



Clinical Research Professionals – Education Session

“It’s All the Rave”

Barb Greguson

Alliance Statistical and Data Center

greguson.barbara@mayo.edu

Alliance for Clinical Trials in Oncology

Fall 2015 Group Meeting



Presentation Objectives

- Address Frequently asked Rave Questions
- Review Specific Medidata Rave Functionality
- Outline Rave Resources
- Brainstorm Ideas for Timely Data Submission
- Obtain Feedback for Future Rave Topics
- Questions

Welcome!

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

The screenshot shows the Medidata web application interface. At the top left is the Medidata logo. In the top right corner, there 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 another green banner with a message about the 2015 R1 Pre-Release. The main content area is divided into two columns. The left column is titled 'Apps' and lists 'BALANCE' (with sub-items 'MMsandbox04 (MMsandbox04)' and 'Mayo Clinic (Mayo)') and 'RAVE'. The right column is titled 'Studies (184)' and 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'.

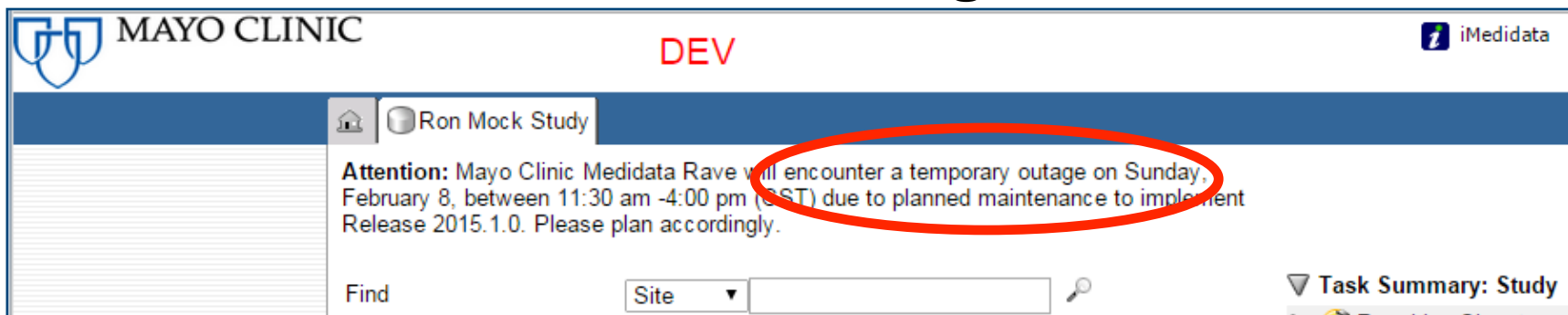
Apps	Studies (184)
BALANCE MMsandbox04 (MMsandbox04) Mayo Clinic (Mayo)	<input type="text"/> A011104 Rave EDC Rave Architect Roles
RAVE	A011104 (DEV) Rave EDC Rave Architect Roles
ECOC ACBIM	A011104 (TST) Rave Modules Rave EDC Rave Architect Roles

Take note of Welcome Messages:

