



Atomic (A021502) SAE Integration and Central Monitoring

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Presentation Objectives

- Illustrate the use of the Rave-CTEP-AERs integration within ATOMIC (A021502)
- Illustrate the use of Central Monitoring within ATOMIC (A021502)
- Communicate the plan for use of the CTSU Central Monitoring Portal

Rave-CTEP-AERs Integration

- Implemented in ATOMIC A021502
 - Requires the reporting of additional fields
 - Verbatim term
 - AE start/stop dates, ongoing status
 - Must report all changes of grades, if known

Rave – CTEP AERs Integration

- The integration changes the timing of Adverse Event (AE) reporting
 - All AEs must be recorded in Rave first
 - All updates to AE data must be first made in Rave, then resubmitted for rule evaluation

New AE form

All fields required for rule evaluation are identified with a red asterisk

Leave report period end date missing until after completion of the entire cycle and form

* Cycle (derived) 2

* Start date of first course/cycle (derived) 1 Sep 2017

* Start date of this course/cycle 6 Sep 2017

Reporting period end date Entry Error

? Reminder: Please complete this field after all adverse events have been entered for this cycle.
Opened To Site from System (06 Sep 2017)

REMINDER: Depending on your settings in Rave, this table may be paginated. If the options are available, click on Paginate and select Show All Lines or click on the numeric page numbers at the bottom right corner of the table. If these options available, you are already viewing the entire table.

#	Verbatim term	Solicited (derived)	*Adverse event term (CTCAE v4.0)	*Adverse event evaluated this cycle?	*Adverse event (grade) description (first 120 characters)	AE start date	End date	AE ongoing	Attribution to study intervention (if grade > 0)	None	Hospitalization	Life-threatening	Death	Disability	Congenital anomaly/birth defect	Required intervention	Other	SAE report recommended (derived)	* AE entry date (derived)	*Time zone (derived)	Adverse event term (CTCAE v4.0) (derived)
1		<input checked="" type="checkbox"/>	Hypothyroidism	Pending						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				Hypothyroidism
2		<input checked="" type="checkbox"/>	Abdominal pain	Pending						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				Abdominal Pain
3		<input checked="" type="checkbox"/>	Constipation	Pending						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				Constipation
4		<input checked="" type="checkbox"/>	Nausea	Pending						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				Nausea
5		<input checked="" type="checkbox"/>	Fatigue	Pending						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				Fatigue
6		<input checked="" type="checkbox"/>	Anorexia	Pending						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				Anorexia
7		<input checked="" type="checkbox"/>	Cough	Pending						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				Cough
8		<input checked="" type="checkbox"/>	Dyspnea	Pending						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				Dyspnea
9	Pt came in with fever of 101 degrees	<input checked="" type="checkbox"/>	Fever	Yes	(1) 38.0 - 39.0 degrees C (100.4 - 102.2 degrees F)	6 Sep 2017		Yes		<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	No	06 Sep 2017 06 34 22 PM	Eastern Standard Time	Fever

New AE form

Do not respond to query, it will go away automatically when the report period end date is added. Please leave as a reminder that the form is not complete.

* Cycle (derived)

* Start date of first course/cycle (derived) ?

* Start date of this course/cycle

Reporting period end date ?

? Reminder: Please complete this field after all adverse events have been entered for this cycle.
Opened To Site from System (06 Sep 2017)



New AE form

This field is derived from the AE form for cycle 1, if missing you need to enter on the cycle 1 AE form



* Cycle (derived)	2
* Start date of <u>first course/cycle</u> (derived) ?	1 Sep 2017
* Start date of <u>this course/cycle</u>	6 Sep 2017

New AE form

Verbatim term is new

AE evaluated is defaulted to "Pending" and must be updated when AE is evaluated

AE start/stop dates and ongoing status are new

After AE is submitted for rule evaluation the AE specific recommendation can be found here

