Pilots - caAERS

This site is a blog to record pilot TESTING activities. The information here is not for production use, nor should it be used to infer the production status of the caAERS system.

caAERS adopters will go through various pilots as they go through the process of adopting caAERS. The pilots will help identify caAERS current strengths and weaknesses, and help the developers determine priority for improvements.

- Mayo Pilot
- Wake Forest Pilot
- CTMS:CALGB Pilot

These pages may include bugs, usability issues that are met, documentation issues, etc. This information should also be included in the caAERS master lists:

- caAERS Documentation Updates needed
- caAERS Bug Reports
- Process and Technical Questions - caAERS

caAERS-to-AdEERS Production Pilot

Goal

- Primary: Successful production usage of caAERS to submit an expedited report to the AdEERS system.

Scope

Pilot Lead	**Mayo Clinic Rochester**
Studies	CTMS:Nine (9) studies 6307 7351 7380 7602 7627 7848 8231 N0543 N0735
Sites	1 - Mayo Clinic Rochester
Clinical Staff	7
Use scenario	• Locally hosted caAERS system • Only AEs requiring AdEERS entered into caAERS • Rules provide reporting requirement confirmation • No central processing
caAERS version used	v1.9.6 (10/01/09); v1.9.6.1 (12/10/09)
caAERS hosted at	Mayo Clinic Rochester
Training dates	10/21,10/23/2009
Pilot Opens	11/16/2009
Pilot Closes	earlier of 20 reports or 4 months (3/15/2010)

Possible Risks

Risk	Risk level	Mitigation Plan

Dependency 3rd party site resources	High • Separate systems team at Mayo for any production system	Pilot will be hosted
Delays due to local CTMS integration	High	CTMS integration removed from pilot scope
Delays due to approval of Mayo IRB	Med	Pending final hosting decision

- Option for adding new pilot sites: Recent discussions with potential adopters indicate interest in using caAERS for AdEERS reporting.
- Releases during pilot: Will be targetted to high priority fixes and support and will be coordinated carefully.

Metrics / measures of success

Metrics

- # Reports Successfully Submitted (total)
- # Reports Successfully Submitted per site
- # Reports Unsuccessfully Submitted (total)
- # Reports Unsuccessfully Submitted per site
- Were the correct reports submitted?
- Were the reports submitted on-time?
- What was the user experience (survey)?
  Mayo survey: http://www.surveymonkey.com/s.aspx?sm=WHKa84EH_2bSc_2fYRpvRqRn7A_3d_3d
- What was the clinical user support (TRI) experience (survey)?
  TRI survey: http://www.surveymonkey.com/s.aspx?sm=6tLjYUzK8aZRVUXizcAK6A_3d_3d
- The % of reports filed that shouldn't have been compared to reporting without caAERS.

Measures of success

- CTEP approves the usage of caAERS

Knowledge Center involvement

- The Knowledge Center is the source of all user facing documentation
- Users will be encouraged to use the Knowledge Center forums to request support and document issues
- The current process of coordinating activities between the KC staff and the caAERS project team will be employed
  - Requests made through the KC and forwarded to the caAERS Project Manager
- Change requests will flow through the normal process whereby requests are documented and forwared to NCI management for review and prioritization.

Training

- Educational and training materials to facilitate implementation are being developed during August 2009.
  - Online help
  - User guide
  - Training videos
  - Train-the-trainer approach
  - CALGB group meeting in early Nov

Post-pilot

- Deployment of CTEP AdEERS web service for CTEP protocol & AdEERS data elements / valid values
- CTCAE v4.0

Pilot Results

General Comments

- Due to the dependency on the AdEERS Web Service, any changes to the AdEERS Web Service must be coordinated tightly with those organizations using the web service.
  - Example 1: The update to AdEERS Web Service v3.0.1 had to be completed by CTIS, deployed to beta, developed in caAERS,

regression tested for back-wards compatibility, deployed to the sites (only 1 - Mayo), validated at the sites, and the AdEERS WS v3.0.1 was able to be deployed to production.
    - Example 2: When the security certificate is updated for the AdEERS Web Service, systems using the web service will not be able to submit until they have updated the key store. This could result in downtime for systems.

- Need to determine who authors the rules.
    - Sites responsibility or Sponsors?

AdEERS Submission Log

Date	Submission Type	Ticket #	Study ID	Comments	Actions
12/15/2009	24hr Notification	1307334	7380		
12/16/2009	Completed Report	1307334	7380	Issue identified regarding AdEERS WS pre-existing conditions uniqueness check	AdEERS WS fix needed to allow multiple "Other" pre-existing conditions provided they are unique.
12/18/2009	24hr Notification	1324736	N0735		
12/23/2009	24hr Notification Withdraw	1324736	N0735	The subject ID needed to be changed to reflect the NCCTG ID (rather than the Mayo ID). Initially, the complete 5-day report was submitted with the updated subject ID, but rejected since the subject ID didn't match the 24hr notification. The 24hr notification was withdrawn using the 24hr withdraw service and the report was resent anew with the updated subject ID. Updating the subject ID would not have been possible without help desk assistance if the completed report had already been submitted as there is no withdraw service for complete reports. Incidences of incorrect subject IDs will likely reduce if caAERS subjects are automatically registered using the caAERS-CTMS web services.	Suggest allowing web service to match only against ticket # and protocol ID to allow subject ID to be updated. Suggest providing a withdraw service for complete reports.
12/23/2009	24hr Notification	1458951	N0735	Replacement notification for ticket #1324736, but with the corrected Subject ID	
12/23/2009	Completed Report	1458951	N0735	Error submitting report due to metastatic site of disease "Iliac" since it has two categories	This will be fixed with the deployment of AdEERS WS v3.0.1, "Iliac" being added to the known issues list for metastatic site of disease.
01/07/2010 03:57:37 PM	24hr Notification	1967908	8231		
01/12/2010 08:46:45 AM	Completed Report	1967908	8231		
01/20/2010	Over-reporting prevented (No report needed)	n/a	N0543	An AE (Grade 2; Obstruction-GI - Small bowel, NOS) was entered into the system by the CRA thinking that a report was required. caAERS indicated a report was not required. This was confirmed by the CRA upon reference to the protocol.	
02/08/2010 05:12:43 PM	Regular Amendment	1967908	8231	Amendment requested by Theradex to change the start date of the course/start date of the first course.	The CRA questioned if the healthcare provider check-box is needed for an amendment - Mary Agnes Templeton to follow-up with the current behavior in AdEERS.

02/9/2010 10:32:49 AM	Regular Report (10-day)	1677573	7351	The report was not able to be retreived in the AdEERS system by querying on the Ticket #, Study ID, and Subject ID. Upon further investigation, this report was withdrawn per request by Pat McNamara as AE reporting was not required per protocol. A protocol specific rule had been authored for this study for "Neutrophils/granulocytes (ANC/AGC)" of grade <= 3. This exception was not triggered in caAERS since this AE was coded using the term "Blood/Bone Marrow - Other (Specify, __) : Blood neutrophils abnormal"	The "Other, specify" term was used since in CTCAE v3.0 the desired term "Neutrophils/granulocytes (ANC/AGC)," did not display in the autocompleter due to too many "Infection - Select" terms. This is not an issue for CTCAE v4, however, increasing the number of results displayed in the autocompleter should fix this issue. Consider supporting withdraw by authorized persons (i.e. Pat McNamara); Revisit authoring of protocol specific exceptions.
02/10/2010 02:13:41 PM	Regular Amendment	1458951	N0735	Amended to add resolution dates for labs and specify additional information that will be faxed.	Open question regarding the reminders sent by AdEERS to fax in the additional information - Mary Agnes confirmed that the reminder emails come from AdEERS staff. Need to display the FAX number in caAERS.
02/18/2010 10:55:57 AM	Regular Report (10-day)	1623704	7627	Upon submission, an error returned from AdEERS indicating that Month required for Primary Date of diagnosis and Prior Therapy start/end dates.	Address date validation in caAERS
03/16/2010 04:20:11 PM	Regular Report (10-day)	1354349	7627	Several issues encountered by the CRA. Technical support was required to resolve	Issues are being addressed as bugs and training issues to prevent in newer versions of the system.
07/15/2010 12:02:38 PM	Regular Report (10-day)	1546047	7627	Two issues encountered by the CRA. 1. when entering AE's if you click on "Add" the selections do not show up (ie:grade) they only show up if you choose "Add Multiple" 2. There are no MD's showing up in her system for prior therapies.	Issues are being addressed as bugs. CRA was able to work around both issues.

Weekly Status Updates

Week	Weekly Submissions	Total Submissions	Total Reports
11/16/09	0	0	0
11/23/09	0	0	0
11/30/09	0	0	0
12/07/09	0	0	0
12/14/09	3 submissions	3 submissions	2 reports
12/21/09	2 submissions; 1 withdraw	5 submissions; 1 withdraw	2 reports
12/28/09	0 submissions	5 submissions; 1 withdraw	2 reports
01/04/10	1 submission	6 submissions; 1 withdraw	3 reports
01/11/10	1 submission	7 submissions; 1 withdraw	3 reports
01/18/10	1 unecessary report prevented	7 submissions; 1 withdraw	3 reports submitted; 1 unecessary report prevented
01/25/10	0 submissions	7 submissions; 1 withdraw	3 reports submitted; 1 unecessary report prevented
02/01/10	0 submissions	7 submissions; 1 withdraw	3 reports submitted; 1 unecessary report prevented
02/08/10	1 submissions; 2 amendments	8 submissions; 2 amendments; 1 withdraw	4 reports submitted; 1 unecessary report prevented

02/15/10	1 submission	9 submissions; 2 amendments; 1 withdraw	5 reports submitted; 1 unecessary report prevented
02/22/10	0 submissions	9 submissions; 2 amendments; 1 withdraw	5 reports submitted; 1 unecessary report prevented
03/01/10	0 submissions	9 submissions; 2 amendments; 1 withdraw	5 reports submitted; 1 unecessary report prevented
03/08/10	0 submissions	9 submissions; 2 amendments; 1 withdraw	5 reports submitted; 1 unecessary report prevented
03/15/10	1 submission	10 submissions; 2 amendments; 1 withdraw	6 reports submitted; 1 unecessary report prevented
07/12/10	1 submission	11 submissions; 2 amendments; 1 withdraw	7 reports submitted; 1 unecessary report prevented

Legend	Meaning
✓	successfully tested in pilot (passed)
✗	unsuccessfully tested in pilot (failed)
	in-scope, but not tested in pilot
N/A	out of scope for pilot

Study Phase	Study Interventions	IND/IDE holder	24hr Notification	Completed Report	24hr Amendment	Complete Amendment	24hr Withdraw
I	Agent	NCI	✓	✓			
I	Agent	Non-NCI	N/A	N/A	N/A	N/A	N/A
I	Agent	Commercial	N/A	N/A	N/A	N/A	N/A
II-IV	Agent	NCI		✓		✓	
II-IV	Agent	Non-NCI	✓	✓		✓	✓
II-IV	Agent	Commercial					
I	Device	NCI	N/A	N/A	N/A	N/A	N/A
I	Device	Non-NCI	N/A	N/A	N/A	N/A	N/A
I	Device	Commercial	N/A	N/A	N/A	N/A	N/A
II-IV	Device	NCI	N/A	N/A	N/A	N/A	N/A
II-IV	Device	Non-NCI	N/A	N/A	N/A	N/A	N/A
II-IV	Device	Commercial	N/A	N/A	N/A	N/A	N/A
I	Surgery		N/A	N/A	N/A	N/A	N/A
II-IV	Surgery		N/A	N/A	N/A	N/A	N/A
I	Radiation		N/A	N/A	N/A	N/A	N/A
II-IV	Radiation		N/A	N/A	N/A	N/A	N/A
I	Multi-modality	NCI	N/A	N/A	N/A	N/A	N/A
I	Multi-modality	Non-NCI	N/A	N/A	N/A	N/A	N/A
I	Multi-modality	Commercial	N/A	N/A	N/A	N/A	N/A
II-IV	Multi-modality	NCI	N/A	N/A	N/A	N/A	N/A
II-IV	Multi-modality	Non-NCI	N/A	N/A	N/A	N/A	N/A
II-IV	Multi-modality	Commercial	N/A	N/A	N/A	N/A	N/A
	ACRIN-CIP		N/A	N/A	N/A	N/A	N/A
	DCP-CCOPS		N/A	N/A	N/A	N/A	N/A

Database Connection Testing

What does this test do?

This test will query the organization table, and print out detailed metrics of how much time it took.

Instructions

1. Unzip the [dbtester.zip|CTMS:Database Connection Testing^dbtester.zip] file in the VM where tomcat is running.

1. Change Directory to the folder having unzipped files.

1. Edit the following properties in "./datasource.properties", to have the same values as that found in $TOMCAT_HOME/conf/caaers/datasource.properties
   datasource.driver=
   datasource.url=
   datasource.username=
   datasource.password=

1. Execute the following commands and send us the results.
   ./runJDBCApp.sh
   ./runSpringJDBCApp.sh

Please perform this on both DEV and PROD for comparison purposes.

Example Results

```
biju-josephs-macbook-pro:dbtester bijujoseph$ ./runSpringJDBCApp.sh
================ JDBC Query =======================================
Total time :649 milliseconds
Application Context Loaded in :377 milliseconds
(7933) fetched in :271 milliseconds
=====================================================================
biju-josephs-macbook-pro:dbtester bijujoseph$ ./runJDBCApp.sh
================ JDBC Query =======================================
Total time :229 milliseconds
Connection opened in :73 milliseconds
Statement created in :9 milliseconds
Query executed in :59 milliseconds
(7933) fetched in :45 milliseconds
ResultSet closed in :0 milliseconds
Statement closed in :0 milliseconds
Connection closed in :0 milliseconds
=====================================================================
```

Mayo Production Pilot Status Updates

The page captures the weekly progress of the caAERS-AdEERS production pilot being conducted by Mayo Clinic Rochester.

Weekly Status Updates

Week	Weekly Submissions	Total Submissions	Total Reports
11/16/09	0	0	0
11/23/09	0	0	0
11/30/09	0	0	0
12/07/09	0	0	0
12/14/09	3 submissions	3 submissions	2 reports
12/21/09	2 submissions; 1 withdraw	5 submissions; 1 withdraw	2 reports
12/28/09	0 submissions	5 submissions; 1 withdraw	2 reports

01/04/10	1 submission	6 submissions; 1 withdraw	3 reports
01/11/10	1 submission	7 submissions; 1 withdraw	3 reports
01/18/10	1 unecessary report prevented	7 submissions; 1 withdraw	3 reports submitted; 1 unecessary report prevented
01/25/10	0 submissions	7 submissions; 1 withdraw	3 reports submitted; 1 unecessary report prevented
02/01/10	0 submissions	7 submissions; 1 withdraw	3 reports submitted; 1 unecessary report prevented
02/08/10	1 submissions; 2 amendments	8 submissions; 2 amendments; 1 withdraw	4 reports submitted; 1 unecessary report prevented
02/15/10	1 submission	9 submissions; 2 amendments; 1 withdraw	5 reports submitted; 1 unecessary report prevented
02/22/10	0 submissions	9 submissions; 2 amendments; 1 withdraw	5 reports submitted; 1 unecessary report prevented
03/01/10	0 submissions	9 submissions; 2 amendments; 1 withdraw	5 reports submitted; 1 unecessary report prevented
03/08/10	0 submissions	9 submissions; 2 amendments; 1 withdraw	5 reports submitted; 1 unecessary report prevented
03/15/10	1 submission	10 submissions; 2 amendments; 1 withdraw	6 reports submitted; 1 unecessary report prevented
07/12/10	1 submission	11 submissions; 2 amendments; 1 withdraw	7 reports submitted; 1 unecessary report prevented

Pathways Excercised

Below is a summary of the various AdEERS pathways that have been excercised via the pilot.

Legend	Meaning
✅	successfully tested in pilot (passed)
❌	unsuccessfully tested in pilot (failed)
	in-scope, but not tested in pilot
N/A	out of scope for pilot

Study Phase	Study Interventions	IND/IDE holder	24hr Notification	Completed Report	24hr Amendment	Complete Amendment	24hr Withdraw
I	**Agent**	**NCI**	✅	✅			
I	**Agent**	**Non-NCI**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**
I	**Agent**	**Commercial**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**
II-IV	**Agent**	**NCI**		✅		✅	
II-IV	**Agent**	**Non-NCI**	✅	✅		✅	✅
II-IV	**Agent**	**Commercial**					
I	**Device**	**NCI**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**
I	**Device**	**Non-NCI**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**
I	**Device**	**Commercial**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**
II-IV	**Device**	**NCI**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**
II-IV	**Device**	**Non-NCI**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**
II-IV	**Device**	**Commercial**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**
I	**Surgery**		**N/A**	**N/A**	**N/A**	**N/A**	**N/A**
II-IV	**Surgery**		**N/A**	**N/A**	**N/A**	**N/A**	**N/A**
I	**Radiation**		**N/A**	**N/A**	**N/A**	**N/A**	**N/A**

II-IV	**Radiation**		**N/A**	**N/A**	**N/A**	**N/A**	**N/A**
I	**Multi-modality**	**NCI**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**
I	**Multi-modality**	**Non-NCI**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**
I	**Multi-modality**	**Commercial**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**
II-IV	**Multi-modality**	**NCI**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**
II-IV	**Multi-modality**	**Non-NCI**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**
II-IV	**Multi-modality**	**Commercial**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**
	ACRIN-CIP		**N/A**	**N/A**	**N/A**	**N/A**	**N/A**
	DCP-CCOPS		**N/A**	**N/A**	**N/A**	**N/A**	**N/A**

Production caAERS-AdEERS upgrade procedures

Production Server Updates

https://cabig-kc.nci.nih.gov/CTMS/KC/index.php/Mayo_Update_Instructions_10/28/09

caAERS System Admin Checks

In Administration >> configure caAERS

- Verify the caAERS help URL is: https://cabig-kc.nci.nih.gov/CTMS/KC/index.php/CaAERSv1.9.6_End_User_Guide
- Verify the caAERS base URL refers to the production system
- Verify the ESB url is correct
- Verify the SMTP information is correct
- Verify Enable Routing & Review = No
- Verify that unidentified mode = No

In Administration >> Track Reports >> System Status

- Verify ServiceMix is active
- Verify the email connection is active

Import MedDRA 12 (https://cabig-kc.nci.nih.gov/CTMS/KC/index.php/CaAERSv1.9.6_End_User_Guide#Import_MedDRA)

Report Definition Updates

1. Import CTMS:report definitions for N0735 and N0543
    a. Assign the Commercial Agent 24hr Notification as the parent report for the Commercial Agent 3-day report
    b. Assign the Non-CTEP IND 24hr Notification as the parent report for the Non-CTEP IND 3-day report
2. Update the delivery recipients to include Submitter, RAU, AdEERS Coordinator (Pat McNamara), Data Coordinator, Jean Hanson (manager), and Treating Physician, Ann Setser (setsera@ctep.nci.nih.gov), Shanda Finnigan (finnigas@mail.nih.gov)
    - Change request: Allow notification recipients to see all other recipients on the notification.
3. Update notification receipients to include Reporter and Jean Hanson (manager)
    a. Add Ann Setser (setsera@ctep.nci.nih.gov), Shanda Finnigan (finnigas@mail.nih.gov) to the time 0 notification
4. Add notification for the day on which the report is due and include the same recipients as above.
5. Update the system delivery details to point to the production AdEERS web service (contact Paul for details)
6. Update the existing reports to conform with the report definitions in http://stage.semanticbits.com/caaers

Update Rules

1. Import all CTMS:rules
2. Enable all rules

Study Updates

1. Verify CTEP ID as primary ID
2. Verify Therapy Type as Drug Administration
3. Add caAERS XML and AdEERS pdf as export formats for all studies
    a. Also add Medwatch as an export format for N0543 and N0735
4. Add in PI to Coordinating Center (not in for three (3) studies but in process)
5. Add Coordinators as Subject Coordinators at Mayo Clinic Rochester

6. Add Data Coordinators to the system and deactivate role from not applicable studies
    - Feature improvement request: allow "associate to all studies" flag to be role based.
7. Click on "Data Entry Complete" button
8. Final subject import
    - Question: will there be any intermediate imports?
9. Investigator addition to the study
    - How to pick from non-study physicians since most physicians will be associated with each study.
10. Assign MedDRA v12 to all studies as the Other MedDRA version

caAERS-AdEERS Known Issues

The table below details known issues for caAERS-AdEERS.

Studies Affected	Issue	Workaround	Who is fixing?	When will it be fixed?
All	Report will not submit if subject's "Metastatic Site of Disease" is "Hilar", "Mediastinum", or "Pelvis"	Select "Other, specify" as the site of metastatic disease and then enter the site in the text box that appears	AdEERS	by 11/18/09
N0543	Report will not submit if date of primary diagnosis is entered	This is an optional field - do not enter	caAERS	v1.9.6.1 - need to schedule release
All	Report will not submit if primary site of disease is "Adrenal Gland"	Enter primary site of disease as "Other, specify" and then enter "Adrenal Gland" in the text box that appears	caAERS	v1.9.6.1 - need to schedule release
7848	Report will not submit with "total dose administered this course" having more than nine digits in front of the decimal.	Enter a value for agent dose and then add a comment in the agent comments reflecting the full dose.	AdEERS	by 11/18/09
All	The treating physician is not automatically being emailed by caAERS upon report delivery	Add the treating physician's email to the CC: box in the caAERS recipients submission page.	caAERS	v1.9.6.1 - need to schedule release

Production Pilot Submissions

Below are listed the AdEERS submissions that were part of the pilot.

AdEERS Submission Log

Date	Submission Type	Ticket #	Study ID	Comments	Actions
12/15/2009	24hr Notification	1307334	7380		
12/16/2009	Completed Report	1307334	7380	Issue identified regarding AdEERS WS pre-existing conditions uniqueness check	AdEERS WS fix needed to allow multiple "Other" pre-existing conditions provided they are unique.
12/18/2009	24hr Notification	1324736	N0735		

12/23/2009	24hr Notification Withdraw	1324736	N0735	The subject ID needed to be changed to reflect the NCCTG ID (rather than the Mayo ID). Initially, the complete 5-day report was submitted with the updated subject ID, but rejected since the subject ID didn't match the 24hr notification. The 24hr notification was withdrawn using the 24hr withdraw service and the report was resent anew with the updated subject ID. Updating the subject ID would not have been possible without help desk assistance if the completed report had already been submitted as there is no withdraw service for complete reports. Incidences of incorrect subject IDs will likely reduce if caAERS subjects are automatically registered using the caAERS-CTMS web services.	Suggest allowing web service to match only against ticket # and protocol ID to allow subject ID to be updated. Suggest providing a withdraw service for complete reports.
12/23/2009	24hr Notification	1458951	N0735	Replacement notification for ticket #1324736, but with the corrected Subject ID	
12/23/2009	Completed Report	1458951	N0735	Error submitting report due to metastatic site of disease "Iliac" since it has two categories	This will be fixed with the deployment of AdEERS WS v3.0.1, "Iliac" being added to the known issues list for metastatic site of disease.
01/07/2010 03:57:37 PM	24hr Notification	1967908	8231		
01/12/2010 08:46:45 AM	Completed Report	1967908	8231		
01/20/2010	Over-reporting prevented (No report needed)	n/a	N0543	An AE (Grade 2; Obstruction-GI - Small bowel, NOS) was entered into the system by the CRA thinking that a report was required. caAERS indicated a report was not required. This was confirmed by the CRA upon reference to the protocol.	
02/08/2010 05:12:43 PM	Regular Amendment	1967908	8231	Amendment requested by Theradex to change the start date of the course/start date of the first course.	The CRA questioned if the healthcare provider check-box is needed for an amendment - Mary Agnes Templeton to follow-up with the current behavior in AdEERS.
02/9/2010 10:32:49 AM	Regular Report (10-day)	1677573	7351	The report was not able to be retreived in the AdEERS system by querying on the Ticket #, Study ID, and Subject ID. Upon further investigation, this report was withdrawn per request by Pat McNamara as AE reporting was not required per protocol. A protocol specific rule had been authored for this study for "Neutrophils/granulocytes (ANC/AGC)" of grade <= 3. This exception was not triggered in caAERS since this AE was coded using the term "Blood/Bone Marrow - Other (Specify, __) : Blood neutrophils abnormal"	The "Other, specify" term was used since in CTCAE v3.0 the desired term "Neutrophils/granulocytes (ANC/AGC)," did not display in the autocompleter due to too many "Infection - Select" terms. This is not an issue for CTCAE v4, however, increasing the number of results displayed in the autocompleter should fix this issue. Consider supporting withdraw by authorized persons (i.e. Pat McNamara); Revisit authoring of protocol specific exceptions.
02/10/2010 02:13:41 PM	Regular Amendment	1458951	N0735	Amended to add resolution dates for labs and specify additional information that will be faxed.	Open question regarding the reminders sent by AdEERS to fax in the additional information - Mary Agnes confirmed that the reminder emails come from AdEERS staff. Need to display the FAX number in caAERS.
02/18/2010 10:55:57 AM	Regular Report (10-day)	1623704	7627	Upon submission, an error returned from AdEERS indicating that Month required for Primary Date of diagnosis and Prior Therapy start/end dates.	Address date validation in caAERS

03/16/2010 04:20:11 PM	Regular Report (10-day)	1354349	7627	Several issues encountered by the CRA. Technical support was required to resolve	Issues are being addressed as bugs and training issues to prevent in newer versions of the system.
07/15/2010 12:02:38 PM	Regular Report (10-day)	1546047	7627	Two issues encountered by the CRA. 1. when entering AE's if you click on "Add" the selections do not show up (ie:grade) they only show up if you choose "Add Multiple" 2. There are no MD's showing up in her system for prior therapies.	Issues are being addressed as bugs. CRA was able to work around both issues.

Mayo Pilot

This site is a blog to record pilot TESTING activities. The information here is not for production use, nor should it be used to infer the production status of the caAERS system.

Mayo caAERS pilot

Purpose: To test in a production environment, the creation and submission of an expedited report to AdEERS system via caAERS for CTEPIND and commercial only agent trials for which Mayo is the lead organization.

Out-of-scope items: Any features in caAERS not directly related to the creation and/or submission of an expedited report to AdEERS (i.e. routine AE capture, non-AdEERS reporting, central processing, etc).

Goal of Pilot: To facilitate the production use of caAERS at Mayo for select trials (i.e. CTEPIND and/or commercial only where Mayo is the lead organization).

Materials and Methods: The pilot will be conducted in three phases: pre-pilot, pilot, and production pilot.

Phase I (pre-pilot)

Purpose: To provide recently trained staff at Mayo additional experience in creating expedited reports in caAERS and to test the proposed methods of comparing reports created via AdEERS to those created via caARES.

Studies: Three (3) studies will be used (N0177, N027D, and LSO38B (NCI# 6246)). Mayo has already compiled and printed the original expedited reporting materials associated with this study.

 # Reports: 5-6 reports total (1-2 from each study)

Method of Assessment: The original processed AdEERS report will be obtained. The adverse event information will be entered into caAERS and the submitted to the staging AdEERS environment. The staging report will be printed and compared line-by-line to the original AdEERS report. Any inconsistencies in the reports will be noted and reported.

Period of Performance: 6/1/08 - 7/31/08

caAERS Version(s) tested: v1.1.2, v1.1.3

Dependencies / Actions::

- Resolution of caAERS installation issue (SematicBits/Mayo - complete 5/18/08)
- Import of relevant study and participant information into caAERS (Mayo - complete)
- Set-up three studies in caAERS demo for Ann and Shanda (SematicBits - complete)
- Installation of caAERS v1.1.3 at Mayo (SemanticBits / Mayo - complete)

Status: Complete

Results / Notes:

- Several issues were identified in the pre-pilot by Mayo and Ann Setser, which were communicated to the development team and resolved in caAERSv1.1.3 (released 7/07/08)
- Several system configuration issues were identified and resolved through the efforts of Mayo personnel and the SemanticBits development team.

Issues identified	Status

caAERS requires day for all dates	Fixed
Hospitalization question needs to "YES/NO" answer	Fixed
Expected should not be mandatory	Fixed
Hospitalization question should only be mandatory if Grade >= 3	Fixed
Disease LOV incorrect (abbreviated)	Fixed
Protocol ID sent to AdEERS must be CTEP ID	Fixed
Pre-filling of certain fields ("Please select" needed)	Fixed
Study definition data different in AdEERS beta than production or caAERS	Ongoing process issue
AdEERS web service validates exact text of several values (TAC, Agent, NSC, LOVs). Imperative that certain study information match exactly as is in AdEERS.	Ongoing process issue
Imperative that LOVs be kept up-to-date (agent lists, race & ethnicity, organizations, labs)	Ongoing process issue

Phase II (pilot)

Purpose: To assess the quality of AdEERS submissions via caAERS for CTEPIND trials where Mayo is the lead on studies that are still active. This testing will NOT evaluate 24hr notifications or report amendments.

Studies: 5 studies

Number of Reports: ~10+ (2+ from each study)

Method of assessment: The original processed AdEERS report will be obtained. The adverse event information will be entered into caAERS and the submitted to the staging AdEERS environment. The staging report will be printed and compared line-by-line to the original AdEERS report. Any inconsistencies in the reports will be noted and reported.