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

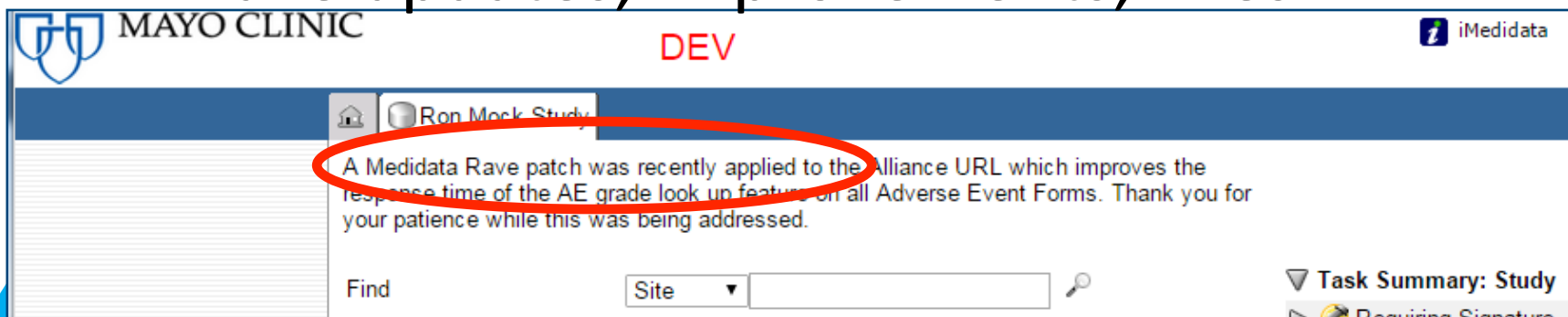
Examples:

- 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)
- Overdue Reports

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:

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

Study Co-Chair

Robert C. Smallridge, M.D.

Mayo Clinic Cancer Center

4500 San Pablo Road, Jacksonville, FL 32224

Tel: 904-953-2392 Fax: 904-953-0272

smallridge.robert@mayo.edu

Study Co-Chair

Michael Menefee, M.D.

Mayo Clinic Cancer Center

4500 San Pablo Road, Jacksonville, FL 32224

Tel: 904-953-8445

menefee.michael@mayo.edu

Community Oncology Co-chair

Balkrishna Jahagirdar, M.D.

Tel: 651-254-3505

jahag001@umn.edu

Correlative Study Co-chair

John A. Copland III, Ph.D.

Tel: 904-953-2000

copland.john@mayo.edu

Experimental Therapeutics

Committee Chair

Charles Erlichman, M.D.

507-266-3200

erlichman.charles@mayo.edu

Experimental Therapeutics

Committee Chair

Gary K. Schwartz, M.D.

212-639-8324

schwartz@mskcc.org

Primary Statistician

Nathan R. Foster, M.S.

507-284-5051

foster.nathan@mayo.edu

Protocol Coordinator

Aimee Farrell

Tel: 773-702-0893 Fax: 312-345-0117

afarrell@uchicago.edu

Data Manager

Barbara Greguson

Tel: 507-284-4798 Fax: 507-266-3722

greguson.barbara@mayo.edu

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/

CTSU:

<https://www.ctsuo.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 circled in red. On the left sidebar, 'Case Report Forms' is circled in red. The main content area shows study details for Alliance A151216, including the title 'Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST)', study chair 'Geoffrey Oxnard, MD', and activation date '08/18/2014'. 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.

Shauna Hillman(log out)

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[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](#)

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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](#)

All CRFs

Availability of Overdue Reports

Alliance Website -> Home Page -> Delinquent/Overdue Reports

Alliance
for Clinical Trials
in Oncology

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Advanced Search

home protocols committees education & training member services news

Welcome

ANNOUNCEMENTS

Alliance Oncology Nursing Committee Seeks GU Liaison

The Alliance Oncology Nursing Committee (A-ONC) is seeking a Genitourinary Liaison. The responsibilities of the A-ONC GU Liaison include but are not limited to:

1. **Mandatory** attendance at all core and main meetings (two meetings/year) - participation in monthly A-ONC teleconferences
2. Review of all new protocols/forms/amendments for the GU oncology program, act as a resource for other Alliance nurses regarding protocol execution within GU related protocols (available via phone and/or email).
3. Collaboration across committees on projects, publications, educational initiatives, research, etc.
4. Provision of nursing perspective and expertise regarding study design and methods; as well as patient education
5. Serving as a Principal and/or Co-investigator on Alliance trials as appropriate
6. Publication/dissemination of Alliance-related research findings.

