Clinical Research Professionals – Education Session

"It's All the Rave"

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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

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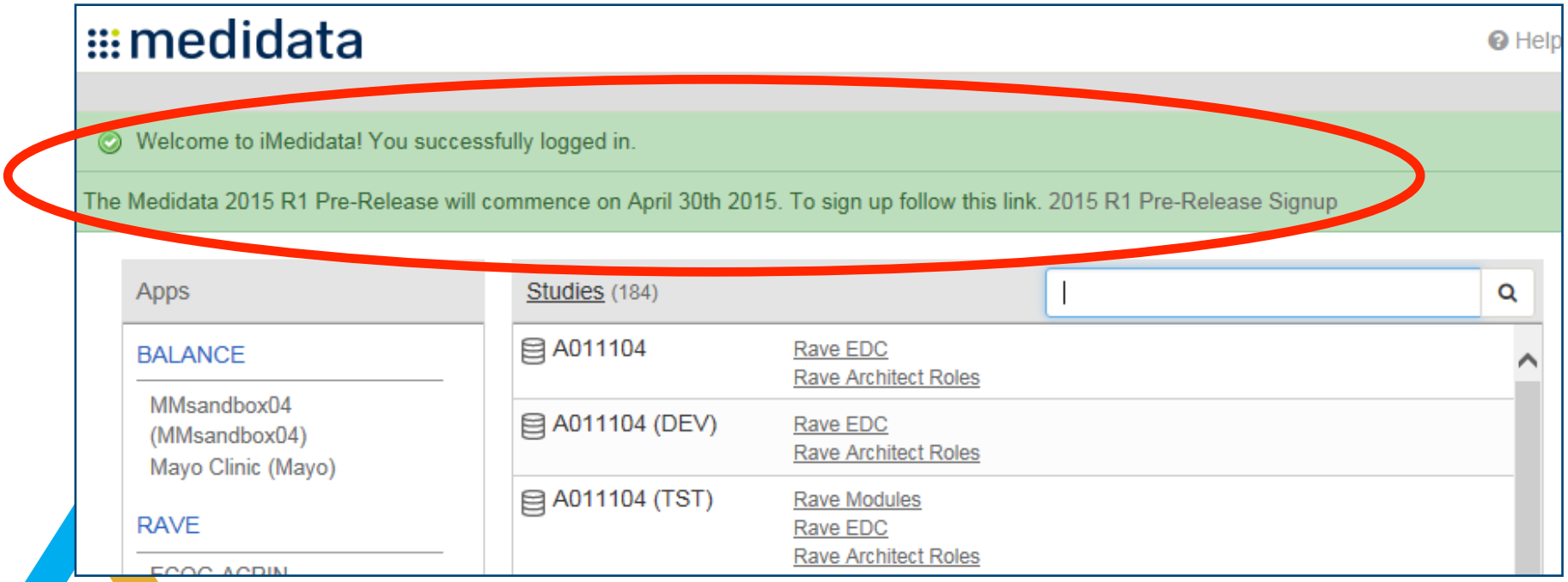
Welcome!

Look for “Welcome Messages” across top of Medidata …



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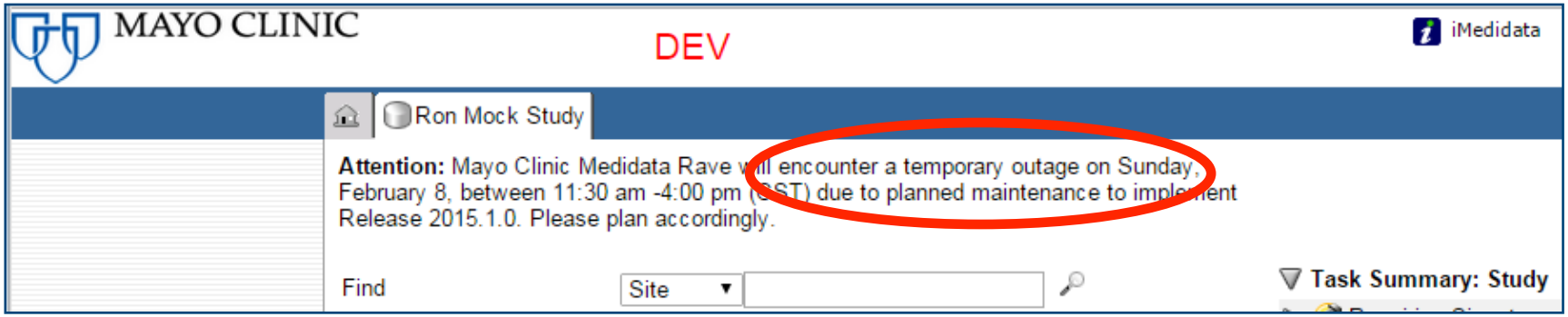
Take note of Welcome Messages:

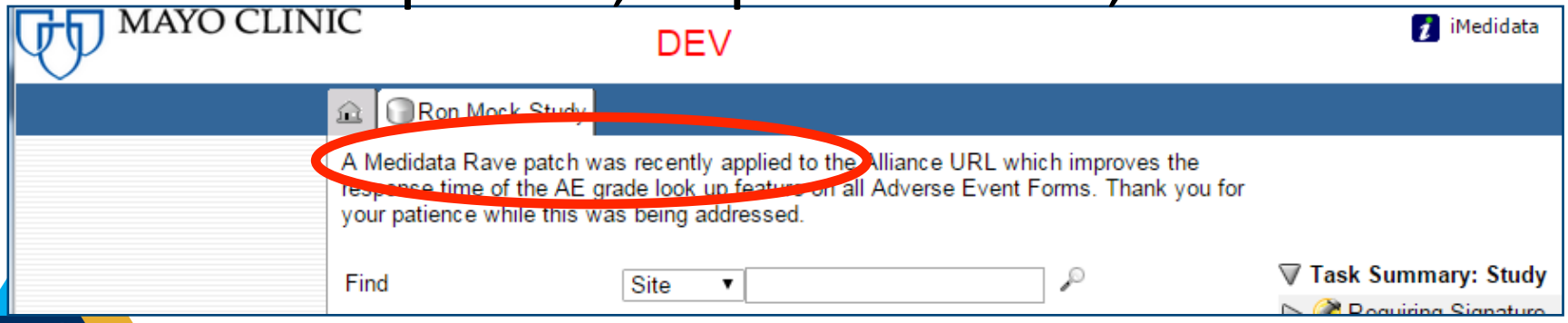
- Displayed on Home, Study & Site pages
- Can be specific to study, role, or combination

Examples:

- Rave maintenance/outage information



- Rave updates, improvements, fixes



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Location, Location, Location!

Where to find...

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

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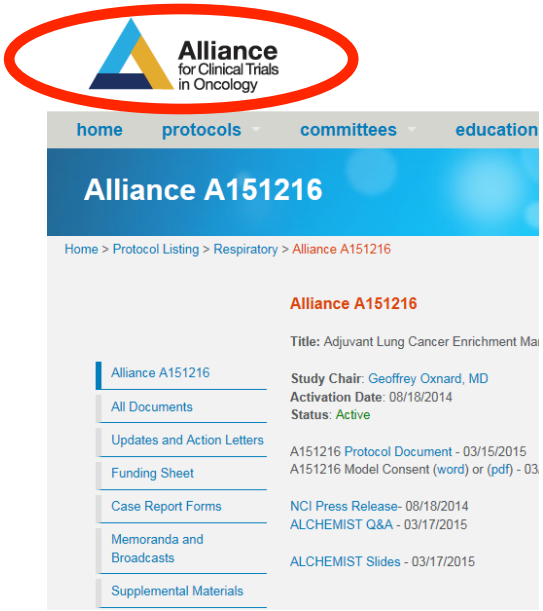
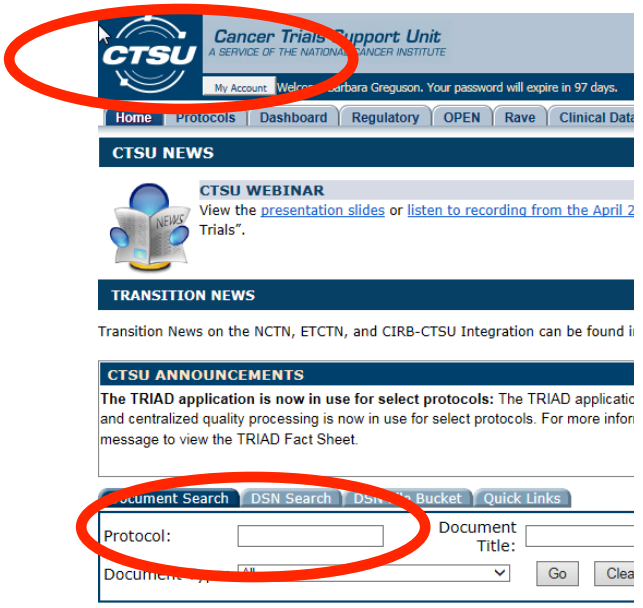
Availability of Protocol Documents





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.

