



**Clinical Research Professionals – Education Session**

***“It’s All the Rave”***

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**Alliance for Clinical Trials in Oncology**

**Spring 2015 Group Meeting**

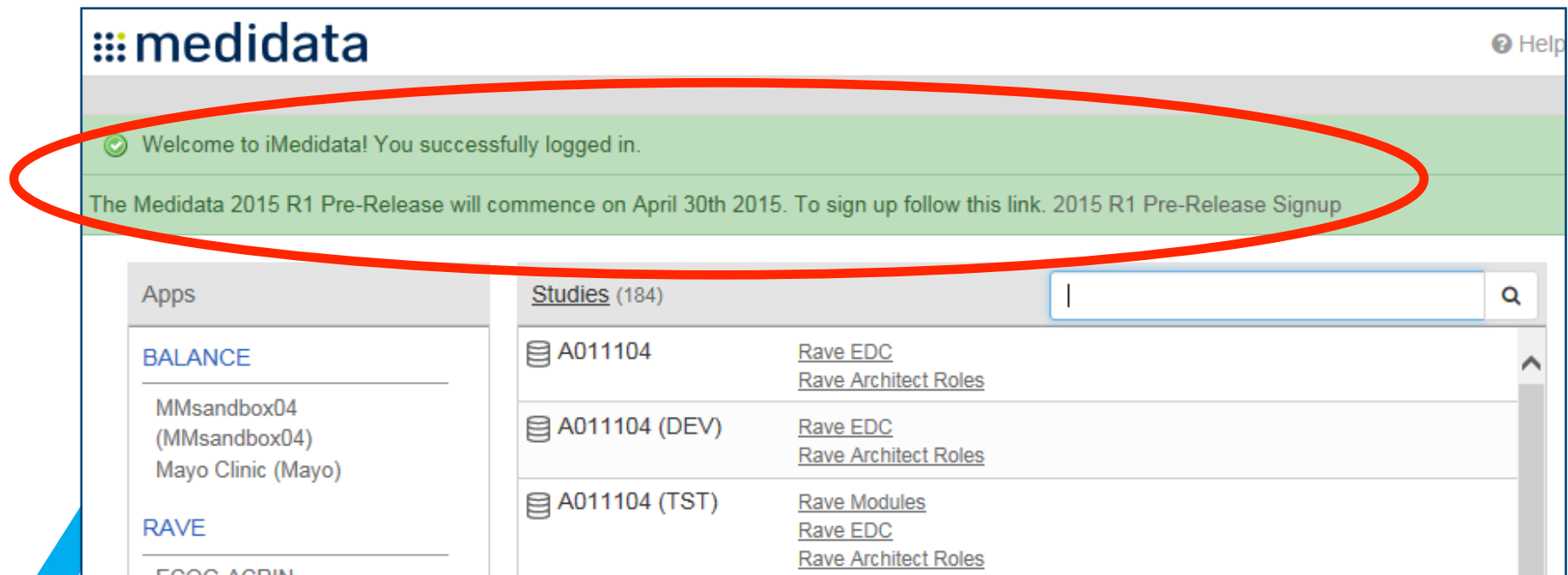


# Presentation Objectives

- Address Frequently asked Rave Questions
- Review Specific Medidata Rave Functionality
- Outline Rave Resources
- Propose Teleconference Option
- Obtain Feedback for Future Rave Topics

# Welcome!

Look for “Welcome Messages”  
across top of Medidata ...



The screenshot displays the Medidata web application interface. At the top left is the Medidata logo, and at the top right is a 'Help' link. A green banner across the top contains a welcome message: 'Welcome to iMedidata! You successfully logged in.' Below this banner is a notification: 'The Medidata 2015 R1 Pre-Release will commence on April 30th 2015. To sign up follow this link. 2015 R1 Pre-Release Signup'. The main content area is divided into two columns. The left column, titled 'Apps', lists 'BALANCE' (with sub-items 'MMsandbox04 (MMsandbox04)' and 'Mayo Clinic (Mayo)') and 'RAVE'. The right column, titled 'Studies (184)', contains a search bar and a list of studies. Each study entry includes a database icon, a study ID, and links for 'Rave EDC' and 'Rave Architect Roles'.

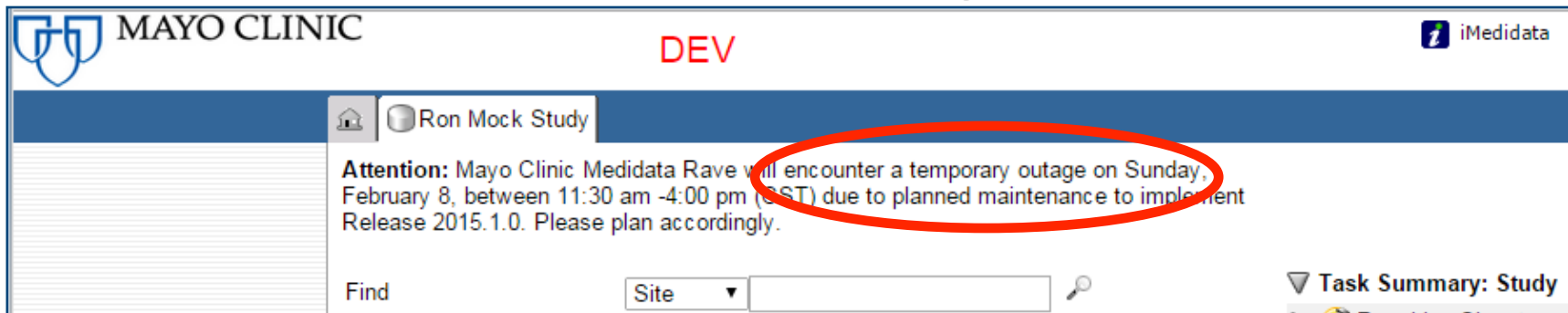
| Apps  | Studies (184)   |
|---|---|
| <b>BALANCE</b><br>MMsandbox04 (MMsandbox04)<br>Mayo Clinic (Mayo) | A011104<br><a href="#">Rave EDC</a><br><a href="#">Rave Architect Roles</a>                                       |
| <b>RAVE</b>   | A011104 (DEV)<br><a href="#">Rave EDC</a><br><a href="#">Rave Architect Roles</a>                                 |
| ECOC ACBIM  | A011104 (TST)<br><a href="#">Rave Modules</a><br><a href="#">Rave EDC</a><br><a href="#">Rave Architect Roles</a> |

## Take note of Welcome Messages:

- Displayed on Home, Study & Site pages
- Can be specific to study, role, or combination

