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# 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 <ul style="list-style-type: none"><li>• Scope</li><li>• Time frame</li></ul>	
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	<ul style="list-style-type: none"><li>• CA: run script to change status to "failed"</li><li>• PA: Issue being fixed</li></ul>
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
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## Attendees

Team	Attendee
SemanticBits	<ul style="list-style-type: none"> <li>Paul Baumgartner</li> </ul>
RPCI	<ul style="list-style-type: none"> <li>Ken Quinn</li> <li>Jen</li> <li>Haidee</li> <li>Kathy</li> <li>Dawn</li> <li>Diane</li> </ul>

## 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	<ul style="list-style-type: none"><li>CA: run script to change status to "failed"</li><li>PA: Issue being fixed</li></ul>
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
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SemanticBits	<ul style="list-style-type: none"> <li>• Paul Baumgartner</li> </ul>
RPCI	<ul style="list-style-type: none"> <li>• Ken Quinn</li> <li>• Haidee</li> <li>• Jen</li> <li>• Kathy</li> <li>• Dawn</li> <li>• Diane</li> </ul>

## 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	<ul style="list-style-type: none"><li>• Paul Baumgartner</li><li>• Bill Dyer</li></ul>
Eli Lilly	<ul style="list-style-type: none"><li>• Jackie Gough</li><li>• Dan, Gary, Joe, Paula, Stephanie, others</li><li>• a mix if CDAs (clinical data analysts), data scientists, managers, CRSs</li></ul>

### 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	<ul style="list-style-type: none"><li>• Paul Baumgartner</li></ul>
RPCI	<ul style="list-style-type: none"><li>• Ken Quinn</li><li>• Haidee</li><li>• Jen</li><li>• Kathy</li><li>• Dawn</li><li>• Diane</li></ul>

## 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, related, unexpected, then field for risk should be mandatory
- When an event is serious, related, 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	<ul style="list-style-type: none"> <li>• Paul Baumgartner</li> <li>• Wesley Wiggins</li> </ul>
UCSF	<ul style="list-style-type: none"> <li>• Sarah Davis</li> <li>• Linda Walsh</li> <li>• Ashwin Koleth</li> </ul>
CBIIT	<ul style="list-style-type: none"> <li>• Eve Shally</li> <li>• Christina Warmington</li> <li>• Santosh Joshi</li> </ul>

## 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 occurrence 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, it 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	<ul style="list-style-type: none"><li>• Paul Baumgartner</li></ul>
CTEP	<ul style="list-style-type: none"><li>• Steve Friedman</li><li>• Shanda Finnigan</li></ul>
CBIIT	<ul style="list-style-type: none"><li>• Mary Agnes Templeton</li></ul>
DCP	<ul style="list-style-type: none"><li>• Anne Tompkins</li></ul>
Roswell Park Cancer Institute	<ul style="list-style-type: none"><li>• Ken Quinn</li><li>• Haidee Kolb</li><li>• Kathy Reitz</li></ul>
City of Hope	<ul style="list-style-type: none"><li>• Susan Pannoni</li></ul>
WFU	<ul style="list-style-type: none"><li>• Bob Morrell</li><li>• Del Jones</li></ul>
Mayo	<ul style="list-style-type: none"><li>• Robbin Peterson</li></ul>
CALGB	<ul style="list-style-type: none"><li>• Nimesh Patel</li></ul>
Norton Healthcare	<ul style="list-style-type: none"><li>• Dennis Fryzel</li></ul>

## 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	<ul style="list-style-type: none"> <li>• Paul Baumgartner</li> </ul>
SAIC-F	<ul style="list-style-type: none"> <li>• Jeff McLean</li> <li>• Peter Yan</li> </ul>

## 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

<b>Recommendations:</b> <ol style="list-style-type: none"> <li>1. Remove "CCTS SOA integration technical approach document " as a deliverable in table 6.2.1, and</li> <li>2. Consolidate the "FDA ERSR support technical document" under Task 3.3 in table 6.2.1.</li> </ol> <ul style="list-style-type: none"> <li>• Per deliverable review meeting (02/25/11), 3.3 should describe the central security; 3.4 should describe the FDA electronic submission.</li> </ul>		
<b>TASK ID</b>	<b>DELIVERABLE</b>	<b>Found in:</b>
Task 3.6	Compliance Report for International AE Report	Table
Task 3.6	A Deployment Guideline of Multi-Site Protocol Study	Table and Document
<b>Recommendation:</b> <ol style="list-style-type: none"> <li>1. Remove "Compliance Report for International AE Report" as a deliverable in table 6.2.1</li> </ol> <ul style="list-style-type: none"> <li>• 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.</li> </ul>		
<b>TASK ID</b>	<b>DELIVERABLE</b>	<b>Found in:</b>
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
<b>Recommendations:</b> <ol style="list-style-type: none"> <li>1. Remove "Quarterly adoption and KC support outline report" as a deliverable in table 6.2.1, and</li> <li>2. Consolidate the "caAERS Compliance Reports for BRIDG, BAM, and FDA regulations" under Task 3.7 in table 6.2.1.</li> </ol> <ul style="list-style-type: none"> <li>• 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.</li> </ul>		
<b>TASK ID</b>	<b>DELIVERABLE</b>	<b>Found in:</b>
Task 5.5	caBIG™ Compatibility Review Submission Package	Document
<b>Recommendation:</b> <ol style="list-style-type: none"> <li>1. Add "caBIG™ Compatibility Review Submission Package" as a deliverable in table 6.2.1.</li> </ol> <ul style="list-style-type: none"> <li>• Per deliverable review meeting (02/25/11), add this to table</li> </ul>		

- 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 <ul style="list-style-type: none"> <li>• <b>BAM harmonization and compliance</b></li> <li>• <b>Report and/or Status of BRIDG Information model harmonization and compliance</b></li> <li>• <b>Report and/or Status of caBIG Silver Level Compatibility</b></li> <li>• <b>Report and/or Status of FDA Regulation Compliance</b></li> </ul>	
N/A	<a href="#">Deliverables Readiness Review</a>	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
<b>Iteration 2</b>							
28xs108-1.2	Monthly Status and Financial Reports	Monthly Status and Financial Reports		<a href="#">June 2009 Status Report</a>	7/10/2009	7/10/2009	Delivered
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		<a href="#">June 2009 Issue Logs</a>	7/10/2009	7/10/2009	Delivered
28xs108-1.1	Project Management Plan	Project Management Plan		Project Management Plan	7/21/2009	7/20/2009	Delivered
28xs108-2.1	Scope and Vision Document	Scope and Vision Document	<a href="#">Vision and Scope Document</a>	Vision and Scope Document	7/21/2009	7/20/2009	Delivered
<b>Iteration 3</b>							
28xs108-1.2	Monthly Status and Financial Reports	Monthly Status and Financial Reports		<a href="#">July 2009 Status Report</a>	8/10/2009	8/10/2009	Delivered
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		<a href="#">July 2009 Issue Logs</a>	8/10/2009	8/10/2009	Delivered
<b>Iteration 4</b>							
28xs108-1.2	Monthly Status and Financial Reports	Monthly Status and Financial Reports		<a href="#">August 2009 Status Report</a>	9/10/2009	9/10/2009	Delivered
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		<a href="#">August 2009 Issue Logs</a>	9/10/2009	9/10/2009	Delivered
<b>Iteration 5</b>							
28xs108-1.2	Monthly Status and Financial Reports	Monthly Status and Financial Reports		<a href="#">September 2009 Status Report</a>	10/10/2009	10/10/2009	Delivered



