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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 nctg-sae
- Last name coordinator
- Email address caaers.app15@gmail.com
- Phone0000000000
- Login Id nctg.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.		✓

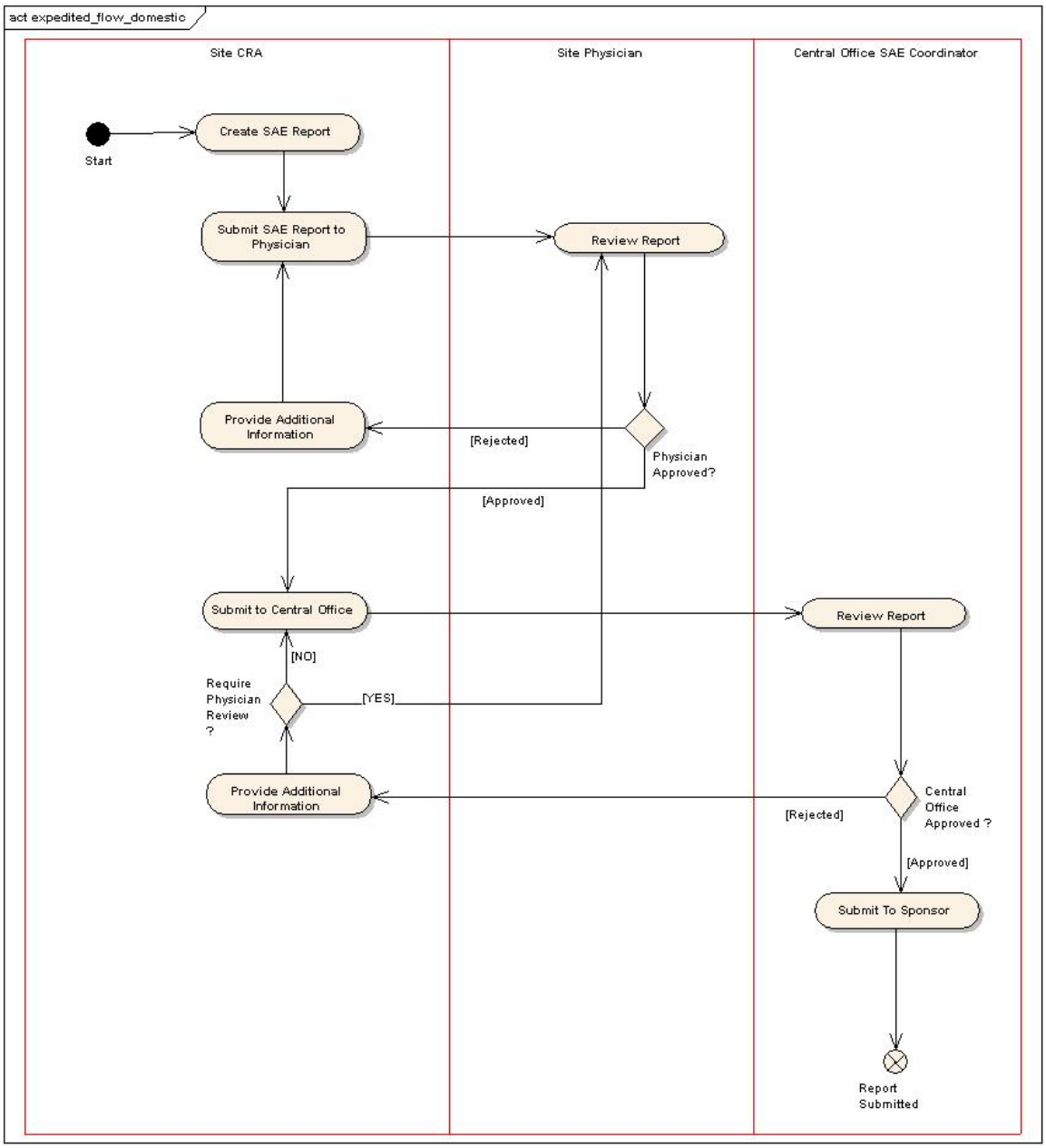
22	Routing and Review is enabled. User creates a course and initiates a report for that course. The report is completed but still not submitted. The system admin enters caAERS and disables routing and review. Any User (user with any role) enters caAERS and reaches the submit page of the edit report flow.	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