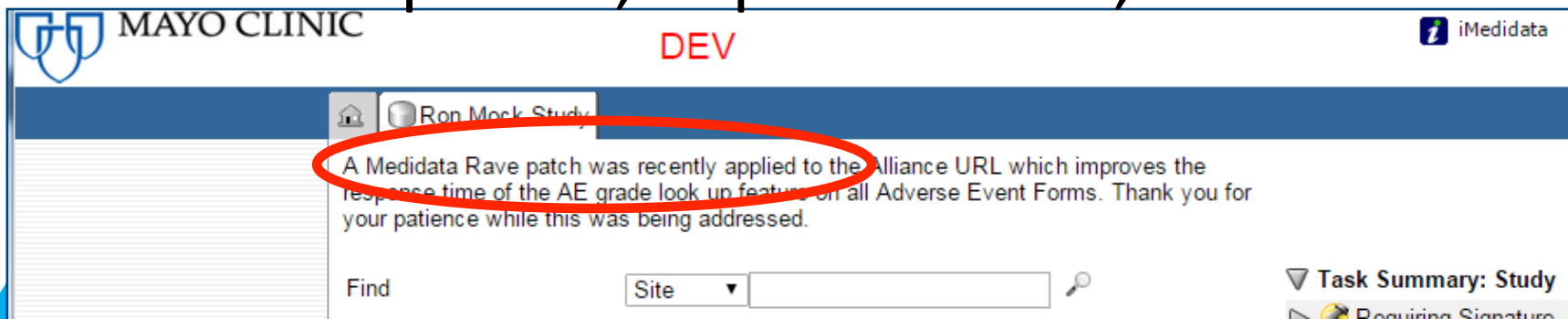
## Examples:

- Rave maintenance/outage information



The screenshot shows the Mayo Clinic iMedidata interface. At the top left is the Mayo Clinic logo and the text "MAYO CLINIC". In the center top, the word "DEV" is displayed in red. At the top right is the iMedidata logo. Below the header, there is a navigation bar with a home icon and a button labeled "Ron Mock Study". The main content area displays an attention message: "Attention: Mayo Clinic Medidata Rave will encounter a temporary outage on Sunday, February 8, between 11:30 am -4:00 pm (EST) due to planned maintenance to implement Release 2015.1.0. Please plan accordingly." This message is circled in red. Below the message is a search bar with the text "Find" and a dropdown menu labeled "Site". At the bottom right, there is a "Task Summary: Study" section.

- Rave updates, improvements, fixes



The screenshot shows the Mayo Clinic iMedidata interface. At the top left is the Mayo Clinic logo and the text "MAYO CLINIC". In the center top, the word "DEV" is displayed in red. At the top right is the iMedidata logo. Below the header, there is a navigation bar with a home icon and a button labeled "Ron Mock Study". The main content area displays a message: "A Medidata Rave patch was recently applied to the Alliance URL which improves the response time of the AE grade look up feature on all Adverse Event Forms. Thank you for your patience while this was being addressed." This message is circled in red. Below the message is a search bar with the text "Find" and a dropdown menu labeled "Site". At the bottom right, there is a "Task Summary: Study" section.




# Location, Location, Location!

## Where to find...

- Protocol documents (in general)
- Paper CRFs
- DSS (Data Submission Schedule)

# Availability of Protocol Documents



home protocols committees education

## Alliance A151216

Home > Protocol Listing > Respiratory > Alliance A151216

**Alliance A151216**

Title: Adjuvant Lung Cancer Enrichment Ma


Study Chair: Geoffrey Oxnard, MD  
Activation Date: 08/18/2014  
Status: Active

A151216 Protocol Document - 03/15/2015  
A151216 Model Consent (word) or (pdf) - 03

NCI Press Release- 08/18/2014  
ALCHEMIST Q&A - 03/17/2015

ALCHEMIST Slides - 03/17/2015

- Alliance A151216
- All Documents
- Updates and Action Letters
- Funding Sheet
- Case Report Forms
- Memoranda and Broadcasts
- Supplemental Materials



Cancer Trials Support Unit  
A SERVICE OF THE NATIONAL CANCER INSTITUTE

My Account Welcome Barbara Greguson. Your password will expire in 97 days.

Home Protocols Dashboard Regulatory OPEN Rave Clinical Data

### CTSU NEWS

#### CTSU WEBINAR

View the [presentation slides](#) or [listen to recording from the April 2 Trials](#)".

#### TRANSITION NEWS

Transition News on the NCTN, ETCTN, and CIRB-CTSU Integration can be found i

#### CTSU ANNOUNCEMENTS

The TRIAD application is now in use for select protocols: The TRIAD applicac and centralized quality processing is now in use for select protocols. For more inform message to view the TRIAD Fact Sheet.

Document Search DSN Search DSN Bucket Quick Links

Protocol:  Document Title:

Document:  Go Clear

**Alliance website vs. CTSU website**

**Q:** Are Alliance protocol documents found on the Alliance website, the CTSU website, or both?

**A:** It depends on the who is listed under the “Participating Organizations” in the protocol.

# Availability of Protocol Documents

ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY  
ALLIANCE A091305

A PHASE 2 RANDOMIZED STUDY OF EFATUTAZONE, AN ORAL PPAR AGONIST, IN COMBINATION WITH PACLITAXEL VERSUS PACLITAXEL IN PATIENTS WITH ADVANCED ANAPLASTIC THYROID CANCER

Industry-supplied agent: Efatutazone (IND #121997, NSC #776711);  
Commercial agent: Paclitaxel

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**Participating Organizations:**  
ALLIANCE/ Alliance for Clinical Trials in Oncology  
ECOG-ACRIN/ECOG-ACRIN Cancer Research Group  
NRG/ NRG Oncology  
SWOG/ SWOG

**Participating Organizations:**  
ALLIANCE/ Alliance for Clinical Trials in Oncology  
ECOG-ACRIN/ECOG-ACRIN Cancer Research Group  
NRG/ NRG Oncology  
SWOG/ SWOG

Multiple Organizations

If multiple organizations are participating, docs are found on both Alliance and CTSU websites.

**Participating Organizations:**  
ALLIANCE/ Alliance for Clinical Trials in Oncology

Alliance Members Only

If Alliance members *only* are participating, docs are found on the Alliance website only.

Alliance:  
[www.allianceforclinicaltrialsinoncology.org/main/](http://www.allianceforclinicaltrialsinoncology.org/main/)

CTSU:  
[www.ctsu.org/](http://www.ctsu.org/)

# Paper CRFs and DSS Availability

Alliance Website -> Study Page -> Case Report Forms

The screenshot shows the Alliance for Clinical Trials in Oncology website. The navigation menu includes 'home', 'protocols', 'committees', 'education & training', 'member services', and 'news'. The 'protocols' menu item is circled in red. Below the navigation is a blue banner for 'Alliance A151216'. A breadcrumb trail 'Home > Protocol Listing > Respiratory > Alliance A151216' is also circled in red. On the left sidebar, 'Case Report Forms' is circled in red. The main content area displays study details for Alliance A151216, including the title 'Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST)', study chair 'Geoffrey Oxnard, MD', activation date '08/18/2014', and status 'Active'. A blue box labeled 'All CRFs' points to a list of PDF documents: 'A151216-Allforms-08182014.pdf', 'A151216-DSS-03152015.pdf', 'A151216-DSS-08182014.pdf', 'A151216-OPENEnrollmentForm-Step0.pdf', and 'A151216-OPENEnrollmentForm-Step1.pdf'. Another blue box labeled 'Data Submission Schedule' points to the 'A151216-DSS-08182014.pdf' document. A large blue arrow points from the right side of the page towards the 'All CRFs' box.

