CRP BREAKOUT:
IT'S ALL ABOUT THE RAVE

Ryan Potaracke
Alliance Fall Meeting 2017; November 2, 2017

Presentation Objectives

- Introduction
- Overview of general Rave icons, navigation tips functions, and common queries
- Overview of the various tools and reports available to CRPs
- Other Rave Resources/Tips
- CALGB Teleform to Rave conversion
- Obtain Feedback for Future Rave Topics

Data Management Team

- Located in Rochester, MN at the Mayo Clinic (CST)

- Who is my Data Manager (DM)?
    - Study contacts, including data management, protocol coordinator, and statistician; should be up to date on Alliance website landing page for each trial.

> **Study Team**
> Data Manager: Ryan Potaracke (507) 538-4370 X 241
> Protocol Coordinator: Colleen Watt (773) 702-4670
> Statistician: Sumithra Mandrekar, PhD (507) 266-6724

- If you cannot identify/reach your DM, please contact:
    - Alliance Service Center:
        - 1-877-442-2542
        - allianceservicecenter@alliancenctn.org

iMedidata Rave

- Medidata Rave is a cloud–based, clinical data management system, used to electronically capture, manage, and report clinical research data.

  - It enables the user to record patient information using forms that are customized for each study.

- Rave is the standard electronic data capture system for all network groups in the NCI (National Clinical Trials Network.)

Gaining Access to iMedidata Rave:

- Access to Rave is <u>not</u> granted through the Data Management office.
- To gain access to Rave:
  - The individual must have the Rave CRA role on their memberships.
  - The Lead CRP will need to add the new CRA to all appropriate memberships via the RUMs tab on the CTSU website.
    - Once they are added to the correct memberships, you will add the Rave CRA role to each.
    - Once this has been completed, the new CRA will receive invitations to any study IRB approved at their site.
      - If you do not receive the appropriate invitations after this has been completed, contact <u>CTSU</u>.

Gaining access to Rave
Below is additional information regarding Rave access that can be found on the CTSU website under the Rave/DQP tab

- **Access to iMedidata:**
- [Click this link to access iMedidata directly using Single Sign On (no login necessary)](#)
- If you are having trouble accessing iMedidata using the Single Sign On link above, please try accessing via URL: https://login.imedidata.com/selectlogin (using your CTEP-IAM credentials)
- Medidata Rave is a clinical data management system being used across the NCI Cancer Therapy Evaluation Program (CTEP) for the entry and management of clinical data for Network Group trials. The iMedidata application is a portal to access Medidata products including Rave. It allows site and Lead Protocol Organization (LPO) users to access studies across multiple Rave URLs by providing a single point of entry. Access to iMedidata and Rave is controlled through the CTEP-IAM system and through role assignments in the CTSU Regulatory Support System (RSS) for site users. To access iMedidata and Rave: Site staff will need to be registered with CTEP and have a valid and active CTEP-IAM account.
- This is the same account (user id and password) used for the CTSU members' website.
- To access studies in Rave, the site user must have been assigned one of the following Rave roles on the relevant LPO or Participating Organization roster:
  - Rave CRA role to enter subject data and respond to queries
  - Read-Only role to simply view data
  - Site Investigator role to enter subject data, respond to queries, and electronically sign forms
  - CRA (LabAdmin) role to enter subject data, respond to queries, and maintain local lab data
  - SLA role to simply view data, and maintain local lab data

Information about browser compatibility, FAQs and known issues can be found at
https://learn.mdsol.com/mcc/about-browser-compatibility-81650569.html
- [Learn More About Rave](#)
- [Rave Roles and Training](#)

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Rave Access and eLearning

- Current access to Rave is also based on eLearning requirements, in conjunction with instructor-led training.

- Your access to a study is available in Rave EDC if you pass the assigned eLearning for that study.

  - If you are assigned to an eLearning and do not have a valid training date, then access to the Rave Studies depends on completion of the eLearning for specified studies.

  - The eLearning Home page can be accessed from:

    - **Rave EDC Study page** – an **eLearning Required** link appears next to a study name that requires eLearning to be completed.

    - The **My Profiles** link on the header of any Rave EDC page.

