	http://jira.semanticbits.com/browse/CAAERS-1470
Expedited Report Search	✓ (for assigned studies)	✗	
Rules module	**AE Coordinator**		
Rules module tab	✗	✗	
Create Rule	✗	✗	
Edit Rule	✗	✗	
Create Report Definition	✗	✗	
Edit Report Definition	✗	✗	
View Report Definition	✗	✗	
Admin module	**AE Coordinator**		
Admin module tab	✗	✗	
create/edit/search Organization	✗	✗	
create/edit/search Research Staff	✗	✗	
configure caAERS	✗	✗	
create/edit/search Investigator	✗	✗	
Import Medra	✗	✗	

IND	✖	✖	
password policy	✖	✖	
Import Study, Subject, ~~Routine AE~~, Research Staff, Investigator	✖	✖	

Testing User Roles and Rights -- Site coordinator

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

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 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 privledges.
- **Subject Coordinator** - Study level filter applies to all application privledges.

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

Data used:

Research Staff Details

Organization type: Study Site

Organization:
Johns Hopkins University (MD017)
First Name:
ae-coord-fn-4
Last Name:
ae-coord-ln-4
Middle Name:
Researcher ID:
Email address:

caaers.app5@gmail.com
Phone:
0000000000
Fax:
User Roles

1. Site coordinator

password: asdfg123!

Assigned to study: 7848

AE module	**Site Coordinator**		
	Expected	**Actual**	**Comments**
AE module tab	✓	✓	
document AEs • evaluation periods • expedited reports • Link from Manage report (when no AEs have been documented yet)	✗	✗	
edit AEs • evaluation periods • expedited report • Links from Manage reports (Submit, Amend, Withdraw, and report to PSC; hyperlink of expedited report and evaluation period)	✗	✗	
View manage reports • view details of evaluation periods, expedited reports, and routine AEs • Print PDFs of expedited reports • View expedited report in AdEERS	✓	✓	
Studies module	**Site Coordinator**		
Studies module tab	✓		
Create Study	✓	✗	User can create study with any study site [CTMS:test-hosting-study2 with Study Site as Prince of Wales Hospital] http://jira.semanticbits.com/browse/CAAERS-1461
Edit Study	✓	✓	
View Study	✓	✓	
Search Studies	✓	✓	
Subjects module	**Site Coordinator**		
Subjects Module tab	✓	✓	

Create and Assign Subject	✓	✗	http://jira.semanticbits.com/browse/CAAERS-1462 Was able to create and assign test-pt-fn5 to Study 5351with study site Cancer Therapy Evaluation Program
Assign a Subject to a Study (Subject already created)	✓	✗	http://jira.semanticbits.com/browse/CAAERS-1464
View Subject	✓	✗	http://jira.semanticbits.com/browse/CAAERS-1463 User should not be able to view Jim Baker assigned to study 7848 with his study site as CTEP
Search Subject	✓	✗	http://jira.semanticbits.com/browse/CAAERS-1463 User should not be able to view Jim Baker assigned to study 7848 with his study site as CTEP
Advanced Search module	**Site Coordinator**		
Advanced Search module tab	✓	✓	
Study Search	✓	✓	
Subject Search	✓	✗	All participants belonging to the study which has one of the study sites as the user's organization are shown. User should not be able to view Jim Baker assigned to study 7848 with his study site as CTEP. http://jira.semanticbits.com/browse/CAAERS-1491
Expedited Report Search	✓	✓	
Rules module	**Site Coordinator**		
Rules module tab	✓	✓	
Create Rule	✓	✓	
Edit Rule	✓	✓	
Create Report Definition	✓	✓	
Edit Report Definition	✓	✓	
View Report Definition	✓	✓	
Admin module	**Site Coordinator**		
Admin module tab	✓		
create/edit/search Organization	✓	✗	create -- denied, search -- all organizations shown edit -- unable to edit and save due to caaers error: 'Nci Identifier already exits in the datbase...!' http://jira.semanticbits.com/browse/CAAERS-1492
create/edit/search Research Staff	✓	✗	create -- can create for any Research Staff search -- all Research Staffshown, edit -- unable to edit and save due to caaers error: 'EmailAddress already in use' http://jira.semanticbits.com/browse/CAAERS-1493
configure caAERS	✓	✓	
create/edit/search Investigator	✓	✓	
Import Medra	✓	✓	
IND	✓	✓	

password policy			Unable to test
Import Study, Subject, ~~Routine AE~~, Research Staff, Investigator			

Testing User Roles and Rights -- Site coordinator -- Coordinating center

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

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 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 privledges.
- **Subject Coordinator** - Study level filter applies to all application privledges.

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

Data used:

Research Staff Details

Organization type: Study Site

Research Staff Details
Organization:
Mayo Clinic Rochester (MN026)
First Name:
ae-coord-fn-4-cc
Last Name:
ae-coord-ln-4-cc
Middle Name:
Researcher ID:
Email address:
caaers.app6@gmail.com

Phone:
0000000000
Fax:
User Roles

1. Site coordinator

password: asdfg123!

Assigned to study: 7848

AE module	**Site Coordinator**		
	Expected	**Actual**	**Comments**
AE module tab	✓	✓	
document AEs • evaluation periods • expedited reports • Link from Manage report (when no AEs have been documented yet)	✗	✗	
edit AEs • evaluation periods • expedited report • Links from Manage reports (Submit, Amend, Withdraw, and report to PSC; hyperlink of expedited report and evaluation period)	✗	✗	
View manage reports • view details of evaluation periods, expedited reports, and routine AEs • Print PDFs of expedited reports • View expedited report in AdEERS	✓	✓	
Studies module	**Site Coordinator**		
Studies module tab	✓	✓	
Create Study	✓	✗	-- Able to create study with any study site http://jira.semanticbits.com/browse/CAAERS-1471 -- Created Study 'test-hosting-study-3 ' with study site as American College of Surgeons Oncology Trials Group
Edit Study	✓	✓	
View Study	✓	✓	
Search Studies	✓	✓	
Subjects module	**Site Coordinator**		

Subjects Module tab	✓	✓	
Create and Assign Subject	✓	✓	
Assign a Subject to a Study (Subject already created)	✓	✗	No participants were shown in Assign a Subject to a Study>>Search subject. [CTMS:expected= test-pt-fn6 assigned to Johns Hopkins University] http://jira.semanticbits.com/browse/CAAERS-1472
View Subject	✓	✗	Able to search and view subjects from other sites. http://jira.semanticbits.com/browse/CAAERS-1473 -- Monish Dombla is assigned to study MAY07-9-01 . MAY07-9-01 coordinating center is Mayo .This is shown correctly -- grady booth assigned to N0177 should not be shown as N0177 Does not have Mayo as coordinating center or study site.This is functioning correctly -- The study WFCCC001 has mayo as one of the study sites. However Richard herd belongs to the CTEP study site and should not be shown.This is functioning incorrectly
Search Subject	✓	✗	Able to search and view subjects from other sites. http://jira.semanticbits.com/browse/CAAERS-1473
Advanced Search module	**Site Coordinator**		
Advanced Search module tab	✓	✓	
Study Search	✓	✗	http://jira.semanticbits.com/browse/CAAERS-1474 -- N027D should be shown because Mayo is study site of N027. This is functioning correctly. -- User is not able to search or view study N0177. mayo is not the coordinating center or study site for this study.This is functioning correctly.
Subject Search	✓	✗	-- http://jira.semanticbits.com/browse/CAAERS-1475 -- Barbara Brown is on N027D and assigned to DCP site.Mayo is not the coordinating center and she is not assigned to Mayo as a Study site. The user tested should not be able to see this subject. This is not functioning correctly.
Expedited Report Search	✓	✗	-- http://jira.semanticbits.com/browse/CAAERS-1476 -- The following AE should not be visible to the user. -- Vasculitis 5 Possible 01/01/2009 N0177 gb-001 -- This is because the study N0177 does not have mayo as study site or coordinating center.
Rules module	**Site Coordinator**		
Rules module tab	✓	✓	
Create Rule	✓	✓	
Edit Rule	✓	✓	
Create Report Definition	✓	✓	
Edit Report Definition	✓	✓	
View Report Definition	✓	✓	
Admin module	**Site Coordinator**		
Admin module tab	✓	✓	
create/edit/search Organization	✓	✗	create -- Access denied edit-- On save, get 'Nci Identifier already exits in the datbase...!' error search -- able to search all orgs http://jira.semanticbits.com/browse/CAAERS-1477

create/edit/search Research Staff	✓	✗	search -- able to search for research staff from all orgs. edit -- unable to edit 'EmailAddress already in use ' error. http://jira.semanticbits.com/browse/CAAERS-1478
configure caAERS	✓	✓	
create/edit/search Investigator	✓	✗	create -- able to create, but unable to pull up the same investigator search -- able to search for investigators from all orgs http://jira.semanticbits.com/browse/CAAERS-1479
Import Medra	✓	✓	
IND	✓	✓	
password policy	✓		
Import Study, Subject, ~~Routine AE~~, Research Staff, Investigator	✓	✓	

Testing User Roles and Rights -- Study coordinator

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

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 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 privledges.
- **Subject Coordinator** - Study level filter applies to all application privledges.

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

Data used:

Research Staff Details

Organization type: Study Site

Organization:Johns Hopkins University (MD017)
First Name:ae-coord-fn-2
Last Name:ae-coord-ln-2
Middle Name:
Researcher ID:
Email address:caaers.app3@gmail.com
Phone:0000000000
Fax:
User Roles
Study coordinator

password: asdfg123!

Assigned to study: 7848

Organization type: Study Site

Participant details #2

First name
dean
Last name
white
Maiden name
Middle name

Date of birth
08/04/2008
Ethnicity
Hispanic or Latino
Race
Asian
Gender
Male
Identifiers
Assigning Authority Identifier Type Identifier
Cancer Therapy Evaluation Program MRN mrn-pt2

Study Subject Assignments
Study Primary ID Study Short Title Site Study Subject Identifier
7848 A Phase II Trial of Intravenous Administration of Reovirus Serotype 3 - Dearing Strain (Reolysin®) in Patients with Metastatic Melanoma Johns Hopkins University
ssi2

AE module	**Study Coordinator**		
	Expected	**Actual**	**Comments**
AE module tab	✅	✅	
document AEs • evaluation periods • expedited reports • Link from Manage report (when no AEs have been documented yet)	❌	❌	

edit AEs • evaluation periods • expedited report • Links from Manage reports (Submit, Amend, Withdraw, and report to PSC; hyperlink of expedited report and evaluation period)	✗	✗	
View manage reports • view details of evaluation periods, expedited reports, and routine AEs • Print PDFs of expedited reports • View expedited report in AdEERS	✓ (for assigned studies)	✓	
Studies module	**Study Coordinator**		
Studies module tab	✓	✓	
Create Study	✓	?	User is able to create study with any organization as study site, not just their own http://jira.semanticbits.com/browse/CAAERS-1453
Edit Study	✓	✓	
View Study	✓	✓	
Search Studies	✓	✓	
Subjects module	**Study Coordinator**		
Subjects Module tab	✓	✗	**Tab is not shown http://jira.semanticbits.com/browse/CAAERS-1454**
Create and Assign Subject	✗	✗	http://jira.semanticbits.com/browse/CAAERS-1532
Assign a Subject to a Study (Subject already created)	✓ (for assigned studies)	✗	http://jira.semanticbits.com/browse/CAAERS-1531
View Subject	✓ (for assigned studies)	✓	
Search Subject	✓ (for assigned studies)	✓	
Advanced Search module	**Study Coordinator**		
Advanced Search module tab	✓	✓	
Study Search	✓	✓	
Subject Search	✓ (for assigned studies)	✗	All subjects belonging to the same study site as Study coordinator are shown http://jira.semanticbits.com/browse/CAAERS-1455
Expedited Report Search	✓ (for assigned studies)	✗	All AEs belonging to the same study site as Study coordinator are shown http://jira.semanticbits.com/browse/CAAERS-1456
Rules module	**Study Coordinator**		

Rules module tab	✗	✗	
Create Rule	✗	✗	
Edit Rule	✗	✗	
Create Report Definition	✗	✗	
Edit Report Definition	✗	✗	
View Report Definition	✗	✗	
Admin module	**Study Coordinator**		
Admin module tab	✗	✗	
create/edit/search Organization	✗	✗	
create/edit/search Research Staff	✗	✗	
configure caAERS	✗	✗	
create/edit/search Investigator	✗	✗	
Import Medra	✗	✗	
IND	✗	✗	
password policy	✗	✗	
Import Study, Subject, ~~Routine AE~~, Research Staff, Investigator	✗	✗	

Testing User Roles and Rights -- Study coordinator -- Coordinating Center

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

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 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 privledges.
- **Subject Coordinator** - Study level filter applies to all application privledges.

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

Data used:

Research Staff Details

Organization type: Study Site

Research Staff Details
Organization:
Mayo Clinic Rochester (MN026)
First Name:
ae-coord-fn-2-cc
Last Name:
ae-coord-ln-2-cc
Middle Name:
Researcher ID:
Email address:
caaers.app8@gmail.com
Phone:
0000000000
Fax:
User Roles

1. Study coordinator

password: asdfg123!

Assigned to study: 7848

Organization type: Study Site

Participant details #2

First name
dean
Last name
white
Maiden name
Middle name

Date of birth
08/04/2008
Ethnicity
Hispanic or Latino
Race
Asian
Gender
Male
Identifiers
Assigning Authority Identifier Type Identifier
Cancer Therapy Evaluation Program MRN mrn-pt2

Study Subject Assignments
Study Primary ID Study Short Title Site Study Subject Identifier
7848 A Phase II Trial of Intravenous Administration of Reovirus Serotype 3 - Dearing Strain (Reolysin®) in Patients with Metastatic Melanoma Johns Hopkins University
ssi2

AE module	**Study Coordinator**		
	Expected	**Actual**	**Comments**
AE module tab	✅	✅	
document AEs • evaluation periods • expedited reports • Link from Manage report (when no AEs have been documented yet)	❌	❌	
edit AEs • evaluation periods • expedited report • Links from Manage reports (Submit, Amend, Withdraw, and report to PSC; hyperlink of expedited report and evaluation period)	❌	❌	
View manage reports • view details of evaluation periods, expedited reports, and routine AEs • Print PDFs of expedited reports • View expedited report in AdEERS	✅ (for assigned studies)	❌	User able to view AEs and other details for any study and participant in caaers. [ex: Barbara Brown on N027D] http://jira.semanticbits.com/browse/CAAERS-1480
Studies module	**Study Coordinator**		
Studies module tab	✅		
Create Study	✅	❌	User is able to create study for with any study site http://jira.semanticbits.com/browse/CAAERS-1481
Edit Study	✅	❌	User is able to edit all studies in caaers. [ex: n027D should not be editable] http://jira.semanticbits.com/browse/CAAERS-1482
View Study	✅	❌	User is able to view all studies in caaers. [ex: n027D should not be shown] http://jira.semanticbits.com/browse/CAAERS-1483
Search Studies	✅	❌	User is able to view all studies in caaers. [ex: n027D should not be shown] http://jira.semanticbits.com/browse/CAAERS-1483
Subjects module	**Study Coordinator**		
Subjects Module tab	✅	❌	**Subject module is not shown http://jira.semanticbits.com/browse/CAAERS-1484**
Create and Assign Subject	❌	❌	http://jira.semanticbits.com/browse/CAAERS-1534\\
Assign a Subject to a Study (Subject already created)	✅ (for assigned studies)	❌	http://jira.semanticbits.com/browse/CAAERS-1533

View Subject	✅ (for assigned studies)	❌	http://jira.semanticbits.com/browse/CAAERS-1535
Search Subject	✅ (for assigned studies)	❌	http://jira.semanticbits.com/browse/CAAERS-1535
Advanced Search module	**Study Coordinator**		
Advanced Search module tab	✅	✅	
Study Search	✅	❌	All studies are shown. [ex: N027D should not be shown] http://jira.semanticbits.com/browse/CAAERS-1486
Subject Search	✅ (for assigned studies)	❌	All subjects are shown. [ex: Barbara Brown assigned to DCP] http://jira.semanticbits.com/browse/CAAERS-1487
Expedited Report Search	✅ (for assigned studies)	❌	All AEs are shown. [ex: AEs for N027D are shown] http://jira.semanticbits.com/browse/CAAERS-1488
Rules module	**Study Coordinator**		
Rules module tab	❌	❌	
Create Rule	❌	❌	
Edit Rule	❌	❌	
Create Report Definition	❌	❌	
Edit Report Definition	❌	❌	
View Report Definition	❌	❌	
Admin module	**Study Coordinator**		
Admin module tab	❌	❌	
create/edit/search Organization	❌	❌	
create/edit/search Research Staff	❌	❌	
configure caAERS	❌	❌	
create/edit/search Investigator	❌	❌	
Import Medra	❌	❌	
IND	❌	❌	
password policy	❌	❌	
Import Study, Subject, ~~Routine AE~~, Research Staff, Investigator	❌	❌	

Testing User Roles and Rights -- Subject coordinator

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

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: Viewable records are based upon filter with respect to the content to which an organization should have access. Organization filtering applies to ALL roles regardless of study assignment 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 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: *A sub-filter to Organization based filtering. Only records associated with the study should be viewable. This is a sub-filtering of organization filtering, thus all organization level filters also apply (i.e. study filtering indicates that a user can only view the content for their study site and for the studies to which they are assigned).

- **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 privledges.
- **Subject Coordinator** - Study level filter applies to all application privledges.

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

Data used:

Research Staff Details

Organization type: Study Site

Organization:
Johns Hopkins University (MD017)
First Name:
ae-coord-fn-3
Last Name:
ae-coord-ln-3
Middle Name:
Researcher ID:
Email address:
caaers.app4@gmail.com
Phone:
0000000000
Fax:
User Roles

1. Subject coordinator

password: asdfg123!

Assigned to study: 7848

AE module	**Subject Coordinator**		
	Expected	**Actual**	**Comments**
AE module tab	✓	✓	
document AEs • evaluation periods • expedited reports • Link from Manage report (when no AEs have been documented yet)	✓ (for assigned studies)	✗	Auto-suggest does not respond to user input. hence user is not able to enter these flows. http://jira.semanticbits.com/browse/CAAERS-1457
edit AEs • evaluation periods • expedited report • Links from Manage reports (Submit, Amend, Withdraw, and report to PSC; hyperlink of expedited report and evaluation period)	✓ (for assigned studies)	✗	http://jira.semanticbits.com/browse/CAAERS-1457
View manage reports • view details of evaluation periods, expedited reports, and routine AEs • Print PDFs of expedited reports • View expedited report in AdEERS	✓ (for assigned studies)	✗	http://jira.semanticbits.com/browse/CAAERS-1457
Studies module	**Subject Coordinator**		
Studies module tab	✓	✓	
Create Study	✗	✗	
Edit Study	✗	✗	
View Study	✓ (for assigned studies)	?	User can edit the study from view mode, by clicking continue button http://jira.semanticbits.com/browse/CAAERS-1432
Search Studies	✓ (for assigned studies)	✓	
Subjects module	**Subject Coordinator**		
Subjects Module tab	✓	✓	

Create and Assign Subject	✓ (for assigned studies)	✗	Subject coordinator can create participant belonging to any study site and assign to any study with that study site. [CTMS: test-pt-fn assgined to N027D] http://jira.semanticbits.com/browse/CAAERS-1458
Assign a Subject to a Study (Subject already created)	✓ (for assigned studies)	✗	No participants are returned in Assign a Subject to a Study>>Search subject. [CTMS:expected = test-pt-ln3] http://jira.semanticbits.com/browse/CAAERS-1459
View Subject	✓ (for assigned studies)	✗	Subject coordinator can view all participants of the study. [CTMS:jim baker on 7848] http://jira.semanticbits.com/browse/CAAERS-1460
Search Subject	✓ (for assigned studies)	✗	Subject coordinator can search all participants of the study. [CTMS:jim baker on 7848] http://jira.semanticbits.com/browse/CAAERS-1460
Advanced Search module	**Subject Coordinator**		
Advanced Search module tab	✓	✓	
Study Search	✓ (for assigned studies)	✓	
Subject Search	✓ (for assigned studies)	✗	Subject coordinator can search all participants of the study http://jira.semanticbits.com/browse/CAAERS-1460
Expedited Report Search	✓ (for assigned studies)	✓	
Rules module	**Subject Coordinator**		
Rules module tab	✗	✗	
Create Rule	✗	✗	
Edit Rule	✗	✗	
Create Report Definition	✗	✗	
Edit Report Definition	✗	✗	
View Report Definition	✗	✗	
Admin module	**Subject Coordinator**		
Admin module tab	✗	✗	
create/edit/search Organization	✗	✗	
create/edit/search Research Staff	✗	✗	

configure caAERS	✗	✗	
create/edit/search Investigator	✗	✗	
Import Medra	✗	✗	
IND	✗	✗	
password policy	✗	✗	
Import Study, Subject, ~~Routine AE~~, Research Staff, Investigator	✗	✗	

Testing User Roles and Rights -- Subject coordinator -- Coordinating Center

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

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 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 privledges.
- **Subject Coordinator** - Study level filter applies to all application privledges.

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

Data used:

Research Staff Details

Organization type: Study Site

Research Staff Details

Organization:
Mayo Clinic Rochester (MN026)
First Name:
ae-coord-fn-3-cc
Last Name:
ae-coord-ln-3-cc
Middle Name:
Researcher ID:
Email address:
caaers.app7@gmail.com
Phone:
0000000000
Fax:

User Roles

Subject coordinator

password: asdfg123!

