iMedidata Rave Tips

Shauna Hillman, MS
ALLIANCE

May 2014

Objectives

- Provide an update on the CTSU integration initiatives
- Provide some Medidata Rave tips to improve data entry

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Outline

CTSU Integrations

- SAE
- Fax portal
- Data quality portal

Rave Tips

- Response box
- Unknown date components
- Help text
- Work around for reporting AEs when response time is long
- Feedback needed

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

SAE Integration

- Data exchange mechanism whereby Rave data is transferred to AdEERS via caAERS
- Data entry, queries and updates will be managed by the site in Rave
- Reduce the redundancy of data collection and subsequent reconciliation between systems
- STATUS:
  - Beta3 testing to begin early summer
  - Expected to be complete Fall 2014

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

SAE Integration Key Message

- Both routine and serious adverse event data will be entered in Rave
- SAE Integration will change the timing of when adverse event data is entered
- The rules validation within the SAE integration will guide the user to when an SAE needs to be reported and in what timeframe

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

CTSU Fax Portal

- Some Rave Case Report Forms (CRFs) may require users to upload supporting documents
- At the March 2012 Alliance Core meetings, the CRP committee indicated all sites did not have scanning capability available
- Lead Protocol Organizations (LPOs) requested Rave users have the ability to upload supporting documents by fax to enable sites without scanning capability to post documents in Rave
- CTSU created the Document Image Portal, which allows Rave users to fax in supporting documents, the documents are converted into PDF files and uploaded to Rave

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

CTSU Fax Portal

Does my study use the Document Image Portal?

- Navigate to the field in the Rave CRF, and click the Save button to see if a hyperlink for the CTSU Fax Cover Page appears within the field
- The CTSU FAX Portal is in pilot phase for testing
- If participating in trial A011202, please use the CTSU Fax portal

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

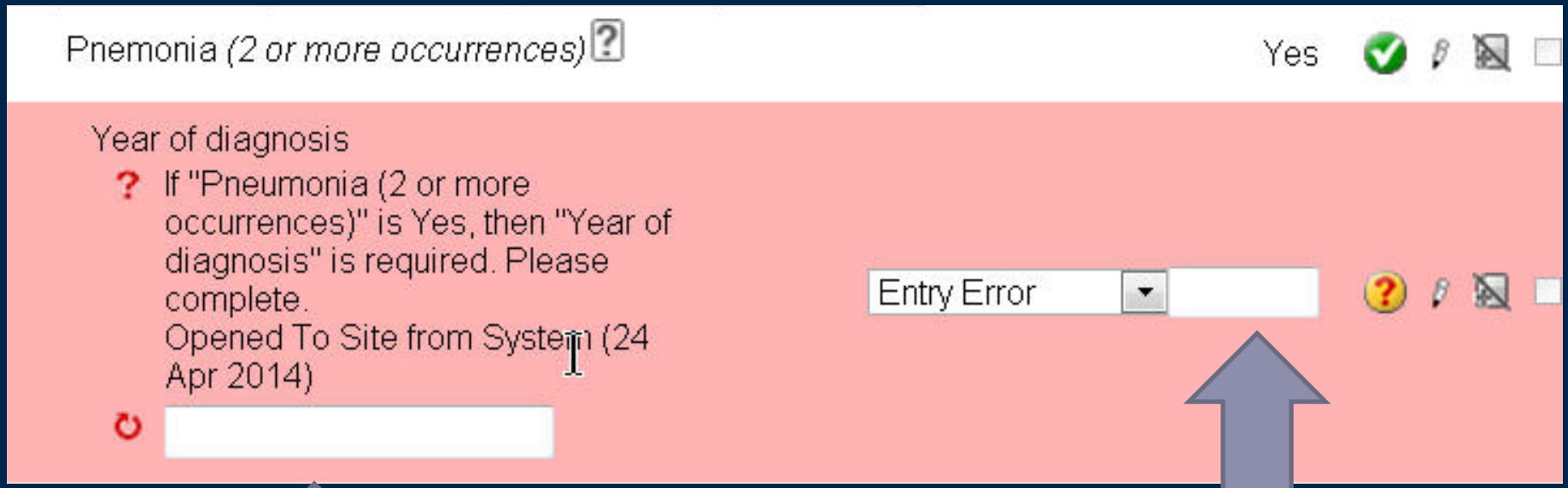
Data Quality Portal (DQP)

- Clinical Data Portal for form and query delinquency reporting
- Will provide a central location for sites and LPOs to generate and review delinquency reports for all studies using Rave
- Data Quality Report (Institution level evaluation report) will be available on this portal.
- STATUS: Estimated to be completed early 2015

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Rave Tips

Response Box



Response box, enter a comment ONLY if you can not correct the data

Data entry box, Update the data if it is entered in error

Unknown Date Components

- Some trials allow for the reporting of an “unknown” day or month
- This is not available in all trials
- You can never report an unknown year
- If a date does allow the reporting of an unknown day or month, help text will alert you
- If you try and enter an “UN” for day or an “UNK” for month and this is not allowed you will receive the nonconformance error
- The use of the unknown date field is most common on baseline forms