Period of Performance: 10/13/08 - 12/19/08

caAERS Version(s) tested: v1.5.1, v1.6

Dependencies and Actions:

- Provision of appropriate studies (CTEPIND, Mayo lead) and related AE information to Mayo (Shanda/Ann - complete)
- Preliminary selection of studies for pilot (Mayo - complete)
- Identification of additional studies to better ensure that there will be AE's to report in the production phase of the pilot (Mayo - complete)
- Identification of caAERS required information not available in Mayo's CTMS system (Mayo - complete)
- Identification of information that cannot be uploaded from local CTMS into caAERS (Mayo - complete)
- Support of uploading study information (i.e. personnel) (Mayo/SemanticBits - complete)
- Import of relevant study and participant information into caAERS (Mayo - complete)

Status: Complete

Results:

See completed CTMS:test scripts.

Issues:

Summary of Issues identified	Status
Agents required by AdEERS beta web service for certain prior therapies	Fixed
Primary Anatomic Site now required by AdEERS beta web service	Fixed
31st of month an invalid date in caAERS	Fixed
"Was investigational agent administered" YES on original report, NO on beta	Fixed
Decimals cannot be sent to AdEERS beta	Open
Unable to add agent to prior therapy "Drug and/or Immunotherapy"	Open
Unable to use "Carboplatin" as a prior therapy agent in AdEERS beta	Open

Phase III (expanded pilot)

Purpose: To assess the quality of AdEERS submissions via caAERS for a broader number of CTEP IND trials where Mayo is the lead. This will not test 24hr notification or amend functionality

Studies: 22 studies where Mayo is the lead

Reports: ~5-10, but dependent upon future occurrence of AEs in these studies.

Method of assessment: Specific assessment criteria are TBD, however, they will focus on the overall production use of caAERS to submit reports to AdEERS.

Period of Performance: 2/11/09-03/31/09

caAERS Version(s) tested: v1.7

Dependencies and Actions:

- Future occurrence of AE's requiring expedited reporting in the selected studies

Status: In-process

Results:

See test scripts

Tester	AdEERS production ticket #	Date of caAERS submission	Submission to AdEERS beta?	Accuracy verified to production AdEERS?	Comments / Supporting Materials
Jean Hanson		02/20/2009	Rejected	N/A	Unable to submit - total dose = 0 rejected by AdEERS web service
Robbin Peterson		02/25/2009	YES		CTMS:email; CTMS:caAERS pdf
Robbin Peterson		02/25/2009	YES		CTMS:email; CTMS:caAERS pdf

Issues:

Summary of Issues identified	Status	Comments / Supporting Materials
Total dose administerd for investigational agent not able to be = 0 (allowed in AdEERS production)	Open	CTMS:caAERS xml, CTMS:email, CTMS:screenshot

WFU Pilot

This site is a blog to records both testing activities leading to Pilot implementation, as well as to document the Pilot experience after implementation. Bug information here is typically version specific and thus not for production use, nor should it be used to infer the production status of the caAERS system.

This page will serve as a log of the Wake Forest Comprehensive Cancer Center's Pilot adoption experience with caAERS. WFU went into live use of caAERS for SAE reporting of its Reseach Base CCOP trial group in July of 2009 after extensive testing and system refinement.

Wake Forest Comprehensive Cancer Center (CCCWFU) has been a caAERS adopter since the project inception, but in 2008 is moving forward as part of its caBIG CCSG Supplement activities with adoption activities of the version 1.0 that it completed contracted testing activities and data sharing work in March of 2008.

Because CCCWFU is continuing with its contracted testing of new iterations of caAERS, and because the nature and workflow of its adoption experience is different from more formal testing, we are creating this page to document the experience and problems encountered, both for developers seeking to improve the application, as well as future adopters seeking to make their adoption as painless as possible.

CCCWFU Pilot adoption Strategy

CCCWFU will focus its initial adoption strategy on its Research Base CCOP. In the initial phase, it will report SAE's on all locally accrued patients. Expansion to affiliate accrued patients will be dependent security infrastructure development.

CCCWFU's Research Base CCOP http://www1.wfubmc.edu/cancer/Researchbase a small number of symptom control trials. Adverse Events, while less common than in treatment trials, still require medwatch and IRB reporting as well as its local Clinical Research Oversight Committee (CROC) reporting, which is email based.

The following trials will used in the pilot

http://clinicaltrials.gov/ct2/show/NCT00369785
http://clinicaltrials.gov/ct2/show/NCT00459134
http://clinicaltrials.gov/ct2/show/NCT00096356
http://clinicaltrials.gov/ct2/show/NCT00354432
http://clinicaltrials.gov/ct2/show/NCT00752895

http://clinicaltrials.gov/ct2/show/NCT00752895\\

CCCWFU Pilot adoption goals

1. To test caAERS integration accross an entire organizational unit
2. To test caAERS UI's and workflows against real life patient/AE management
3. To assess the ease of adoption of the caAERS application by users who were not involved in development testing.
4. To assess caAERS's stability and reliability in a live trial environment

CCCWFU Pilot adoption tasks

System Prep

1. Instantiate a virtual server (done 02/2008)
2. Identify appropriate version of caAERS to use (done 05/20/2008) (caAERS v. 1.1.2)
3. Install caAERS on virtual server (done 05/21/2008)
4. Create user accounts (begun 05/21/2008)
5. Create staff listings (Completed 7/1/2008)
6. Create trials (Completed 07/24/08)
7. Import medra codes (done 07/02/2008)
8. Import rules (CTEP) (done 07/02/2008)
9. Create local reports (begun 2/14/2009)
10. Create local rules (Completed 2/15/2009)
11. Add local patients (Completed 01/15/2009)
12. Validate a version of caAERS that meets user requirments, completed 6/30/2009

Operational testing

1. Register new patients
2. Report SAE's
3. Manage trials (open, close etc)

CCCWFU Pilot Staff

Bob Morrell bmorrell@wfubmc.edu

Del Jones deljones@wfubmc.edu

Steven Cheng zcheng@wfubmc.edu

Sarah Hahne shahne@wfubmc.edu

CCCWFU Pilot adoption Notes:

caAERS 1.1.2 was set up on a Windows 2003 virtual server inside the WFUBCM firewall. Install was very problematic, due to insufficient documentation of subcomponent versions to be used and problems with Tomcat. During the Pilot adoption, it was sequentially upgraded to 1.9.2

Steven Cheng's intallation notes:

1. The installation guide is out of date, such as missing Ant as a prerequisite. Two steps in installing Tomcat, enable https connections and generate an SSL certificate, are not necessary when use the installer to install caAERS.
2. The current caAERS has problem running with the windows installer version of Tomcat, and works with the zip version of Tomcat. This is a big issue, and took me a lot of time to figure out.
3. caAERS installer is the old version through caBig web site, have to download the latest one from semanticbits web site.
4. Postgres database encoding method is not stated in the installation guide.
5. There are not enough information for pre-required software in the installation guide. For general users, this is the most difficult section.

The links in the installation guide just point to the download index page. There are several components on the index page, users have to decide which one to be download. The best solution is that developers download all pre-required software in advance and save it as a zip file and let users download the file from theirs website.

6. Setting Tomcat running as a windows service needs to be addressed.

All Research Base staff were added as users to the operational instance of caAERS. Each user recieved the email notifying them of their new account. The following problems were encountered

- The certificate security warning scared most users into not proceeding to the site until verbally assured, and even afterwards makes them very nervous.
- On one user, the email address was entered incorrectly. Because this is a key identifier, there is no method for editing and correcting this mistake.
- No format is listed for phone numbers, but the UI will not accept this required field unless it is in the correct format. (and the format is the last one anyone would guess!)
- Most users had considerable difficulty logging in the first time. Almost every user tried to login with just their username, without the email domain added. Instructions here would be helpful. Others were unaware of the password rules (need to be displayed). Several users had to go back and use the forgot password feature to try a second time.
- The pre-loaded set of organizations caused problems that are still being sorted out. Wake Forest Comprehensive Cancer Center was already in there, and some users were placed there, while Research Base staff created the Wake Forest University Health Sciences (the medical school's official name)organization and placed most of the staff there. When protocols were created later, they were linked to Wake Forest Comprehensive Cancer Center which meant that most of the staff (including the staff member that created it) could not view the protocol.
- Along with the previous point, a member of one organization should not be able to create a protocol for another organization
- MAJOR PROBLEM: a protocol manager was entering a real protocol. Abstraction took quite a while. Apparently she spent more than the 10 minute timeout time on the first tab, and when she hit next, she was logged out and her work was lost. Intermediate saves are needed. Alternatively the autologout needs to be keyed to entry into boxes and or an alert countdown of logout set off.
- She was unable to back navigate to agents once at treatment assignments without entering an arm name
- There was a major problem entering IND numbers, as the format was not accepted. This was only resolved when it was realized that the IND's must be instantiated in the administrative module, prior to protocol creation.
- She did not realize that one PI had not been added till she got ot page 7, when she switched to administration, all her work was lost
-

Additional comments about the Study Entry system: Sarah Hahne

- After completing each of the 10 pages, all work was lost when the 'save' button was clicked. As mentioned above, 'save' button on all 10 pages would be helpful.
- A protocol is able to be saved when only the details page is completed then the save button is clicked on page 10.
- When I used the search engine to find the protocol mentioned above, I was unable to bring it up using the identifier or study title. It was retrieved however when I entered the identifier in the *results* section in the primary ID field and clicking on search.
- By pulling up the study through the search engine, the 'save' and 'save and continue' buttons appear. These buttons are very useful, but are not present on pages that need refreshing. Ie. When adding investigators, save was not an option after the initial investigator was entered therefore all information on subsequent investigators is lost when continue is pressed.
- On the agent page, the agent name was rejected unless the highlight on agent button was deactivated then reactivated.
- I was unable to find several of our CCOP sites on the site list. (Beaumont CCOP and LSU Shreveport Health Sciences MB-CCOP)

Creating Patients: Sarah Hahne

- Overall, the creating a patient section was very straight forward and easy to use.
- An error message appeared when patient's birthday was entered using 0 as a placeholder. I.e. 03/06/1931 instead of 3/6/1937 The next time a birthday was entered with a 0, no error message was received.
- When editing patient information, after clicking the save button the page does not proceed to the next screen. Perhaps a 'save and continue' button would eliminate the question of if the information has actually been saved.
- I was unable to switch a patient ID# from 'ID assigned by an organization' to an 'ID assigned by a system.' After deleting the organization ID and entering it as a system ID, I received an error message saying the ID already existed.
- On the review page (4) the birthday is listed with the day before the month.
- The third page seems redundant since the primary patient identifier is already selected on the first page.
  The following comments added 7/16/08: S. Hahne:
- When entering a subject, the drop down menu for site on the first page had only 5 options. Wake Forest University Health Sciences was not included in the list. On one occurrence, refreshing the page brought up the entire site list but lost all subject information. During another entry, Wake Forest University Health Sciences was not one of the 5 options even after logging in and out, refreshing the page and closing the browser. Additional patients could not be entered because the WFU site was unavailable on the site menu.
- On page 1, the system will not allow an organization or system identifier to be deleted. Organization ID instead of system ID was accidently clicked. The additional fields for organization ID would not delete even after red 'X' was clicked. The system would not allow user to continue without another organization ID being entered. The page had to be closed and information re-entered.
- On page 2, having identifier as the first option instead of short title would save a few key strokes.
  The following comment was added on 7/30/08: Sarah Hahne
- The system does not allow the same patient to be registered on 2 studies. The patient will have a different study identifier, but the medical record number will remain the same.
  The following comment was added on 10/8/08: Sarah Hahne
- When searching for patients on a particular study, not all patients appear in the search results. (Ie: I did a patient search for study 91105, only 5 patients appear in the search results when there are 16 patients actually entered into caAERS for this study.)

Import rules and MedDRA codes: Steven Cheng 07/03/2008, Bob Morrell 8/7/2007

- MedDRA cdoes must be imported on the server locallly. It failed when import on the client pc.

- Rules can be imported on the client pc.
- Reports import without mandatory fields.

Update research staff: Steven Cheng 07/10/2008

- Everytime update research staff, must re-assign user role. The problem is that two uers roles, subject coordinator and study coordinator, are automatically unchecked.

Report Definition

- The location and order that Report definition (before rule definiton) was not intuitive, (since report definition was a sub page of rules management)
- A simple medwatch form is not a pre-loaded option as a report, nor are all the fields that a medwatch uses available.

High Priority Items to be addressed

- At the beginning of the protocol creation workflow, a "before you begin" flag should list those things that must be addressed before you create a protocol (PI, IND, Site etc)
- Time out needs to either run off key strokes or have an alert and a "I am still here button" otherwise people who spend more than 10 minutes on any page prior to the final save are kicked out. (completed in later versions)
- Partial saves need to be addressed (completed in later versions)
- Documentation on how to handle IND's is needed
- Becuase the core of caAERS is its rules engine, any fields used in rules need to be identified on screen, and documentation for that field needs to be reviewed before the users first create protocols.
- Install procedures need better documentation, with particular attention to incorporating the correct version of subcomponents in the install file itself, rather than referrring to third party sites that may change versions without warning.
- Password complexity requirement need to be addressed on the reset password page.
- System administrator should have the ability to deactivate some components, such as research staff, investigator and organization. In addition, deactivated components should not be displayed in the work any more unless they keep active status*.*
- The ability to add protocols in developement (prior to irb approval) needs to be added.
- A full medwatch report is a requirement, but as currently configured, caAERS cannot do this. This is a show stopping bug for non ctep/dcp medwatch submissions (such as reports going to IRB, FDA, or trial sponsor) This bug has since been resolved. (completed in later versions)

Adding Protocols In Development: Del Jones

Wake Forest has a new protocol in development that I was attempting to enter into caAERS. When you get to the "Status" tab in the drop down box there is no option to select "In Development". This study is currently at our IRB under review and has also been reviewed by DCP. Being able to enter new studies that will be opening soon would be of great benefit. We could go back after the study has been opened and change the status to "Active" when accrual has begun.

Testing Version 1.5

1. "Create Research Staff" Unable to create staff was given a detailed error message saying "Contact system administrator came up each time.
2. Webpage expired and was kicked out when trying to locate a disease.
3. I was unable to redefine the evaluation period tabs (Ex. We use Week 4, Week 10, etc.) - Paul stated this has been defined as a critical bug and would be resolved next week.
4. When entering solicited AE's two items with this study were not located. "Constitutional Symptoms - Hyperactivity, Neurology - Other-Nervousness. We usually have at least one item in the solicited AE's that we add this way. They are outlined on our "Toxicity Assessment Sheet" that is located in our appendices.

5. When trying to add the agent "North American Ginseng CVT-E002 COLD-fX" was unable to be located and it would not let me add it.

6. In the CTCAE Version 3.0 at the end of each section there is a line that says "Other Specify". We need the ability to add other symptoms that have been required by the protocol.

7. We were able to create a medwatch form in a simple test, however, there was an issue viewing the pdf file that was produced, tracked to a problem with rendering image based checkboxes. A solution has been developed and will be included in the next iteration. Testing will proceed since some pdf versions can view the files. This bug was fixed in the next version

Testing Version 1.7

Version 1.7 contained all the bug fixes necessary to become fully operational. Testing on this version primarily focused on the configuration and firing of local rules. The only issues found were not show stoppers:

1. The rules entry interface needs an error checker to avoid incomplete (missing operand) entry
2. Multiple reports will not fire if more than one are listed as amendable.

3. Rule firing is dependent upon the state of those rules at the time of creation of the patient treatment period. Questions exist wheter other variable changs (sponsor etc) changed at the trial level after the patient creation will prevent rules firing properly

First adoption attempt. (3/09)

03/09/2009 We had successfully upgraded our operational instance and after retro entry of previous SAE's. Some of the prior pWe immediately encountered issues dealing with disease, and how it was represented on the resulting Medwatch forms. These problems are exacerbated by Research Base's focus on symptom control, rather than treatment trials. Semantic bits enabled a fix/workaround for this problem but it is still somewhat out of synch with what is needed in symptom control/prevention trials

1. Operational Instance/Test Instance: You can look up a subject. Check subjects details, but you cannot check "Subject Medical History". Error message appears each time. Doesn't matter what patient or study. (completed in later versions)

2. Test Instance: Fax number not marked as required until after you pass the reporter tab when entering an AE. (this can be fixed by entering the fax number for the staff members at their creation)

3. Test Instance: Question: Was drug dose reduced. If you answer no them the next box is disabled, but it is a required field and you cannot submit the AE without it. (completed in later versions)

4. Del had problems when she attempted to enter cancer diagnosis. Some do not really match. Some diagnoses are just not in the drop down system, and nothing compares to it. I am not sure if this our nomenclature problem or yours. A work around for this problem was found.

5. Not applicable is not a choice for some fields where the should be (mentioned previously) (completed in later versions)

My observations were that 3 fields associated with diagnosis are required to file an event: diagnosis, (body)site, and diagnosis date (month and year at minimum) (disabled in current version)

Besides the fact that prevention trials will not have this, symptom control trials could enter it, but then three problems going forward and back

1) If we have to populate all disease possibilities at the protocol level, it becomes problematic if many diseases are accepted (completed in later versions)

2) We cannot assign disease at the subject level because of the crash error mentioned (completed in later versions)

3) All the diseases mentioned in the protocol screen populate the agent indicated field in the medwatch (completed in later versions)

My first pass at a suggested fix:

1) Add a disease choice "Multiple, to be assigned per subject" which would allow selection of any disease at the time of subject registration or while entering an AE.

2) Add a No disease option, which would disable the requirement of the 3 disease fields mentioned above

3) Make the three disease fields required by default (except when overwritten by #2) but allow, during report definition that they can be unchecked and made not required

4) For any agent, create a field listing what it is indicated for.

5) Figure out where lot number should go. We sometimes have that and I never did see where that was entered.

6) Add NA as an option choice where appropriate

Final Adoption

Official live use begain 7/7/2009 after staff training. While the problems described above were sometime significant, some problems in caAERS reflected problems with current systems and approaches (for instance while we ask that the symptom being targeted for control be in the "indicated for" medwatch field, rather than the patient's original cancer (which the therapy was not treating) which comes from the patient's disease field, it turns out that a good number of medwatch forms filed previously did list the original cancer disease. There remain some bugs (significantly in the lab results area) and there is need for greater logic between question fields and answer dependent followup fields. All of these problems have current workarounds, and or pending fixes. Because the output is within the variation of past reports, WFU decided that the rules engine's consistancy and the utility of multiple edits and pdf creation warranted this initial live adoption. We hope as further system tweaks come we can expand the scope of our implementation of their system.

Our first live use of the system occurred in late July 2009. It ran afoul of the known disease bug (a training issue on our part, but also a error catching problem in caAERS in that the system crashed without explaination), but once disease was removed from the report, The system worked as planned. However the actual submission of the medwatch form pdf was thwarted by the fact that FDA did not accept pdf forms by email, requiring that we print the form and fax it to the FDA. An email to fax feature is being explored, as is trying to convince the FDA to take emails pdf's or other interface.

Overall the nurses liked the interface, but wanted greater guidance on what needed to be filled in and what did not.

Meeting Agendas & Minutes - caAERS

This is where you can access all caAERS meeting minutes. Action items will be highlighted.

01-04-10 Roswell Park Meeting Minutes - caAERS

Meeting Information

When: Mon 10:00-11:00am ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
10am	Administrative Items	Paul Baumgartner
	Discussion of parallel pilot • Scope • Time frame	
11am	Meeting Adjourns	

Open Actions/Issues Items

Action/Issue	Assigned to	Due Date	Status
Request CTEP for list of RPCI AdEERS from the past 6months	Paul	12/07/09	Requested
Add feature request to allow "enabling" rules modifications upon save	Paul	TBD	Open
Change label of "Outcome" to "Seriousness Criteria"	Paul	07/15/09	Open
Add feature request for question "Does this place the subject at an increased risk?"	Paul	TBD	Open
Add feature request to support IRB usage and tracking of reports	Paul	TBD	Open
Evaluate adding "Unanticipated problem" to the list of seriousness criteria	Paul	TBD	Open
Evaluate adding rules effective dates and rules versions for the same rule set to support rules changing over time	Paul	TBD	Open
Evaluate new feature of allowing rules to be assigned to the study without having to author a study specific rule	Paul	TBD	Open
Problem w/ AdEERS report stuck in-progress	SB	ASAP	• CA: run script to change status to "failed" • PA: Issue being fixed
Issue w/ enabling rule	SB (CAAERS-2280)	7/10/09	Open
Issue w/ disease not being saved during reporting	SB	TBD	Open
Issue w/ edit AE link throwing error	SB	TBD	Open

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner
RPCI	• Ken Quinn • Jen • Haidee • Kathy • Dawn • Diane

Meeting Notes

Pilot

- Initial timeframe
  - 20 reports or 2 months
  - Begin in new year
  - Personnel will be the caAERS project team
- Scope (Reports)
  - AdEERS reporting
  - MedWatch Reporting
  - IRB report - TBD (need Risk question)
- Expedited Reporting only

01-07-10 All Hands Meeting Minutes - caAERS

Meeting Information

When: every 1st Thursday 12-1pm ET
Phone for today: 877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
12pm	Welcome	Paul Baumgartner
	Announcements	Paul
	Adopter updates	Adopters
	Open forum	Adopters
	Upcoming activities	Paul
1pm	Meeting adjourns	

Meeting Notes

Action Items

Task	Assignees	Status
Determine if grid node is needed for caXchange access to COPPA services	Paul	Ccomplete - grid node not needed
Add Brenda to CDE reuse discussions with Lynne and Diane	Paul	Complete - meeting on 1/8/09
Add agent based "expectedness" as a topic for future discussion	Paul	Open
Send WFU instructions on PostGres DB copying	Paul	Open
Revisit use case for getting data OUT of caAERS	Paul	Open

Attendees

SemanticBits

Paul
Wesley

Wake

Bob
Del
Steven

Mayo

Brad
Jean

CALGB

Robert
Debbie
Robin
Nimesh
Susan
Kelly
Alli
Todd

NCI

Anne Tompkins (DCP)
Brenda Maeske (SAIC)

Roswell Park

Haidee
Kathy
Ken

Announcements

- v2.0 Released - Monday 12/14/2009
  - Part of the caBIG Suite v2.0 release on the same day
  - Hardened of all functionality currently in caAERS
  - Support for searching the NCI Enterprise Services of person, organization, protocol abstraction, and the related correlations between them (aka - the "COPPA" services) - caXchange required to use this functionality.
  - Silver compatibility package already submitted - approval expected early 2010.
- caAERS-AdEERS pilot is LIVE at Mayo Clinic Rochester
  - Two expedited reports to date - 6 submissions

- caAERS-AdEERS pilot summary

Adopter Updates

Mayo

- One report started in AdEERS, Jean trying to intercept so that it can be done in caAERS.

CALGB

- Installed v2.0 yesterday, minus SA upgrades. Will be updating UAT system for next week's testing.

WFU

- Steven needs help to copy the PostGres DB

Roswell Park

- Parallel pilot
  - 7 studies
  - Also entering studies on the fly
  - Goal is 8 weeks / ~20 reports
  - Expedited reporting only (just for the pilot)
  - Studies requiring MedWatch & AdEERS reporting
  - Reporting to IRB is outside of scope, but will need to be into production pilot

ISSUE: System seems slow

SOAP security fix worked - web services moving forward

Open Forum

- Need to revisit use case for getting data OUT of caAERS
  - Meeting with WFU stats guys
  - RPCI also interested

Upcoming Activities

- Mayo continuing pilot
- WFU upgrading to v2.0 on production and adding a Yoga intervention trial to caAERS
- CALGB upgrading to v2.0, functional testing sessions in Jan, pilot still anticipated in Spring 2010
- RPCI beginning parallel pilot

New feature activities:

Key	Summary	Issue Type
CAAERS-3130	Support entry of verbatim first	New Feature
CAAERS-3281	Addition of field "Does this place participant at increased risk?" to expedited flow	New Feature
CAAERS-3390	Prevent user from manually selecting wrong type of report for study	Improvement
CAAERS-3397	User is able to delete required sub-sections resulting in a failed submission	Improvement
CAAERS-3461	Allow configuration of Mandatory, Optional, and N/A fields on capture AE screen	Improvement
CAAERS-2438	Develop a generic and dynamic caAERS report template	New Feature
CAAERS-3457	Support the usage of caXchange and COPPA in a stand-alone mode	New Feature
	AE Enterprise Service	New Feature
CAAERS-3452	Analysis for support electronic submission to the FDA	New Feature
CAAERS-1910	Analysis for expanding AE query API and Service	Improvement
CAAERS-3322	PA services to support: Disease, Agent, Arm, IND	New Feature

08-30-10 Roswell Park Meeting Minutes - caAERS

Meeting Information

When: Monday 10am-11am ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
10am	Administrative Items	Paul Baumgartner
	Demo of Patient Registration interface	Haidee & Ken
	Discussion of next steps	
11am	Meeting Adjourns	

Open Actions/Issues Items

Action/Issue	Assigned to	Due Date	Status
Request CTEP for list of RPCI AdEERS from the past 6months	Paul	12/07/09	Requested
Add feature request to allow "enabling" rules modifications upon save	Paul	TBD	Open
Change label of "Outcome" to "Seriousness Criteria"	Paul	07/15/09	Open
Add feature request for question "Does this place the subject at an increased risk?"	Paul	TBD	Open
Add feature request to support IRB usage and tracking of reports	Paul	TBD	Open
Evaluate adding "Unanticipated problem" to the list of seriousness criteria	Paul	TBD	Open
Evaluate adding rules effective dates and rules versions for the same rule set to support rules changing over time	Paul	TBD	Open
Evaluate new feature of allowing rules to be assigned to the study without having to author a study specific rule	Paul	TBD	Open
Problem w/ AdEERS report stuck in-progress	SB	ASAP	• CA: run script to change status to "failed" • PA: Issue being fixed
Issue w/ enabling rule	SB (CAAERS-2280)	7/10/09	Open
Issue w/ disease not being saved during reporting	SB	TBD	Open
Issue w/ edit AE link throwing error	SB	TBD	Open

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner

RPCI	• Ken Quinn • Haidee • Jen • Kathy • Dawn • Diane

Meeting Notes

Demo of Patient Registration interface

- EXPeRT patient registration sent to caAERS
- ACTION: determine if there is a way to turn off the "Active X" message. If a user clicks "no" on the pop-up, the registration message won't be sent.
- ACTION: Should patient DOB be required in the participant web-service.

Next Steps

- If not news after the annual meeting, plan is to move forward with the production pilot using dual entry into caAERS and AdEERS.
- RPCI may consider using caAERS in production even without the AdEERS submission interface.

Status of CTEP

- Meeting this week (hopefully) with CTEP
- Paul will keep Ken posted on status
- Ken would like to see if we can get some dates from CTEP regarding when they will allow pilot sites. A date is viewed as important to drive this.

Interface for participants

- Need study information
- Need to ensure study is created in caAERS first.
  Option 1: Load all studies into caAERS (even those that won't be reported from caAERS).
    - Question: How does Mayo (and CALGB) ensure they are only sending participants who are on studies that are already in caAERS.
    - Answer (Brad): Mayo filters the patients that are included in caAERS to ensure only patients on studies in caAERS are sent. If a study is added to caAERS later, Mayo creates all existing patients in caAERS. The create participant message is sent based on a query of the log table which tracks which subjects have been added to caAERS already.
      Option 2: Restrict patient interface to only use those studies in caAERS.

Paul's thoughts: Build a study interface so that when studies are built in eRT they get messaged to caAERS
Also, utilize Option 2 to ensure that only studies in caAERS have participants sent.

Question: What is the required information for importing a study?
Question: Do studies entered via import or message require the Data Entry Complete button to be checked?
Question: Is there a way to check the flag via import or message (rather than from UI)?
Question: If a new study-subject is messaged to caAERS via an update participant message, what happens?
Answer: It is rejected with the response of "participant does not exist"

10-18-10 Demo to Eli Lilly - caAERS

Meeting Information

When: Monday 10:30am-12pm ET
Phone: provided by Lilly
Passcode: provided by Lilly
Web: provided by Lilly
Meeting ID: provided by Lilly

Agenda

Time	Item	Facilitator
10:30am	Introductions	Paul Baumgartner
5min	Review agenda	
5min	caAERS Overview	
1hr	caAERS demo	
remainder	integration discussion	

Meeting Notes

Attendees

Team	Attendee
NCI-CBIIT	• Paul Baumgartner • Bill Dyer
Eli Lilly	• Jackie Gough • Dan, Gary, Joe, Paula, Stephanie, others • a mix if CDAs (clinical data analysts), data scientists, managers, CRSs

Notes

- Main question is: how can caAERS integrate with an EDC system?
  - demoed available API's, imports, and UI
  - discussed the upcoming NCI Enterprise Services for AEs
- Lilly would like to use caAERS for entering ALL AEs and then send the AE data to an EDC (InForm, Rave, etc) to be combined with the other study data.
  - Q for Lilly: Why not use InForm to enter data and then send to caAERS? A: Because the user interfaces in InForm for AE entry have been problematic and are not as good for entering AEs as those in caAERS.