Assigned to study: 7848

AE module	**Subject Coordinator**		
	Expected	**Actual**	**Comments**
AE module tab	✅	✅	
document AEs • evaluation periods • expedited reports • Link from Manage report (when no AEs have been documented yet)	✅ (for assigned studies)	✅	
edit AEs • evaluation periods • expedited report • Links from Manage reports (Submit, Amend, Withdraw, and report to PSC; hyperlink of expedited report and evaluation period)	✅ (for assigned studies)	✅	
View manage reports • view details of evaluation periods, expedited reports, and routine AEs • Print PDFs of expedited reports • View expedited report in AdEERS	✅ (for assigned studies)	✅	
Studies module	**Subject Coordinator**		
Studies module tab	✅	✅	
Create Study	❌	❌	
Edit Study	❌	❌	

View Study	✓ (for assigned studies)	✓	
Search Studies	✓ (for assigned studies)	✓	
Subjects module	**Subject Coordinator**		
Subjects Module tab	✓		
Create and Assign Subject	✓ (for assigned studies)		Subject coordinator can create participant belonging to any study site and assign to any study with that study site. [CTMS:test-pt-fn7 assigned to N027D] http://jira.semanticbits.com/browse/CAAERS-1489
Assign a Subject to a Study (Subject already created)	✓ (for assigned studies)		No participants are returned in Assign a Subject to a Study>>Search subject. [CTMS:expected = test-pt-ln3] http://jira.semanticbits.com/browse/CAAERS-1490
View Subject	✓ (for assigned studies)	✓	
Search Subject	✓ (for assigned studies)	✓	
Advanced Search module	**Subject Coordinator**		
Advanced Search module tab	✓	✓	
Study Search	✓ (for assigned studies)	✓	
Subject Search	✓ (for assigned studies)	✓	
Expedited Report Search	✓ (for assigned studies)	✓	
Rules module	**Subject Coordinator**		
Rules module tab	✗	✗	
Create Rule	✗	✗	

Edit Rule	✗	✗	
Create Report Definition	✗	✗	
Edit Report Definition	✗	✗	
View Report Definition	✗	✗	
Admin module	**Subject Coordinator**		
Admin module tab	✗	✗	
create/edit/search Organization	✗	✗	
create/edit/search Research Staff	✗	✗	
configure caAERS	✗	✗	
create/edit/search Investigator	✗	✗	
Import Medra	✗	✗	
IND	✗	✗	
password policy	✗	✗	
Import Study, Subject, ~~Routine AE~~, Research Staff, Investigator	✗	✗	

Non Functional Test Cases

Adverse Events create-update -- Load tests

Pre-conditions:

1. Study FS5876.1 exists.
2. Subject (jh-subject-001) jh subject1 is assigned to this study on site Johns Hopkins.
3. Routing and review is enabled.
4. User is assigned as RS to study site Johns Hopkins with role AE coordinator [md017crafn md017cra]
5. Page load time is measure approximately in seconds.

create course

	Scenario	Response time v2.1.1	Response time v2.1.2	Remarks
	User is in report Adverse events page. User types "C5876.1" in the search box for study. Autosuggest shows the list of results.	60	<1	
	User is in report Adverse events page. User types "jh" in the search box for subject. Autosuggest shows the list of results.	3	<1	
	User is in report Adverse events page. User types "jh-subject-001" in the search box for subject. User chooses subject from list of results. User type "5876" in search box for study.	2	--	Unable to choose study after choosing subject
	User creates a new course in the new course pop up and clicks save. User gets course successfully created message.	6	<4	

edit course

	Scenario	Page Load time v2.1.1	Page Load time v2.1.2	Remarks
	User is in manage Adverse events page. User types "C5876.1" in the search box for study. Autosuggest shows the list of results.	60	<1	
	User is in manage Adverse events page. User types "jh" in the search box for subject. Autosuggest shows the list of results.	3	<1	
	User is in manage Adverse events page. User types "jh-subject-001" in the search box for subject. User chooses subject from list of results. User type "5876" in search box for study.	2	--	Unable to choose study after choosing subject
	User edits existing course in the course pop up and clicks save. User gets course successfully updated message.	4	<4	
	User is in report Adverse events page. User fills in details for study, subject and course and clicks continue. User is taken to the Adverse events page. This course type has no solicited AEs	4	<6	

Create Aes

	Scenario	Page Load time v2.1.1	Page Load time v2.1.2	Remarks
	User is in CAE>>adverse events page. User adds an observed AE. The observed AE is added. There are 20 solicited AEs for this course	8	<1	
	User is in CAE>>adverse events page. User adds an observed AE that is duplicate of a solicited AE. The relevant solicited AE is expanded.	Not tested	3	
	User is in CAE>>adverse events page. User adds an observed AE of grade 5. User clicks save and report and is taken to "Review and report" page. Caaers recommends the CTEP 24 Hour Notification. There are 20 solicited AEs + 4 observed AEs for this course.	18	<30	
	User is in CAE>>adverse events page. User adds an observed AE of grade 5. User clicks save and report and is taken to "Review and report" page. Caaers recommends the CTEP 24 Hour Notification. There are 3 observed AEs for this course.	8	<6	

Edit Aes

	Scenario	Page Load time v2.1.1	Page Load time v2.1.2	Remarks
	User is in CAE>>AE for an existing course and adds end date to an observed AE and clicks "save and report". User is taken to is taken to "Review and report" page. There are 20 solicited AEs + 4 observed AEs for this course.	19	<31	
	User is in CAE>>AE for an existing course and adds end date to an observed AE and clicks "save and report". User is taken to is taken to "Review and report" page.There are 3 observed AEs for this course.	8	<6	

Invoke Rule Recommendation

	Scenario	Page Load time	Remarks
	User is in CAE>>Review and report. Caaers recommends the CTEP 24 Hour Notification. There are 3 observed AEs for this course.	8	<6

Create AE Report

	Scenario	Page Load time v2.1.1	Page Load time v2.1.2	Remarks
	User is in CAE>>Review and report. Caaers recommends the CTEP 24 Hour Notification. User clicks report button. User is taken to exp AE flow. There are 3 AEs	6	<7	

Edit AE Report

	Scenario	Response time v2.1.1	Response time v2.1.2	Remarks
	User is in exp AE flow >> reporter. User fills in all mandatory details. User clicks continue and taken to exp AE>> AE page. There are 3 AEs	9	<10	
	User is in exp AE flow>> AE page. User clicks continue and is taken to Describe event page. There are 3 AEs	8	<8	
	User is in exp AE flow>>Labs and clicks on Review and submit tab. user is taken to the review and submit tab. Errors are shown for missing attribution. There are 3 AEs	6	<9	
	User is in exp AE flow>>Review and submit and clicks on subject details. user is taken to the subject details tab. There are 3 AEs.	5	<9	
	User is in exp AE flow>>subject details. User clicks to add Metastatic disease site. A new Metastatic disease site panel is added. There are 3 AEs.	3	2	
	User moves from exp AE flow>>Labs to exp AE flow>>Attribution. There are 3 AEs	5	<9	
	User is in exp AE flow>>Attribution and fills in the attribution values. User clicks continue and is taken to exp AE flow>>Additional info. There are 3 AEs	5	<8	
	User moves from exp AE flow>>Additional info to review and submit tab. No errors are thrown. There are 3 AEs	5	<9	

Submit 24 hr CTEP report

	Scenario	Page Load time	Remarks
	User has a complete report in review and submit tab. User submits the CTEP 24 Hour Notification to adeers.		

Submit child 5 day CTEP report

	Scenario	Page Load time	Remarks
	User submits child CTEP 5 day report.		

Amend child 5 day CTEP report

	Scenario	Page Load time	Remarks
	User amends a submitted report with a CTEP 24 Hour amendment.		
	User submits child CTEP 24 Hour amendment.		
	User submits child CTEP 5 day report to complete amendment.		

Withdraw child 5 day report

	Scenario	Page Load time	Remarks

Submit 10 day CTEP report

	Scenario	Page Load time	Remarks
	User submits CTEP 10 day report.		

Amend 10 day CTEP report

	Scenario	Page Load time	Remarks
	User amends a submitted report with a CTEP 10 day report.		

Autocompleter Scenarios for AE coordinator

Pre-conditions

1. Study is C5876.1
2. Study site is **02002** Hospital Militar Central.
3. AE coordinator is hmc AE coordinator with email calgb.biju@caaers.org and username hmc-ae-coord associated to Hospital Militar Central.
4. Report reviewer is paulfn paulln with email calgb.paul@caaers.org and username paul associated to CALGB.
5. Subject is 02002_C5876.1_SSI500 registered on **02002** Hospital Militar Central.
6. Page load time is measure approximately in seconds.

NOTE: For each scenario where there is 'Service Temporarily Unavailable' error requires the system to be rebooted. Average testing time is 25 mins for each row of the table below. IE was not used for executing tests below. The times were recorded using FF add-ons for better accuracy.

Report AEs page

	Scenario	Page Load time v2.1.1	Page Load time v2.1.2	Remarks
	User logs in as AE coordinator	6	<7	
	User clicks on report AE page.	4	<4	
	User is in report AE page and types '5' in the study auto-suggest.	120	<1	Got '503 Service Temporarily Unavailable' message
	User is in report AE page and types '5876' in the study auto-suggest.	120	<1	Got '503 Service Temporarily Unavailable' message
	User is in report AE page and types '5876.1' in the study auto-suggest.	58	<1	
	User is in report AE page and types '5876' in the subject auto-suggest.	120	<2	Got '503 Service Temporarily Unavailable' message
	User is in report AE page and types '5876.1' in the subject auto-suggest.	120	<1	Got '503 Service Temporarily Unavailable' message
	User is in report AE page and types '02002_C5876.1' in the subject auto-suggest.	120	<1	Got '503 Service Temporarily Unavailable' message
	User is in report AE page and types '02002_C5876.1_SSI500' in the subject auto-suggest.	<1	<1	

User is logged in as system admin. User is in Report AE page. For study autocompleter user types in string C5876.1. This has 10 results. 19 secs [FF]

manage reports page

	Scenario	Page Load time v2.1.1		Remarks
	User logs in as AE coordinator	6	<7	
	User clicks on manage reports page.	4	<4	

	User is in manage reports page and types '5' in the study auto-suggest.	120	<1	Got '503 Service Temporarily Unavailable' message
	User is in manage reports page and types '5876' in the study auto-suggest.	120	<1	Got '503 Service Temporarily Unavailable' message
	User is in manage reports page and types '5876.1' in the study auto-suggest.	49	<1	
	User is in manage reports page and types '5876' in the subject auto-suggest.	120	2	Got '503 Service Temporarily Unavailable' message
	User is in manage reports page and types '5876.1' in the subject auto-suggest.	120	<1	Got '503 Service Temporarily Unavailable' message
	User is in manage reports page and types '02002_C5876.1' in the subject auto-suggest.	120	<1	Got '503 Service Temporarily Unavailable' message
	User is in manage reports page and types '02002_C5876.1_SSI500' in the subject auto-suggest.	<1	<1	

Autocompleter Scenarios for Report Reviewer

Pre-conditions

1. Study is C5876.1
2. Study site is **02002** Hospital Militar Central.
3. AE coordinator is hmc AE coordinator with email calgb.biju@caaers.org and username hmc-ae-coord associated to Hospital Militar Central.
4. Report reviewer is paulfn paulln with email calgb.paul@caaers.org and username paul associated to CALGB.
5. Subject is 02002_C5876.1_SSI500 registered on **02002** Hospital Militar Central.
6. Page load time is measure approximately in seconds.

Report AEs page

	Scenario	Page Load time v2.1.1	Page Load time v2.1.2	Remarks
	User logs in as Report Reviewer	6	<7	
	User clicks on Routing and review page.	4	<4	
	User is in Routing and review page and types '5' in the study auto-suggest.	120	<1	Got '503 Service Temporarily Unavailable' message
	User is in Routing and review page and types '5876' in the study auto-suggest.	120	<1	Got '503 Service Temporarily Unavailable' message
	User is in Routing and review page and types '5876.1' in the study auto-suggest.	52	<1	
	User is in Routing and review page and types '5876' in the subject auto-suggest.	120	<1	Got '503 Service Temporarily Unavailable' message
	User is in Routing and review page and types '5876.1' in the subject auto-suggest.	120	<1	Got '503 Service Temporarily Unavailable' message
	User is in Routing and review page and types '02002_C5876.1' in the subject auto-suggest.	120	<1	Got '503 Service Temporarily Unavailable' message
	User is in Routing and review page and types '02002_C5876.1_SSI500' in the subject auto-suggest.	<1	<1	
	User is in Routing and review page and types '02' in the study site auto-suggest.	--	--	No matches found
	User is in Routing and review page and types '02002' in the study site auto-suggest.	--	--	No matches found
	User is in Routing and review page and types 'Hospital' in the study site auto-suggest.	<1	<1	
	User is in Routing and review page and types 'Militar' in the study site auto-suggest.	<1	<1	

Load Test Plan - CALGB

Goal

The primary goal is to load test caAERS when it contains a significant amount of data. Currently the response times for various actions are recorded manually by using a stop watch such as the one found on http://www.online-stopwatch.com/.

Test environment details

URL	https://qa.oracle.semanticbits.com/caaers/
Application	caAERS v2.1.1
Java	
DB URL	jdbc:oracle:thin:@10.10.10.235:1521:db99
DB schema	caaers_perf
DB dump	svn://10.10.10.220/QA-DB-dumps/oracle/caaers_oracle_qa.dmp
OS	
Email Server	10.10.10.235
WebMail	https://duncan.herndon.semanticbits.com:8443/yawebmail/
Browser	IE 7

Data Volume

Below table shows how much data we need to populate to bootstrap the test system.

	Light	Normal	High
Study	10	100	300
Study C5876.1	• **02001** Catedra De Oncologia Univ-Salvador • **02002** Hospital Militar Central The above sites have 800 participants registered		
Study Site	20	100 per Study	300 per Study
Study Personnel	1 per study site	10 per study site	30 per study site
Investigator	3 per site	25 per site	50 per site
Subject	10 subjects per site	50 subjects per site	100 subjects per site
Course	4 course for a subject per study site	6 course for a subject per study site	8 course for a subject per study site
Adverse events	10 per course	50 per course	100 per course
Reports	1 report per subject per course each having 5 adverse events	2 reports per course per subject each having 10 adverse events	5 reports per course per subject each having 20 adverse events

Concurrent Usage

We are aiming to simulate tests with max 20 concurrent users.

Module/Flow	Light	Normal	High
Study	1	2	10
Admin	1	2	10
Subject	2	10	50
Adverse Events	2	10	50

Test data

Studies

https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/Testing/adeers%20test%20matrix/exportedstudy_5876.xml
https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/Testing/adeers%20test%20matrix/exportedstudy_8231.xml
https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/Testing/adeers%20test%20matrix/exportedstudy_calgb_50403.xml
https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/Testing/adeers%20test%20matrix/exportedstudy_n027d.xml
https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/Testing/adeers%20test%20matrix/exportedstudy_n0543xx.xml
https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/Testing/adeers%20test%20matrix/exportedstudy_n0735xx.xml

For load testing we will use the following as the template to generate 100 studies. The naming conventions for sponsor and coordinating center identifiers are FS5876.**x** and C5876.**x** respectively. *(Note:- x is a running number)*
https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/Testing/adeers%20test%20matrix/exportedstudy_5876.xml

Research Staff

In addition to below mentioned research staff, we will auto create 10 research staff per site having 'Study Coordinator and Subject Coordinator roles and their login account will use the naming convention **nci-code**.rs**x.***(Note:- x is a running number)*

LoginID	Site	Roles	Password	Email	First Name	Last Name
~~biju~~	CALGB	Study coordinator	Caaers123!	calgb.biju@caaers.org	bijufn	bijuln
paul	CALGB	Central office report reviewer	Caaers123!	calgb.paul@caaers.org	paulfn	paulln
~~karthik~~	CALGB	Subject coordinator	Caaers123!	calgb.karthik@caaers.org	karthikfn	karthikln
~~sameer~~	CALGB	Site coordinator	Caaers123!	calgb.sameer@caaers.org	sameerfn	sameerln
~~ion~~	CALGB	Data coordinator	Caaers123!	calgb.ion@caaers.org	ionfn	ionln
~~srini~~	CALGB	Adverse event coordinator	Caaers123!	calgb.srini@caaers.org	srinifn	sriniln
~~monish~~	CALGB	Central office report reviewer ,Data coordinator	Caaers123!	calgb.monish@caaers.org	monishfn	monishln
~~wesley~~	CALGB	Subject coordinator ,Study coordinator, Site coordinator	Caaers123!	calgb.wess@caaers.org	wesleyfn	wesleyln
md017.cra	Johns Hopkins University	~~Subject~~ AE coordinator	Caaers123!	md017.cra@caaers.org	md017crafn	md017craln
~~md017.sc~~	Johns Hopkins University	Study coordinator	Caaers123!	md017.sc@caaers.org	md017scfn	md017scln
~~md017.aec~~	Johns Hopkins University	Study coordinator	Caaers123!	md017.aec@caaers.org	md017aecfn	md017aecln
~~mi020.cra~~	Wayne State University	Subject coordinator	Caaers123!	mi020.cra@caaers.org	md020crafn	md020craln
~~mi020.sc~~	Wayne State University	Subject coordinator	Caaers123!	mi020.sc@caaers.org	md020scfn	md020scln
~~mi020.aec~~	Wayne State University	Subject coordinator	Caaers123!	mi020.aec@caaers.org	md020aecfn	md020aecln

Investigators

In addition to below mentioned investigators, we will auto create 2 investigators per site and their login account will use the naming convention **nci-code**.inv**x.***(Note:- x is a running number)*

LoginID	Site	Password	Email
vinay	CALGB	Caaers123!	calgb.vinay@null.net
ram	CALGB	Caaers123!	calgb.ram@null.net
ben	CALGB	Caaers123!	calgb.ben@null.net
md017.pi	Johns Hopkins University	Caaers123!	md017.pi@null.net
md017.si	Johns Hopkins University	Caaers123!	md017.si@null.net
mi020.pi	Wayne State University	Caaers123!	mi020.pi@null.net
mi020.si	Wayne State University	Caaers123!	mi020.si@null.net

Subject

One hand created subject belonging to Johns Hopkins University assigned to C5876.1.

first name: jh

lastname: subject1

subject ID: jh-subject-001

Subjects will be auto generated, the naming convention followed for them are
First name : M**x**
Last name : J**x**
Subject Identifier : **NCICode**_SI**x**
Study Subject Identifier : **NCICode**_**StudyPrimaryID**_SSI**x***(Note:- x is a running number)*

Execution plan

Loading bootstrap data

The the following will be loaded via the UI import functionality.

- Study
- Investigator
- Research staff
- Subject

The following will be created via UI initially.

- Course
- Adverse events
- Report

Course and adverse events will be created via the AE management service secondarily to mimic loading of historic data.

Test Procedures

Test Procedures

Notes on selenium tests

Setting up Firefox to permanently accept certificates

From: http://townx.org/blog/elliot/dealing-self-signed-ssl-certificates-when-running-selenium-server-firefox

1. Shutdown all firefox windows
2. On the command prompt type: firefox -ProfileManager
3. Choose to create a new profile and save the profile in your project folder.
4. Browse to your https URL and accept the certificate permanently.
5. Close the firefox browser.
6. Delete everything in the profile directory except for the **cert_override.txt** and **cert8.db** files.
7. Start selenium server as:

```
java -jar C:\DOCUME~1\KARTHI~1\Desktop\SELENI~1\SELENI~1.0-B\SE13AE~1.0-B\selenium-server.jar
-firefoxProfileTemplate  C:\workspace\caaersTests\resources
```

"C:\workspace\caaersTests\resources" is the location of my profile folder.

Performance testing for caAERS

The document lists out the various scenarios where performance testing will help.