Quick Links

- Alliance Directory
- Audit Resources
- Bibliography (Alliance Publications)
- BioMS
- Contact Us
- CRP Resources
- Frequently Used Documents
- **Delinquency/Overdue Reports**
- Legacy Sites
- Meetings
- Meeting Presentations & Materials

Availability of Overdue Reports

Alliance Website -> Home Page -> Delinquent/Overdue Reports

Alliance
for Clinical Trials
in Oncology

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Delinquency/Overdue Reports

Home > Education & Training > Delinquency/Overdue Reports

Overdue Reports for trials utilizing JCCS or Rave data entry system (Alliance, Legacy ACOSOG and NCCTG)

- Less Than 30 Days Overdue
- Materials Greater Than 30 Days Overdue
- Materials Greater Than 120 Days Overdue
- Materials Submission Completeness Rate

Delinquency Reports for trials utilizing Teleform system (Legacy CALGB)

- Delinquency

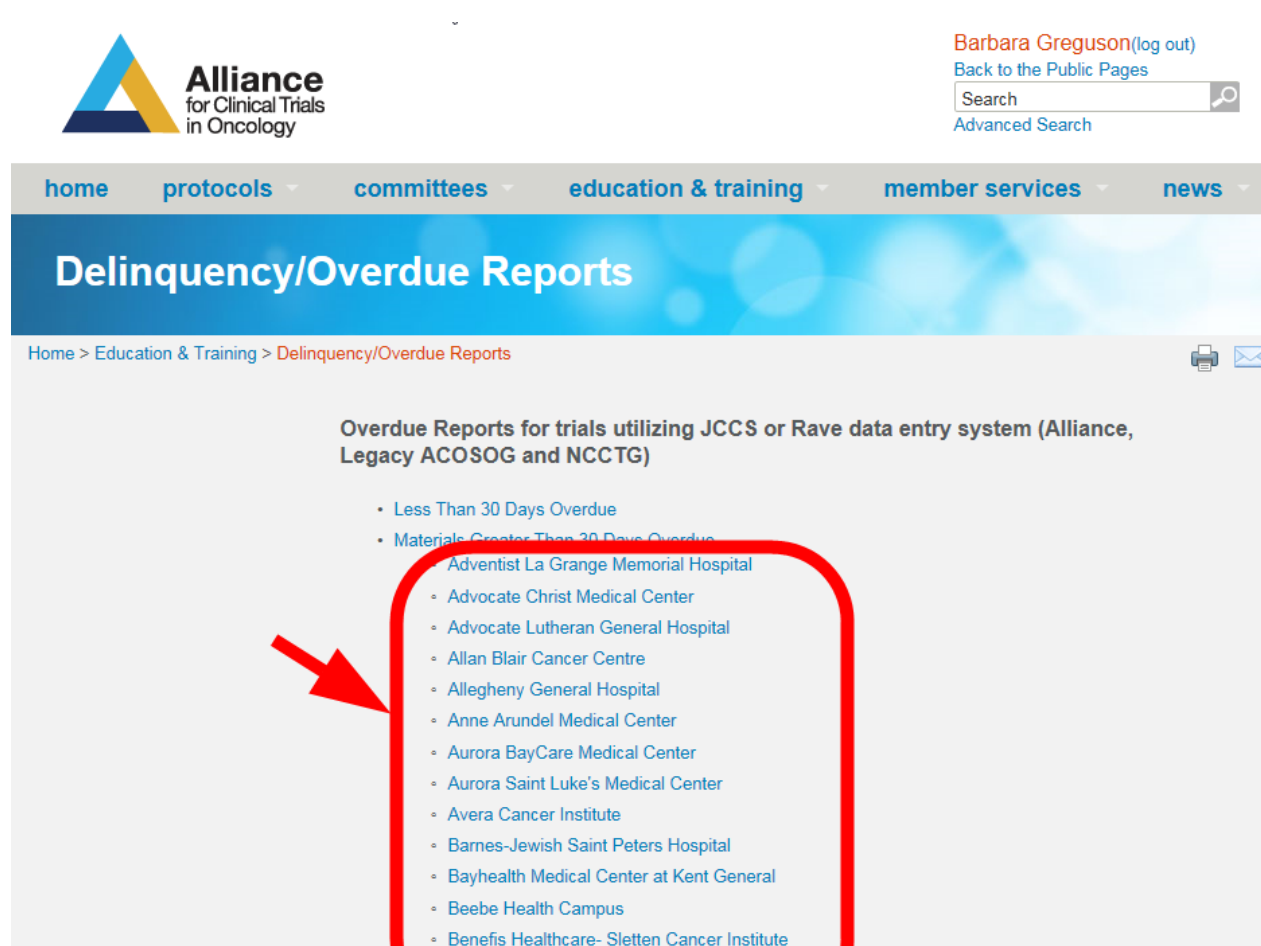
disclaimer site map contact us



Select Report ...

Availability of Overdue Reports

Alliance Website -> Home Page -> Delinquent/Overdue Reports



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for Clinical Trials
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Delinquency/Overdue Reports

[Home](#) > [Education & Training](#) > [Delinquency/Overdue Reports](#)

Overdue Reports for trials utilizing JCCS or Rave data entry system (Alliance, Legacy ACOSOG and NCCTG)

- Less Than 30 Days Overdue
- Materials Greater Than 30 Days Overdue
 - [Adventist La Grange Memorial Hospital](#)
 - [Advocate Christ Medical Center](#)
 - [Advocate Lutheran General Hospital](#)
 - [Allan Blair Cancer Centre](#)
 - [Allegheny General Hospital](#)