Indicator of whether AE is solicited

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Verbatim term	Solicited (derived)	* Adverse event term (CTCAE v4.0)	* Adverse event evaluated this cycle?	* Adverse event (grade) description (first 120 characters)	AE start date	End date	AE ongoing	Attribution to study intervention (if grade > 0)	None ?	Hospitalization ?	Life-threatening ?	Death ?	Disability ?	Congenital anomaly/birth defect ?	Required intervention ?	Other	SAE report recommended (derived)	* AE entry date (derived)	* Time zone (derived)	Adverse event term (CTCAE v4.0) (derived)
-	<input checked="" type="checkbox"/>	Hypothyroidism	Pending	-	-	-	-	-	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	-	-	-	Hypothyroidism
-	<input checked="" type="checkbox"/>	Abdominal pain	Pending	-	-	-	-	-	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	-	-	-	Abdominal Pain
-	<input checked="" type="checkbox"/>	Constipation	Pending	-	-	-	-	-	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	-	-	-	Constipation
-	<input checked="" type="checkbox"/>	Nausea	Pending	-	-	-	-	-	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	-	-	-	Nausea
-	<input checked="" type="checkbox"/>	Fatigue	Pending	-	-	-	-	-	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	-	-	-	Fatigue
-	<input checked="" type="checkbox"/>	Anorexia	Pending	-	-	-	-	-	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	-	-	-	Anorexia
-	<input checked="" type="checkbox"/>	Cough	Pending	-	-	-	-	-	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	-	-	-	Cough
-	<input checked="" type="checkbox"/>	Dyspnea	Pending	-	-	-	-	-	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	-	-	-	Dyspnea
Pt came in with fever of 101 degrees	<input checked="" type="checkbox"/>	Fever	Yes	(1) 38.0 - 39.0 degrees C (100.4 - 102.2 degrees F)	6 Sep 2017	-	Yes	-	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	No	06 Sep 2017 06 34 22 PM	Eastern Standard Time	Fever

New Expedited Reporting Evaluation Form

A **query** fires anytime a new AE is entered or an existing AE is updated. Check the **checkbox** and save the form to submit the AE for rule evaluation

If a query is present on the AE form, you will **NOT** be able to send the AE for rule evaluation until after the query is resolved

[Link to CTEP-AERs here](#)

Recommendation provided here and is populated after form is submitted

Subject: 9113876
Page: Expedited Reporting Evaluation - Treatment 02

Form Instructions ?

A delay is expected when the safety system is called for AE evaluation.
Note: Do not open more than one ticket per course/cycle in CTEP-AERs. If more than one serious adverse event occurs this course/cycle, amend the report so both events are entered on the same ticket.

Course/Cycle # (derived) 2

Send all AEs for evaluation

? Whenever the AE form is updated, the adverse events have to be evaluated to determine if expedited reporting is recommended. Please check this check box and save the form to determine if expedited reporting is recommended.
Opened To Site from System (31 Oct 2017)

Entry Error

Recommended action for report (derived)

An expedited report is NOT recommended. If the Investigator believes an expedited report IS warranted, use the link below to move to CTEP-AERs to complete the expedited report.
Opened To Site from System (07 Sep 2017) Acknowledge

Click this link to complete the safety report

Report ID (derived) REP0028057

Attribution

- Attribution is not required for expedited AE reporting
- However, it is required for routine AE reporting
 - A query identifying missing attributions will be issued only after the report period end date is entered

Central Monitoring

- Central Monitoring is required for A021502
- See the Data Submission Schedule (DSS) for a list of all data fields requiring central monitoring and the corresponding source documents that are expected
- To begin this trial, all Source Documents should be attached directly in Rave

Central Monitoring

Required source documents prefilled on form

If other indicated, specify report type here

Attach document here

Page: Supporting Documentation: Baseline - Baseline
Cycle

#	Serial # of document	Date of assessment	Report type	Specify report type	Attachment <small>(max file size 10 MB)</small>
1	1	<input type="text"/> ... <input type="text"/>	H & P	<input type="text"/>	<input type="button" value="Browse..."/>
2	2	<input type="text"/> ... <input type="text"/>	Colonoscopy Report	<input type="text"/>	<input type="button" value="Browse..."/>
3	3	<input type="text"/> ... <input type="text"/>	Pathology report from colonoscopy	<input type="text"/>	<input type="button" value="Browse..."/>
4	4	<input type="text"/> ... <input type="text"/>	Pathology report from surgery	<input type="text"/>	<input type="button" value="Browse..."/>
5	5	<input type="text"/> ... <input type="text"/>	Operative report	<input type="text"/>	<input type="button" value="Browse..."/>
6	6	<input type="text"/> ... <input type="text"/>	Imaging report	<input type="text"/>	<input type="button" value="Browse..."/>
7	7	<input type="text"/> ... <input type="text"/>	dMMR testing results	<input type="text"/>	<input type="button" value="Browse..."/>
8	8	<input type="text"/> ... <input type="text"/>	Informed Consent (redacted signature page)	<input type="text"/>	<input type="button" value="Browse..."/>
9	9	<input type="text"/> ... <input type="text"/>	Other	<input type="text"/>	<input type="button" value="Browse..."/>
10	10	<input type="text"/> ... <input type="text"/>	...	<input type="text"/>	<input type="button" value="Browse..."/>

Central Monitoring

- Piloting CTSU Central Monitoring Portal (CMP)
- If feasible, may use the CMP for this trial in the future

Questions?