Shauna Hillman(log out)  
Back to the Public Pages  
Search  
Advanced Search

home protocols committees education & training member services news

## Alliance A151216

Home > Protocol Listing > Respiratory > Alliance A151216

### Alliance A151216

Title: Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST)  
Study Chair: Geoffrey Oxnard, MD  
Activation Date: 08/18/2014  
Status: Active

A151216 Protocol Document - 03/15/2015  
A151216 Model Consent (word) or (pdf) - 03/15/2015

NCI Press Release- 08/18/2014  
ALCHEMIST Q&A - 03/17/2015

Alliance A151216  
All Documents  
Updates and Action Letters  
Funding Sheet  
Case Report Forms  
Memoranda and Broadcasts  
Supplemental Materials

### All CRFs

### Data Submission Schedule

### Case Report Forms

- A151216-Allforms-08182014.pdf
- A151216-DSS-03152015.pdf
- A151216-DSS-08182014.pdf
- A151216-OPENEnrollmentForm-Step0.pdf
- A151216-OPENEnrollmentForm-Step1.pdf

ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY





# Add Event

When to use Add Event to create a specific event form ...

The screenshot displays a user interface for a clinical trial. At the top, there is a navigation bar with a home icon, a subject ID 'A081105', a study name 'Stage II Testing Round 3', and a user ID 'SLH002'. On the left, a sidebar lists various visit types: 'SLH002', 'Baseline', 'Treatment 01: 01-Feb-2010', 'Off Treatment', 'Survival Follow-up 02: N Contact', and 'Survival Follow-up 03: 0 Apr-2010'. The main area shows a 'Subject Enrollment' section with a table of visits:

| Visit    | Date        |
|----------|-------------|
| Baseline | 15 Jan 2010 |

Below the table, there is a section for 'Task Summary: Subject' with several expandable items: 'NonConformant Data', 'Open Queries', 'Sticky Notes', and 'Overdue Data'. At the bottom of the main area, there is a section for 'Reports' with two items: 'Query Detail - Query Detail Report' and 'Subject PDF Report - Subject PDF Report'. The 'Add Event' button, which is circled in red, is located below the 'Add Event' text and consists of a dropdown menu and an 'Add' button.

ALLIANCE  
FOR CLINICAL TRIALS IN ONCOLOGY

CRF Version 2900 - Page Generated: 20 Apr 2015 14:56:40 Central Daylight Time

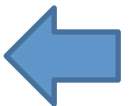
# Use the “Add Event” functionality ...

**New Primary:** When a New Primary tumor needs to be recorded mid-study.

**Consent Withdrawal:** When a patient decides to withdraw their consent.

**Lost to Follow Up:** When a patient is officially lost to follow up.

**Study Specific Forms:** Forms for events that are needed for a specific study, but not expected.



# Free-Text Fields

## What is it and when to use it ...

### Free-Text Field:

Those data entry fields that accept any alpha-numeric characters.

### Free-Text Field Examples:

Comments, Other (specify).



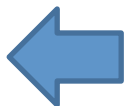
# Free-Text Fields

## Question:

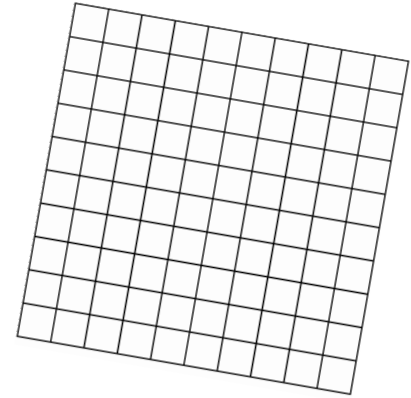
When entering Free Text, how many alphanumeric characters are typically allowed?

## Answer:

200 characters



# Grid View



**Within Rave, view patient forms in ...**

- “Calendar View” (default)
- “Grid View” (click toggle)

★ Use Grid View to see and access ALL forms (eCRFs) per patient; Subject level only

# Reminder: Grid View Available

**Calendar View**

INIC TST iMedidata Messages My Profile Help Home Logout  
User: Shauna Hillman (Clinical Research Associate)

A151216 Stage II Testing Round 18 SLH001

SLH001  
Baseline  
Specimen Adequacy (1)  
Survival and Disease Status Follow-Up 01: 15-May-2010

Subject Enrollment

| Visit   | Date        |
|---|-------------|
| Baseline  | 30 Jun 2010 |
| Survival and Disease Status Follow-Up 01: 15-May-2010 | 14 Jul 2010 |

Task Summary: Subject

| Pages                 |
|-----------------------|
| NonConformant Data: 0 |
| Open Queries: 3       |
| Sticky Notes: 0       |
| Overdue Data: 8       |

**Grid View**

Toggle

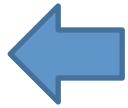
A151216 Stage II Testing Round 18 SLH001

Subject Enrollment

| All  | SLH001 | Baseline | Specimen Adequacy (1) | Survival and Disease Status Follow-Up 01: 15-May-2010 | All  |
|--|--------|----------|-----------------------|---|--|
| Subject Enrollment   |        |          |                       |   | Subject Enrollment   |
| Institutional Contacts   |        |          |                       |   | Institutional Contacts   |
| Screening  |        |          |                       |   | Screening  |
| On-Study   |        |          |                       |   | On-Study   |
| On-Study: Epidemiology Questionnaire                                   |        |          |                       |   | On-Study: Epidemiology Q   |
| On-Study: Patient's Smoking History                                    |        |          |                       |   | On-Study: Patient's Smokin   |
| On-Study: Patient's Environmental and Occupational Exposures           |        |          |                       |   | On-Study: Patient's Environ  |
| On-Study: Patient's Family and General Information                     |        |          |                       |   | On-Study: Patient's Family Information                                 |
| On-Study: Surgery (for resection of tumor)                             |        |          |                       |   | On-Study: Surgery (for resection of tumor)                             |
| Supporting Documentation: Baseline                                     |        |          |                       |   | Supporting Documentation: Baseline                                     |
| Specimen Submission: Blood   |        |          |                       |   | Specimen Submission: Blood   |
| Specimen Submission: Tissue  |        |          |                       |   | Specimen Submission: Tissue  |
| EGFR/ALK Testing Results (Internal Use Only - RGI)                     |        |          |                       |   | EGFR/ALK Testing Results (Internal Use Only - RGI)                     |
| Patient Status: Baseline   |        |          |                       |   | Patient Status: Baseline   |
| Patient Status: Survival and Disease Status Follow-Up/Event Monitoring |        |          |                       |   | Patient Status: Survival and Disease Status Follow-Up/Event Monitoring |
| All  | SLH001 | Baseline | Specimen Adequacy (1) | Survival and Disease Status Follow-Up 01: 15-May-2010 | All  |

