



CRP Data Manager: Meet Your Data Manager

Jenny Darcy – Associate Director Alliance

Julie Moriarity – IT Liaison (Alliance Service Center)

Chelsea Schultz – IT Liaison (Alliance Service Center)

Tiffany Schafer – Data Manager Supervisor

Alliance Spring Group Meeting - May 12, 2016

Please note: This is merely an outline of the presentation. If clarification or further education on a particular part of the presentation is needed, please reach out to the Alliance Service Center.



Presentation Objectives

- Provide a high level overview of the Alliance Data Management team
 - Introduce each attending Data Manager
 - Provide Rave Tips
 - Provide a high level overview of Overdue Reports
 - Provide Terminated Legacy CALGB studies link

Data Management Team



From Back to Front:

Left to Right: Razan, Zack, Marcia, Andy, Ryan K., Luke, Craig, Tracy, Kayla, Lisa

Left to Right: Cristina, Deb, Emma, Pam, Carla, Janet, Joyce, Jenny, Tiffany W., Amy, Barb, Tasha

Left to Right: Pat K., Pat M., Jordan, Tiffany S., Natalie, Ryan P., Jen, Jenny

Left to Right: Becky, Gina, Jennifer, Sasha, Chelsea

Marcia Wilson



- Coordinator – Research Operations – Data Management Unit



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Jenny Darcy



- Associate Director Alliance



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Misty Bova-Solem



- CALGB 10603



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Carla Hilton



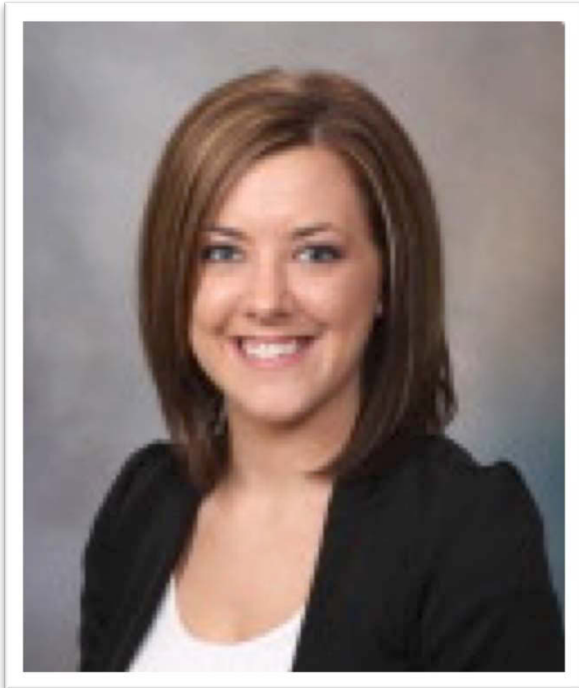
- A041401
- A071402
- A071101
- N107C
- N1174
- N057K
- N0572
- N0574
- N0577
- N0872
- N0874
- N0877

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- CALGB 140503
- CALGB 90203
 - Gina, Janet & Tasha