 - [Anne Arundel Medical Center](#)
 - [Aurora BayCare Medical Center](#)
 - [Aurora Saint Luke's Medical Center](#)
 - [Avera Cancer Institute](#)
 - [Barnes-Jewish Saint Peters Hospital](#)
 - [Bayhealth Medical Center at Kent General](#)
 - [Beebe Health Campus](#)
 - [Benefis Healthcare- Sletten Cancer Institute](#)



Select Participating Site ...

Availability of Overdue Reports

Alliance Website -> Home Page -> Delinquent/Overdue Reports

Protocol, QCS, Phone	Patient, Initials, Date on, Last contact	Material	Item	Target Date	Overdue Date	Days Overdue
A112233	9988776					
Barbara Gregusson (507) 284-4798	BGL 08/06/2015 10/09/2015	Rave Form Rave Form Rave Form Rave Form Rave Form	Treatment 01: TI-CE Cycle 1, Supporting Documentation Baseline, Supporting Documentation: Baseline Baseline, Specimen Submission: Baseline Baseline, PRO/QOL: EORTC QLQ-C30 (Version 3) Baseline, PRO/QOL: EORTC QLQ-TC26	08/20/2015 09/03/2015 09/03/2015 09/03/2015 09/03/2015	09/04/2015 09/18/2015 09/18/2015 09/18/2015 09/18/2015	48 34 34 34 34

... a report is generated and may be printed or saved as a .PDF file:

- Study Number
- Data Manager name and phone
- Patient identifiers
- Over item listing, overdue date, number of days overdue



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.

Icon Key

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

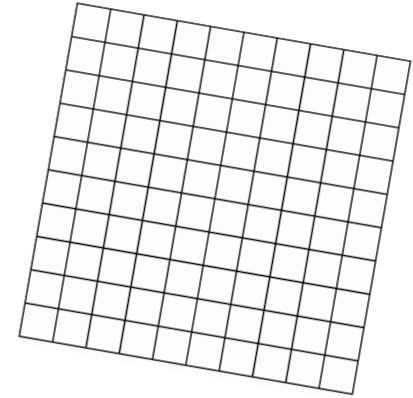
Question:

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	Task Summary: Subject	Pages
Baseline	30 Jun 2010	NonConformant Data	0
Survival and Disease Status Follow-Up 01: 15-May-2010	14 Jul 2010	Open Queries	3
		Sticky Notes	0
		Overdue Data	8