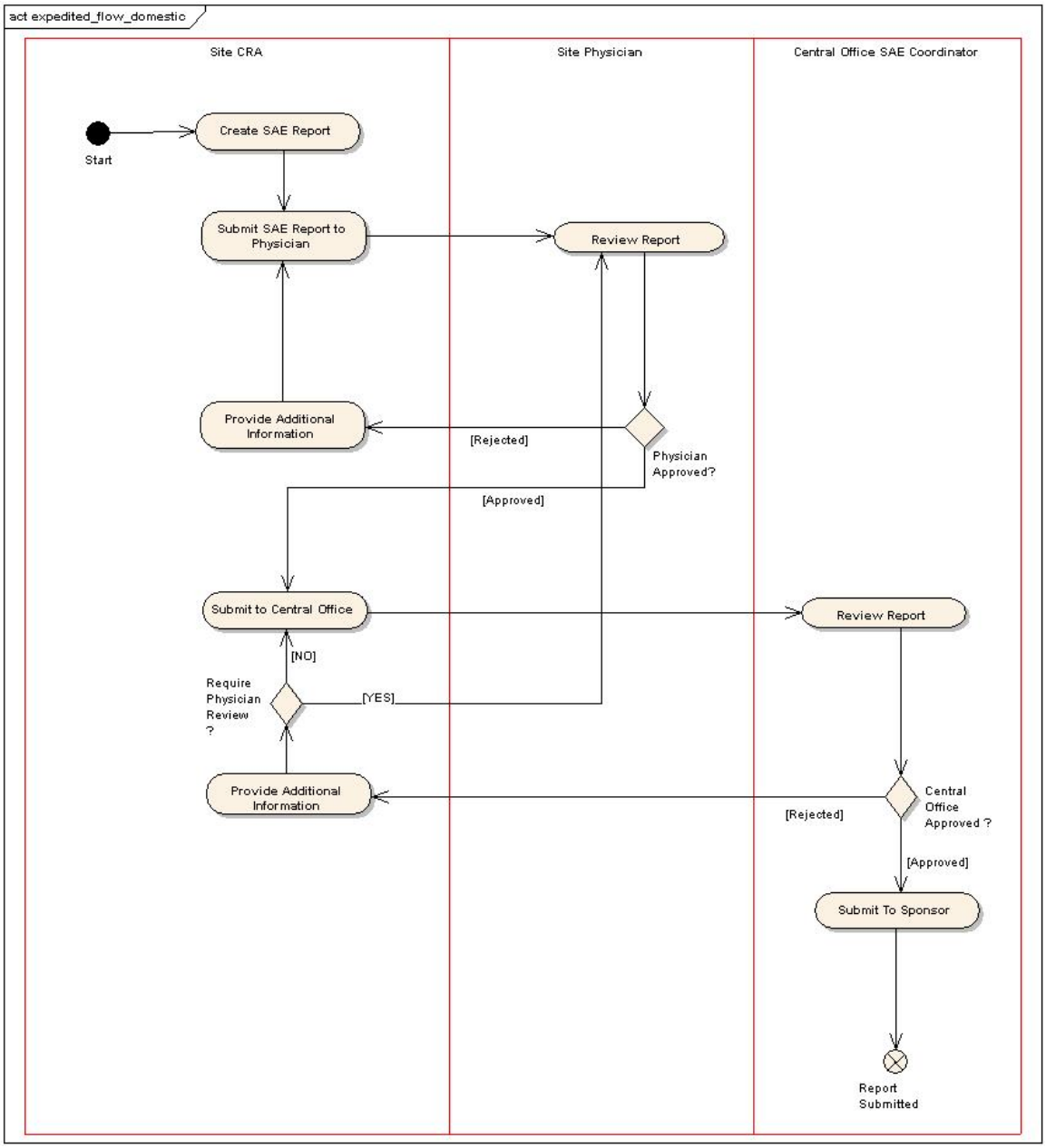
1. Create Expedited Report
2. Select Study
3. Select Subject
4. Select Course
    a. Create Course if needed
5. Click "Continue"
   On Enter Adverse Events Page
6. Enter an AE term
    a. Type "Nausea", select the term

