

Background

User Acceptance Testing (UAT) is a process to obtain confirmation by a Subject Matter Expert (SME), preferably the owner or client of the object under test, through trial or review, that the modification or addition meets mutually agreed-upon requirements. In software development, UAT is one of the final stages of a project and often occurs before a client or customer accepts the new system.

The customer specifies scenarios to test when a user story has been correctly implemented. A story can have one or many acceptance tests, whatever it takes to ensure the functionality works. Acceptance tests are black box system tests - they only require the application. Each acceptance test represents some expected result from the system. Customers are responsible for verifying the correctness of the acceptance tests and reviewing test scores to decide which failed tests are of highest priority. Acceptance tests are also used as regression tests prior to a production release. A user story is not considered complete until it has passed its acceptance tests.

The results of these tests give confidence to the clients as to how the system will perform in production. They may also be a legal or contractual requirement for acceptance of the system.

Test Scenarios

UAT scenarios for v 1.3

- [Study Module](#)
 - Add solicited AEs to a study
 - Add a reporting period type to a study
 - Delete an existing reporting period type from a study
 - create instructions to be displayed in the AE module for a reporting period type
 - delete solicited AEs from a study
 - set up study manually
- [AE Module](#)
 - Create a reporting period
 - modify a reporting period
 - document baseline AEs
 - document treatment AEs
 - save incomplete ae data in a reporting period
 - document AE(s) that require expedited reporting
 - complete an expedited report
 - select a different report than suggested
 - Add more/modify existing AEs for a reporting period
- [Import Data](#)
 - import a subject
 - import an update to a subject
 - import an investigator
 - import an update to an investigator
 - import a research staff
 - import an update to a research staff
 - import an update to a study
- [Local caAERS Testing](#) (can't be done on hosted demo version)
 - install caAERS as an upgrade

UAT Scenarios for version 1.4

- Subject Module
 - Add a subject and add medical history
 - Assign a subject to a study and add medical history
- AE Module
 - Create an expedited report
 - Modify an expedited report
 - Amend an expedited report
 - Create a second report for an evaluation period

UAT Scenarios for future testing

- Rules Module
 - create a sponsor rule
 - create an institution rule
 - Create Report Definition
 - View report definitions
- Import Data
 - import a study
- Local caAERS Testing (can't be done on hosted demo version)
 - install caAERS using the installer
 - install caAERS manually
 - import MedDRA v 9
 - import MedDRA v 11
 - import routine AEs
 - import rules

- import MedDRA v 10

Test Scenario

User Story 1

Create a reporting period

Scenario Description

Open a patient/study combination and add a reporting period where you can collect AEs.

User Story 2

Modify a reporting period - change the type

Scenario Description

Open a patient/study combination to which you've already added a reporting period. Change the reporting period type and save.

User Story 3

Modify a reporting period - change the dates

Scenario Description

Open a patient/study combination to which you've already added a reporting period. Change the date and save.

User Story 4

Document Baseline AEs

Scenario Description

Open a patient/study combination and add Baseline AEs for the patient. Baseline AEs are AEs that are captured at the time of registration and are thus not reported on.

User Story 5

Document treatment AEs

Scenario Description

Open a patient/study combination and add Treatment AEs for the patient.

User Story 6

Save incomplete AE data for a reporting period

Scenario Description

- Open a patient/study combination and add multiple Treatment AEs for the patient.

- Leave the Grade blank and click Save.
- Exit, then bring the same patient/study combination & treatment reporting period. Was the AE info saved?
- Click Save & Continue without making changes. Does it behave as expected?

User Story 7

Select a different report than suggested

Scenario Description

- Open a patient/study combination and add multiple Treatment AEs for the patient, with one or more of them considered serious
- Go to the select report/overview page and view the required reports
- select a report that was not suggested

User Story 8

Add additional AEs to a reporting period

Scenario Description

- Go to Manage Reports for a patient/study combination
- Select a reporting period
- Enter Additional AEs
- Modify existing AEs
- Click Save & Continue

User Story 9

Complete an expedited report

Scenario Description

- Go to Manage Reports for a patient/study combination
- select an expedited report
- complete the expedited report

Import UATs

This page last changed on Aug 07, 2008 by [ReedJ](#).