Q: What licenses do you have to have to use caAERS
Action: Bill to send the caBIG license

-
  - Are we properly licensing 3rd party software?
- Spontaneous AEs?

10-25-10 Roswell Park Meeting Minutes - caAERS

Meeting Information

When: Monday 10am-11am ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator

10am	Administrative Items	Paul Baumgartner
	Review of Friday's caAERS-AdEERS call	Ken
	Discussion of next steps	
11am	Meeting Adjourns	

Open Actions/Issues Items

Action/Issue	Assigned to	Due Date	Status
Change label of "Outcome" to "Seriousness Criteria"	Paul	07/15/09	Open
Evaluate adding "Unanticipated problem" to the list of seriousness criteria	Paul	TBD	Open
Evaluate adding rules effective dates and rules versions for the same rule set to support rules changing over time	Paul	TBD	Open
Evaluate new feature of allowing rules to be assigned to the study without having to author a study specific rule	Paul	TBD	Open
Allow custom PDF to be exported from the system	Paul	now	open
Need to have notifications be able to be sent without a report	Paul	now	open

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner
RPCI	• Ken Quinn • Haidee • Jen • Kathy • Dawn • Diane

Meeting Notes

caAERS-to-AdEERS status

- Discussion w/ Mayo and CALGB on Friday 10/22
  - Mayo and CALGB are committed to caAERS, but are currently not moving forward until CTEP approves
- RPCI planning on moving forward w/ parallel pilot
- CALGB planning on using caAERS
  - What about RAVE?
- Construct a strongly worded letter to try to and move caAERS-to-AdEERS forward.

UP reporting

- At impasse
  - UP reporting process not nailed down
  - Original process changed
  - now stuck
  - process as defined doesn't work since missing a notification piece

- Problem w/ field rule
    - If event is serious, releated, unexpected, then field for risk should be mandatory
- When an event is serious, releated, unexpected, need a notification out to doc to fill out a Roswell UP form
    - CRC enters info into caAERS
    - Exports out of caAERS, takes to doc, doc attributes and signs on the print out
- If increased risk, UP form is complete
- Need to have notifications be able to be sent without a report

Removal of Study fields

Study Interventions

02-08-11 TRANSCEND Meeting Minutes - caAERS

Meeting Information

When: Tues 2/08/11 2-3pm ET

Agenda

Time	Item	Facilitator
2pm	Introductions	Eve Shalley
	Discussion of Expectedness Requirements	
	Discussion of Tolven AE integration	
	Action Items and Next Steps	Eve Shalley
3pm	Meeting Adjourns	

Attendees

Team	Attendee
caAERS	• Paul Baumgartner • Wesley Wiggins
UCSF	• Sarah Davis • Linda Walsh • Ashwin Koleth
CBIIT	• Eve Shally • Christina Warmington • Santosh Joshi

Meeting Notes

Expectedness

1. The expected incidence (i.e. the frequency) of each adverse event is entered into the system.
    - The expected incidence of each adverse event is entered for each arm.

        - **Question:** Does there need to be support for adding in the incidence for a particular patient cohort as well (i.e. by gender, by age, etc.)?
        - It would be a *nice to have* feature if the expected frequency of occurance for a particular grade of an adverse event could be entered in addition to the overall expected frequency for the adverse event.
        - **Question:** Where does the expected frequency come from? The Protocol?
            - **Question:** For "unexpected" adverse events, is the expected frequency zero?
            - **Question:** How is frequency calculated (# events per time)?
                - % patients experiencing a particular symptom (*whith what attribution?*) during the specific period of time (i.e. *duration of the study*, *duration of a course*, duration of a study plus follow-up_, etc...)
                - Expected frequency might be calculated from Phase I data
2. As adverse events are record on the study, the system would calculate the actual frequency of AE occurrence.
3. The actual frequency would be compared to the expected frequency for the arm and for the experimental arm.
    - **Question:** Is a comparison to the expected frequency for any defined cohort or grouping needed too?
        - Example (by cohort): Fractures are expected in X% of cohort A.
        - Example (by grouping): Gastrointestinal AEs (not a specific AE, but a collection of AEs) are expected in X% of study participants over the course of the study.
    - The calculated frequency would likely need to meet some defined level of statistical significance.
        - **Need input regarding analytical methods/options desired**
4. If the actual rate of AE occurrence exceeds a comparator expected threshold, then a notification is triggered to defined recipients.
    - **Question:** What sort of safety reporting would need to be triggered, if any?

Tolven integration

- Tolven is the CDMS being used for the I-SPY II trial.
- AE data is entered into Tolven via electronic CRF.
    - Currently, AE data is entered every three (3) weeks corresponding with the end of the course / cycle.
    - SAE which require reporting are communicated to the Data Coordinating Center (DCC) via phone call.
        - The DCC initiates the SAE reporting process via a paper form (believed to be a MedWatch 3500A).
        - The PI completes the SAE form
        - The DCC submits the form to the FDA.
- Once the data is entered into Tolven, is should be sent into caAERS.
    - caAERS will be used primarily for expedited reporting and for the calculation of expectedness.
    - **Question:** Need to address patient registration integration into caAERS.
    - **Question:** Is there a need to address updates to the study in caAERS (i.e. new ARMS, etc)

Next Steps / Actions

Action	Assigned to
Write-up summary of use case / requirements for expectedness and Tolven integration and circulate for review	Paul

02-03-11 All Hands Meeting Minutes - caAERS

Meeting Information

When: every 1st Thursday 12-1pm ET
Phone for today: 877-810-8617
Passcode: 2764499
Web: http://cbiit.acrobat.com/caaersproject/

Agenda

Time	Item	Facilitator
12pm	Welcome	Paul Baumgartner
	Announcements	Paul
	Adopter updates / Open Forum	All
1pm	Meeting adjourns	

Attendees

Team	Attendee
caAERS	• Paul Baumgartner
CTEP	• Steve Friedman • Shanda Finnigan
CBIIT	• Mary Agnes Templeton
DCP	• Anne Tompkins
Roswell Park Cancer Institute	• Ken Quinn • Haidee Kolb • Kathy Reitz
City of Hope	• Susan Pannoni
WFU	• Bob Morrell • Del Jones
Mayo	• Robbin Peterson
CALGB	• Nimesh Patel
Norton Healthcare	• Dennis Fryzel

Meeting Notes

Announcements

- v2.3 to be released on 02/28/11

caAERS-AdEERS Update

- Study Web Service has been proposed to keep study data in sync between AdEERS and caAERS
  - **Ken:** What about Rules? What about preventing sites from erroneously modifying their caAERS?
    - **Shanda:** Out of scope; sites will be on the "honor system." Would need to be handled by referencing the protocol.
  - **Ken:** What are the time lines?
    - **Steve:** Looking at ~3 months from start to finish. Currently working on funding arrangements with CBIIT.

Roswell Park Update

- Looking at caAERS to handle all of their AEs
  - Current limitations of caAERS regarding this:
    1. The inability to attribute routine AEs to each study intervention, the disease, or an other cause.
       - Does anyone else require this? **City of Hope does (Susan)**
    2. The inability to have the same AE term recorded more than once in a course.
       - Other folks need this too.
       - **Shanda:** Need to ensure caAERS can only report the "worst" AE for the course.
- **Comment (Susan):** We're looking at entering all AEs into an EDC and then sending them to caAERS/Rules Engine via services

Expectedness and the FDA Final Rule

- CTEP generally considers AEs that occur to >20% of patients as "expected"
- General discussion on how to accommodate the use case where caAERS knows the expected % of occurrence and then calculates the actual rate real-time and fires off reports and alerts accordingly.
- **Shanda:** Final Rule from FDA relates to this. She will forward and include me on an upcoming CTEP meeting to discuss.

02-25-11 Deliverable Review Meeting Minutes - caAERS

Meeting Information

When: Fri 2/25/11 11am-12:30pm ET

Agenda

Time	Item	Facilitator
11am	Introductions	
12:30pm	Meeting Adjourns	

Attendees

Team	Attendee
caAERS	• Paul Baumgartner
SAIC-F	• Jeff McLean • Peter Yan

Meeting Notes

Review Deliverable Reconciliation

TASK ID	DELIVERABLE	Found in:
Task 3.3	CCTS SOA integration technical approach document	Table
Task 3.3	FDA ERSR support technical document	Document
Task 3.4	FDA ERSR support technical document	Table
Recommendations: 1. Remove "CCTS SOA integration technical approach document " as a deliverable in table 6.2.1, and 2. Consolidate the "FDA ERSR support technical document" under Task 3.3 in table 6.2.1. • Per deliverable review meeting (02/25/11), 3.3 should describe the central security; 3.4 should describe the FDA electronic submission.		
TASK ID	**DELIVERABLE**	**Found in:**

Task 3.6	Compliance Report for International AE Report	Table
Task 3.6	A Deployment Guideline of Multi-Site Protocol Study	Table and Document
Recommendation: 1. Remove "Compliance Report for International AE Report" as a deliverable in table 6.2.1 • Per deliverable review meeting (02/25/11), two 3.6 deliverables. AE compliance for international will be a summary of what is supported and what is not.		
TASK ID	**DELIVERABLE**	**Found in:**
Task 3.7	Quarterly adoption and KC support outline report	Table
Task 3.7	caAERS Compliance Reports for BRIDG, BAM, and FDA regulations	Document
Task 3.8	caAERS Compliance Reports for BRIDG, BAM, and FDA regulations	Table
Recommendations: 1. Remove "Quarterly adoption and KC support outline report" as a deliverable in table 6.2.1, and 2. Consolidate the "caAERS Compliance Reports for BRIDG, BAM, and FDA regulations" under Task 3.7 in table 6.2.1. • Per deliverable review meeting (02/25/11), use the docs as in the table. Task 3.7 will be a 1-liner that refers to the monthly status report.		
TASK ID	**DELIVERABLE**	**Found in:**
Task 5.5	caBIG™ Compatibility Review Submission Package	Document
Recommendation: 1. Add "caBIG™ Compatibility Review Submission Package" as a deliverable in table 6.2.1. • Per deliverable review meeting (02/25/11), add this to table		

- Status post review

Review of Milestones

Task ID	Milestone	Status
N/A	Project Kickoff	Complete - 7/1/2009
N/A	Design Review	Complete – 5/27/2010
N/A	Compliance Review • **BAM harmonization and compliance** • **Report and/or Status of BRIDG Information model harmonization and compliance** • **Report and/or Status of caBIG Silver Level Compatibility** • **Report and/or Status of FDA Regulation Compliance**	
N/A	Deliverables Readiness Review	Complete – 02/25/2011

Review of Deliverables

Contract Deliverable Number	Contract Deliverable Name	Project Artifact Name	Working Copy Link	Final, Published Copy Link	Due Date	Date Delivered	Status
Iteration 2							
28xs108-1.2	Monthly Status and Financial Reports	Monthly Status and Financial Reports		June 2009 Status Report	7/10/2009	7/10/2009	Delivere
28xs108-4.2	Completed Test activity logs, test result reports, and bugs and fixes reports	Completed Test activity logs, test result reports, and bugs and fixes reports		June 2009 Issue Logs	7/10/2009	7/10/2009	Delivere
28xs108-1.1	Project Management Plan	Project Management Plan		Project Management Plan	7/21/2009	7/20/2009	Delivere
28xs108-2.1	Scope and Vision Document	Scope and Vision Document	Vision and Scope Document	Vision and Scope Document	7/21/2009	7/20/2009	Delivere
Iteration 3							
28xs108-1.2	Monthly Status and Financial Reports	Monthly Status and Financial Reports		July 2009 Status Report	8/10/2009	8/10/2009	Delivere
28xs108-4.2	Completed Test activity logs, test result reports, and bugs and fixes reports	Completed Test activity logs, test result reports, and bugs and fixes reports		July 2009 Issue Logs	8/10/2009	8/10/2009	Delivere
Iteration 4							
28xs108-1.2	Monthly Status and Financial Reports	Monthly Status and Financial Reports		August 2009 Status Report	9/10/2009	9/10/2009	Delivere
28xs108-4.2	Completed Test activity logs, test result reports, and bugs and fixes reports	Completed Test activity logs, test result reports, and bugs and fixes reports		August 2009 Issue Logs	9/10/2009	9/10/2009	Delivere
Iteration 5							
28xs108-1.2	Monthly Status and Financial Reports	Monthly Status and Financial Reports		September 2009 Status Report	10/10/2009	10/10/2009	Delivere
28xs108-4.2	Completed Test activity logs, test result reports, and bugs and fixes reports	Completed Test activity logs, test result reports, and bugs and fixes reports		September 2009 Issue Logs	10/10/2009	10/10/2009	Delivere
Iteration 6							
28xs108-1.2	Monthly Status and Financial Reports	Monthly Status and Financial Reports		October 2009 Status Report	11/10/2009	11/10/2009	Delivere

28xs108-4.2	Completed Test activity logs, test result reports, and bugs and fixes reports	Completed Test activity logs, test result reports, and bugs and fixes reports		October 2009 Issue Logs	11/10/2009	11/10/2009	Delivere
28xs108-5	Compatibility Review Submission Package including CDE Use Report, Annotated XML Files, API Document, Use Case, UML Model, SRSS, SIW report, Test Logs, Technical Guide etc.)	Compatibility Review Submission Package including CDE Use Report, Annotated XML Files, API Document, Use Case, UML Model, SRSS, SIW report, Test Logs, Technical Guide etc.)		caAERS v2.0 Silver Level Review Package	2 weeks prior to the completion of the project performance period	11/18/2009	Delivere
Iteration 7							
28xs108-1.2	Monthly Status and Financial Reports	Monthly Status and Financial Reports		November 2009 Status Report	12/10/2009	12/10/2009	Delivere
28xs108-4.2	Completed Test activity logs, test result reports, and bugs and fixes reports	Completed Test activity logs, test result reports, and bugs and fixes reports		November 2009 Issue Logs	12/10/2009	12/10/2009	Delivere
Iteration 8							
28xs108-1.2	Monthly Status and Financial Reports	Monthly Status and Financial Reports		December 2009 Status Report	1/10/2010	1/10/2010	Delivere
28xs108-4.2	Completed Test activity logs, test result reports, and bugs and fixes reports	Completed Test activity logs, test result reports, and bugs and fixes reports		December 2009 Issue Logs	1/10/2010	1/10/2010	Delivere
Iteration 9							
28xs108-1.2	Monthly Status and Financial Reports	Monthly Status and Financial Reports		January 2010 Status Report	2/10/2010	2/10/2010	Delivere
28xs108-4.2	Completed Test activity logs, test result reports, and bugs and fixes reports	Completed Test activity logs, test result reports, and bugs and fixes reports		January 2010 Issue Logs	2/10/2010	2/10/2010	Delivere
Iteration 10							
28xs108-1.2	Monthly Status and Financial Reports	Monthly Status and Financial Reports		February 2010 Status Report	3/10/2010	3/10/2010	Delivere
28xs108-4.2	Completed Test activity logs, test result reports, and bugs and fixes reports	Completed Test activity logs, test result reports, and bugs and fixes reports		February 2010 Issue Logs	3/10/2010	3/10/2010	Delivere

Iteration 11							
28xs108-1.2	Monthly Status and Financial Reports	Monthly Status and Financial Reports		March 2010 Status Report	4/10/2010	4/10/2010	Delivere
28xs108-4.2	Completed Test activity logs, test result reports, and bugs and fixes reports	Completed Test activity logs, test result reports, and bugs and fixes reports		March 2010 Issue Logs	4/10/2010	4/10/2010	Delivere
Iteration 12							
28xs108-1.2	Monthly Status and Financial Reports	Monthly Status and Financial Reports		April 2010 Status Report	5/10/2010	5/10/2010	Delivere
28xs108-4.2	Completed Test activity logs, test result reports, and bugs and fixes reports	Completed Test activity logs, test result reports, and bugs and fixes reports		April 2010 Issue Logs	5/10/2010	5/10/2010	Delivere
Iteration 13							
28xs108-1.2	Monthly Status and Financial Reports	Monthly Status and Financial Reports		May 2010 Status Report	6/10/2010	6/10/2010	Delivere
28xs108-4.2	Completed Test activity logs, test result reports, and bugs and fixes reports	Completed Test activity logs, test result reports, and bugs and fixes reports		May 2010 Issue Logs	6/10/2010	6/10/2010	Delivere
Iteration 14							
28xs108-1.2	Monthly Status and Financial Reports	Monthly Status and Financial Reports		June 2010 Status Report	7/10/2010	7/10/2010	Delivere
28xs108-4.2	Completed Test activity logs, test result reports, and bugs and fixes reports	Completed Test activity logs, test result reports, and bugs and fixes reports		June 2010 Issue Logs	7/10/2010	7/10/2010	Delivere
Iteration 15							
28xs108-1.2	Monthly Status and Financial Reports	Monthly Status and Financial Reports		July 2010 Status Report	8/10/2010	8/10/2010	Delivere
28xs108-4.2	Completed Test activity logs, test result reports, and bugs and fixes reports	Completed Test activity logs, test result reports, and bugs and fixes reports		July 2010 Issue Logs	8/10/2010	8/10/2010	Delivere
Iteration 16							
28xs108-1.2	Monthly Status and Financial Reports	Monthly Status and Financial Reports		August 2010 Status Report	9/10/2010	9/10/2010	Delivere

28xs108-4.2	Completed Test activity logs, test result reports, and bugs and fixes reports	Completed Test activity logs, test result reports, and bugs and fixes reports		August 2010 Issue Logs	9/10/2010	9/10/2010	Delivere
Iteration 17							
28xs108-1.2	Monthly Status and Financial Reports	Monthly Status and Financial Reports		September 2010 Status Report	10/10/2010	10/10/2010	Delivere
28xs108-4.2	Completed Test activity logs, test result reports, and bugs and fixes reports	Completed Test activity logs, test result reports, and bugs and fixes reports		September 2010 Issue Logs	10/10/2010	10/10/2010	Delivere
Iteration 18							
28xs108-1.2	Monthly Status and Financial Reports	Monthly Status and Financial Reports		October 2010 Status Report	11/10/2010	11/10/2010	Delivere
28xs108-4.2	Completed Test activity logs, test result reports, and bugs and fixes reports	Completed Test activity logs, test result reports, and bugs and fixes reports		October 2010 Issue Logs	11/10/2010	11/10/2010	Delivere
Iteration 19							
28xs108-1.1	Project Management Plan	Iteration Implementation Plan		Dec 2010 Plan	12/10/2010	12/10/2010	Delivere
28xs108-1.2	Monthly Status and Financial Reports	Monthly Status and Financial Reports		Nov 2010 Status Report	12/10/2010	12/10/2010	Delivere
28xs108-4.2	Completed Test activity logs, test result reports, and bugs and fixes reports	Completed Test activity logs, test result reports, and bugs and fixes reports		Nov 2010 issue log	12/10/2010	12/10/2010	Delivere
Iteration 20							
28xs108-1.1	Project Management Plan	Iteration Implementation Plan		Jan 2011 Plan	01/15/2011	01/15/2011	Delivere
28xs108-1.2	Monthly Status and Financial Reports	Monthly Status and Financial Reports		Dec 2010 Status Report	01/15/2011	01/15/2011	Delivere
28xs108-4.2	Completed Test activity logs, test result reports, and bugs and fixes reports	Completed Test activity logs, test result reports, and bugs and fixes reports		Dec 2010 issue log	01/15/2011	01/15/2011	Delivere
Iteration 21							
28xs108-1.1	Project Management Plan	Iteration Implementation Plan		Feb 2011 Plan	02/10/2011	02/10/2011	Delivere
28xs108-1.2	Monthly Status and Financial Reports	Monthly Status and Financial Reports		Jan 2011 Status Report	02/10/2011	02/10/2011	Delivere

28xs108-4.2	Completed Test activity logs, test result reports, and bugs and fixes reports	Completed Test activity logs, test result reports, and bugs and fixes reports		Jan 2011 issue log	02/10/2011	02/10/2011	Delivere
Iteration 22 **(Feb 2011)**							
28xs108-1.2	Monthly Status and Financial Reports	Monthly Status and Financial Reports	Feb 2011 Status Report	Feb 2011 Status Report	03/10/2011		
28xs108-1.3	Project Summary Report	Project Summary Report			03/10/2011		
28xs108-2.2	Use Cases, and Software and System Requirements and Specifications or CFSS and CFAS	Use Cases, and Software and System Requirements and Specifications or CFSS and CFAS	Use Cases System Requirements AE Mgmt Service Specifications Safety Reporting Service Specifications	Use Cases System Requirements AE Mgmt Service Specifications Safety Reporting Service Specifications	At the completion of the project		
28xs108-2.3	Updated UML Model, Architectures, and Master Design Document	Updated UML Model, Architectures, and Master Design Document	UML Model Architecture Master Design Document	UML Model v2.3 Architecture Master Design Document	At the completion of the project		
28xs108-2.4	Implementation Plan	Implementation Plan	Implementation Plan	Implementation Plan	12/10/2009		
28xs108-3.1	AdEERS integration and support technical document	AdEERS integration and support technical document	AdEERS integration and support technical document				

28xs108-3.2	Enterprise Service integration technical approach document	Enterprise Service integration technical approach document	Enterprise Service integration technical approach document				
28xs108-3.3	CCTS SOA integration technical approach document	CCTS SOA integration technical approach document	CCTS SOA integration technical approach document				
28xs108-3.4	FDA ERSR support technical document	FDA ERSR support technical document	FDA ERSR support technical document				
28xs108-3.5	Maintained and revised caAERS Prioritized Feature List	Maintained and revised caAERS Prioritized Feature List	Maintained and revised caAERS Prioritized Feature List		Initial draft due 6/14/2009		
28xs108-3.6	Compliance Report for International AE Report	Compliance Report for International AE Report	Compliance Report for International AE Report		12/10/2009		
28xs108-3.7	Quarterly adoption and KC support outline report	Quarterly adoption and KC support outline report	Quarterly adoption and KC support outline report				
28xs108-3.8	caAERS Compliance Reports for BRIDG, BAM, and FDA regulations	caAERS Compliance Reports for BRIDG, BAM, and FDA regulations	BRIDG v3.0.2 Compliance Report BAM v1.1 Compliance Report FDA Regulations Compliance Report				
28xs108-3.6	A Deployment Guideline of Multi-Site Protocol Study	A Deployment Guideline of Multi-Site Protocol Study			12/10/2009		
28xs108-4.1	Updated Master Test Plan, Test Scripts and Procedures	Updated Master Test Plan, Test Scripts and Procedures	Master Test Plan Test Scripts and Procedures	Master Test Plan Test Scripts and Procedures	Test plan and procedures due: 9/10/2009 Final test scripts due at completion of project		
28xs108-4.2	Completed Test activity logs, test result reports, and bugs and fixes reports	Completed Test activity logs, test result reports, and bugs and fixes reports	Completed Test activity logs [pre-release testing] test result reports bugs and fixes reports	Completed Test activity logs test result reports bugs and fixes reports			

28xs108-6.1	Installation Package, Source Code, and Release Notes	Installation Package, Source Code, and Release Notes	Installation Package and Release Notes Source Code	Installation Package Source Code Release Notes	Each release		
28xs108-6.2	Installation Guide	Installation Guide	Installation Guide	Installation Guide	Each release		
28xs108-6.3	Updated and maintained caAERS Demonstration Web Site	Updated and maintained caAERS Demonstration Web Site	Demo site: https://demo.semanticbits.com/caaers Username: SYSTEM_ADMIN Password: system_admin		Each release		
28xs108-7	caAERS User Manual, Admin Guide, Programmer Guide, and API documentation	caAERS User Manual, Admin Guide, Programmer Guide, and API documentation	User Manual Admin Guide Programmer Guide (java docs) API documentation (technical integration guide)	User Manual Admin Guide Programmer Guide API documentation	Each release		
28xs108-8.1	Reviewed and Commented Use Case Documentation and SRS Document	Reviewed and Commented Use Case Documentation and SRS Document	Reviewed and Commented Use Case Documentation and SRS Document (point back to use cases and requirements)		At project completion		
28xs108-8.2	Critiqued Test Approach Document & Adopter Test Approach Plan	Critiqued Test Approach Document & Adopter Test Approach Plan	Critiqued Test Approach Document & Adopter Test Approach Plan (adoption plan)		At project completion		
28xs108-8.3	Test Results Report	Test Results Report	Test Results Report				
28xs108-8.4	Reviewed and Commented End User Guide's	Reviewed and Commented End User Guide's	Reviewed and Commented End User Guide's (ref user guide - ref Laura Jackel review with vijay);		Each release		
28xs108-8.5	Reviewed, Commented, and Approved Developer's Deployment Plan	Reviewed, Commented, and Approved Developer's Deployment Plan	Reviewed, Commented, and Approved Developer's Deployment Plan (install guide; release package)				

Next Steps / Actions

Action	Assigned to

03-07-11 Roswell Park Meeting Minutes - caAERS

Meeting Information

When: Mon 10:00-11:00am ET

Phone: 1-877-810-8617
Passcode: 2764499
Web: http://cbiit.acrobat.com/caaersproject/

Agenda

Time	Item	Facilitator
10am	Administrative Items	Ken Quinn
	Discussion of parallel pilot	
11am	Meeting Adjourns	

Open Actions/Issues Items

Action/Issue	Assigned to	Due Date	Status

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner
RPCI	• Ken Quinn • Jen • Haidee
CRS Compliance	• Jan • Dawn • Nancy

- Diane
- Val Ping
- Laurie
- Kathy

Absent	• Linda

Meeting Notes

Production Pilot

- Will be a parallel pilot
- Will result in additional work
- Study selection:

- Ken would like v2.3

caAERS meetings

10-16-09 Mayo Pilot Meeting Minutes - caAERS

Meeting Information

When: Friday 9-10am ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
9am	Review Task list	Paul
10am	Meeting Adjourns	

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner
Mayo	• Sharon Elcombe • Jean Hanson
NCI	• Ann Setser • Shanda Finnigan

Pilot Action Items

Task	Target Date	Status	Who	Comments
Provide CTEP memo for Mayo IRB	Before Go-live	Complete (10/15/09)	Shanda	memo will be added to study file
Obtain IRB approval	14-Oct	Modified	Sharon	SE: "We do not need IRB approval but I do need the memo to file with the regulatory files for these studies. We will just need to report this in the annual progress report."
Send Mayo memo to Mayo Rochester clinics	21-Oct	Pending	Sharon	
Deploy v1.9.6 on Dev Oracle	15-Oct	Complete (10/15/09)	Mayo Systems	All below tasks dependent on this
Load investigators into Dev	16-Oct	Pending above	Brad	Dependent on Dev v1.9.6 update
Load studies into Dev	16-Oct	Pending above	Jennifer	SB provided XML for import; only investigator assignment and study review req
Load study participants	16-Oct	Pending above	Brad	
Perform basic functional test on Dev	19-Oct	Pending above	Brad	
Finalize study specific rules	16-Oct	Discussion scheduled 10/16	Mayo protocol coordinators/ CTEP/Ann	Ann's doc in review by Mayo protocol coordinators (Angie)
Author study specific rules	16-Oct	Pending above	Paul	

Finalize rules for NCCTG studies	16-Oct	Optional	Jean	Optional; May need to override lack of caAERS recommendation
Author NCCTG rules	16-Oct	Pending above	Paul	Optional
Test study specific rules	20-Oct	Pending above	Ann/Shanda	Paul to send account to Ann & Shanda
Finalize notifications from caAERS	16-Oct	In-process	Jean, Paul	Add Ann and Shanda to notification for initiation
Test notifications from caAERS	20-Oct	In-process	Jean, Paul	Add Ann and Shanda to notification for initiation
Add CRA users to Dev	20-Oct		Brad	
Train CRAs	21,23-Oct	Dates being finalized	Jean	
Train TRI	21-Oct	Dates being finalized	Shanda, Paul	
Upgrade Production system	29-Oct	Pending	Mayo Systems	
Perform functional test on Production to production AdEERS	29-Oct	Pending above	Brad, Paul, CTIS	Paul to coordinate with CTIS and Mayo
Go Live	30-Oct	Pending		

Meeting Notes

- Discussed the Mayo 3-day and 7-day reporting requirement
  - This requirement was primarily to support central processing to ensure that the central office had a couple days to review and submit to CTEP within the 5-day and 10-day timeframe, respectively
  - For the pilot, the decision was made to use the standard 5 and 10 day turn around time since central processing will not be used
- Discussed the adverse event reporting rules for the NCCTG protocols
  - One protocol is a non-CTEP IND and another is a commercial agent only trial.
  - According to the protocol, the requirements for expedited reporting to AdEERS are study specific.
  - Mayo is inclined to author study specific rules for these two studies
  - Ann in comfortable without study specific rules
  - If there are no study specific rules, the CRAs will need to be trained that "Override" may be required, especially on these two studies.

