

# 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



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)														<b>\</b>	2					
* Start date of first course/cycle (derived) ?															- \	1 Sep 2017				
* Start date of	of this cour	rse/cycle																		6 Sep 2017
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_	<b>✓</b>	Anorexia	Pending	_	_	_	_	_									_	_		Anorexia
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Pt came in with fever of 101 degrees			Yes	(1) 38.0 - 39.0 degrees C (100.4 - 102.2 degrees F)	6 Sep 2017	_	Yes	_	<b></b> ✓								No	2017 06	Standard	Fever
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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)
- 0



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 first course/cycle (derived) ?

1 Sep 2017

\* Start date of this course/cycle

6 Sep 2017



Verbatim term is new

available, you are already viewing the entire table.

Fever

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

AE start/stop dates and ongoing status are

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

06 Sep

No

2017 06

34 22 PM Time

Eastern

Standard

Fever

Indicator of whether AE is solicited

(1) 38.0 - 39.0

(100.4 - 102.2

2017

Yes

degrees C

\*Adverse event (grade) Adverse Attribution to \* AE grade AE study date ongoing intervention (if None ?) | None | Hospitalization threatening | Required SAE report Adverse event term Death Disability Verbatim Solicited \*Adverse event event description anomaly/birth entry intervention Other recommended zone (CTCAE v4.0) (derived) term (CTCAE v4.0) evaluated date (derived) (derived) this cycle? (first 120 (derived) characters) Hypothyroidism Pending Hypothyroidism Abdominal pain Pending Abdominal Pair Constipation Pending Constipation Pending Nausea Nausea Fatigue Pending Fatigue Pending Anorexia Anorexia Cough Pending Cough Dyspnea Pendina Dyspnea

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Pt came in

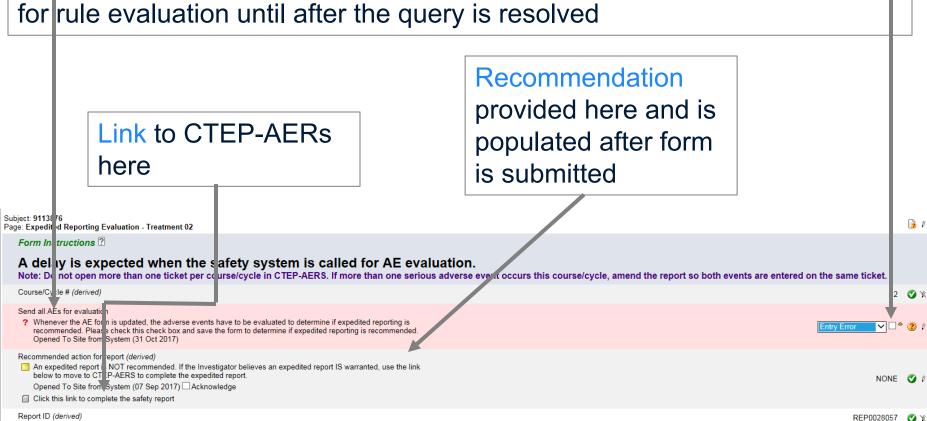
with fever

of 101

# 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



#### **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 <u>after</u> the report period end date is entered

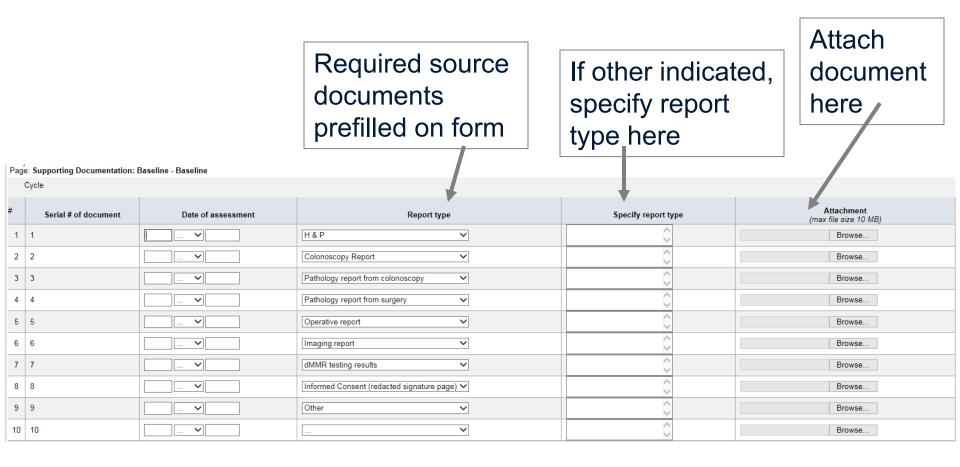


## **Central Monitoring**

- 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**





# **Central Monitoring**

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



# **Questions?**