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	Delivered
<b>Iteration 6</b>							
28xs108-1.2	Monthly Status and Financial Reports	Monthly Status and Financial Reports		October 2009 Status Report	11/10/2009	11/10/2009	Delivered
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	Delivered
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	Delivered
<b>Iteration 7</b>							
28xs108-1.2	Monthly Status and Financial Reports	Monthly Status and Financial Reports		November 2009 Status Report	12/10/2009	12/10/2009	Delivered
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	Delivered
<b>Iteration 8</b>							
28xs108-1.2	Monthly Status and Financial Reports	Monthly Status and Financial Reports		December 2009 Status Report	1/10/2010	1/10/2010	Delivered
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	Delivered
<b>Iteration 9</b>							
28xs108-1.2	Monthly Status and Financial Reports	Monthly Status and Financial Reports		January 2010 Status Report	2/10/2010	2/10/2010	Delivered
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	Delivered

<b>Iteration 10</b>							
28xs108-1.2	Monthly Status and Financial Reports	Monthly Status and Financial Reports		<a href="#">February 2010 Status Report</a>	3/10/2010	3/10/2010	Delivered
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		<a href="#">February 2010 Issue Logs</a>	3/10/2010	3/10/2010	Delivered
<b>Iteration 11</b>							
28xs108-1.2	Monthly Status and Financial Reports	Monthly Status and Financial Reports		<a href="#">March 2010 Status Report</a>	4/10/2010	4/10/2010	Delivered
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		<a href="#">March 2010 Issue Logs</a>	4/10/2010	4/10/2010	Delivered
<b>Iteration 12</b>							
28xs108-1.2	Monthly Status and Financial Reports	Monthly Status and Financial Reports		<a href="#">April 2010 Status Report</a>	5/10/2010	5/10/2010	Delivered
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		<a href="#">April 2010 Issue Logs</a>	5/10/2010	5/10/2010	Delivered
<b>Iteration 13</b>							
28xs108-1.2	Monthly Status and Financial Reports	Monthly Status and Financial Reports		<a href="#">May 2010 Status Report</a>	6/10/2010	6/10/2010	Delivered
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		<a href="#">May 2010 Issue Logs</a>	6/10/2010	6/10/2010	Delivered
<b>Iteration 14</b>							
28xs108-1.2	Monthly Status and Financial Reports	Monthly Status and Financial Reports		<a href="#">June 2010 Status Report</a>	7/10/2010	7/10/2010	Delivered
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		<a href="#">June 2010 Issue Logs</a>	7/10/2010	7/10/2010	Delivered
<b>Iteration 15</b>							
28xs108-1.2	Monthly Status and Financial Reports	Monthly Status and Financial Reports		<a href="#">July 2010 Status Report</a>	8/10/2010	8/10/2010	Delivered

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		<a href="#">July 2010 Issue Logs</a>	8/10/2010	8/10/2010	Delivered
<b>Iteration 16</b>							
28xs108-1.2	Monthly Status and Financial Reports	Monthly Status and Financial Reports		<a href="#">August 2010 Status Report</a>	9/10/2010	9/10/2010	Delivered
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		<a href="#">August 2010 Issue Logs</a>	9/10/2010	9/10/2010	Delivered
<b>Iteration 17</b>							
28xs108-1.2	Monthly Status and Financial Reports	Monthly Status and Financial Reports		<a href="#">September 2010 Status Report</a>	10/10/2010	10/10/2010	Delivered
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		<a href="#">September 2010 Issue Logs</a>	10/10/2010	10/10/2010	Delivered
<b>Iteration 18</b>							
28xs108-1.2	Monthly Status and Financial Reports	Monthly Status and Financial Reports		<a href="#">October 2010 Status Report</a>	11/10/2010	11/10/2010	Delivered
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		<a href="#">October 2010 Issue Logs</a>	11/10/2010	11/10/2010	Delivered
<b>Iteration 19</b>							
28xs108-1.1	Project Management Plan	Iteration Implementation Plan		<a href="#">Dec 2010 Plan</a>	12/10/2010	12/10/2010	Delivered
28xs108-1.2	Monthly Status and Financial Reports	Monthly Status and Financial Reports		<a href="#">Nov 2010 Status Report</a>	12/10/2010	12/10/2010	Delivered
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		<a href="#">Nov 2010 issue log</a>	12/10/2010	12/10/2010	Delivered
<b>Iteration 20</b>							
28xs108-1.1	Project Management Plan	Iteration Implementation Plan		<a href="#">Jan 2011 Plan</a>	01/15/2011	01/15/2011	Delivered
28xs108-1.2	Monthly Status and Financial Reports	Monthly Status and Financial Reports		<a href="#">Dec 2010 Status Report</a>	01/15/2011	01/15/2011	Delivered

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		<a href="#">Dec 2010 issue log</a>	01/15/2011	01/15/2011	Delivered
<b>Iteration 21</b>							
28xs108-1.1	Project Management Plan	Iteration Implementation Plan		<a href="#">Feb 2011 Plan</a>	02/10/2011	02/10/2011	Delivered
28xs108-1.2	Monthly Status and Financial Reports	Monthly Status and Financial Reports		<a href="#">Jan 2011 Status Report</a>	02/10/2011	02/10/2011	Delivered
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		<a href="#">Jan 2011 issue log</a>	02/10/2011	02/10/2011	Delivered
<b>Iteration 22 (Feb 2011)</b>							
28xs108-1.2	Monthly Status and Financial Reports	Monthly Status and Financial Reports	<a href="#">Feb 2011 Status Report</a>	<a href="#">Feb 2011 Status Report</a>	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	<a href="#">Use Cases</a> <a href="#">System Requirements</a> <a href="#">AE Mgmt Service Specifications</a> <a href="#">Safety Reporting Service Specifications</a>	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	<a href="#">UML Model</a> <a href="#">Architecture</a> <a href="#">Master Design Document</a>	<a href="#">UML Model v2.3</a> Architecture Master Design Document	At the completion of the project		
28xs108-2.4	Implementation Plan	Implementation Plan	<a href="#">Implementation Plan</a>	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	<a href="#">Maintained and revised caAERS Prioritized Feature List</a>		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	<a href="#">BRIDG v3.0.2 Compliance Report</a> <a href="#">BAM v1.1 Compliance Report</a> 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: <a href="https://demo.semanticbits.com/caaers">https://demo.semanticbits.com/caaers</a>  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 ( <b>install guide; release package</b> )				
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## 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
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### Attendees