02-25-10 WFU Meeting Minutes - caAERS

Meeting Information

When: Thursday 11:00am-12:00pm ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
11am	Administrative Items	Paul Baumgarnter
	Status/Issues	
12pm	Meeting Adjourns	

Actions / Issues

Issue / Feature	Impact/Priority	Status	Reporter/Requestor

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner
WFU	• Bob Morrell • Del
NCI	Mary Agnes

Meeting Notes

- Demo of WFU's autograding system
- Some normal ranges are gender based (i.e. hemaglobin)
- Some normal ranges are different for pediatrics
    - At WFU, autograding is turned off for pediatrics
- Many grades 1,2 are purely quantitative, however, the distinction between a grade 3 and 4 is often qualitative (eg. absence or presence of Life Threatening consequenses, respectively).
- Many terms have ranges for different types of labs; this raises a policy issue about which test wins if there is a conflict in the grade.
    - Who wins?
- The user can ALWAYS override the grade
    - If the lab comes from an outside lab with a different range of normals
- Leukemia patients - ~1/2 of AEs are labs
- WFU's system allows users to see all of the labs for the cycle
- WFU updates normals fairly infrequently (last update in 2005), however, the normals needs to be able to be updated.
- Sometimes a normal range runs into grade 1 or grade 2.
    - Example: Ionized Calcium grade 1: LLN - 1.0 mmol/g, however, WFU has LLN 1.0 (Normal is 1.0 - 1.3)
- Some labs have a pair of AE terms (one for low and one for high); this is primarily relavent for Solicted AEs
    - Example: A subject has High Glucose as an AE. Low Glucose is also a solicited AEs on a study and would also need to be graded as a grade 0 (not technically normal, but not out of range for low).

09-21-09 Roswell Park Meeting Minutes - caAERS

Meeting Information

When: Mon 10:00-11:30am ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
10am	Administrative Items	Paul Baumgartner
	Discussion of clinical significance	
	Next steps • pilot discussion • internal demo to Linda's group • process mapping • PSC and caXchange	

11am	Meeting Adjourns	

Open Actions/Issues Items

Action/Issue	Assigned to	Due Date	Status
Add feature request to allow "enabling" rules modifications upon save	Paul	TBD	Open
Change label of "Outcome" to "Seriousness Criteria"	Paul	07/15/09	Open
Add feature request for question "Does this place the subject at an increased risk?"	Paul	TBD	Open
Add feature request to support IRB usage and tracking of reports	Paul	TBD	Open
Evaluate adding "Unanticipated problem" to the list of seriousness criteria	Paul	TBD	Open
Evaluate adding rules effective dates and rules versions for the same rule set to support rules changing over time	Paul	TBD	Open
Evaluate new feature of allowing rules to be assigned to the study without having to author a study specific rule	Paul	TBD	Open
Problem w/ AdEERS report stuck in-progress	SB	ASAP	• CA: run script to change status to "failed" • PA: Issue being fixed
Issue w/ enabling rule	SB (CAAERS-2280)	7/10/09	Open
Issue w/ disease not being saved during reporting	SB	TBD	Open
Issue w/ edit AE link throwing error	SB	TBD	Open

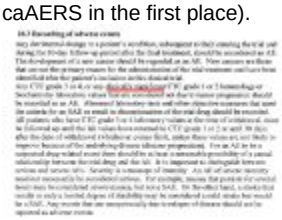
Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner
RPCI	• Ken Quinn • Jen • Haidee • Kathy • Dawn

Meeting Notes

"Clinical Significance"

- Per the protocol excerpt, discussed that this is for determining what is an AE (i.e. what needs to be recorded as an AE and entered into caAERS in the first place).



- The rules regarding "What is considered an AE for this protocol?" are determined in the protocol. It's up to the nurse to understand the protocol and to know what is/isn't considered an AE for the particular protocol.
- Other examples of criteria used to determine what is/isn't an AE:
- Worsening of pre-existing conditions,
- recurring/unresolved AEs

Pilot

- Internal meeting to be held on Thurs. w/ Dr. Joyce Yasko (VP - Clinical Research Admin and Services)
- ID additional CTEP sponsored, non-group studies that could be candidates for RPCI to pilot
    - Current Roswell study (non-group, AdEERS required) is ID 6789 (Roswell Park ID 55305)
    - Paul to load study into demo site

PSC/caAERS/caXchange

- Plan is to use web services to integrate registration events with caAERS and PSC
    - Paul to confirm w/ PSC group the availability of services for local CTMS integration
    - caXchange will not be used

Next Steps

- Process mapping meeting next Monday (9/28/09) 10-11am
    - Paul to cancel meeting
- Internal demo to Linda and her four managers
    - Ken to invite Paul

Current process flow is:

1. CRC (Clinical Research Coordinator) enters ALL AEs into EDE (eRT/CDMS system)
2. CRC then enters Serious AEs into AdEERS
3. PI (ideally) determines if this puts the patient at increased risk
4. CRC then completes the UP (Unanticipated Problem) form if the AE puts the patient at increased risk
5. UP form is sent to Dawn and Nancy for entry into the IRB database
    - IRB does NOT want any AEs that are not UPs

Roswell needs to integrate with their EDE (eRT/CDMS)

- enter into into caAERS or EDE?
- message from EDE to caAERS or caAERS to EDE (or both)?
- discussion that all study participant info is entered into eRT but that all AEs are entered into caAERS
    - messaging AEs back into EDE might not be needed
    - big selling point for caAERS is that ALL AEs would have to be entered into caAERS in order for CRCs to be able to continue their workflow
    - Would increase compliance
    - Current issue is that analysis needs to be done, but all AEs haven't been entered in order for analysis to be done

- Webinar by CDISC/CDASH for compliance

09-17-09 Mayo Meeting Minutes - caAERS

Meeting Information

When: Thursday 12:00-1:00pm ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
12am	Administrative Items	
	Status/Issues	
1pm	Meeting Adjourns	

Action Items

Action Item	Assigned to	Due Date	Status
Send CALGB Excel converter	Paul	TBD	cancelled - Jennifer to key in studies

Review study loader XML; evaluate manual edits	Brad	7/2/09	cancelled - Jennifer to key in studies
Load a study into the production caAERS box	Brad / Jennifer	7/2/09	
Perform functional testing on production	TBD	8/6/09	all but AdEERS submissions can be tested; AdEERS testing can occur after next caAERS release
Investigate reason for emails being sent despite removing SMTP configuration	Srini	Complete	
Can "open study" be flipped via services	Srini		
If study is not open and a patient is added, is there an informative error code			
Must be able to change SYSTEM ADMIN password	Paul	Open	
Suggestion to have a "service" specific role that would prevent UI login			
Perform functional testing on Brad's box	Robbin, Jennifer, et al	8/25/09	In Progress
Develop draft pilot testing script	Paul / Mayo	9/18/09	In Progress
Confirm report submission for pilot studies to AdEERS beta	Paul	9/18/09	In Progress
Test previously submitted AdEERS for pilot studies (from Demo)	Paul	9/24/09	Pending above
Verify that the link to the AdEERS report will be updated when production AdEERS is used	Paul	9/18/09	In Progress
Coordinate w/ AdEERS technical team (CTIS) to ensure they are ready for GO LIVE on 10/15/09	Paul	9/24/09	In Progress

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner
Mayo	• Jean Hanson • Brad Anderson • Robbin Peterson • Jennifer Frank
NCI	

Meeting Notes

- Enter Subject, add a Save after assigning the subject, and also after subject medical history.
- Discussed the re-focusing of the caAERS - AdEERS pilot
  - Hosting of caAERS by SB/CBIIT/CTEP
  - Mayo's responsibility would be for expedited report entry and submission (remove systems/configuration/integration dependencies)
  - A configured and loaded pilot system will be available on 10/1/09.
  - ~2 weeks of testing
  - CRA training on 10/12 & 10/14
  - Go live on 10/15
- This approach will truly pilot caAERS as an alternative front end to AdEERS. Additional confounding variables will be removed.
- Mayo will continue their own technical integration

No objections to the proposal
Sonja to follow-up with Sharon
Paul to follow-up with CBIIT project owners

09-17-09 WFU Meeting Minutes - caAERS

Meeting Information

When: Thursday 11:00am-12:00pm ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
11am	Administrative Items	Paul Baumgarnter
	Status/Issues	
12pm	Meeting Adjourns	

Actions / Issues

Issue / Feature	Impact/Priority	Status	Reporter/Requestor
Rule seems like it's enabled, but in-fact, is not • Confirm which rules were run	HIGH	Open	Bob (WFU)
Allow mandatory field configuration for submitter	Med	Open	Bob (WFU)
Prevent illegal characters for being entered into text fields	Med - causes report transformation to fail	Open	Bob (WFU)
Difficulty with using course • Most studies don't have course • Need to be able to differentiate between a change in one AE and a new AE • Suggestion is to make AE term + start date the primary key • Issue would be that users might end a grade 2 AE and give a new start date when it changed grade	High	Open	Bob (WFU nurses)
Bob to send training videos	Low	Open	Bob
What needs to be done to prevent the certificate exception from showing	Med	Open	Paul
Must be able to change the SYSTEM_ADMIN password	HIGH	Open	Paul
Update install instructions to provide recommended heap space (tomcat) & memory requirements	Med	Open	Paul

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner

WFU	• Bob Morrell • Del • Steven
NCI	Michele Elhman

Meeting Notes

Status

- Added mandatory sections
- Operational instance is v1.9.2
- Need to assess how the study status is impacting the ability to add patients, AEs, and search results
- Yoga study is coming up; symptom management for women w/ Breast Cancer on chemo.
    - Will have yoga between chemo
    - General quality of life; Mood and fatigue symptoms are two main categories
    - Del will add protocol; Study condition should be something like: "quality of life symptoms"

- Need to determine the issues with v1.9.2
    - Suppression of printing of labels when there is no value
    - "Indicated for" still an issue

-
    - # of PI's on Study
    - Sarah ran into issues with adding an investigator
    - Need to be able to delete an investigator if it has not yet been saved (rather than just deactivate)
    - Deactivate will not allow you to continue.
    - Usability issues here
    - On Create Study, there is no summary header

- Install issues:
    - Had to add a little piece of code to Tomcat
    - Steven is updating the install instructions

- Must still be able to access the study and adverse events after the study is closed.
    - This happens as a regular part of trials.
    - PB update - no bug; only Data Entry Status = Incomplete prevents adding subjects & AEs

- Usability issue with the "Open Study" feature
    - Need to have a message that indicates that the study is not yet "ready"
    - What is the difference between this and the "Study Open for Accrual?"
    - Bob recommends showing all, but having a pop-up that indicates why it cannot be accessed
    - At WFU, "Open to Accrual" is only used once the systems are set up and error checks occur
    - Should be able to see protocols not open to accrual during a search (flag as not open)
    - "Anticipated Open Date", "IRB approval date", "Open Date" (can be any date).

- Issue with a Research Staff user not getting email for account creation.
    - Bob will follow-up with Gina; behavior is strange and might point to an issue with Gina's account.

- A common scenario is to enter dates in the past

09-10-09 WFU Meeting Minutes - caAERS

Meeting Information

When: Thursday 11:00am-12:00pm ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
11am	Administrative Items	Paul Baumgarnter

	Status/Issues	
12pm	Meeting Adjourns	

Actions / Issues

Issue / Feature	Impact/Priority	Status	Reporter/Requestor
Rule seems like it's enabled, but in-fact, is not • Confirm which rules were run	HIGH	Open	Bob (WFU)
Allow mandatory field configuration for submitter	Med	Open	Bob (WFU)
Prevent illegal characters for being entered into text fields	Med - causes report transformation to fail	Open	Bob (WFU)
Difficulty with using course • Most studies don't have course • Need to be able to differentiate between a change in one AE and a new AE • Suggestion is to make AE term + start date the primary key • Issue would be that users might end a grade 2 AE and give a new start date when it changed grade	High	Open	Bob (WFU nurses)
Bob to send training videos	Low	Open	Bob
What needs to be done to prevent the certificate exception from showing	Med	Open	Paul
Must be able to change the SYSTEM_ADMIN password	HIGH	Open	Paul
Update install instructions to provide recommended heap space (tomcat) & memory requirements	Med	Open	Paul

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner
WFU	• Bob Morrell • Del • Steven
NCI	Michele Elhman

Meeting Notes

Status

- Added mandatory sections

- Bob needs to add mandatory fields for report definitions
- After this is done and tested on test, the operational instance will be updated
- Sarah's issue

-
  - # of PI's on Study
  - Sarah ran into issues with adding an investigator
  - Need to be able to delete an investigator if it has not yet been saved (rather than just deactivate)
  - Deactivate will not allow you to continue.
  - Usability issues here
  - On Create Study, there is no summary header

- Install issues:

    - Had to add a little piece of code to Tomcat
    - Steven is updating the install instructions

- Must still be able to access the study and adverse events after the study is closed.
    - This happens as a regular part of trials.
    - PB update - no bug; only Data Entry Status = Incomplete prevents adding subjects & AEs

- Usability issue with the "Open Study" feature
    - Need to have a message that indicates that the study is not yet "ready"
    - What is the difference between this and the "Study Open for Accrual?"
    - Bob recommends showing all, but having a pop-up that indicates why it cannot be accessed
    - At WFU, "Open to Accrual" is only used once the systems are set up and error checks occur
    - Should be able to see protocols not open to accrual during a search (flag as not open)
    - "Anticipated Open Date", "IRB approval date", "Open Date" (can be any date).

- Issue with a Research Staff user not getting email for account creation.
    - Bob will follow-up with Gina; behavior is strange and might point to an issue with Gina's account.

- A common scenario is to enter dates in the past

09-14-09 Roswell Park Meeting Minutes - caAERS

Meeting Information

When: Mon 10:00-11:30am ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
10am	Administrative Items	Paul Baumgartner
	caAERS-to-AdEERS pilot	
	Review of recent issues • Advanced search	
11am	Meeting Adjourns	

Open Actions/Issues Items

Action/Issue	Assigned to	Due Date	Status
Add feature request to allow "enabling" rules modifications upon save	Paul	TBD	Open
Change label of "Outcome" to "Seriousness Criteria"	Paul	07/15/09	Open
Add feature request for question "Does this place the subject at an increased risk?"	Paul	TBD	Open
Add feature request to support IRB usage and tracking of reports	Paul	TBD	Open
Evaluate adding "Unanticipated problem" to the list of seriousness criteria	Paul	TBD	Open
Evaluate adding rules effective dates and rules versions for the same rule set to support rules changing over time	Paul	TBD	Open
Evaluate new feature of allowing rules to be assigned to the study without having to author a study specific rule	Paul	TBD	Open

Problem w/ AdEERS report stuck in-progress	SB	ASAP	• CA: run script to change status to "failed" • PA: Issue being fixed
Issue w/ enabling rule	SB (CAAERS-2280)	7/10/09	Open
Issue w/ disease not being saved during reporting	SB	TBD	Open
Issue w/ edit AE link throwing error	SB	TBD	Open

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner
CALGB	• Ken Quinn • Jen • Haidee • Kathy

Meeting Notes

- Discussed release date move
- Discussed interest of Roswell Park as being a pilot site
    - Interest is there.
    - Next step is for Roswell to follow-up with management
    - Current Roswell study (non-group, AdEERS required) is ID 6789 (Roswell Park ID 55305)
    - Paul to load study into demo site

Current process flow is:

1. CRC (Clinical Research Coordinator) enters ALL AEs into EDE (eRT/CDMS system)
2. CRC then enters Serious AEs into AdEERS
3. PI (ideally) determines if this puts the patient at increased risk
4. CRC then completes the UP (Unanticipated Problem) form if the AE puts the patient at increased risk
5. UP form is sent to Dawn and Nancy for entry into the IRB database
    - IRB does NOT want any AEs that are not UPs

Roswell needs to integrate with their EDE (eRT/CDMS)

- enter into into caAERS or EDE?
- message from EDE to caAERS or caAERS to EDE (or both)?
- discussion that all study participant info is entered into eRT but that all AEs are entered into caAERS
    - messaging AEs back into EDE might not be needed
    - big selling point for caAERS is that ALL AEs would have to be entered into caAERS in order for CRCs to be able to continue their workflow
    - Would increase compliance
    - Current issue is that analysis needs to be done, but all AEs haven't been entered in order for analysis to be done

- Webinar by CDISC/CDASH for compliance

09-17-09 CALGB Meeting Minutes - caAERS

Meeting Information

When: Thursday 1:00-2:00pm ET
Phone: 1-877-810-8617

Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
1pm	Administrative Items	
2pm	Meeting Adjourns	

Actions / Issues / Requests

Action Item	Assigned to	Due Date	Status
Provide descriptions/wsdls for updates to web services	Paul	7/16/09	Complete
Provide guidance on training availability	Paul	7/2/09	
Trigger participant message upon registration	Robert	7/02/09	
Functional testing of Routing and Review and notifications	Team	7/16/09	
Issue with wildcard reference for user ID	Srini	7/17/09	Fixed v1.9.5
JX Transformation Error still occurring	Srini	7/17/09	Added as bug
For AE's where there is a AE select term (i.e. Pain, Kidney), the full term isn't showing	SB	7/17/09	Fixed v1.9.5
Alphabetize Research Staff and Investigator lists in reporter drow down	SB		Added as feature request
Add functionality of being able to restart/repair serviceMix connection from this page	SB		Added as feature request
Add CTEP ID to the Investigator drop-down list in reporter tab	SB		

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner
CALGB	• Nimesh Patel • Robert Dale • Amish Shah • Susan Sutherland • Debbie Sawyer • Allision Booth • Kelly (training coordinator) • Robin

Meeting Notes

- Need MedDRA (Paul to follow-up)
  - If no MedDRA, system should still be usable for Other, Specify terms (use text/verbatim)
- Follow-up with study that didn't upload (from Robert)
- Release next week
- Back-up best practices?
  - What would the recommendation be?
  - Configuration files (tomcat, service mix, caAERS)?
  - Spring context xmls (caAERS core, acegi, web)
  - User provided configs

- Date field should support easier date entry (i.e. missing leading zeros are okay)
- F2F w/ CALGB and SemanticBits
- Other TAC is a bug - fixed in v1.9.6
- Need to be able to configure the fields in the Capture AE page
    - If there are fields required for the rules to run that are not shown or are blank, probably should have some flag.
- Not clear which fields are mandatory prior to submitting routine AEs to Data Coordinator
- "Submit to Data Coordinator" is hidden in the Comments slider. Need to find a more prominent place.
- Report view check box
    - Not clear, perhaps rename "View report fields?"
    - Change button name from "Apply now" to something more intuitive
    - Only show check box if there is more than one report
- Routing and review options not showing in Review and Submit
- Unable to find reports in Routing and Review
- CALGB test caAERS instance is available remotely
    - Need the fake users
- CALGB would like a F2F
    - alternative proposed is group Centra testing sessions.
- Amish is leaving
    - Josh Yoder is taking over (+ Nimesh)
    - PPD (Pharmaceutical Product D) - CRO
- Follow-up w/ CALGB-50401; is this a CTEP IND or not?
- Role names for PRO CTCAE system are preferred
- Add CTEP ID to the Investigator drop-down list in reporter tab
    - CALGB recently had to add this to their system to support multiple "John Smith's"
    - Would a CRA be able to distinguish one investigator from another based on their CTEP ID? Perhaps they can pick one and see the email, phone, and address (if available) and then determine if it's the right one. What other info would a CRA use to ensure it is the correct investigator?

10-13-09 Mayo Meeting Minutes - caAERS

Meeting Information

When: Tuesday 11:30-12:30pm ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
11:30am	Administrative Items	
	Status/Issues	
12:30pm	Meeting Adjourns	

Pilot Action Items

Task	Target Date	Status	Who	Comments
Provide CTEP memo for Mayo IRB	Before Go-live	Complete (10/15/09)	Shanda	memo will be added to study file

Obtain IRB approval	14-Oct	Modified	Sharon	SE: "We do not need IRB approval but I do need the memo to file with the regulatory files for these studies. We will just need to report this in the annual progress report."
Send Mayo memo to Mayo Rochester clinics	21-Oct	Pending	Sharon	
Deploy v1.9.6 on Dev Oracle	15-Oct	Complete (10/15/09)	Mayo Systems	All below tasks dependent on this
Load investigators into Dev	16-Oct	Pending above	Brad	Dependent on Dev v1.9.6 update
Load studies into Dev	16-Oct	Pending above	Jennifer	SB provided XML for import; only investigator assignment and study review req
Load study participants	16-Oct	Pending above	Brad	
Perform basic functional test on Dev	19-Oct	Pending above	Brad	
Finalize study specific rules	16-Oct	Discussion scheduled 10/16	Mayo protocol coordinators/ CTEP/Ann	Ann's doc in review by Mayo protocol coordinators (Angie)
Author study specific rules	16-Oct	Pending above	Paul	
Finalize rules for NCCTG studies	16-Oct	Optional	Jean	Optional; May need to override lack of caAERS recommendation
Author NCCTG rules	16-Oct	Pending above	Paul	Optional
Test study specific rules	20-Oct	Pending above	Ann/Shanda	Paul to send account to Ann & Shanda
Finalize notifications from caAERS	16-Oct	In-process	Jean, Paul	Add Ann and Shanda to notification for initiation
Test notifications from caAERS	20-Oct	In-process	Jean, Paul	Add Ann and Shanda to notification for initiation
Add CRA users to Dev	20-Oct		Brad	
Train CRAs	21,23-Oct	Dates being finalized	Jean	
Train TRI	21-Oct	Dates being finalized	Shanda, Paul	
Upgrade Production system	29-Oct	Pending	Mayo Systems	
Perform functional test on Production to production AdEERS	29-Oct	Pending above	Brad, Paul, CTIS	Paul to coordinate with CTIS and Mayo
Go Live	30-Oct	Pending		

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner

Mayo	• Jean Hanson • Brad Anderson • Sonja Hamilton • Jennifer Frank • Robbin Peterson
NCI	

Meeting Notes

- Walked through open actions

Misc Actions

Action Item	Assigned to	Due Date	Status
Can "open study" be flipped via services?	Srini	TBD	Open
If study is not open and a patient is added, add an informative error code	Paul	TBD	Open
Must be able to change SYSTEM ADMIN password	Paul	v2.0	Inprogress
Suggestion to have a "service" specific role that would prevent UI login	Paul	TBD	Open
Obtain current list of notifications from AdEERS to Mayo folks	Jean	16-Oct	In-progress

12-03-09 All Hands Meeting Minutes - caAERS

Meeting Information

When: every 1st Thursday 12-1pm ET
Phone for today: 877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
12pm	Welcome	Paul Baumgartner
	Announcements	Paul
	Adopter updates	Adopters
	Open forum	Paul
1pm	Meeting adjourns	

Meeting Notes

Attendees

SemanticBits

Paul
Wesley

Wake

Bob
Del
Steven

Mayo

Brad
Jennifer

CALGB

Robert
Debbie
Robin
Nimesh

NCI

Anne Tompkins (DCP)
Brenda Maeske (SAIC)

Roswell Park

Haidee
Kathy
Ken

Announcements

- v2.0 Release - Monday 12/14/2009 (tenative)
  - This will be part of the caBIG Suite v2.0 release on the same day
  - Hardening of all functionality currently in caAERS
  - Support for searching the NCI Enterprise Services of person, organization, protocol abstraction, and the related correlations between them (aka - the "COPPA" services) - caXchange required to use this functionality.
  - Silver compatibility package already submitted - approval expected early 2010.
- v1.9.6.1 Release - Tuesday 12/8/2009
  - patch release of v1.9.6 to support recent AdEERS changes. Only recommended for Mayo Clinic Rochester
- caAERS-AdEERS pilot is LIVE at Mayo Clinic Rochester
  - No expedited reports to date
  - caAERS-AdEERS pilot summary
- Immunovative Therapies Ltd is now a caAERS adopter
  - using caAERS v1.9.6 in production for two trials
    http://www.clinicaltrials.gov/ct2/show?term=immunovative&rank=1
    http://www.clinicaltrials.gov/ct2/show/NCT00861965?term=immunovative&rank=2

Adopter Updates

Mayo

- Study set-up and production pilot
- Automation of patient registration into caAERS
  - Initially, a job will run (~hrly); XML will be generated, and pushed into caAERS via WebServices
  - Method of monitoring still in flux.

CALGB

- Additional testing pending v2.0
- SLF4J used for webservice error logging/handling.
  - Adds to a log and kicks out an email

WFU

- Entered Yoga study into caAERS
- Question on progress of FDA electronic submission

Roswell Park

- Working on technical integration
    - Studies and Study Participants
- WebServices working, however, questions remain:
    - webservices vs. ESB (servicemix/caXchange)
    - UAMB call next Friday (re: caXchange)
    - CDMS creation of XMLs in process
- v2.0 will be tested and will begin a parallel pilot
- planning on using caAERS for all AEs and for unanticipated problem reporting.

Open Forum

- (Kathy) expectedness at event level (for the protocol overall)
    - expectedness at agent level is what is desired at RPCI

Action Items

Task	Assignees	Due Date	Status
Determine if grid node is needed for caXchange access to COPPA services	Paul		
Add Brenda to CDE reuse discussions with Lynne and Diane	Paul		
Add agent based "expectedness" as a topic for future discussion	Paul		

12-07-09 Roswell Park Meeting Minutes - caAERS

Meeting Information

When: Mon 10:00-11:00am ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
10am	Administrative Items • PSC and caXchange • Meeting w/ UAMS (Kumar to attend)	Paul Baumgartner
	Discussion of parallel pilot • Scope • Time frame	
11am	Meeting Adjourns	

Open Actions/Issues Items

Action/Issue	Assigned to	Due Date	Status
Request CTEP for list of RPCI AdEERS from the past 6months	Paul	12/07/09	Requested

Add feature request to allow "enabling" rules modifications upon save	Paul	TBD	Open
Change label of "Outcome" to "Seriousness Criteria"	Paul	07/15/09	Open
Add feature request for question "Does this place the subject at an increased risk?"	Paul	TBD	Open
Add feature request to support IRB usage and tracking of reports	Paul	TBD	Open
Evaluate adding "Unanticipated problem" to the list of seriousness criteria	Paul	TBD	Open
Evaluate adding rules effective dates and rules versions for the same rule set to support rules changing over time	Paul	TBD	Open
Evaluate new feature of allowing rules to be assigned to the study without having to author a study specific rule	Paul	TBD	Open
Problem w/ AdEERS report stuck in-progress	SB	ASAP	• CA: run script to change status to "failed" • PA: Issue being fixed
Issue w/ enabling rule	SB (CAAERS-2280)	7/10/09	Open
Issue w/ disease not being saved during reporting	SB	TBD	Open
Issue w/ edit AE link throwing error	SB	TBD	Open

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner
RPCI	• Ken Quinn • Jen • Haidee • Kathy • Dawn • Diane

Meeting Notes

Pilot

- Initial timeframe
  - 20 reports or 2 months
  - Begin in new year
- Scope (Reports)
  - AdEERS reporting
  - MedWatch Reporting
  - IRB report - TBD (need Risk question)
- Expedited Reporting only

09-08-09 Roswell Park Meeting Minutes - caAERS

Meeting Information

When: Tues 1:00-2:00pm ET

Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
1pm	Administrative Items	Paul Baumgartner
2pm	Meeting Adjourns	

Open Actions/Issues Items

Action/Issue	Assigned to	Due Date	Status
Add feature request to allow "enabling" rules modifications upon save	Paul	TBD	Open
Change label of "Outcome" to "Seriousness Criteria"	Paul	07/15/09	Open
Add feature request for question "Does this place the subject at an increased risk?"	Paul	TBD	Open
Add feature request to support IRB usage and tracking of reports	Paul	TBD	Open
Evaluate adding "Unanticipated problem" to the list of seriousness criteria	Paul	TBD	Open
Evaluate adding rules effective dates and rules versions for the same rule set to support rules changing over time	Paul	TBD	Open
Evaluate new feature of allowing rules to be assigned to the study without having to author a study specific rule	Paul	TBD	Open
Problem w/ AdEERS report stuck in-progress	SB	ASAP	• CA: run script to change status to "failed" • PA: Issue being fixed
Issue w/ enabling rule	SB (CAAERS-2280)	7/10/09	Open
Issue w/ disease not being saved during reporting	SB	TBD	Open
Issue w/ edit AE link throwing error	SB	TBD	Open

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner
CALGB	• Ken Quinn • Jen • Nancy • Haidee • Kathy • Debbie Kensy - IT Research Coord / Nurse • Linda Schmeeder - Dir of Study Implementation (CRC's boss)

Meeting Notes

- Discussion of sharing data between EMR (Eclipsys), CDMS (eRT), and caAERS

- Source documentation (i.e. EMR) MUST be first
- Cannot drive patient care records from research data sources (unethical - might show that patient care was biased based upon needs of research)

09-10-09 Mayo Meeting Minutes - caAERS

Meeting Information

When: Thursday 12:00-1:00pm ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
12am	Administrative Items	
	Status/Issues	
1pm	Meeting Adjourns	

Action Items

Action Item	Assigned to	Due Date	Status
Send CALGB Excel converter	Paul	TBD	cancelled - Jennifer to key in studies
Review study loader XML; evaluate manual edits	Brad	7/2/09	cancelled - Jennifer to key in studies
Load a study into the production caAERS box	Brad / Jennifer	7/2/09	
Perform functional testing on production	TBD	8/6/09	all but AdEERS submissions can be tested; AdEERS testing can occur after next caAERS release
Investigate reason for emails being sent despite removing SMTP configuration	Srini	Complete	
Can "open study" be flipped via services	Srini		
If study is not open and a patient is added, is there an informative error code			
Must be able to change SYSTEM ADMIN password	Paul	Open	
Suggestion to have a "service" specific role that would prevent UI login			
Perform functional testing on Brad's box	Robbin, Jennifer, et al	8/25/09	In Progress

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner

Mayo	• Jean Hanson • Brad Anderson • Robbin Peterson • Jennifer Frank • Sonja Hamilton
NCI	

Meeting Notes

- Discussed the re-focusing of the caAERS - AdEERS pilot
  - Hosting of caAERS by SB/CBIIT/CTEP
  - Mayo's responsibility would be for expedited report entry and submission (remove systems/configuration/integration dependencies)
  - A configured and loaded pilot system will be available on 10/1/09.
  - ~2 weeks of testing
  - CRA training on 10/12 & 10/14
  - Go live on 10/15
- This approach will truly pilot caAERS as an alternative front end to AdEERS. Additional confounding variables will be removed.
- Mayo will continue their own technical integration

No objections to the proposal
Sonja to follow-up with Sharon
Paul to follow-up with CBIIT project owners

12-14-09 Roswell Park Meeting Minutes - caAERS

Meeting Information

When: Mon 10:00-11:00am ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
10am	Administrative Items • PSC and caXchange • Meeting w/ UAMS (Kumar to attend)	Paul Baumgartner
	Discussion of parallel pilot • Scope • Time frame	
11am	Meeting Adjourns	

Open Actions/Issues Items

Action/Issue	Assigned to	Due Date	Status
Request CTEP for list of RPCI AdEERS from the past 6months	Paul	12/07/09	Requested
Add feature request to allow "enabling" rules modifications upon save	Paul	TBD	Open
Change label of "Outcome" to "Seriousness Criteria"	Paul	07/15/09	Open

Add feature request for question "Does this place the subject at an increased risk?"	Paul	TBD	Open
Add feature request to support IRB usage and tracking of reports	Paul	TBD	Open
Evaluate adding "Unanticipated problem" to the list of seriousness criteria	Paul	TBD	Open
Evaluate adding rules effective dates and rules versions for the same rule set to support rules changing over time	Paul	TBD	Open
Evaluate new feature of allowing rules to be assigned to the study without having to author a study specific rule	Paul	TBD	Open
Problem w/ AdEERS report stuck in-progress	SB	ASAP	• CA: run script to change status to "failed" • PA: Issue being fixed
Issue w/ enabling rule	SB (CAAERS-2280)	7/10/09	Open
Issue w/ disease not being saved during reporting	SB	TBD	Open
Issue w/ edit AE link throwing error	SB	TBD	Open

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner
RPCI	• Ken Quinn • Jen • Haidee • Kathy • Dawn • Diane

Meeting Notes

UP reporting update

- Protocol level reporting not done in caAERS
  - IRB representative has a concern over one process for subject level and another process for protocol level.
  - Some UP data would be in caAERS and some (protocol level) UP data would be in a separate DB.
  - Only 6-7 UP's a year

Who fills out AEs?
Who fills our SAE reports?
Who fills out UP's? IRB's form; PI's responsibility;

Questions for the IRB UP form (not for caAERS):
Should the consent be revised?
Should the protocol be advised?
Should previous participants be notified?