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Tiffany Schafer



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Lisa Schreurs



- A031102
- A091302
- A091305
- A091404

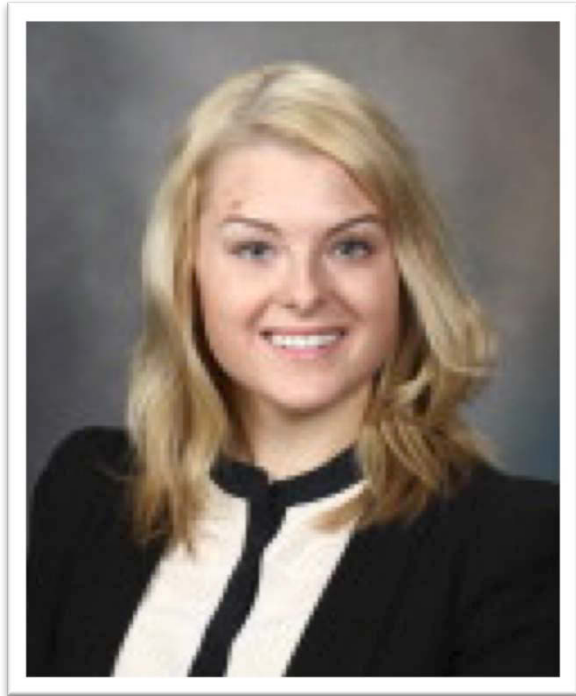


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Gina Squires



- CALGB140503
 - transitioning to Tasha McDevitt
- CALGB 90203
 - Gina, Janet and Tasha
- CALGB 30607
- CALGB 140202
 - temporarily

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Tiffany Winter



- A011106
- Z11102



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Alliance Service Center



Phone: 1-877-442-2542

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Email: allianceservicecenter@alliancencn.org

Rave Tips and Tools

- Queries in Rave
- Calendar vs Grid View (DSS)
- Institutional Contact Form
- Dictionary vs Free Text Fields
- Help Text vs Instructional Text

Queries in Rave

Response Box vs Data Field

- Response Box
 - Found below the query text
 - Used to provide further clarification
- Data Field
 - Found to the right of the question
 - Used for the actual data

Response Box vs Data Field

Response Box

Used to provide further clarification related the data field.

Data Field

Where you enter the value.

The screenshot shows a section titled "PRO/QOL ASSESSMENT(S)". The first question is "Did the participant complete the assessment (Population Pharmacokinetics Questionnaire)?" with a "Yes" button and a green checkmark icon. Below this, a red shaded area contains a question: "(If yes), date completed". A red box highlights a text input field for the date. To the right, a blue box highlights a dropdown menu with "Entry Error" selected, followed by a text input field and another dropdown menu. Below the red area is a section titled "CONCOMITANT MEDICATIONS" with a note: "If there are any new concomitant medications or changes to existing concomitant medications, please report on Concomitant Medications CRF."

Please use the window "scroll" to move to the right on the screen. The Rave case report form is larger than most computer screen widths.

Answering a Query

- Does not require a response in the “Response Box” if you are able to complete the data field.

PRO/QOL ASSESSMENT(S)

Did the participant complete the assessment (*Population Pharmacokinetics Questionnaire*)? Yes

(If yes), date completed

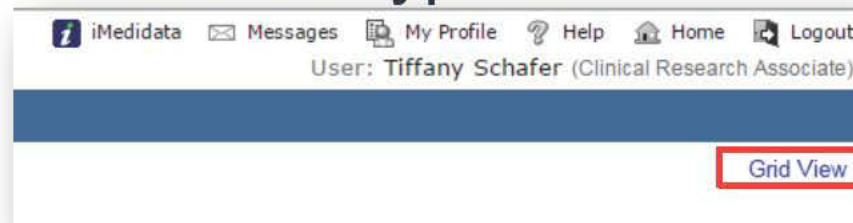
? If "Did the participant complete the assessment?" is Yes then "date completed" is required. Please reconcile.
Opened To Site from System (28 Jul 2015)

Entry Error 1 Jan 2016

- When you complete the data field, the response box grays out.



Calendar vs Grid View

- Calendar view
 - Default view
 - Table
- Grid view
 - Accessed via blue hyperlink



- Grid

Calendar View

Visit	Date
 Baseline	14 Aug 2014
 Treatment 01: Pomalidomide + Dexamethasone + Ixazomib 01-Aug-2014	28 Aug 2014
 Treatment 02: Pomalidomide + Dexamethasone + Ixazomib 03-Sep-2014	26 Sep 2014
 Off Treatment	24 Sep 2014
 Survival Follow-up 03: 17-Nov-2014	10 Dec 2014