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Rave Icons

Forms Icons

Icon	Description
	CRF never touched
	CRF is incomplete
	CRF is non-conformant
	CRF is complete
	CRF has one or more open queries
	CRF has one or more answered queries
	CRF requires verification
	CRF requires review
	CRF is entry locked
	CRF is locked
	CRF is inactive
	CRF requires translation
	CRF requires coding
	CRF is overdue
	CRF requires signature
	Form is waiting for First Pass Data Entry
	Form requires Second Pass Data Entry
	Form requires Reconciliation

Subject Icons

Icon	Description
	Subject never touched
	Subject has incomplete data
	Subject has non-conformant data
	Subject has completed data
	Subject has open queries
	Subject has answered queries
	Subject has data that requires verification
	Subject has data that requires review
	Subject has entry locked fields
	Subject has locked data
	Subject has inactive data
	Subject has data that requires coding
	Subject has data that is overdue for data entry
	Subject has data that requires translation
	Subject has data that requires signature
	Subject has "in doubt" status

Status Icons

Icon	Description
	Never Touched
	Answered Query
	Incomplete
	Requires Verification
	Non-Conformant
	Requires Review
	Complete
	Entry Lock
	Overdue
	Locked
	Inactive
	Requires Translation
	Requires Coding
	Requires Signature
	Query Open
	Requires Coder Coding

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Rave Icons

- This table illustrates status hierarchy in Rave EDC, in order of priority (highest to lowest):

- Status icons are specific to your role.

Status	Icon	Description
Non Conformant	⚠	Invalid data point. Data entered is in a format that is inconsistent with the format expected for a particular field.
Locked	🔒	Data point or associated queries or sticky notes cannot be changed.
Open Query	❓	Open query exists for a data point that has not been answered.
Answered Query	⏻	Query on a data point has been answered but has not been closed.
Requires Translation	↩	Field or data point requires translation.
Requires Coding	🗊	Field or data point requires coding.
Requires Verification	🗋	Field or data point requires verification.
Requires Review	👁	Field or data point requires review.
Read only Opened Query	❓	User has read only permission to an open query on a data point.
Read only Answered Query	⏻	User has read only permission to an answered query on a data point.
Pending for Verification	🗋	Data point is pending for verification.
Is Overdue	⊘	Data with an overdue status. In other words, the date is in the past.
Pending for Review	👁	Data point is pending review.
Entry Locked	🔑	Data point has been locked.
Untouched	⚪	Data point has not been entered.
Incomplete	🟢	Value entered for a data point is incomplete and does not comply with requirements.
Requires Signature	🖊	Field or data point requires signature.
Entered Complete	✅	Data entered for a field or data point is complete and complies with requirements.
Entered Empty	✅	Data entered for a field or data point is empty and complies with requirements.

Navigation Tips - Pages

Study Page
The study page displays a list of studies that you can click to access.

Site page
The Site page displays when you select a study from the Study page. The site page displays a list of sites that you can click to access.
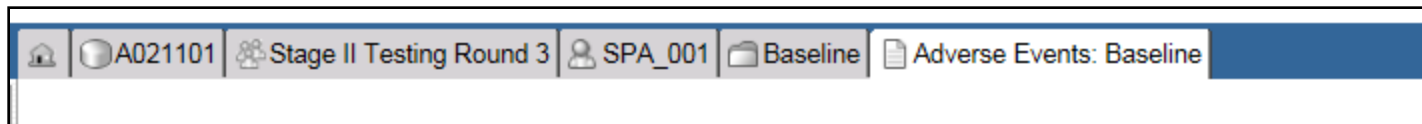
Navigation Tips - Pages

Subject home Page
The Subject home page displays when you select a site from the Site page. You can enter a new subject or select from a list of existing subjects.

Baseline
Screening
On-Study
Adverse Events: Baselin
RECIST Measurements: Baseline
Specimen Submission: Tissue
Radiographic Imaging Assessment: Local Revie
Patient Status: Baseline
Supporting Documentation: Baseline
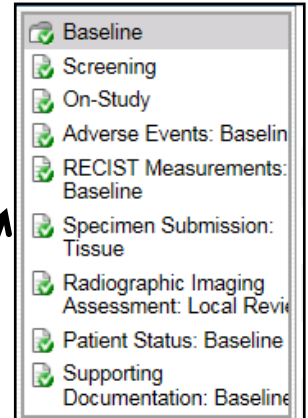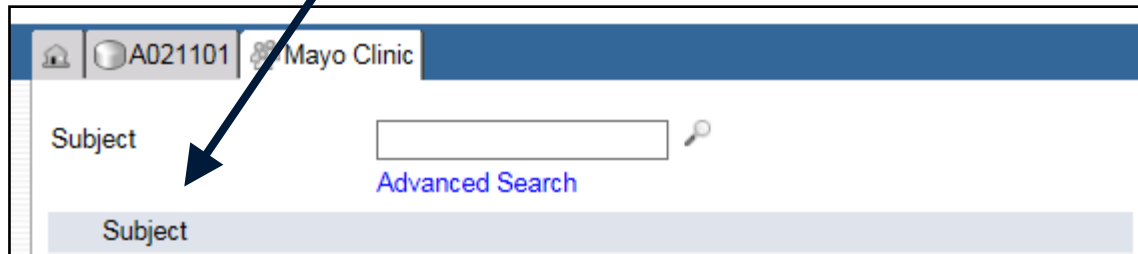
Data Pages
Specific pages that contain subject data.