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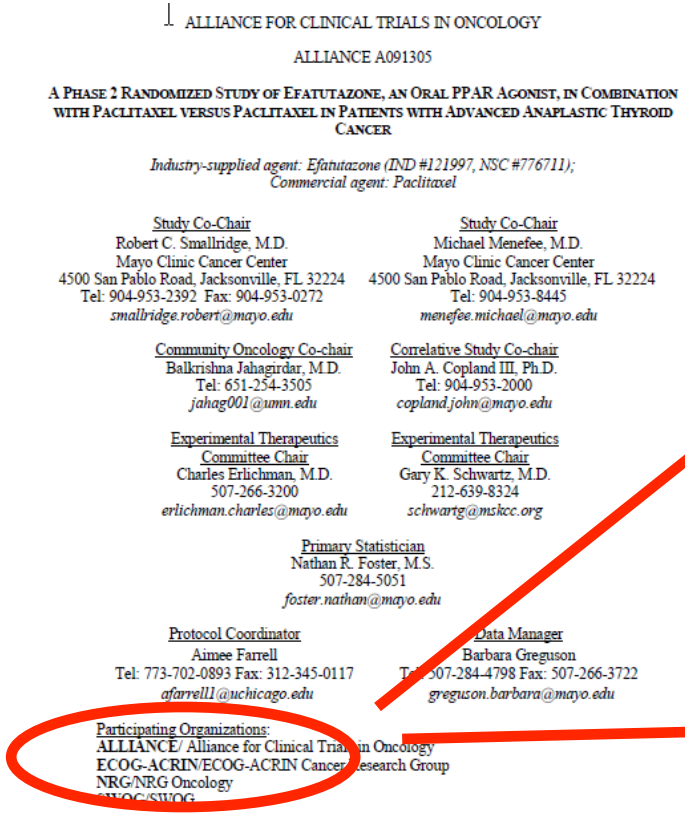
Availability of Protocol Documents



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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
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Correlative Study Co-chair
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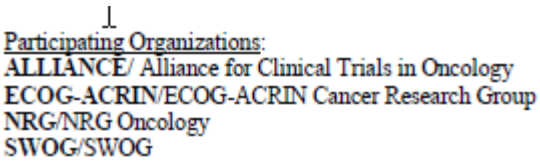
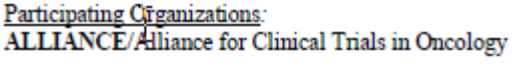
Participating Organizations:
ALLIANCE/ Alliance for Clinical Trials in Oncology
ECOG-ACRIN/ECOG-ACRIN Cancer Research Group
NRG/NRG Oncology
SWOG/SWOG



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/

CTSU:
https://www.ctsu.org/

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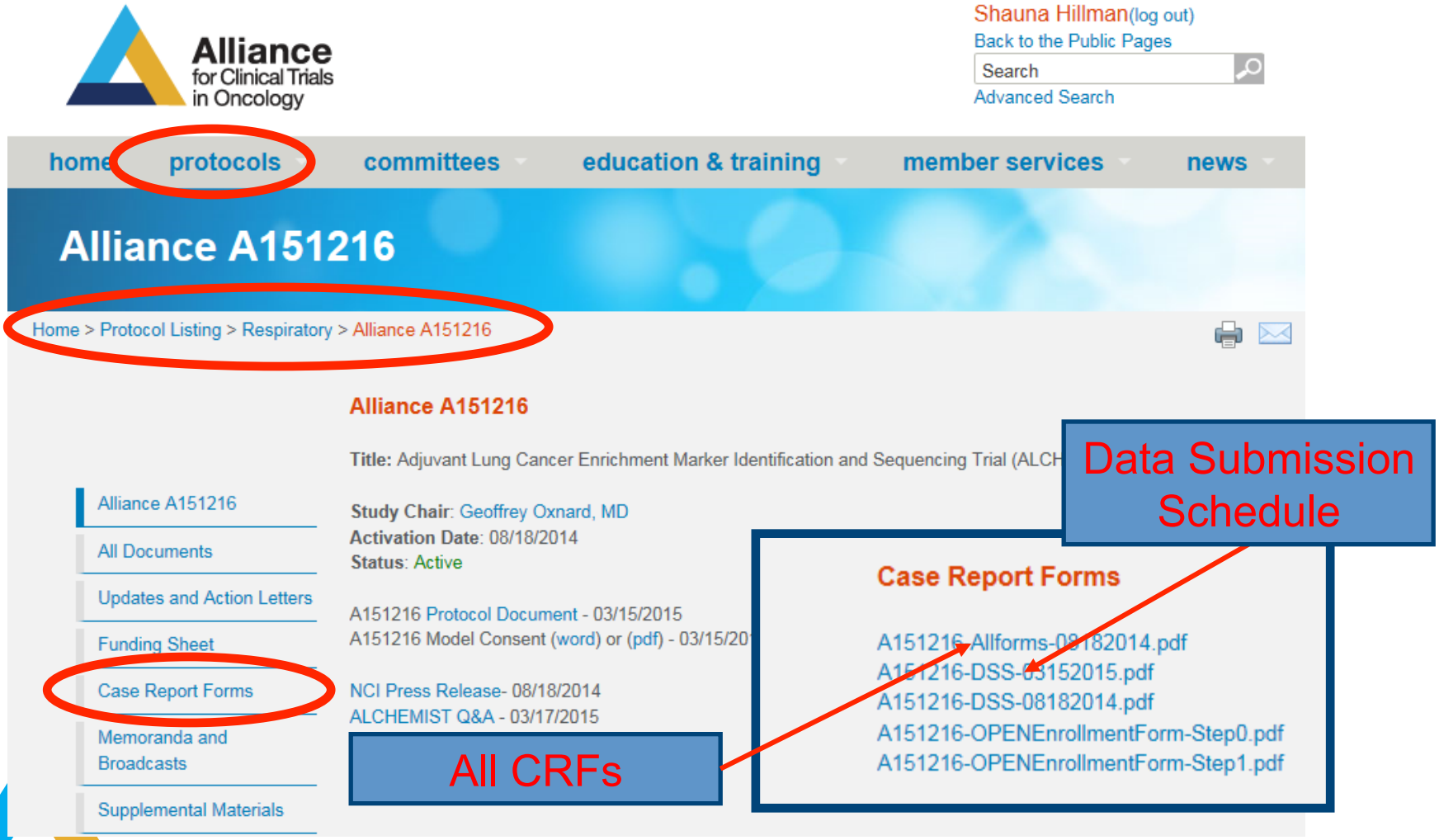
Paper CRFs and DSS Availability

Alliance Website -> Study Page -> Case Report Forms



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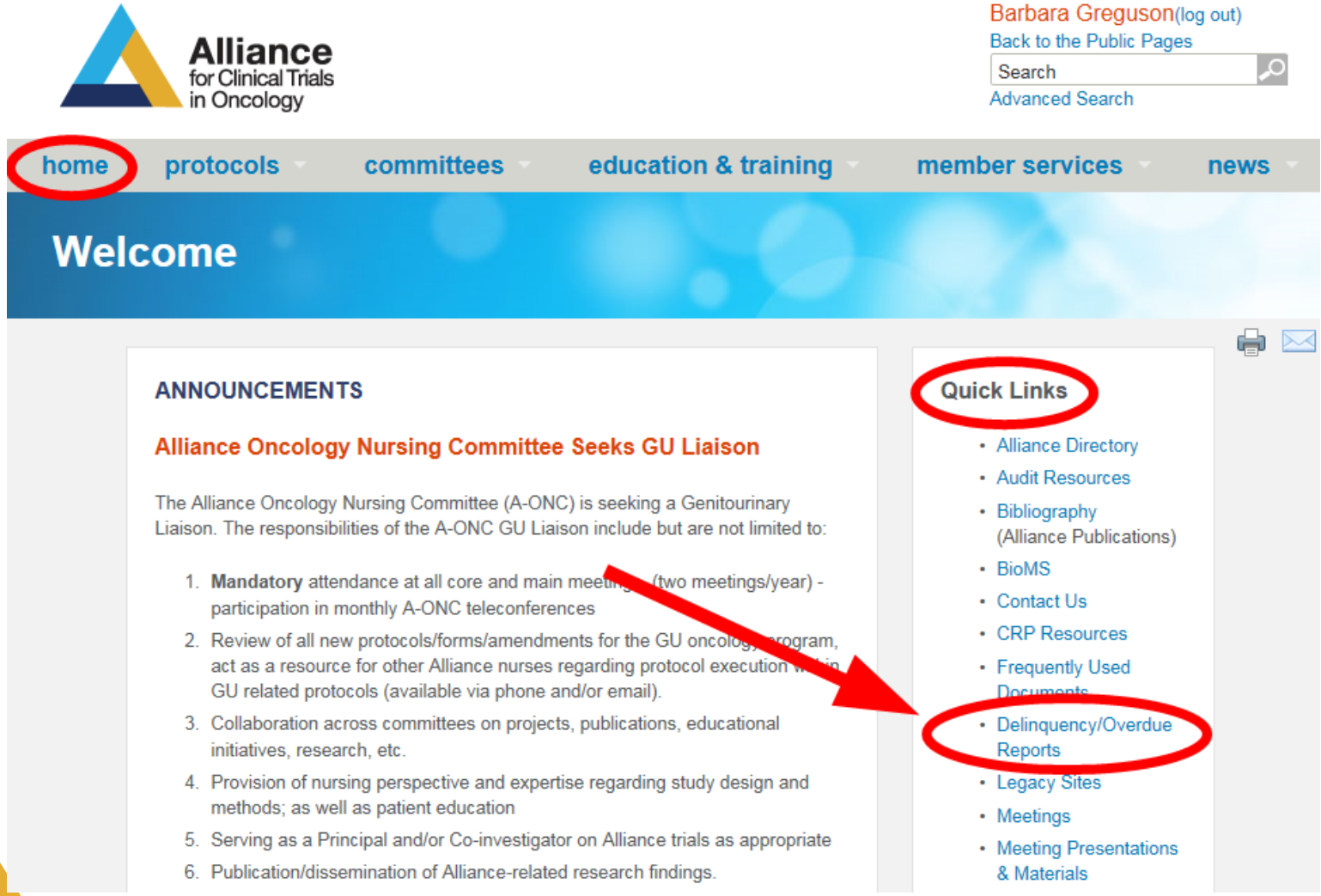
Availability of Overdue Reports