Grid View

Subject Enrollment Calendar View

All	Baseline	Treatment 01: Enzalutamatide alone 10-Apr-2015	Treatment 02: Enzalutamatide alone 08-May-2015	Treatment 03: Enzalutamatide alone 05-Jun-2015	Treatment 04: Enzalutamatide alone	Treatment 05: Enzalutamatide alone	Off Treatment	Clinical Follow-up 06: 28-Jul- 2015	Clinical Follow-up 07: 28-Jul- 2015	Clinical Follow-up 08: 28-Jul- 2015	Survival Follow-up 09:	Survival Follow-up 10	Concomitant Medication	All
Institutional Contacts	📄													Institutional Contacts
On-Study	📄													On-Study
On-Study: Prior Therapy to Treat the Primary Tumor	📄													On-Study: Prior Therapy to Treat the Primary Tumor
On-Study: Prior Therapy to Treat Biochemical Relapse	📄													On-Study: Prior Therapy to Treat Biochemical Relapse
On-Study: Prior Therapy to Treat Metastatic Disease	📄													On-Study: Prior Therapy to Treat Metastatic Disease
Laboratory Tests and Results: Baseline	📄													Laboratory Tests and Results: Baseline
Laboratory Tests and Results: Baseline (PSA)	📄													Laboratory Tests and Results: Baseline (PSA)
Specimen Submission: Blood (Baseline - Substudies)	📄													Specimen Submission: Blood (Baseline - Substudies)
Population Pharmacokinetics Questionnaire			📄	📄	📄	📄								Population Pharmacokinetics Questionnaire
Adverse Events: Baseline	📄													Adverse Events: Baseline
PCWG2 Bone Scan Assessment: Baseline	📄													PCWG2 Bone Scan Assessment: Baseline
Measurements (Non- Measurable Disease Only): Baseline	📄													Measurements (Non- Measurable Disease Only): Baseline
Supporting Documentation: Baseline	📄													Supporting Documentation: Baseline
PRO/QOL: Registration Fatigue/Uniscale Assessment	📄													PRO/QOL: Registration Fatigue/Uniscale Assessment
Patient Status: Baseline	📄													Patient Status: Baseline
Treatment (Intervention)		📄	📄	📄	📄	📄								Treatment (Intervention)
Adverse Events: Solicited		📄	📄	📄	📄	📄								Adverse Events: Solicited
Adverse Events: Other				📄										Adverse Events: Other
PCWG2 Bone Scan Assessment			📄							📄				PCWG2 Bone Scan Assessment
Measurements (Non- Measurable Disease Only)			📄											Measurements (Non- Measurable Disease Only)
Supporting Documentation			📄							📄				Supporting Documentation
Laboratory Tests and Results		📄	📄	📄	📄	📄								Laboratory Tests and Results
Specimen Submission: Blood (Substudies)			📄	📄										Specimen Submission: Blood (Substudies)

Data Submission Schedule

- Found on Alliance and CTSU website
- No longer found within the Alliance protocols
 - Allows for data submission schedule updates to be streamlined

Alliance Website

www.allianceforclinicaltrialsinoncology.org

- Sign in
- Search for appropriate study in upper right hand corner

Chelsea Schultz (log out)

[Back to the Public Pages](#)

A151216

[Advanced Search](#)

Alliance A151216

Title: Adjuvant lung cancer enrichment marker identification and sequencing trial (ALCHEMIST)

[Alliance A151216](#)

[All Documents](#)

[Updates and Action Letters](#)

[Funding Sheet](#)

[Case Report Forms](#)

[Memoranda and
Broadcasts](#)

[Supplemental Materials](#)

[DSMB Statement and
Study Summary](#)

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

[ALCHEMIST Slides](#) - 03/17/2015

The Alliance website hosts the most up-to-date versions of all Alliance protocol materials. For additional materials prepared by CTSU, please click [here](#).