Grid View

Toggle

MAYO CLINIC 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

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
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

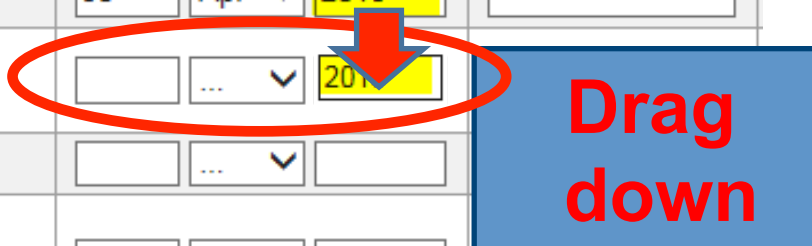
It's a Drag

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 ^o	None ^o			<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 ^o	None ^o			<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 ^o	None ^o			<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 ^o	None ^o			<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 ^o	None ^o			<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 ^o	None ^o			<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 ^o	None ^o			<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 ^o	None ^o			<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 ^o	None ^o			<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 ^o	None ^o			<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 ^o	None ^o			<input checked="" 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 ^o	None ^o			<input checked="" 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 ^o	None ^o			<input checked="" 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 ^o	None ^o			<input checked="" 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 ^o	None ^o			<input checked="" 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 ^o	None ^o			<input checked="" 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 ^o	None ^o			<input checked="" 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 ^o	None ^o			<input checked="" 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 ^o	None ^o			<input checked="" 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 ^o	None ^o			<input checked="" 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