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.~~		

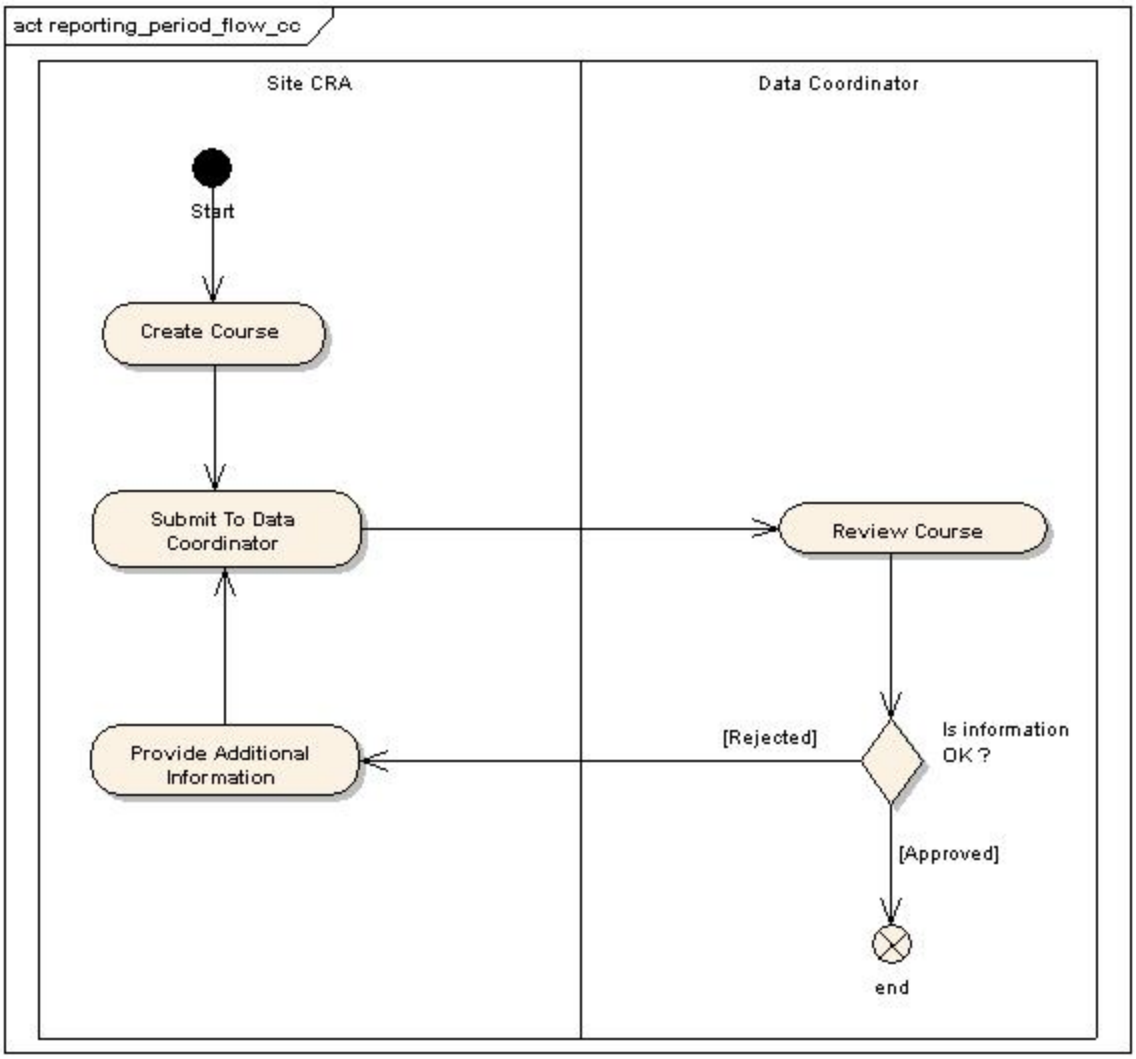
Questions

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		✓

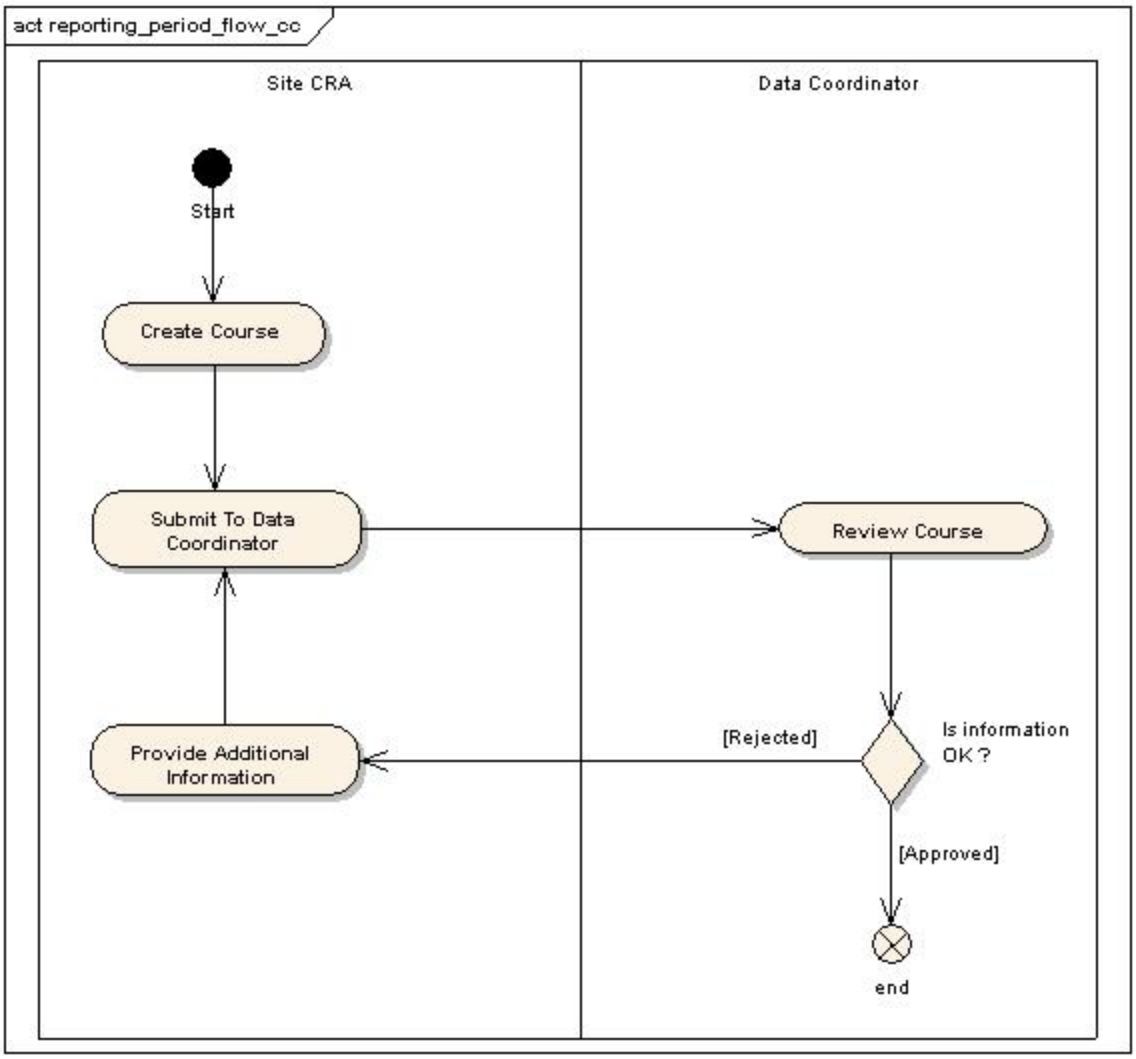
Questions

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 5 UC - Internal Routing and Review

Module 5 - Internal (institutional) Routing and Reviewing

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

5. Internal Routing and Review

Scope: system - caAERS
Level: User Goal
Trigger:

Brief Description

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

Primary Actor

caAERS system, AdEERS system

Secondary Actor

caAERS user

Preconditions

none

Steps

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

Extensions

none

Sub-Flows

Determining user rights

Post Conditions

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

Data Items

-

Special\Non-Functional Requirements

-

Open Issues

-

5.1a Routing and Reviewing - caAERS UC draft

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

Brief Description

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

Preconditions

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

Requirements

- Must have the ability to query a study and return all sites
- Need to add pagination to the search results page for display of large number of results.
- Should allow for a collapse/expand functionality on each result container.
- Must ensure that the search functionality for routing and review has the appropriate security calls
- Need to determine how routing will work for CALGB given they don't use roles for security - they will likely need to support study functional roles (i.e. PI, Site investigator, Reporter, etc).
- Each study will have two different workflows for each study site: one workflow for expedited reports, one for routine AEs
- Expedited report flow:
    1. (domestic) Site CRA (entry) -> Physician (review) -> Site CRA (submit) -> CALGB Central Office (review) -> Submit to AdEERS
    2. (international) Site CRA (entry) -> Physician (review) -> Monitor (review) -> CALGB Central Office (review) -> Submit to AdEERS
- Routine AE flow:
    1. Site CRA -> CALGB Data Coordinator -> Finalize
    2. Site CRA -> Main Member Data Coordinator -> CALGB Data Coordinator -> Finalize
- Need ability to see who (or what role) a review is going to. Will help folks pick the correct review.
- Need to be able to have different review flows for different sites and for different things being reviewd (Routine vs Expedited).
- Possibly could use ability to have different review flows for different studies as well.
  UAT scenarios need to test the different scenarios.
- Comments must have date AND time stamp.
- Have new comment window below the most recently added comment.
- Have a show all / show none collapse ability for the comments.
- A link to the item needing review must be included in the report.
- Notifications for review need to have configurable substitution variables.