Possible flow: Two reports, one with UP notification (triggered when Related, Unexpected, and Serious) and one without UP notification. There would be a link in the SAE notification w/ possible UP that would direct the PI to the UP form. The UP tracking is then outside of caAERS.

09-03-09 WFU Meeting Minutes - caAERS

Meeting Information

When: Thursday 11:00am-12:00pm ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
11am	Administrative Items	Paul Baumgarnter
	Status/Issues	
12pm	Meeting Adjourns	

Actions / Issues

Issue / Feature	Impact/Priority	Status	Reporter/Requestor
Rule seems like it's enabled, but in-fact, is not • Confirm which rules were run	HIGH	Open	Bob (WFU)
Allow mandatory field configuration for submitter	Med	Open	Bob (WFU)
Prevent illegal characters for being entered into text fields	Med - causes report transformation to fail	Open	Bob (WFU)
Difficulty with using course • Most studies don't have course • Need to be able to differentiate between a change in one AE and a new AE • Suggestion is to make AE term + start date the primary key • Issue would be that users might end a grade 2 AE and give a new start date when it changed grade	High	Open	Bob (WFU nurses)
Bob to send training videos	Low	Open	Bob
What needs to be done to prevent the certificate exception from showing	Med	Open	Paul
Must be able to change the SYSTEM_ADMIN password	HIGH	Open	Paul
Update install instructions to provide recommended heap space (tomcat) & memory requirements	Med	Open	Paul

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner
WFU	• Bob Morrell • Del • Steven
NCI	Michele Elhman

Meeting Notes

Status

- Reviewed issues

- Bob needs to add mandatory fields for report definitions
- After this is done and tested on test, the operational instance will be updated
- Sarah's issue

-
    - # of PI's on Study
    - Sarah ran into issues with adding an investigator
    - Need to be able to delete an investigator if it has not yet been saved (rather than just deactivate)
    - Deactivate will not allow you to continue.
    - Usability issues here
    - On Create Study, there is no summary header

- Install issues:
    - Had to add a little piece of code to Tomcat
    - Steven is updating the install instructions

- Must still be able to access the study and adverse events after the study is closed.
    - This happens as a regular part of trials.
    - PB update - no bug; only Data Entry Status = Incomplete prevents adding subjects & AEs

- Usability issue with the "Open Study" feature
    - Need to have a message that indicates that the study is not yet "ready"
    - What is the difference between this and the "Study Open for Accrual?"
    - Bob recommends showing all, but having a pop-up that indicates why it cannot be accessed
    - At WFU, "Open to Accrual" is only used once the systems are set up and error checks occur
    - Should be able to see protocols not open to accrual during a search (flag as not open)
    - "Anticipated Open Date", "IRB approval date", "Open Date" (can be any date).

- Issue with a Research Staff user not getting email for account creation.
    - Bob will follow-up with Gina; behavior is strange and might point to an issue with Gina's account.

- A common scenario is to enter dates in the past

09-03-09 DCP Meeting Minutes - caAERS

Meeting Information

When: Thursday 3:00-4:00pm ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
3pm	Administrative Items	
4pm	Meeting Adjourns	

Actions / Issues / Requests

Action Item	Assigned to	Due Date	Status
Elaborate further at DCP & CCSA the concept of Course vs Reporting Period	Anne, Linda	TBD	Open

Attendees

Team	Attendee
SemanticBits	Paul Baumgartner
DCP	Anne Tompkins
CCSA	Linda Doody

Meeting Notes

- Discussed I-Spy 2 with Linda
    - CCSA will be using caAERS
    - The study is planned to open in November
    - The IND and IDE applications are being sent to the FDA today
    - All agents on the protocol will share the same IND
    - Agents will move in an out of the study based upon certain criteria

Anne question:

- I'm looking at the Review and Report page. There are several AEs listed, but only one is "new". How do I know if the others have been reported?

BIG issue requiring further discussion:

- For DCP (and many other organizations), AEs are collected on a continuim over the course of the study.
  Examples:
- Grade 1 AE goes to grade 2.
  **The grade 1 has a start and end date and the grade 2 has a start and end date.
    - The lack of the gap between the grade 1 and grade 2 indicates a worsening of the AE.
    - A gap between the grades would indicate two separate AEs
    - Both should be able to be reported in the same course
- The Grade 2 AE becomes a serious grade 3
    - An end-date to the non-serious AE is recorded and the serious grade 3 AE is reported with a start date as the beginning of the grade 1 (i.e. first place where there is a gap).
      Question: What items can be updated in the AE that warrant considering the previous AE closed and the start of a new AE
    - increase in grade: end date for earlier grade = start date of new grade AE
    - no change in grade, but a change in another criteria (seriousness? attribution?)

- The following must be supported:
  An AE occurs on a course. It is serious and requires reporting. The AE resolves.
  The AE recurrs on the same course. It is also serious. It must be able to be reported as a separate event. It is a separate event.

During walk through with Anne on Study May06; Subject David Miller; course 4/1/09; AE - (2nd data collection); received a NullValueinNestedPath error.

09-03-09 CALGB Meeting Minutes - caAERS

Meeting Information

When: Thursday 1:00-2:00pm ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
1pm	Administrative Items	
2pm	Meeting Adjourns	

Actions / Issues / Requests

Action Item	Assigned to	Due Date	Status
Provide descriptions/wsdls for updates to web services	Paul	7/16/09	Complete
Provide guidance on training availability	Paul	7/2/09	
Trigger participant message upon registration	Robert	7/02/09	
Functional testing of Routing and Review and notifications	Team	7/16/09	

Issue with wildcard reference for user ID	Srini	7/17/09	Fixed v1.9.5
JX Transformation Error still occurring	Srini	7/17/09	Added as bug
For AE's where there is a AE select term (i.e. Pain, Kidney), the full term isn't showing	SB	7/17/09	Fixed v1.9.5
Alphabetize Research Staff and Investigator lists in reporter drow down	SB		Added as feature request
Add functionality of being able to restart/repair serviceMix connection from this page	SB		Added as feature request
Add CTEP ID to the Investigator drop-down list in reporter tab	SB		

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner
CALGB	• Nimesh Patel • Robert Dale • Amish Shah • Susan Sutherland • Debbie Sawyer • Allision Booth • Kelly (training coordinator) • Robin

Meeting Notes

- Other TAC is a bug - fixed in v1.9.6
- Need to be able to configure the fields in the Capture AE page
  - If there are fields required for the rules to run that are not shown or are blank, probably should have some flag.
- Not clear which fields are mandatory prior to submitting routine AEs to Data Coordinator
- "Submit to Data Coordinator" is hidden in the Comments slider. Need to find a more prominent place.
- Report view check box
  - Not clear, perhaps rename "View report fields?"
  - Change button name from "Apply now" to something more intuitive
  - Only show check box if there is more than one report
- Routing and review options not showing in Review and Submit
- Unable to find reports in Routing and Review
- Follow-up w/ CALGB-50401; is this a CTEP IND or not?
- Role names for PRO CTCAE system are preferred
- Add CTEP ID to the Investigator drop-down list in reporter tab
  - CALGB recently had to add this to their system to support multiple "John Smith's"
  - Would a CRA be able to distinguish one investigator from another based on their CTEP ID? Perhaps they can pick one and see the email, phone, and address (if available) and then determine if it's the right one. What other info would a CRA use to ensure it is the correct investigator?

08-26-09 Roswell Park Meeting Minutes - caAERS

Meeting Information

When: Wed 8/26 1:00-2:00pm ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
1pm	Administrative Items	Paul Baumgarnter
	Discussion of caAERS progress/issues	Paul Baumgarnter
2pm	Meeting Adjourns	

Open Actions/Issues Items

Action/Issue	Assigned to	Due Date	Status

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner
Roswell Park	• Ken Quinn • Dawn • Nancy • Haidee

Meeting Notes

- Nancy account login troubleshooting
  - Nancy unable to log-in from desk
  - Tried during meeting with new password and it worked
- Paul tested lock-out during call
  - Account locked after two failed attempts regardless of configuration
  - Message to user is unclear (invalid credentials)
  - Added as issues to JIRA
- The Genentech report issue is still open
  - Paul able to reproduce - logged as a bug
- Advice requested regarding a recommended setup for having PSC and caAERS and using caXchange to broker messages
  - Will caXchange need to be on a separate server?
  - Does PSC support web services for patient registration events

08-13-09 Mayo Meeting Minutes - caAERS

Meeting Information

When: Thursday 12:00-1:00pm ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
11am	Administrative Items	
	Status/Issues	

12pm	Meeting Adjourns	

Action Items

Action Item	Assigned to	Due Date	Status
Send CALGB Excel converter	Paul	TBD	cancelled - Jennifer to key in studies
Review study loader XML; evaluate manual edits	Brad	7/2/09	cancelled - Jennifer to key in studies
Load a study into the production caAERS box	Brad / Jennifer	7/2/09	
Perform functional testing on production	TBD	8/6/09	all but AdEERS submissions can be tested; AdEERS testing can occur after next caAERS release
Investigate reason for emails being sent despite removing SMTP configuration	Srini	Complete	
Can "open study" be flipped via services	Srini		
If study is not open and a patient is added, is there an informative error code			
Must be able to change SYSTEM ADMIN password	Paul	Open	
Suggestion to have a "service" specific role that would prevent UI login			
Perform functional testing on Brad's box	Robbin, Jennifer, et al	8/25/09	In Progress

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner
Mayo	• Sonja Hamilton • Brad Anderson • Robbin Peterson • Jennifer Frank
NCI	

Meeting Notes

Status

- v1.9.5 loaded on older system
- Updated report definitions
- Reviewed issue with deleting TACs (position of delete X is not intuitive)
- Discussed issue with saving upon moving to a different tab (not intuitive)

General production pilot timeline:

6/25/09 - finalize list of studies
7/09/09 - functional testing of production system
7/15/09 - loading caAERS with protocol data for pilot
7/15/09 - begin implementation of participant registration message
8/06/09 - caAERS release
8/31/09 - caAERS release
9/15/09 - complete testing of participant registration message
9/15/09 - CRA training
10/15/09 - begin pilot

08-13-09 CALGB Meeting Minutes - caAERS

Meeting Information

When: Thursday 1:00-2:00pm ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
1pm	Administrative Items	
2pm	Meeting Adjourns	

Actions / Issues / Requests

Action Item	Assigned to	Due Date	Status
Provide descriptions/wsdls for updates to web services	Paul	7/16/09	Complete
Provide guidance on training availability	Paul	7/2/09	
Trigger participant message upon registration	Robert	7/02/09	
Functional testing of Routing and Review and notifications	Team	7/16/09	
Issue with wildcard reference for user ID	Srini	7/17/09	Fixed v1.9.5
JX Transformation Error still occurring	Srini	7/17/09	Added as bug
For AE's where there is a AE select term (i.e. Pain, Kidney), the full term isn't showing	SB	7/17/09	Fixed v1.9.5
Alphabetize Research Staff and Investigator lists in reporter drow down	SB		Added as feature request
Add functionality of being able to restart/repair serviceMix connection from this page	SB		Added as feature request
Add CTEP ID to the Investigator drop-down list in reporter tab	SB		

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner
CALGB	• Nimesh Patel • Robert Dale • Amish Shah • Susan Sutherland • Debbie Sawyer • Allision Booth • Kelly (training coordinator) • Robin

Meeting Notes

- Update on pilot
  - Risk for CALGB is resource constraints this fall.

- Not clear which fields are mandatory prior to submitting routine AEs to Data Coordinator
- "Submit to Data Coordinator" is hidden in the Comments slider. Need to find a more prominent place.

- Add CTEP ID to the Investigator drop-down list in reporter tab
    - CALGB recently had to add this to their system to support multiple "John Smith's"
    - Would a CRA be able to distinguish one investigator from another based on their CTEP ID? Perhaps they can pick one and see the email, phone, and address (if available) and then determine if it's the right one. What other info would a CRA use to ensure it is the correct investigator?

08-12-09 WFU Meeting Minutes - caAERS

Meeting Information

When: Thursday 11:00am-12:00pm ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
11am	Administrative Items	Paul Baumgarnter
	Status/Issues	
12pm	Meeting Adjourns	

Actions / Issues

Issue / Feature	Impact/Priority	Status	Reporter/Requestor
Rule seems like it's enabled, but in-fact, is not • Confirm which rules were run	HIGH	Open	Bob (WFU)
Allow mandatory field configuration for submitter	Med	Open	Bob (WFU)
Prevent illegal characters for being entered into text fields	Med - causes report transformation to fail	Open	Bob (WFU)
Difficulty with using course • Most studies don't have course • Need to be able to differentiate between a change in one AE and a new AE • Suggestion is to make AE term + start date the primary key • Issue would be that users might end a grade 2 AE and give a new start date when it changed grade	High	Open	Bob (WFU nurses)
Bob to send training videos	Low	Open	Bob
What needs to be done to prevent the certificate exception from showing	Med	Open	Paul
Must be able to change the SYSTEM_ADMIN password	HIGH	Open	Paul
Update install instructions to provide recommended heap space (tomcat) & memory requirements	Med	Open	Paul

Attendees

Team	Attendee

SemanticBits	• Paul Baumgartner
WFU	• Bob Morrell • Del • Steven
NCI	• Michele Elhman

Meeting Notes

Status

- Next week demo mandatory fields/sections for reports
- Reviewed 1.9.2 issues with Del
  - Had to do with organization filtering - fixed in v1.9.5
  - Workaround is to use SYSTEM_ADMIN
- Review some install issues with Steven & Biju

08-10-09 caAERS Pilot Discussion Meeting Minutes

Meeting Information

When: Monday 3:00-4:00pm EST
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
3pm	Review of pilot plans	Paul Baumgarnter
4:15pm	Meeting adjourns	

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner
CBIIT	Ann Setser
CTEP	Shanda Finnigan Steve Friedman

Issues / Actions

Issue / Action	Assignee	Due Date	Status
Confirm official process (i.e. Amendment, memo, etc), if any, for notifying CALGB & Mayo that caAERS reporting is okay for these studies	Shanda	08/18	Open

Set up meeting with CALGB & Mayo	Paul	8/18	Open
Set up hands-on session (2hr) w/ Ann and Shanda	Paul	8/17	Complete
How many reports is enough to call the pilot complete	Ann / Shanda	TBD	Open

Meeting Notes

Reviewed the caAERS-AdEERS pilot plan wiki

Significant discussion on Training

- Ann and Shanda committed to training on caAERS
- Paul expressed goal of August to harden all training materials and user documentation

Timelines to begin submission of reports a month or two behind desired expectations

- Discussion of dependencies (training, system validation)
- AdEERS web services still being updated (notification lists)

Updated goals

- Secondary goal: Identify area of improvement within the CURRENT process (i.e. how can this process work better?)
- Tertiary goal: Identify areas of improvement from an ideal process (i.e. how should the process work?)

Updated metrics of performance

- Were the correct reports submitted?
- Were the reports submitted on-time?
- What was the user experience (survey)?
- What was the clinical user support (TRI) experience (survey)?

08-06-09 All Hands Meeting Minutes - caAERS

Meeting Information

When: every 1st Thursday 12-1pm ET
Phone for today: 877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
12pm	Administrative Items • v1.9.5 Release today • Adopter issues / highlights	Paul Baumgartner

	v1.9.5 Demo
	• General Usability
	  • Navigation
	  • Highlighting
	• AE reporting
	  • AdEERS 24 hr notification support
	  • Review and Report updates
	  • Expedited AE flow updates
	• Print forms
	• Advanced Search UI
		Paul

1pm	**User Meeting ends**	
1pm	Technical Meeting begins	

	Administration updates in v1.9.5
	
	• Report Definition updates
	  • Type/Group/Parent
	• Study data entry status
	• Research Staff
	  • All studies
	  • Active / Inactive
	  • Multiple organizations
	• Investigator account option
	• Report Tracking
	  • Unsticking -stuck report	

	Service updates in v1.9.5 • Security • Add subject • Add site • Add staff • AE Management service	
2pm	Technical Meeting adjourns	

Action Items

Task	Assignee	Due Date	Status

Meeting Notes

Attendees and Updates

SemanticBits

Paul

Wake

Bob
Del
Steven

Mayo

Brad
Sharon
Jennifer

CALGB

Jenny
Susan
Robert
Debbie
Amish
Allison

NCI

Anne Tompkins (DCP)
Ann Setser(CBIIT)
Michele Ehlman (NCI)

Roswell Park

v1.9.5 Demo

07-16-09 Mayo Meeting Minutes - caAERS

Meeting Information

When: Thursday 12:00-1:00pm ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
11am	Administrative Items • AdEERS submissions unavailable until next caAERS release (7/31/09)	Paul Baumgarnter
	Demo new functionality • Logging reports • Printing Forms	
	Status/Issues	
12pm	Meeting Adjourns	

Action Items

Action Item	Assigned to	Due Date	Status
Send CALGB Excel converter	Paul	TBD	cancelled - Jennifer to key in studies
Review study loader XML; evaluate manual edits	Brad	7/2/09	cancelled - Jennifer to key in studies
Load a study into the production caAERS box	Brad / Jennifer	7/2/09	
Perform functional testing on production	TBD	8/6/09	all but AdEERS submissions can be tested; AdEERS testing can occur after next caAERS release
Finalize list of studies for pilot	Sharon / Jean	7/2/09	Complete - nine studies selected
Investigate reason for emails being sent despite removing SMTP configuration	Srini	Open	
Send Jennifer CTEP excel sheet for nine studies	Paul	ASAP	Complete - 7/9/09 (post-meeting)

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner • Srini Akkala

Mayo	• Sonja Hamilton • Jean Hansen • Brad Anderson • Robbin Peterson • Jennifer Frank
NCI	

Meeting Notes

Status

- Participant service ready to go.
- Investigator - must be able to supress account notifications
    - Initially, NO investigators will be logging into caAERS. Mayo does NOT want to be confuse their investigators with login information for a system they will not use.
- Jennifer will be manually keying in study information.
- Jean having issue with logging into system
    - Resolved - issue was that login ID was for another system

Logging

- Will be helpful

Print AE worksheet

- Likely to be used as a CRF for some smaller centers
- Recently there was a discussion at Mayo about how to improve the efficiency and harmonization between electronic CRFs and paper CRFs
    - Mayo may use this after all

General production pilot timeline:

6/25/09 - finalize list of studies
7/09/09 - functional testing of production system
7/15/09 - loading caAERS with protocol data for pilot
7/15/09 - begin implementation of participant registration message
7/31/09 - caAERS release
8/15/09 - CRA training
9/01/09 - complete testing of participant registration message
9/15/09 - begin pilot

07-09-09 WFU Meeting Minutes - caAERS

Meeting Information

When: Thursday 11:00am-12:00pm ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
11am	Administrative Items	Paul Baumgarnter
	Status/Issues	

	Demo new functionality • Print forms • Report logging	
12pm	Meeting Adjourns	

Actions / Issues

Issue / Feature	Impact/Priority	Status	Reporter/Requestor
Rule seems like it's enabled, but in-fact, is not • Confirm which rules were run	HIGH	Open	Bob (WFU)
Allow mandatory field configuration for submitter	Med	Open	Bob (WFU)
Prevent illegal characters for being entered into text fields	Med - causes report transformation to fail	Open	Bob (WFU)
Difficulty with using course • Most studies don't have course • Need to be able to differentiate between a change in one AE and a new AE • Suggestion is to make AE term + start date the primary key • Issue would be that users might end a grade 2 AE and give a new start date when it changed grade	High	Open	Bob (WFU nurses)
Bob to send training videos	Low	Open	Bob

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner • Srini
WFU	• Bob Morrell • Kim Sweat • Steven
NCI	

Meeting Notes

Status

- Internal kick-off meeting for caAERS production
- Test system down - will update with next release
- Abstraction of study agents would be very helpful
- Display AE term + grade better in MedWatch (uses a lot of space)
- Add logic to "Agent Reduced" related fields
- Evaluate issues associated with an undefined course and multiple distinct AEs of the same term that could occur within that course
- Mandatory section rules - the ACTION section, it's not clear what the action is doing.
- AE CRF - start/end date? Verbatim?

07-09-09 Mayo Meeting Minutes - caAERS

Meeting Information

When: Thursday 12:00-1:00pm ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
11am	Administrative Items • AdEERS submissions unavailable until next caAERS release (7/31/09)	Paul Baumgarnter
	Demo new functionality • Logging reports • Printing Forms	
	Status/Issues	
12pm	Meeting Adjourns	

Action Items

Action Item	Assigned to	Due Date	Status
Send CALGB Excel converter	Paul	TBD	cancelled - Jennifer to key in studies
Review study loader XML; evaluate manual edits	Brad	7/2/09	cancelled - Jennifer to key in studies
Load a study into the production caAERS box	Brad / Jennifer	7/2/09	
Perform functional testing on production	TBD	8/6/09	all but AdEERS submissions can be tested; AdEERS testing can occur after next caAERS release
Finalize list of studies for pilot	Sharon / Jean	7/2/09	Complete - nine studies selected
Investigate reason for emails being sent despite removing SMTP configuration	Srini	Open	
Send Jennifer CTEP excel sheet for nine studies	Paul	ASAP	Complete - 7/9/09 (post-meeting)

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner • Srini Akkala
Mayo	• Sonja Hamilton • Jean Hansen • Brad Anderson • Robbin Peterson • Jennifer Frank
NCI	

Meeting Notes

Status

- Participant service ready to go.
- Investigator - must be able to supress account notifications
    - Initially, NO investigators will be logging into caAERS. Mayo does NOT want to be confuse their investigators with login information for a system they will not use.
- Jennifer will be manually keying in study information.
- Jean having issue with logging into system
    - Resolved - issue was that login ID was for another system

Logging

- Will be helpful

Print AE worksheet

- Likely to be used as a CRF for some smaller centers
- Recently there was a discussion at Mayo about how to improve the efficiency and harmonization between electronic CRFs and paper CRFs
    - Mayo may use this after all

General production pilot timeline:

6/25/09 - finalize list of studies
7/09/09 - functional testing of production system
7/15/09 - loading caAERS with protocol data for pilot
7/15/09 - begin implementation of participant registration message
7/31/09 - caAERS release
8/15/09 - CRA training
9/01/09 - complete testing of participant registration message
9/15/09 - begin pilot

07-09-09 CALGB Meeting Minutes - caAERS

Meeting Information

When: Thursday 1:00-2:00pm ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
1pm	Administrative Items • AdEERS submissions N/A until release	Paul Baumgarnter
	New Development Demo • Logging • Print CRFs	Paul Baumgarnter
	Status/Issues	
2pm	Meeting Adjourns	

Actions / Issues / Requests

Action Item	Assigned to	Due Date	Status

Provide descriptions/wsdls for updates to web services	Paul	7/16/09	
Provide guidance on training availability	Paul	7/2/09	
Trigger participant message upon registration	Robert	7/02/09	
Functional testing of Routing and Review and notifications	Team	7/16/09	
Issue with wildcard reference for user ID	Srini	7/17/09	Added as bug
JX Transformation Error still occurring	Srini	7/17/09	Added as bug
For AE's where there is a AE select term (i.e. Pain, Kidney), the full term isn't showing	SB	7/17/09	Added as bug
Alphabetize Research Staff and Investigator lists in reporter drow down	SB		Added as feature request
Add functionality of being able to restart/repair serviceMix connection from this page	SB		Added as feature request

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner
CALGB	• Nimesh Patel • Robert Dale • Amish Shah • Susan Sutherland • Debbie Sawyer

Meeting Notes

Logging Page

- Add functionality of being able to restart/repair serviceMix connection from this page

Print CRF

- No start date needed
- Consider allowing a pick-list of configurable instructions
- Provide spot for verbatim

Verbatim first

- How to map lab AEs?
- "Not feeling well" - verbatim might map to several terms (or none)

Debbie's issues

- IE6 buttons look bad (known)
- Other TAC description not showing up (known)
- Agent adjustment not showing up (known)
- For AE's where there is a AE select term (i.e. Pain, Kidney), the full term isn't showing (need to add and test other specify w/ MedDRA).
- Alphabatize Research Staff and Investigator lists in reporter drow down
- Add CTEP ID to the Investigator drop-down list in reporter tab
    - CALGB recently had to add this to their system to support multiple "John Smith's"
    - Would a CRA be able to distinguish one investigator from another based on their CTEP ID? Perhaps they can pick one and see the email, phone, and address (if available) and then determine if it's the right one. What other info would a CRA use to ensure it is the correct investigator?

07-06-09 Roswell Park Meeting Minutes - caAERS

Meeting Information

When: Monday 10:00-11:00am ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
10am	Administrative Items	Paul Baumgarnter
11am	Meeting Adjourns	

Open Actions/Issues Items

Action/Issue	Assigned to	Due Date	Status
Add feature request to allow "enabling" rules modifications upon save	Paul	TBD	Open
Change label of "Outcome" to "Seriousness Criteria"	Paul	07/15/09	Open
Review MedDRA and/or CTCAE for terms to use for non-AE Unanticipated Problem Reporting	Kathy	TBD	Open
Add feature request for question "Does this place the subject at an increased risk?"	Paul	TBD	Open
Add feature request to support IRB usage and tracking of reports	Paul	TBD	Open
Evaluate adding "Unanticipated problem" to the list of seriousness criteria	Paul	TBD	Open
Evaluate adding rules effective dates and rules versions for the same rule set to support rules changing over time	Paul	TBD	Open
Evaluate new feature of allowing rules to be assigned to the study without having to author a study specific rule	Paul	TBD	Open
Fix password issue(s)	SB	ASAP	Open
Problem w/ AdEERS report stuck in-progress	SB	ASAP	• CA: run script to change status to "failed" • PA: Issue being fixed
Issue w/ enabling rule	SB (CAAERS-2280)	7/10/09	Open
Issue w/ disease not being saved during reporting	SB	TBD	Open
Issue w/ edit AE link throwing error	SB	TBD	Open

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner

CALGB	• Ken Quinn • Jen • Nancy • Haidee

Meeting Notes

07-02-09 All Hands Meeting Minutes - caAERS

Meeting Information

When: every 1st Thursday 12-1pm ET
Phone for today: 877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
12pm	Administrative Items	Paul Baumgartner
	Adopter sharing: • activities • issues • July activities	Paul, Adopters
	Features implemented in June • Navigation (demo) • Report logging / Happy.jsp (mock-up) • Print forms • Updates to services • Advanced Search UI	Paul
1pm	Meeting ends	

Issues / Feature Requests

Issue / Feature	Impact/Priority	Status	Reporter/Requestor
Rule seems like it's enabled, but in-fact, is not • Confirm which rules were run	HIGH	Open	Bob (WFU)
Allow mandatory field configuration for submitter	Med	Open	Bob (WFU)
Prevent illegal characters for being entered into text fields	Med - causes report transformation to fail	Open	Bob (WFU)

Open Action Items

Task	Assignee	Due Date	Status
Follow-up w/ CRF harmonization RE: capture AE worksheet	Paul		Open
Follow-up regarding persisting/recurring AE reporting for CTEP	Paul, Ann, Shanda		Open

Meeting Notes

Attendees and Updates

SemanticBits

Paul

Wake

Bob
Del
Steven

- Experience of over-reporting
- Tried to fire rules, but didn't fire
- Issue was that rules were not enabled
    - MUST have confirmation which rules were run or to ensure that the rules are in-fact enabled.
- Training next week for staff.