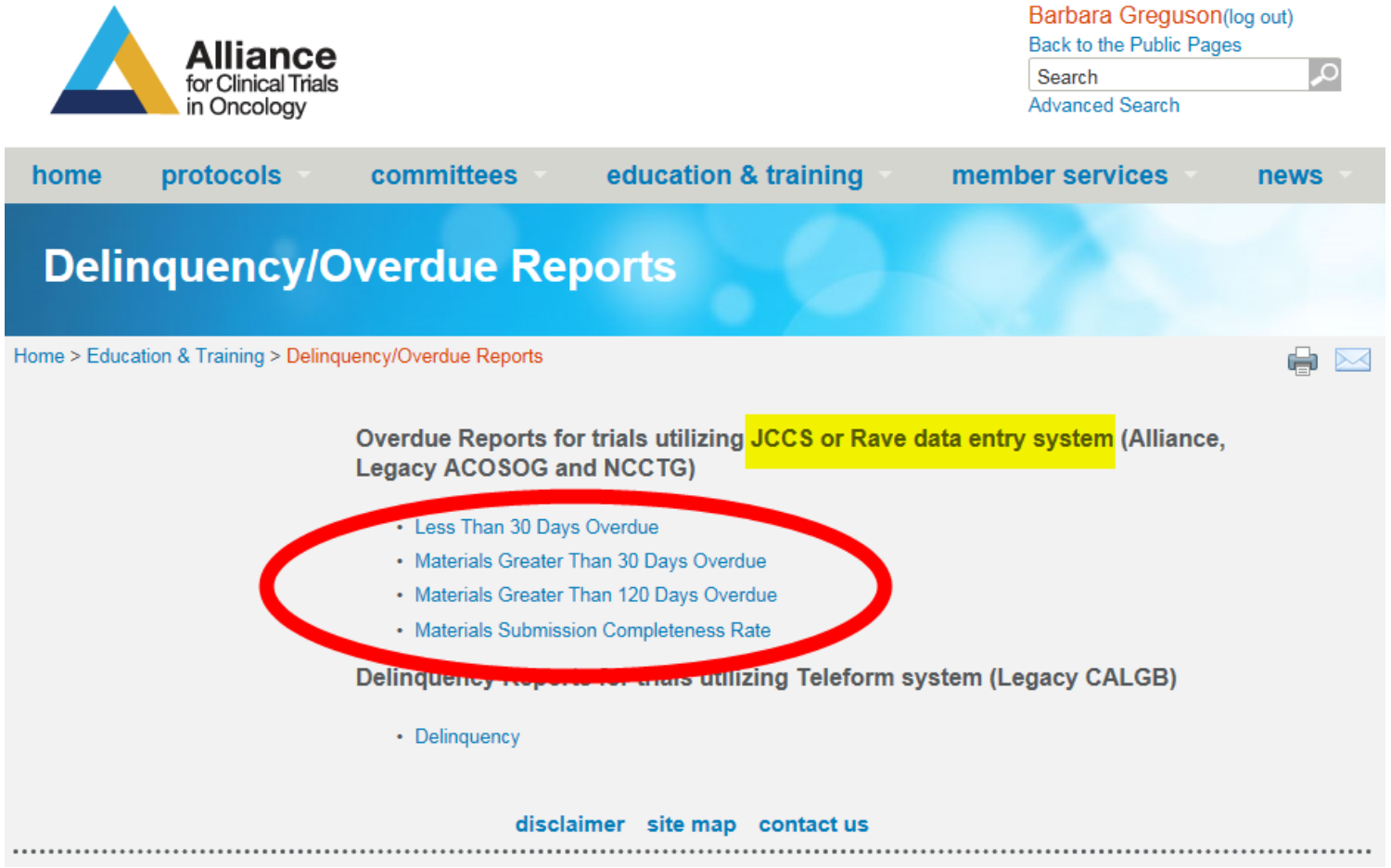
Alliance Website -> Home Page -> Delinquent/Overdue Reports



ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY

Availability of Overdue Reports

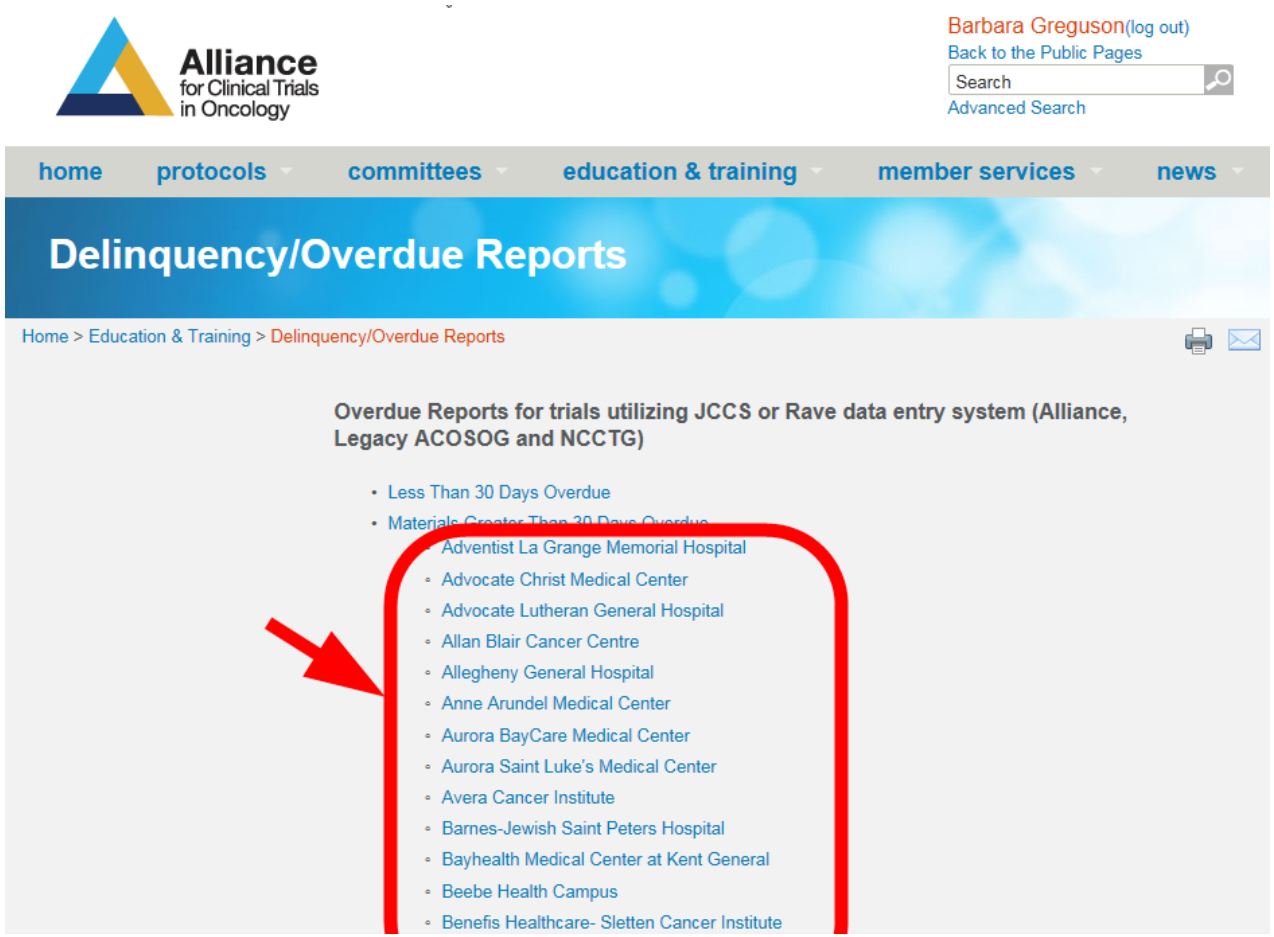
Alliance Website -> Home Page -> Delinquent/Overdue Reports