Alliance A151216

All Documents

Updates and Action Letters

Funding Sheet

Case Report Forms

Memoranda and
Broadcasts

Supplemental Materials

DSMB Statement and
Study Summary

Alliance A151216

A151216-01.pdf
A151216-MCF-01.docx
A151216-MCF-01.pdf
A151216-ALCHEMIST-FAQ-03172015.pdf
A151216-ALCHEMIST-SlideDeck-03172015.ppt

Updates and Action Letters

A151216-Update01.pdf
A151216-Activation.pdf

Funding Sheet

A151216-Fndsheets-01012015.pdf

Case Report Forms

A151216-DSS-05012015.pdf
A151216-Allforms-05012015.pdf
A151216-OPENEnrollmentForm-Step0.pdf
A151216-OPENEnrollmentForm-Step1.pdf

Memoranda and Broadcasts

Broadcast-A1512-6-A081105-ECOGACRIN4512-Study Activation-08182014.pdf

Supplemental Materials

A151216-ScrollCalculator-04152015.pptx
A151216-PatientHandout-12012014.pdf

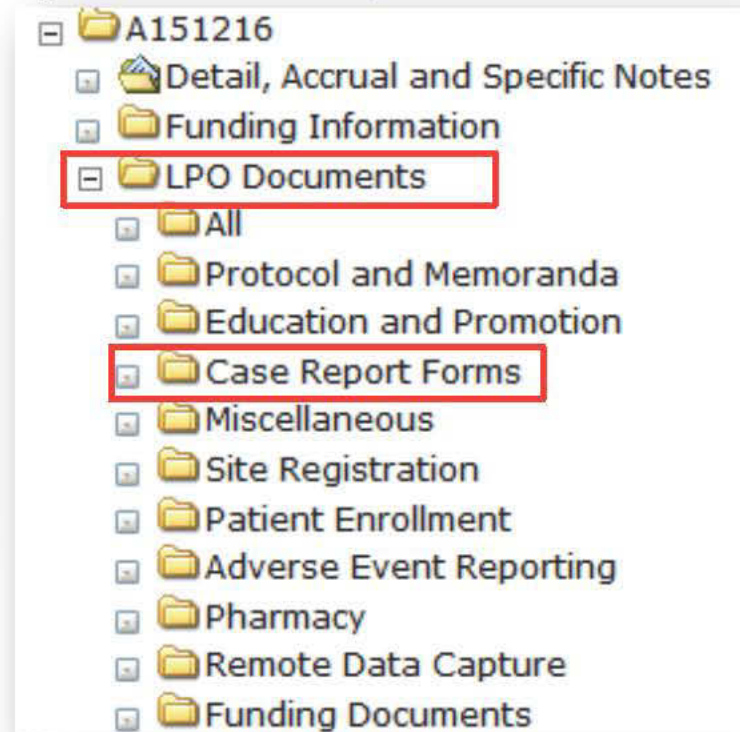
DSMB Statement and Study Summary

A151216-StudySummary-112014.pdf

CTSU Website

www.ctsu.org

- Sign in
- Click “protocol” tab
- Search for appropriate study



Documents				
#	Document Title	Document Date	Format	Post Date
Protocol				
1	Protocol Document (NCI Version Date 02/09/2015)	03/15/15	PDF	03/18/15
2	Update #1	03/15/15	PDF	03/18/15
3	Alliance Study Summary - November 2014		PDF	11/13/14
4	ALCHEMIST News Release	08/18/14	PDF	09/03/14
5	Memorandum: Activation Notice	08/18/14	PDF	08/18/14
Education and Promotion Materials				
1	Time & Events	08/18/14	PDF	08/18/14
2	Schema	03/15/15	PDF	03/18/15
3	Protocol Card	02/09/15	PDF	03/27/15
4	Physician Fact Sheet	02/09/15	PDF	03/27/15
5	Scroll Calculator		Powerpoint	04/16/15
6	Alchemist Frequently Asked Questions (FAQs) - May 2015		PDF	05/08/15
7	ALCHEMIST Overview Slide Set- November 2014		PDF	03/18/15
8	Patient Education Materials NOTE: This document has been approved by the CIRB for patient distribution.	11/01/14	PDF	12/03/14
9	ALCHEMIST Trial Summary Sheet	05/13/15	PDF	05/14/15
Case Report Forms				
1	Data collection for this study will be done exclusively through Medidata Rave. Please see the data submission section of the protocol for further instructions. The Rave system can be accessed through the iMedidata portal at https://login.imedidata.com .			
2	Data Submission Schedule	05/01/15	PDF	05/05/15
3	All Forms Packet	05/01/15	PDF	05/05/15