Team	Attendee
SemanticBits	<ul style="list-style-type: none"> <li>Paul Baumgartner</li> </ul>
RPCI	<ul style="list-style-type: none"> <li>Ken Quinn</li> <li>Jen</li> <li>Haidee</li> </ul>
CRS Compliance	<ul style="list-style-type: none"> <li>Jan</li> <li>Dawn</li> <li>Nancy</li> </ul>

- Diane
- Val Ping

- Laurie
- Kathy

Absent	• Linda
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## 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 is 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 Baumgartner
	Status/Issues	
12pm	Meeting Adjourns	

### Actions / Issues

Issue / Feature	Impact/Priority	Status	Reporter/Requestor
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### Attendees

Team	Attendee
SemanticBits	<ul style="list-style-type: none"> <li>• Paul Baumgartner</li> </ul>
WFU	<ul style="list-style-type: none"> <li>• Bob Morrell</li> <li>• Del</li> </ul>
NCI	Mary Agnes

### Meeting Notes

- Demo of WFU's autograding system
- Some normal ranges are gender based (i.e. hemoglobin)
- 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 consequences, 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 relevant for Solicited 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 <ul style="list-style-type: none"><li>• pilot discussion</li><li>• internal demo to Linda's group</li><li>• process mapping</li><li>• PSC and caXchange</li></ul>	
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	<ul style="list-style-type: none"><li>• CA: run script to change status to "failed"</li><li>• PA: Issue being fixed</li></ul>
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	<ul style="list-style-type: none"><li>• Paul Baumgartner</li></ul>



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	<ul style="list-style-type: none"><li>Paul Baumgartner</li></ul>

Mayo	<ul style="list-style-type: none"> <li>• Jean Hanson</li> <li>• Brad Anderson</li> <li>• Robbin Peterson</li> <li>• Jennifer Frank</li> </ul>
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 <ul style="list-style-type: none"> <li>• Confirm which rules were run</li> </ul>	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 <ul style="list-style-type: none"> <li>• Most studies don't have course</li> <li>• Need to be able to differentiate between a change in one AE and a new AE</li> <li>• Suggestion is to make AE term + start date the primary key <ul style="list-style-type: none"> <li>• Issue would be that users might end a grade 2 AE and give a new start date when it changed grade</li> </ul> </li> </ul>	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	<ul style="list-style-type: none"> <li>• Paul Baumgartner</li> </ul>
WFU	<ul style="list-style-type: none"> <li>• Bob Morrell</li> <li>• Del</li> <li>• Steven</li> </ul>
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 <ul style="list-style-type: none"> <li>• Confirm which rules were run</li> </ul>	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 <ul style="list-style-type: none"> <li>• Most studies don't have course</li> <li>• Need to be able to differentiate between a change in one AE and a new AE</li> <li>• Suggestion is to make AE term + start date the primary key               <ul style="list-style-type: none"> <li>• Issue would be that users might end a grade 2 AE and give a new start date when it changed grade</li> </ul> </li> </ul>	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	<ul style="list-style-type: none"> <li>• Paul Baumgartner</li> </ul>



WFU	<ul style="list-style-type: none"> <li>• Bob Morrell</li> <li>• Del</li> <li>• Steven</li> </ul>
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 <ul style="list-style-type: none"> <li>• Advanced search</li> </ul>	

11am	Meeting Adjourns	
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## 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	<ul style="list-style-type: none"> <li>CA: run script to change status to "failed"</li> <li>PA: Issue being fixed</li> </ul>
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	<ul style="list-style-type: none"> <li>Paul Baumgartner</li> </ul>
CALGB	<ul style="list-style-type: none"> <li>Ken Quinn</li> <li>Jen</li> <li>Haidee</li> <li>Kathy</li> </ul>

## 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:

- CRC (Clinical Research Coordinator) enters ALL AEs into EDE (eRT/CDMS system)
- CRC then enters Serious AEs into AdEERS
- PI (ideally) determines if this puts the patient at increased risk
- CRC then completes the UP (Unanticipated Problem) form if the AE puts the patient at increased risk
- 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	<ul style="list-style-type: none"><li>• Paul Baumgartner</li></ul>

CALGB	<ul style="list-style-type: none"> <li>• Nimesh Patel</li> <li>• Robert Dale</li> <li>• Amish Shah</li> <li>• Susan Sutherland</li> <li>• Debbie Sawyer</li> <li>• Allision Booth</li> <li>• Kelly (training coordinator)</li> <li>• Robin</li> </ul>
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## 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	<ul style="list-style-type: none"> <li>Paul Baumgartner</li> </ul>
Mayo	<ul style="list-style-type: none"> <li>Jean Hanson</li> <li>Brad Anderson</li> <li>Sonja Hamilton</li> <li>Jennifer Frank</li> <li>Robbin Peterson</li> </ul>
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 (tentative)
  - 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>

## 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

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Time	Item	Facilitator
10am	Administrative Items <ul style="list-style-type: none"> <li>• PSC and caXchange</li> <li>• Meeting w/ UAMS (Kumar to attend)</li> </ul>	Paul Baumgartner
	Discussion of parallel pilot <ul style="list-style-type: none"> <li>• Scope</li> <li>• Time frame</li> </ul>	
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	<ul style="list-style-type: none"> <li>• CA: run script to change status to "failed"</li> <li>• PA: Issue being fixed</li> </ul>
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	<ul style="list-style-type: none"> <li>• Paul Baumgartner</li> </ul>
RPCI	<ul style="list-style-type: none"> <li>• Ken Quinn</li> <li>• Jen</li> <li>• Haidee</li> <li>• Kathy</li> <li>• Dawn</li> <li>• Diane</li> </ul>

## 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	<ul style="list-style-type: none"><li>• CA: run script to change status to "failed"</li><li>• PA: Issue being fixed</li></ul>
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	<ul style="list-style-type: none"><li>• Paul Baumgartner</li></ul>
CALGB	<ul style="list-style-type: none"><li>• Ken Quinn</li><li>• Jen</li><li>• Nancy</li><li>• Haidee</li><li>• Kathy</li><li>• Debbie Kensy - IT Research Coord / Nurse</li><li>• Linda Schmeeder - Dir of Study Implementation (CRC's boss)</li></ul>