User Story 1

- Import a subject
- Import an update to a subject

Scenario Description

1. a subject is added to a study
2. Create an XML for the subject to import into caAERS
3. Open caAERS and import the XML
4. Go to the Subject Module and open the subject to verify the record was created
5. Modify the XML file
6. Import the updated XML file
7. Go to the Subject Module and open the subject to verify the change was made

User Story 2

- Import an investigator
- Import an update to an investigator

Scenario Description

1. An investigator joins the organization
2. Create an XML for the investigator to import into caAERS
3. Open caAERS and import the XML
4. Go to the investigator Module and open the subject to verify the record was created
5. Modify the XML file
6. Import the updated XML file
7. Go to the investigator Module and open the subject to verify the change was made

User Story 3

- Import a research staff
- Import an update to a research staff

Scenario Description

1. a research staff joins the organization
2. Create an XML for the research staff to import into caAERS
3. Open caAERS and import the XML
4. Go to the research staff Module and open the subject to verify the record was created
5. Modify the XML file
6. Import the updated XML file
7. Go to the research staff Module and open the subject to verify the change was made

User Story 4

Import an update to a study

Scenario Description

1. The study status changes
2. create an xml that includes that change
3. Open caAERS and import the XML
4. Go to the study module & open the study to verify the change was made

This page last changed on Aug 07, 2008 by [ReedJ](#).

Test Scenarios

User Story 1

Install caAERS - upgrade

Scenario Description

Download the caAERS 1.3 files and install as an upgrade.

User Story 2

Import MedDRA v 10

Scenario Description

- Open caAERS and import MedDRA v 10
- Open a study and verify you can select MedDRA v 10 for AE terminology and/or "MedDRA for Other"

Test Scenario

User Story 1

- add reporting period types
- add solicited AEs to a study

Scenario Description

Open an existing study in caAERS. Add a reporting period type for the study. Add one or more solicited AEs that you want to collect data on.

User Story 2

- delete reporting period type
- delete solicited AEs

Scenario Description

Open a study that is already in caAERS. Remove the Post-treatment reporting period. The investigator is done collecting information on a certain AE, so delete it.

User Story 3

- add MedDRA version for "other"

Scenario Description

Open an existing study in caAERS. Verify the Disease terminology vocabulary and add the MedDRA version to use when you choose "Other - specify" as the AE term.

User Story 4

- Create instructions to be displayed when capturing Baseline AEs

Scenario Description

Open an existing study in caAERS. Add instructions to be displayed on the AE collection screen when you collect Baseline AEs.

User Story 5

Add solicited AE to list - reporting period already created for a patient

Scenario Description

1. Create a Treatment reporting period for a patient & add an AE.
2. Close the patient and open the study
3. Add one or more solicited AEs for the Treatment reporting period
4. Save the study and open the patient study combination again
5. Open the treatment reporting period again. Do the newly added solicited AEs appear?
6. Create a new Treatment reporting period. Do the newly added solicited AEs appear?

User Story 6

Delete a reporting period type - reporting period type used

Scenario Description

1. Create a Treatment reporting period for a patient & add an AE.
2. Close the patient and open the study
3. Delete the Treatment reporting period type
4. Save the study and open the patient study combination again
5. Open the treatment reporting period again. What does it show for the reporting period type?

User Story 7

Create a study manually

Scenario Description

Add a new study to caAERS

- does it require all the expected fields?
- does it require fields that it shouldn't?