Particpant Name: Joe chandler

Study: 5876

[CTMS:Tested by Karthik Iyer and Ram Seethiraju]

	Scenario	FF Time (secs)	IE7 time (secs)	Log
	For a course user adds 115 AEs in CAE>>Adverse event which are of grade 4. This will trigger a 10 day ctep report which includes all 115 AEs. Time for moving from CAE>>Adverse Events -> CAE>>review and report is measured.	56.15	53	57 requests-1.16MB(931 KB from cache)
	For a course user adds 115 AEs in CAE>>Adverse event which are of grade 1. 1 more AE will be of grade 4. THis will trigger a 10 day ctep report which includes one AE. Time for moving from CAE>>Adverse Events -> CAE>>review and report is measured.	52.62	54	57 requests-1.16MB(931 KB from cache)
	User enters the manage reports page for said subject and study. The time for moving into Manage reports page is measured.	7.32	12	53 requests-1.07MB(980 KB from cache)
	User enters the report AEs page for said subject, study and course. The time for moving into CAE>>Adverse Events page [CTMS:with 200 AEs is measured].	22.84	23	83 requests-2.42 MB(1.02 MB from cache)

[CTMS:Tested by Karthik Iyer and Ram Seethiraju]

	Page transition [CTMS:from -> to] FF3	10 AEs	20 AEs	40 AEs	
	Login to caaers	--	--	--	2.42
	CAE>>Adverse Events -> CAE>>review and report	5.27	18.58	24.68	
	CAE>>review and report -> Exp.AE flow>>Reporter	9.58	10.74	15.03	
	Exp.AE flow>>Reporter -> Exp.AE flow>>Adverse Events	17.54	17.81	29.76	
	Exp.AE flow>>Adverse Events -> Exp.AE flow>>Attribution	12.74	11.6	16.58	
	Exp.AE flow>>Attribution -> Exp.AE flow>>Review and submit	9.41	26.89	15.02	

	Objective	Setup	Action

	To measure time for evaluation of 100 AEs by rules engine.	There exists a course with 500 Observed AEs and 50 Solicited AEs each with one AE of grade 5 and rest of grade 0 or 1.* This will allow caAERs to trigger the 24 hr notification.	User moves from CAE>>Adverse Events to CAE>> review and report and measures the time of transition.
	To measure page loading time of ExpAE flow>>Adverse events with 50 AEs on the page	The report has 50 AEs associated with it	User moves from ExpAE flow>>reporter to ExpAE flow>>Adverse events
	To measure time loading existing study with 30 study agents.	There exists a study with 30 study agents.	User moves from study>>therapies page to study>>agents page and measures time of transition.
	To measure time loading existing study with 40 study diseases.	There exists a study with 40 study diseases.	User moves from study>>Treatment Assignments page to study>>disease page and measures time of transition.
	To measure time loading existing study with 50 expected AEs.	There exists a study with 50 expected AEs.	User moves from study>>Evaluation Period Types page to study>>Expected AEs page and measures time of transition.
	To measure time for logging into caaers	The cache of the browser is cleared.	User logs in to caaers and measures time of transition
	To measure time for create/edit course pop up to appear	User is in Report AEs page and chooses a study and subject.	User clicks on create new course and measures time for the div pop up to load.
	To measure the time for seaching single study when 50 studies are available	Caaers has 50 studies available	User is in Study>>Search studies and searches for a single study

Performance Testing for caAERS v. 2.4-SNAPSHOT

caaers Version: caAERS v. 2.4-SNAPSHOT (2011-02-24 11:59:49)

DB type: oracle

Browser version: 3.6.13

user: mayo-super-user / Hello-12

Create Study flow

Study used: FS5876.5

- From Manage Studies to edit study >> Overview : 10.03s
- edit study >> Overview to edit study >> details: 2.97s
- edit study >> details to edit study >> interventions: 6.41s
- edit study >> interventions to edit study >> Treatment assignments: 6.91s
- edit study >> Treatment assignments to edit study >> disease: 5.86s
- edit study >> disease to edit study >> solicited AEs: 8.37s
- edit study >> solicited AEs to edit study >> expected AEs: 7.52s
- edit study >> expected AEs to edit study >> sites: 6.7s
- edit study >> sites to edit study >> investigators: 6.89s
- edit study >> investigators to edit study >> personnel: 5.9s
- edit study >> personnel to edit study >> identifiers: 7.21s

Create Subject flow

Study used: FS5876.5

- Enter Subject >> details to Enter Subject >>Choose Study: 2.01s
- Enter Subject >>Choose Study to Enter Subject>>Medical History: 3.44s
- Enter Subject>>Medical History to Enter Subject>>Summary: 1.55s

- Enter Subject>>Summary to Enter Subject>>Confirmation: 2.89s

Manage Subject flow

Study used: FS5876.5

Subject used: (02018_SI1) FN1 LN1 - (02018_C5876.5_SSI1)

- Manage Subject>>Search to Enter Subject>>summary: 1.9s
- Enter Subject>>summary to Enter Subject>>details: 3.9s
- Enter Subject>>details to Enter Subject>>Medical History: 2.21s
- Enter Subject>>Medical History to Enter Subject>>Confirmation:1.63

Personnel Flow

Personnel used: study-qa-mgr

- Search personnel to Edit personnel: 2.85s
- Edit personnel to Confirmation: 6.61s

Testing HIPAA compliance

	Description. R=Required. A=Addressable	Implementation	Pass / Fail
	Access Control(R) Include mechanism to allow access only to those persons or software programs that are authorized.	Access to caAERS is controlled by assigning user to roles with various restrictions and privileges. User are authorized by the system administrator to gain access to various parts of the system	
	Unique User Identification (R) Assign a unique name and/or number for tracking user identity.	Each Research staff who is authorized to work on the caAERS is given role based access by assigning user identity based on unique email address.	
	Emergency Access Procedure (R) Establish procedures for obtaining necessary electronic protected health information during an emergency.	In case a user loses his / her authorization credentials, information can be retrieved by superuser [CTMS:administrator] who has access to all information in caAERS. In case caAERS is unavailable to service requests, information can still be retrieved by appropriate queries to the database.	
	Automatic Logoff (A) Include mechanism that terminates an electronic session after a predetermined time of inactivity.	caAERS is designed to automatically log off an user after 30 mins of inactivity.	
	Encryption and Decryption (A) Include mechanism to encypt and decrypt electronic protected health information.	caAERS is a web based application. Information transferred between browser and server is encrypted using AES 256 bit encryption.	
	Audit Controls (R) Include mechanism that records and examines activity in information systems that contain or use electronically protected health information	Auditing is available in caaers. Information about client IP address, adding and/or editing of domain objects etc are logged in the DB.	
	Integrity (R) Implement mechanism to protect electronic protected health information from improper alteration or destruction	Information integrity is protected by allowing only authorized users to make alterations. caAERS also enforces a number of domain specific business rules to ensure data is not corrupted.	
	Authenticate Electronic Protected Health Information (A) Include mechanism to corroborate that electronic protected information has not been altered or destroyed in an unauthorized manner.	??	??
	Person or Entity Authentication (R) Include mechanism to verify that person or entity seeking access to electronic protected health information is the one claimed.	Authentication is done through exchange of security certificates. Before authorizing a user to access caAERS, credentials of the user are authenticated by a suitable authority [CTMS:out of scope for caAERS]	
	Transmission Security (R) Include mechanism to guard against unauthorized access to electronic protected health information that is being transmitted over an electronic communications network.	caAERS transmits information by encrypting using SSL technology that uses AES 256 bit encryption.	

	Integrity Controls (A) Include mechanism to ensure electronically transmitted electronic protected health information is not improperly modified without detection until disposed of.	???	??
	Encryption (A) Include mechanism to encrypt electronic protected health information whenever deemed appropriate	caAERS transmits information by encrypting using SSL technology that uses AES 256 bit encryption.	

Test Procedures -- caAERS v2.1.1 Load Testing

Environment

Variable	Version
Version	v2.1.1
Build	caAERS v. 2.1.1-SNAPSHOT (2010-04-01 10:30:40)
URL	https://oracle.qa.semanticbits.com/caaers/
Hardware (bit level)	32bit
OS (bit level)	32 bit
Kernel Version	Linux version 2.6.18-92.el5xen (mockbuild@builder16.centos.org) (gcc version 4.1.2 20071124 (Red Hat 4.1.2-42)) #1 SMP Tue Jun 10 19:55:54 EDT 2008
Virtual Server (Yes/No)	Yes
Java (bit level)/Version	build 1.5.0_16-b02
DB (bit level)	32 bit
DB content	Existing
DB type	Oracle
DB version	Oracle Database 11g Release 11.2.0.1.0 - 64bit Production
DB connection URL	jdbc.oracle.thin:@10.10.10.235:1521:db99
DB schema name	caaers_perf / caaers_perf
Tomcat	5.5.23
ServiceMix	3.3
caXchange	NA
Browser version	IE 7

Pre-Loaded Data

Element	Number #	Load Category	Loading Comments
# Studies	100	Med-Heavy	Unable to import (~7mb) - imports are limited to 1-2mb max
# Study Sites / Study	100	Med-Heavy	
# "Active" Study Sites / Study	20	Normal	
# Research Staff / Site	10	Heavy	Associate to all studies flag needs to be examined for improvements
# Investigators / Site	3	Light	
# Subjects / Study Site	40	Med-Heavy	

# Courses / Subject	0	Light	
# AE's / Course	0	Light	

Component	Test Procedure Link	1 user - Results	2 concurrent users	5 concurrent users	10 concurrent users	20 concurrent users	Comments
create course							
edit course							
Create Aes							
Edit Aes							
Invoke Rule Recommendation							
Create AE Report							
Edit AE Report							
Submit 24 hr CTEP report							
Submit child 5 day CTEP report							
Amend child 5 day CTEP report							
Withdraw child 5 day report							
Submit 10 day CTEP report							
Amend 10 day CTEP report							
Edit Rules							
Edit Report Definitions							
Edit Study							
Web Service Create Study							
Web Service Update Study							
Web Service Create Research Staff (user)							
Web Service Update Research Staff							
Web Service Create Investigator (user)							
Web Service Create Investigator (non-user)							
Web Service Update Investigator							
Web Service Create Subject							
Web Service Update Subject							
Delete Rules - SAE Reporting Rules							
Import Rules - SAE Reporting Rules							
Import Rules - Mandatory sections Rules							

Import Report Definitions							
Import MedDRA							
Import organization							
Import agents							
Create Study Specific SAE Reporting Rules							
Create Study							
Submit AdEERS Report (NCI IND)							
Submit AdEERS Report (NCI IDE)							
Submit AdEERS Report (non-NCI IND)							
Submit AdEERS Report (non-NCI IDE)							
Submit AdEERS Report (Commercial Agent)							
Submit AdEERS Report (Commercial Device)							
Submit AdEERS Report (Radiation)							
Submit AdEERS Report (Surgery)							
Create Report Notifications							
Submit Report Notifications							
Withdraw Report Notifications							
Amend Report Notifications							
Report Reminder Notifications							
Modify Report Mandatory Fields							
Modify CAE Mandatory Fields							
Forgot/Reset password							
Inactivity Reminder							
Grace Period Logout							
Amend a Report							
Withdraw a Report							

Web testing for caAERS

Benchmark for Performance testing in caAERS

Pre-conditions

1. A maximum of 40 concurrent users are logged in.
2. The average number of users in caAERS will be 10.
3. JMeter will be used as a tool to perform stress testing.
4. Security for caAERS is disabled [CTMS:to facilitate JMeter testing].
5. caAERS version 1.9.2 will be used for testing.

Targets

Maximum number of studies that can be searched using wildcard search: ??

Maximum number of participants that can be searched when using wildcard search: ??

Maximum number of Investigators that can be searched when using wildcard search: ??

	Scenario	Best Case [CTMS:5 users]	Average Case [CTMS:10 users]	Worst Case [CTMS:40 users]
	Response time for landing page in caAERS	5 secs	10 secs	15 secs
	Create study			
	Edit study			
	Create Investigator			
	Edit Investigator			
	Create Research Staff			
	Edit Research Staff			
	Create Investigator			
	Edit Investigator			
	Create Subject			
	Edit Subject			
	Create Report			
	Edit report			

Hardware used

1. Schema is created in oracle DB at:caaers_perf@sbhost02.herndon.semanticbits.com
2. The caaers app will be hosted at: http://derek.semanticbits.com:15080/caaers
3. CATALINA_HOME=/usr/local/tomcats/caaers/trunk/oracle/apache-tomcat-perf

Questions

1. How many domain objects of each type are supposed exist? For ex: how many studies, investigators, research staff etc
2. How many participants are assigned to each study?
3. How many agents, TACs, sites, investigators, research staff, solicited AEs are expected per study?
4. How many reports are expected per study-participant assignment?
5.

To Do List

- Create a baseline DB dump for caAERS.
- Write out test scenarios against which to measure page load times.
- Create a benchmark document to set up worst case response times in caAERS.
- Set up security disabled caAERS on appropriate machine.
- Set up JMeter for running a simple use case in caAERS.

Notes
Comparo: http://blackanvil.blogspot.com/2006/06/shootout-load-runner-vs-grinder-vs.html

Release Testing - caAERS

Environment

	Version	v2.1

	Build	caAERS v. 2.0.1-SNAPSHOT (2010-01-26 11:28:56)
	URL	https://oracle.qa.semanticbits.com/caaers/
	Hardware (bit level)	32bit
	OS (bit level)	32 bit
	Kernel Version	Linux version 2.6.18-92.el5xen (mockbuild@builder16.centos.org) (gcc version 4.1.2 20071124 (Red Hat 4.1.2-42)) #1 SMP Tue Jun 10 19:55:54 EDT 2008
	Virtual Server (Yes/No)	Yes
	Java (bit level)/Version	build 1.5.0_16-b02
	DB (bit level)	32 bit
	DB content	Existing
	DB type	Oracle
	DB version	Oracle Database 10g Enterprise Edition Release 10.2.0.1.0 - Prod
	Tomcat	5.5.23
	ServiceMix	3.3
	caXchange	NA
	Browser version	IE 7

Component	Test Procedure	Results	Comments
Fresh Installation			
Upgrade from v2.0			
Upgrade from v1.9.6.1			
Delete Rules - SAE Reporting Rules			
Import Rules - SAE Reporting Rules			
Import Rules - Mandatory sections Rules			
Import Report Definitions			
Import Study			
Import Research Staff			
Import Investigator			
Import Aes			
Import MedDRA			
Import Subject			
Create Rules			
Create Report Definitions			
Create Study			
Create Research Staff (user)			
Create Investigator (user)			

Create Investigator (non-user)			
create course			
edit course			
Create Aes			
Create MedDRA			
Create Subject			
Edit Rules			
Edit Report Definitions			
Edit Study			
Edit Research Staff (user)			
Edit Investigator (user)			
Edit Investigator (non-user)			
Edit Aes			
Edit Subject			
Web Service Create Study			
Web Service Update Study			
Web Service Create Research Staff (user)			
Web Service Update Research Staff			
Web Service Create Investigator (user)			
Web Service Create Investigator (non-user)			
Web Service Update Investigator			
Web Service Create Aes			
Web Service Update Aes			
Web Service Create Subject			
Web Service Update Subject			
Invoke Rule Recommendation			
Create AE Report			
Edit AE Report			
Submit AdEERS Report (NCI IND)			
Submit AdEERS Report (NCI IDE)			
Submit AdEERS Report (non-NCI IND)			
Submit AdEERS Report (non-NCI IDE)			
Submit AdEERS Report (Commercial Agent)			
Submit AdEERS Report (Commercial Device)			
Submit AdEERS Report (Radiation)			
Submit AdEERS Report (Surgery)			
Create Report Notifications			
Submit Report Notifications			
Withdraw Report Notifications			

Amend Report Notifications			
Report Reminder Notifications			
Submit non-AdEERS Report			
Modify Report Mandatory Fields			
Modify CAE Mandatory Fields			
Forgot/Reset password			
Inactivity Reminder			
Grace Period Logout			
Amend a Report			
Withdraw a Report			
Expected Aes in CAE			
Solicited Aes in CAE			
Creation of Custom Report			
Printing of Custom Report			
Sending of Custom Report			
Average Page Load (seconds)			
Code Coverage - Files			
Code Coverage - Classes			
Code Coverage - Methods			
Code Coverage - Lines			
Code Coverage - Packages			
Re-Running the Rules			
Search for study by identifier [COPPA]			
Search for study by short title [COPPA]			
Search for organization by name [COPPA]			
Search for organization by NCI ID [COPPA]			
Search for Research staff [COPPA]			
Search for Investigator [COPPA]			
Broadcast study from C3PR [CCTS]			
Broadcast registration from C3PR [CCTS]			

Release Testing - caAERS v1.5

Test Case Matrix for caAERS v 1.5

The following is the list of test cases created for caAERS v 1.5:

Module 1 Adverse Event Data	Module 2 caAERS to local CTMS	Module 3 Vocabulary	Module 4 Reporting	Module 5 Routing & Reviewing	Module 12 Expectedness	Module 13 Security	CTMSi	Misc
Enter AEs (UC 1.1, UC 1.2.2, UC 1.2.3, UC 1.3, UC 1.4)		medDRA import						
Associating Solicited AEs to a study (UC 1.2.1)								

Legends

The following icons are used to signify whether the tests passed or failed

- Test passed
- Test Failed
- The basic functioning is correct but needs to be communicated clearly to the user. [CTMS:For example, Error is thrown but the error message is not informative enough]
- The functionality of this feature is unimplemented or unknown at the time of testing.

Release Testing - caAERS v2.1.3

Environment

	Version	v2.1
	Build	caAERS v. 2.1.3
	URL	https://oracle.qa.semanticbits.com/caaers/
	Hardware (bit level)	32bit
	OS (bit level)	32 bit
	Kernel Version	Linux version 2.6.18-92.el5xen (mockbuild@builder16.centos.org) (gcc version 4.1.2 20071124 (Red Hat 4.1.2-42)) #1 SMP Tue Jun 10 19:55:54 EDT 2008
	Virtual Server (Yes/No)	Yes
	Java (bit level)/Version	build 1.5.0_16-b02
	DB (bit level)	32 bit
	DB content	Existing

	DB type	Oracle
	DB version	Oracle Database 11g Release 11.2.0.1.0 - 64bit Production
	Tomcat	5.5.23
	ServiceMix	3.3
	caXchange	NA
	Browser version	IE 7

Component	Test Procedure	Results	Comments
Fresh Installation			
Upgrade from v2.0			
Upgrade from v1.9.6.1			
Delete Rules - SAE Reporting Rules		✓	
Import Rules - SAE Reporting Rules		✓	
Import Rules - Mandatory sections Rules		✓	
Import Report Definitions		✓	
Import Study		✓	
Import Research Staff		✓	
Import Investigator		✓	
Import Agent specific expected AEs			
Import MedDRA			
Import Subject		✓	
Create Rules		✓	
Create Report Definitions		✓	
Create Study		✓	
Create Research Staff (user)		✓	
Create Investigator (user)		✓	
Create Investigator (non-user)		✓	
create course		✓	
edit course		✓	
Create Aes		✓	
Create MedDRA		✓	
Create Subject		✓	

Edit Rules		✓	
Edit Report Definitions		✓	
Edit Study		✓	
Edit Research Staff (user)		✓	
Edit Investigator (user)		✓	
Edit Investigator (non-user)		✓	
Edit Aes		✓	
Edit Subject		✓	
Web Service Create Study		✓	
Web Service Update Study		✓	
Web Service Create Research Staff (user)		✓	
Web Service Update Research Staff		✓	
Web Service Create Investigator (user)		✓	
Web Service Create Investigator (non-user)		✓	
Web Service Update Investigator		✓	
Web Service Create Aes		✓	
Web Service Update Aes		✓	
Web Service Create Subject		✓	
Web Service Update Subject		✓	
Invoke Rule Recommendation		✓	
Create AE Report		✓	
Edit AE Report		✓	
Submit AdEERS Report (NCI IND)		✓	
Submit AdEERS Report (NCI IDE)			
Submit AdEERS Report (non-NCI IND)			
Submit AdEERS Report (non-NCI IDE)			
Submit AdEERS Report (Commercial Agent)			
Submit AdEERS Report (Commercial Device)			
Submit AdEERS Report (Radiation)			
Submit AdEERS Report (Surgery)			
Create Report Notifications		✓	
Submit Report Notifications		✓	
Withdraw Report Notifications		✓	

Amend Report Notifications			
Report Reminder Notifications			
Submit non-AdEERS Report			
Modify Report Mandatory Fields			
Modify CAE Mandatory Fields			
Forgot/Reset password		✅	
Inactivity Reminder		✅	
Grace Period Logout		✅	
Amend a Report		✅	
Withdraw a Report		✅	
Expected Aes in CAE		✅	
Solicited Aes in CAE		✅	
Creation of Custom Report			
Printing of Custom Report			
Sending of Custom Report			
site CRA sends Report to site physician for review		✅	
site Physician approves report		✅	
site CRA sends complete report to Central Office report reviewer		✅	
Central Office report reviewer submits report.		✅	
site CRA sends a course to Data Coordinator for review			
Data Coordinator approves course			

Release Testing - caAERS v2.1.3.1

Environment

	Version	v2.1.3.1
	Build	caAERS v. 2.1.3.1
	URL	https://oracle.qa.semanticbits.com/caaers/
	Hardware (bit level)	32bit
	OS (bit level)	32 bit
	Kernel Version	Linux version 2.6.18-92.el5xen (mockbuild@builder16.centos.org) (gcc version 4.1.2 20071124 (Red Hat 4.1.2-42)) #1 SMP Tue Jun 10 19:55:54 EDT 2008
	Virtual Server (Yes/No)	Yes
	Java (bit level)/Version	build 1.5.0_16-b02
	DB (bit level)	32 bit
	DB content	Existing
	DB type	Oracle
	DB version	Oracle Database 11g Release 11.2.0.1.0 - 64bit Production
	Tomcat	5.5.23
	ServiceMix	3.3
	caXchange	NA
	Browser version	IE 7

Component	Test Procedure	Results	Comments
Fresh Installation			
Upgrade from v2.0			
Upgrade from v1.9.6.1			
Delete Rules - SAE Reporting Rules		✓	
Import Rules - SAE Reporting Rules		✓	
Import Rules - Mandatory sections Rules		✓	
Import Report Definitions		✓	
Import Study		✓	
Import Research Staff		✓	
Import Investigator		✓	
Import Agent specific expected AEs		✓	
Import MedDRA			
Import Subject		✓	