- Editing of the report or evaluation period by the reviewer (rather than just leaving comments) should be restricted to reviews being done by the same site where data entry occurred. The reason for this is that the information included in caAERS must match the source documentation.
- When reviewing data entered by another site, only comments back to the site regarding needed changes should be included to ensure that source documentation is appropriately updated prior to making changes in caAERS.
- Physician sign-off should be a status.
- Submit should be a status.
- Need the ability for reviewer to go into the report and make changes, with log of changes included in the comments panel. Ideally this would be something that a physician could do.
- In order for physicians to use this functionality, there must be a link in the notification email that takes them to the exact record requiring review. For report reviews, a pdf of the the report included in the email would be beneficial.
- Within a flow (capture AE or reporting), there should be the ability to change the review status (i.e. "Save and Send to Review").

Steps

Main Success Scenario

1. caAERS user searches for items to be reviewed; Search can be any of the following:
    a. Patient
    b. Study + Site (if only one site available, then it's defaulted to that site)
    c. Patient + Study (doesn't need Site since patient is only on Study at one site)
    d. Patient + Review status
    e. Study + Site + Review status
2. caAERS brings up review page; page always be organized by Subject and Study:
    a. Page Header will include the Search criteria selected by the user
    b. Each Subject/Study result will be organized in a separate box
        i. The header for the Subject/Study result will contain the Study Title, Protocol Authority ID, and Coordinating Center ID if the search is restricted by Subject
        ii. The header for the Subject/Study result will contain the Subject first and last name, Primary ID, and Study-Subject ID if the search is restricted by Study.
    c. The column headers for the results should look similar to the snapshot
    
    d. ~~Patient~~ ### ~~Organized by Study, then Evaluation Period (which expands to show AEs and Reports)~~
    e. ~~Study~~ ### ~~Organized by Patient, then Evaluation Period (which expands to show AEs and Reports)~~
    f. ~~Patient + Study~~ ### ~~Looks like current manage report page~~
    g. ~~Patient + Review status~~ ### ~~Two tables, one for evaluation period, one for Reports~~
        i. ~~Report table will have the following columns, non-expandable: Report Name, Study, Report Format (current options dropdown) Comments, and Status~~
        ii. ~~Evaluation period table will have the following columns: Evaluation Period, Study, Comments, Status. Each row will expand to show reports and AEs, similar to current manage reports.~~
    h. ~~Study + Review status~~ ### ~~Two tables, one for evaluation period, one for Reports~~
        i. ~~Report table will have the following columns, non-expandable: Report Name, Patient ID, Report Format (current options dropdown) Comments, and Status~~
        ii. ~~Evaluation period table will have the following columns: Evaluation Period, Patient ID, Comments, Status. Each row will expand to show reports and AEs, similar to current manage reports.~~
3. caAERS user reviews the information
    a. expands the different areas to see full details
    b. uses the Report format dropdown to chose a view to view the expedited report
4. Reviewer adds comments and/or changes the status
    a. Each evaluation period and expedited report has a comments field associated to it
    b. Each evaluation period and expedited report has a status field associated to it
5. *Question: Does this page need a "Save" button, or will changing the Status and adding the comments automatically save the changes?*
6. caAERS sends out notifications for items that have changed
    a. e-mail notifications, based on roles and specific research staff in the system
    b. inbox notifications, built into the caAERS application
7.

Extensions

?

Post Conditions

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

Data Items

Statuses

Statuses are discussed in detail on the following two pages:

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

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

Attributions

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

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

Special/Non-Functional Requirements

Business Rules

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

Open Issues

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

Models & User Interface Prototype

5.1 Routing and Reviewing a Reporting Period

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

Brief Description

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

Preconditions

- user has access to the AE module

Steps

Main Success Scenario

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

Extensions

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

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

Sub-Flows

- caAERS determines user access
- 1.1 Enter Observed AEs

Post Conditions

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

Data Items

Statuses

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

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

- Locked
-

Special\Non-Functional Requirements

Roles & Rights

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

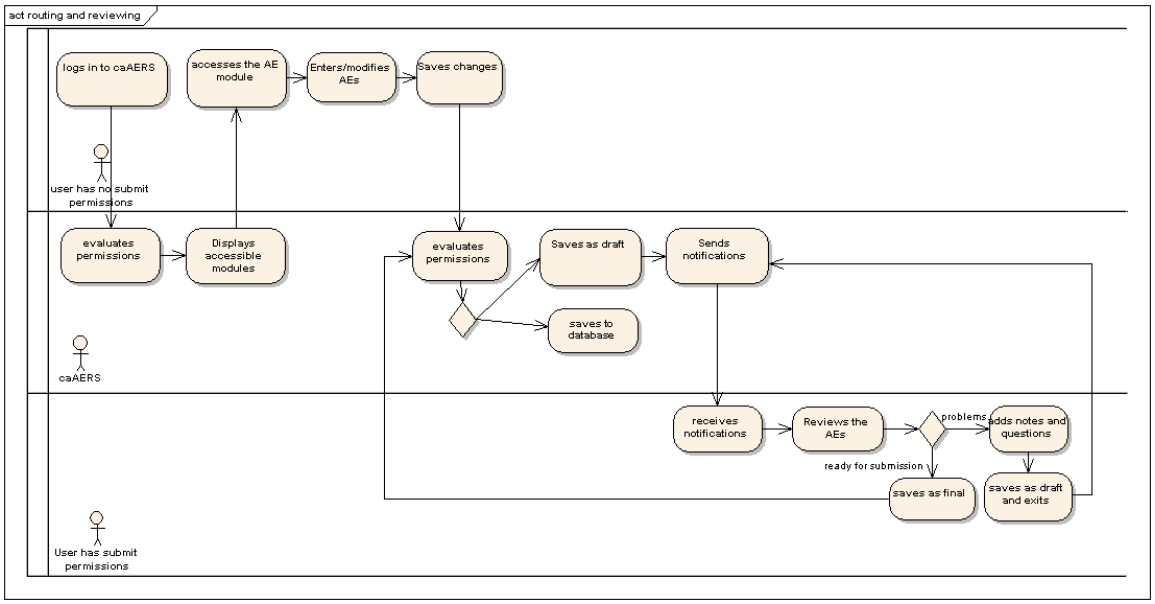
Business Rules

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

Open Issues

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

Models & User Interface Prototype



5.2 Routing and Reviewing an Expedited Report

Primary Actor: caAERS User - no AE submit permissions
Supporting/Secondary Actor: caAERs, caAERS user with submit permissions

Scope: sub-system, AE module
Level: User Goal
Trigger:

Brief Description

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

Preconditions

- user has access to the AE module

Steps

Main Success Scenario

1. caAERS User 1 logs into caAERS and accesses the AE module
2. caAERS User 1 enters/modifies AEs
3. caAERS User 1 saves the AEs
    a. caAERS evaluates the permissions
    b. caAERS saves the changes (see data items)
    c. caAERS checks for notification rules
        i. caAERS sends appropriate notifications
        ii. Notification will be role based
    d. caAERS prompts for expedited report
4. caAERS User 1 creates the expedited report
5. caAERS User 1 sets the status (to?)
6. caAERS User 1 saves the report
    a. caAERS saves the changes
    b. caAERS checks for notification rules
        i. caAERS sends appropriate notifications
        ii. Notification will be role based
7. caAERS User 2 logs in to caAERS and accesses the AE module
8. caAERS evaluates the permissions
    a. If the user has review permissions, caAERS will allow access to a reviewer notes field
        - button for user to press next to each reporting period that will pop up a field to enter notes
        - reviewers note field on personnel page of expedited report?
    b. caAERS will allow the user to change the status of the reporting period
9. caAERS User 2 opens the "Manage Reporting Periods and AEs"
10. caAERS User 2 reviews Reporting Period & AE info
11. caAERS User 2 locates expedite reports and opens it
12. caAERS User 2 reviews the expedited report
13. caAERS User 2 enters any notes they feel are necessary
14. caAERS User 2 changes the status & saves the expedited report
    a. based on status selected, different things need to happen
15. caAERS saves the expedited report and updates the status

Extensions

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

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

Sub-Flows

- caAERS determines user access
- 1.1 Enter Observed AEs

Post Conditions

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

- some reporting periods have been completed and are ready to be finalized
- some reporting periods are finalized