Version 1.3 UAT Results

General Information

Testers

Mayo	Wake	CALGB
	Del Jones	
Robbin	Sarah Hahne	Debbie Sawyer
Jean Hansen	Bob Morrell	
	Janet Stack	

Study Module Summary

UAT Case	Mayo Tested? Y/N	Wake Tested? Y/N	CALGB Tested? Y/N	Passed IE 7.0? Y/N	Passed Firefox? Y/N	Bugs, Issues
1. add reporting period types 2. add solicited AEs to a study	y, y	y	y	y, n ,y	y	1. (Robbin) After entering a new reporting period, I hit "edit instructions" then decided to not enter anything in it, you are not able to get rid of the box. No x in the corner 2. (Jean) Would like to be able to add multiple terms in multiple categories without needed to

UAT Case	Mayo Tested? Y/N	Wake Tested? Y/N	CALGB Tested? Y/N	Passed IE 7.0? Y/N	Passed Firefox? Y/N	Bugs, Issues
						<p>go back to the previous screen after adding terms for one category</p> <p>3. (Jean) Search function did not work when searching by study ID (N027D)</p> <p>4. (Jean) I left short title and typed "N" and then a list was provided. Not intuitive to hold ctrl/alt key when adding multiple terms for one category.</p> <p>5. (Debbie) Liked: Returned terms quickly and were easy to add. Didn't like: Couldn't figure out a way to reorder the reporting periods. Should be able to put them in sequence.</p> <p>6. (Del) When I selected to choose multiple AE's a light blue covering came over the entire screen. I thought it was going to hinder me from making my selection but it didn't.</p> <p>7. (Del) In choosing multiple AE's the categories came down then</p>

UAT Case	Mayo Tested? Y/N	Wake Tested? Y/N	CALGB Tested? Y/N	Passed IE 7.0? Y/N	Passed Firefox? Y/N	Bugs, Issues
						the subcategories. In our studies we usually have AE's in different categories. For example (GI, Dermatology). The multiple selection only allowed for multiple selections within the same category. If I were to choose multiple they would definitely be in different categories.
<ul style="list-style-type: none"> delete reporting period type delete solicited AEs 	y,y	y	y	y,y,y	y	<ol style="list-style-type: none"> (Jean) It would be nice to have the word "delete" show on the screen when the cursor is hovered over the red X (Debbie) Liked confirm delete question (Del) I liked the ease of adding the reporting period type. Deleting the solicited AE's was also easy. (Del) The space could become limited if you needed to add more columns than there is space for. We use for example: Baseline, Week 4, Week 10, EOS and 4 Weeks

UAT Case	Mayo Tested? Y/N	Wake Tested? Y/N	CALGB Tested? Y/N	Passed IE 7.0? Y/N	Passed Firefox? Y/N	Bugs, Issues
						post-RX
add MedDRA version for "other"	y,n	y	y	y,y	y	1. (Robbin) Would be nice to have arrows to scroll down lists that pop up
Create instructions to be displayed when capturing Baseline AEs	n,y	y	y,y	y	n	<ol style="list-style-type: none"> 1. (Jean) Can the edit instructions be in larger print. I had to look for it. Can an instruction be attached to only 1 AE or does it need to be attached to all AEs? 2. (Debbie) Instructions can be added but don't appear anywhere 3. (Del) It was easy to use once I found it. It took me a while to figure out where the AE collection screen was. It was not obvious to look under Reporting Period Type to locate that screen. Different terminology is used by each institution to describe some of the same things. We need to make sure that we find a

UAT Case	Mayo Tested? Y/N	Wake Tested? Y/N	CALGB Tested? Y/N	Passed IE 7.0? Y/N	Passed Firefox? Y/N	Bugs, Issues
						terminology that will be clear to all who use this.
Add solicited AE to list - reporting period already created for a patient	y ,n	y	y	n	n,n	<ol style="list-style-type: none"> 1. (Robbin) Received error message to contact system administrator each time I tried to save bew AE's that I had added 2. (Debbie) Reporting period (create) should be (create/edit). Not sure I like the create/edit in parentheses or if it should be a button. 3. (Debbie) Review & Report page did not look correct (1.3.1, 08-14) 4. (Janet) expected the solicited AE to show up in the reporting period
Delete a reporting period type - reporting period type used	y,n		y	n	n	<ol style="list-style-type: none"> 1. (Robbin) error messages 2. (Debbie) Steps worked, but got errors on steps 2 & 3 (contact admin, no details)
Create a study	n,n		y		y	<ol style="list-style-type: none"> 1. (Debbie) Did not like having