**Calendar View**

**Grid View**



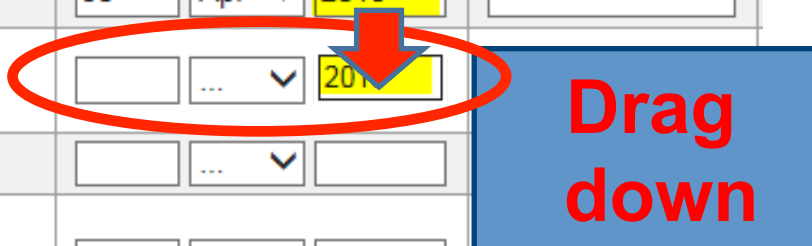
# It's a Drag

Did you know that you can  
“Highlight-n-Drag” to copy  
data fields within Rave?



# Rave Tip: Highlight year from previous date and Drag to new location

| # | Lab test name   | Was lab specimen collected?                                   | Sample collection date |     |      | Lab value |
|---|---|---|------------------------|-----|------|-----------|
| 1 | White Blood Cells (WBC), #, Blood                     | <input checked="" type="radio"/> Yes <input type="radio"/> No | 30                     | Apr | 2015 |           |
| 2 | Absolute Neutrophil Count (ANC), Blood                | <input type="radio"/> Yes <input type="radio"/> No            |                        | ... | 2015 |           |
| 3 | Platelets, Blood                                      | <input type="radio"/> Yes <input type="radio"/> No            |                        | ... |      |           |
| 4 | Glomerular Filtration Rate, Manual Calculation, Blood | <input type="radio"/> Yes <input type="radio"/> No            |                        | ... |      |           |



## Applications:

- When entering multiple dates on a form
- QOLs to enter "Pt did not complete"



**NOTE: Works in Firefox, not IE or Chrome**





# Use your Pagination!

What is “Pagination”, when is it used, and how are the display settings changed?

| #  | 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                    | <input type="checkbox"/>     | 0 <sup>o</sup>      | None <sup>o</sup>               |                               |   | <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"/> <input type="checkbox"/> <input type="checkbox"/> |
| 2  | Diarrhea                  | 10012727                    | <input type="checkbox"/>     | 0 <sup>o</sup>      | None <sup>o</sup>               |                               |   | <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"/> <input type="checkbox"/> <input type="checkbox"/> |
| 3  | Constipation              | 10010774                    | <input type="checkbox"/>     | 0 <sup>o</sup>      | None <sup>o</sup>               |                               |   | <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"/> <input type="checkbox"/> <input type="checkbox"/> |
| 4  | Vomiting                  | 10047700                    | <input type="checkbox"/>     | 0 <sup>o</sup>      | None <sup>o</sup>               |                               |   | <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"/> <input type="checkbox"/> <input type="checkbox"/> |
| 5  | Dyspepsia                 | 10013946                    | <input type="checkbox"/>     | 0 <sup>o</sup>      | None <sup>o</sup>               |                               |   | <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"/> <input type="checkbox"/> <input type="checkbox"/> |
| 6  | Edema limbs               | 10050068                    | <input type="checkbox"/>     | 0 <sup>o</sup>      | None <sup>o</sup>               |                               |   | <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"/> <input type="checkbox"/> <input type="checkbox"/> |
| 7  | Arthralgia                | 10003239                    | <input type="checkbox"/>     | 0 <sup>o</sup>      | None <sup>o</sup>               |                               |   | <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"/> <input type="checkbox"/> <input type="checkbox"/> |
| 8  | Bone pain                 | 10006002                    | <input type="checkbox"/>     | 0 <sup>o</sup>      | None <sup>o</sup>               |                               |   | <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"/> <input type="checkbox"/> <input type="checkbox"/> |
| 9  | Myalgia                   | 10028411                    | <input type="checkbox"/>     | 0 <sup>o</sup>      | None <sup>o</sup>               |                               |   | <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"/> <input type="checkbox"/> <input type="checkbox"/> |
| 10 | Headache                  | 10019211                    | <input type="checkbox"/>     | 0 <sup>o</sup>      | None <sup>o</sup>               |                               |   | <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"/> <input type="checkbox"/> <input type="checkbox"/> |

Were (other) adverse events assessed during most recent period?  Yes, but no reportable adverse events occurred

Comments

Printable Version View PDF Icon Key  
CRF Version 3775 - Page Generated: 22 Apr 2015 11:58:01 Central Daylight Time  
FOR CURRENT REVIEW ONLY

Save Cancel

# Pagination

When using a log line table, only so many log lines may be displayed at one time. Pagination allows the user to “page” through multiple lists of log lines using a drop-down menu.

| #  | 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                    | <input type="checkbox"/>    | 0 <sup>o</sup>      | None <sup>o</sup>               |                               |   | <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"/> <input type="checkbox"/> <input type="checkbox"/> |
| 2  | Diarrhea                  | 10012727                    | <input type="checkbox"/>    | 0 <sup>o</sup>      | None <sup>o</sup>               |                               |   | <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"/> <input type="checkbox"/> <input type="checkbox"/> |
| 3  | Constipation              | 10010774                    | <input type="checkbox"/>    | 0 <sup>o</sup>      | None <sup>o</sup>               |                               |   | <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"/> <input type="checkbox"/> <input type="checkbox"/> |
| 4  | Vomiting                  | 10047700                    | <input type="checkbox"/>    | 0 <sup>o</sup>      | None <sup>o</sup>               |                               |   | <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"/> <input type="checkbox"/> <input type="checkbox"/> |
| 5  | Dyspepsia                 | 10013946                    | <input type="checkbox"/>    | 0 <sup>o</sup>      | None <sup>o</sup>               |                               |   | <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"/> <input type="checkbox"/> <input type="checkbox"/> |
| 6  | Edema limbs               | 10050068                    | <input type="checkbox"/>    | 0 <sup>o</sup>      | None <sup>o</sup>               |                               |   | <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"/> <input type="checkbox"/> <input type="checkbox"/> |
| 7  | Arthralgia                | 10003239                    | <input type="checkbox"/>    | 0 <sup>o</sup>      | None <sup>o</sup>               |                               |   | <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"/> <input type="checkbox"/> <input type="checkbox"/> |
| 8  | Bone pain                 | 10006002                    | <input type="checkbox"/>    | 0 <sup>o</sup>      | None <sup>o</sup>               |                               |   | <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"/> <input type="checkbox"/> <input type="checkbox"/> |
| 9  | Myalgia                   | 10028411                    | <input type="checkbox"/>    | 0 <sup>o</sup>      | None <sup>o</sup>               |                               |   | <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"/> <input type="checkbox"/> <input type="checkbox"/> |
| 10 | Headache                  | 10019211                    | <input type="checkbox"/>    | 0 <sup>o</sup>      | None <sup>o</sup>               |                               |   | <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"/> <input type="checkbox"/> <input type="checkbox"/> |