Unknown Date Components

	Regimen name	Regimen received	Other, specify	Start date	Stop date
1	Radiotherapy	Yes		01 Jan 2010	Entry Error ...
	Stop date ? If "Regimen received" is Yes then "Stop date" is required. Please reconcile. Opened To Site from System (15 Apr 2014) thereapy end date is currently unknown. ...				
2	Docetaxel	Yes		un Jan 2010	un Feb 2010

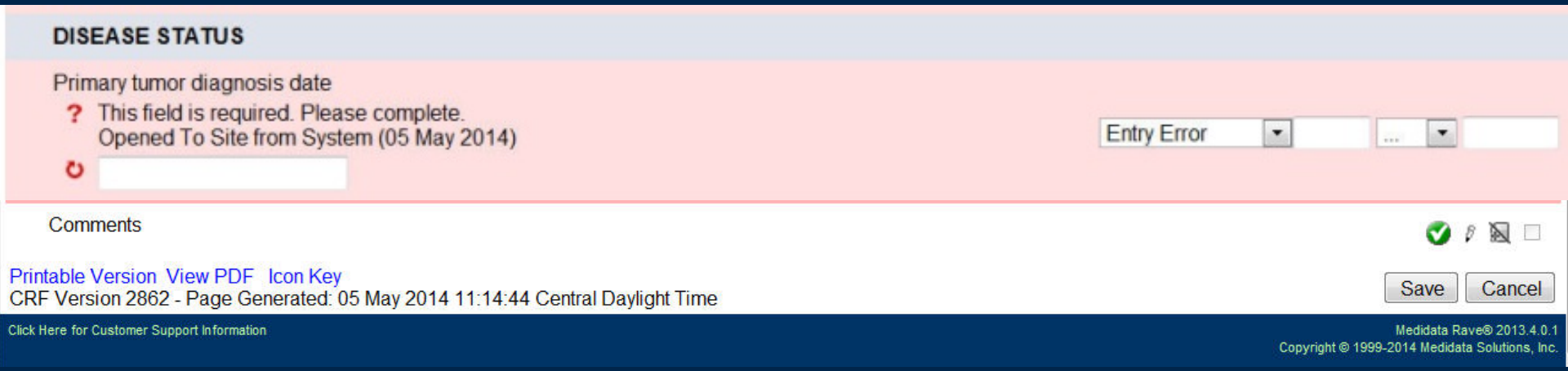
ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY

Unknown Date Component

- If the unknown format is not used and you do not have a complete date, leave the date missing
- Add a comment in the response box indicating why the date is missing
- If you know part of the date like the year or month and year, indicate the known portion of the date in the comment field located at the bottom of the form

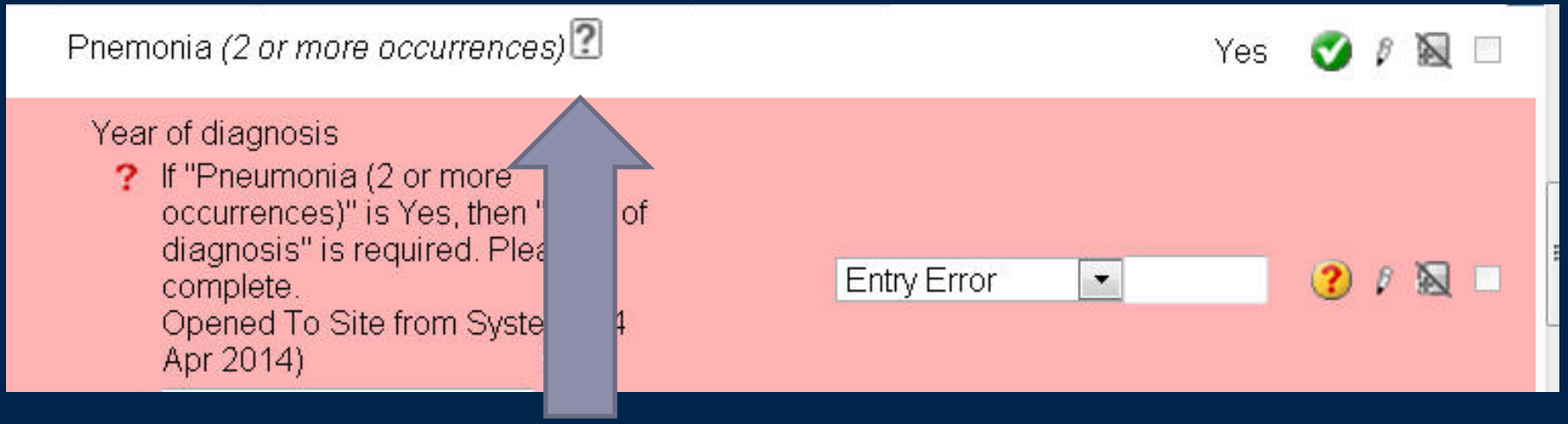
ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Unknown Date Component