## 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	<ul style="list-style-type: none"> <li>Paul Baumgartner</li> </ul>
Mayo	<ul style="list-style-type: none"> <li>Jean Hanson</li> <li>Brad Anderson</li> <li>Robbin Peterson</li> <li>Jennifer Frank</li> <li>Sonja Hamilton</li> </ul>
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
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10am	Administrative Items <ul style="list-style-type: none"> <li>• PSC and caXchange</li> <li>• Meeting w/ UAMS (Kumar to attend)</li> </ul>	Paul Baumgartner
	Discussion of parallel pilot <ul style="list-style-type: none"> <li>• Scope</li> <li>• Time frame</li> </ul>	
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	<ul style="list-style-type: none"> <li>• CA: run script to change status to "failed"</li> <li>• PA: Issue being fixed</li> </ul>
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	<ul style="list-style-type: none"> <li>• Paul Baumgartner</li> </ul>
RPCI	<ul style="list-style-type: none"> <li>• Ken Quinn</li> <li>• Jen</li> <li>• Haidee</li> <li>• Kathy</li> <li>• Dawn</li> <li>• Diane</li> </ul>

## 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 out 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 <ul style="list-style-type: none"><li>• Confirm which rules were run</li></ul>	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 <ul style="list-style-type: none"><li>• Most studies don't have course</li><li>• Need to be able to differentiate between a change in one AE and a new AE</li><li>• Suggestion is to make AE term + start date the primary key<ul style="list-style-type: none"><li>• Issue would be that users might end a grade 2 AE and give a new start date when it changed grade</li></ul></li></ul>	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
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## Attendees

Team	Attendee
SemanticBits	<ul style="list-style-type: none"> <li>Paul Baumgartner</li> </ul>
WFU	<ul style="list-style-type: none"> <li>Bob Morrell</li> <li>Del</li> <li>Steven</li> </ul>
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 and 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 continuum 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 recurs 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



## Agenda

Time	Item	Facilitator
1pm	Administrative Items	
2pm	Meeting Adjourns	

## Actions / Issues / Requests

Action Item	Assigned to	Due Date	Status
Provide descriptions/wsdl 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 drop 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	<ul style="list-style-type: none"><li>• Paul Baumgartner</li></ul>
CALGB	<ul style="list-style-type: none"><li>• Nimesh Patel</li><li>• Robert Dale</li><li>• Amish Shah</li><li>• Susan Sutherland</li><li>• Debbie Sawyer</li><li>• Allision Booth</li><li>• Kelly (training coordinator)</li><li>• Robin</li></ul>

## 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 Baumgartner
	Discussion of caAERS progress/issues	Paul Baumgartner
2pm	Meeting Adjourns	

### Open Actions/Issues Items

Action/Issue	Assigned to	Due Date	Status
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### Attendees

Team	Attendee
SemanticBits	<ul style="list-style-type: none"> <li>• Paul Baumgartner</li> </ul>
Roswell Park	<ul style="list-style-type: none"> <li>• Ken Quinn</li> <li>• Dawn</li> <li>• Nancy</li> <li>• Haidee</li> </ul>

### 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	<ul style="list-style-type: none"> <li>• Paul Baumgartner</li> </ul>

Mayo	<ul style="list-style-type: none"> <li>• Sonja Hamilton</li> <li>• Brad Anderson</li> <li>• Robbin Peterson</li> <li>• Jennifer Frank</li> </ul>
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/wsdl 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	<ul style="list-style-type: none"> <li>Paul Baumgartner</li> </ul>
CALGB	<ul style="list-style-type: none"> <li>Nimesh Patel</li> <li>Robert Dale</li> <li>Amish Shah</li> <li>Susan Sutherland</li> <li>Debbie Sawyer</li> <li>Allision Booth</li> <li>Kelly (training coordinator)</li> <li>Robin</li> </ul>

## 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 Baumgartner
	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 <ul style="list-style-type: none"> <li>Confirm which rules were run</li> </ul>	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 <ul style="list-style-type: none"> <li>• Most studies don't have course</li> <li>• Need to be able to differentiate between a change in one AE and a new AE</li> <li>• Suggestion is to make AE term + start date the primary key               <ul style="list-style-type: none"> <li>• Issue would be that users might end a grade 2 AE and give a new start date when it changed grade</li> </ul> </li> </ul>	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	<ul style="list-style-type: none"> <li>• Paul Baumgartner</li> </ul>
WFU	<ul style="list-style-type: none"> <li>• Bob Morrell</li> <li>• Del</li> <li>• Steven</li> </ul>
NCI	<ul style="list-style-type: none"> <li>• Michele Elhman</li> </ul>

## 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
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3pm	Review of <a href="#">pilot plans</a>	Paul Baumgarnter
4:15pm	Meeting adjourns	

## Attendees

Team	Attendee
SemanticBits	<ul style="list-style-type: none"> <li>Paul Baumgartner</li> </ul>
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 <ul style="list-style-type: none"><li>• v1.9.5 Release today</li><li>• Adopter issues / highlights</li></ul>	Paul Baumgartner
	v1.9.5 Demo <ul style="list-style-type: none"><li>• General Usability<ul style="list-style-type: none"><li>• Navigation</li><li>• Highlighting</li></ul></li><li>• AE reporting<ul style="list-style-type: none"><li>• AdEERS 24 hr notification support</li><li>• Review and Report updates</li><li>• Expedited AE flow updates</li></ul></li><li>• Print forms</li><li>• Advanced Search UI</li></ul>	Paul
1pm	User Meeting ends	
1pm	Technical Meeting begins	
	Administration updates in v1.9.5 <ul style="list-style-type: none"><li>• Report Definition updates<ul style="list-style-type: none"><li>• Type/Group/Parent</li></ul></li><li>• Study data entry status</li><li>• Research Staff<ul style="list-style-type: none"><li>• All studies</li><li>• Active / Inactive</li><li>• Multiple organizations</li></ul></li><li>• Investigator account option</li><li>• Report Tracking<ul style="list-style-type: none"><li>• Unsticking -stuck report</li></ul></li></ul>	
	Service updates in v1.9.5 <ul style="list-style-type: none"><li>• Security</li><li>• Add subject</li><li>• Add site</li><li>• Add staff</li><li>• AE Management service</li></ul>	
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 <ul style="list-style-type: none"><li>AdEERS submissions unavailable until next caAERS release (7/31/09)</li></ul>	Paul Baumgarnter
	Demo new functionality <ul style="list-style-type: none"><li>Logging reports</li><li>Printing Forms</li></ul>	
	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	<ul style="list-style-type: none"> <li>Paul Baumgartner</li> <li>Srini Akkala</li> </ul>
Mayo	<ul style="list-style-type: none"> <li>Sonja Hamilton</li> <li>Jean Hansen</li> <li>Brad Anderson</li> <li>Robbin Peterson</li> <li>Jennifer Frank</li> </ul>
NCI	