Create Rules		✓	
Create Report Definitions		✓	
Create Study		✓	
Export Study			
Import the above exported Study			
Create Research Staff (user)		✓	
Create Investigator (user)		✓	
Create Investigator (non-user)		✓	
create course		✓	
edit course		✓	
Create Aes		✓	
Create MedDRA			
Create Subject		http://jira.semanticbits.com/browse/CAAERS-3943 http://jira.semanticbits.com/browse/CAAERS-3994	
Edit Rules		✓	
Edit Report Definitions		✓	
Edit Study		✓	
Edit Research Staff (user)		✓	
Edit Investigator (user)		✓	
Edit Investigator (non-user)		✓	
Edit Aes		✓	
Edit Subject		http://jira.semanticbits.com/browse/CAAERS-3943 http://jira.semanticbits.com/browse/CAAERS-3994	
Web Service Create Study		✓	
Web Service Update Study		✓	
Web Service Create Research Staff (user)		✓	
Web Service Update Research Staff		✓	
Web Service Create Investigator (user)		✓	
Web Service Create Investigator (non-user)		✓	
Web Service Update Investigator		✓	
Web Service Create Aes		✓	
Web Service Update Aes		✓	
Web Service Create Subject		✓	

Web Service Update Subject		✅	
Invoke Rule Recommendation		✅	
Create AE Report		✅	
Edit AE Report		✅	
Submit 24-hr AdEERS Report (NCI IND)		✅	
Submit child 5 day AdEERS Report (NCI IND)		✅	
Amend child 5 day AdEERS Report (NCI IND)		✅	
Withdraw child 5 day AdEERS Report (NCI IND)		✅	
Submit 10 day AdEERS Report (NCI IND)		✅	
Amend 10 day AdEERS Report (NCI IND)		✅	
Create Report Notifications		✅	
Submit Report Notifications		✅	
Withdraw Report Notifications		✅	
Amend Report Notifications		✅	
Report Reminder Notifications			
Submit non-AdEERS Report			
Modify Report Mandatory Fields			
Modify CAE Mandatory Fields			
Forgot/Reset password			
Inactivity Reminder		✅	
Grace Period Logout		✅	
Withdraw a Report		✅	
Expected Aes in CAE			
Solicited Aes in CAE		✅	
Creation of Custom Report			
Printing of Custom Report			
Sending of Custom Report			
site CRA sends complete report to Central Office report reviewer		✅	
Central Office report reviewer submits report.		✅	

site CRA sends a course to Data Coordinator for review		✅	
Data Coordinator approves course		✅	

Release Testing - caAERS v2.2-RC2

Environment

	Version	v2.1
	Build	caAERS v. 2.2-RC2-SNAPSHOT (2010-08-05 10:20:35)
	URL	https://oracle.qa.semanticbits.com/caaers/
	Hardware (bit level)	32bit
	OS (bit level)	32 bit
	Kernel Version	Linux version 2.6.18-92.el5xen (mockbuild@builder16.centos.org) (gcc version 4.1.2 20071124 (Red Hat 4.1.2-42)) #1 SMP Tue Jun 10 19:55:54 EDT 2008
	Virtual Server (Yes/No)	Yes
	Java (bit level)/Version	build 1.5.0_16-b02
	DB (bit level)	32 bit
	DB content	Existing
	DB type	Oracle
	DB version	Oracle Database 10g Enterprise Edition Release 10.2.0.1.0 - Prod
	Tomcat	5.5.23
	ServiceMix	3.3
	caXchange	NA
	Browser version	IE 7

Component	Test Procedure	Results	Comments
Fresh Installation			
Upgrade from v2.0			
Upgrade from v1.9.6.1			
Delete Rules - SAE Reporting Rules		✅	
Import Rules - SAE Reporting Rules		✅	
Import Rules - Mandatory sections Rules		✅	
Import Report Definitions		✅	
Import Study		✅	
Import Research Staff		✅	
Import Investigator		✅	
Import Aes		--	
Import MedDRA		✅	
Import Subject		✅	
Create Rules		✅	
Create Report Definitions		✅	
Create Study		✅	
Create Research Staff (user)		✅	
Create Investigator (user)		✅	
Create Investigator (non-user)		✅	
create course		✅	
edit course		✅	
Create Aes		✅	
Create MedDRA			
Create Subject		✅	
Edit Rules		✅	
Edit Report Definitions		✅	
Edit Study		✅	
Edit Research Staff (user)		✅	
Edit Investigator (user)		✅	
Edit Investigator (non-user)		✅	

Edit Aes		✓	
Edit Subject		✓	
Web Service Create Study		✗	CAAERS-4270
Web Service Update Study		✓	
Web Service Create Research Staff (user)		✓	
Web Service Update Research Staff		✓	
Web Service Create Investigator (user)		✓	
Web Service Create Investigator (non-user)		✓	
Web Service Update Investigator		✓	
Web Service Create Aes		✗	CAAERS-4274
Web Service Update Aes		✗	CAAERS-4274
Web Service Create Subject		✗	CAAERS-4272
Web Service Update Subject		✓	
Invoke Rule Recommendation		✓	
Create AE Report		✓	
Edit AE Report		✓	
Submit AdEERS Report (NCI IND)		✓	
Submit AdEERS Report (NCI IDE)			
Submit AdEERS Report (non-NCI IND)			
Submit AdEERS Report (non-NCI IDE)			
Submit AdEERS Report (Commercial Agent)			
Submit AdEERS Report (Commercial Device)			
Submit AdEERS Report (Radiation)			
Submit AdEERS Report (Surgery)			
Create Report Notifications		✓	
Submit Report Notifications		✓	
Withdraw Report Notifications			
Amend Report Notifications			
Report Reminder Notifications			
Submit non-AdEERS Report			
Modify Report Mandatory Fields			
Modify CAE Mandatory Fields		✓	
Forgot/Reset password		✓	
Inactivity Reminder		✓	

Grace Period Logout		✅	
Amend a Report		✅	
Withdraw a Report			
Expected Aes in CAE			
Solicited Aes in CAE		✅	
Creation of Custom Report			
Printing of Custom Report			
Sending of Custom Report			
Average Page Load (seconds)			

Release Testing - caAERS v. 2.2-RC3

Environment

	Build	caAERS v. 2.2-RC3
	URL	https://oracle.qa.semanticbits.com/caaers/
	Hardware (bit level)	32bit
	OS (bit level)	32 bit
	Kernel Version	Linux version 2.6.18-92.el5xen (mockbuild@builder16.centos.org) (gcc version 4.1.2 20071124 (Red Hat 4.1.2-42)) #1 SMP Tue Jun 10 19:55:54 EDT 2008
	Virtual Server (Yes/No)	Yes

	Java (bit level)/Version	build 1.5.0_16-b02
	DB (bit level)	32 bit
	DB content	Existing
	DB type	Oracle
	DB version	Oracle Database 10g Enterprise Edition Release 10.2.0.1.0 - Prod
	Tomcat	5.5.23
	ServiceMix	3.3
	caXchange	NA
	Browser version	IE 7
	Test time	20 hours

Component	Test Procedure	Results	Comments
Fresh Installation			
Upgrade from v2.0			
Upgrade from v1.9.6.1			
Delete Rules - SAE Reporting Rules			
Import Rules - SAE Reporting Rules		✓	
Import Rules - Mandatory sections Rules		✓	
Import Report Definitions		✓	
Import Study		✓	
Import Research Staff		✓	
Import Investigator		✓	
Import MedDRA		✓	
Import Subject		✓	
Create Rules		✓	
Create Report Definitions		✗	CAAERS-4330
Create Study		✓	
Create Research Staff (user)		✓	
Create Investigator (user)		✓	
Create Investigator (non-user)		✓	
create course		✓	
edit course		✓	
Create Aes		✓	

Create MedDRA			
Create Subject		✅	
Edit Rules		✅	
Edit Report Definitions		✅	
Edit Study		✅	
Edit Research Staff (user)		✅	
Edit Investigator (user)		✅	
Edit Investigator (non-user)		✅	
Edit Aes		✅	
Edit Subject		✅	
Web Service Create Study		✅	
Web Service Update Study		✅	
Web Service Create Research Staff (user)		✅	
Web Service Update Research Staff		❌	CAAERS-4333
Web Service Create Investigator (user)		✅	
Web Service Create Investigator (non-user)		✅	
Web Service Update Investigator		✅	
Web Service Create Aes		✅	
Web Service Update Aes		✅	
Web Service Create Subject		❌	CAAERS-4334
Web Service Update Subject		❌	CAAERS-4334
Invoke Rule Recommendation		✅	
Create AE Report		✅	
Edit AE Report		✅	
Submit CTEP 24 hr report		✅	
Submit CTEP 5 day report [child]		✅	
Submit CTEP 24 hr amendment		✅	
Submit CTEP 5 day amendment [child]		✅	
Submit CTEP 10 day report		✅	
Submit CTEP 10 day amendment		✅	

Create Report Notifications			
Submit Report Notifications			
Withdraw Report Notifications			
Amend Report Notifications			
Report Reminder Notifications			
Submit non-AdEERS Report			
Modify Report Mandatory Fields			
Modify CAE Mandatory Fields			
Forgot/Reset password			
Inactivity Reminder			
Grace Period Logout			
Amend a Report			
Withdraw a Report			
Expected Aes in CAE			
Solicited Aes in CAE			
Creation of Custom Report			
Printing of Custom Report			
Sending of Custom Report			
Average Page Load (seconds)			

Release Testing - caAERS v. 2.3-M1-SNAPSHOT

Environment

	Build	**caAERS v. 2.3-M1-SNAPSHOT (2010-10-27 04:52:25)**
	URL	https://oracle.qa.semanticbits.com/caaers/
	Hardware (bit level)	32bit
	OS (bit level)	32 bit
	Kernel Version	Linux version 2.6.18-92.el5xen (mockbuild@builder16.centos.org) (gcc version 4.1.2 20071124 (Red Hat 4.1.2-42)) #1 SMP Tue Jun 10 19:55:54 EDT 2008
	Virtual Server (Yes/No)	Yes
	Java (bit level)/Version	build 1.5.0_16-b02
	DB (bit level)	32 bit
	DB content	Existing
	DB type	Oracle
	DB version	Oracle Database 10g Enterprise Edition Release 10.2.0.1.0 - Prod
	Tomcat	5.5.23
	ServiceMix	3.3
	caXchange	NA
	Browser version	IE 7
	Test time	12 hours

Component	Test Procedure	Results
Fresh Installation		
Upgrade from v2.0		
Upgrade from v1.9.6.1		
Delete Rules - SAE Reporting Rules		✓
Import Rules - SAE Reporting Rules		✓
Import Rules - Mandatory sections Rules		
Import Report Definitions		✓
Import Study		✗ Unable to search for imported study
Import Research Staff		✗ Unable to search for imported RS
Import Investigator		✓
Import Organization		✓
Import MedDRA		
Import Subject		✓

Create Rules		✓
Create Report Definitions		✓
Create Study		✓
Create Research Staff (user)		✓
Create Investigator (user)		✓
Create Investigator (non-user)		✓
create course		✓
edit course		✓
Create Aes		✓
Create MedDRA		
Create Subject		✓
Edit Rules		✓
Edit Report Definitions		✓
Edit Study		✓
Edit Research Staff (user)		✓
Edit Investigator (user)		✓
Edit Investigator (non-user)		✓
Edit Aes		✓
Edit Subject		✓
Web Service Create Study		
Web Service Update Study		
Web Service Create Research Staff (user)		
Web Service Update Research Staff		
Web Service Create Investigator (user)		
Web Service Create Investigator (non-user)		
Web Service Update Investigator		
Web Service Create Aes		
Web Service Update Aes		
Web Service Create Subject		
Web Service Update Subject		
Invoke Rule Recommendation		✓
Create AE Report		✓
Edit AE Report		✓
Submit CTEP 24 hr report		✓

Submit CTEP 5 day report [child]		✅
Submit CTEP 24 hr amendment		✅
Submit CTEP 5 day amendment [child]		✅
Submit CTEP 10 day report		✅
Submit CTEP 10 day amendment		✅
Create Report Notifications		✅
Submit Report Notifications		✅
Withdraw Report Notifications		
Amend Report Notifications		
Report Reminder Notifications		
Submit non-AdEERS Report		
Modify Report Mandatory Fields		
Modify CAE Mandatory Fields		
Forgot/Reset password		✅
Inactivity Reminder		✅
Grace Period Logout		✅
Amend a Report		✅
Withdraw a Report		✅
Expected Aes in CAE		
Solicited Aes in CAE		
Creation of Custom Report		
Printing of Custom Report		
Sending of Custom Report		
Average Page Load (seconds)		

Release Testing - caAERS v. 2.3-RC1

Environment

	Build	caAERS v. 2.3-RC1-SNAPSHOT (2011-01-27 12:54:19)
	URL	https://oracle.qa.semanticbits.com/caaers/
	Hardware (bit level)	32bit
	OS (bit level)	32 bit
	Kernel Version	Linux version 2.6.18-92.el5xen (mockbuild@builder16.centos.org) (gcc version 4.1.2 20071124 (Red Hat 4.1.2-42)) #1 SMP Tue Jun 10 19:55:54 EDT 2008
	Virtual Server (Yes/No)	Yes
	Java (bit level)/Version	build 1.5.0_16-b02
	DB (bit level)	32 bit
	DB content	Existing
	DB type	Oracle
	DB version	Oracle Database 10g Enterprise Edition Release 10.2.0.1.0 - Prod
	Tomcat	5.5.23
	ServiceMix	3.3
	caXchange	NA
	Browser version	IE 7
	Test time	6 hours

Component	Test Procedure	Results
Fresh Installation		
Upgrade from v2.0		
Delete Rules - SAE Reporting Rules		
Import Rules - SAE Reporting Rules		
Import Rules - Mandatory sections Rules		

Import Report Definitions		✓
Import Study		✓
Import Research Staff	CAAERS-4675	X
Import Investigator	CAAERS-4674	✓
Import Organization		✓
Import MedDRA		
Import Subject		
Create Rules		
Create Report Definitions		
Create Study		
Create Research Staff (user)		✓
Create Investigator (user)		✓
Create Investigator (non-user)		✓
create course		✓
edit course		
Create Aes		✓
Create MedDRA		
Create Subject		✓
Edit Rules		✓
Edit Report Definitions		✓
Edit Study		✓
Edit Research Staff (user)		✓
Edit Investigator (user)		✓
Edit Investigator (non-user)		✓
Edit Aes		✓
Edit Subject		✓
Web Service Create Study	CAAERS-4676	
Web Service Update Study	CAAERS-4676	
Web Service Create Research Staff (user)	CAAERS-4676	
Web Service Update Research Staff	CAAERS-4676	
Web Service Create Investigator	CAAERS-4676	

Web Service Update Investigator	CAAERS-4676	
Web Service Create Aes		
Web Service Update Aes		
Web Service Create Subject		
Web Service Update Subject		
Invoke Rule Recommendation		
Create AE Report		
Edit AE Report		
Submit CTEP 24 hr report	INSTITUTION_INFORMATION: INS_BR1_ERR - INSTITUTION_NAME and CTEP_ID association is not valid ADVERSE_EVENT_CTC: AER_BR1_ERR - Provide an accurate CTCAE Version, CATEGORY, AE_TERM, SELECT_AE (if applicable) and GRADE association	
Submit CTEP 5 day report [child]	Unable to test due to above error	
Submit CTEP 24 hr amendment	Unable to test due to above error	
Submit CTEP 5 day amendment [child]	Unable to test due to above error	
Submit CTEP 10 day report	CAAERS-4667 INSTITUTION_INFORMATION: INS_BR1_ERR - INSTITUTION_NAME and CTEP_ID association is not valid ADVERSE_EVENT_CTC: AER_BR1_ERR - Provide an accurate CTCAE Version, CATEGORY, AE_TERM, SELECT_AE (if applicable) and GRADE association	
Submit CTEP 10 day amendment	Unable to test due to above error	
Create Report Notifications		
Submit Report Notifications		
Withdraw Report Notifications		
Amend Report Notifications		
Report Reminder Notifications		
Submit non-AdEERS Report		
Modify Report Mandatory Fields		
Modify CAE Mandatory Fields		
Forgot/Reset password		
Inactivity Reminder		

Grace Period Logout		✅
Withdraw a Report		✅
Expected Aes in CAE		?
Solicited Aes in CAE		✅
Creation of Custom Report		✅
Printing of Custom Report		
Sending of Custom Report		
Average Page Load (seconds)		

Smoke tests for caAERS -- caAERS v2.1.1

Environment

	Version	v2.1.1
	Build	caAERS v. 2.1.1-SNAPSHOT (2010-04-01 10:30:40)
	URL	https://oracle.qa.semanticbits.com/caaers/
	Hardware (bit level)	32bit
	OS (bit level)	32 bit
	Kernel Version	Linux version 2.6.18-92.el5xen (mockbuild@builder16.centos.org) (gcc version 4.1.2 20071124 (Red Hat 4.1.2-42)) #1 SMP Tue Jun 10 19:55:54 EDT 2008

	Virtual Server (Yes/No)	Yes
	Java (bit level)/Version	build 1.5.0_16-b02
	DB (bit level)	32 bit
	DB content	Existing
	DB type	Oracle
	DB version	Oracle Database 10g Enterprise Edition Release 10.2.0.1.0 - Prod
	Tomcat	5.5.23
	ServiceMix	3.3
	caXchange	NA
	Browser version	IE 7

Component	Test Procedure	Results	Comments
Fresh Installation		NA	
Upgrade from v2.0		NA	
Upgrade from v1.9.6.1		NA	
Delete Rules - SAE Reporting Rules		✓	
Import Rules - SAE Reporting Rules		✓	
Import Rules - Mandatory sections Rules		✓	
Import Report Definitions		~~CAAERS-3861~~ ✓	
Import Study		✓	
Import Research Staff		✓	
Import Investigator		✓	
~~Import Aes~~	-	~~NA~~	-
Import MedDRA		✓	
Import Subject		✓	
Import organization		CAAERS-3865	
Import agents		✓	
Create Rules		✓	
Create Report Definitions		✓	
Create Study		✓	
Create Research Staff (user)		✓	
Create Investigator (user)		✓	

Create Investigator (non-user)		✅	
create course		✅	
edit course		✅	
Create Aes		✅	
Create MedDRA		✅	
Create Subject		✅	
Edit Rules		✅	
Edit Report Definitions		✅	
Edit Study		✅	
Edit Research Staff (user)		✅	
Edit Investigator (user)		✅	
Edit Investigator (non-user)		✅	
Edit Aes		✅	
Edit Subject		✅	
Web Service Create Study		✅	
Web Service Update Study		✅	
Web Service Create Research Staff (user)		✅	
Web Service Update Research Staff		CAAERS-3867	
Web Service Create Investigator (user)		✅	
Web Service Create Investigator (non-user)		✅	
Web Service Update Investigator		✅	
Web Service Create Aes		✅	
Web Service Update Aes		✅	
Web Service Create Subject		✅	
Web Service Update Subject		✅	
Invoke Rule Recommendation		✅	
Create AE Report		✅	
Edit AE Report		✅	
Submit 24 hr CTEP report		✅	
Submit child 5 day CTEP report		✅	
Amend child 5 day CTEP report		✅	

Withdraw child 5 day report		✅	
Submit 10 day CTEP report		✅	
Amend 10 day CTEP report		✅	
Submit AdEERS Report (NCI IND)		✅	
Submit AdEERS Report (NCI IDE)			
Submit AdEERS Report (non-NCI IND)			
Submit AdEERS Report (non-NCI IDE)			
Submit AdEERS Report (Commercial Agent)			
Submit AdEERS Report (Commercial Device)			
Submit AdEERS Report (Radiation)			
Submit AdEERS Report (Surgery)			
Create Report Notifications		✅	
Submit Report Notifications		✅	
Withdraw Report Notifications		✅	
Amend Report Notifications			
Report Reminder Notifications			
Submit non-AdEERS Report			
Modify Report Mandatory Fields		✅	
Modify CAE Mandatory Fields		CAAERS-3863	
Forgot/Reset password			
Inactivity Reminder		✅	
Grace Period Logout		✅	
Amend a Report		✅	
Withdraw a Report		✅	
Expected Aes in CAE		✅	
Solicited Aes in CAE		✅	
Creation of Custom Report			
Printing of Custom Report			
Sending of Custom Report			
Average Page Load (seconds)		3	

Smoke tests for caAERS -- caAERS v2.1.2

Environment

	Version	v2.1.2
	Build	caAERS v. 2.1.2-SNAPSHOT (2010-04-29 12:50:16)
	URL	https://oracle.qa.semanticbits.com/caaers/
	Hardware (bit level)	32bit
	OS (bit level)	32 bit
	Kernel Version	Linux version 2.6.18-92.el5xen (mockbuild@builder16.centos.org) (gcc version 4.1.2 20071124 (Red Hat 4.1.2-42)) #1 SMP Tue Jun 10 19:55:54 EDT 2008
	Virtual Server (Yes/No)	Yes
	Java (bit level)/Version	build 1.5.0_16-b02
	DB (bit level)	64 bit
	DB content	Existing
	DB type	Oracle
	DB version	Oracle Database 11g Release 11.2.0.1.0 - 64bit Production
	Tomcat	5.5.23
	ServiceMix	3.3
	caXchange	NA
	Browser version	IE 7

Component	Test Procedure	Results	Comments
Fresh Installation		NA	
Upgrade from v2.0		NA	
Upgrade from v1.9.6.1		NA	
Delete Rules - SAE Reporting Rules			
Import Rules - SAE Reporting Rules			
Import Rules - Mandatory sections Rules			
Import Report Definitions			

Import Study		✅	
Import Research Staff		✅	
Import Investigator		✅	
~~Import Aes~~	-		-
Import MedDRA			
Import Subject		✅	
Import organization		CAAERS-3950	
Import agents		✅	
Create Rules		✅	
Create Report Definitions		✅	
Create Study		✅	
Create Research Staff (user)		✅	
Create Investigator (user)		✅	
Create Investigator (non-user)		✅	
create course		✅	
edit course		✅	
Create Aes		✅	
Create MedDRA			
Create Subject		✅	
Edit Rules		✅	
Edit Report Definitions		✅	
Edit Study		✅	
Edit Research Staff (user)		✅	
Edit Investigator (user)		✅	
Edit Investigator (non-user)		✅	
Edit Aes		✅	
Edit Subject		✅	
Web Service Create Study		✅	
Web Service Update Study		✅	
Web Service Create Research Staff (user)		⚠	
Web Service Update Research Staff		✅	

Web Service Create Investigator (user)		⚠	
Web Service Create Investigator (non-user)		✓	
Web Service Update Investigator		✓	
Web Service Create Aes			
Web Service Update Aes			
Web Service Create Subject		✓	
Web Service Update Subject		✓	
Invoke Rule Recommendation		✓	
Create AE Report		✓	
Edit AE Report		✓	
Submit 24 hr CTEP report		✓	
Submit child 5 day CTEP report		✓	
Amend child 5 day CTEP report		✓	
Withdraw child 5 day report		✓	
Submit 10 day CTEP report		✓	
Amend 10 day CTEP report		✓	
Submit AdEERS Report (NCI IND)		✓	
Submit AdEERS Report (NCI IDE)			
Submit AdEERS Report (non-NCI IND)			
Submit AdEERS Report (non-NCI IDE)			
Submit AdEERS Report (Commercial Agent)			
Submit AdEERS Report (Commercial Device)			
Submit AdEERS Report (Radiation)		✓	
Submit AdEERS Report (Surgery)			
Create Report Notifications		✓	
Submit Report Notifications		✓	
Withdraw Report Notifications		CAAERS-3944	
Amend Report Notifications		CAAERS-3944	
Report Reminder Notifications			
Submit non-AdEERS Report			
Modify Report Mandatory Fields			
Modify CAE Mandatory Fields			
Forgot/Reset password		✓	

Inactivity Reminder		✅	
Grace Period Logout		✅	
Amend a Report		✅	
Withdraw a Report		✅	
Expected Aes in CAE		CAAERS-3946	
Solicited Aes in CAE		✅	
Creation of Custom Report			
Printing of Custom Report			
Sending of Custom Report			

Note: Following tests were conducted logged in as SYSTEM ADMIN.