Were (other) adverse events assessed during most recent period?  Yes, but no reportable adverse events occurred

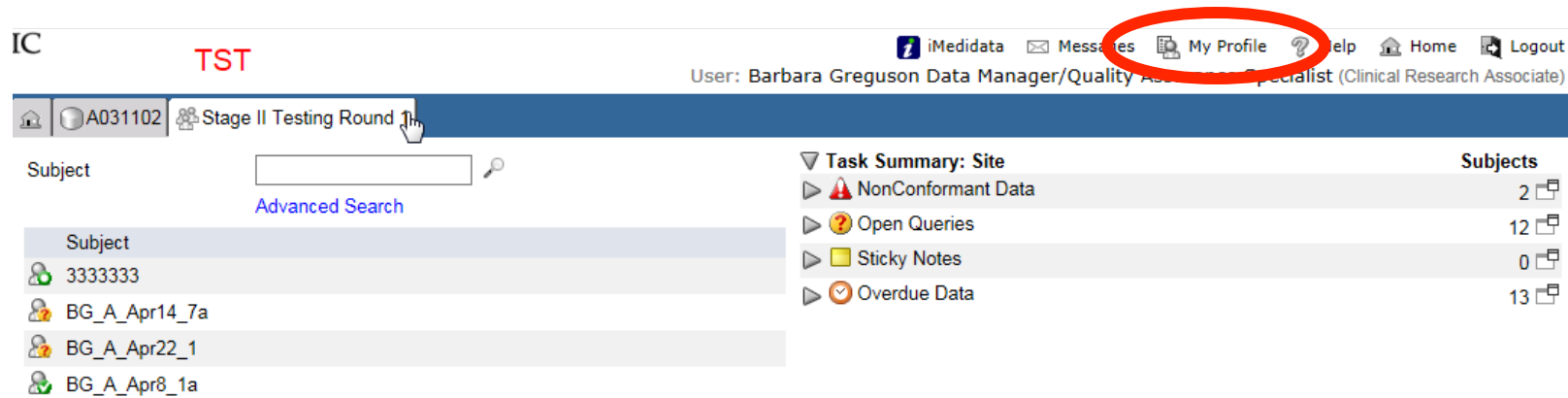
Comments

Printable Version View PDF Icon Key  
CRF Version 3775 - Page Generated: 22 Apr 2015 11:58:01 Central Daylight Time  
FOR CURRENT REVIEW ONLY

Save Cancel

# Pagination

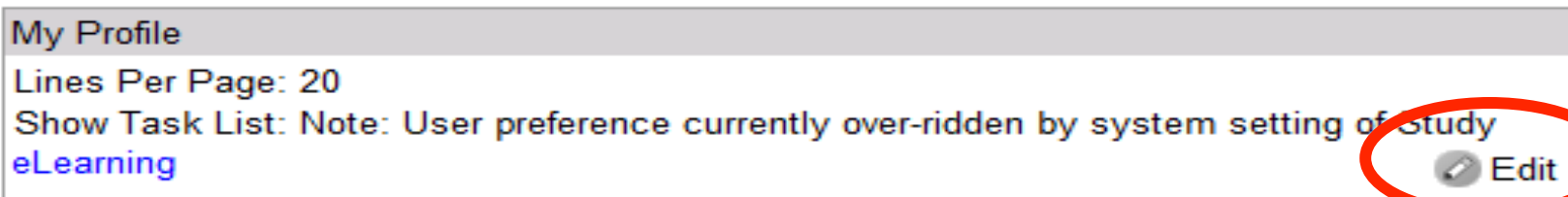
You may update your Pagination settings by going into the Home Page under “My Profile”.



The screenshot shows the top navigation bar of the iMedidata system. The user is identified as Barbara Greguson, a Data Manager/Quality Assurance Specialist. The 'My Profile' menu item is circled in red. Below the navigation bar, the main content area is divided into several sections: a search bar for subjects, a list of subjects, a task summary table, and a list of tasks.

| Task Summary: Site | Subjects |
|--------------------|----------|
| NonConformant Data | 2        |
| Open Queries       | 12       |
| Sticky Notes       | 0        |
| Overdue Data       | 13       |

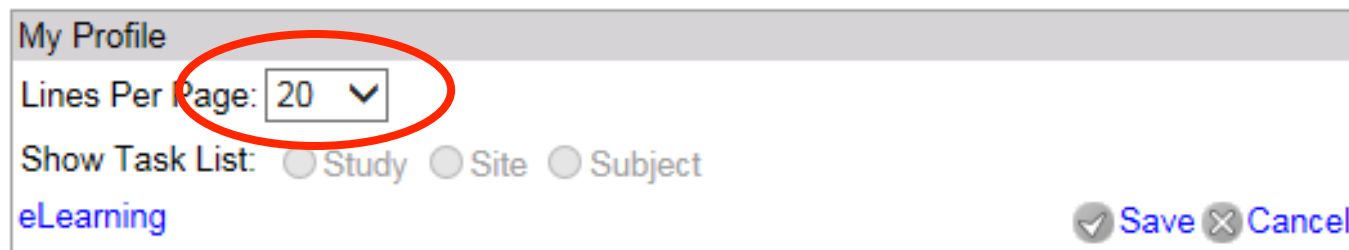
Click the “edit” icon,



The screenshot shows the 'My Profile' settings page. The settings are: 'Lines Per Page: 20' and 'Show Task List: Note: User preference currently over-riden by system setting of Study'. The 'Edit' button is circled in red.

# Pagination

Update the number of lines displaying from 20 to 200, so all lines of a log line table may be displayed at once.



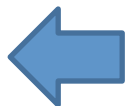
My Profile

Lines Per Page: 20 ▾

Show Task List:  Study  Site  Subject

eLearning  Save  Cancel

You may select from preset options: 5, 10, 20, 25, 50, 100 or 200 lines.



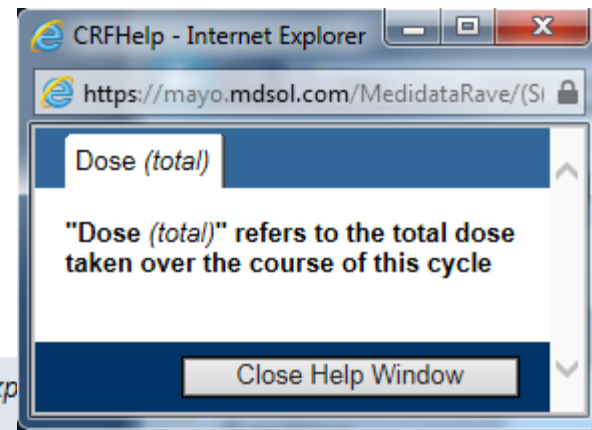
# Help Text



What is Help Text, when is it available, and how is it used?