Select Report …

Availability of Overdue Reports

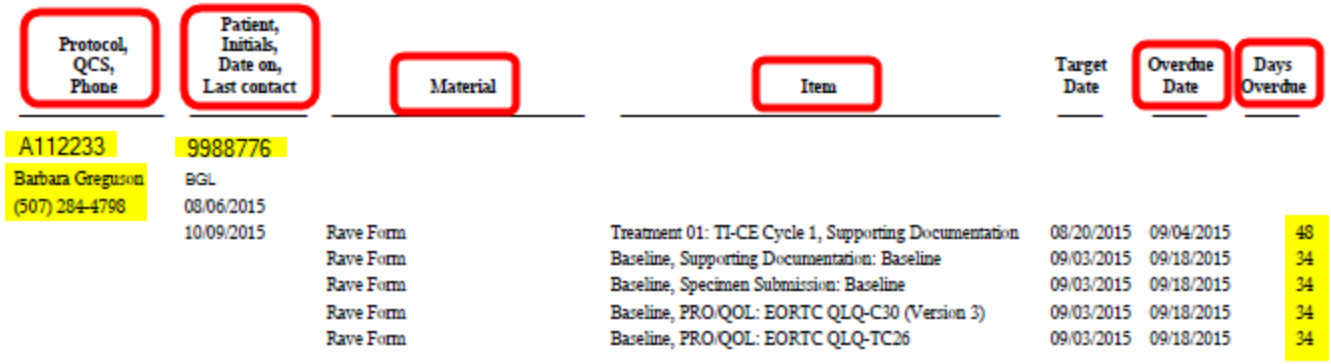
Alliance Website -> Home Page -> Delinquent/Overdue Reports



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 Barbara Greguson (507) 284-4798	9988776 BGL 08/06/2015 10/09/2015					
		Rave Form	Treatment 01: TI-CE Cycle 1, Supporting Documentation	08/20/2015	09/04/2015	48
		Rave Form	Baseline, Supporting Documentation: Baseline	09/03/2015	09/18/2015	34
		Rave Form	Baseline, Specimen Submission: Baseline	09/03/2015	09/18/2015	34
		Rave Form	Baseline, PRO/QOL: EORTC QLQ-C30 (Version 3)	09/03/2015	09/18/2015	34
		Rave Form	Baseline, PRO/QOL: EORTC QLQ-TC26	09/03/2015	09/18/2015	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

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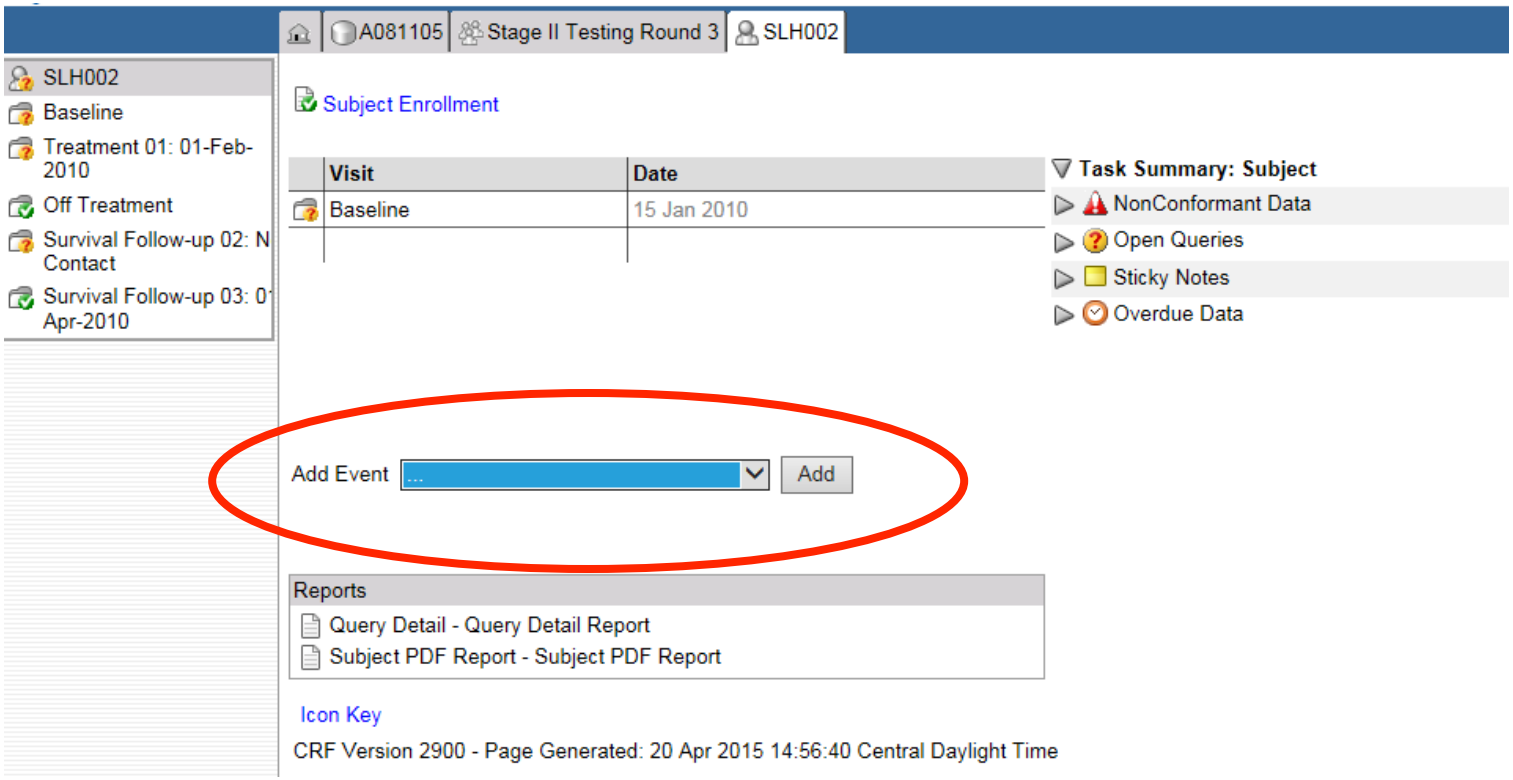
Add Event

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



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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.

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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).

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Free-Text Fields

Question:

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

Answer:

200 characters

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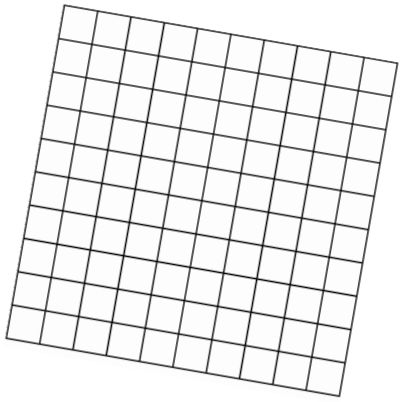
Grid View



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

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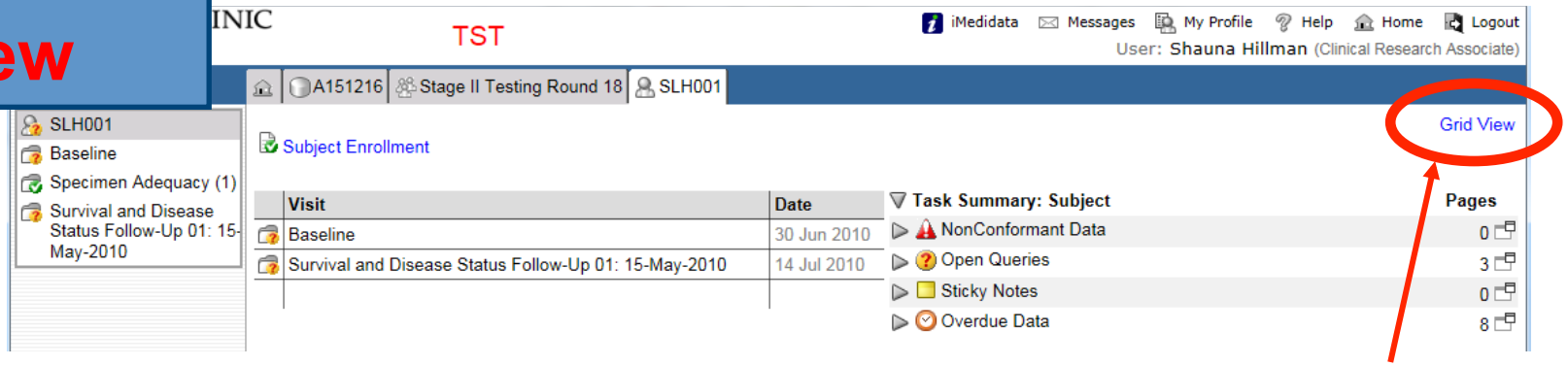
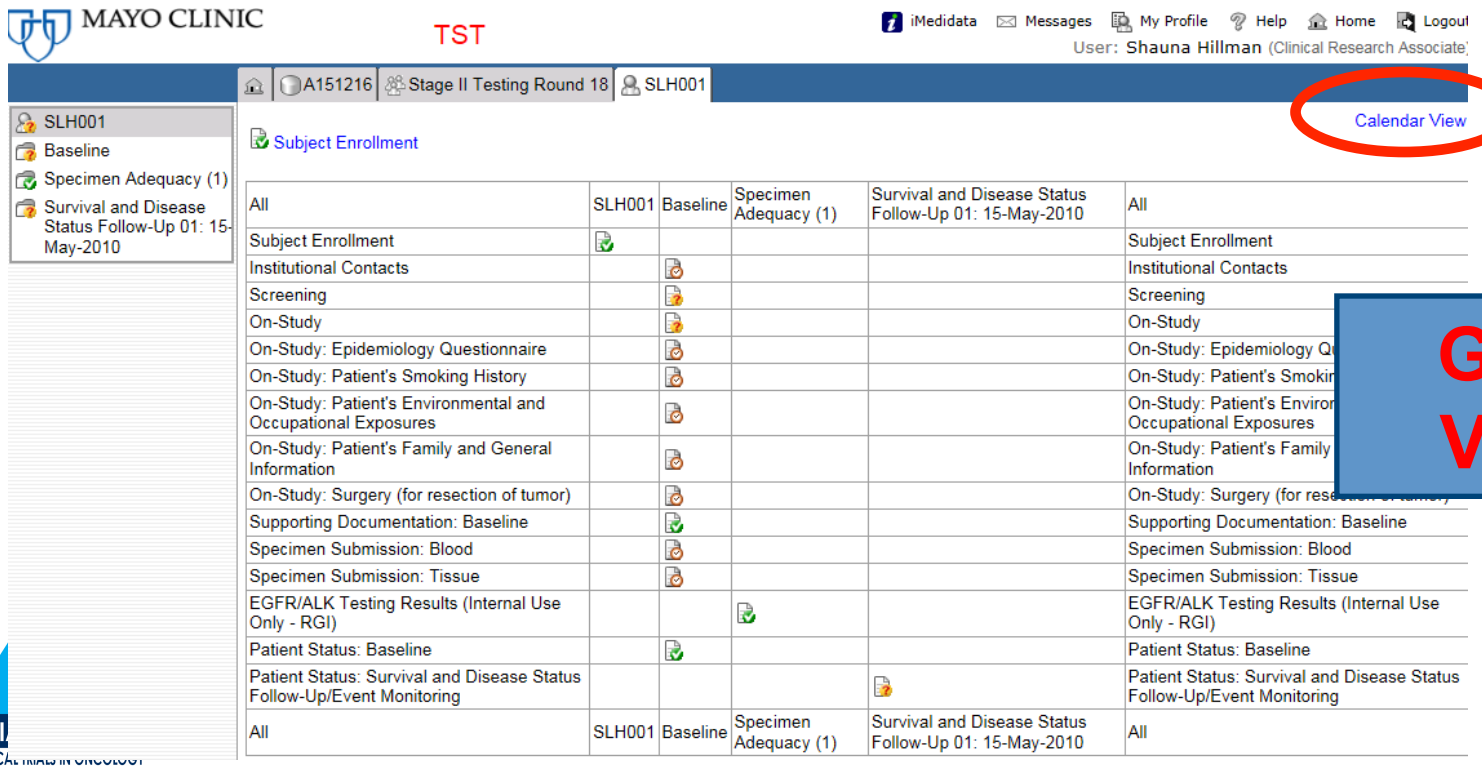
Reminder: Grid View Available