Institutional Contact Form

- Who the Data Manager will contact at the site
- Lives in the “Baseline” folder within Rave
- Updated by the site

Institutional Contact Form

Subject: TS009
Page: Institutional Contacts - Baseline

INSTRUCTIONS: Use this form to identify who the Data Manager should contact for quality assurance purposes. Please update this information if there are any changes to the contact information while the patient is still on study.

Cycle

CRA

Name (first, last)	Tiffany Schafer	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Email	Tiffany@mayo.edu	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Phone (example: 999-999-9999)	555-555-5555	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

LEAD CRA

Name (first, last)	Chelsea Schultz	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Email	Chelsea@mayo.edu	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Phone (example: 999-999-9999)	555-555-5555	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

SITE INVESTIGATOR

Name (first, last)	John Doe	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Email	Doe@mayo.edu	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Phone (example: 999-999-9999)	555-555-5555	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Is the reference radiologist or local investigator available for bone imaging interpretation? Yes

Comments

Printable Version View PDF Icon Key
CRF Version 3690 - Page Generated: 11 Apr 2016 07:51:20 Central Daylight Time

Save Cancel



Dictionary vs Free Text

Free Text Fields

Dictionary Fields

#	Concomitant agent name	Dose	Units of measure	Frequency	Indication	Start date	Stop date
1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/> <small><< Back 1/21 Next >></small> Accelerate hematopoietic recovery Acidity Adrenal suppression Allergic reaction Allergy Alopecia Anemia Anesthesia Anorexia Anti-angina	<input type="text"/>	<input type="text"/>

Add a new Log line Inactivate
Comments

Printable Version View PDF Icon Key
CRF Version 3890 - Page Generated: 11 Apr 2016 07:53:39 Central Daylight Time

Help Text vs Instructional Text

- Help text appears next to applicable field
- Instructional text appears above the applicable section of the form

Help Text vs Instructional Text

Instruction: "Dose level (day 1)" refers to the measured amount of each study agent expected to be administered on the first day of this cycle. "Dose (total dose)" refers to the total dose taken during the entire cycle. For example: For this trial, if a patient took their medication daily for 21 days, the total dose this cycle would equal 3,150 mg (21 days x 150 mg).

#	Agent name	Dose level (day 1)	Units of measure	Dose (total dose)	Units of measure	Was protocol treatment modified?	Was protocol treatment omitted?	Was protocol treatment delayed?	Start date	Stop date	
1	Erlotinib/Placebo	150	mg	2850	mg	No ^a	Yes	No	09 Dec 2015	30 Dec 2015	✓ ✎ 📄 ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

CRFHelp - Internet Explorer
[https://mayo.mdsol.com/MedidataRave/\(S\(efvht5djhkq01](https://mayo.mdsol.com/MedidataRave/(S(efvht5djhkq01)

Was protocol treatment modified?

A modification indicates a change in dose level during the current cycle. However, if a modification was issued after the last dose was received in the current cycle, the modification should be reported on the subsequent cycle. "Yes, planned" should be selected if the dose level was changed according to protocol guidelines (i.e. due to adverse events, lab values, etc.); "Yes, unplanned" should be selected if the dose level change was not a part of protocol guidelines (e.g. vacation, mistake, etc.). Held doses (including omissions and delays) should not be reported as modifications.