Test cases for caAERS v1.1.3

Use case context: Release Notes for caAERS v1.1.3

The latest release of caAERS pilot version incorporates a number of improvements to the user interface as well as minor bug fixes. We list them below:

1. Changes to collection of Hospitalization information:
    a. **v1.1.2 scenario:** Currently, if CTC grade > 2, the user has to choose 'Hospitalization' in the Enter AEs tab as one of the values of 'Hospitalization' or 'Prolonged Hospitalization' .
    b. **v1.1.3 scenario:** For CTEP studies, if grade is <=2 then it is not mandatory for hospitalization information to be recorded. In case of CTC grade > 2 the user needs to record hospitalization information as follows: 'Hospitalization / Prolonged Hospitalization ?' : Select one of the values of: 'Yes' or 'No'
    c. The following flows are affected by the change:
        i. creation / import of rules.
        ii. import of routine AEs.
        iii. creation of expedited AEs/routine AEs.
        iv. AdEERS reporting.
2. Changes to collection of Expectedness information:
    a. **v1.1.2 scenario:** Currently for all studies it is mandatory for the user to mention expectedness [CTMS:in 'Enter AEs' tab] with one of the values of 'Yes' or 'No'.
    b. **v1.1.3 scenario:** Since it is not mandatory for users to mention expectedness for studies with CTEP INDs, caAERS will not display expectedness information in the 'Enter AEs' tab. For a CTEP IND study expectedness will be assigned a default value of 'No', and is hidden from users.
    c. The following flows are affected by the change:CTMS:TBD
3. Users may need to export their existing rule sets, transform them to reflect changes to the domain concepts and re-import them into caAERS.
4. Date format changes:
    a. **v1.1.2 scenario:** Dates were captured in MM/DD//YYYY for the following fields:
        i. Enter AEs >> Patient Details >> Date of initial diagnosis.
        ii. Enter AEs >> Prior therapies >> Therapy start date.
    b. **v1.1.3 scenario:** Dates will be captured in MM/YYYY format for the above fields. i.e. mentioning day will be optional.
    c. The following flows are affected by the change:
        i. creation of expedited AEs.
        ii. AdEERS reporting.
        iii. System rules.
5. System rule and error message updated in Enter AEs >> Course and Agent. Error message now says: "'Unit of measure' must be provided if 'Total dose administered this course' is provided."

	Scenario	Result
1	User enter an AE with grade>2. The 'Hospitalization / Prolonged Hospitalization ?' field should become mandatory. User should **not** be able to proceed without answering 'Yes/No' to this field.	
2	User enter an AE with grade<=2. The 'Hospitalization / Prolonged Hospitalization ?' field should become optional. User should be able to proceed without answering 'Yes/No' to this field.	
3	User creates a routine AE with grade 3 or greater. This should automatically become a SAE and when user enters the edit SAE flow, he should **not** be allowed to proceed without entering the hospitalization information.	
4	User enter an AE with grade>2. The value of 'Yes/No' chosen by the user should be reflected in the generated Adeers report at the adeers website.	
5	User enters an AE and mentions 'expectedness' as 'Yes'. In the 'Select report' page, report A should be selected as the necessary action. [CTMS:the rules will be set up to fire this action].	
6	User enters an AE and mentions 'expectedness' as 'No'. In the 'Select report' page, report B should be selected as the necessary action. [CTMS:the rules will be set up to fire this action].	
7	User enters an AE and mentions 'expectedness' as 'Please select'. In the 'Select report' page, report B should be selected as the necessary action. [CTMS:the rules will be set up to fire this action].	
8	In Enter AEs >> Patient Details >> Date of initial diagnosis, date is mentioned in the MM/YYYY format.	
9	In Enter AEs >> Patient Details >> Date of initial diagnosis, an invalid date is mentioned [CTMS:for example -ve values for MM and YYYY]	
10	In Enter AEs >> Prior therapies >> Therapy start date, date is mentioned in the MM/YYYY format.	
11	In Enter AEs >> Prior therapies >> Therapy end date, date is mentioned in the MM/YYYY format.	
12	In Enter AEs >> Prior therapies >> Therapy start date, an invalid date is mentioned [CTMS:for example -ve values for MM and YYYY]	

13	In Enter AEs >> Prior therapies >> Therapy end date, an invalid date is mentioned [CTMS:for example -ve values for MM and YYYY]	
14	User has entered specific dates Enter AEs >> Patient Details >> Date of initial diagnosis, Enter AEs >> Prior therapies >> Therapy start date, and Enter AEs >> Prior therapies >> Therapy end date. The corresponding fields in the Adeers are checked to see if the values are reflected.	
15	In Enter AEs>> Course and Agent, user enters total dose for study agent but does not choose a specific UOM. caAERS should throw the following error message: "'Unit of measure' must be provided if 'Total dose administered this course' is provided."	

Test Cases for Advanced Search

Test Setup

caaers URL: https://oracle.qa.semanticbits.com/caaers/

caaers version: caAERS v. 2.2.1-SNAPSHOT [trunk]

DB details

DB type*:* oracle

DB version: Oracle Database 10g Enterprise Edition Release 10.2.0.1.0 - Prod

hostname: sbhost02.herndon.semanticbits.com

port: 1521

SID: SBQA

schema username/password: caaers_perf2/caaers_perf2

login details

username: mayo-data-analyst

password: Hello-23

user role: Data Analyst

associated site: MN026

associated study: 5876

at coordinating center: MN026

participant associated to study at study sites: (82709jlkj) Vas Gans, (h) h h, (wayne-pt2) wayne pt2

Test Scenarios

Report Search

Search for report by name

Scenario

1. User is in enter criteria tab.
2. User chooses to search for report
3. User adds a new report search critierion
4. The criterion is specified as: report name equal to CTEP 24 Hour SAE Notification
5. User clicks continue.
6. User is in select view tab.
7. User selecst search object as report.

8. User select attributes as id, name, organization, submitted on, and report status
9. User clicks search.
10. User is in search results tab.

Expected

The id, name, organization, submitted on, and report status of reports with report name equal to CTEP 24 Hour SAE Notification are shown.

CAAERS-4413

SQL script

```
---all reports
SELECT R.Id,
  X.Name,
  Rv.Submitted_On,
  DECODE( Rv.Status_Code, 1, 'PENDING', 2, 'COMPLETED', 3, 'WITHDRAWN', 4, 'INPROCESS', 5 , 'FAILED',
6, 'REPLACED', 7, 'AMENDED', 8 , 'WITHDRAW_FAILED', 'Dont Know' ) AS status
FROM Report_Schedules R
JOIN report_versions rv
ON rv.report_id = r.id
JOIN Report_Calendar_Templates x
ON x.Id            = R.Rct_Id
WHERE R.Report_Id IN
  (SELECT Id
  FROM Ae_Reports
  WHERE Reporting_Period_Id IN
    (SELECT Id
    FROM Ae_Reporting_Periods
    WHERE Assignment_Id IN
      (SELECT id
      FROM Participant_Assignments
      WHERE Study_Site_Id IN
        (SELECT Id
        FROM Study_Organizations
        WHERE Study_Id IN
          (SELECT Id
          FROM Studies
          WHERE Id IN
            (SELECT Study_Id
            FROM Study_Organizations
            WHERE Id IN
              (SELECT Study_Sites_Id
              FROM Study_Personnel
              WHERE Site_Research_Staffs_Id IN
                (SELECT Id
                FROM Site_Research_Staffs
                WHERE Researchstaff_Id IN
                  ( SELECT Id FROM Research_Staffs WHERE Login_Id = 'mayo-data-analyst'
                  )
                )
              )
            AND type IN ( 'SCC' , 'SST')
            )
          )
        )
      )
    )
  )
AND x.name = 'CTEP 24 Hour SAE Notification'
ORDER BY R.Id
```

Search for report by course start date

Scenario

1. User is in enter criteria tab.
2. User chooses to search for report
3. User adds a new report search critierion
4. The criterion is specified as: course start date greater than 07/30/2010
5. User clicks continue.
6. User is in select view tab.
7. User selecst search object as report.
8. User select attributes as id, name, organization, submitted on, and report status
9. User clicks search.
10. User is in search results tab.

Expected

The id, name, organization, submitted on, and report status of reports with course start date greater than 07/30/2010 are shown.

SQL script

```
SELECT R.Id,
  X.Name,
  Rv.Submitted_On,
  DECODE( Rv.Status_Code, 1, 'PENDING', 2, 'COMPLETED', 3, 'WITHDRAWN', 4, 'INPROCESS', 5 , 'FAILED',
6, 'REPLACED', 7, 'AMENDED', 8 , 'WITHDRAW_FAILED', 'Dont Know' ) AS status
FROM Report_Schedules R
JOIN report_versions rv
ON rv.report_id = r.id
JOIN Report_Calendar_Templates x
ON x.Id            = R.Rct_Id
WHERE R.Report_Id IN
  (SELECT Id
  FROM Ae_Reports
  WHERE Reporting_Period_Id IN
    (SELECT Id
    FROM Ae_Reporting_Periods
    WHERE Assignment_Id IN
      (SELECT id
      FROM Participant_Assignments
      WHERE Study_Site_Id IN
        (SELECT Id
        FROM Study_Organizations
        WHERE Study_Id IN
          (SELECT Id
          FROM Studies
          WHERE Id IN
            (SELECT Study_Id
            FROM Study_Organizations
            WHERE Id IN
              (SELECT Study_Sites_Id
              FROM Study_Personnel
              WHERE Site_Research_Staffs_Id IN
                (SELECT Id
                FROM Site_Research_Staffs
                WHERE Researchstaff_Id IN
                  ( SELECT Id FROM Research_Staffs WHERE Login_Id = 'mayo-data-analyst'
                  )
                )
              )
            AND type IN ( 'SCC' , 'SST')
            )
          )
        )
      )
    AND start_date > '30-JUL-10'
    )
  )
ORDER BY R.Id
```

Search for report by investigational agent administered

Scenario

1. User is in enter criteria tab.
2. User chooses to search for report
3. User adds a new report search critierion
4. The criterion is specified as:investigational agent administered equal to yes
5. User clicks continue.
6. User is in select view tab.
7. User selecst search object as report.
8. User select attributes as id, name, organization, submitted on, and report status
9. User clicks search.
10. User is in search results tab.

Expected

The id, name, organization, submitted on, and report status of reports with investigational agent administered equal to yes are shown.

SQL SCRIPT

```
SELECT R.Id,
  X.Name,
  Rv.Submitted_On,
  DECODE( Rv.Status_Code, 1, 'PENDING', 2, 'COMPLETED', 3, 'WITHDRAWN', 4, 'INPROCESS', 5 , 'FAILED',
6, 'REPLACED', 7, 'AMENDED', 8 , 'WITHDRAW_FAILED', 'Dont Know' ) AS status
FROM Report_Schedules R
JOIN report_versions rv
ON rv.report_id = r.id
JOIN Report_Calendar_Templates x
ON x.Id            = R.Rct_Id
WHERE R.Report_Id IN
  (SELECT aer.Id
  FROM Ae_Reports aer
  JOIN treatments t
  ON aer.id=t.report_id
  WHERE Reporting_Period_Id IN
    (SELECT Id
    FROM Ae_Reporting_Periods
    WHERE Assignment_Id IN
      (SELECT id
      FROM Participant_Assignments
      WHERE Study_Site_Id IN
        (SELECT Id
        FROM Study_Organizations
        WHERE Study_Id IN
          (SELECT Id
          FROM Studies
          WHERE Id IN
            (SELECT Study_Id
            FROM Study_Organizations
            WHERE Id IN
              (SELECT Study_Sites_Id
              FROM Study_Personnel
              WHERE Site_Research_Staffs_Id IN
                (SELECT Id
                FROM Site_Research_Staffs
                WHERE Researchstaff_Id IN
                  ( SELECT Id FROM Research_Staffs WHERE Login_Id = 'mayo-data-analyst'
                  )
                )
              )
            AND type IN ( 'SCC' , 'SST')
            )
          )
        )
      )
    )
  AND t.inv_agent_adminstrd = 1
  )
ORDER BY R.Id
```

Search for report by report status

Scenario

1. User is in enter criteria tab.
2. User chooses to search for report
3. User adds a new report search critierion
4. The criterion is specified as: report status not equal to completed
5. User clicks continue.
6. User is in select view tab.
7. User selecst search object as report.
8. User select attributes as id, name, organization, created on, submitted on, and report status
9. User clicks search.

10. User is in search results tab.

Expected

The id, name, organization, created on, submitted on, and report status of reports with report status not equal to completed are shown.

SQL script

```
SELECT R.Id,
  X.Name,
  Rv.Submitted_On,
  rv.created_on,
  DECODE( Rv.Status_Code, 1, 'PENDING', 2, 'COMPLETED', 3, 'WITHDRAWN', 4, 'INPROCESS', 5 , 'FAILED',
6, 'REPLACED', 7, 'AMENDED', 8 , 'WITHDRAW_FAILED', 'Dont Know' ) AS status
FROM Report_Schedules R
JOIN report_versions rv
ON rv.report_id = r.id
JOIN Report_Calendar_Templates x
ON x.Id            = R.Rct_Id
WHERE R.Report_Id IN
  (SELECT aer.Id
  FROM Ae_Reports aer
  WHERE Reporting_Period_Id IN
    (SELECT Id
    FROM Ae_Reporting_Periods
    WHERE Assignment_Id IN
      (SELECT id
      FROM Participant_Assignments
      WHERE Study_Site_Id IN
        (SELECT Id
        FROM Study_Organizations
        WHERE Study_Id IN
          (SELECT Id
          FROM Studies
          WHERE Id IN
            (SELECT Study_Id
            FROM Study_Organizations
            WHERE Id IN
              (SELECT Study_Sites_Id
              FROM Study_Personnel
              WHERE Site_Research_Staffs_Id IN
                (SELECT Id
                FROM Site_Research_Staffs
                WHERE Researchstaff_Id IN
                  ( SELECT Id FROM Research_Staffs WHERE Login_Id = 'mayo-data-analyst'
                  )
                )
              )
            AND type IN ( 'SCC' , 'SST')
            )
          )
        )
      )
    )
  )
AND rv.status_code <> 2
ORDER BY R.Id
```

Search for report by report name and study

Scenario

1. User is in enter criteria tab.
2. User chooses to search for report
3. User adds a new report search critierion
4. The criterion is specified as: report name equal to CTEP 24 Hour SAE Notification and study equal to (5876) Phase II Trial of Flavopiridol and Cisplatin in Advanced Epithelial Ovarian and Primary Peritoneal Carcinomas - XYZ

5. User clicks continue.
6. User is in select view tab.
7. User selecst search object as report.
8. User select attributes as id, short title, name and report status
9. User clicks search.
10. User is in search results tab.

Expected

The id, short title, name and report status of reports withreport name equal to CTEP 24 Hour SAE Notification and study equal to (5876) Phase II Trial of Flavopiridol and Cisplatin in Advanced Epithelial Ovarian and Primary Peritoneal Carcinomas - XYZ are shown.

SQL SCRIPT

```
SELECT R.Id,
  (SELECT short_title
  FROM studies
  WHERE id IN
    (SELECT STUDY_ID
    FROM study_organizations
    WHERE id IN
      (SELECT study_site_id
      FROM participant_assignments
      WHERE id IN
        (SELECT ASSIGNMENT_ID
        FROM ae_reporting_periods
        WHERE id IN
          (SELECT REPORTING_PERIOD_ID
          FROM ae_reports
          WHERE id IN
            (SELECT REPORT_ID FROM report_schedules WHERE id = rv.id
            )
          )
        )
      )
    )
  ) AS study_short_title,
  X.Name,
  DECODE( Rv.Status_Code, 1, 'PENDING', 2, 'COMPLETED', 3, 'WITHDRAWN', 4, 'INPROCESS', 5 , 'FAILED',
6, 'REPLACED', 7, 'AMENDED', 8 , 'WITHDRAW_FAILED', 'Dont Know' ) AS status
FROM Report_Schedules R
JOIN report_versions rv
ON rv.report_id = r.id
JOIN Report_Calendar_Templates x
ON x.Id            = R.Rct_Id
WHERE R.Report_Id IN
  (SELECT aer.Id
  FROM Ae_Reports aer
  WHERE Reporting_Period_Id IN
    (SELECT Id
    FROM Ae_Reporting_Periods
    WHERE Assignment_Id IN
      (SELECT id
      FROM Participant_Assignments
      WHERE Study_Site_Id IN
        (SELECT Id
        FROM Study_Organizations
        WHERE Study_Id IN
          (SELECT s.Id
          FROM Studies s
          JOIN identifiers i
          ON i.stu_id = s.id
          WHERE s.Id IN
            (SELECT Study_Id
            FROM Study_Organizations
            WHERE Id IN
              (SELECT Study_Sites_Id
              FROM Study_Personnel
```

```
            WHERE Site_Research_Staffs_Id IN
              (SELECT Id
              FROM Site_Research_Staffs
              WHERE Researchstaff_Id IN
                ( SELECT Id FROM Research_Staffs WHERE Login_Id = 'mayo-data-analyst'
                )
              )
            )
          AND type IN ( 'SCC' , 'SST')
          )
        AND i.value='5876'
        )
      )
    )
  )
)
```

```
AND x.name = 'CTEP 24 Hour SAE Notification'
ORDER BY R.Id;
```

Search for report by report name and study short name

Scenario

1. User is in enter criteria tab.
2. User chooses to search for report
3. User adds a new report search critierion
4. The criterion is specified as: report name equal to CTEP 24 Hour SAE Notification and study short title not equal to carcinoma
5. User clicks continue.
6. User is in select view tab.
7. User selecst search object as report.
8. User select attributes as id, short title, name, organization, created on, submitted on and report status
9. User clicks search.
10. User is in search results tab.

Expected

The id, short title, name, organization, created on, submitted on and report status of reports with report name equal to CTEP 24 Hour SAE Notification and study short title not equal to carcinoma are shown.