Data Items

Statuses

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

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

Special\Non-Functional Requirements

Roles & Rights

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

Business Rules

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

Open Issues

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

Models & User Interface Prototype

5.3 Routing and Review Setup

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

Brief Description

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

Preconditions

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

Steps

First Setup Screen - Details

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

Second Setup Page - Workflow

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

Sub-Flow - modify Study Details

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

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

Post Conditions

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

Data Items

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

Special\Non-Functional Requirements

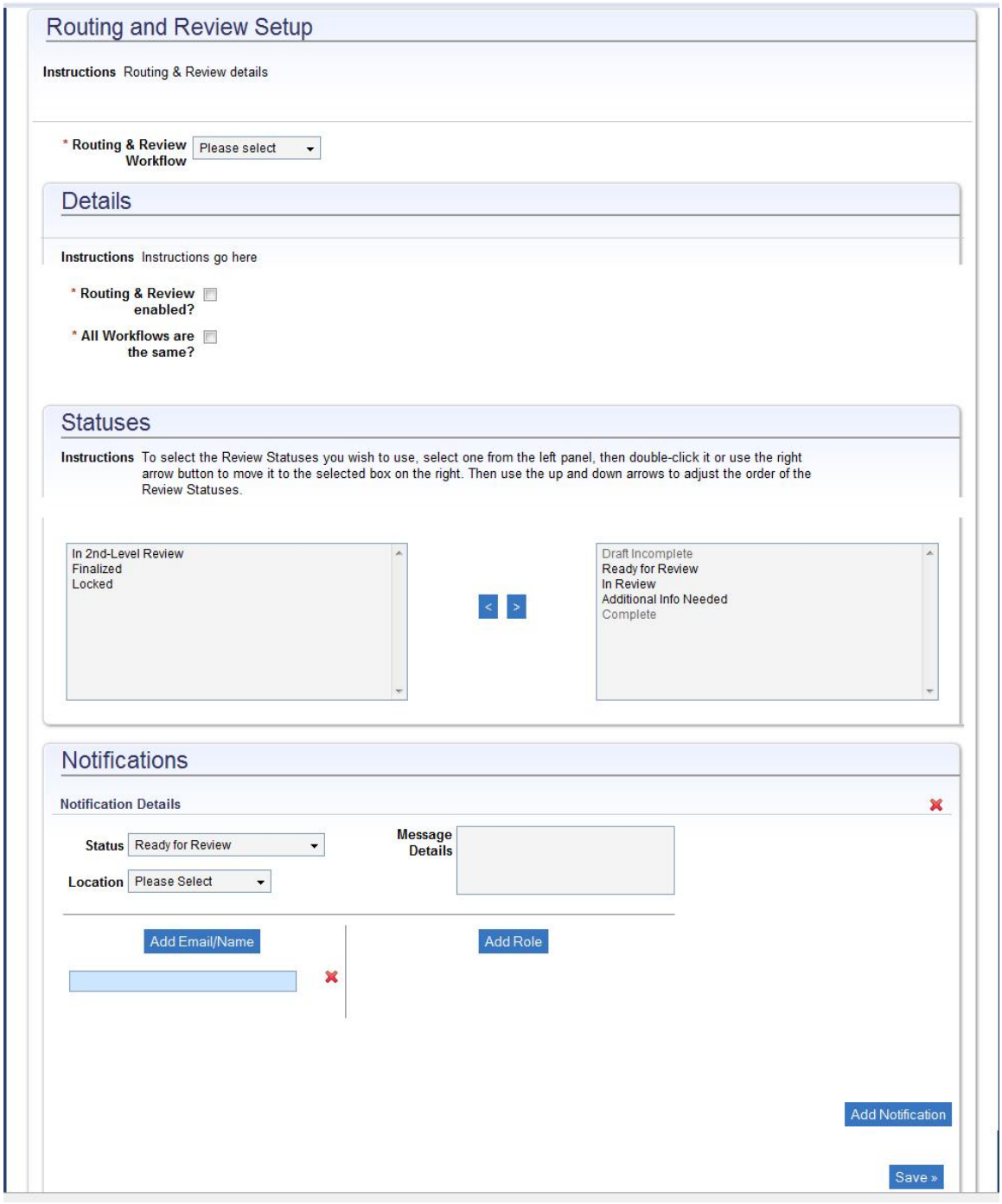
- ?