Calendar View



Toggle



Grid View

It's a Drag

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

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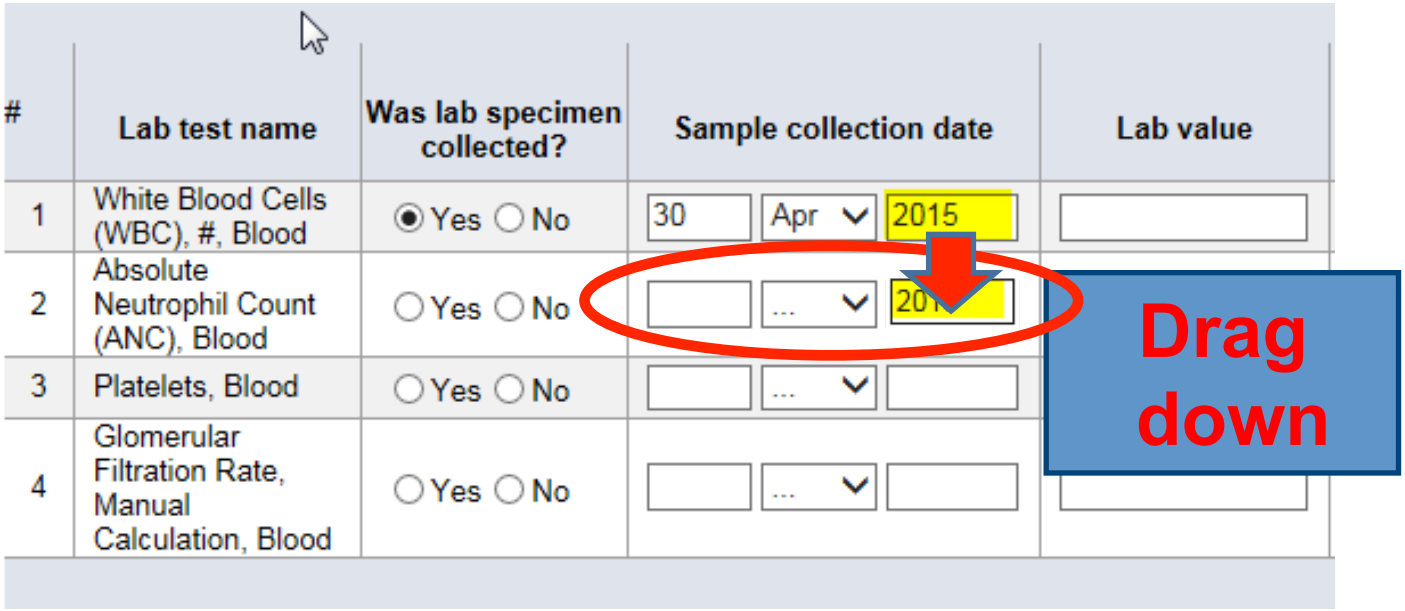
Rave Tip: Highlight year from previous date and Drag to new location



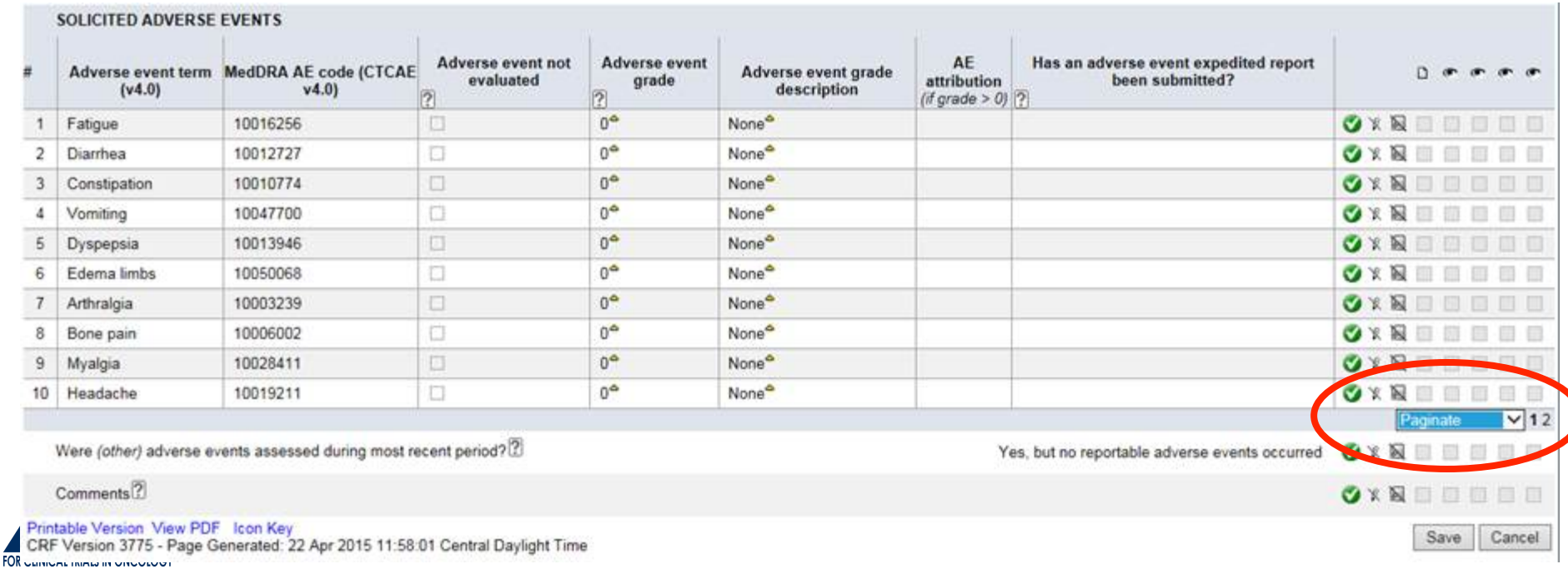
Applications:

- 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?