NOTE: "Dose level (day 1)" refers to the measured amount of each study agent expected to be taken on day 1. "Dose (total)" refers to the total dose taken over the course of this cycle.

| # | Agent name | Not required per protocol | Dose level (day 1) | Units of measure | Dose (total) | Units of measure | Was protocol treatment modified? | Was protocol treatment delayed (interrupted)?      |
|---|------------|---------------------------|--------------------|------------------|--------------|------------------|----------------------------------|--|
| 1 | Sorafenib  | <input type="checkbox"/>  |                    | mg               |              | mg               | ...                              | <input type="radio"/> Yes <input type="radio"/> No |
| 2 | Everolimus | <input type="checkbox"/>  |                    | mg               |              | mg               | ...                              | <input type="radio"/> Yes <input type="radio"/> No |



# Help Text



Please check the Help Text icon, if you have any questions about the data field:

- Carefully selected - only data fields which need clarification or parameters
- Hidden to make form clean and user friendly
- Different than “Instructional Text”



# Query Response

When to use the different entry fields (boxes), if presented with a query ...

Hemoglobin

? This field is required. Please complete.  
Opened To Site from System (04 Sep 2013)

0

Entry Error  g/dL ?

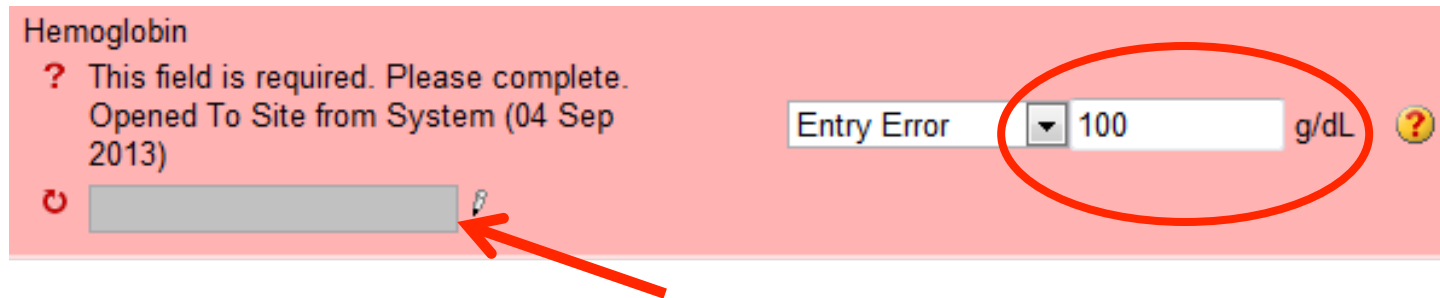
**User Response Field**

**Data Entry Field**

# Responding to Queries

You can respond to queries in two ways:

- Modify the data in the data entry field. If no response is required, the response box will be greyed out.



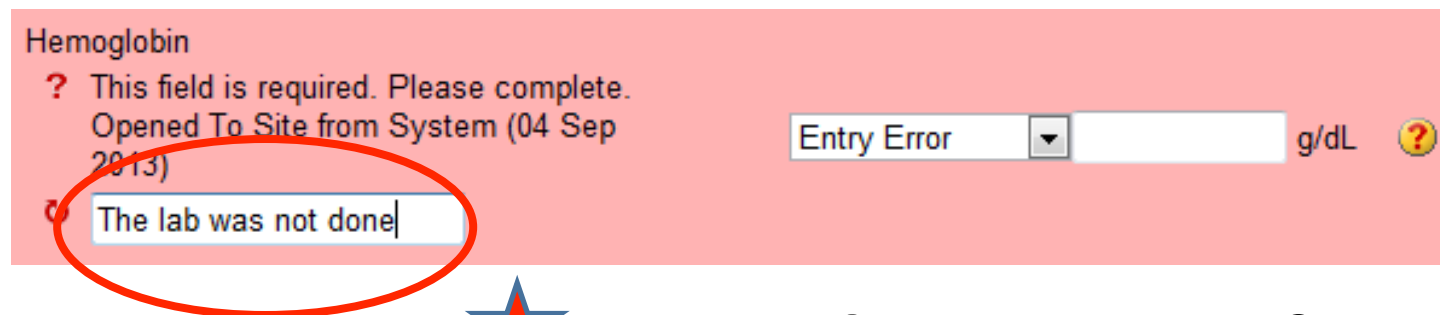
Hemoglobin  
? This field is required. Please complete.  
Opened To Site from System (04 Sep 2013)

Entry Error [v] 100 g/dL ?

[Greyed-out response box]

A red circle highlights the '100' value in the data entry field. A red arrow points to the greyed-out response box.

- Provide an explanation in the user response box (free-text), if data cannot be corrected/not available.

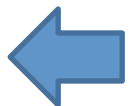


Hemoglobin  
? This field is required. Please complete.  
Opened To Site from System (04 Sep 2013)

Entry Error [v] g/dL ?

The lab was not done

A red circle highlights the text 'The lab was not done' in the response box.












# Non-Conformant



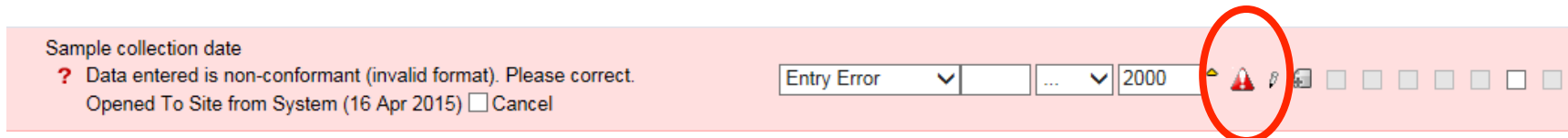
## How to interpret Non-Conformant data queries ...

Sample collection date  
? Data entered is non-conformant (invalid format). Please correct.  
Opened To Site from System (16 Apr 2015)  Cancel






Entry Error ▼ ... ▼ 2000       

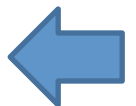
- ★ Non-Conformant queries: data entered was NOT in the format that was expected!

# Queries: Non-Conformant



## Examples:

-  A text string was entered, when a number was expected; “one” instead of “1”
-  A partial date was entered, but a full date was expected
-  A “specify” response was not provided, when an “other” was selected
-  A comment was provided that was longer than the allowed 200 characters
-  Many more unique scenarios!



# When To Comment

When is it appropriate to use a “Comments” data field ...