Close Help Window

CRFHelp - Internet Explorer
[https://mayo.mdsol.com/MedidataRave/\(S\(efvht5djhkq01](https://mayo.mdsol.com/MedidataRave/(S(efvht5djhkq01)

Was protocol treatment omitted?

An omission indicates a dose was skipped and not made up, or that the drug was discontinued.

Close Help Window

CRFHelp - Internet Explorer
[https://mayo.mdsol.com/MedidataRave/\(S\(efvht5djhkq01](https://mayo.mdsol.com/MedidataRave/(S(efvht5djhkq01)

Was protocol treatment delayed?

A delay indicates dose was postponed or not received when expected.

Close Help Window

Attachments

- Attachments should be on individual log lines
 - Protocol calls for a Pathology Report and an Operative. There should be a Pathology Report on one log line and an Operative Report on the next log line.
- Attachments should be de-identified
 - This will be queried if found to have visible identifiers. The site will be responsible to re-upload the document correctly de-identified.
- Attachments should include patient ID

Cycle				
#	Date of assessment	Report type	Specify report type	Attachment (max file size 10 MB)
4	20-Jan-2015	Serum Protein Electrophoresis	SPEP	1.20.15.pdf
2	20-Jan-2015	Serum Free Light Chain Assay	Serum FLC	1.20.15.pdf
3	20-Jan-2015	Lab report	Hematology	1.20.15.pdf
4	20-Jan-2015	Lab report	Chemistry	1.20.15.pdf
5	20-Jan-2015	Serum Quantitative Immunoglobulins	Immunoglobulins	1.20.15.pdf
6	25 Feb 2015	Other	end of tr 1 labs	pwr 2 25 15.pdf

Add a new Log line Inactivate

Above is an example of grouping attachments.

Below is an example of individualizing attachments.

Cycle				
#	Date of assessment	Report type	Specify report type	Attachment (max file size 10 MB)
1	30 Sep 2014	Pathology report		Pathology_Redacted.pdf
2	10 Oct 2014	Serum or urine immunofixations		SPEP and IF_Redacted.pdf
3	10 Oct 2014	Serum Protein Electrophoresis		SPEP_Redacted.pdf
4	30 Sep 2014	Cytogenetic report		Cytogenetics_Redacted.pdf
5	30 Sep 2014	Lab report	LDH, Phos, beta 2 microglobulin	LDH Phos B2M_Redacted.pdf
6	06 Oct 2014	Lab report	Mg and CRP	CRP Mg_Redacted.pdf
7	10 Oct 2014	Lab report	CBC, Comp, Light Chains, Immunoglobulins	CBC CMP Light Chains IGs_Redacted.pdf

Delinquency/Overdue Reports

The screenshot shows the Alliance for Clinical Trials in Oncology website. At the top left is the logo, and at the top right is the user name 'Chelsea Schultz(log out)' with links for 'Back to the Public Pages', 'Search', and 'Advanced Search'. A navigation bar contains links for 'home', 'protocols', 'committees', 'education & training', 'member services', and 'new'. A blue banner below the navigation bar says 'Welcome Chelsea'. The main content area is divided into two columns. The left column has an 'ANNOUNCEMENTS' section with a heading 'Alliance CRPs: Upgrade Your Web Browser by May 2' and text explaining that users accessing certain websites need to upgrade their browsers by May 2, 2016. It lists supported browsers: Internet Explorer 11, Mozilla Firefox 42, Google Chrome 48, Edge 13, and Safari 7. The right column has a 'Quick Links' section with a list of links. The link 'Delinquency/Overdue Reports' is highlighted with a red rectangular box.