## Meeting Notes

### Status

- Participant service ready to go.
- Investigator - must be able to suppress 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 Baumgartner
	Status/Issues	
	Demo new functionality <ul style="list-style-type: none"><li>• Print forms</li><li>• Report logging</li></ul>	
12pm	Meeting Adjourns	

## Actions / Issues

Issue / Feature	Impact/Priority	Status	Reporter/Requestor
Rule seems like it's enabled, but in-fact, is not <ul style="list-style-type: none"><li>• Confirm which rules were run</li></ul>	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 <ul style="list-style-type: none"><li>• Most studies don't have course</li><li>• Need to be able to differentiate between a change in one AE and a new AE</li><li>• Suggestion is to make AE term + start date the primary key<ul style="list-style-type: none"><li>• Issue would be that users might end a grade 2 AE and give a new start date when it changed grade</li></ul></li></ul>	High	Open	Bob (WFU nurses)
Bob to send training videos	Low	Open	Bob

## Attendees

Team	Attendee
SemanticBits	<ul style="list-style-type: none"><li>• Paul Baumgartner</li><li>• Srin</li></ul>
WFU	<ul style="list-style-type: none"><li>• Bob Morrell</li><li>• Kim Sweat</li><li>• Steven</li></ul>
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 <ul style="list-style-type: none"><li>• AdEERS submissions unavailable until next caAERS release (7/31/09)</li></ul>	Paul Baumgarnter
	Demo new functionality <ul style="list-style-type: none"><li>• Logging reports</li><li>• Printing Forms</li></ul>	
	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	<ul style="list-style-type: none"><li>• Paul Baumgartner</li><li>• Srin Akkala</li></ul>
Mayo	<ul style="list-style-type: none"><li>• Sonja Hamilton</li><li>• Jean Hansen</li><li>• Brad Anderson</li><li>• Robbin Peterson</li><li>• Jennifer Frank</li></ul>
NCI	

## Meeting Notes

### Status

- Participant service ready to go.
- Investigator - must be able to suppress account notifications
  - Initially, NO investigators will be logging into caAERS. Mayo does NOT want to be confused by 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
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1pm	Administrative Items <ul style="list-style-type: none"> <li>• AdEERS submissions N/A until release</li> </ul>	Paul Baumgarnter
	New Development Demo <ul style="list-style-type: none"> <li>• Logging</li> <li>• Print CRFs</li> </ul>	Paul Baumgarnter
	Status/Issues	
2pm	Meeting Adjourns	

## Actions / Issues / Requests

Action Item	Assigned to	Due Date	Status
Provide descriptions/wsdl 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 drop 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	<ul style="list-style-type: none"> <li>• Paul Baumgartner</li> </ul>
CALGB	<ul style="list-style-type: none"> <li>• Nimesh Patel</li> <li>• Robert Dale</li> <li>• Amish Shah</li> <li>• Susan Sutherland</li> <li>• Debbie Sawyer</li> </ul>

## 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).
- Alphabetize 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	<ul style="list-style-type: none"><li>• CA: run script to change status to "failed"</li><li>• PA: Issue being fixed</li></ul>
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
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## Attendees

Team	Attendee
SemanticBits	<ul style="list-style-type: none"> <li>Paul Baumgartner</li> </ul>
CALGB	<ul style="list-style-type: none"> <li>Ken Quinn</li> <li>Jen</li> <li>Nancy</li> <li>Haidee</li> </ul>

## 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: <ul style="list-style-type: none"> <li>activities</li> <li>issues</li> <li>July activities</li> </ul>	Paul, Adopters
	Features implemented in June <ul style="list-style-type: none"> <li>Navigation (demo)</li> <li>Report logging / Happy.jsp (mock-up)</li> <li>Print forms</li> <li>Updates to services</li> <li>Advanced Search UI</li> </ul>	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 <ul style="list-style-type: none"> <li>Confirm which rules were run</li> </ul>	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)

## 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	<b>Statement of Work Review</b> <ul style="list-style-type: none"><li>• Major Responsibilities</li><li>• Milestones</li><li>• Deliverables</li></ul>	
10min	<b>Deliverable Logistics</b> <ul style="list-style-type: none"><li>• Due dates</li><li>• Method of delivery</li></ul>	

20min	Project Management Approach <ul style="list-style-type: none"> <li>• <a href="#">Review Project Plan</a></li> <li>• <a href="#">Planned features</a></li> <li>• Agile Unified Process</li> <li>• Use of meetings</li> <li>• PM tools (wiki, JIRA, KC, <a href="#">backlog</a>)</li> </ul>	
remainder	Discussion / Questions	
2pm	Meeting Adjourns	

## Action Items

Action Item	Assigned to	Due Date	Status

## Attendees

Team	Attendee
SemanticBits	<ul style="list-style-type: none"> <li>• Paul Baumgartner (Project Manager)</li> <li>• Ram Chilukuri (Project Director)</li> </ul>
SAIC-F	<ul style="list-style-type: none"> <li>• Peter Yan (COTR)</li> <li>• Jennifer Thomas (contracts specialist)</li> <li>• Nancy Roche (CTMS WS Program Manager)</li> </ul>
NCI-CBIIT	<ul style="list-style-type: none"> <li>• Christo Andonyadis (project owner)</li> <li>• John Speakman (project owner)</li> </ul>

## 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	<ul style="list-style-type: none"> <li>Paul Baumgartner</li> </ul>
CALGB	<ul style="list-style-type: none"> <li>Ken Quinn</li> <li>Kathy Reitz</li> <li>Dawn</li> </ul>

## 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:
    - 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. Invalid 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 Baumgartner
	Status/Issues	
12pm	Meeting Adjourns	

### Action Items

Action Item	Assigned to	Due Date	Status

### Attendees

Team	Attendee
SemanticBits	<ul style="list-style-type: none"> <li>• Paul Baumgartner</li> </ul>
WFU	<ul style="list-style-type: none"> <li>• Bob Morrell</li> <li>• Kim Sweat</li> </ul>
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 Baumgartner
	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	<ul style="list-style-type: none"> <li>• Paul Baumgartner</li> </ul>
Mayo	<ul style="list-style-type: none"> <li>• Sonja Hamilton</li> <li>• Jean Hansen</li> <li>• Brad Anderson</li> <li>• Robbin Peterson</li> </ul>
NCI	<ul style="list-style-type: none"> <li>• Michele Elhman</li> </ul>