SQL SCRIPT

```
SELECT R.Id,
  (SELECT short_title
  FROM studies
  WHERE id IN
    (SELECT STUDY_ID
    FROM study_organizations
    WHERE id IN
      (SELECT study_site_id
      FROM participant_assignments
      WHERE id IN
        (SELECT ASSIGNMENT_ID
        FROM ae_reporting_periods
        WHERE id IN
          (SELECT REPORTING_PERIOD_ID
          FROM ae_reports
          WHERE id IN
            (SELECT REPORT_ID FROM report_schedules WHERE id = rv.id
            )
          )
        )
      )
    )
  AND short_title <> 'carcinoma'
  ) AS study_short_title,
  X.Name,
  rv.Submitted_On,
  rv.created_on,
  DECODE( Rv.Status_Code, 1, 'PENDING', 2, 'COMPLETED', 3, 'WITHDRAWN', 4, 'INPROCESS', 5 , 'FAILED',
6, 'REPLACED', 7, 'AMENDED', 8 , 'WITHDRAW_FAILED', 'Dont Know' ) AS status
FROM Report_Schedules R
JOIN report_versions rv
ON rv.report_id = r.id
JOIN Report_Calendar_Templates x
ON x.Id            = R.Rct_Id
WHERE R.Report_Id IN
  (SELECT aer.Id
  FROM Ae_Reports aer
  WHERE Reporting_Period_Id IN
    (SELECT Id
    FROM Ae_Reporting_Periods
    WHERE Assignment_Id IN
```

```
    (SELECT id
    FROM Participant_Assignments
    WHERE Study_Site_Id IN
      (SELECT Id
      FROM Study_Organizations
      WHERE Study_Id IN
        (SELECT s.Id
        FROM Studies s
        JOIN identifiers i
        ON i.stu_id = s.id
        WHERE s.Id IN
          (SELECT Study_Id
          FROM Study_Organizations
          WHERE Id IN
            (SELECT Study_Sites_Id
            FROM Study_Personnel
            WHERE Site_Research_Staffs_Id IN
              (SELECT Id
              FROM Site_Research_Staffs
              WHERE Researchstaff_Id IN
                ( SELECT Id FROM Research_Staffs WHERE Login_Id = 'mayo-data-analyst'
                )
              )
            )
          AND type IN ( 'SCC' , 'SST')
          )
        AND i.value='5876'
        )
      )
    )
  )
)
```

```
AND x.name = 'CTEP 24 Hour SAE Notification'
ORDER BY R.Id;
```

Search for report by report name and subject

Scenario

1. User is in enter criteria tab.
2. User chooses to search for report
3. User adds a new report search critierion
4. The criterion is specified as: report name equal to CTEP 24 Hour SAE Notification and subject first name equal to wayne
5. User clicks continue.
6. User is in select view tab.
7. User select search object as report.
8. User select attributes as id, name, organization, created on, report status, first name, and last name
9. User clicks search.
10. User is in search results tab.

Expected

The id, name, organization, created on, report status, first name, and last name of reports with report name equal to CTEP 24 Hour SAE Notification and subject first name equal to wayne are shown.

SQL SCRIPT

```
SELECT R.Id,
  X.Name,
  rv.created_on,
  DECODE( Rv.Status_Code, 1, 'PENDING', 2, 'COMPLETED', 3, 'WITHDRAWN', 4, 'INPROCESS', 5 , 'FAILED',
6, 'REPLACED', 7, 'AMENDED', 8 , 'WITHDRAW_FAILED', 'Dont Know' ) AS status,
  p.first_name,
  p.last_name
FROM Report_Schedules R
JOIN report_versions rv
ON rv.report_id = r.id
JOIN Report_Calendar_Templates x
ON x.Id = R.Rct_Id
JOIN ae_reports
ON ae_reports.id=R.REPORT_ID
JOIN ae_reporting_periods
ON ae_reporting_periods.id = ae_reports.reporting_period_id
JOIN participant_assignments
ON participant_assignments.id=ae_reporting_periods.assignment_id
JOIN participants p
ON p.id            =participant_assignments.participant_id
WHERE R.Report_Id IN
  (SELECT aer.Id
  FROM Ae_Reports aer
  WHERE Reporting_Period_Id IN
    (SELECT Id
    FROM Ae_Reporting_Periods
    WHERE Assignment_Id IN
      (SELECT id
      FROM Participant_Assignments
      WHERE Study_Site_Id IN
        (SELECT Id
        FROM Study_Organizations
        WHERE Study_Id IN
          (SELECT Id
          FROM Studies
          WHERE Id IN
            (SELECT Study_Id
            FROM Study_Organizations
            WHERE Id IN
              (SELECT Study_Sites_Id
              FROM Study_Personnel
              WHERE Site_Research_Staffs_Id IN
                (SELECT Id
                FROM Site_Research_Staffs
                WHERE Researchstaff_Id IN
                  ( SELECT Id FROM Research_Staffs WHERE Login_Id = 'mayo-data-analyst'
                  )
                )
              )
            AND type IN ( 'SCC' , 'SST')
            )
          )
        )
      )
    )
  )
AND p.first_name='wayne'
AND x.name      = 'CTEP 24 Hour SAE Notification'
ORDER BY R.Id
```

Search for report by report status and subject first name

Scenario

1. User is in enter criteria tab.
2. User chooses to search for report
3. User adds a new report search critierion
4. The criterion is specified as: report status equal to pending , subject first name not equal to vas and subject first name not equal to h
5. User clicks continue.
6. User is in select view tab.
7. User selecst search object as report.
8. User select attributes as id, name, organization, created on, report status, first name, and last name
9. User clicks search.
10. User is in search results tab.

Expected

The id, name, organization, created on, report status, first name, and last name of reports with report status equal to pending , subject first name not equal to vas and subject first name not equal to h are shown.

SQL SCRIPT

```
SELECT R.Id,
  X.Name,
  rv.created_on,
  DECODE( Rv.Status_Code, 1, 'PENDING', 2, 'COMPLETED', 3, 'WITHDRAWN', 4, 'INPROCESS', 5 , 'FAILED',
6, 'REPLACED', 7, 'AMENDED', 8 , 'WITHDRAW_FAILED', 'Dont Know' ) AS status,
  p.first_name,
  p.last_name
FROM Report_Schedules R
JOIN report_versions rv
ON rv.report_id = r.id
JOIN Report_Calendar_Templates x
ON x.Id = R.Rct_Id
JOIN ae_reports
ON ae_reports.id=R.REPORT_ID
JOIN ae_reporting_periods
ON ae_reporting_periods.id = ae_reports.reporting_period_id
JOIN participant_assignments
ON participant_assignments.id=ae_reporting_periods.assignment_id
JOIN participants p
ON p.id            =participant_assignments.participant_id
WHERE R.Report_Id IN
  (SELECT aer.Id
  FROM Ae_Reports aer
  WHERE Reporting_Period_Id IN
    (SELECT Id
    FROM Ae_Reporting_Periods
    WHERE Assignment_Id IN
      (SELECT id
      FROM Participant_Assignments
      WHERE Study_Site_Id IN
        (SELECT Id
        FROM Study_Organizations
        WHERE Study_Id IN
          (SELECT Id
          FROM Studies
          WHERE Id IN
            (SELECT Study_Id
            FROM Study_Organizations
            WHERE Id IN
              (SELECT Study_Sites_Id
              FROM Study_Personnel
              WHERE Site_Research_Staffs_Id IN
                (SELECT Id
                FROM Site_Research_Staffs
                WHERE Researchstaff_Id IN
                  ( SELECT Id FROM Research_Staffs WHERE Login_Id = 'mayo-data-analyst'
                  )
                )
              )
            AND type IN ( 'SCC' , 'SST')
            )
          )
        )
      )
    )
  )
AND p.first_name <> 'vas'
AND p.first_name <> 'h'
AND Rv.Status_Code=1
ORDER BY R.Id
```

AE Search

Search for AEs by grade

Scenario

1. User is in enter criteria tab.
2. User chooses to search for AE
3. User adds a new AE search critierion
4. The criterion is specified as: AE grade equal to 3.
5. User clicks continue.
6. User is in select view tab.
7. User select search object as AE.
8. User select attributes as id, grade, verbatim, CTCAE term, and other meddra
9. User clicks search.
10. User is in search results tab.

Expected

The id, grade, verbatim, CTCAE term, and other meddra of AEs with grade equal to 3 are shown.

SQL SCRIPT

```
SELECT ae.id,
  ae.grade_code,
  ae.details_for_other,
  (SELECT term
  FROM ctc_terms
  WHERE id IN
    (SELECT term_id FROM ae_terms WHERE ADVERSE_EVENT_ID=ae.id
    )
  ) AS ctc_term,
  (SELECT meddra_code FROM meddra_llt WHERE id =ae.low_level_term_id
  ) AS other_meddra
FROM adverse_events ae
WHERE ae.REPORT_ID IN
  (SELECT aer.Id
  FROM Ae_Reports aer
  WHERE Reporting_Period_Id IN
    (SELECT Id
    FROM Ae_Reporting_Periods
    WHERE Assignment_Id IN
      (SELECT id
      FROM Participant_Assignments
      WHERE Study_Site_Id IN
        (SELECT Id
        FROM Study_Organizations
        WHERE Study_Id IN
          (SELECT Id
          FROM Studies
          WHERE Id IN
            (SELECT Study_Id
            FROM Study_Organizations
            WHERE Id IN
              (SELECT Study_Sites_Id
              FROM Study_Personnel
              WHERE Site_Research_Staffs_Id IN
                (SELECT Id
                FROM Site_Research_Staffs
                WHERE Researchstaff_Id IN
                  ( SELECT Id FROM Research_Staffs WHERE Login_Id = 'mayo-data-analyst'
                  )
                )
              )
            AND type IN ( 'SCC' , 'SST')
            )
          )
        )
      )
    )
  )
AND ae.grade_code=3
ORDER BY ae.id
```

Search for AEs by CTC term

Scenario

1. User is in enter criteria tab.
2. User chooses to search for AE
3. User adds a new AE search critierion
4. The criterion is specified as: CTCAE term equal to Vasculitis.
5. User clicks continue.
6. User is in select view tab.
7. User select search object as AE.
8. User select attributes as id, grade, verbatim, CTCAE term, and other meddra
9. User clicks search.

10. User is in search results tab.

Expected

The id, grade, verbatim, CTCAE term, and other meddra of AEs with CTCAE term equal to vasculitis are shown.

SQL SCRIPT v1

```
SELECT ae.id,
  ae.grade_code,
  ae.details_for_other,
  (SELECT term
  FROM ctc_terms
  WHERE id IN
    (SELECT term_id FROM ae_terms WHERE ADVERSE_EVENT_ID=ae.id
    )
  ) AS ctc_term,
  (SELECT meddra_code FROM meddra_llt WHERE id =ae.low_level_term_id
  ) AS other_meddra
FROM adverse_events ae
WHERE ae.REPORT_ID IN
  (SELECT aer.Id
  FROM Ae_Reports aer
  WHERE Reporting_Period_Id IN
    (SELECT Id
    FROM Ae_Reporting_Periods
    WHERE Assignment_Id IN
      (SELECT id
      FROM Participant_Assignments
      WHERE Study_Site_Id IN
        (SELECT Id
        FROM Study_Organizations
        WHERE Study_Id IN
          (SELECT Id
          FROM Studies
          WHERE Id IN
            (SELECT Study_Id
            FROM Study_Organizations
            WHERE Id IN
              (SELECT Study_Sites_Id
              FROM Study_Personnel
              WHERE Site_Research_Staffs_Id IN
                (SELECT Id
                FROM Site_Research_Staffs
                WHERE Researchstaff_Id IN
                  ( SELECT Id FROM Research_Staffs WHERE Login_Id = 'mayo-data-analyst'
                  )
                )
              )
            AND type IN ( 'SCC' , 'SST')
            )
          )
        )
      )
    )
  )
AND ae.id IN
  (SELECT ADVERSE_EVENT_ID
  FROM ae_terms
  WHERE term_id IN
    (SELECT id FROM ctc_terms WHERE term='Vasculitis'
    )
  )
ORDER BY ae.id
```

—

SQL SCRIPT shorter version

```
 SELECT ae.id,
  ae.grade_code,
  ae.details_for_other,
  (SELECT term
  FROM ctc_terms
  WHERE id IN
    (SELECT term_id FROM ae_terms WHERE ADVERSE_EVENT_ID=ae.id
    )
  ) AS ctc_term,
  (SELECT meddra_code FROM meddra_llt WHERE id =ae.low_level_term_id
  ) AS other_meddra
FROM adverse_events ae
WHERE ae.REPORT_ID IN (select id from table(getAeReportsForUser('mayo-data-analyst')))
AND ae.id IN
  (SELECT ADVERSE_EVENT_ID
  FROM ae_terms
  WHERE term_id IN
    (SELECT id FROM ctc_terms WHERE term='Vasculitis'
    )
  )
ORDER BY ae.id
```

Search for AEs by verbatim

Scenario

1. User is in enter criteria tab.
2. User chooses to search for AE
3. User adds a new AE search critierion
4. The criterion is specified as: verbatim like rrr.
5. User clicks continue.
6. User is in select view tab.
7. User select search object as AE.
8. User select attributes as id, grade, verbatim, CTCAE term, and other meddra
9. User clicks search.
10. User is in search results tab.

Expected

The id, grade, verbatim, CTCAE term, and other meddra of AEs with verbatim like rrr are shown.

SQL SCRIPT

```
SELECT ae.id,
 ae.grade_code,
 ae.details_for_other,
 (SELECT term
 FROM ctc_terms
 WHERE id IN
   (SELECT term_id FROM ae_terms WHERE ADVERSE_EVENT_ID=ae.id
   )
 ) AS ctc_term,
 (SELECT meddra_code FROM meddra_llt WHERE id =ae.low_level_term_id
 ) AS other_meddra
FROM adverse_events ae
WHERE ae.REPORT_ID IN
 (SELECT aer.Id
 FROM Ae_Reports aer
 WHERE Reporting_Period_Id IN
   (SELECT Id
   FROM Ae_Reporting_Periods
   WHERE Assignment_Id IN
     (SELECT id
     FROM Participant_Assignments
     WHERE Study_Site_Id IN
       (SELECT Id
       FROM Study_Organizations
       WHERE Study_Id IN
         (SELECT Id
         FROM Studies
         WHERE Id IN
           (SELECT Study_Id
           FROM Study_Organizations
           WHERE Id IN
             (SELECT Study_Sites_Id
             FROM Study_Personnel
             WHERE Site_Research_Staffs_Id IN
               (SELECT Id
               FROM Site_Research_Staffs
               WHERE Researchstaff_Id IN
                 ( SELECT Id FROM Research_Staffs WHERE Login_Id = 'mayo-data-analyst'
                 )
               )
             )
           AND type IN ( 'SCC' , 'SST')
           )
         )
       )
     )
   )
 )
AND ae.details_for_other LIKE '%rrr%'
ORDER BY ae.id
```

Search for AEs by CTC term and study short title

Scenario

1. User is in enter criteria tab.
2. User chooses to search for AE
3. User adds a new AE search critierion
4. The criterion is specified as: CTCAE term equal to vasculitis and study short title like flavopiridol.
5. User clicks continue.
6. User is in select view tab.
7. User select search object as AE.
8. User select attributes as id, grade, verbatim, CTCAE term, other meddra, short title, CC identifier and FS identifier
9. User clicks search.

10. User is in search results tab.

Expected

The id, grade, verbatim, CTCAE term, other meddra, short title, CC identifier and FS identifier of AEs with CTCAE term equal to vasculitis and study short title like flavopiridol are shown.

SQL SCRIPT

```
SELECT ae.id,
  ae.grade_code,
  ae.details_for_other,
  (SELECT term
  FROM ctc_terms
  WHERE id IN
    (SELECT term_id FROM ae_terms WHERE ADVERSE_EVENT_ID=ae.id
    )
  ) AS ctc_term,
  (SELECT meddra_code FROM meddra_llt WHERE id =ae.low_level_term_id
  ) AS other_meddra,
  ae.RETIRED_INDICATOR,
  (SELECT studies.short_title
  FROM studies
  WHERE id IN
    (SELECT Study_Id
    FROM study_organizations
    WHERE id IN
      (SELECT Study_Site_Id
      FROM participant_assignments
      WHERE id IN
        (SELECT Assignment_Id
        FROM Ae_Reporting_Periods
        WHERE id IN
          (SELECT Reporting_Period_Id FROM Ae_Reports WHERE id =ae.REPORT_ID
          )
        )
      )
    )
  ) AS study_short_title,
  (SELECT identifiers.value
  FROM identifiers
  WHERE STU_ID IN
    (SELECT studies.id
    FROM studies
    WHERE id IN
      (SELECT Study_Id
      FROM study_organizations
      WHERE id IN
        (SELECT Study_Site_Id
        FROM participant_assignments
        WHERE id IN
          (SELECT Assignment_Id
          FROM Ae_Reporting_Periods
          WHERE id IN
            (SELECT Reporting_Period_Id FROM Ae_Reports WHERE id =ae.REPORT_ID
            )
          )
        )
      )
    )
  AND identifiers.type='Coordinating Center Identifier'
  ) AS cc_identifier,
  (SELECT identifiers.value
  FROM identifiers
  WHERE STU_ID IN
    (SELECT studies.id
    FROM studies
```

```
    WHERE id IN
      (SELECT Study_Id
      FROM study_organizations
      WHERE id IN
        (SELECT Study_Site_Id
        FROM participant_assignments
        WHERE id IN
          (SELECT Assignment_Id
          FROM Ae_Reporting_Periods
          WHERE id IN
            (SELECT Reporting_Period_Id FROM Ae_Reports WHERE id =ae.REPORT_ID
            )
          )
        )
      )
    )
  AND identifiers.type='Protocol Authority Identifier'
  ) AS FS_identifier
FROM adverse_events ae
WHERE ae.REPORT_ID IN
  (SELECT aer.Id
  FROM Ae_Reports aer
  WHERE Reporting_Period_Id IN
    (SELECT Id
    FROM Ae_Reporting_Periods
    WHERE Assignment_Id IN
      (SELECT id
      FROM Participant_Assignments
      WHERE Study_Site_Id IN
        (SELECT Id
        FROM Study_Organizations
        WHERE Study_Id IN
          (SELECT Id
          FROM Studies
          WHERE Id IN
            (SELECT Study_Id
            FROM Study_Organizations
            WHERE Id IN
              (SELECT Study_Sites_Id
              FROM Study_Personnel
              WHERE Site_Research_Staffs_Id IN
                (SELECT Id
                FROM Site_Research_Staffs
                WHERE Researchstaff_Id IN
                  ( SELECT Id FROM Research_Staffs WHERE Login_Id = 'mayo-data-analyst'
                  )
                )
              )
            AND type IN ( 'SCC' , 'SST')
            )
          AND short_title LIKE '%Flavopiridol%'
          )
        )
      )
    )
  )
AND ae.id IN
  (SELECT ADVERSE_EVENT_ID
  FROM ae_terms
  WHERE term_id IN
    (SELECT id FROM ctc_terms WHERE term='Vasculitis'
    )
```

```
  )
ORDER BY ae.id
```

Search for AEs by CTC term and study.

Scenario

1. User is in enter criteria tab.
2. User chooses to search for AE
3. User adds a new AE search critierion
4. The criterion is specified as: CTCAE term equal to vasculitis and study equal to 5876.
5. User clicks continue.
6. User is in select view tab.
7. User select search object as AE.
8. User select attributes as id, grade, verbatim, CTCAE term, other meddra, short title, CC identifier and FS identifier
9. User clicks search.
10. User is in search results tab.

Expected

The id, grade, verbatim, CTCAE term, other meddra, short title, CC identifier and FS identifier of AEs with CTCAE term equal to vasculitis and study equal to 5876 are shown.

SQL SCRIPT

```
SELECT ae.id,
 ae.grade_code,
 ae.details_for_other,
 (SELECT term
 FROM ctc_terms
 WHERE id IN
   (SELECT term_id FROM ae_terms WHERE ADVERSE_EVENT_ID IN (ae.id)
   )
 ) AS ctc_term,
 (SELECT meddra_code FROM meddra_llt WHERE id IN (ae.low_level_term_id)
 ) AS other_meddra,
 s.short_title,
 (SELECT value
 FROM identifiers i
 WHERE s.id = i.stu_id
 AND i.type ='Protocol Authority Identifier'
 ) AS Funding_Sponsor_Identifier,
 (SELECT value
 FROM identifiers i
 WHERE s.id = i.stu_id
 AND i.type ='Coordinating Center Identifier'
 ) AS Coordinating_Center_Identifier
FROM adverse_events ae
JOIN ae_reports ar
ON ar.id=ae.REPORT_ID
JOIN ae_reporting_periods arp
ON arp.id=ar.REPORTING_PERIOD_ID
JOIN participant_assignments pa
ON pa.id = arp.ASSIGNMENT_ID
JOIN study_organizations so
ON so.id=pa.study_site_id
JOIN studies s
ON s.id=so.study_id
JOIN identifiers i
ON i.stu_id         = s.id
WHERE ae.REPORT_ID IN
 (SELECT ae_Reports.Id
 FROM ae_Reports
 WHERE Reporting_Period_Id IN
   (SELECT Id
```

```
   FROM Ae_Reporting_Periods
   WHERE Assignment_Id IN
     (SELECT id
     FROM Participant_Assignments
     WHERE Study_Site_Id IN
       (SELECT Id
       FROM Study_Organizations
       WHERE Study_Id IN
         (SELECT Id
         FROM Studies
         WHERE Id IN
           (SELECT Study_Id
           FROM Study_Organizations
           WHERE Id IN
             (SELECT Study_Sites_Id
             FROM Study_Personnel
             WHERE Site_Research_Staffs_Id IN
               (SELECT Id
               FROM Site_Research_Staffs
               WHERE Researchstaff_Id IN
                 ( SELECT Id FROM Research_Staffs WHERE Login_Id = 'mayo-data-analyst'
                 )
               )
             )
           AND type IN ( 'SCC' , 'SST')
           )
         )
       )
     )
   )
 )
AND ae.id IN
 (SELECT ADVERSE_EVENT_ID
 FROM ae_terms
 WHERE term_id IN
   (SELECT id FROM ctc_terms WHERE term='Vasculitis'
   )
 )
```

```
AND i.value = '5876'
ORDER BY ae.id
```

Search for AEs by CTC term and study long title.

Scenario

1. User is in enter criteria tab.
2. User chooses to search for AE
3. User adds a new AE search critierion
4. The criterion is specified as: CTCAE term equal to vasculitis and study long title not equal to test.
5. User clicks continue.
6. User is in select view tab.
7. User select search object as AE.
8. User select attributes as id, grade, verbatim, CTCAE term, other meddra, short title, long title, CC identifier and FS identifier
9. User clicks search.
10. User is in search results tab.