UAT Case	Mayo Tested? Y/N	Wake Tested? Y/N	CALGB Tested? Y/N	Passed IE 7.0? Y/N	Passed Firefox? Y/N	Bugs, Issues
manually						<p>to add investigators before I could complete adding study manually. Also had problems with inputting IND as shown in protocol. It would not let me enter CALGB as the IND holder for Midostaurin.</p> <ol style="list-style-type: none"> (Debbie) Confirmation page is not very readable. Suggestion is to remove blue overlay (Debbie) Confirmation page of Added subject to new study; Screen layout needs work

AE Module summary

UAT Case	Mayo Tested? Y/N	Wake Tested? Y/N	CALGB Tested? Y/N	Passed IE 7.0? Y/N	Passed Firefox? Y/N	Comments
Create a reporting period	y,n		n	y		
modify a reporting period	y,n	y	y	y, y		1. (Debbie) - IE6, so take with a grain of salt: When I tried to

UAT Case	Mayo Tested? Y/N	Wake Tested? Y/N	CALGB Tested? Y/N	Passed IE 7.0? Y/N	Passed Firefox? Y/N	Comments
- change the type						<p>save the change to the reporting period type I received an IE error message. When I closed the error message the value had not changed. When I went out of the screen and came back in on that screen's tab the value had changed.</p> <p>2. (Sarah) Easy to modify text; The order of each reporting period is unable change without deleting each period and reentering them.</p>
modify a reporting period - change the dates	y,n	y	y	y,n		<p>1. (Debbie) Could the save successful message be displayed on the prior screen?</p> <p>2. (Sarah) On the reporting period page, there are no dates viewable</p>
document baseline AEs	n,n	y	y		n	<p>1. (Debbie) Tested IE6.0, problems</p> <p>2. (Bob) No, there is no obvious place to go to enter baseline; There is no obvious link to</p>

UAT Case	Mayo Tested? Y/N	Wake Tested? Y/N	CALGB Tested? Y/N	Passed IE 7.0? Y/N	Passed Firefox? Y/N	Comments
						<p>Baseline. User would have to know to go to AE and create a period called baseline. And because the type is not displayed with the period dates, I did not know that a baseline had already been created</p> <p>3. (Bob) arm assignment should not be a required field for baseline</p> <p>4. (Bob) rules issue? Ok, this gets weirder and weirder. The previous SAE script I sent you I was accidentally running on a baseline period. (was not obvious to me) when I went back and entered a second (!!) grade 5 event in a second period (there should be a rule against that.) it said no rule fired and when checked that event it crashed immediately</p>
document treatment AEs	y,n		n	n		<p>1. (Robbin) Unable to enter error message each time I try to</p>

UAT Case	Mayo Tested? Y/N	Wake Tested? Y/N	CALGB Tested? Y/N	Passed IE 7.0? Y/N	Passed Firefox? Y/N	Comments
						save an AE
save incomplete ae data in a reporting period	y,n	y	y	n	n	<ol style="list-style-type: none"> 1. (Robbin) Unable to enter error message each time I try to save an AE 2. (Debbie) Tested IE6.0, problems with layout 3. (Bob) I first went in on the incorrect patient. When I tried to go back simply by clicking on the beginning tab, I insisted on a period. After selected a period and went back I pulled up a different patient and received a system error. However after starting over I was able to enter the multiple terms, but was unable to save them all expected grading and other variables to be filled in. the period was saved. I went back and added two, completing all information on one, but only partially on the other. Neither was saved. 4. (Bob) There is no window or indication that a save worked.

UAT Case	Mayo Tested? Y/N	Wake Tested? Y/N	CALGB Tested? Y/N	Passed IE 7.0? Y/N	Passed Firefox? Y/N	Comments
						<p>there is no warning when you leave a window that your work has not been saved.</p> <p>5. (Bob) It may be the case that a CRA will enter 5 new AE's but some of the grades may be pending. (for instance they know it occurred, was part of other lab related events with a hospitalization, but not know what the grade or attribution is. The user needs to be able to save partials.</p> <p>6.</p>
select a different report than suggested	n,n	y	y	n		<p>1. (Debbie) Tested IE6.0, error message</p> <p>2. (Sarah) - The link to a patient's study calendar brought up a 'page not found' window.</p> <p>3. (Sarah) - After entering AE information and clicking 'Save and Continue.' I received "Return HOMe error (no details provided); tried second patient, received different error "failed</p>