SOLICITED ADVERSE EVENTS

#	Adverse event term (v4.0)	MedDRA AE code (CTCAE v4.0)	Adverse event not evaluated	Adverse event grade	Adverse event grade description	AE attribution (if grade > 0)	Has an adverse event expedited report been submitted?
1	Fatigue	10016256	☐	0	None		
2	Diarrhea	10012727	☐	0	None		
3	Constipation	10010774	☐	0	None		
4	Vomiting	10047700	☐	0	None		
5	Dyspepsia	10013946	☐	0	None		
6	Edema limbs	10050068	☐	0	None		
7	Arthralgia	10003239	☐	0	None		
8	Bone pain	10006002	☐	0	None		
9	Myalgia	10028411	☐	0	None		
10	Headache	10019211	☐	0	None		

Paginate 1 2

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

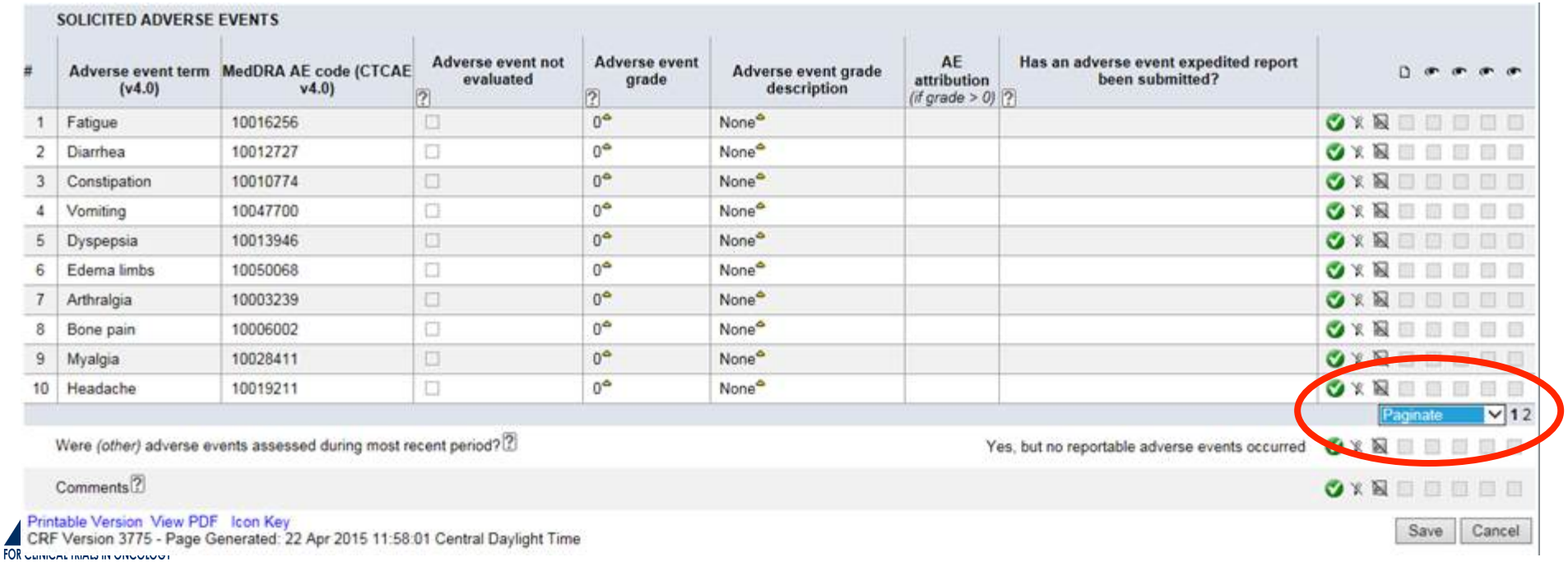
Comments

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

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.



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6	Edema limbs	10050068		0	None		
7	Arthralgia	10003239		0	None		
8	Bone pain	10006002		0	None		
9	Myalgia	10028411		0	None		
10	Headache	10019211		0	None		

Paginate 1 2

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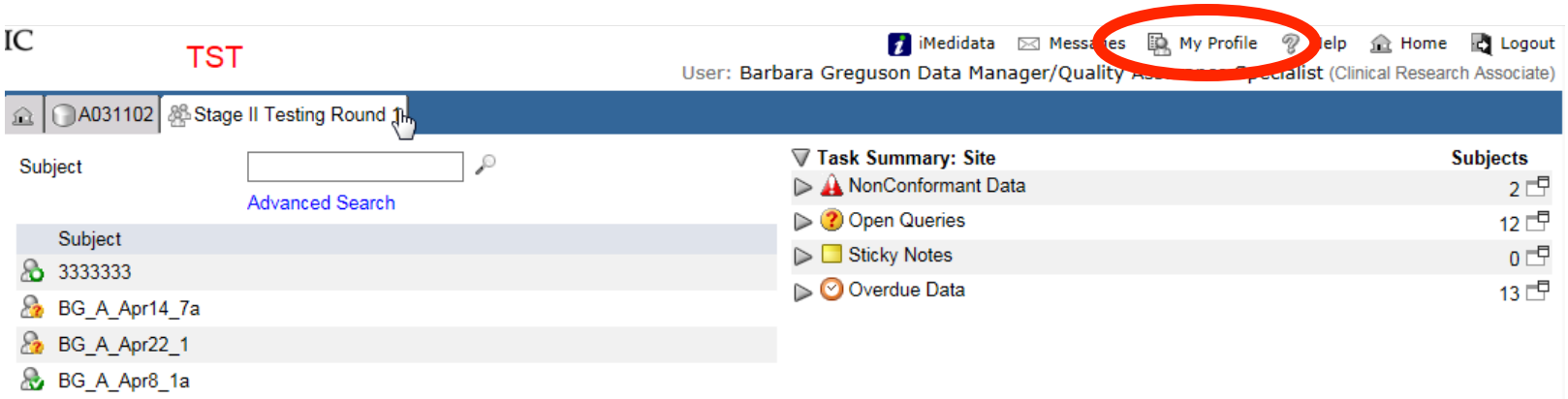
Comments

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

Save Cancel

Pagination

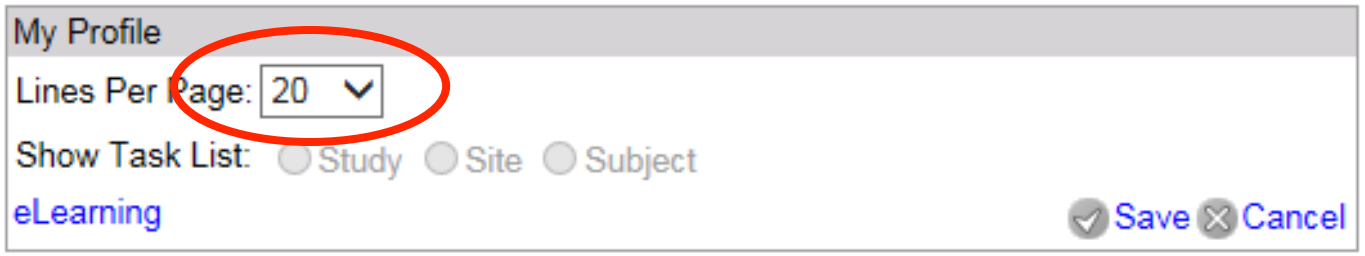
You may update your Pagination settings by going into the Home Page under “My Profile”.



Click the “edit” icon,

Pagination

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



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

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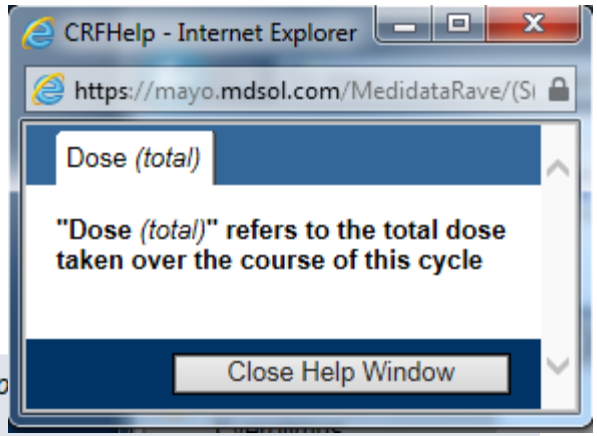
Help Text

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 exp
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	☐		mg		mg	...	○ Yes ○ No
2	Everolimus	☐		mg		mg	...	○ Yes ○ No

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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”

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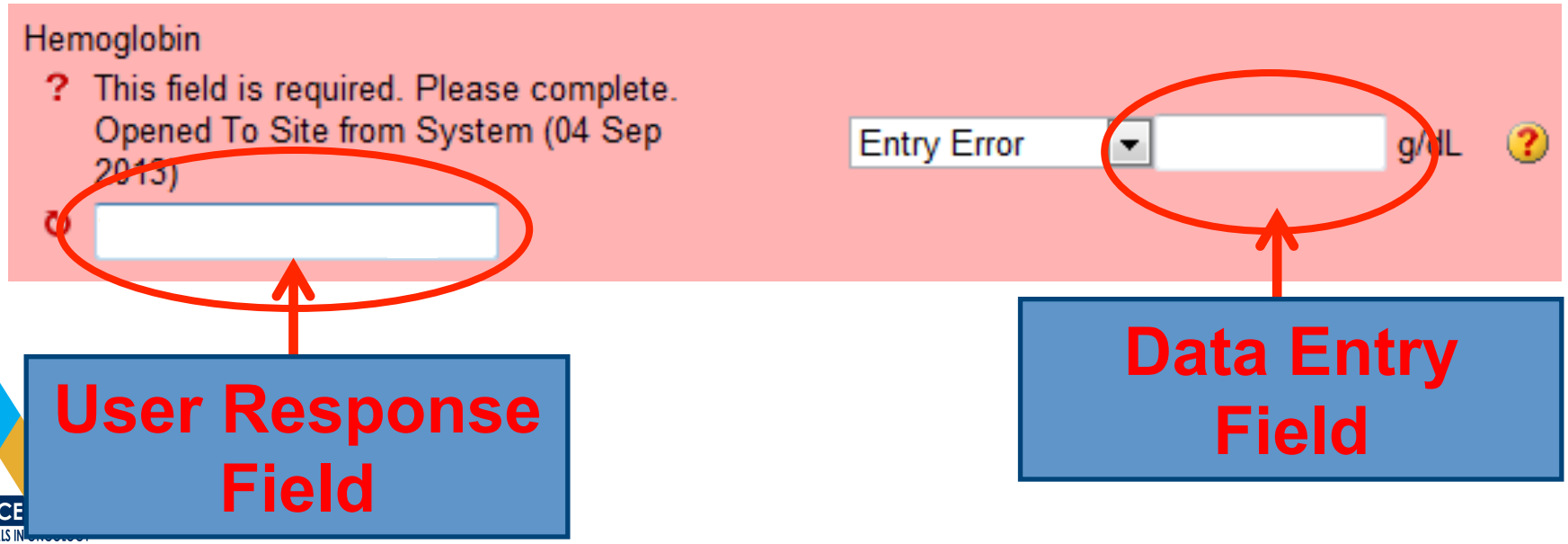
Query Response