Mayo

Brad
Sonja
Sharon
Jennifer

- caAERS installed on Oracle. Pending functional testing.
- Parallel testing continued (~15 reports - no, issues after early reports)
- Pilot testing
    - Nine (9) studies ID
    - Staff for those studies being entered
    - In process of loading data for those studies
    - ? Regarding protocol "amendment" if necessary
- Upcoming study w/ EORTC - interested in using caAERS for submission of SAE reports

CALGB

Jenny
Susan
Robert
Debbie
Amish
Allison

- Group meeting in Chicago
- Wildcard bug needs addressing prior to loading research staff and investigators
- Debbie has been testing; entered a previous AdEERS
- Pilot Studies
    - 7 Studies
    - Sites selected (most active for the studies)
- Functional testing

NCI

Anne Tompkins (DCP)
Ann Setser (CBIIT)
Michele Ehlman (NCI)

Roswell Park

Recent Development

- Navigation (demo)
    - No comments

- Report logging (mock-up)
    - CALGB - exactly what was needed

- Updates to services
  - mentioned - no comment
- Advanced Search UI
  - mentioned - no comment
- Printed CRF's/AE entry worksheets
  - Need to be able to print as blank forms
  - Suggestion to add "print forms/worksheet" as a link on the dashboard
  - For now, the form will be able to be printed from the Study module and from the Capture AE screen
  - Form will not contain the patient name initially
  - Nice to have: Patient name in form (possible issues with completing wrong form/patient)
  - Nice to have: Listing of previous non-solicited AEs for quick follow-up
  - CALGB - this is not a CRF because we don't want people to send the form to us as primary study documentation; that said, some site IRBs require a form/worksheet to be provided prior to approving the protocol to see the information being collected.
  - Others - it really is a CRF
  - Ultimately, a CRF or a worksheet depends on the usage.
  - Sharon suggested to follow-up with the eCRF harmonization effort
- Discussed "end-date" of AE
  - Not required by CTEP or FDA
  - CTEP does have different rules for new vs. persisting vs. recurring AEs - end-date or resolution of AE is needed in order to know if a previously reported AE resolved or is persisting.
- Post-meeting troubleshooting with Bob and Del
  - Illegal characters in Precis was causing report generation to fail.

07-01-09 caAERS Kick-off

Meeting Information

When: Wednesday July 1, 2009 1:00-2:00pm ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
1pm	Introductions	Paul Baumgartner
15min	Statement of Work Review • Major Responsibilities • Milestones • Deliverables	
10min	Deliverable Logistics • Due dates • Method of delivery	
20min	Project Management Approach • Review Project Plan • Planned features • Agile Unified Process • Use of meetings • PM tools (wiki, JIRA, KC, backlog)	
remainder	Discussion / Questions	
2pm	Meeting Adjourns	

Action Items

Action Item	Assigned to	Due Date	Status

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner (Project Manager) • Ram Chilukuri (Project Director)
SAIC-F	• Peter Yan (COTR) • Jennifer Thomas (contracts specialist) • Nancy Roche (CTMS WS Program Manager)
NCI-CBIIT	• Christo Andonyadis (project owner) • John Speakman (project owner)

Meeting Notes

Statement of Work Review

Major Responsibilities

*

Milestones

*

Deliverables

*

Deliverable Logistics

Due dates

*

Method of delivery

*

Project Management Approach

Review Project Plan

*

Agile Unified Process

*

Use of meetings

Daily Scrum

- ***Weekly Adopters calls***
- ***Monthly All-hands calls***

*

PM tools

Wiki

*

JIRA

*

Knowledge Center

*

06-29-09 Roswell Park Meeting Minutes - caAERS

Meeting Information

When: Monday 10:00-11:00am ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
10am	Administrative Items	Paul Baumgarnter
11am	Meeting Adjourns	

Action Items

Action Item	Assigned to	Due Date	Status
Add feature request to allow "enabling" rules modifications upon save	Paul	TBD	Open
Change label of "Outcome" to "Seriousness Criteria"	Paul	07/15/09	Open
Review MedDRA and/or CTCAE for terms to use for non-AE Unanticipated Problem Reporting	Kathy	TBD	Open
Add feature request for question "Does this place the subject at an increased risk?"	Paul	TBD	Open
Add feature request to support IRB usage and tracking of reports	Paul	TBD	Open
Evaluate adding "Unanticipated problem" to the list of seriousness criteria	Paul	TBD	Open
Evaluate adding rules effective dates and rules versions for the same rule set	Paul	TBD	Open
Evaluate new feature of allowing rules to be assigned to the study without having to author a study specific rule	Paul	TBD	Open

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner
CALGB	• Ken Quinn • Kathy Reitz • Dawn

Meeting Notes

Issues with password

- Issues with password reset for Kathy and Ken
    - Other users have been able to login
      The issues are as follows:
      A. Invalid Token

1. The user is added and the email is sent
2. Email is sent to notify user
3. Entire link is copied and pasted into browser
4. User changes password
5. User receives "Invalid token" error
    - Log shows the following error:
      SendFailedException: Invalid Addresses; nested exception is: com.sun.mail.smtp.SMTPAddressFailedException: 550 #5.1.0 Address rejected.
      B. Invaild username / password (Kathy)
6. The user clicks on forgot password
7. The user follows the entire link in the forgot password email
8. The user changes the password and clicks "save"
9. The system confirms password successfully saved
10. The user tries to login and receives the "invalid username / password" error.

A follow-up call is being set up for later today to discuss

Hospitalization issue

- The issue with hospitalization outcome toggling has changed so that it won't fire the rules the first time through (it used to fire correctly the first time through, but on subsequent rules evaluations it would toggle off then on).
- The only field that was toggling was hospitalization.
- Ken created a separate rule to fire hospitalization independently of outcome.
    - This rule wasn't firing.
    - Reason was because it wasn't re-enabled after updating.
- We were able to enable the rule and move past

Unanticipated problem reporting

- Required for RPCI IRB
- Issue with "Outcomes" label - not an outcome but actually "Seriousness Criteria" - need to change label.
- RPCI will use serious criteria of "Other Relevant Event" to fire the rules for unanticipated problem reporting
    - The issue remains regarding what to code as the AE - CTCAE doesn't have an "Other, Other specify"
    - Kathy, et. al. will look through MedDRA and CTCAE to see what is available that can be used.
- caAERS is still missing the question: "Does this place the subject at an increased risk?" - Add as feature request.
- caAERS could be used by the IRB to track and manage these reports as well.
    - Additional fields of "Should informed consent be modified?, Should investigators be notified?, Should participants be notified?, etc.

Rules

- Since some studies may last several years, they may use a rule set that has since been replaced by a newer rules version.
    - There is a real possibility that studies sponsored by the same organization will have different rules versions applied.
    - This can be supported by the usage of study specific rules, however, this may not be the most user friendly method to associate rules to a study.
    - Ken suggested allowing rules (and rule versions) to be able to be assigned at the study level.

06-25-09 WFU Meeting Minutes - caAERS

Meeting Information

When: Thursday 11:00am-12:00pm ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
11am	Administrative Items	Paul Baumgarnter
	Status/Issues	
12pm	Meeting Adjourns	

Action Items

Action Item	Assigned to	Due Date	Status

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner
WFU	• Bob Morrell • Kim Sweat
NCI	

Meeting Notes

Status

- Test system down
- ALL events entered thus far did not require AE reporting
  - This has been confirmed by a CRA (Gina)
  - Previous events were over-reported
- Del entering in a bogus study for training purposes
  - protocol entered today
  - bogus event being entered for training.
  - training begins next week to staff (2-3 nurses)
  - likely live in 3-4 weeks.
- Next step might be to roll-out caAERS to remote sites that are participating on WFU research base trials.

Other notes:

06-25-09 Mayo Meeting Minutes - caAERS

Meeting Information

When: Thursday 12:00-1:00pm ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
11am	Administrative Items	Paul Baumgarnter
	Status/Issues	
12pm	Meeting Adjourns	

Action Items

Action Item	Assigned to	Due Date	Status
Send data from CTEP	Paul	6/20/09	Complete 6/22/09
Send CALGB Excel converter	Paul	TBD	pending - code being reviewed by SB
Review study loader XML; evaluate manual edits	Brad	7/2/09	
Load a study into the production caAERS box	Brad / Jennifer	7/2/09	
Perform functional testing on production	TBD	7/2/09	
Finalize list of studies for pilot	Sharon / Jean	7/2/09	

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner
Mayo	• Sonja Hamilton • Jean Hansen • Brad Anderson • Robbin Peterson
NCI	• Michele Elhman

Meeting Notes

Status

- Participant service - Michael has a plan to message participant registration events to caAERS
  - no timelines set; Brad and Michael need to discuss.

Options for loading caAERS w/ study definitions:

1. Manually key in studies (not preferred)
2. Use Excel loader (not preferred - issues with access to the production box; Excel loader skips some validations)
3. Use CALGB Excel to XML tool (not preferred - issues with access to production box)
4. Generate XMLs from CTMS and manually edit/verify the below items (preferred):
   - Protocol ID
   - Study Therapies
   - TACs
   - Agents
   - IND Holder

    - Phase
    - Study diseases

- Final list of studies should be able to be determined by next week.

General production pilot timeline:

6/25/09 - finalize list of studies
7/09/09 - functional testing of production system
7/15/09 - loading caAERS with protocol data for pilot
7/15/09 - begin implementation of participant registration message
7/31/09 - caAERS release
8/15/09 - CRA training
9/01/09 - complete testing of participant registration message
9/15/09 - begin pilot

Re-review of dashboard:

General feedback:

- Keep it simple - less is more
- For CRA's main usage is "show me my reports that are in-process (pending and overdue)"
- For Data Coordinators (at Groups), main use is "show me all in-process reports from my sites"
    - Recently submitted or withdrawn reports would be a useful dash as well.

06-25-09 CALGB Meeting Minutes - caAERS

Meeting Information

When: Thursday 1:00-2:00pm ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
1pm	Administrative Items	Paul Baumgarnter
	Status/Issues	
2pm	Meeting Adjourns	

Action Items

Action Item	Assigned to	Due Date	Status
Schedule point release • for service updates to support adding sites and staff	Paul	6/30/09	Release will be mid-late July
Check data elements for studies 50501 and 50401	Paul	6/12/09	Complete
Ping Shanda re: AdEERS queries	Paul	6/12/09	Complete
Send Paul Excel to XML code	Robert	6/12/09	Complete

Send Paul CRF examples	Josh	6/12/09	Complete 6/11/09
Send data provided by Shanda	Paul	6/19/09	Complete
Provide descriptions/wsdls for updates to web services	Paul	6/30/09	
Provide guidance on training availability	Paul	7/2/09	
Trigger participant message upon registration	Robert	7/02/09	
Functional testin of Routing and Review and notifications	Team	7/16/09	

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner
CALGB	• Nimesh Patel • Robert Dale • remainder of team at group meeting in Chicago

Meeting Notes

Technical Integration Status

- Investigator & Research Staff Services:
  - Implemented
  - Issue with wildcard reference for user ID
- Participant service:
  - XML generator
  - To occur next week - trigger message upon registration attempt
- Study service:
  - Implemented
  - Excel loader will be run 1st, then XML import (to add sites, staff, and investigators), and the UI config (to add solicited AE's, etc)
  - Many study definition elements are not in CALGB's system - future strategy is still TBD

CALGB's excel loader takes the excel data elements and inserts them into the service message

- - Creates the associations between personnel and study, but does not add personnel if they already exist (which the Excel loader does)

Administrative Portlets/Dashboard

- Show caAERS -> ESB status
- Show ESB status
- Show report submission activity

06-18-09 Mayo Meeting Minutes - caAERS

Meeting Information

When: Thursday 12:00-1:00pm ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
11am	Administrative Items	Paul Baumgarnter
	Status/Issues	
12pm	Meeting Adjourns	

Action Items

Action Item	Assigned to	Due Date	Status
Send data from CTEP	Paul	6/20/09	
Send CALGB Excel converter	Paul	TBD	code being reviewed by SB
Review study loader XML; evaluate manual edits	Brad	TBD	
Load a study into the production caAERS box	Brad / Jennifer	TBD	
Perform functional testing on production			

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner
Mayo	• Sonja Hamilton • Sharon Elcombe • Jean Hansen • Brad Anderson • Robbin Peterson

Meeting Notes

Status

- Participant service - Michael has a plan to message participant registration events to caAERS
    - no timelines set

Options for loading caAERS w/ study definitions:

1. Manually key in studies (not preferred)
2. Use Excel loader (not preferred - issues with access to the production box; Excel loader skips some validations)
3. Use CALGB Excel to XML tool (not preferred - issues with access to production box)
4. Generate XMLs from CTMS and manually edit/verify the below items (preferred):

- Protocol ID
- Study Therapies
- TACs
- Agents
- IND Holder
- Phase
- Study diseases

- Paul received reports from Shanda regarding AdEERS reports; Paul to format reports and forward.

- Final list of studies should be able to be determined by next week.

General production pilot timeline:

6/25/09 - finalize list of studies
7/31/09 - caAERS release

06-18-09 CALGB Meeting Minutes - caAERS

Meeting Information

When: Thursday 1:00-2:00pm ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
1pm	Administrative Items	Paul Baumgarnter
	Status/Issues	
2pm	Meeting Adjourns	

Action Items

Action Item	Assigned to	Due Date	Status
Schedule point release • for service updates to support adding sites and staff	Paul	6/30/09	Release will be mid-late July
Check data elements for studies 50501 and 50401	Paul	6/12/09	Complete
Ping Shanda re: AdEERS queries	Paul	6/12/09	Complete
Send Paul Excel to XML code	Robert	6/12/09	
Send Paul CRF examples	Josh	6/12/09	Complete 6/11/09
Send data provided by Shanda	Paul	6/19/09	
Provide descriptions/wsdls for updates to web services	Paul	6/30/09	
Provide guidance on training availability	Paul	7/2/09	

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner
CALGB	• Nimesh Patel • Robert Dale • Amish • Allison • Susan • Debbie

Meeting Notes

- Next week is group meeting - only Robert and Nimesh will be available.
- Bug with Therapy Type not being added via services
- Request for Training support when CALGB begins to role caAERS out to CRAs (Aug/Sept timeframe)

06-11-09 WFU Meeting Minutes - caAERS

Meeting Information

When: Thursday 11:00am-12:00pm ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
11am	Administrative Items	Paul Baumgarnter
	Status/Issues	
	Input needed: • dashboard mock-up • CRF • Physician vs. Investigator	
12pm	Meeting Adjourns	

Action Items

Action Item	Assigned to	Due Date	Status

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner
WFU	• Bob Morrell • Steven Cheng • Kim Sweat • Del Jones
NCI	• Michele Elhman

Meeting Notes

- Status
  - Current testing resulted in no AE reports. Indicates that Wake was over reporting.
    - Dashboard:

      Other notes:
    - Pre-existing conditions need a better list (i.e. not just CTEP's list)

- Might need to be able to attribute to a pre-existing condition (especially for symptom management trials - Cancer is the preexisting condition that usually causes the AE).
- "Dose reduced, specify new" should be a dynamic field associated with the "Was dose reduced?" field
- If Grade 5, several fields should automatically be filled in: Present status = Fatal/Died, etc.
- When creating courses, need a better interface for folks to see what courses have already been created (to avoid overlaps and gaps)
- Dates should be smart (i.e. can't have an AE start date prior to the start date of the course, etc).

06-11-09 Mayo Meeting Minutes - caAERS

Meeting Information

When: Thursday 12:00-1:00pm ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
11am	Administrative Items	Paul Baumgarnter
	Status/Issues	
	Input needed: • dashboard mock-up • CRF • Physician vs. Investigator	
12pm	Meeting Adjourns	

Action Items

Action Item	Assigned to	Due Date	Status

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner
Mayo	• Sonja Hamilton • Robbin Peterson • Jean Hansen • Brad Anderson

Meeting Notes

- Status
  - Open project - data is pulled into caAERS (rather than pushed)
    - Dashboard:

06-11-09 CALGB Meeting Minutes - caAERS

Meeting Information

When: Thursday 1:00-2:00pm ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
1pm	Administrative Items	Paul Baumgarnter
	Status/Issues	
	Input needed: • dashboard mock-up • CRF • Physician vs. Investigator • Review of Testing Feedback	
2pm	Meeting Adjourns	

Action Items

Action Item	Assigned to	Due Date	Status
Schedule point release • for service updates to support adding sites and staff	Paul	6/30/09	Open
Check data elements for studies 50501 and 50401	Paul	6/12/09	Open
Ping Shanda re: AdEERS queries	Paul	6/12/09	Open
Send Paul Excel to XML code	Robert	6/12/09	Open
Send Paul CRF examples	Josh	6/12/09	Complete 6/11/09

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner
CALGB	• Amish Shah • Nimesh Patel • Robert Dale • Josh Yoder • Susan Sutherland • Debbie Sawyer • Robin Heinze

Meeting Notes

Status

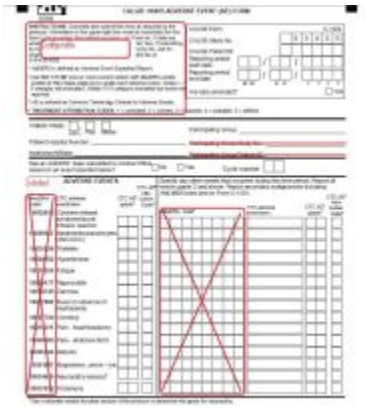
- Continuing integration
- Populated Excel sheet with data from two possible pilot studies
- Created a script that takes the Excel file, converts it to XML, and then sends to caAERS via the study message
- Need report from Shanda regarding the # of AEs, the sites, and reporters for the eight (8) pilot studies.
    - This will be used for determining the sites and staff to focus on for training.

Dashboard

- Recently purchased JBoss Portal
- Interested in being able to expose portlets in an enterprise portal

CRF

- CTMS:Pre-existing condition form
- CTMS:AE form



- The CRF should mirror the process flow of caAERS and contain/require the same data elements
- This will not be an official form
- CALGB will use caAERS as the source of record
- CALGB doesn't want sites to send them the form form entry into caAERS (this is the current process, but will be changing)
- The form should support displaying standard and custom instruction text
- The form should be able to be exported in pdf

Physician vs Investigator

- Essentially the same
- Upon adding to the system, physicians can be added to appropriate studies for the site with the role of Investigator.
- They will be changed to PI or Site PI as appropriate in the Study module

Testing results review

From CALGB caAERS Testing: 5/21/09

1. Signed in as a site CRA. Study tab is present. First screen shows study summary, which is fine. Subsequent screens show study details and allows editing. Site CRA should not be able to edit the study. Is this a role problem or a permissions problem?
Response: Access to the flow is enabled through the presence of the "Continue" button on the overview page. This is a bug and will be queued for fixing.
2. A link is present which reads "View person's schedule in study calendar?" The link does not work. Should the link point to patient's reporting cycles already entered thus far?
Response: Fixed.
3. The first time we enter date of patient's first course, it is not pre-populated (even though a previous, first course had already been entered). Later in the application, we see this field again and it is pre-populated.
Response: This should not occur. We are unable to reproduce, but will monitor.
4. When entering new AEs, Treatment Assignment is requested. Should this be pre-populated from previous entry?
Response: Per our discussion on 6/11/09, we will not pre-populate TAC.
5. Mostly the date format still does not except M-D-YYYY.
Response: We will evaluate the date fields for M-D-YYYY compatibility
6. When entering an event for AdEERS, if we enter one solicited event, we are required to grade all the solicited events (even if they are not applicable to the report). We need to do more testing here, had I not submitted to DC earlier in the process, this may not have occurred.
Response: This should not occur. We are unable to reproduce, but will monitor.
7. At some point prior to submitting the final report, we were asked if we wanted to add any additional adverse events. Do we need this question, since we've already entered the events and requested to report them? Can't we use the tabs to go back and enter more if needed. However, if we keep the question and add an event from that point in the application, there are errors. The application did not retain the grade provided, and maybe didn't ask for attribution either. Need more testing to pinpoint the errors.
Response: Per our discussion on 6/11/09, users should add the AEs in the beginning and then move through the flow. We will work to improve the ability to navigate between the AE entry and AE reporting flows.

06-04-09 All Hands Meeting Minutes - caAERS

Meeting Information

When: every 1st Thursday 12-1pm ET
Phone for today: 877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
12pm	Administrative Items	Paul Baumgartner
	Adopter sharing: • activities • issues • June activities	Paul, Adopters
	Multi-site user question	
	Features implemented in May • Field highlighting (demo) • AE import service • Soft delete • User de-activation • AE query API and UI	Paul
1pm	Meeting ends	

Issues / Feature Requests

Issue / Feature	Impact/Priority	Status	Reporter/Requestor
"In progress" report issue occuring	Med - requires restarting of Tomcat and ServiceMix	Intitial fix didn't work; Have other sites experienced this?	
To support easier integration w/ local security, need to move data filtering context files outside of .jar and .war	Med - would simplify	Open - SB looking at designing a robust method for users to add their own context files.	CALGB
Indication on MedWatch doesn't really make sense for prevention trials	Med - inaccurate data	Open - difference between "disease" and "study focus"// Propose renaming "study conditions" to "study focus"	Wake
Addition of AE duration to rules	Med - needed to support certain trials (surgery)	Open	Wake
Bone marrow transplant interventions support	Med	Open	CALGB, Wake
CALGB submit issue	High	In-progress	CALGB

Open Action Items

Task	Assignee	Due Date	Status

Meeting Notes

Attendees and Updates

SemanticBits

Paul

Wake

Bob

Mayo

Brad
Robbin

- caAERS installed on Oracle. Pending functional testing.

CALGB

Nimesh
Robin
Susan
Robert
Debbie
Amish
Allison

-

NCI

Anne Tompkins (DCP)
Shanda Finnigan (CTEP)

-

Roswell Park

Ken Quinn
Kathy Rietz

-

New Development

- Develop AE consumer service
  Method of logging report submission statuses
  Organization consumer service and allow multiple org IDs
  Add Security to Web Services
  Improve AE query API
  Advanced search improvments
  Print blank reports and Capture AE screens
  Manage Report and Routing/Review Improvements
  User registration for NCI hosted caAERS
  Mandatory field highlighting
  Add Participant Improvements
  Admin page improvements & search improvements, Rules UI, rules flow
  Javascript Navigation
  Update Help documentation; reference Wiki

09-28-10 Mayo Pilot Meeting Minutes - caAERS

Meeting Information

When: Tuesday 11:30am-12pm ET
Phone: 1-877-810-8617
Passcode: 2764499

Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
11:30am	Review Task list	Paul
12pm	Meeting Adjourns	

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner
Mayo	• Sharon Elcombe • Jean Hanson
NCI	• Ann Setser • Shanda Finnigan

Pilot Action Items

Want to enter into Rave and send to caAERS for use as SAE rules

Site knows it is an SAE, then into caAERS and then sent to AdEERS.

When Mayo is NOT the data center they would use caAERS rather than Rave

- Wouldn't build a study in Rave

upirtso (unanticipated problem reporting; unexpected, serious, possibe, probable, or definite, increased risk?)

Would have a need to support more than just cancer.

10-05-10 Mayo Meeting Minutes - caAERS

Meeting Information

When: Tuesday 11:30am-12:30pm ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
11:30am	CTCAE version	Paul Baumgarnter
12pm	Meeting Adjourns	

Actions / Issues

Issue / Feature	Impact/Priority	Status	Reporter/Requestor

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner
Mayo	• Sharon Elcombe • Jean Hanson • Robbin Peterson • Jennifer Frank
NCI	Mary Agnes

Meeting Notes

- A new expedited report was triggered in the Mayo pilot for study 7627.
- The submission of the report to AdEERS failed
  - The report used CTCAE v3.0 but AdEERS expected CTCAE v4.0
- The study CTCAE version was recently upgraded to v4.0.
  - This is reflected in an email from Shanda Finnigan on 8/12/10.
  - This upgrade is not reflected in the protocol (i.e. there is no amendment).
  - Routine AEs are still being collected and reported to CDUS in CTCAE v3.0.
- **ACTION:** Paul to follow-up to deterimine if it is a requirement to record in one terminology and report to AdEERS in another.
- Mayo has caAERS v1.9.6.1 which does NOT support CTCAE v4.0.
- **ACTION:** Mayo will need to upgrade to a later version of caAERS in order to continue submitting reports for studies requiring CTCAE v4.0 for AdEERS.
  - Timeline for upgrade:
    - ~ 10/08/10: Update and test upgrade scripts for v1.9.6.1 to v2.2 upgrade (DEV)
    - ~ 10/18/10: Schedule and apply the upgrade to the Mayo v1.9.6.1 test system (Cris Rhea)
    - ~ 10/25/10: Validate v2.2 on Mayo test (Jennifer, et al)
    - ~ 11/01/10: Schedule and apply the upgrade to the Mayo v1.9.6.1 PROD system (Cris Rhea)
    - ~ 11/02/10: Validate v2.2 on Mayo PROD (Jennifer, et al)
    - ~ 11/02/10: Notify CRAs to resume reporting via caAERS (Jean)
- **ACTION:** Jean will send an email to the pilot CRAs instructing them to report via AdEERS for all pilot studies *except* for the two (2) NCCTG studies.
  - Jean will instruct Jill Burton to export the AdEERS .pdf from caAERS, withdraw this report in caAERS, and then report this event directly to AdEERS.

10-07-10 All Hands Meeting Minutes - caAERS

Meeting Information

When: every 1st Thursday 12-1pm ET
Phone for today: 877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
12pm	Welcome	Paul Baumgartner
	Review Agenda • Call for items	Paul
	Overview of caAERS v2.2	Paul

	What's next for caAERS • Device support	Paul
	Use Cases: recurring and continuing AEs	Paul
	news: FDA guidance 21 CFR Part 213, 220	Paul
	Community sharing / updates	Adopters
1pm	Meeting adjourns	

Meeting Notes

Attendees

SemanticBits

Paul
Wesley

Wake

Bob

Mayo

CALGB

Robin

NCI

Mary Agnes Templeton (CBIIT)
Brenda Maeske (SAIC)

Roswell Park

Haidee
Kathy

DFCI

Barbara Mackey

Duke

Vijaya Chadaram

JHU

Alla
Mike Fox

Overview of caAERS v2.2

- AE Reporter Dashboard
- Additional role granularity
    - Harmonization with the Suite
- Improved User Guide documentation

What's next

- Adding device at the study level
- Improved support for prevention, symptom control, and non-agent trials

Use Case review

- Recurring - any AE of the same term where that term previously existed and was resolved (regardless of grade, etc)
    - Resolution date becomes mandatory for the earlier AE if trying to enter the same term.
    - Each recurring AE is treated as a distinct AE.
- Continuing - Any AE without a resolution date
- Worsening - Any AE where that term was previously entered and the resolution date of the lower grade AE is the same as the start date of the higher grade AE.
    - A worsening AE is treated as a distinct AE.
- Improving - Any AE where that term was previously entered and the resolution date of the higher grade AE is the same as the start date of the lower grade AE.
    - An improving AE is treated as a distinct AE.

Review of FDA guidance

- Epidemiological study reporting
    - need to research some specific examples
    - Guidance basically just eliminates this type of study as an exception.

- Determining if AEs are occurring at a rate higher than expected
    - Difficult to determine realtime
    - RPCI uses their UP reporting as a manual method to monitor

- Bioavailability study reporting
    - Phase I PK studies
    - Not really performed at the sites on the call
    - Guidance basically just eliminates this type of study as an exception.

- Bioequivalence
    - Generic vs brand name study
    - Not really performed at the sites on the call (mostly for Pharma)
    - Guidance basically just eliminates this type of study as an exception.