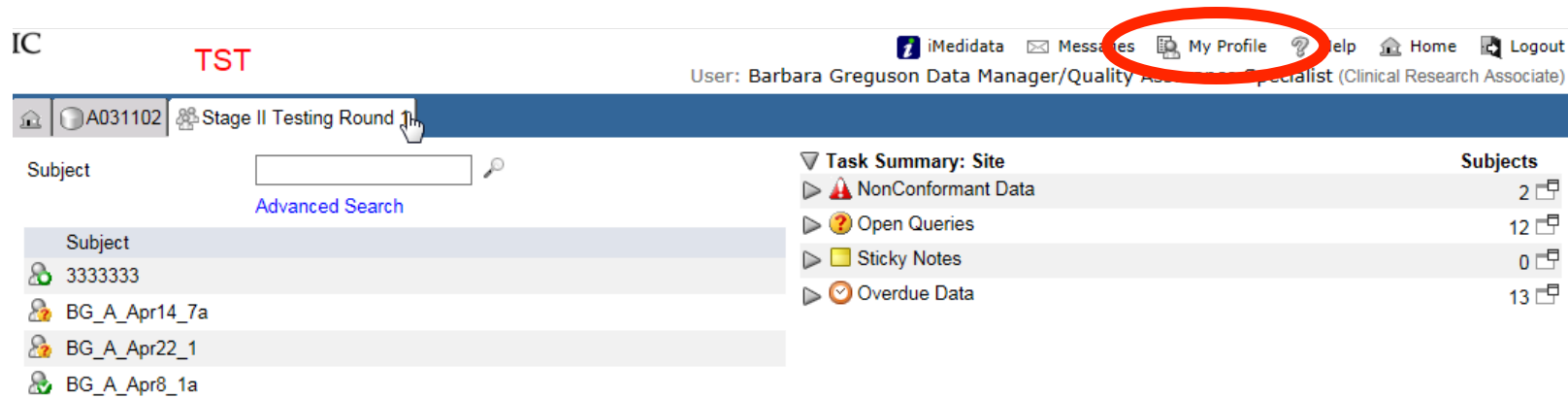
Comments

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

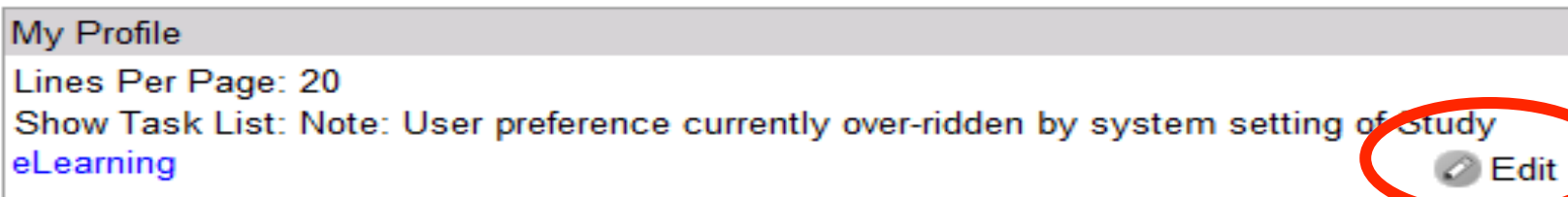
Pagination

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



The screenshot shows the iMedidata web application interface. At the top, the user is logged in as Barbara Greguson, a Data Manager/Quality Assurance Specialist. The navigation bar includes links for iMedidata, Messages, My Profile (circled in red), Help, Home, and Logout. Below the navigation bar, the current study is identified as A031102, Stage II Testing Round 1. A search bar for subjects is visible, with a list of subjects including 3333333, BG_A_Apr14_7a, BG_A_Apr22_1, and BG_A_Apr8_1a. On the right side, a 'Task Summary: Site' table is displayed, showing counts for NonConformant Data (2), Open Queries (12), Sticky Notes (0), and Overdue Data (13).

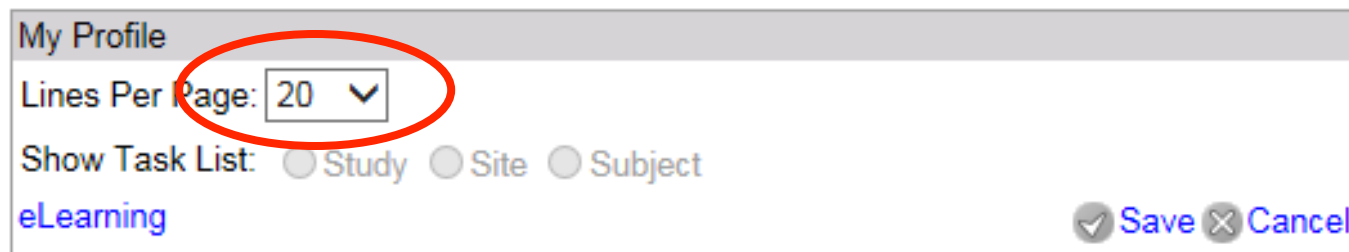
Click the “edit” icon,



The screenshot shows the 'My Profile' settings page. The settings include 'Lines Per Page: 20' and 'Show Task List: Note: User preference currently over-ridden by system setting of Study'. An 'Edit' button with a pencil icon 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.

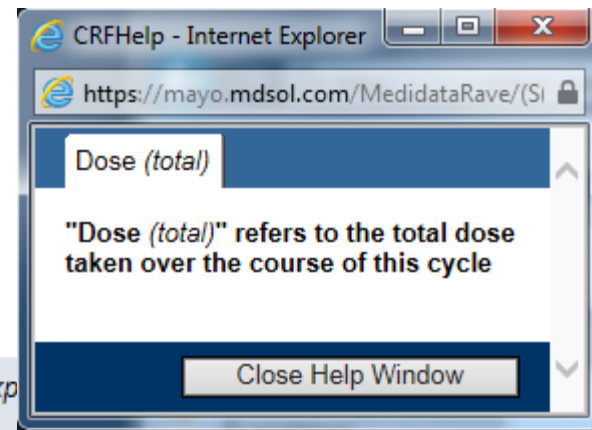
Help Text



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 ?