Alliance
for Clinical Trials
in Oncology

Chelsea Schultz(log out)
Back to the Public Pages
Search
Advanced Search

home protocols committees education & training member services new

Welcome Chelsea

ANNOUNCEMENTS

Alliance CRPs: Upgrade Your Web Browser by May 2

Alliance CRPs accessing the following websites - ACOSOG: <https://ncctg.mayo.edu/acosog/> and NCCTG: <https://ncctg.mayo.edu/> to gain access to the Remote Data Entry system for legacy ACOSOG and NCCTG studies will need to upgrade their web browsers before May 2, 2016.


If your web browser version is out of date or TLS 1.2 has been disabled, work with your local IT Help Desk to enable use of TLS 1.2 in your existing web browser or upgrade to one of the following web browsers:

- Internet Explorer version 11
- Mozilla Firefox version 42
- Google Chrome version 48
- Edge version 13,
- Safari version 7

After May 2, users who are using old versions of web browsers will no longer be able to view the web pages. If you have any questions, contact the Alliance Service Center at allianceservicecenter@alliancenctn.org.

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
- OPEN
- Policies & Procedures
- RAVE
- Recent Postings
- Study Summaries
- Study Terminations of Patient Follow-up
- Tools & Calculators



Overdue/Delinquency Reports



Chelsea Schultz (log out)

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[Advanced Search](#)

[home](#) [protocols](#) [committees](#) [education & training](#) [member services](#) [news](#)

Delinquency/Overdue Reports

[Home](#) > [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](#)



Delinquency/Overdue Reports



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[Advanced Search](#)

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Delinquency/Overdue Reports

[Home](#) > [Delinquency/Overdue Reports](#)



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

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- [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](#)



Delinquency Tip

- If you feel there is an error in your report, reach out to the Alliance Service Center.

Reminders



Resolving Teleform Submission Issues for Legacy CALGB Studies

The use of Chrome, Firefox and Safari browsers creates an issue in submitting data via Teleform for legacy CALGB studies. Due to this issue, it is necessary for all forms to be submitted using Internet Explorer.

Refer to the [attached document](#) for additional information regarding Teleform submission.

If there are any questions or concerns, please contact the Alliance Service Center at 877-442-2542 or e-mail AllianceServiceCenter@allianceNCTN.org.

Alliance for Clinical Trials in Oncology

[attached document](#)



Teleform Submission Workflow

- Site enters data on CRF online
- Site clicks “Submit”
- Site is prompted to print the CRF
- Site clicks “Submit to CALGB”
- Site receives “Confirmation of Submission”
- Form goes to Teleform Verifiers
 - Team of DMs
- Data from the form is then sent to tables in the database



The overall submission timeline is >24 hours

Reason forms fail with confirmation

- Export Fails
 - Submitted an amendment online
 - Submitted with wrong study ID
 - Submitted with wrong patient ID
 - Double data entry
 - Same form/same dates entered multiple times
 - Start and/or End dates missing
 - mm/dd/yyyy
 - Required fields left blank
 - Some studies error until you complete these fields

A031201- Prostate

- PCWG2 (Section 13.1)
 - Visceral and lymph node lesions will be assessed using a modified form of RECIST 1.1 criteria
 - Report longest diameter for all soft tissue lesions, including nodes
- Brief Pain Index (Section 4.6.3) Appendix II
 - Asymptomatic or mildly symptomatic from prostate cancer.
 - A score of 0-1 on BPI-SF Question #3 is considered asymptomatic
 - score of 2-3 will be considered mildly symptomatic
 - ≥ 4 the patient is ineligible

Take Home Message

- CALGB has completed its transition to the Alliance Statistical and Data Center
 - All amended forms/supporting documentation should be mailed to:
ALLIANCE
Attn: <insert study>
RO_FF_03_24-CC/NW Clinic
200 First Street SW
Rochester, MN 55906
- Direct any and all questions to the Alliance Service Center:
 - 1-877-442-2542
 - Allianceservicecenter@alliancenctn.org



Questions?