### 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 <ul style="list-style-type: none"><li>for service updates to support adding sites and staff</li></ul>	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/wsdl's 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	<ul style="list-style-type: none"><li>Paul Baumgartner</li></ul>
CALGB	<ul style="list-style-type: none"><li>Nimesh Patel</li><li>Robert Dale</li><li>remainder of team at group meeting in Chicago</li></ul>

## 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 Baumgartner
	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	<ul style="list-style-type: none"><li>• Paul Baumgartner</li></ul>
Mayo	<ul style="list-style-type: none"><li>• Sonja Hamilton</li><li>• Sharon Elcombe</li><li>• Jean Hansen</li><li>• Brad Anderson</li><li>• Robbin Peterson</li></ul>

## 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 Baumgartner
	Status/Issues	
2pm	Meeting Adjourns	

### Action Items

Action Item	Assigned to	Due Date	Status
Schedule point release <ul style="list-style-type: none"> <li>• for service updates to support adding sites and staff</li> </ul>	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/wsdl for updates to web services	Paul	6/30/09	
Provide guidance on training availability	Paul	7/2/09	

### Attendees

Team	Attendee
SemanticBits	<ul style="list-style-type: none"> <li>• Paul Baumgartner</li> </ul>

CALGB	<ul style="list-style-type: none"> <li>• Nimesh Patel</li> <li>• Robert Dale</li> <li>• Amish</li> <li>• Allison</li> <li>• Susan</li> <li>• Debbie</li> </ul>
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## 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 Baumgartner
	Status/Issues	
	Input needed: <ul style="list-style-type: none"> <li>• dashboard mock-up</li> <li>• CRF</li> <li>• Physician vs. Investigator</li> </ul>	
12pm	Meeting Adjourns	

### Action Items

Action Item	Assigned to	Due Date	Status

### Attendees

Team	Attendee
SemanticBits	<ul style="list-style-type: none"> <li>• Paul Baumgartner</li> </ul>
WFU	<ul style="list-style-type: none"> <li>• Bob Morrell</li> <li>• Steven Cheng</li> <li>• Kim Sweat</li> <li>• Del Jones</li> </ul>

NCI	<ul style="list-style-type: none"> <li>Michele Elhman</li> </ul>
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## 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: <ul style="list-style-type: none"> <li>dashboard mock-up</li> <li>CRF</li> <li>Physician vs. Investigator</li> </ul>	
12pm	Meeting Adjourns	

### Action Items

Action Item	Assigned to	Due Date	Status

### Attendees

Team	Attendee
SemanticBits	<ul style="list-style-type: none"> <li>Paul Baumgartner</li> </ul>

Mayo	<ul style="list-style-type: none"> <li>• Sonja Hamilton</li> <li>• Robbin Peterson</li> <li>• Jean Hansen</li> <li>• Brad Anderson</li> </ul>
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## 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: <ul style="list-style-type: none"> <li>• dashboard mock-up</li> <li>• CRF</li> <li>• Physician vs. Investigator</li> <li>• Review of Testing Feedback</li> </ul>	
2pm	Meeting Adjourns	

## Action Items

Action Item	Assigned to	Due Date	Status
Schedule point release <ul style="list-style-type: none"> <li>• for service updates to support adding sites and staff</li> </ul>	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	<ul style="list-style-type: none"> <li>Paul Baumgartner</li> </ul>
CALGB	<ul style="list-style-type: none"> <li>Amish Shah</li> <li>Nimesh Patel</li> <li>Robert Dale</li> <li>Josh Yoder</li> <li>Susan Sutherland</li> <li>Debbie Sawyer</li> <li>Robin Heinze</li> </ul>

## 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

- 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.
- 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.
- 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.
- 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: <ul style="list-style-type: none"><li>• activities</li><li>• issues</li><li>• June activities</li></ul>	Paul, Adopters
	Multi-site user question	
	Features implemented in May <ul style="list-style-type: none"><li>• Field highlighting (demo)</li><li>• AE import service</li><li>• Soft delete</li><li>• User de-activation</li><li>• AE query API and UI</li></ul>	Paul
1pm	Meeting ends	

### Issues / Feature Requests

Issue / Feature	Impact/Priority	Status	Reporter/Requestor
"In progress" report issue occurring	Med - requires restarting of Tomcat and ServiceMix	Initial 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	<ul style="list-style-type: none"><li>• Paul Baumgartner</li></ul>
Mayo	<ul style="list-style-type: none"><li>• Sharon Elcombe</li><li>• Jean Hanson</li></ul>
NCI	<ul style="list-style-type: none"><li>• Ann Setser</li><li>• Shanda Finnigan</li></ul>

### 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, possible, 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

## Agenda

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

## Actions / Issues

Issue / Feature	Impact/Priority	Status	Reporter/Requestor
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## Attendees

Team	Attendee
SemanticBits	<ul style="list-style-type: none"><li>• Paul Baumgartner</li></ul>
Mayo	<ul style="list-style-type: none"><li>• Sharon Elcombe</li><li>• Jean Hanson</li><li>• Robbin Peterson</li><li>• Jennifer Frank</li></ul>
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 determine 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

## Agenda

Time	Item	Facilitator
12pm	Welcome	Paul Baumgartner
	Review Agenda <ul style="list-style-type: none"><li>• Call for items</li></ul>	Paul
	Overview of <a href="#">caAERS v2.2</a>	Paul
	What's next for caAERS <ul style="list-style-type: none"><li>• Device support</li></ul>	Paul
	Use Cases: <a href="#">recurring</a> and <a href="#">continuing</a> AEs	Paul
	<a href="#">news</a> : FDA guidance <a href="#">21 CFR Part 213, 220</a>	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
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## 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 Baumgartner
	Status/Issues	
12pm	Meeting Adjourns	

## Actions / Issues

Issue / Feature	Impact/Priority	Status	Reporter/Requestor
-----------------	-----------------	--------	--------------------

## Attendees

Team	Attendee
SemanticBits	<ul style="list-style-type: none"><li>Paul Baumgartner</li></ul>
WFU	<ul style="list-style-type: none"><li>Bob Morrell</li><li>Del Jones</li><li>Steven</li></ul>
NCI-CBIIT	<ul style="list-style-type: none"><li>Mary Agnes Templeton</li></ul>

## 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:

- Create a new organization in caAERS for each department and author the rule set for that department
- Create a protocol specific rule set for each study
- 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 manageable 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
<ul style="list-style-type: none"> <li>• Treatment</li> <li>• Supportive Care</li> <li>• Prevention</li> <li>• Symptom Amelioration</li> <li>• Quality of Life</li> </ul>	<ul style="list-style-type: none"> <li>• Breast Cancer</li> <li>• Nausea</li> <li>• Cancer</li> <li>• etc</li> </ul>	<ul style="list-style-type: none"> <li>• People with Breast Cancer</li> <li>• Chemo patients</li> <li>• Breast cancer chemo patients</li> <li>• Black women</li> <li>• etc</li> </ul>