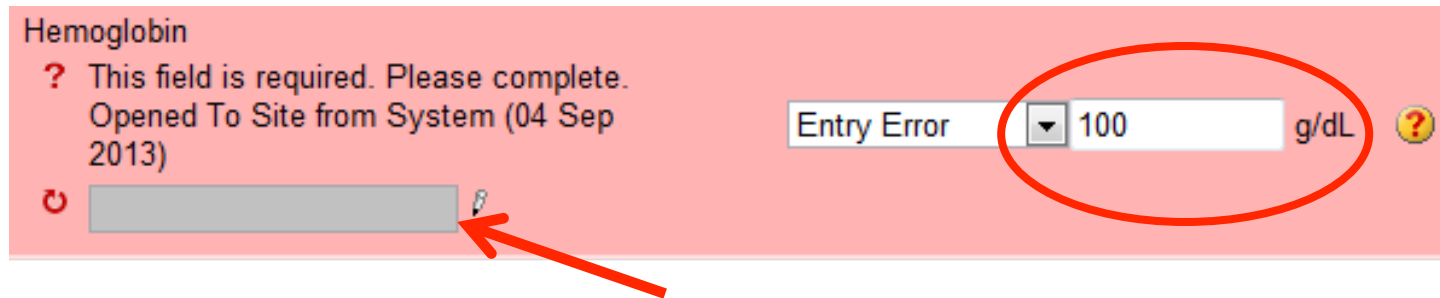
User Response Field

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.



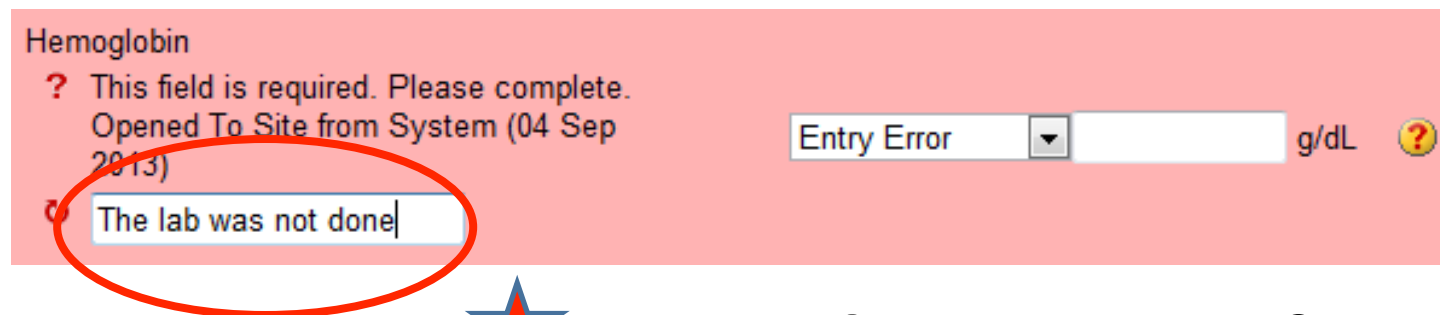
Hemoglobin
? This field is required. Please complete.
Opened To Site from System (04 Sep 2013)

Entry Error [v] 100 g/dL ?

[Greyed out response box]

A red circle highlights the 'Entry Error' dropdown menu and the value '100'. 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 response box containing the text 'The lab was not done'.

Non-Conformant



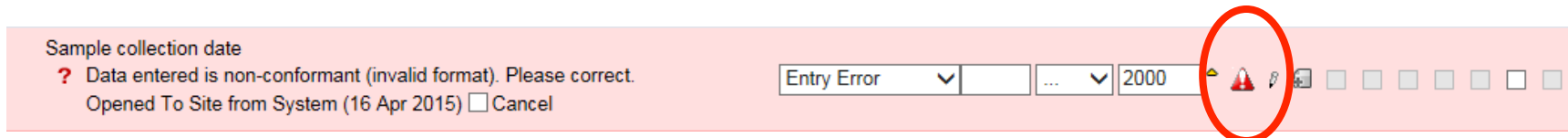
How to interpret Non-Conformant data queries ...

