iMedidata Rave Tips

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ALLIANCE

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Objectives

• Provide an update on the CTSU integration initiatives
• Provide some Medidata Rave tips to improve data entry
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
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
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
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.
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.
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
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 nonconformant error.
- The use of the unknown date field is most common on baseline forms.
### Unknown Date Components

<table>
<thead>
<tr>
<th>Regimen name</th>
<th>Regimen received</th>
<th>Other, specify</th>
<th>Start date</th>
<th>Stop date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiotherapy</td>
<td>Yes</td>
<td></td>
<td>01 Jan 2010</td>
<td>Entry Error</td>
</tr>
</tbody>
</table>

**Stop date**

- If "Regimen received" is Yes then "Stop date" is required. Please reconcile.
- Opened To Site from System (15 Apr 2014)
- Therapy end date is currently unknown.

<table>
<thead>
<tr>
<th></th>
<th>Stop date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Docetaxel</td>
<td>un Jan 2010 un Feb 2010</td>
</tr>
</tbody>
</table>

**Start date**

If day is unknown, enter **UN**; if month is unknown, enter **UNK**.

[Close Help Window]
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.
DISEASE STATUS

Primary tumor diagnosis date

? This field is required. Please complete.
Opened To Site from System (05 May 2014)

Comments

Entry Error
Help Text

Help text icon

If 2 or more occurrences, indicate the year of the first diagnosis.
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
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
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 ?
Questions???