Action Items

Task	Assignees	Due Date	Status

10-14-10 WFU Meeting Minutes - caAERS

Meeting Information

When: Thursday 11:00am-12:00pm ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
11am	Administrative Items	Paul Baumgarnter
	Status/Issues	
12pm	Meeting Adjourns	

Actions / Issues

Issue / Feature	Impact/Priority	Status	Reporter/Requestor

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner
WFU	• Bob Morrell • Del Jones • Steven
NCI-CBIIT	• Mary Agnes Templeton

Meeting Notes

Related past item

- Once WFU expands the use of caAERS to other departments, how will it be ensured that the correct set of rules is fires? Is there a need for institutional subdivisions in caAERS?

Three options right now:

1. Create a new organization in caAERS for each department and author the rule set for that department
2. Create a protocol specific rule set for each study
3. Author the rules to include the therapy type as a condition since all of the departments are divided based upon therapy type.

Need to analyze this further.

Updates

- Wake had two MedWatch reports faxed to Del.
    - The CRA (Sarah Hahne) had tried to enter the info into caAERS but got stuck
    - Del to follow-up

Discussion: User provisioning

- The specific assignment of staff to studies in order to grant them access to the study is overkill
    - Most folks should have system access without being specifically listed as an assigned study personnel
    - For WFU-Research Base, staff allowed to work on a study are the same for all studies
    - At WFU as a whole, pretty much everyone should be able to create and submit an AE report

- The study team (i.e. folks with specific roles on a study) are largely specified by the IRB
    - PI / Study Chair; Statistician, Study Coordinator; Consenting Professional; Lead CRA; Protocol Nurse
    - These are people specifically assigned to the study with domain roles (rather than user roles).
    - These study personnel may not be users in the system, but would still need to be included as study personnel to ensure they get appropriate notifications.
      ACTION : Update the study personnel roles with the appropriate domain specific roles and remove the requirement that study personnel be system users (similar to investigators).
    - The domain study specific role names may vary from organization to organization.
      ACTION : Allow the study personnel roles to be system configurable by a Business Admin. These should also be the roles used elsewhere in the application (i.e notifications).

- WFU uses **groups** to control permissions in a managable way.
    - EX. Group of physicians, group of CRAs, department, disease focus, etc
    - users are added to the group
      ACTION : Allow permission groups to be added in the system. Users should be added to groups. Studies should be able to be added to groups. This will allow users to be given permissions to studies without having to specify each individual user with study access.
      ACTION : Need to analyze this in conjunction with the requirement that different departments need to be specified, each with separate reporting rules.

- WFU would also like a flag at the group level that grants all users read access to all information.
    - This is essentially the same as giving each user a Data Analyst role with access to the group's sites and studies.

Disease vs Indication vs Focus

Should "Study Disease" be changed to "Study Indication?"

Study has a:

Type	Indication	Population Focus
• Treatment • Supportive Care • Prevention • Symptom Amelioration • Quality of Life	• Breast Cancer • Nausea • Cancer • etc	• People with Breast Cancer • Chemo patients • Breast cancer chemo patients • Black women • etc

- Wake needs a way to generate a report of all "Breast Cancer" studies (for example) that include any studies treating breast cancer, but also focused on breast cancer populations.
    - caAERS may not need this level of granularity

In CTRP a study has a:

Type	Purpose	Disease
• Interventional • Observational	• Treatment • Preventive • Supportive Care • Screening • Diagnostic • Health Services Research • Basic Science • Other	

- This needs more analysis

Unneeded study fields

- Replace "Short Title" and "long title" with a single title field
- Remove Precis
- Remove Description
- Remove Multi-institutional
- Remove Status
- ? Remove AdEERS reporting?
- ? Remove study design ?
- Keep Phase

12-08-10 DCP Meeting Minutes - caAERS

Meeting Information

When: Wednesday 11:00am-12:00pm ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
11am	Administrative Items	
12pm	Meeting Adjourns	

Attendees

Team	Attendee
SemanticBits	Paul Baumgartner
DCP	Anne Tompkins

Meeting Notes

- Obtained new DCP SAE form from Anne (http://prevention.cancer.gov/clinicaltrials/management/pio/instructions)
  - **Action:** Need to update this in caAERS
- Discussed why WFU is not sending AE reports to DCP via email (nci_dcp_pio@mail.nih.gov)
  - Currently reports being mailed or faxed
  - **ACTION:** Paul to follow-up with WFU

	CCOP	non-CCOP
aka	Research Base	Consortia
Study types	• Symptom management • a few prevention	• Prevention only
SAE reporting method	• AdEERS (Groups) - daily email from AdEERS to DCP • MedWatch (non-Groups) - emailed, mailed, faxed • If using a DCP IND, then report using the non-CCOP flow	• DCP SAE form to CCSA and Medical Monitor

For CCOPs, usage of caAERS is dependent upon allowance of submissions by CTEP.

- ? - would CTEP allow for production caAERS-AdEERS submissions for DCP studies?

For non-CCOPs (Consortia):

- Oracle Clinical RDC used to collect routine AEs
- Very few SAEs since these are prevention studies
- A hosted caAERS could be of benefit
- Two likely scenarios:
  1. Oracle Clinical RDC -> All AEs -> caAERS (rules run, SAE reports completed) -> SAE reports to DCP
     - issue is that entry of AEs into RDC is not timely (i.e. end of month) and SAEs would likely be reported late
  2. SAEs -> caAERS (rules confirmation, reports completed) -> SAE reports to DCP and SAE info back into RDC

Protocol DB at DCP has protocol data for all DCP studies.

*Question: How would caAERS know if a study was CCOPs or non-CCOPs?

-
  - Symptom Management would always be CCOPs, however, Prevention could be either
  - This is important in order to trigger the correct reporting recommendation

Study Focus Discussion:

Study Type	Focus / Indication	Study Disease
Prevention	Cancer	Cancer
Symptom Control	Nausea	Breast Cancer

- Study Focus / Indication should replace current notion of disease.
  - This is the condition of study, not necessarily the patient's disease.
- Study Disease isn't needed for caAERS.
- The Patient disease is needed in caAERs (would be a pre-existing condition / co-morbidity)
- Study Disease is needed in other systems in order to allow for a query to be executed to find all studies for Breast Cancer (etc).
- If the Study Type is Treatment, then the Study Focus would be the diseases under treatment (just as it is now), of which each study subject has the disease.
  - In the expedited flow, this would show as an attributable cause.
- If the Study Type is not Treatement, then the Study Focus would not be an attributable cause in the SAE report.

    - Any diseases that the study subject has (including cancer) would be listed in pre-existing conditions.

- **ACTION:** Paul to mock-up Study Type and Study Focus and circulate
    - Need to research BRIDG, CDE's, COPPA, and RSS regarding these elements.

12-09-10 WFU Meeting Minutes - caAERS

Meeting Information

When: Thursday 11:00am-12:00pm ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
11am	Administrative Items	Paul Baumgarnter
	Status/Issues	
12pm	Meeting Adjourns	

Actions / Issues

Issue / Feature	Impact/Priority	Status	Reporter/Requestor

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner
WFU	• Bob Morrell • Del Jones • Steven
NCI-CBIIT	• Mary Agnes Templeton

Meeting Notes

Update on submissions to AdEERS

- Bob suggested that

02-15-10 CALGB Meeting Minutes - caAERS

Meeting Information

When: Monday 9:30am-11:00amET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
9:30am	Review Routing and Review	
11am	Meeting Adjourns	

Meeting Notes

Action Item	Assigned to	Due Date	Status

- Should physician review be removed for the initial CALGB workflow?
  - Physician's may not be logging into the system and if a CRA sends it to the physician for review, then Central Office cannot make comments and transition workflow.
  - More discussion on Physician Review needed.
  - Can the checkbox be configurable so that for certain physicians (or sites) the checkbox is disabled for CRAs?
- Issue with pdf applet
  - JRE 1.6.0_17 - not working
  - De-bug - pdf viewer applet and add as a system config requirement if needed
- Workflow emails not going out for Central Office Report Reviewer.
- Next meeting tomorrow (Tues 2/16/10)
  - Debbie will attend
  - Update will be added to Report Reviewer (Nimesh)

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner • Biju Joseph
CALGB	• Nimesh Patel • Todd Crook

02-22-10 CALGB Meeting Minutes - caAERS

Meeting Information

When: Thursday 1-2pm ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
1pm	Routing and Review testing	
2pm	Meeting Adjourns	

Meeting Notes

Testing of Routing and Review with the team. Several issues and improvements identified.

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner • Biju Joseph
CALGB	• Nimesh Patel • Todd Crook

02-29-10 CALGB Meeting Minutes - caAERS

Meeting Information

When: Thursday 1-2pm ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
1pm	Routing and Review testing	
2pm	Meeting Adjourns	

Meeting Notes

Discussion of routing and review.

Expedited reports, should they be locked from CRA editing while in Central Office Review?

- - May want to allow editing until the Central Office has started review (would need a flag to "Start Review").

Change data entry status to be meaningful.

For DC remove Manage Reports tab

Bug with deleting a TAC of null on 50701
username:

Send all workflow diagrams to CALGB.

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner • Biju Joseph
CALGB	• Nimesh Patel • Todd Crook

03-18-10 WFU Meeting Minutes - caAERS

Meeting Information

When: Thursday 11:00am-12:00pm ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
12pm	Administrative Items	Paul Baumgarnter
	Status/Issues	
1pm	Meeting Adjourns	

Actions / Issues

Issue / Feature	Impact/Priority	Status	Reporter/Requestor

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner
WFU	• Bob Morrell • Del • Steven Cheng
NCI	Mary Agnes

Meeting Notes

- Demo of WFU's autograding system
- Some normal ranges are gender based (i.e. hemaglobin)
- Some normal ranges are different for pediatrics
    - At WFU, autograding is turned off for pediatrics
- Many grades 1,2 are purely quantitative, however, the distinction between a grade 3 and 4 is often qualitative (eg. absence or presence of Life Threatening consequenses, respectively).
- Many terms have ranges for different types of labs; this raises a policy issue about which test wins if there is a conflict in the grade.
    - Who wins?
- The user can ALWAYS override the grade
    - If the lab comes from an outside lab with a different range of normals
- Leukemia patients - ~1/2 of AEs are labs
- WFU's system allows users to see all of the labs for the cycle
- WFU updates normals fairly infrequently (last update in 2005), however, the normals needs to be able to be updated.
- Sometimes a normal range runs into grade 1 or grade 2.
    - Example: Ionized Calcium grade 1: LLN - 1.0 mmol/g, however, WFU has LLN 1.0 (Normal is 1.0 - 1.3)
- Some labs have a pair of AE terms (one for low and one for high); this is primarily relavent for Solicted AEs
    - Example: A subject has High Glucose as an AE. Low Glucose is also a solicited AEs on a study and would also need to be graded as a grade 0 (not technically normal, but not out of range for low).

From CTCAE 4 workshop by Anne and Ann:

- Verbatim
    - From patient and physician - which one wins?
    - For a lab AE, what do you do?

    - Does the verbatim need to be in-hand or entered into the system?

- Lab grades: Overriding lab grades (a "laboma" - an abherant lab)
- all grades are subject to override by physician's descretion.
- Many labs are not purely gradable based on labs.

Must support the Behavioral - Other therapy types.

04-08-10 WFU Meeting Minutes - caAERS

Meeting Information

When: Thursday 11:00am-12:00pm ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
12pm	Administrative Items	Paul Baumgarnter
	Status/Issues	
1pm	Meeting Adjourns	

Actions / Issues

Issue / Feature	Impact/Priority	Status	Reporter/Requestor

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner
WFU	• Bob Morrell • Del • Steven Cheng
NCI	Mary Agnes

Meeting Notes

- Demo of WFU's autograding system
- Some normal ranges are gender based (i.e. hemaglobin)
- Some normal ranges are different for pediatrics
    - At WFU, autograding is turned off for pediatrics
- Many grades 1,2 are purely quantitative, however, the distinction between a grade 3 and 4 is often qualitative (eg. absence or presence of Life Threatening consequenses, respectively).
- Many terms have ranges for different types of labs; this raises a policy issue about which test wins if there is a conflict in the grade.
    - Who wins?
- The user can ALWAYS override the grade
    - If the lab comes from an outside lab with a different range of normals
- Leukemia patients - ~1/2 of AEs are labs
- WFU's system allows users to see all of the labs for the cycle
- WFU updates normals fairly infrequently (last update in 2005), however, the normals needs to be able to be updated.
- Sometimes a normal range runs into grade 1 or grade 2.
    - Example: Ionized Calcium grade 1: LLN - 1.0 mmol/g, however, WFU has LLN 1.0 (Normal is 1.0 - 1.3)
- Some labs have a pair of AE terms (one for low and one for high); this is primarily relavent for Solicted AEs

    - Example: A subject has High Glucose as an AE. Low Glucose is also a solicited AEs on a study and would also need to be graded as a grade 0 (not technically normal, but not out of range for low).

From CTCAE 4 workshop by Anne and Ann:

- Verbatim
    - From patient and physician - which one wins?
    - For a lab AE, what do you do?
    - Does the verbatim need to be in-hand or entered into the system?

- Lab grades: Overriding lab grades (a "laboma" - an abherant lab)
- all grades are subject to override by physician's descretion.
- Many labs are not purely gradable based on labs.

Must support the Behavioral - Other therapy types.

Verbatim:

- WFU pulling together an SOP for verbatim
- Issues: What is verbatim? Patient's words? Doc's words? Nurse's words?
- WFU's SOP states that the verbatim be there in the source data prior to selecting a term
    - It would NOT need to be entered into the system prior to picking a term
    - WFU's system will support selecting the term and then entering verbatim
    - WFU does not require verbatim for labs and the will NOT use any system that would require this (doesn't make sense)
- Open issue with Solicited AE's about verbatim first
- Adding verbatim is a HUGE change in process. Many, many open questions about the requirements for use.
- Conveyed as only applicable for CTCAE v4 (per presentations by Ann Setser)

05-27-10 caAERS Design Review

Meeting Information

When: Thurs May 27, 2010 11:00am-2:30pm ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
11am	Introductions	Paul Baumgarnter
	Vision and Scope - https://wiki.nci.nih.gov/display/caAERS/Vision+and+Scope+-+caAERS	Paul
	Project Management Approach • Agile Unified Process • Schedule • Use of meetings • PM tools (wiki, JIRA, KC)	Paul
	Test Plan	Paul
	Requirements-https://wiki.nci.nih.gov/x/tIh8 • Backlog- https://wiki.nci.nih.gov/display/caAERS/Product+Backlog+-+caAERS or see Real-time backlog	Paul
	Use Cases-https://wiki.nci.nih.gov/x/8YR8	Paul
	Design Model-https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/models/caAERS_model.eap	Paul
	Demo-https://demo.semanticbits.com/caAERS	Paul

	Architecture-https://wiki.nci.nih.gov/display/caAERS/Technical+Architecture+Guide+-+caAERS and Technologies • Diagrams - https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/DesignReview/Diagrams.pdf • SOA	Denis / Vinay
	Design Documents-https://wiki.nci.nih.gov/x/ihay • Earlier Designshttps://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs	Biju
	Enterprise Services • AE Management • Safety Reporting	
remainder	Discussion / Questions	
2:30pm	Meeting Adjourns	

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner (Project Manager) • Ram Chilukuri (Project Director) • Vinay Kumar (Architect) • Denis Krylov (Architect) • Wesley Wiggins (Business Analyst) • Biju Joseph (Technical Lead) • Srini Akkala (Technical Lead)
SAIC-F	• Jeff McLean (COTR) • Nancy Roche (CTMS WS Program Manager) * Steve
NCI-CBIIT	• Christo Andonyadis (project owner)

Meeting Notes

Introduction

- caAERS team will present application design to SAIC Frederick reps (Nancy R., Jeff M.)
- Nancy R. commented that static copies of deliverables are needed
  - Jeff M. will review list of required deliverables next week
  - should coordinate deliverable "snapshot" with Suite release cycle (every ~4-5 months)

Vision and Scope

- Scope is expanding to include enterprise services
  - decompose app functionality into NCI Enterprise Services

Requirements

- reviewed functional modules
  - When discussing the Vocabulary Mapping Service module, Christo commented that caAERS team would be called on to provide requirements for NES Vocabulary Service
  - External Agency Reporting could be considered Safety Reporting
  - Module 9 Patient Reported Adverse Events
    - this requirement could be satisfied by intergration with PRO-CTCAE
    - Nancy R. suggested that caAERS make a connection with Outcomes Group

        - Module 10 - Data Mining for Risk Patterns
            - Adverse Event Data Warehouse may no longer apply as we shift to federated data models
        - Module 12 - Decision Support for AE Expectedness
            - recently implemented support for Agent Specific Adverse Event List (ASAEL)
        - Module 13 - Security
            - had discussion on unified security - noted that roles/design has been presented to Braulio (NCI Security Coordinator) and he has given his approval
        - Steve raised the possibility of integration with caLIMS - general consensus was that this is likely out-of-scope - caAERS would need actual results, not lab management details
- Nancy R. was asked how we came up with services for the Suite
    - Ram C. commented that the services were developed as a prototyped solutions to address inter-application data sharing - going forward the Suite services will be deprecated and will be replaced by NCI Enterprise Services
- Nancy R. would like to see slide that shows milestones for the next year
- Nancy R. will get BAM mapping sheet form Michele E.

Overview of Use Cases

Reviewed Domain Analysis Model

Discussion of Documentation Review by NCI technical writing staff

- mainly made formatting/convention changes
- some reorganization
- removed admin guide - became technical integration guide

Architecture Presentation (implementation)

- discussed layers
- Presented overall architecture diagram
    - Jeff M. asked if all Suite apps could put together similar diagram
        - answer: diagram should be the same for caAERS, PSC and C3PR - LabViewer will be different because they use different technical solutions
- Nancy R. suggested that the Requirements (left column) category in the Requirement/Solution Matrix should have links to the detailed list of associated requirements
- Reviewed Requirements/Solution matrix
- demo of rule creation
    - Nancy R. asked if Drools was part of caBIG tech stack?
- answer: no - Nancy asked if it should be - Christo A. said it may make sense incorporate it into the NCI Enterprise Services standards
    - C3PR uses Drools as well
- Nancy R. asked if we have explored common database schema for all CTMS apps?
    - answer: this would be counter to the NCI Enterprise Services

Action Items

Action Item	Assigned to	Due Date	Status
Submit deliverables in PDF at the time of next Suite release	caAERS team	July 31, 2010	Assigned

06-08-10 Mayo Meeting Minutes - caAERS

Meeting Information

When: Tuesday 11:30am-12:30pm ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
1pm	Administrative Items	Paul Baumgarnter
	Review New / Open issues	

2pm	Meeting Adjourns	

Actions / Issues

Issue / Feature	Impact/Priority	Status	Reporter/Requestor

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner
Mayo	• Sonja Hamilton • Jean Hanson • Brad Anderson
NCI	Mary Agnes

Meeting Notes

- Mayo internal meeting regarding the caAERS adoption plan today at 3pm.
- Review of Dashboard
  - Task Notifications box should be reduced and display "There are no notifications to display" when there are no notifications.
  - Expedited Reporting box: Instead of a clickable report name, have a java script action button with appropriate actions (Edit, Withdraw, Amend, Add AEs, Export, Submit).
  - Expedited Reporting box: Suggestion to split apart the sections for Past Due reports (existing), In-process reports, and Submitted reports.
  - An Adverse Events box should be included listing the recent courses where AEs were entered (this should be a scrollable list too) and displaying the Study, Subject, Course, and # AEs.
  - A portlet including the Enter AE autocompleter for study, subject, and course should be included on the dashboard.

06-11-10 WFU Meeting Minutes - caAERS

Meeting Information

When: Friday 1-2pm ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
1pm	Administrative Items	Paul Baumgarnter
	Review New / Open issues	
2pm	Meeting Adjourns	

Actions / Issues

Issue / Feature	Impact/Priority	Status	Reporter/Requestor

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner
WFU	• Bob Morrell • Del
NCI	Mary Agnes

Meeting Notes

- Bug?: Labs not showing up after selecting category
  - Issue was that all lab fields were Not Applicable in the Report Definitions.
- Bug: Microbiology test information (site, date, infectious agent) not printed on MedWatch
- Action(Paul): Document the fields which cannot be made N/A
- New Feature: Need to list the "Additional Information" selected on the MedWatch report and/or list out (or remind) user to include any selected pieces of Additional Information.
  - The additional information check boxes, if selected, need to do something.
- Improvement: Advanced Search "Export search results ..." should be a button.
- Improvement: Attribution section needs to be printed on the MedWatch (under Describe Event section).

06-17-10 WFU Meeting Minutes - caAERS

Meeting Information

When: Thursday 11:00am-12:00pm ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
11am	Administrative Items	Paul Baumgarnter
	Status/Issues	
12pm	Meeting Adjourns	

Actions / Issues

Issue / Feature	Impact/Priority	Status	Reporter/Requestor

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner • Wes Wiggins

WFU	• Bob Morrell

Meeting Notes

Looking forward

- Research Base
  - Routine AEs
  - Adding affiliate site patients
    - May want to use import
  - Submission to the FDA
    - This is big since the completion of a report in caAERS takes longer than paper
- CRM (Clinical Resource Management)
  - Group that runs all of the treatment trials
  - WFU doesn't have any of their own treatment trials that require CTEP reporting
  - WFU wants to be part of the CALGB pilot
- Data Sharing
  - Need to have data sharing addressed, perhaps at the CTMS F2F

Task for WFU:

- Differences in time for paper vs. electronic

New feature:
Have the fields for an appropriate report type (i.e. MedWatch) be flagged in the Mandatory Fields page.
Have the MedWatch display multiple pages better
Support for attachements or a flag that an attachment is being sent.

06-22-10 Mayo Meeting Minutes - caAERS

Meeting Information

When: Tuesday 11:30am-12:30pm ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
11:30am	Administrative Items	Paul Baumgarnter
	Review New / Open issues	
12pm	Meeting Adjourns	

Actions / Issues

Issue / Feature	Impact/Priority	Status	Reporter/Requestor

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner

Mayo	• Sonja Hamilton • Jean Hanson • Brad Anderson
NCI	Mary Agnes

Meeting Notes

- Additional studies for possible piloting: N0871 and N0879
  - N0879 (Robbin) - 2 patients enrolled of up to 75; Multiple drugs; No expected issues from PI; non-NCI IND; CTCAE v4.0
  - N0871 (Sarah Hanson) - non-NCI IND; CTCAE v3.0
- Robbin - CRA's likely to find the term in the CTCAE prior to going into caAERS (especially w/ v4.0).
  - Need to assess the ability of the autocompleter to function as a search mechanism for CTCAE terms. (Example: low glucose, how to find "hypoglycemia").
  - For labs, Mayo CRA's typically would not enter the actual lab value into the verbatim. This could be a useful process change especially in support of audits for AEs and grades.
- Mayo internal meeting regarding the caAERS adoption plan today at 3pm.
- Review of Dashboard
  - Task Notifications box should be reduced and display "There are no notifications to display" when there are no notifications.
  - Expedited Reporting box: Instead of a clickable report name, have a java script action button with appropriate actions (Edit, Withdraw, Amend, Add AEs, Export, Submit).
  - Expedited Reporting box: Suggestion to split apart the sections for Past Due reports (existing), In-process reports, and Submitted reports.
  - An Adverse Events box should be included listing the recent courses where AEs were entered (this should be a scrollable list too) and displaying the Study, Subject, Course, and # AEs.
  - A portlet including the Enter AE autocompleter for study, subject, and course should be included on the dashboard.

06-24-10 WFU Meeting Minutes - caAERS

Meeting Information

When: Thursday 11:00am-12:00pm ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
11am	Administrative Items	Paul Baumgarnter
	Status/Issues	
12:30pm	Meeting Adjourns	

Actions / Issues

Issue / Feature	Impact/Priority	Status	Reporter/Requestor

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner

WFU	• Bob Morrell • Del Jones
NCI-CBIIT	• Mary Agnes Templeton

Meeting Notes

Looking forward

- Reviewing and updating the rules for Research Base
  - The general feeling at WFU is that they are too strict
  - Would like to re-establish a base rule set that can be used as the starting part for generating protocol specific rules.

- Reviewed the Verbatim first functionality
  - WFU requires verbatim for labs to indicate which lab the AE was based upon (due to the fact that multiple different labs support the same AE).
  - Acceptable to have lab name (and value possibly?) entered in verbatim. This would be much simpler from a user interface perspective and a CRA training perspective.
  - Having a separate lab check box would be confusing and inconsistent - Further, for some AE the verbatim IS needed.

- CTEP still needs to define in official guidance what the verbatim is
  - Is it what is in the chart?, what the patient said?, what the doctor said?, what the nurse noted?
  - If any of the above, is there a need to record the source of the verbatim?

- New Feature Request: Add a field for lab value to be specifically entered.
  - Question: Would there also need to be a reference vocabulary to select the lab name? If not, how would the system know which lab the lab value corresponded to (especially relevant for AE's that can be supported by multiple different labs).

- CTCAE v4.0 lab question
- Proteinurea = +2 is a grade 2 Proteinurea. This also qualifies as a grade 1 Chronic Kidney Failure. Should both AEs be entered? Another example would be for Creatinine.

- Research Base
  - Routine AEs
  - Adding affiliate site patients
    - May want to use import
  - Submission to the FDA
    - This is big since the completion of a report in caAERS takes longer than paper

- CRM (Clinical Resource Management)
  - Group that runs all of the treatment trials
  - WFU doesn't have any of their own treatment trials that require CTEP reporting
  - WFU wants to be part of the CALGB pilot

- Data Sharing
  - Need to have data sharing addressed, perhaps at the CTMS F2F

Task for WFU:

- Differences in time for paper vs. electronic

New feature:
Have the fields for an appropriate report type (i.e. MedWatch) be flagged in the Mandatory Fields page.
Have the MedWatch display multiple pages better
Support for attachements or a flag that an attachment is being sent.

07-08-10 WFU Meeting Minutes - caAERS

Meeting Information

When: Thursday 11:00am-12:00pm ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
11am	Administrative Items	Paul Baumgarnter
	Status/Issues	
12pm	Meeting Adjourns	

Actions / Issues

Issue / Feature	Impact/Priority	Status	Reporter/Requestor

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner
WFU	• Bob Morrell • Del Jones
NCI-CBIIT	• Mary Agnes Templeton

Meeting Notes

- Once WFU expands the use of caAERS to other departments, how will it be ensured that the correct set of rules is fires? Is there a need for institutional subdivisions in caAERS?

Three options right now:

1. Create a new organization in caAERS for each department and author the rule set for that department
2. Create a protocol specific rule set for each study
3. Author the rules to include the therapy type as a condition since all of the departments are divided based upon therapy type.

Need to analyze this further.

v2.0.1

- Issue with deleting study diseases - after adding, unable to delete unless the "SAVE" button has been clicked first.
- Issue with "Other, specify" study diseases - if a existing condition has already been selected, it is only cleared if the clear button is clicked.
- Issue with "Other, specify" when no matches are found, the drop-down prevents clicking "Add Condition" - need to add "Add Condition" to the dropdown (i.e. "No matches found - Add as a new condition")
- Need a new clear button (not intuitive).
- Need to remove status from caAERS (not a AE related field) - agreed by MA, BM
- Study set-up complete - need to update the label and make it consistent.
- As a Study Coordinator or Site Coord at the coord center or sponsor, unable to search for and see studies. Problem is fix if the organization is added as a study site.

Looking forward

- Reviewing and updating the rules for Research Base
  - The general feeling at WFU is that they are too strict
  - Would like to re-establish a base rule set that can be used as the starting part for generating protocol specific rules.
- Reviewed the Verbatim first functionality
  - WFU requires verbatim for labs to indicate which lab the AE was based upon (due to the fact that multiple different labs support the same AE).
  - Acceptable to have lab name (and value possibly?) entered in verbatim. This would be much simpler from a user interface

perspective and a CRA training perspective.
    - Having a separate lab check box would be confusing and inconsistent - Further, for some AE the verbatim IS needed.

- CTEP still needs to define in official guidance what the verbatim is
    - Is it what is in the chart?, what the patient said?, what the doctor said?, what the nurse noted?
    - If any of the above, is there a need to record the source of the verbatim?

- New Feature Request: Add a field for lab value to be specifically entered.
    - Question: Would there also need to be a reference vocabulary to select the lab name? If not, how would the system know which lab the lab value corresponded to (especially relevant for AE's that can be supported by multiple different labs).

- CTCAE v4.0 lab question
- Proteinurea = +2 is a grade 2 Proteinurea. This also qualifies as a grade 1 Chronic Kidney Failure. Should both AEs be entered? Another example would be for Creatinine.

- Research Base
    - Routine AEs
    - Adding affiliate site patients
        - May want to use import
    - Submission to the FDA
        - This is big since the completion of a report in caAERS takes longer than paper

- CRM (Clinical Resource Management)
    - Group that runs all of the treatment trials
    - WFU doesn't have any of their own treatment trials that require CTEP reporting
    - WFU wants to be part of the CALGB pilot

- Data Sharing
    - Need to have data sharing addressed, perhaps at the CTMS F2F

Task for WFU:

- Differences in time for paper vs. electronic

New feature:
Have the fields for an appropriate report type (i.e. MedWatch) be flagged in the Mandatory Fields page.
Have the MedWatch display multiple pages better
Support for attachements or a flag that an attachment is being sent.