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 form 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
- Comments:** This field is highlighted with a red box and a red arrow pointing to it from a blue callout box.

Each field has a status indicator (green checkmark), an edit icon, a delete icon, and a checkbox. At the bottom right, there are 'Save' and 'Cancel' buttons.

**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 [▲]	Yes [▲]	Physical exam	1.5 cm [▲]	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	A151216 - 9101547 EGFR results.pdf	
(If yes), was an EGFR mutation identified? ? If "was an EGFR mutation identified?" is Yes, then at least one of the EGFR mutation types should be Yes. Please reconcile. Opened To Site from System (02 Mar 2015) 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 [A151216 - 9101547_EGFR_results.pdf](#)   




(If yes), was an EGFR mutation identified?
? If "was an EGFR mutation identified?" is Yes, then at least one of the EGFR mutation types should be Yes. Please reconcile.
Opened To Site from System (02 Mar 2015)
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

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

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 '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 'Audit', 'User', and a timestamp. Red circles highlight the 'User' column entries: 'Chelsea Schultz (5032 - schultz.chelsea@mavo.edu?)', 'System', and 'Jennifer Howgate-Klingaman (6463 - Jennifer.Howgate-Klingaman@sluhn.org)'. Three blue 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. The bottom of the page shows 'CRF Version 3135 - Page Generated: 21 Apr 2015'.

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?)	08:29:05
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)	02 Mar 2015 08:29:05
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)	08:29:05

Browsers

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

- ✓ Chrome v30.0
- ✓ IE v8.0
- ✓ Opera v17.0
- ✓ Firefox 24.0
- ✓ Safari v7.0



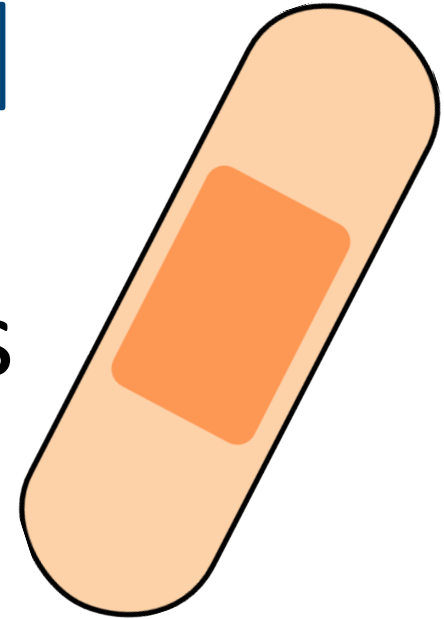
Medidata
recommends the
latest version of your
chosen browser, at
least these listed
versions or newer.

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

Bandaid: 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 or
1-888-823-5923 for assistance.
Contact 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

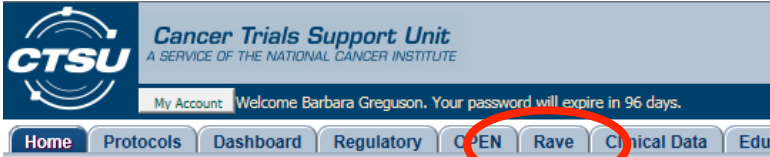
https://rave-webhelp.s3.amazonaws.com/EDC/WebHelp_ENG/EDC.htm

* 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
A SERVICE OF THE NATIONAL CANCER INSTITUTE

My Account | Welcome Barbara Greguson. Your password will expire in 96 days.

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

CTSU NEWS

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](#).

Learn More About Rave

Rave resource materials

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- [For ETCIN sites: CIMS Rave User Guide \(on the Theradex website Downloads page\)](#)

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?

Brainstorming ... Ideas for Timely Data Submission