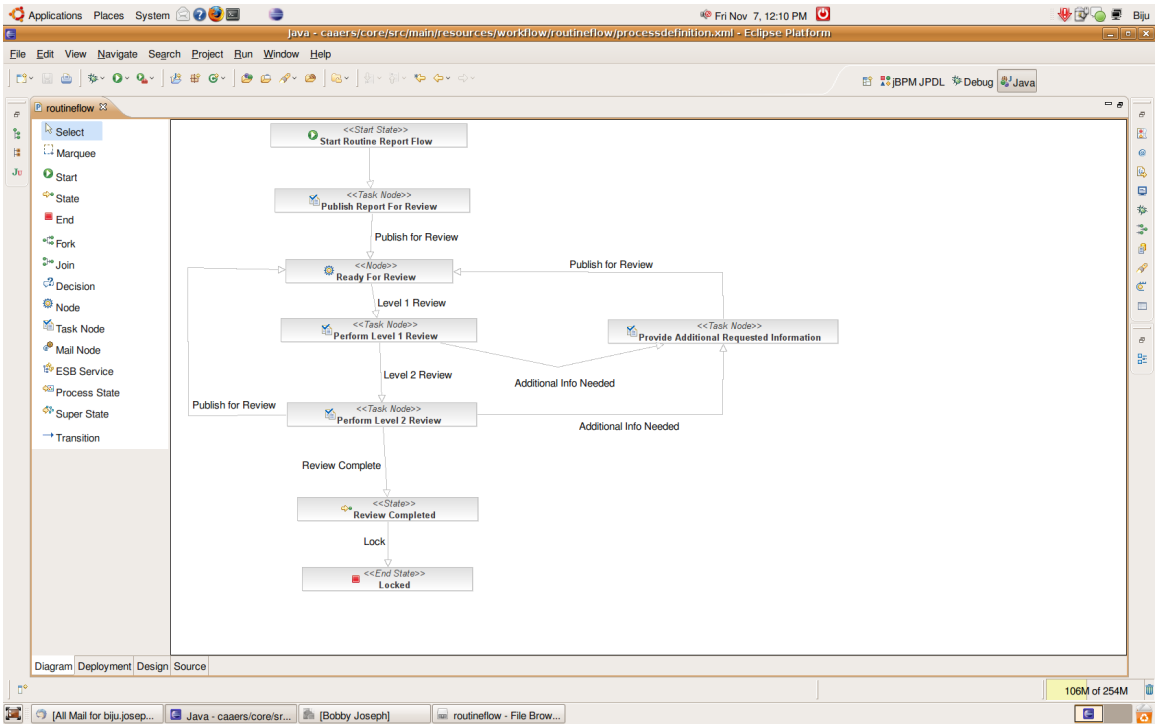
Open Issues

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

Models & User Interface Prototype

You need flash player installed to preview ppt and pdf files


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



5.4 Central Processing

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

Brief Description

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

Preconditions

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

Steps

AdEERS to AdEERS Central Processing - current process

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

caAERS to AdEERS Central Processing

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

caAERS to caAERS Central Processing - out of scope?

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

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

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

AdEERS to caAERS Central Processing - out of scope

Extensions

Report requires central processing but wasn't flagged as such

Sub-Flows

caAERS determines user access
Enter expedited report

Post Conditions

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

Data Items

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

Special\Non-Functional Requirements

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

Business Rules

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

Open Issues

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

Models & User Interface Prototype

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

Assigning Permissions - UC draft

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

Brief Description

Enter a brief description

Preconditions

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

Steps

Main Success Scenario

1. Enter the main steps

Extensions

Enter any alternative flows, failure flows, and exceptions

Sub-Flows

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

Post Conditions

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

Data Items

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

Special\Non-Functional Requirements

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

Open Issues

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

Models & User Interface Prototype

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

caAERS R&R Reqt

Routing & Reviewing
Items to consider

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

caAERS Routing & Reviewing Brainstorming

Add a Routing and Reviewing task in the Admin Module

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

Modifying the Research Staff page

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

?

Routing and Review Task

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

Routing & Review Statuses for caAERS

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

Routing and Review Whiteboard

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

Wake

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

Mayo

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

CALGB

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

CTEP

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

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

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

Wake

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

Mayo

na

CALGB

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

CTEP

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

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

Wake

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

Mayo

na

CALGB

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

CTEP

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

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

Wake

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

Mayo

na

CALGB

na

CTEP

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

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

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

Wake

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

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

Mayo

na

CALGB

For routine reports we are reviewing:

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

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

Wake

Both

Mayo

na

CALGB

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

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

Wake

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

Mayo

na

CALGB

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

Module 5 Internal Routing Use Cases (caAERS)

Module 5 - Internal (Institutional) Routing and Review

Updating Study Organizations (caAERS UC)

Study Abstraction - Sponsors, Committees and Organizations

Brief Description	This use case links sponsors, committees and organizations (entered as "Organizations" into caAERS) that are important to the management of the Study as they relate to the recording and reporting of AEs. The Study Coordinator will be able to enter/update information about these entities. The basic course of action is to link an Organization to the protocol by adding the Organization to a collection associated with the protocol. The SC will then decide whether the organization is concerned with all AE Reports entered into the system or only for those Reports which involve a particular Agent or Device.
Primary Actor	Study Coordinator (SC)
Preconditions	1. The Study exists in the system. 2. SC has entered all appropriate institutional values for the coded elements: Sponsor, Committees and Organizations into the system. 3. SC has found the desired Study.
Basic Flow of Events	1. The SC navigates to the Study abstraction screen - Sponsors, Committees, and Organizations. 2. The SC searches for the desired protocol (Use Case 1.13). 3. The SC selects a Sponsor, Committee, or Organization and associates it with the Study. 4. The SC enters the appropriate data regarding this association. (See Data table) 5. The system stores the information.
Postconditions	Sponsors, committees and/or organizations have been associated with the Study.
Notes	Detailed information about the Sponsor, Committee, or Organization will be entered and edited through an administrative interface. To facilitate study-specific changes in this information, the Study Coordinator may need to have access to this interface, but it will not be reentered here. The Actions taken with respect to these entities will be described by the Rulesets.

Special Requirements

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