Expected

The id, grade, verbatim, CTCAE term, other meddra, short title, long title, CC identifier and FS identifier of AEs with CTCAE term equal to vasculitis and study long title not equal to test are shown.

SQL SCRIPT

```
SELECT ae.id,
 ae.grade_code,
 ae.details_for_other,
 (SELECT term
 FROM ctc_terms
 WHERE id IN
   (SELECT term_id FROM ae_terms WHERE ADVERSE_EVENT_ID IN (ae.id)
   )
 ) AS ctc_term,
 (SELECT meddra_code FROM meddra_llt WHERE id IN (ae.low_level_term_id)
 ) AS other_meddra,
 s.short_title,
 s.long_title,
 (SELECT value
 FROM identifiers i
 WHERE s.id = i.stu_id
 AND i.type ='Protocol Authority Identifier'
 ) AS Funding_Sponsor_Identifier,
 (SELECT value
 FROM identifiers i
 WHERE s.id = i.stu_id
 AND i.type ='Coordinating Center Identifier'
 ) AS Coordinating_Center_Identifier
FROM adverse_events ae
JOIN ae_reports ar
ON ar.id=ae.REPORT_ID
JOIN ae_reporting_periods arp
ON arp.id=ar.REPORTING_PERIOD_ID
JOIN participant_assignments pa
ON pa.id = arp.ASSIGNMENT_ID
JOIN study_organizations so
ON so.id=pa.study_site_id
JOIN studies s
ON s.id=so.study_id
JOIN identifiers i
ON i.stu_id         = s.id
WHERE ae.REPORT_ID IN
 (SELECT ae_Reports.Id
 FROM ae_Reports
 WHERE Reporting_Period_Id IN
```

```
   (SELECT Id
   FROM Ae_Reporting_Periods
   WHERE Assignment_Id IN
     (SELECT id
     FROM Participant_Assignments
     WHERE Study_Site_Id IN
       (SELECT Id
       FROM Study_Organizations
       WHERE Study_Id IN
         (SELECT Id
         FROM Studies
         WHERE Id IN
           (SELECT Study_Id
           FROM Study_Organizations
           WHERE Id IN
             (SELECT Study_Sites_Id
             FROM Study_Personnel
             WHERE Site_Research_Staffs_Id IN
               (SELECT Id
               FROM Site_Research_Staffs
               WHERE Researchstaff_Id IN
                 ( SELECT Id FROM Research_Staffs WHERE Login_Id = 'mayo-data-analyst'
                 )
               )
             )
           AND type IN ( 'SCC' , 'SST')
           )
         )
       )
     )
   )
 )
AND ae.id IN
 (SELECT ADVERSE_EVENT_ID
 FROM ae_terms
 WHERE term_id IN
   (SELECT id FROM ctc_terms WHERE term='Vasculitis'
   )
 )
```

```
AND s.long_title <> 'test'
ORDER BY ae.id
```

Search for AEs by CTC term and subject.

Scenario

1. User is in enter criteria tab.
2. User chooses to search for AE
3. User adds a new AE search critierion
4. The criterion is specified as: CTCAE term equal to vasculitis and subject equal to (wayne-pt2) wayne pt2.
5. User clicks continue.
6. User is in select view tab.
7. User select search object as AE.
8. User select attributes as id, grade, verbatim, CTCAE term, other meddra, first name, last name and subject primary id
9. User clicks search.
10. User is in search results tab.

Expected

The id, grade, verbatim, CTCAE term, other meddra, first name, last name and subject primary id of AEs with CTCAE term equal to vasculitis and subject equal to (wayne-pt2) wayne pt2 are shown.

SQL SCRIPT

```
SELECT ae.id,
 ae.grade_code,
 ae.details_for_other,
 (SELECT term
 FROM ctc_terms
 WHERE id IN
   (SELECT term_id FROM ae_terms WHERE ADVERSE_EVENT_ID=ae.id
   )
 ) AS ctc_term,
 (SELECT meddra_code FROM meddra_llt WHERE id =ae.low_level_term_id
 ) AS other_meddra,
 p.first_name,
 p.last_name,
 (SELECT value
 FROM identifiers i
 WHERE p.id             = i.participant_id
 AND i.primary_indicator=1
 ) AS subject_primary_id
FROM adverse_events ae
JOIN ae_reports ar
ON ar.id=ae.REPORT_ID
JOIN ae_reporting_periods arp
ON arp.id=ar.REPORTING_PERIOD_ID
JOIN participant_assignments pa
ON pa.id = arp.ASSIGNMENT_ID
JOIN participants p
ON p.id             =pa.PARTICIPANT_ID
WHERE ae.REPORT_ID IN
 (SELECT id FROM TABLE(getAeReportsForUser('mayo-data-analyst'))
 )
AND ae.id IN
 (SELECT ADVERSE_EVENT_ID
 FROM ae_terms
 WHERE term_id IN
   (SELECT id FROM ctc_terms WHERE term='Vasculitis'
   )
 )
AND p.id IN
 (SELECT participant_id FROM identifiers WHERE value = 'wayne-pt2'
 )
ORDER BY ae.id
```

Search for AEs by CTC term and subject race.

Scenario

1. User is in enter criteria tab.
2. User chooses to search for AE
3. User adds a new AE search critierion
4. The criterion is specified as: CTCAE term equal to vasculitis and subject race equal to asian.
5. User clicks continue.
6. User is in select view tab.
7. User select search object as AE.
8. User select attributes as id, grade, verbatim, CTCAE term, other meddra, first name, last name, subject primary id and race
9. User clicks search.
10. User is in search results tab.

Expected

The id, grade, verbatim, CTCAE term, other meddra, first name, last name, subject primary id and race of AEs with CTCAE term equal to vasculitis and subject race equal to asian are shown.

SQL SCRIPT

```
SELECT ae.id,
 ae.grade_code,
 ae.details_for_other,
 (SELECT term
 FROM ctc_terms
 WHERE id IN
   (SELECT term_id FROM ae_terms WHERE ADVERSE_EVENT_ID=ae.id
   )
 ) AS ctc_term,
 (SELECT meddra_code FROM meddra_llt WHERE id =ae.low_level_term_id
 ) AS other_meddra,
 p.first_name,
 p.last_name,
 (SELECT value
 FROM identifiers i
 WHERE p.id             = i.participant_id
 AND i.primary_indicator=1
 ) AS subject_primary_id,
 p.race
FROM adverse_events ae
JOIN ae_reports ar
ON ar.id=ae.REPORT_ID
JOIN ae_reporting_periods arp
ON arp.id=ar.REPORTING_PERIOD_ID
JOIN participant_assignments pa
ON pa.id = arp.ASSIGNMENT_ID
JOIN participants p
ON p.id             =pa.PARTICIPANT_ID
WHERE ae.REPORT_ID IN
 (SELECT id FROM TABLE(getAeReportsForUser('mayo-data-analyst'))
 )
AND ae.id IN
 (SELECT ADVERSE_EVENT_ID
 FROM ae_terms
 WHERE term_id IN
   (SELECT id FROM ctc_terms WHERE term='Vasculitis'
   )
 )
AND p.race='Asian'
ORDER BY ae.id
```

Search for AEs by verbatim and subject first name.

Scenario

1. User is in enter criteria tab.
2. User chooses to search for AE
3. User adds a new AE search critierion
4. The criterion is specified as: verbatim like rrr and subject first name equal to wayne.
5. User clicks continue.
6. User is in select view tab.
7. User select search object as AE.
8. User select attributes as id, grade, verbatim, CTCAE term, other meddra, first name, last name, and subject primary id
9. User clicks search.
10. User is in search results tab.

Expected

The id, grade, verbatim, CTCAE term, other meddra, first name, last name, and subject primary id of AEs with verbatim like rrr and subject first name equal to wayne are shown.

SQL SCRIPT

```
SELECT ae.id,
  ae.grade_code,
  ae.details_for_other,
  (SELECT term
  FROM ctc_terms
  WHERE id IN
    (SELECT term_id FROM ae_terms WHERE ADVERSE_EVENT_ID IN (ae.id)
    )
  ) AS ctc_term,
  (SELECT meddra_code FROM meddra_llt WHERE id IN (ae.low_level_term_id)
  ) AS other_meddra,
  p.first_name,
  p.last_name,
  (SELECT value
  FROM identifiers i
  WHERE p.id             = i.participant_id
  AND i.primary_indicator=1
  ) AS subject_primary_id
FROM adverse_events ae
JOIN ae_reports ar
ON ar.id=ae.REPORT_ID
JOIN ae_reporting_periods arp
ON arp.id=ar.REPORTING_PERIOD_ID
JOIN participant_assignments pa
ON pa.id = arp.ASSIGNMENT_ID
JOIN participants p
ON p.id             =pa.PARTICIPANT_ID
WHERE ae.REPORT_ID IN
  (SELECT ae_Reports.Id
  FROM ae_Reports
  WHERE Reporting_Period_Id IN
    (SELECT Id
    FROM Ae_Reporting_Periods
    WHERE Assignment_Id IN
      (SELECT id
      FROM Participant_Assignments
      WHERE Study_Site_Id IN
        (SELECT Id
        FROM Study_Organizations
        WHERE Study_Id IN
          (SELECT Id
          FROM Studies
          WHERE Id IN
            (SELECT Study_Id
            FROM Study_Organizations
            WHERE Id IN
              (SELECT Study_Sites_Id
              FROM Study_Personnel
              WHERE Site_Research_Staffs_Id IN
                (SELECT Id
                FROM Site_Research_Staffs
                WHERE Researchstaff_Id IN
                  ( SELECT Id FROM Research_Staffs WHERE Login_Id = 'mayo-data-analyst'
                  )
                )
              )
            AND type IN ( 'SCC' , 'SST')
            )
          )
        )
      )
    )
  )
AND ae.details_for_other LIKE '%rrr%'
AND p.first_name='wayne'
ORDER BY ae.id
```

Search for AEs by grade and study.

Scenario

1. User is in enter criteria tab.
2. User chooses to search for AE
3. User adds a new AE search critierion
4. The criterion is specified as: grade greater than or equal to 3 and study equal to 5876.
5. User clicks continue.
6. User is in select view tab.
7. User select search object as AE.
8. User select attributes as id, grade, attribution, verbatim, CTCAE term, other meddra, Study Coordinating Center Identifier,and Study Funding Sponsor Identifier
9. User clicks search.
10. User is in search results tab.

Expected

The id, grade, attribution, verbatim, CTCAE term, other meddra, Study Coordinating Center Identifier,and Study Funding Sponsor Identifier of AEs with grade greater than or equal to 3 and study equal to 5876 are shown.

SQL SCRIPT

```
SELECT ae.id,
  ae.grade_code,
  DECODE( ae.ATTRIBUTION_SUMMARY_CODE, 1, 'UNRELATED', 2, 'UNLIKELY', 3, 'POSSIBLE', 4, 'PROBABLE', 5
, 'DEFINITE', 'Dont Know' ) AS attribution,
  ae.details_for_other,
  (SELECT term
  FROM ctc_terms
  WHERE id IN
    (SELECT term_id FROM ae_terms WHERE ADVERSE_EVENT_ID IN (ae.id)
    )
  ) AS ctc_term,
  (SELECT meddra_code FROM meddra_llt WHERE id IN (ae.low_level_term_id)
  ) AS other_meddra,
  (SELECT value
  FROM identifiers i
  WHERE s.id = i.stu_id
  AND i.type ='Protocol Authority Identifier'
  ) AS Funding_Sponsor_Identifier,
  (SELECT value
  FROM identifiers i
  WHERE s.id = i.stu_id
  AND i.type ='Coordinating Center Identifier'
  ) AS Coordinating_Center_Identifier
FROM adverse_events ae
JOIN ae_reports ar
ON ar.id=ae.REPORT_ID
JOIN ae_reporting_periods arp
ON arp.id=ar.REPORTING_PERIOD_ID
JOIN participant_assignments pa
ON pa.id = arp.ASSIGNMENT_ID
JOIN study_organizations so
ON so.id=pa.study_site_id
JOIN studies s
ON s.id=so.study_id
JOIN identifiers i
ON i.stu_id         = s.id
WHERE ae.REPORT_ID IN
  (SELECT ae_Reports.Id
  FROM ae_Reports
  WHERE Reporting_Period_Id IN
    (SELECT Id
    FROM Ae_Reporting_Periods
    WHERE Assignment_Id IN
      (SELECT id
```

```
      FROM Participant_Assignments
      WHERE Study_Site_Id IN
        (SELECT Id
        FROM Study_Organizations
        WHERE Study_Id IN
          (SELECT Id
          FROM Studies
          WHERE Id IN
            (SELECT Study_Id
            FROM Study_Organizations
            WHERE Id IN
              (SELECT Study_Sites_Id
              FROM Study_Personnel
              WHERE Site_Research_Staffs_Id IN
                (SELECT Id
                FROM Site_Research_Staffs
                WHERE Researchstaff_Id IN
                  ( SELECT Id FROM Research_Staffs WHERE Login_Id = 'mayo-data-analyst'
                  )
                )
              )
            AND type IN ( 'SCC' , 'SST')
            )
          )
        )
      )
    )
  )
AND ae.grade_code >= 3
```

```
AND i.value        = '5876'
ORDER BY ae.id
```

Search for AEs by grade, study and subject first name.

Scenario

1. User is in enter criteria tab.
2. User chooses to search for AE
3. User adds a new AE search critierion
4. The criterion is specified as: grade greater than or equal to 3, study equal to 5876 and subject first name like wayne.
5. User clicks continue.
6. User is in select view tab.
7. User select search object as AE.
8. User select attributes as id, grade, attribution, verbatim, CTCAE term, other meddra, subject first name, subject last name, subject primary id, Study Coordinating Center Identifier,and Study Funding Sponsor Identifier
9. User clicks search.
10. User is in search results tab.

Expected

The id, grade, attribution, verbatim, CTCAE term, other meddra, subject first name, subject last name, subject primary id, Study Coordinating Center Identifier,and Study Funding Sponsor Identifier of AEs with grade greater than or equal to 3, study equal to 5876 and subject first name like wayne are shown.

SQL SCRIPT

```
SELECT ae.id,
  ae.grade_code,
  DECODE( ae.ATTRIBUTION_SUMMARY_CODE, 1, 'UNRELATED', 2, 'UNLIKELY', 3, 'POSSIBLE', 4, 'PROBABLE', 5
, 'DEFINITE', 'Dont Know' ) AS attribution,
  ae.details_for_other,
  (SELECT term
  FROM ctc_terms
  WHERE id IN
    (SELECT term_id FROM ae_terms WHERE ADVERSE_EVENT_ID IN (ae.id)
    )
  ) AS ctc_term,
  (SELECT meddra_code FROM meddra_llt WHERE id IN (ae.low_level_term_id)
  ) AS other_meddra,
  p.first_name,
  p.last_name,
  (SELECT value
  FROM identifiers i
  WHERE p.id             = i.participant_id
  AND i.primary_indicator=1
  ) AS subject_primary_id,
  (SELECT value
  FROM identifiers i
  WHERE s.id = i.stu_id
  AND i.type ='Protocol Authority Identifier'
  ) AS Funding_Sponsor_Identifier,
  (SELECT value
  FROM identifiers i
  WHERE s.id = i.stu_id
  AND i.type ='Coordinating Center Identifier'
  ) AS Coordinating_Center_Identifier
FROM adverse_events ae
JOIN ae_reports ar
ON ar.id=ae.REPORT_ID
JOIN ae_reporting_periods arp
ON arp.id=ar.REPORTING_PERIOD_ID
JOIN participant_assignments pa
ON pa.id = arp.ASSIGNMENT_ID
JOIN participants p
```

```
ON p.id=pa.participant_id
JOIN study_organizations so
ON so.id=pa.study_site_id
JOIN studies s
ON s.id=so.study_id
JOIN identifiers i
ON i.stu_id         = s.id
WHERE ae.REPORT_ID IN
  (SELECT ae_Reports.Id
  FROM ae_Reports
  WHERE Reporting_Period_Id IN
    (SELECT Id
    FROM Ae_Reporting_Periods
    WHERE Assignment_Id IN
      (SELECT id
      FROM Participant_Assignments
      WHERE Study_Site_Id IN
        (SELECT Id
        FROM Study_Organizations
        WHERE Study_Id IN
          (SELECT Id
          FROM Studies
          WHERE Id IN
            (SELECT Study_Id
            FROM Study_Organizations
            WHERE Id IN
              (SELECT Study_Sites_Id
              FROM Study_Personnel
              WHERE Site_Research_Staffs_Id IN
                (SELECT Id
                FROM Site_Research_Staffs
                WHERE Researchstaff_Id IN
                  ( SELECT Id FROM Research_Staffs WHERE Login_Id = 'mayo-data-analyst'
                  )
                )
              )
            AND type IN ( 'SCC' , 'SST')
            )
          )
        )
      )
    )
  )
AND ae.grade_code >= 3
AND i.value        = '5876'
```

```
AND p.first_name LIKE '%wayne%'
ORDER BY ae.id
```

Study Search

Search for study by short title

Scenario

1. User is in enter criteria tab.
2. User chooses to search for study
3. User adds a new study search critierion
4. The criterion is specified as: short title like carcinoma.
5. User clicks continue.
6. User is in select view tab.
7. User select search object as study.
8. User select attributes as short title and long title.
9. User clicks search.
10. User is in search results tab.

Expected

The short title and long title of studies with carcinoma in the short title are shown.

SQL SCRIPT

```
SELECT s.short_title,
  s.long_title
FROM Studies s
WHERE s.Id IN
  (SELECT Study_Id
  FROM Study_Organizations
  WHERE Id IN
    (SELECT Study_Sites_Id
    FROM Study_Personnel
    WHERE Site_Research_Staffs_Id IN
      (SELECT Id
      FROM Site_Research_Staffs
      WHERE Researchstaff_Id IN
        ( SELECT Id FROM Research_Staffs WHERE Login_Id = 'mayo-data-analyst'
        )
      )
    )
  AND type IN ( 'SCC' , 'SST')
  )
AND s.short_title LIKE '%Carcinoma%'
```

Search for study by treatment assignment code

Scenario

1. User is in enter criteria tab.
2. User chooses to search for study
3. User adds a new study search critierion
4. The criterion is specified as:treatment assignment code equal to A.
5. User clicks continue.
6. User is in select view tab.
7. User select search object as study.
8. User select attributes as short title , long title and treatment assignment code.
9. User clicks search.
10. User is in search results tab.

Expected

The short title, long title and treatment assignment code of studies with A in the treatment assignment code are shown.

SQL SCRIPT

```
SELECT s.short_title,
  s.long_title,
  ta.code AS treatment_assignment
FROM Studies s
JOIN treatment_assignment ta
ON ta.study_id=s.id
WHERE s.Id   IN
  (SELECT Study_Id
  FROM Study_Organizations
  WHERE Id IN
    (SELECT Study_Sites_Id
    FROM Study_Personnel
    WHERE Site_Research_Staffs_Id IN
      (SELECT Id
      FROM Site_Research_Staffs
      WHERE Researchstaff_Id IN
        ( SELECT Id FROM Research_Staffs WHERE Login_Id = 'mayo-data-analyst'
        )
      )
    )
  AND type IN ( 'SCC' , 'SST')
  )
AND ta.code='A';
```

Search for study by agent name

Scenario

1. User is in enter criteria tab.
2. User chooses to search for study
3. User adds a new study search critierion
4. The criterion is specified as: agent name equal to 649890::Alvocidib (flavopiridol).
5. User clicks continue.
6. User is in select view tab.
7. User select search object as study.
8. User select attributes as short title , long title and agent name.
9. User clicks search.
10. User is in search results tab.

Expected

The short title, long title and agent name of studies with Alvocidib (flavopiridol) in agent name are shown.

SQL SCRIPT

```
SELECT s.id,
  s.short_title,
  s.long_title,
  aa.name AS treatment_assignment
FROM Studies s
JOIN study_agents sa
ON sa.study_id=s.id
JOIN agents aa
ON sa.agent_id=aa.id
WHERE s.Id   IN
  (SELECT Study_Id
  FROM Study_Organizations
  WHERE Id IN
    (SELECT Study_Sites_Id
    FROM Study_Personnel
    WHERE Site_Research_Staffs_Id IN
      (SELECT Id
      FROM Site_Research_Staffs
      WHERE Researchstaff_Id IN
        ( SELECT Id FROM Research_Staffs WHERE Login_Id = 'mayo-data-analyst'
        )
      )
    )
  AND type IN ( 'SCC' , 'SST')
  )
AND aa.name='Alvocidib (flavopiridol)'
```

Subject Search

Search for subject by first name

Scenario

1. User is in enter criteria tab.
2. User chooses to search for subject
3. User adds a new subject search critierion
4. The criterion is specified as: first name equal to wayne.
5. User clicks continue.
6. User is in select view tab.
7. User select search object as subject.
8. User select attributes as first name and last name.
9. User clicks search.
10. User is in search results tab.

Expected

The first name and last name of subjects with wayne in the first name are shown.