- 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
<ul style="list-style-type: none"> <li>• Interventional</li> <li>• Observational</li> </ul>	<ul style="list-style-type: none"> <li>• Treatment</li> <li>• Preventive</li> <li>• Supportive Care</li> <li>• Screening</li> <li>• Diagnostic</li> <li>• Health Services Research</li> <li>• Basic Science</li> <li>• Other</li> </ul>	

- 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

## 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](mailto: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	<ul style="list-style-type: none"><li>• Symptom management</li><li>• a few prevention</li></ul>	<ul style="list-style-type: none"><li>• Prevention only</li></ul>
SAE reporting method	<ul style="list-style-type: none"><li>• AdEERS (Groups) - daily email from AdEERS to DCP</li><li>• MedWatch (non-Groups) - emailed, mailed, faxed</li><li>• If using a DCP IND, then report using the non-CCOP flow</li></ul>	<ul style="list-style-type: none"><li>• DCP SAE form to CCSA and Medical Monitor</li></ul>

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 Treatment, 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 Baumgartner
	Status/Issues	
12pm	Meeting Adjourns	

### Actions / Issues

Issue / Feature	Impact/Priority	Status	Reporter/Requestor
-----------------	-----------------	--------	--------------------

### Attendees

Team	Attendee
SemanticBits	<ul style="list-style-type: none"> <li>• Paul Baumgartner</li> </ul>
WFU	<ul style="list-style-type: none"> <li>• Bob Morrell</li> <li>• Del Jones</li> <li>• Steven</li> </ul>
NCI-CBIIT	<ul style="list-style-type: none"> <li>• Mary Agnes Templeton</li> </ul>

### 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
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- 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	<ul style="list-style-type: none"><li>• Paul Baumgartner</li><li>• Biju Joseph</li></ul>
CALGB	<ul style="list-style-type: none"><li>• Nimesh Patel</li><li>• Todd Crook</li></ul>

## 02-22-10 CALGB Meeting Minutes - caAERS

### Meeting Information

When: Thursday 1-2pm ET  
Phone: 1-877-810-8617  
Passcode: 2764499

## 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	<ul style="list-style-type: none"><li>• Paul Baumgartner</li><li>• Biju Joseph</li></ul>
CALGB	<ul style="list-style-type: none"><li>• Nimesh Patel</li><li>• Todd Crook</li></ul>

## 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	<ul style="list-style-type: none"><li>• Paul Baumgartner</li><li>• Biju Joseph</li></ul>
CALGB	<ul style="list-style-type: none"><li>• Nimesh Patel</li><li>• Todd Crook</li></ul>

## 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 Baumgartner
	Status/Issues	
1pm	Meeting Adjourns	

### Actions / Issues

Issue / Feature	Impact/Priority	Status	Reporter/Requestor
-----------------	-----------------	--------	--------------------

## Attendees

Team	Attendee
SemanticBits	<ul style="list-style-type: none"><li>• Paul Baumgartner</li></ul>
WFU	<ul style="list-style-type: none"><li>• Bob Morrell</li><li>• Del</li><li>• Steven Cheng</li></ul>
NCI	Mary Agnes

### Meeting Notes

- Demo of WFU's autograding system
- Some normal ranges are gender based (i.e. hemoglobin)
- 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 consequences, 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 relevant for Solicited 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 aberrant lab)
- all grades are subject to override by physician's discretion.
- 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 Baumgartner
	Status/Issues	
1pm	Meeting Adjourns	

### Actions / Issues

Issue / Feature	Impact/Priority	Status	Reporter/Requestor
-----------------	-----------------	--------	--------------------

### Attendees

Team	Attendee
SemanticBits	<ul style="list-style-type: none"> <li>• Paul Baumgartner</li> </ul>
WFU	<ul style="list-style-type: none"> <li>• Bob Morrell</li> <li>• Del</li> <li>• Steven Cheng</li> </ul>
NCI	Mary Agnes

### Meeting Notes

- Demo of WFU's autograding system
- Some normal ranges are gender based (i.e. hemoglobin)
- 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 consequences, 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 relevant for Solicited 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 aberrant lab)
- all grades are subject to override by physician's discretion.
- 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 - <a href="https://wiki.nci.nih.gov/display/caAERS/Vision+and+Scope++caAERS">https://wiki.nci.nih.gov/display/caAERS/Vision+and+Scope++caAERS</a>	Paul
	Project Management Approach <ul style="list-style-type: none"> <li>• <a href="#">Agile Unified Process</a></li> <li>• <a href="#">Schedule</a></li> <li>• Use of meetings</li> <li>• PM tools (wiki, <a href="#">JIRA</a>, <a href="#">KC</a>)</li> </ul>	Paul

	Test Plan	Paul
	Requirements- <a href="https://wiki.nci.nih.gov/x/tlh8">https://wiki.nci.nih.gov/x/tlh8</a> <ul style="list-style-type: none"> <li>Backlog- <a href="https://wiki.nci.nih.gov/display/caAERS/Product+Backlog+-+caAERS">https://wiki.nci.nih.gov/display/caAERS/Product+Backlog+-+caAERS</a> or see Real-time backlog</li> </ul>	Paul
	Use Cases- <a href="https://wiki.nci.nih.gov/x/8YR8">https://wiki.nci.nih.gov/x/8YR8</a>	Paul
	Design Model- <a href="https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/models/caAERS_model.eap">https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/models/caAERS_model.eap</a>	Paul
	Demo- <a href="https://demo.semanticbits.com/caAERS">https://demo.semanticbits.com/caAERS</a>	Paul
	Architecture- <a href="https://wiki.nci.nih.gov/display/caAERS/Technical+Architecture+Guide+-+caAERS">https://wiki.nci.nih.gov/display/caAERS/Technical+Architecture+Guide+-+caAERS</a> and Technologies <ul style="list-style-type: none"> <li>Diagrams - <a href="https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/DesignReview/Diagrams.pdf">https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/DesignReview/Diagrams.pdf</a></li> <li>SOA</li> </ul>	Denis / Vinay
	Design Documents- <a href="https://wiki.nci.nih.gov/x/ihay">https://wiki.nci.nih.gov/x/ihay</a> <ul style="list-style-type: none"> <li>Earlier Designs<a href="https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs">https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs</a></li> </ul>	Biju
	Enterprise Services <ul style="list-style-type: none"> <li>AE Management</li> <li>Safety Reporting</li> </ul>	
remainder	Discussion / Questions	
2:30pm	Meeting Adjourns	