The screenshot shows a data entry interface for a clinical trial. The breadcrumb trail at the top reads: A081105 > Stage II Testing Round 3 > SLH003 > Treatment 01: > Patient Status: Treatment (Intervention). The form contains several sections: 'Date of most recent contact' (1 Jan 2012), 'Death date', 'Cause of death?', 'If other cause of death, specify', 'DISEASE STATUS' (Was disease status evaluated during this reporting period? No), '(If yes), date of most recent disease status evaluation', '(If yes), has the patient developed a first relapse or progression (recurrence) that has not been previously reported?', 'Date of progression (or recurrence)', 'PROTOCOL TREATMENT' (Will the patient continue protocol treatment (intervention) in the subsequent cycle?), 'NEW PRIMARY' (Has the patient had a new primary that has not been previously reported? No), and 'Comments'. A red rectangular box highlights the 'Comments' field at the bottom of the form. To the right of the 'Comments' field, there is a blue box with the text 'Comments data field' and a red arrow pointing to the 'Comments' field.

Comments data field

# When should Comments be used?

| NODE MEASUREMENTS |                    |                              |                          |                      |                             |                             |                         |
|-------------------|--------------------|------------------------------|--------------------------|----------------------|-----------------------------|-----------------------------|-------------------------|
| #                 | Serial # of lesion | Lesion site(s)               | Was this site evaluated? | Method of evaluation | Perpendicular measurement A | Perpendicular measurement B | Product of measurements |
| 1                 | One                | Right Neck Node <sup>▲</sup> | Yes <sup>▲</sup>         | Physical exam        | 1.5 cm <sup>▲</sup>         | cm                          |                         |

**Lesion site(s)**

? This target lesion site has been modified. Please confirm the current lesion measurement is correct.  
Opened To Site from System (08 Dec 2014)

answered

**Was this site evaluated?**

? If "Lesion site" is present, then "Was this site evaluated?" is required. Please reconcile.  
Opened To Site from System (08 Dec 2014)

answered

**Perpendicular measurement B**

? If "Was this site evaluated?" is Yes, then "Perpendicular measurement B" is required. Please reconcile.  
Opened To Site from System (08 Dec 2014)



see comment section

Comments

one dimension given for right cervical lymph node. left supraclavicular node is subcentimeter. No perpendicular measurements are given

If there is pertinent information that should be considered by the Study Team, but cannot be recorded or clearly captured by the CRF data fields.


































# Audit Trail

| EGFR   |  |   |
|--|--|---|
| EGFR mutation status assessed  | Yes  |    |
| (If yes), attach the local report for EGFR here  | <a href="#">A151216 - 9101547 EGFR results.pdf</a> |    |
| (If yes), was an EGFR mutation identified?<br>? If "was an EGFR mutation identified?" is Yes, then at least one of the EGFR mutation types should be Yes. Please reconcile.<br>Opened To Site from System (02 Mar 2015)<br>corrected | Yes  |    |
| (If EGFR mutation identified),   |  |   |
| Exon 19 deletion   | Yes  |    |
| L858R  | No   |    |
| T790M  | No   |    |
| Exon 20 insertion  | No   |    |
| G719A/G719C/G719S  | No   |    |
| L861Q  | No   |   |
| Other EGFR mutation  | No   |  |
| If other EGFR mutation, specify  |  |  |

Q: Where is the audit trail available in Rave?

A: Click on the Data Status Icon to view the audit trail for a particular data field.

# Audit Trail

|  |  |
|--|--|
| EGFR   |  |
| EGFR mutation status assessed  | Yes     |
| (If yes), attach the local report for EGFR here  | <a href="#">A151216 - 9101547_EGFR_results.pdf</a>    |
| (If yes), was an EGFR mutation identified?<br>? If "was an EGFR mutation identified?" is Yes, then at least one of the EGFR mutation types should be Yes. Please reconcile.<br>Opened To Site from System (02 Mar 2015)<br>corrected | Yes     |
| (If EGFR mutation identified),   |  |
| Exon 19 deletion   | Yes     |
|  | No      |
|  | No      |
|  | No      |
|  | No      |
|  | No      |
| Other EGFR mutation  | No      |
| If other EGFR mutation, specify  |     |

Select Status Icon to get Audit Trail

Navigation: A151216 TEST\_SITE 9101547 Baseline On-Study Audits

Data Point - (If yes), was an EGFR mutation identified?  
Parent: Record - On-Study  
Siblings: Data Point - (If yes), was an EGFR mutation identified?

| Audit  | User   | Time                 |
|--|--|----------------------|
| User closed query 'If "was an EGFR mutation identified?" is Yes, then at least one of the EGFR mutation types should be Yes. Please reconcile.' (Site from System)               | Chelsea Schultz (5032 - schultz.chelsea@mayo.edu3)     | 05 Mar 2015 16:08:10 |
| Query 'If "was an EGFR mutation identified?" is Yes, then at least one of the EGFR mutation types should be Yes. Please reconcile.' answered with 'corrected' (Site from System) | Jennifer Howgate-Klingaman (6463 - jhowgate@sluhn.org) | 02 Mar 2015 08:35:29 |
| User opened query 'If "was an EGFR mutation identified?" is Yes, then at least one of the EGFR mutation types should be Yes. Please reconcile.' (Site from System)               | Jennifer Howgate-Klingaman (6463 - jhowgate@sluhn.org) | 02 Mar 2015 08:29:05 |
| User entered 'Yes (1)'   | Jennifer Howgate-Klingaman (6463 - jhowgate@sluhn.org) | 02 Mar 2015 08:29:05 |

CRF Version 3135 - Page Generated: 21 Apr 2015 08:58:34 Central Daylight Time

Date/Time

Audit (action) to data field

Audit (action) to data field

# Audit Trail

- The User column shows actions recorded by the CRP, DM, and System (queries).
- The DM and the CRP can view the audit trail.

The screenshot shows a web application interface with a navigation bar at the top containing icons for home, a user ID (A151216), a site name (TEST\_SITE), another user ID (9101547), and tabs for Baseline, On-Study, and Audits. The main content area displays an audit trail for a data point: "Data Point - (If yes), was an EGFR mutation identified?". Below this, a table lists audit events with columns for the action description and the user who performed it. Red circles highlight the user names in the "User" column: "Chelsea Schultz (5032 - schultz.chelsea@mavo.edu?)", "System", and "Jennifer Howgate-Klingaman (6463 - Jennifer.Howgate-Klingaman@sluhn.org)". Three blue callout boxes with red text and arrows point to these entries: "DM Trail" points to Chelsea Schultz, "System Trail" points to System, and "CRP Trail" points to Jennifer Howgate-Klingaman. A blue arrow points from the bottom right towards the audit trail table.

| Audit   | User   | Timestamp            |
|---|--|----------------------|
| User closed query 'If "was an EGFR mutation identified?" is Yes, then at least one of the EGFR mutation types should be Yes. Please reconcile.' (Site from System).               | Chelsea Schultz (5032 - schultz.chelsea@mavo.edu?)                       |                      |
| Query 'If "was an EGFR mutation identified?" is Yes, then at least one of the EGFR mutation types should be Yes. Please reconcile.' answered with 'corrected' (Site from System). | Jennifer Howgate-Klingaman (6463 - Jennifer.Howgate-Klingaman@sluhn.org) |                      |
| User opened query 'If "was an EGFR mutation identified?" is Yes, then at least one of the EGFR mutation types should be Yes. Please reconcile.' (Site from System).               | System   | 08:29:05             |
| User entered 'Yes (1)'  | Jennifer Howgate-Klingaman (6463 - Jennifer.Howgate-Klingaman@sluhn.org) | 02 Mar 2015 08:29:05 |

# Browsers

Currently, Rave can be accessed using any one of five browsers...