SQL SCRIPT

```
SELECT p.first_name,
  p.last_name
FROM participants p
WHERE p.id IN
  (SELECT pa.participant_id
  FROM Participant_Assignments pa
  WHERE Study_Site_Id IN
    (SELECT Id
    FROM Study_Organizations
    WHERE Study_Id IN
      (SELECT Id
      FROM Studies
      WHERE Id IN
        (SELECT Study_Id
        FROM Study_Organizations
        WHERE Id IN
          (SELECT Study_Sites_Id
          FROM Study_Personnel
          WHERE Site_Research_Staffs_Id IN
            (SELECT Id
            FROM Site_Research_Staffs
            WHERE Researchstaff_Id IN
              ( SELECT Id FROM Research_Staffs WHERE Login_Id = 'mayo-data-analyst'
              )
            )
          )
        AND type IN ( 'SCC' , 'SST')
        )
      )
    )
  )
AND p.first_name='wayne'
```

Search for subject by Study subject identifier

Scenario

1. User is in enter criteria tab.
2. User chooses to search for subject
3. User adds a new subject search critierion
4. The criterion is specified as: study subject identifier equal to ssi-u8923489234.
5. User clicks continue.
6. User is in select view tab.
7. User select search object as subject.
8. User select attributes as first name, last name and study subject identifier.
9. User clicks search.
10. User is in search results tab.

Expected

The first name, last name and study subject identifier of subjects with ssi-u8923489234 in the study subject identifier are shown.

SQL SCRIPT

```
SELECT p.first_name,
  p.last_name,
  pa.study_subject_identifier
FROM participants p
JOIN participant_assignments pa
ON pa.participant_id=p.id
WHERE p.id         IN
  (SELECT pa.participant_id
  FROM Participant_Assignments pa
  WHERE Study_Site_Id IN
    (SELECT Id
    FROM Study_Organizations
    WHERE Study_Id IN
      (SELECT Id
      FROM Studies
      WHERE Id IN
        (SELECT Study_Id
        FROM Study_Organizations
        WHERE Id IN
          (SELECT Study_Sites_Id
          FROM Study_Personnel
          WHERE Site_Research_Staffs_Id IN
            (SELECT Id
            FROM Site_Research_Staffs
            WHERE Researchstaff_Id IN
              ( SELECT Id FROM Research_Staffs WHERE Login_Id = 'mayo-data-analyst'
              )
            )
          )
        AND type IN ( 'SCC' , 'SST')
        )
      )
    )
  )
AND pa.study_subject_identifier='ssi-u8923489234'
```

Search for subject by race

Scenario

1. User is in enter criteria tab.
2. User chooses to search for subject
3. User adds a new subject search critierion
4. The criterion is specified as: race equal to Asian.
5. User clicks continue.
6. User is in select view tab.
7. User select search object as subject.
8. User select attributes as first name, last name and race.
9. User clicks search.
10. User is in search results tab.

Expected

The first name, last name and race of subjects with race equal to Asian are shown.

SQL SCRIPT

```
SELECT p.first_name,
  p.last_name,
  p.race
FROM participants p
WHERE p.id IN
  (SELECT pa.participant_id
  FROM Participant_Assignments pa
  WHERE Study_Site_Id IN
    (SELECT Id
    FROM Study_Organizations
    WHERE Study_Id IN
      (SELECT Id
      FROM Studies
      WHERE Id IN
        (SELECT Study_Id
        FROM Study_Organizations
        WHERE Id IN
          (SELECT Study_Sites_Id
          FROM Study_Personnel
          WHERE Site_Research_Staffs_Id IN
            (SELECT Id
            FROM Site_Research_Staffs
            WHERE Researchstaff_Id IN
              ( SELECT Id FROM Research_Staffs WHERE Login_Id = 'mayo-data-analyst'
              )
            )
          )
        AND type IN ( 'SCC' , 'SST')
        )
      )
    )
  )
AND p.race = 'Asian'
```

Search for subject by ethnicity

Scenario

1. User is in enter criteria tab.
2. User chooses to search for subject
3. User adds a new subject search criterion
4. The criterion is specified as: ethnicity equal to Hispanic or Latino.
5. User clicks continue.
6. User is in select view tab.
7. User select search object as subject.
8. User select attributes as first name, last name and ethnicity.
9. User clicks search.
10. User is in search results tab.

Expected

The first name, last name and race of subjects with ethnicity equal to Hispanic or Latino are shown.

SQL SCRIPT

```
SELECT p.first_name,
  p.last_name,
  p.race
FROM participants p
WHERE p.id IN
  (SELECT pa.participant_id
  FROM Participant_Assignments pa
  WHERE Study_Site_Id IN
    (SELECT Id
    FROM Study_Organizations
    WHERE Study_Id IN
      (SELECT Id
      FROM Studies
      WHERE Id IN
        (SELECT Study_Id
        FROM Study_Organizations
        WHERE Id IN
          (SELECT Study_Sites_Id
          FROM Study_Personnel
          WHERE Site_Research_Staffs_Id IN
            (SELECT Id
            FROM Site_Research_Staffs
            WHERE Researchstaff_Id IN
              ( SELECT Id FROM Research_Staffs WHERE Login_Id = 'mayo-data-analyst'
              )
            )
          )
        AND type IN ( 'SCC' , 'SST')
        )
      )
    )
  )
AND p.ethnicity='Hispanic or Latino'
```

Test cases for User Person refactoring

Test cases for Person

Create Person mandatory fields

- User is logged in as Person and Org Info Manager. mayo-po-mgr3 / Hello-12
- User navigates to Administration>>Personnel>>Create/Edit Personnel

Expected

The following fields are marked as mandatory:

- First Name
- Last Name
- Email address
- Type of person
- Organization

P&O manager cannot create user

- User is logged in as Person and Org Info Manager. mayo-po-mgr3 / Hello-12
- User navigates to Administration>>Personnel>>Create/Edit Personnel

Expected

The following fields are disabled:

- Create as User
- All roles information

P&O manager cannot create person outside of associated org

- User is logged in as Person and Org Info Manager. mayo-po-mgr3 / Hello-12 who is associated to MN026
- User navigates to Administration>>Personnel>>Create/Edit Personnel
- User adds necessary mandatory details

Expected

The organization auto-suggest allows only value for MN026

P&O manager creates person who is investigator

- User is logged in as Person and Org Info Manager. mayo-po-mgr3 / Hello-12 who is associated to MN026
- User navigates to Administration>>Personnel>>Create/Edit Personnel
- User adds necessary mandatory details
- User marks person type as investigator and clicks save

Expected

Person of type investigator is created successfully

P&O manager creates person from existing user

- User is logged in as Person and Org Info Manager. mayo-po-mgr3 / Hello-12 who is associated to MN026
- User navigates to Administration>>Personnel>>Search Personnel
- User searches for users with mayo-study-all-roles3
- User is in edit person flow for this user
- User checks the create as person checkbox
- The type of person is specified as Research staff
- The person identifier is specified as mayo-study-all-roles3
- User clicks save

Expected

Person is created out of existing user successfully

Actual

Currently, it is not being saved as person

Test cases for User

Create User mandatory fields

- User is logged in as User Admin. mayo-ua-admin3 / Hello-12
- User navigates to Administration>>Personnel>>Create/Edit Personnel

Expected

The following fields are marked as mandatory:

- First Name
- Last Name
- Email address
- Username

User admin cannot create person

- User is logged in as User Admin. mayo-ua-admin3 / Hello-12
- User navigates to Administration>>Personnel>>Create/Edit Personnel

Expected

The following fields are disabled:

- Create as person
- Person Identifier
- Person Type

User admin cannot create user outside of associated org

- User is logged in as User Admin. mayo-ua-admin3 / Hello-12 who is associated to MN026
- User navigates to Administration>>Personnel>>Create/Edit Personnel
- User adds necessary mandatory details
- For study creator role, user adds an organization

Expected

The organization auto-suggest allows only value for MN026

User admin creates user who is AE reporter

- User is logged in as User Admin. mayo-ua-admin3 / Hello-12 who is associated to MN026
- User navigates to Administration>>Personnel>>Create/Edit Personnel
- User adds necessary mandatory details
- User adds a role of AE reporter at site MN026 and study 5876

Expected

AE reporter is created successfully

User admin creates user from existing person

- User is logged in as User Admin. mayo-ua-admin3 / Hello-12 who is associated to MN026
- User navigates to Administration>>Personnel>>Search Personnel
- User searches for users with person identifier mayo-inv45
- User is in edit person flow for this person
- User checks the create as user checkbox
- The type of user is specified as AE reporter at 5876 and MN026
- The username is specified as mayo-inv45
- User clicks save

Expected

User is created out of existing person successfully

Actual

Currently, not being able to search for person identifier mayo-inv45

	CAAERS-4640

Test scripts

Preconditions

1. User is logged in as system admin.
2. Study 5876 exists in the system.
3. XML for 5876 is available here

Create Adverse Event Course

1. User navigates to Adverse Events>>Report Adverse Events
2. In study autosuggest, user types '5876' and chooses study 5876.
3. In subject autosuggest, user types 'wayne' and chooses subject 'ssi-wayne-pt1'
4. In the course/cycle drop down, user select 'create new'
5. In the course pop up, user fills in
    a. Start date of first course/cycle
    b. Start date of this course/cycle
    c. End date of this course/cycl
    d. Treatment type
    e. Course/cycle
    f. Treatment assignment
6. User clicks save.
7. There is a confirmation message: 'Course/Cycle created successfully'

Add Adverse Events to Course

(Continued from above)

1. User clicks continue.
2. User is now in the Course>>Adverse Events page.
3. User types 'Vasculitis' in the autosuggest.
4. User chooses the term from the suggestion list and clicks 'Add'
5. The term is added to the course.
6. User add information about the AE
    a. grade = 5
    b. start date = today
    c. Attribution to study intervention= Possible
    d. Did AE cause hospitalization? = Yes
    e. Expected? = No
7. User clicks save
8. There is a confirmation message: ' Information saved successfully'

Invoke Rules Engine recommendation

(Continued from above)

1. User clicks save and report.
2. User is taken to the review and report page
3. Caaers will recommend creation of 'CTEP 24 Hour Notification'

Create data-complete CTEP 24 Hour Notification

(Continued from above)

1. User clicks on 'report'
2. User is now in create flow for CTEP 24 Hour Notification
3. user fills in the required information about the reporter and treating physician.
4. User clicks save and continue
5. User is now in Adverse events tab.
6. If any details about the AE needs to be updated user can do so here.
7. Updating AE details will cause caaers to recommend that the rules engine be re-run
8. If no AE details have been modified, user can click save and continue.
9. In the 'describe event' tab, the following details are specified:
    a. Description & treatment of event(s)
    b. Date of recovery or death
    c. Has the subject been re-treated?
    d. date removed from protocol
    e. Autopsy performed.
10. User clicks save and continue.
11. In the course tab, details of the course will be pre-filled.
12. If there is no change, click save and continue.
13. In the study interventions tab, user fills in details of the study agent used.
14. User clicks save and continue.
15. In the Subject details tab, user fills in details such as disease info, conmeds, prior therapies and pre-existing conditions.

16. User clicks save and continue.
17. User is in the other causes tab.
18. If there are no other causes, click save and continue.
19. User is in the labs tab.
20. If there are no labs, click save and continue.
21. user is in the attribution tab.
22. User sets attribution to each possible cause to Possible.
23. User clicks save and continue.
24. User is in the additional info tab.
25. If there are no additional info, user clicks save and continue.
26. User is in the review and submit tab.
27. User can verify the report is data compete when there is a 'Ready to submit! ' message in this tab.

Submit CTEP 24 Hour Notification

(Continued from above)

1. User clicks on actions button, a drop down list of actions is shown.
2. User clicks submit.
3. User is now in the submit report flow.
4. Details for submitter are pre-filled based on whether submitter is a reporter or physician.
5. User clicks save and continue.
6. User is shown a list of recipients who will receive notification of submission status.
7. User clicks submit and in the submission status tab, user is shown the message 'Submission in Progress'
8. User navigates to Adverse Events>>manage reports.
9. user clicks continue after choosing appropriate study and subject.
10. User clicks the appropriate course and checks the status of report submission.
11. User should see report submission status as 'Submitted on 05/26/2010'

Create Agent

UI related Test Cases

Date field validations

	Date field Location	Business rule	Pass / Fail	Other
	Report AE> Create/Edit course>>Start date of first course/cycle	Date cannot be future date (01/20/9999)	✗	
	Report AE> Create/Edit course>>Start date of this course/cycle	Date cannot be future date (01/20/9999)	✗	
	Report AE> Create/Edit course>>End date of this course/cycle	Date cannot be future date (01/20/9999)	✗	
	Report AE> Create/Edit course>>Start date of first course/cycle	Date cannot be Invalid date (14/33/1999)	✗	
	Report AE> Create/Edit course>>Start date of this course/cycle	Date cannot be Invalid date (14/33/1999)	✗	
	Report AE> Create/Edit course>>End date of this course/cycle	Date cannot be Invalid date (14/33/1999)	✗	
	Report AE> Create/Edit course>> Start/End date of this course/cycle	Start Date cannot be later than end date	✓	
	Report AE> Create/Edit course. User sets Start date of first course/cycle later than Start date of this course/cycle.	Start date of this course/cycle cannot be earlier than the Start date of first course/cycle	✓	
	CAE>>Adverse Events>>AE start date	Date cannot be future date (01/20/9999)	✓	
	CAE>>Adverse Events>>AE start date	Date cannot be Invalid date (14/33/1999)	✓	

	CAE>>Adverse Events>>AE end date	Date cannot be future date (01/20/9999)	✓	
	CAE>>Adverse Events>>AE end date	Date cannot be Invalid date (14/33/1999)	✓	
	CAE>>Adverse Events>>AE start/end date	Start Date cannot be later than end date	✗	
	CAE>>Review and report>>AE start date	Date cannot be Invalid date (14/33/1999)	✓	
	CAE>>Review and report>>AE start date	Date cannot be future date (01/20/9999)	✓	
	Expedited report flow>>Adverse Events>>AE start date	Date cannot be future date (01/20/9999)	✓	
	Expedited report flow>>Adverse Events>>AE start date	Date cannot be Invalid date (14/33/1999)	✓	
	Expedited report flow>>Adverse Events>>AE end date	Date cannot be future date (01/20/9999)	✓	
	Expedited report flow>>Adverse Events>>AE end date	Date cannot be Invalid date (14/33/1999)	✓	
	Expedited report flow>>Adverse Events>>AE start/end date	Start Date cannot be later than end date	✗	
	Expedited report flow>>Describe Events>>Date of recovery or death	Date cannot be future date (01/20/9999)	✓	
	Expedited report flow>>Describe Events>>Date of recovery or death	Date cannot be Invalid date (14/33/1999)	✓	
	Expedited report flow>>Describe Events>>Date removed from protocol	Date cannot be future date (01/20/9999)	✓	
	Expedited report flow>>Describe Events>>Date removed from protocol	Date cannot be future date (01/20/9999)	✓	
	Expedited report flow>>Describe Events, User sets present status to Recovered/Resolved with Sequelae. Date of recovery or death is blank	"Date of recovery or death" must be provided if "Present status" has one of following values: "Fatal/died," "Recovered/resolved without sequelae," or "Recovered/resolved with sequelae."	✓	
	Expedited report flow>>Describe Events, User sets present status to Fatal/died . Date removed from protocol is blank	"Date removed from protocol treatment" must be provided if "Present status" is "Fatal/died."	✓	
	Expedited report flow>>Describe Events, User sets present status to Fatal/died. User sets Date of recovery or death earlier than Date removed from protocol treatment.	"Date removed from protocol treatment" can not be after "Date of recovery or death;" it should be either the same day or earlier.	✓	
	Expedited report flow>>Course>>Start date of first course.	Date cannot be Invalid date (14/33/1999)	✓	
	Expedited report flow>>Course>>Start date of first course.	Date cannot be future date (01/20/9999)	✓	
	Expedited report flow>>Course>>Start date of course associated with expedited report	Date cannot be Invalid date (14/33/1999)	✓	
	Expedited report flow>>Course>>Start date of course associated with expedited report	Date cannot be future date (01/20/9999)	✓	
	Expedited report flow>>Course. user sets Start date of first course later than Start date of course associated with expedited report	Start date of this course/cycle cannot be earlier than the Start date of first course/cycle	✗	
	Expedited report flow>>Study Intervention>>Agent>>Date last administered.	Date cannot be future date (01/20/9999)	✓	
	Expedited report flow>>Study Intervention>>Agent>>Date last administered.	Date cannot be Invalid date (14/33/1999)	✓	
	Expedited report flow>>Study Intervention>>Radiation>>Date of last treatment	Date cannot be future date (01/20/9999)	✓	
	Expedited report flow>>Study Intervention>>Radiation>>Date of last treatment	Date cannot be Invalid date (14/33/1999)	✗	

	Expedited report flow>>Subject details>>Disease information>>Date of initial diagnosis	Date cannot be future date (01/20/9999)	✗	
	Expedited report flow>>Subject details>>Disease information>>Date of initial diagnosis	Date cannot be Invalid date (14/33/1999)	✓	
	Expedited report flow>>Subject details>>conmed>> start date	Date cannot be future date (01/20/9999)	✗	
	Expedited report flow>>Subject details>>conmed>> start date	Date cannot be Invalid date (14/33/1999)	✓	
	Expedited report flow>>Subject details>>conmed>> end date	Date cannot be future date (01/20/9999)	✗	
	Expedited report flow>>Subject details>>conmed>> end date	Date cannot be Invalid date (14/33/1999)	✓	
	Expedited report flow>>Subject details>>conmed. The end date is before the start date.	The "End date" can not be before the "Start Date."	✓	
	Expedited report flow>>Subject details>>Prior therapies>>start date	Date cannot be future date (01/20/9999)	✗	
	Expedited report flow>>Subject details>>Prior therapies>>start date	Date cannot be Invalid date (14/33/1999)	✓	
	Expedited report flow>>Subject details>>Prior therapies>>end date	Date cannot be future date (01/20/9999)	✗	
	Expedited report flow>>Subject details>>Prior therapies>>end date	Date cannot be Invalid date (14/33/1999)	✓	
	Expedited report flow>>Subject details>>Prior therapies. start date is set after the end date.	"Therapy end date" can not be before "Therapy start date;" it should be the same date or later	✓	
	Expedited report flow>>Labs>>Baseline date	Date cannot be future date (01/20/9999)	✓	
	Expedited report flow>>Labs>>Baseline date	Date cannot be Invalid date (14/33/1999)	✓	
	Expedited report flow>>Labs>>worst date	Date cannot be future date (01/20/9999)	✓	
	Expedited report flow>>Labs>>worst date	Date cannot be Invalid date (14/33/1999)	✓	
	Expedited report flow>>Labs>>Recovery date	Date cannot be future date (01/20/9999)	✓	
	Expedited report flow>>Labs>>Recovery date	Date cannot be Invalid date (14/33/1999)	✓	
	Subject>>Enter subject>>Date of birth	Date cannot be future date (01/20/9999)	✓	
	Subject>>Enter subject>>Date of birth	Date cannot be Invalid date (14/33/1999)	✓	
	Subject>>Edit subject>>details>>Date of birth	Date cannot be future date (01/20/9999)	✓	
	Subject>>Edit subject>>details>>Date of birth	Date cannot be Invalid date (14/33/1999)	✓	
	Subject>>Edit subject>>Subject Medical History>> Date of initial diagnosis	Date cannot be future date (01/20/9999)	✗	
	Subject>>Edit subject>>Subject Medical History>> Date of initial diagnosis	Date cannot be Invalid date (14/33/1999)	✗	
	Subject>>Edit subject>>Subject Medical History>>conmed start date	Date cannot be future date (01/20/9999)	✗	
	Subject>>Edit subject>>Subject Medical History>>conmed start date	Date cannot be Invalid date (14/33/1999)	✗	
	Subject>>Edit subject>>Subject Medical History>>conmed end date	Date cannot be future date (01/20/9999)	✗	

	Subject>>Edit subject>>Subject Medical History>>conmed end date	Date cannot be Invalid date (14/33/1999)	✗	
	Subject>>Edit subject>>Subject Medical History>>conmed end date is before start date	The "End date" can not be before the "Start Date."	✓	
	Subject>>Edit subject>>Subject Medical History>>prior therapy start date	Date cannot be future date (01/20/9999)	✗	
	Subject>>Edit subject>>Subject Medical History>>prior therapy start date	Date cannot be Invalid date (14/33/1999)	✗	
	Subject>>Edit subject>>Subject Medical History>>prior therapy end date	Date cannot be future date (01/20/9999)	✗	
	Subject>>Edit subject>>Subject Medical History>>prior therapy end date	Date cannot be Invalid date (14/33/1999)	✗	
	Subject>>Edit subject>>Subject Medical History>>conmed end date is before start date	The "End date" can not be before the "Start Date."	✓	

List of system level mandatory fields in expedited AE flow

1. Enter AEs
    a. CTC term
    b. Grade
    c. Start date
2. Course and Agent
    a. Treatment assignment code [Error message: **Missing description of treatment assignment or dose level**] -- Should this be a field level or rules level check? revisit this.
3. Reporter
    a. Reporter details
        i. First name
        ii. Last name
        iii. E-mail address
    b. Physician details
        i. First name
        ii. Last name
        iii. E-mail address
4. Pre-Existing Conditions
    a. Pre-existing condition 1 [Error message: **Either a known pre Existing Condition or other is required**] -- Should this be a field level or rules level check? revisit this.
5. Prior Therapies
    a. Prior therapy 1 [Error message: **Prior Therapy is required**] -- Should this be a field level or rules level check? revisit this. Conmeds.
6. Attribution
    a. attribution_of_cause_to_AE [Error message: **Missing attributionMap[CTMS:courseAgent][CTMS:0][CTMS:0]**] -- Needs to be made readable.

Submit report flow

1. Submitter
    a. Physician sign-off
        i. Physician sign-off
    b. Submitter details
        i. First name
        ii. Last name
        iii. E-mail address