## Attendees

Team	Attendee
SemanticBits	<ul style="list-style-type: none"> <li>Paul Baumgartner (Project Manager)</li> <li>Ram Chilukuri (Project Director)</li> <li>Vinay Kumar (Architect)</li> <li>Denis Krylov (Architect)</li> <li>Wesley Wiggins (Business Analyst)</li> <li>Biju Joseph (Technical Lead)</li> <li>Srini Akkala (Technical Lead)</li> </ul>
SAIC-F	<ul style="list-style-type: none"> <li>Jeff McLean (COTR)</li> <li>Nancy Roche (CTMS WS Program Manager) * Steve </li> </ul>
NCI-CBIIT	<ul style="list-style-type: none"> <li>Christo Andonyadis (project owner)</li> </ul>

## 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



## Agenda

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

## Actions / Issues

Issue / Feature	Impact/Priority	Status	Reporter/Requestor
-----------------	-----------------	--------	--------------------

## Attendees

Team	Attendee
SemanticBits	<ul style="list-style-type: none"><li>Paul Baumgartner</li></ul>
Mayo	<ul style="list-style-type: none"><li>Sonja Hamilton</li><li>Jean Hanson</li><li>Brad Anderson</li></ul>
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 autocomplete 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 Baumgartner
	Review New / Open issues	

2pm	Meeting Adjourns	
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## Actions / Issues

Issue / Feature	Impact/Priority	Status	Reporter/Requestor
-----------------	-----------------	--------	--------------------

## Attendees

Team	Attendee
SemanticBits	<ul style="list-style-type: none"> <li>Paul Baumgartner</li> </ul>
WFU	<ul style="list-style-type: none"> <li>Bob Morrell</li> <li>Del</li> </ul>
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 Baumgartner
	Status/Issues	
12pm	Meeting Adjourns	

## Actions / Issues

Issue / Feature	Impact/Priority	Status	Reporter/Requestor
-----------------	-----------------	--------	--------------------

## Attendees

Team	Attendee
SemanticBits	<ul style="list-style-type: none"><li>• Paul Baumgartner</li><li>• Wes Wiggins</li></ul>
WFU	<ul style="list-style-type: none"><li>• Bob Morrell</li></ul>

## 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 attachments 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 Baumgartner
	Review New / Open issues	
12pm	Meeting Adjourns	

### Actions / Issues

Issue / Feature	Impact/Priority	Status	Reporter/Requestor
-----------------	-----------------	--------	--------------------

## Attendees

Team	Attendee
SemanticBits	<ul style="list-style-type: none"><li>Paul Baumgartner</li></ul>
Mayo	<ul style="list-style-type: none"><li>Sonja Hamilton</li><li>Jean Hanson</li><li>Brad Anderson</li></ul>
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 Baumgartner
	Status/Issues	
12:30pm	Meeting Adjourns	

### Actions / Issues

Issue / Feature	Impact/Priority	Status	Reporter/Requestor
-----------------	-----------------	--------	--------------------

## Attendees

Team	Attendee
SemanticBits	<ul style="list-style-type: none"> <li>Paul Baumgartner</li> </ul>
WFU	<ul style="list-style-type: none"> <li>Bob Morrell</li> <li>Del Jones</li> </ul>
NCI-CBIIT	<ul style="list-style-type: none"> <li>Mary Agnes Templeton</li> </ul>

## 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 attachments 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 Baumgartner
	Status/Issues	
12pm	Meeting Adjourns	

## Actions / Issues

Issue / Feature	Impact/Priority	Status	Reporter/Requestor
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## Attendees

Team	Attendee
SemanticBits	<ul style="list-style-type: none"><li>Paul Baumgartner</li></ul>
WFU	<ul style="list-style-type: none"><li>Bob Morrell</li><li>Del Jones</li></ul>
NCI-CBIIT	<ul style="list-style-type: none"><li>Mary Agnes Templeton</li></ul>

## 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:

- Create a new organization in caAERS for each department and author the rule set for that department
- Create a protocol specific rule set for each study
- 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).
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  - Having a separate lab check box would be confusing and inconsistent - Further, for some AE the verbatim IS needed.
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- 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 attachments 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
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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 <ul style="list-style-type: none"> <li>• Scope</li> <li>• Time frame</li> </ul>	
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	<ul style="list-style-type: none"> <li>• CA: run script to change status to "failed"</li> <li>• PA: Issue being fixed</li> </ul>



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	<ul style="list-style-type: none"> <li>Paul Baumgartner</li> </ul>
RPCI	<ul style="list-style-type: none"> <li>Ken Quinn</li> <li>Jen</li> <li>Haidee</li> <li>Kathy</li> <li>Dawn</li> <li>Diane</li> </ul>

## 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 <ul style="list-style-type: none"> <li>Scope</li> <li>Time frame</li> </ul>	
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	<ul style="list-style-type: none"> <li>CA: run script to change status to "failed"</li> <li>PA: Issue being fixed</li> </ul>
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	<ul style="list-style-type: none"> <li>Paul Baumgartner</li> </ul>
RPCI	<ul style="list-style-type: none"> <li>Ken Quinn</li> <li>Jen</li> <li>Haidee</li> <li>Kathy</li> <li>Dawn</li> <li>Diane</li> </ul>

## 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 relevance 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 occasionally 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 <ul style="list-style-type: none"> <li>• Scope</li> <li>• Time frame</li> </ul>	
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
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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	<ul style="list-style-type: none"> <li>CA: run script to change status to "failed"</li> <li>PA: Issue being fixed</li> </ul>
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	<ul style="list-style-type: none"> <li>Paul Baumgartner</li> </ul>
RPCI	<ul style="list-style-type: none"> <li>Ken Quinn</li> <li>Jen</li> <li>Kathy</li> <li>Dawn</li> <li>Diane</li> </ul>

## 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 <ul style="list-style-type: none"><li>• Scope</li><li>• Time frame</li></ul>	
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
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Problem w/ AdEERS report stuck in-progress	SB	ASAP	<ul style="list-style-type: none"><li>• CA: run script to change status to "failed"</li><li>• PA: Issue being fixed</li></ul>
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	<ul style="list-style-type: none"><li>• Paul Baumgartner</li></ul>
RPCI	<ul style="list-style-type: none"><li>• Ken Quinn</li><li>• Jen</li><li>• Kathy</li><li>• Dawn</li><li>• Diane</li></ul>

## 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 <ul style="list-style-type: none"><li>• Scope</li><li>• Time frame (to be mapped out)</li></ul>	
	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
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## Attendees

Team	Attendee
SemanticBits	<ul style="list-style-type: none"> <li>Paul Baumgartner</li> </ul>
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## Meeting Notes

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- Meeting this week (hopefully) with CTEP
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- Need to ensure study is created in caAERS first.
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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
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#### 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