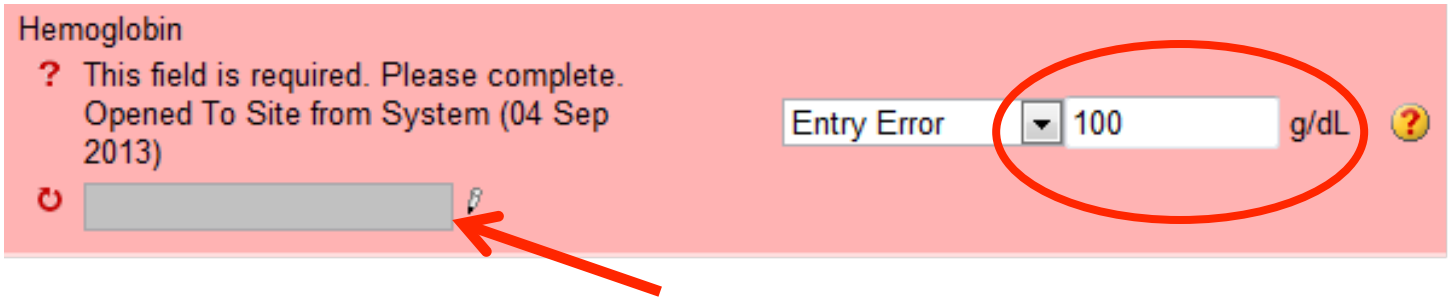
When to use the different entry fields (boxes), if presented with a query …



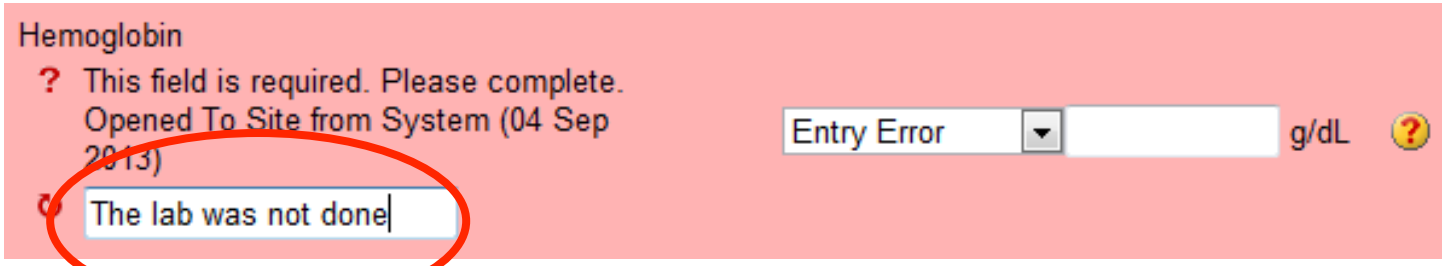
Responding to Queries

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.



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



Remember to SAVE form!

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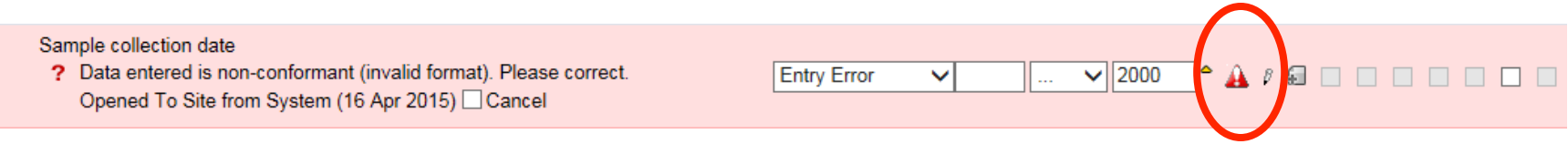
Non-Conformant

How to interpret Non-Conformant data queries …



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

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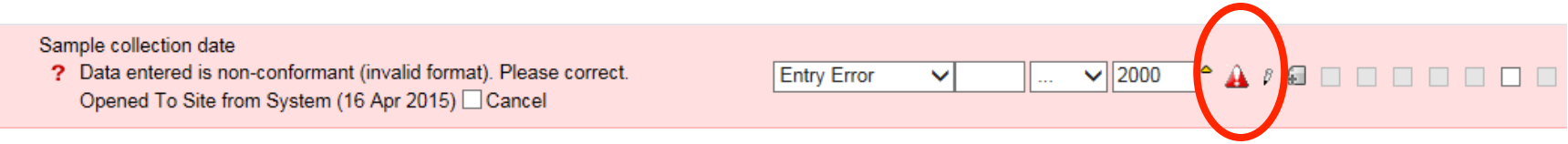
Queries: Non-Conformant



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!

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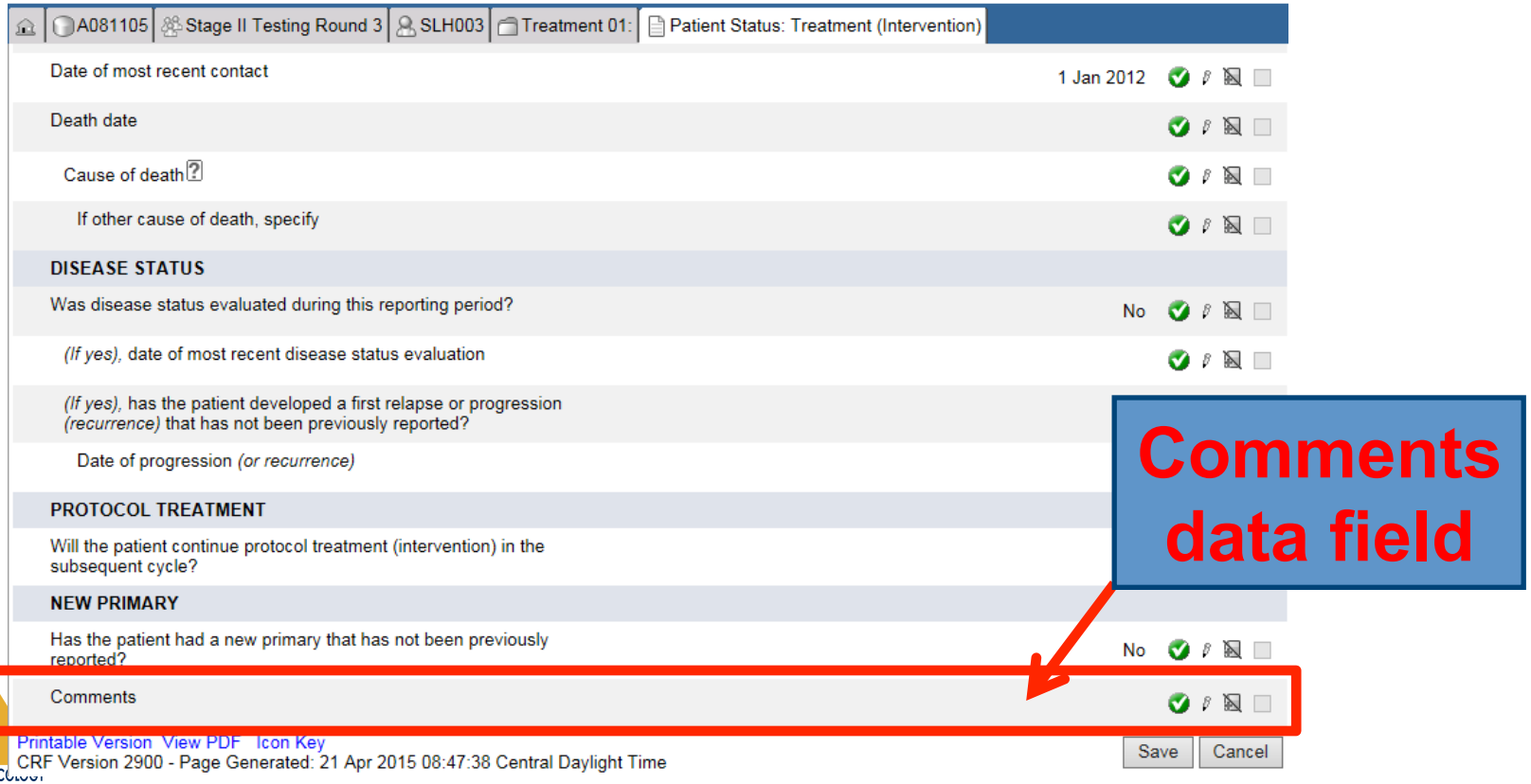
When To Comment

When is it appropriate to use a "Comments" data field …



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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.