- ✓ Chrome v20
- ✓ IE v8
- ✓ Opera v10
- ✓ Firefox 24
- ✓ Safari v5

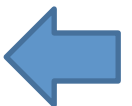


**Medidata**  
recommends the  
latest version of your  
chosen browser, at  
least these listed  
versions or newer.



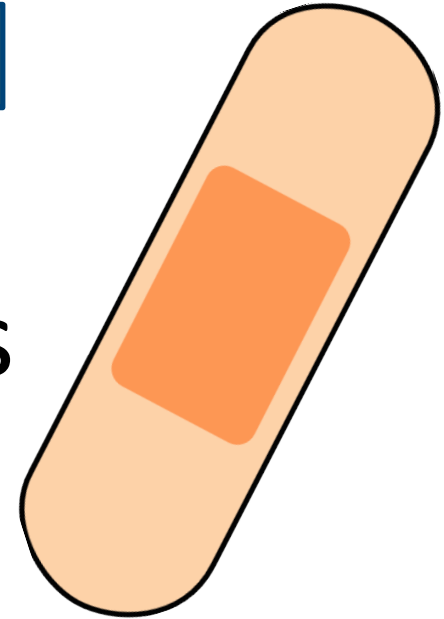
# Browser Availability

- Medidata discontinued support for Internet Explorer version 7 (IE7) browser in early 2015 (IE v8 is now needed).
- Keeping browsers up to date ensures a more secure, speedy, attractive, and functional experience for all web-based software used.
- *Note: each one may have quirks when running reports, depending on version. If you have trouble with one browser, try a different one.*



# AE Bandaid

Painful entries of AE grades have “speedy recovery” ...



**History:** Entering severity grades within AE log tables took unusually long time to process.

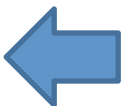
**Meanwhile:** “Work around” was suggested to speed up process.

# AE Reporting

**Bandaïd:** January 2015, Medidata implemented a patch to speed up the dynamic populations of AE grades.

**Current:** “Work around” no longer needed. Reported feedback indicates that speed issue is fixed and now acceptable.

**Site Poll: How many have seen improvement? How many still having slow response?**



# Rave Access

**Q:** What resources are available if you are unable to access Rave or a study within Rave?

**A:** #1 – Lead CRP  
#2 – CTSU website  
#3 – CTSU

If you have questions about this please contact the [CTSU Help Desk](#).

## Learn More About Rave

### Rave resource materials

- [Medidata Account Activation and Study Invitation Acceptance](#)
- [CTEP-IAM Account Fact Sheet](#)
- [CTSU Newsletter Articles on Rave \(March 2012\)](#)
- [Frequently Asked Questions About iMedidata and Rave](#)
- [For ETCTN sites: CTMS Rave User Guide \(on the Theradex website Downloads page\)](#)

Help Desk at [ctsucontact@westat.com](mailto:ctsucontact@westat.com) or 1-888-823-5923 for assistance.  
Contact [roster@alliancenctn.org](mailto:roster@alliancenctn.org) for Alliance rostering assistance.

# Rave Access

## Common Reasons for denied access:

- Rostering issues
- Appropriate Rave Roles
- Missing requirements (eLearning, regulatory, CTEP-IAM credentials)

★ Start with the Lead CRP at your site, then escalate to CTSU resources.

# Rave Resources

## Online Resources:

### - Medidata Rave help website

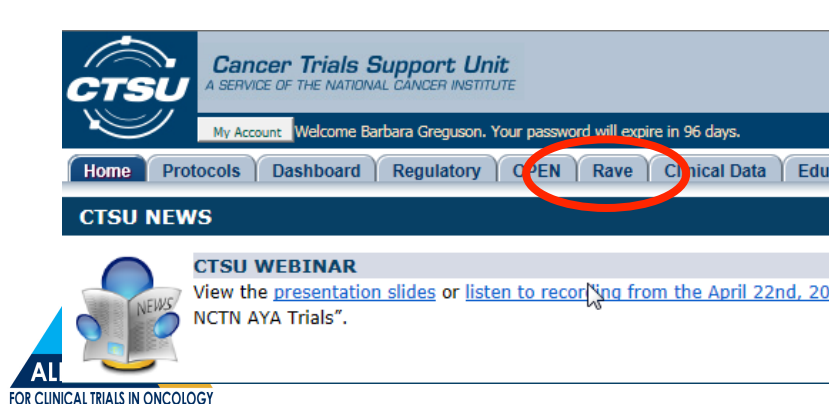
[https://rave-webhelp.s3.amazonaws.com/EDC/WebHelp\\_ENG/EDC.htm](https://rave-webhelp.s3.amazonaws.com/EDC/WebHelp_ENG/EDC.htm)

\* Contains learning modules for wide range of Rave topics

### - CTSU Rave Web help website

<https://www.ctsu.org>

\* Under the 'Rave' tab, scroll to the bottom of the page to find link to a listing of frequently asked questions about iMedidata and Rave.



**CTSU** Cancer Trials Support Unit  
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My Account | Welcome Barbara Greguson. Your password will expire in 96 days.

Home Protocols Dashboard Regulatory **OPEN** **Rave** Clinical Data Edu

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**CTSU WEBINAR**  
View the [presentation slides](#) or [listen to recording from the April 22nd, 2014 NCTN AYA Trials](#).

**ALL**  
FOR CLINICAL TRIALS IN ONCOLOGY

If you have questions about this please contact the [CTSU Help Desk](#).

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- [Frequently Asked Questions About iMedidata and Rave](#)
- [For ETCIN sites: CIMS Rave User Guide \(on the Theradex website Downloads page\)](#)

# Rave Resources

## Other Resource:

### Data Manager (DM)

\* Your study Data Manager is more than happy to help you with data entry and Rave questions. We are here for YOU!

- **DM Contact information** is located within the 'Resources Section' of each protocol
- **Please send an email** with details documented to clearly communicate the scenario. Screen shots are great, if applicable.
- **Phone calls may be helpful** in certain scenarios to describe situations that are complex to document. A follow up email to detail the phone call discussion is requested to document the decisions made.

# Rave Web Conferences?

Proposing to hold this same session again in one month...

- For those who missed this presentation
- For those who would like further review and support

**Site Poll: How many would be interested in quarterly Rave Web Conferences for presentations and questions?**