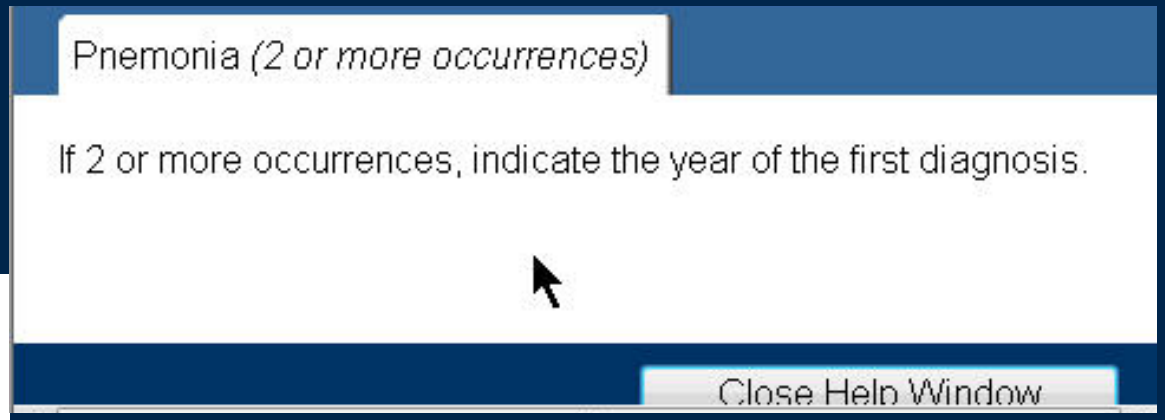


ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Help Text

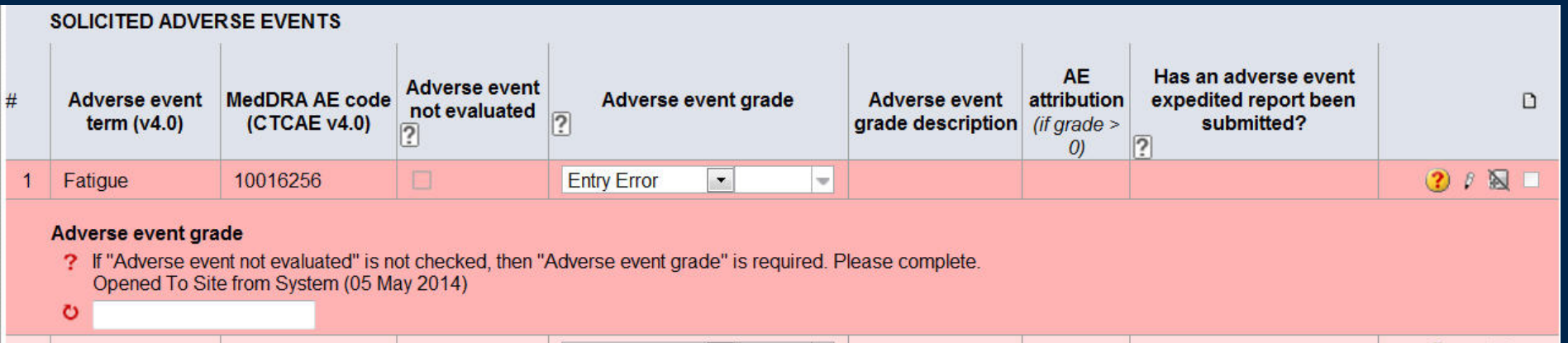


Help text icon



Routine AE Reporting

- Work around if response time is slow when entering solicited AE grade
  - This may occur if there is a large number of solicited AEs for a given form (~10 or more)
- Save the Form first



SOLICITED ADVERSE EVENTS

#	Adverse event term (v4.0)	MedDRA AE code (CTCAE v4.0)	Adverse event not evaluated	Adverse event grade	Adverse event grade description	AE attribution *(if grade > 0)*	Has an adverse event expedited report been submitted?	
1	Fatigue	10016256	☐	Entry Error				

Adverse event grade

? If "Adverse event not evaluated" is not checked, then "Adverse event grade" is required. Please complete.
Opened To Site from System (05 May 2014)

Feedback Needed - How would you prefer to get instructional text?

- In a separate “forms instructions” document located with the Data Submission Schedule and Forms Packet on the CTSU web site
  - Provides the maximum amount of flexibility for updates / changes
- Directly on the Rave Form
  - Provides the least amount of flexibility for updates/ changes as it requires a migration in Rave
  - Most proactive as user does not have to go looking for the instruction

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Feedback Needed - How would you prefer to get instructional text?

- Help text in Rave
  - Also requires migration in Rave
  - Less clutter on the Rave form
  - Still at the fingertips of the user by selecting the

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Questions???