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Audit Trail

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.

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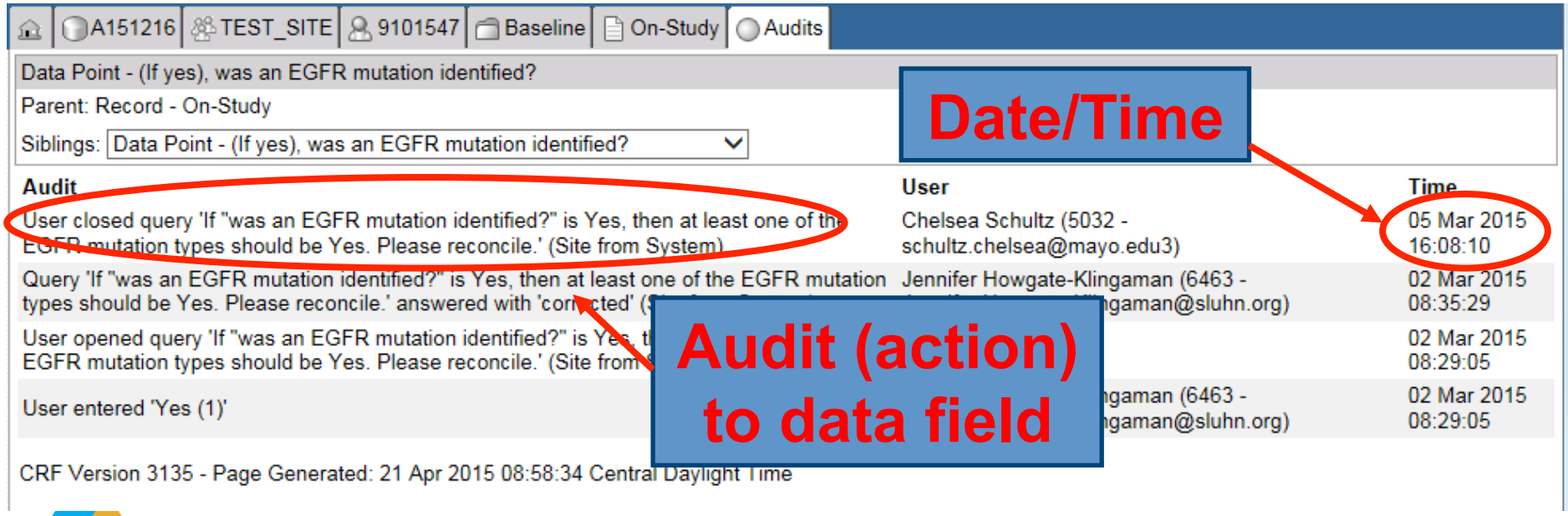
Audit Trail



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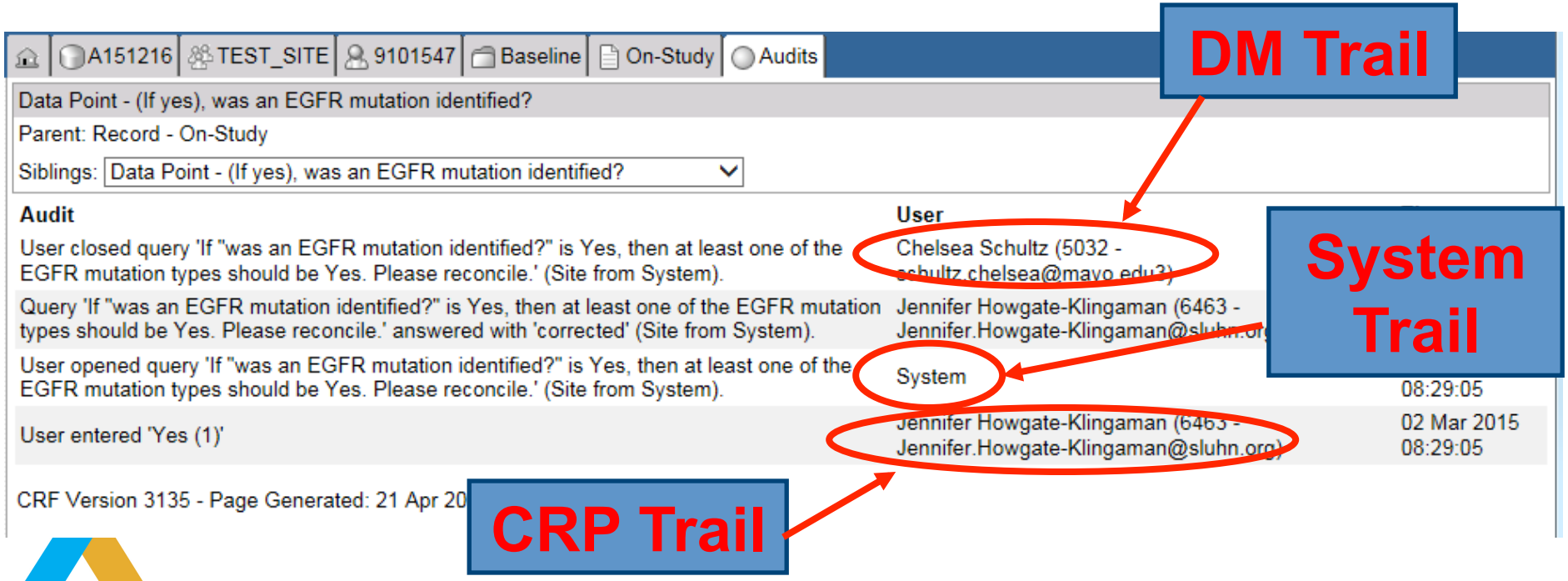
Audit Trail

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

- The DM and the CRP can view the audit trail.



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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.

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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.*

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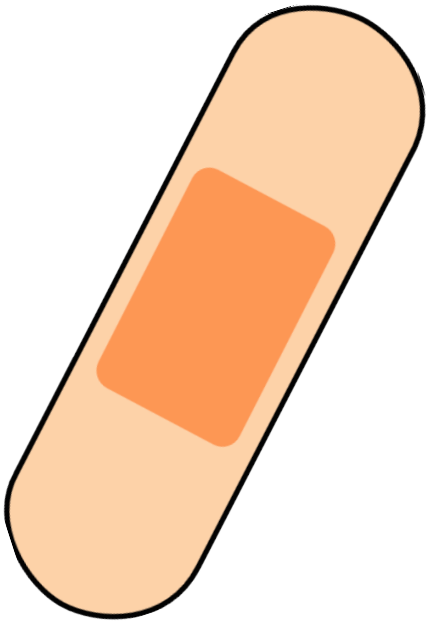
AE Bandaid



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.

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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?

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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

Help Desk at **ctsucontact@westat.com** or 1-888-823-5923 for assistance.
Contact **roster@alliancenctn.org** for Alliance rostering assistance.

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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.

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Rave Resources

Online Resources:

- **Medidata** Rave help website

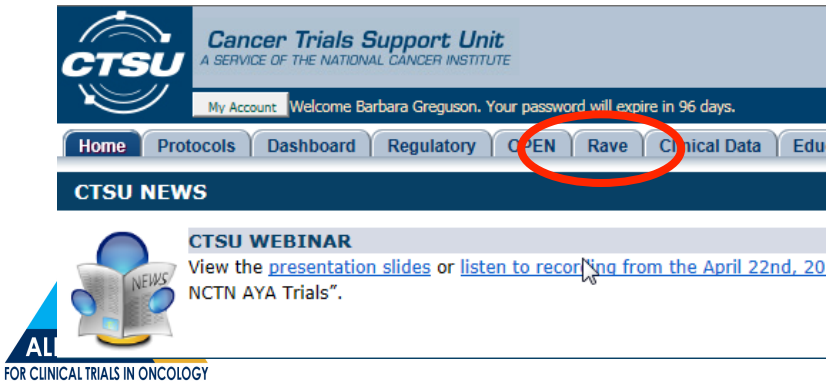
https://rave-webhelp.s3.amazonaws.com/EDC/WebHelp_ENG/EDC.htm

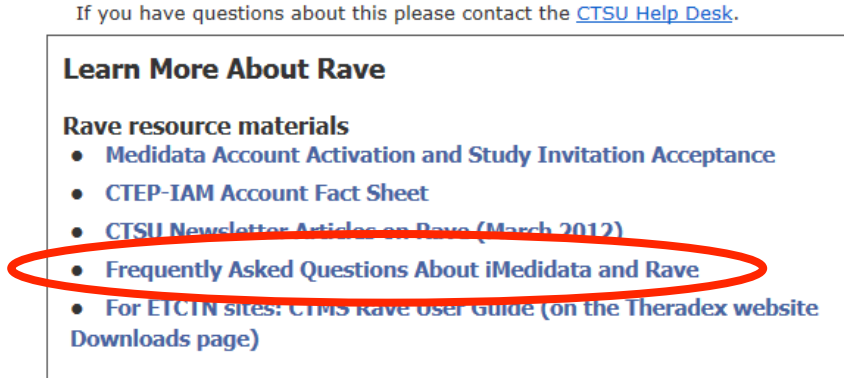
* Contains learning modules for wide range of Rave topics

- **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.





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?

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Brainstorming …
Ideas for
Timely Data Submission

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