UAT Case	Mayo Tested? Y/N	Wake Tested? Y/N	CALGB Tested? Y/N	Passed IE 7.0? Y/N	Passed Firefox? Y/N	Comments
						to convert property value....."
Add more/modify existing AEs for a reporting period	n,n	y	y		sorta	<ol style="list-style-type: none"> 1. (Debbie) Tested IE6.0, problems with layout; Notice second conduction abnormality appears with grade 5-Death displaying. Is there a reason it does that? I was able to select a lower grade; On the add multiple screen, user needs instruction to hold Ctrl to select multiple terms. This wouldn't be obvious to the average user. 2. (Bob) It was not obvious how to edit a reporting period (no part of the screen was a link) When I finally clicked on Hmoglobin, the entire period came up. The period should be a link, and should be marked as the place to click to edit AE's in the period 3. (Bob) Attribution, Hospitalization and expected should be disabled for grade 0's 4. (Bob) Newly added terms should not be so separated

UAT Case	Mayo Tested? Y/N	Wake Tested? Y/N	CALGB Tested? Y/N	Passed IE 7.0? Y/N	Passed Firefox? Y/N	Comments
						<p>from solicited templates (maybe put the add at the bottom). This will prevent duplicates</p> <p>5. (Bob) On the last page, observed and solicited flip. Ideally, they should appear in one grid sort, with some kind of coloration. This too will prevent duplicates</p>
complete an expedited report	n,n	y	y		n,n	<p>1. (Debbie) It seemed like action should be first on line not the term. When I selected the action for caAERS, I received a system error message and was thrown back to the home page. This was a problem using Firefox v 2.0.0.16</p> <p>2. (Bob) No, I added a grade 5, unexpected, definitely related and it did not prompt for a SAE report. In manage report a blank line appeared above the list of solicited and with a dropdown with adeers pdf as a choice, when selected, it</p>

UAT Case	Mayo Tested? Y/N	Wake Tested? Y/N	CALGB Tested? Y/N	Passed IE 7.0? Y/N	Passed Firefox? Y/N	Comments
						<p>created an error. Went back and added in all the missing values, still no report required and it created another missing row</p> <p>3. (Bob) In the review and report screen the columns do not match up</p>

Local Install summary

UAT Case	Mayo Tested? Y/N	Wake Tested? Y/N	CALGB Tested? Y/N	Passed IE 7.0? Y/N	Passed Firefox? Y/N	Comments
install caAERS as an upgrade						
import MedDRA v 10						

Import summary

UAT Case	Mayo Tested? Y/N	Wake Tested? Y/N	CALGB Tested? Y/N	Passed IE 7.0? Y/N	Passed Firefox? Y/N	Comments
import a subject						
import an update to a subject						
import an investigator						
import an update to an investigator						
import a research staff						
import an update to a research staff						
import an update to a study						

General caAERS comments

Wake

AE module:

1. Why look up protocol as well as patient?
2. Normal or evaluated for grade? WHY are these included?
3. Why notes/verbatim for added AE but not for solicited
4. Why 3 buttons: Save, save & continue, save & back??
5. "Do not seem to require" should be first to make the SAE override note
6. What is the Save and manage reports button?
7. Search sometimes does not engage (if number is changed in the middle instead of erasing and entering entire number again)
8. Did not add AE term, logged out, rechecked and was added to solicited AEs but not added to AE terms.
9. The auto complete failed several times, I think when she mistyped and then went to the middle of the string and corrected.
10. The % search for names did not work any more, and indeed no matter what we did we only got five patients, none of which we were looking for, until we went to identifiers.
11. The Reporting Period types in trial is not an obvious header when the main content there is AE templates
12. When editing a protocol it was unclear to us whether we could complete the save only on the tab we changed, or whether we needed to go to the end of the tab sequence to save
13. The caAERS home page link (the big letters) was discovered by us only by accident when trying to get back to the main screen.
14. The save versus save and continue as well as some wording continues to challenge people new to the program.