07-21-10 DCP Meeting Minutes - caAERS

Meeting Information

When: Wednesday 11:00am-12:00pm ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
11am	Administrative Items	
12pm	Meeting Adjourns	

Attendees

Team	Attendee
SemanticBits	Paul Baumgartner
DCP	Anne Tompkins
CCSA	Linda Doody

Meeting Notes

- Update caAERS generic grading scale for CTCAE v4 and send updated screenshot
- Send Anne screenshots of selecting report formats, the report itself (MedWatch, CIOMS, DCP).
- Rules screenshots TBD

03-02-10 Roswell Park Meeting Minutes - caAERS

Meeting Information

When: Tues 1-2pm ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
1pm	Administrative Items	Paul Baumgartner
	Discussion of parallel pilot • Scope • Time frame	
2pm	Meeting Adjourns	

Open Actions/Issues Items

Action/Issue	Assigned to	Due Date	Status
Request CTEP for list of RPCI AdEERS from the past 6months	Paul	12/07/09	Requested
Add feature request to allow "enabling" rules modifications upon save	Paul	TBD	Open
Change label of "Outcome" to "Seriousness Criteria"	Paul	07/15/09	Open
Add feature request for question "Does this place the subject at an increased risk?"	Paul	TBD	Open
Add feature request to support IRB usage and tracking of reports	Paul	TBD	Open
Evaluate adding "Unanticipated problem" to the list of seriousness criteria	Paul	TBD	Open
Evaluate adding rules effective dates and rules versions for the same rule set to support rules changing over time	Paul	TBD	Open
Evaluate new feature of allowing rules to be assigned to the study without having to author a study specific rule	Paul	TBD	Open
Problem w/ AdEERS report stuck in-progress	SB	ASAP	• CA: run script to change status to "failed" • PA: Issue being fixed
Issue w/ enabling rule	SB (CAAERS-2280)	7/10/09	Open
Issue w/ disease not being saved during reporting	SB	TBD	Open
Issue w/ edit AE link throwing error	SB	TBD	Open

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner
RPCI	• Ken Quinn • Jen • Haidee • Kathy • Dawn • Diane

Meeting Notes

Pilot

- One drug, two administrations for the same TAC (bolus followed by 2-day continuous administration).
  - AdEERS does not support this
  - Industry trials reportedly want to know which is from bolus vs continuous administration.
- New Feature - need to be able to withdraw a submitted report
- Performance painfully slow - need to set-up a call with Kumar and Biju
- The "retreated" question is showing as a required field.

03-15-10 Roswell Park Meeting Minutes - caAERS

Meeting Information

When: Monday 10am-11am ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
10am	Administrative Items	Paul Baumgartner
	Discussion of parallel pilot • Scope • Time frame	
11am	Meeting Adjourns	

Open Actions/Issues Items

Action/Issue	Assigned to	Due Date	Status
Request CTEP for list of RPCI AdEERS from the past 6months	Paul	12/07/09	Requested

Add feature request to allow "enabling" rules modifications upon save	Paul	TBD	Open
Change label of "Outcome" to "Seriousness Criteria"	Paul	07/15/09	Open
Add feature request for question "Does this place the subject at an increased risk?"	Paul	TBD	Open
Add feature request to support IRB usage and tracking of reports	Paul	TBD	Open
Evaluate adding "Unanticipated problem" to the list of seriousness criteria	Paul	TBD	Open
Evaluate adding rules effective dates and rules versions for the same rule set to support rules changing over time	Paul	TBD	Open
Evaluate new feature of allowing rules to be assigned to the study without having to author a study specific rule	Paul	TBD	Open
Problem w/ AdEERS report stuck in-progress	SB	ASAP	• CA: run script to change status to "failed" • PA: Issue being fixed
Issue w/ enabling rule	SB (CAAERS-2280)	7/10/09	Open
Issue w/ disease not being saved during reporting	SB	TBD	Open
Issue w/ edit AE link throwing error	SB	TBD	Open

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner
RPCI	• Ken Quinn • Jen • Haidee • Kathy • Dawn • Diane

Meeting Notes

Pilot

- One drug, two administrations for the same TAC (bolus followed by 2-day continuous administration).
  - AdEERS does not support this
  - Industry trials reportedly want to know which is from bolus vs continuous administration.
  - Not sure which field would capture IV-push vs IV Continuous (CIV). Probably these would be two separate routes (IV-push, CIV).
  - Still being debated internally at RPCI regarding relavence for AE reporting.
  - The differences in these seem to be relevant since the dose in the body would be different from a push vs a CIV.
  - Not sure if this is scientifically relevant or just clinically relevant.
- New Feature - need to be able to withdraw a submitted report
- Performance painfully slow
  - Observed performance today - looked good
  - Saving Rules is one page that gets hung up.
  - Other pages in the report flow occassionally get stuck (spinner just spins)
  - Need to set-up a call with Kumar and Biju to figure out a mechanism to monitor the progress.
- The "retreated" question is showing as a required field.

- Troubleshooting the Prior Therapy w/ NULL agent issue created by Nancy
  - Fixed with a SQL script by Biju
  - Unable to reproduce now - keep an eye on it
- Continuing to perform parallel testing
- Need to test non-AdEERS reports and check the status in Track Reports
- Target v2.5 as the production pilot version.
  - Withdraw is a must have.

04-05-10 Roswell Park Meeting Minutes - caAERS

Meeting Information

When: Monday 10am-11am ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
10am	Administrative Items	Paul Baumgartner
	Discussion of parallel pilot • Scope • Time frame	
11am	Meeting Adjourns	

Open Actions/Issues Items

Action/Issue	Assigned to	Due Date	Status
Request CTEP for list of RPCI AdEERS from the past 6months	Paul	12/07/09	Requested
Add feature request to allow "enabling" rules modifications upon save	Paul	TBD	Open
Change label of "Outcome" to "Seriousness Criteria"	Paul	07/15/09	Open
Add feature request for question "Does this place the subject at an increased risk?"	Paul	TBD	Open
Add feature request to support IRB usage and tracking of reports	Paul	TBD	Open
Evaluate adding "Unanticipated problem" to the list of seriousness criteria	Paul	TBD	Open
Evaluate adding rules effective dates and rules versions for the same rule set to support rules changing over time	Paul	TBD	Open
Evaluate new feature of allowing rules to be assigned to the study without having to author a study specific rule	Paul	TBD	Open
Problem w/ AdEERS report stuck in-progress	SB	ASAP	• CA: run script to change status to "failed" • PA: Issue being fixed
Issue w/ enabling rule	SB (CAAERS-2280)	7/10/09	Open

Issue w/ disease not being saved during reporting	SB	TBD	Open
Issue w/ edit AE link throwing error	SB	TBD	Open

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner
RPCI	• Ken Quinn • Jen • Kathy • Dawn • Diane

Meeting Notes

Study Set up

- Wrong TACs entered (CALGB 10603) "RemInd 1" "RemInd 2"
  - AdEERS rejects
  - Unable delete
  - Unable to edit TAC code if already associated with course
  - Need to be able to update TAC if needs to be corrected
  - Need to be able to delete TAC if not needed
  - Need to be able to not send the TAC to AdEERS (i.e. send as "Other") if it doesn't match.
    - Perhaps, if it is a non-CTEP IND or a commercial agent only study, then send "Other" with the TAC description as the description.
-
  - Updated the courses to refer to a different tac "Other"
  - When the TAC is updated at the enter AEs level, it must update in the report(s) as well.
- stdb.out log file is huge
  - 3Gb
  - 1Mb already and hasn't done anything
-
  - Need AdEERS beta system to be in synch with production (requirement for AdEERS)
  - AdEERS beta being used as source information for protocol data entered into caAERS
  - The data must match as folks are using beta to test submissions prior to submission to production.

06-14-10 Roswell Park Meeting Minutes - caAERS

Meeting Information

When: Monday 10am-11am ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
10am	Administrative Items	Paul Baumgartner

	Discussion of parallel pilot • Scope • Time frame	
11am	Meeting Adjourns	

Open Actions/Issues Items

Action/Issue	Assigned to	Due Date	Status
Request CTEP for list of RPCI AdEERS from the past 6months	Paul	12/07/09	Requested
Add feature request to allow "enabling" rules modifications upon save	Paul	TBD	Open
Change label of "Outcome" to "Seriousness Criteria"	Paul	07/15/09	Open
Add feature request for question "Does this place the subject at an increased risk?"	Paul	TBD	Open
Add feature request to support IRB usage and tracking of reports	Paul	TBD	Open
Evaluate adding "Unanticipated problem" to the list of seriousness criteria	Paul	TBD	Open
Evaluate adding rules effective dates and rules versions for the same rule set to support rules changing over time	Paul	TBD	Open
Evaluate new feature of allowing rules to be assigned to the study without having to author a study specific rule	Paul	TBD	Open
Problem w/ AdEERS report stuck in-progress	SB	ASAP	• CA: run script to change status to "failed" • PA: Issue being fixed
Issue w/ enabling rule	SB (CAAERS-2280)	7/10/09	Open
Issue w/ disease not being saved during reporting	SB	TBD	Open
Issue w/ edit AE link throwing error	SB	TBD	Open

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner
RPCI	• Ken Quinn • Jen • Kathy • Dawn • Diane

Meeting Notes

Status of CTEP

- Meeting this week (hopefully) with CTEP
- Paul will keep Ken posted on status

- Ken would like to see if we can get some dates from CTEP regarding when they will allow pilot sites. A date is viewed as important to drive this.

Interface for participants

- Need study information
- Need to ensure study is created in caAERS first.
  Option 1: Load all studies into caAERS (even those that won't be reported from caAERS).
  - Question: How does Mayo (and CALGB) ensure they are only sending participants who are on studies that are already in caAERS.
  - Answer (Brad): Mayo filters the patients that are included in caAERS to ensure only patients on studies in caAERS are sent. If a study is added to caAERS later, Mayo creates all existing patients in caAERS. The create participant message is sent based on a query of the log table which tracks which subjects have been added to caAERS already.
    Option 2: Restrict patient interface to only use those studies in caAERS.

Paul's thoughts: Build a study interface so that when studies are built in eRT they get messaged to caAERS
Also, utilize Option 2 to ensure that only studies in caAERS have participants sent.

Question: What is the required information for importing a study?
Question: Do studies entered via import or message require the Data Entry Complete button to be checked?
Question: Is there a way to check the flag via import or message (rather than from UI)?
Question: If a new study-subject is messaged to caAERS via an update participant message, what happens?

06-21-10 Roswell Park Meeting Minutes - caAERS

Meeting Information

When: Monday 10am-11am ET
Phone: 1-877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
10am	Administrative Items	Paul Baumgartner
	Discussion of parallel pilot • Scope • Time frame (to be mapped out)	
	No meetings for next 3 weeks	
11am	Meeting Adjourns	

Open Actions/Issues Items

Action/Issue	Assigned to	Due Date	Status
Request CTEP for list of RPCI AdEERS from the past 6months	Paul	12/07/09	Requested
Add feature request to allow "enabling" rules modifications upon save	Paul	TBD	Open
Change label of "Outcome" to "Seriousness Criteria"	Paul	07/15/09	Open
Add feature request for question "Does this place the subject at an increased risk?"	Paul	TBD	Open
Add feature request to support IRB usage and tracking of reports	Paul	TBD	Open
Evaluate adding "Unanticipated problem" to the list of seriousness criteria	Paul	TBD	Open

Evaluate adding rules effective dates and rules versions for the same rule set to support rules changing over time	Paul	TBD	Open
Evaluate new feature of allowing rules to be assigned to the study without having to author a study specific rule	Paul	TBD	Open
Problem w/ AdEERS report stuck in-progress	SB	ASAP	• CA: run script to change status to "failed" • PA: Issue being fixed
Issue w/ enabling rule	SB (CAAERS-2280)	7/10/09	Open
Issue w/ disease not being saved during reporting	SB	TBD	Open
Issue w/ edit AE link throwing error	SB	TBD	Open

Attendees

Team	Attendee
SemanticBits	• Paul Baumgartner
RPCI	• Ken Quinn • Jen • Kathy • Dawn • Diane

Meeting Notes

Status of CTEP

- Meeting this week (hopefully) with CTEP
- Paul will keep Ken posted on status
- Ken would like to see if we can get some dates from CTEP regarding when they will allow pilot sites. A date is viewed as important to drive this.

Interface for participants

- Need study information
- Need to ensure study is created in caAERS first.
  Option 1: Load all studies into caAERS (even those that won't be reported from caAERS).
  - Question: How does Mayo (and CALGB) ensure they are only sending participants who are on studies that are already in caAERS.
  - Answer (Brad): Mayo filters the patients that are included in caAERS to ensure only patients on studies in caAERS are sent. If a study is added to caAERS later, Mayo creates all existing patients in caAERS. The create participant message is sent based on a query of the log table which tracks which subjects have been added to caAERS already.
    Option 2: Restrict patient interface to only use those studies in caAERS.

Paul's thoughts: Build a study interface so that when studies are built in eRT they get messaged to caAERS
Also, utilize Option 2 to ensure that only studies in caAERS have participants sent.

Question: What is the required information for importing a study?
Question: Do studies entered via import or message require the Data Entry Complete button to be checked?
Question: Is there a way to check the flag via import or message (rather than from UI)?
Question: If a new study-subject is messaged to caAERS via an update participant message, what happens?
Answer: It is rejected with the response of "participant does not exist"

08-05-10 All Hands Meeting Minutes - caAERS

Meeting Information

When: every 1st Thursday 12-1pm ET
Phone for today: 877-810-8617
Passcode: 2764499
Web: http://ncicb.centra.com
Meeting ID: caAERS Project

Agenda

Time	Item	Facilitator
12pm	Welcome	Paul Baumgartner
	Announcements	Paul
	Adopter updates	Adopters
	Open forum	Adopters
	Upcoming activities	Paul
1pm	Meeting adjourns	

Meeting Notes

Action Items

Task	Assignees	Status

Attendees

SemanticBits

Paul
Wesley

Wake

Bob
Del
Steven

Mayo

Brad

CALGB

Debbie
Robin
Nimesh

NCI

Anne Tompkins (DCP)
Mary Agnes Templeton (CBIIT)
Brenda Maeske (SAIC)

Roswell Park

Haidee
Ken

City of Hope

Susan Pannoni

Announcements

- v2.0 Released - Monday 12/14/2009
  - Part of the caBIG Suite v2.0 release on the same day
  - Hardened of all functionality currently in caAERS
  - Support for searching the NCI Enterprise Services of person, organization, protocol abstraction, and the related correlations between them (aka - the "COPPA" services) - caXchange required to use this functionality.
  - Silver compatibility package already submitted - approval expected early 2010.
- caAERS-AdEERS pilot is LIVE at Mayo Clinic Rochester
  - Two expedited reports to date - 6 submissions
  - caAERS-AdEERS pilot summary

Adopter Updates

Mayo

- One report started in AdEERS, Jean trying to intercept so that it can be done in caAERS.

CALGB

- Installed v2.0 yesterday, minus SA upgrades. Will be updating UAT system for next week's testing.

WFU

- Steven needs help to copy the PostGres DB

Roswell Park

- Parallel pilot
  - 7 studies
  - Also entering studies on the fly
  - Goal is 8 weeks / ~20 reports
  - Expedited reporting only (just for the pilot)
  - Studies requiring MedWatch & AdEERS reporting
  - Reporting to IRB is outside of scope, but will need to be into production pilot

ISSUE: System seems slow

SOAP security fix worked - web services moving forward

Open Forum

- Need to revisit use case for getting data OUT of caAERS
  - Meeting with WFU stats guys
  - RPCI also interested

Upcoming Activities

- Mayo continuing pilot
- WFU upgrading to v2.0 on production and adding a Yoga intervention trial to caAERS
- CALGB upgrading to v2.0, functional testing sessions in Jan, pilot still anticipated in Spring 2010
- RPCI beginning parallel pilot

New feature activities:

Key	Summary	Issue Type
CAAERS-3130	Support entry of verbatim first	New Feature
CAAERS-3281	Addition of field "Does this place participant at increased risk?" to expedited flow	New Feature
CAAERS-3390	Prevent user from manually selecting wrong type of report for study	Improvement
CAAERS-3397	User is able to delete required sub-sections resulting in a failed submission	Improvement
CAAERS-3461	Allow configuration of Mandatory, Optional, and N/A fields on capture AE screen	Improvement
CAAERS-2438	Develop a generic and dynamic caAERS report template	New Feature
CAAERS-3457	Support the usage of caXchange and COPPA in a stand-alone mode	New Feature
	AE Enterprise Service	New Feature
CAAERS-3452	Analysis for support electronic submission to the FDA	New Feature
CAAERS-1910	Analysis for expanding AE query API and Service	Improvement
CAAERS-3322	PA services to support: Disease, Agent, Arm, IND	New Feature

User Acceptance Testing

Add Study Intervention (UAT)

User Story	Add intervention information to the study record.
Main Scenario Description	1. Log in as Study Creator 2. Click Studies tab 3. Click Enter Study 4. Enter mandatory study details 5. Click Save & Continue 6. On the Interventions screen, click Add under Agents 7. In the "Agent" auto-suggestion box search begin typing and select an agent from the results list 8. Click Add under Devices 9. Select "Other" 10. Complete all of the fields for the device 11. Click Add under Other Interventions 12. Select the intervention type 13. Enter other intervention name and description 14. Click Save and Continue
Alternative Scenario	1. Follow Main Scenario through Step 8 2. Begin typing a term in the auto-suggestion box 3. Select the desired term from the resulting list
Special Considerations	
Tester Information	
Test Results	
General Comments	
Specific Issues	
Issues to Raise	

Report Adverse Event with Interventions (UAT)

User Story	Report an adverse events for a study with interventions
Main Scenario Description	1. Log in as Adverse Event Reporter 2. Click the Adverse Events tab 3. In the 'Study' autosuggestion box, begin typing 'User Acceptance' 4. When **UAT-S1** appears in the list, select it (your user must be authorized to access study "UAT-S1") 5. In the 'Subject' autosuggestion box, begin typing the name or ID of the subject for whom you want to report an AE 6. Select the course,'COURSE TITLE' a. Click 'Edit' to create a new course if none exists 7. Click 'Continue' 8. On the Adverse Events screen, enter 'TEXT' in the verbatim field and click 'Add' 9. In the Grade section, select 4: Life-threatening consequences, urgent intervention indicated 10. For "Attribution to study intervention", select 'Definite' 11. For "Did AE cause hospitalization?", select Yes 12. Click 'Save & Report' 13. Confirm that the recommended action is to complete a CIP Expedited Report 14. Click 'Report'
Alternative Scenario	
Special Considerations	
Tester Information	
Test Results	
General Comments	
Specific Issues	
Issues to Raise	

User Acceptance Testing - caAERS 1.x

Note
This page is an archive.

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 version 1.7

Study Module

- - Configure Expected AEs

Adverse Events Module

- Enter Expected and Unexpected AEs

UAT Scenarios for version 1.6

UAT Scenarios v1.6.doc

Version 1.6 UAT Results

- Rules Module
  - Export a report definition
  - Import a report definition
- Study Module
  - Add a condition instead of a disease
  - Add "other - specify" in solicited AE terms
- Subject Module
  - Assign a subject a condition instead of a disease
- AE Module
  - Access started expedited reports from the Enter AE module
  - Unlock/amend an expedited report from the Enter AE module
  - Add verbatim to solicited AEs
  - Save a partially complete evaluation period (observed AEs don't have all attributes)
  - Save a Medwatch PDF (Wake)
- Documentation
  - Review User Guide
  - Review Admin Guide
  - Review Help Files

UAT Scenarios for version 1.5.1

UAT Scenarios v1.5.doc

Version 1.5.1 UAT Results

- Admin Module
  - Create research staff
  - Create investigator (per Wake Forest's request)
- Study Module
  - Add an investigator to a study
- 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 v 1.3

General UAT Scenarios.doc

Technical UAT Scenarios.doc

Version 1.3 UAT Results

- Study Module
  - Add solicited AEs to a study
  - Add an evaluation period type to a study
  - Delete an existing evaluation period type from a study
  - create instructions to be displayed in the AE module for an evaluation 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
  - import MedDRA v 10

UAT Scenarios for future testing

- Study Module
  - Enter expected AEs
- AE Module
  - Add AEs and view the automatic determination of expectedness
- 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

AE Module UATs

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

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

Local Install UATs

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"

Study Module UATs - caAERS

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?

Technical UAT Results

General Information

Tests release early August 2008. No test results received thus far

Testers

Mayo	Wake	CALGB

Test Results

Import Tests 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
• 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						

Test for Local Installation version of caAERS 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

Install caAERS - upgrade						
Import MedDRA v 10						

General Comments

Adopter Site (Mayo for example)

-

Version 1.3 UAT Results

General Information

Testers

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

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 go back to the previous screen after adding terms for one category 3. (Jean) Search function did not work when searching by study ID (N027D) 4. (Jean) I left short title and typed "N" and then a list was provided. Not intuitive to hold ctl/alt key when adding multiple terms for one category. 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. 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. 7. (Del) In choosing multiple AE's the categories came down then 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.

• delete reporting period type • delete solicited AEs	y,y	y	y	y,y,y	y	1. (Jean) It would be nice to have the word "delete" show on the screen when the cursor is hovered over the red X 2. (Debbie) Liked confirm delete question 3. (Del) I liked the ease of adding the reporting period type. Deleting the solicited AE's was also easy. 4. (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 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	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 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	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	1. (Robbin) error messages 2. (Debbie) Steps worked, but got errors on steps 2 & 3 (contact admin, no details)
Create a study manually	n,n		y		y	1. (Debbie) Did not like having 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. 2. (Debbie) Confirmation page is not very readable. Suggestion is to remove blue overlay 3. (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 - change the type	y,n	y	y	y, y		1. (Debbie) - IE6, so take with a grain of salt: When I tried to 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. 2. (Sarah) Easy to modify text; The order of each reporting period is unable change without deleting each period and reentering them.
modify a reporting period - change the dates	y,n	y	y	y,n		1. (Debbie) Could the save successful message be displayed on the prior screen? 2. (Sarah) On the reporting period page, there are no dates viewable
document baseline AEs	n,n	y	y		n	1. (Debbie) Tested IE6.0, problems 2. (Bob) No, there is no obvious place to go to enter baseline; There is no obvious link to 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 3. (Bob) arm assignment should not be a required field for baseline 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
document treatment AEs	y,n		n	n		1. (Robbin) Unable to enter error message each time I try to save an AE
save incomplete ae data in a reporting period	y,n	y	y	n	n	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. there is no warning when you leave a window that your work has not been saved. 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.
select a different report than suggested	n,n	y	y	n		1. (Debbie) Tested IE6.0, error message 2. (Sarah) - The link to a patient's study calendar brought up a 'page not found' window. 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 to convert property value....."

Add more/modify existing AEs for a reporting period	n,n	y	y		sorta	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 from solicited templates (maybe put the add at the bottom). This will prevent duplicates 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
complete an expedited report	n,n	y	y		n,n	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 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 created an error. Went back and added in all the missing values, still no report required and it created another missing row 3. (Bob) In the review and report screen the columns do not match up

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.

Version 1.5.1 UAT Results

General Information

Testers

Mayo	Wake	CALGB
	Del Sarah	Debbie Susan

Version 1.5.1 specific tests

Admin Module Summary

UAT Case	Wake Tested? Y/N	CALGB Tested? Y/N	Passed IE 7.0? Y/N	Passed Firefox? Y/N	Bugs, Issues
Add a research staff			Y	Y Y	Susan - Could research staff be affiliated w more than one site, similar to investigators
Add an investigator			Y	Y Y	Debbie - could the investigator number be loaded from somewhere?

Study Module Summary

UAT Case	Wake Tested? Y/N	CALGB Tested? Y/N	Passed IE 7.0? Y/N	Passed Firefox? Y/N	Bugs, Issues
Assign an investigator to a study			Y	Y Y	Debbie - Curious why if active in the system, we have to indicate status again. Is this a Cancer Center requirement?

Subject Module Summary

UAT Case	Wake Tested? Y/N	CALGB Tested? Y/N	Passed IE 7.0? Y/N	Passed Firefox? Y/N	Bugs, Issues

Add a subject and add medical history			Y	Y Y	Sarah - • Shouldn't be able to add 3 different identifiers w/o getting an error • Helpful if only one primary ID could be selected (is allowing multiple primary ids?) • Using the Back button on the browser causes an error and all info is lost • Should get error/warning if you add a future date for date of initial diagnosis • Is not clear that 'Add' means 'Save' on the medical history pageSusan - • Should get error/warning if you add a future date for date of initial diagnosis • Should get error/warning if no end date is provided for conmed when it's indicated that it has been discontinued • Auto-fill box did not work for prior therapy agent • CALGB does not use names, can we change the label to name/initials? • CALGB patient identifier should be group identifier by default Debbie - Can the study subject identifier on the choose study screen be taken from the previous screen where the primary indicator was chosen?
Assign a subject to a study and add medical history			Y	Y	Susan - • should cross check between studies for medical history • should include any medical history previously entered Debbie - Can the study subject identifier on the choose study screen be taken from the previous screen where the primary indicator was chosen?

AE Module Summary

UAT Case	Wake Tested? Y/N	CALGB Tested? Y/N	Passed IE 7.0? Y/N	Passed Firefox? Y/N	Bugs, Issues
Create an expedited report			N	N N	Del - didn't require a report, nothing happened when "manually select report" was selected Susan - • expected errors if grade, attribution, hospitalization were blank; at the least it shouldn't have said no reports were required • inconsistent - most of the system has "Add a ..." button when adding a new record, but when adding a routine report, the system has a "click here" text • Received major error (An error occurred while getting property "evaluatedAdverseEvents" from an instance of class gov.nih.nci.cabig.caaers.domain.AdverseEventReportingPeriod) when I went to manage reports, entered a study and pt ID and then clicked Continue. I went through Enter AEs to enter a new report. • After submitting an AE that did not require an AdEERS, it was not clear what I should do to exit or start a new report. I know there are written instructions but I'm not sure not CRAs will read. Also, I think a confirmation telling me that the report was submitted successfully would be nice. • Completing the AdEERS was fairly easy. It was not obvious how to change which event was the primary AE.Debbie - • received error on 10501. • Different study allows user to Enter name here for evaluation period and then doesn't force a description. Or should user be allowed to keep EPOCH name as "Enter name here"? • The click here to add AEs could be a button on the screen so it jumps out at people. It doesn't need to be a huge button

Modify an expedited report				n/a Y	Susan - no way to access submitted report (didn't know the arrows on manage report expanded to show the reports) Debbie - I was forced to attribute the AE to agent or disease. Aren't there times when the AE is related to neither and the AE is required to be reported?
Amend an expedited report				n/a ?	Susan - no way to access submitted report (didn't know the arrows on manage report expanded to show the reports) Debbie - If the AEs were previously entered for a period and the SAE submitted, why does the enter AE screen show the evaluation period as still in-progress?
Create a second expedited report for an evaluation period				N N	Susan - couldn't see the list of the reports that had been submitted to know if a second one had been created Debbie - It does show multiple reports. I saved but didn't submit, how do I get back to submit the report without having to enter another AE that would require reporting?

Tests from version 1.3 that failed

Study Module Summary

UAT Case	Wake Tested? Y/N	CALGB Tested? Y/N	Passed IE 7.0? Y/N	Passed Firefox? Y/N	Bugs, Issues
Delete a reporting period type - reporting period type used				N	Debbie - Couldn't complete, issues reported via mail

AE Module summary

UAT Case	Wake Tested? Y/N	CALGB Tested? Y/N	Passed IE 7.0? Y/N	Passed Firefox? Y/N	Comments
document baseline AEs				N Y/N	Susan - • The attribution, expectedness, and hospitalization fields were still active. I would like to see these inactivated for the baseline forms. • Was able to complete these fields and I just got an error screen, but no specific error telling me that I shouldn't be completing these fields for baseline forms. Debbie - can the system recognize baseline AEs as needing grade only?
save incomplete ae data in a reporting period					
select a different report than suggested					Debbie - General question: The reporting table requires grade 3 and higher unexpected events that are unrelated or unlikely related to treatment to be reported. This reported event may also be unrelated to the disease. The caAERS system will not let you complete the report unless you have an attribution of possible or higher to either the treatment or the disease. Is this a rule that can be modified?

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

Version 1.6 UAT Results

General Information

Testers

Mayo	Wake	CALGB

Version 1.6 specific tests

Rules 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
Export a report definition						
Import a report defintion						

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
Add a condition instead of a disease						
Add "other - specify" in solicited AE terms						

Subject 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
Assign a subject a condition instead of a disease						

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	Bugs, Issues
Access started expedited reports from the Enter AE module						
Unlock/amend an expedited report from the Enter AE module						
Add verbatim to solicited AEs						
Submit a Medwatch PDF (Wake)						

Previous Tests that needed to be tested again

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
Delete a reporting period type - reporting period type used						

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
document baseline AEs						
save incomplete ae data in a reporting period						
Create an expedited report						
Create a second expedited report for an evaluation period						

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