⌂ | ○ A021101 | 🗞 Mayo Clinic

Subject [   ] 🔍
Advanced Search

Subject

⌂ | ○ A021101 | 🗞 Stage II Testing Round 3 | 👤 SPA_001 | 🗀 Baseline | 📄 Adverse Events: Baseline

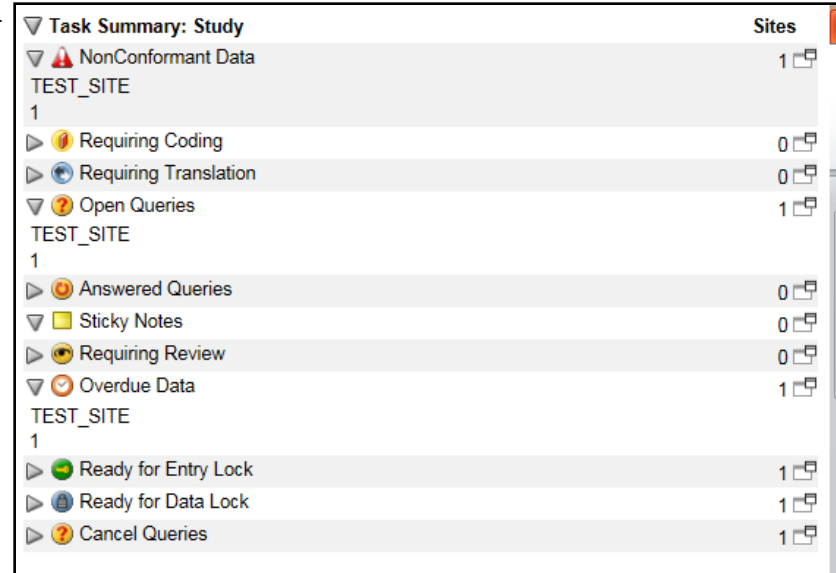ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Navigation Tips -Task Summary

The task summary is an easy way to quickly identify data issues such as non-conformant data, overdue data, open queries, etc.
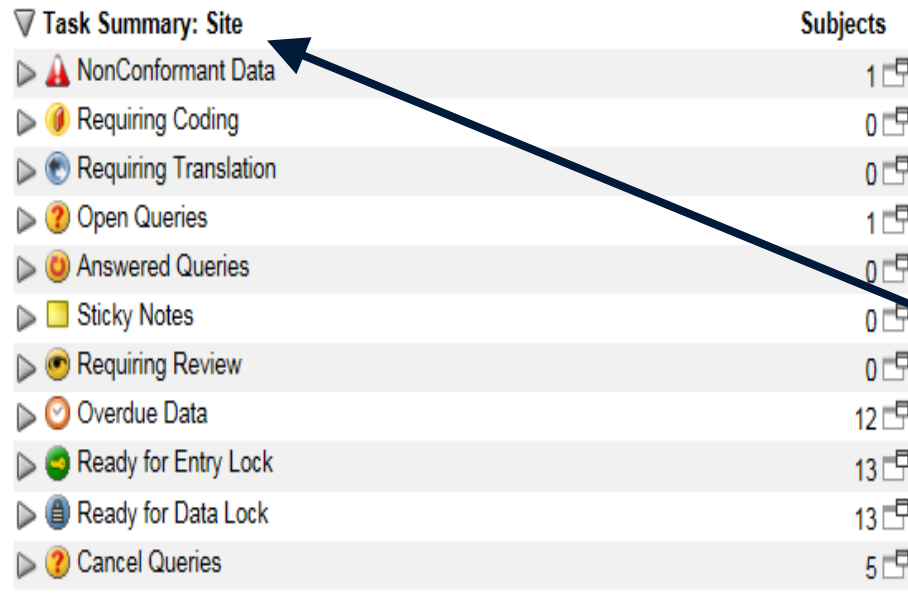

▽ Task Summary: Study	Sites
▷ ⚠ NonConformant Data	1
▷ 🟠 Requiring Coding	0
▷ 🔵 Requiring Translation	0
▷ ❓ Open Queries	13
▷ 🔴 Answered Queries	8
▷ 🟨 Sticky Notes	2
▷ ⚫ Requiring Review	0
▷ 🟠 Overdue Data	115
▷ 🟢 Ready for Entry Lock	538
▷ 🔵 Ready for Data Lock	538
▷ ❓ Cancel Queries	72

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Navigation Tips -Task Summary

The Task Summary on the **study level** displays the number of sites within that study that contains the selected item. *In this example, this study has 1 site with non-conformant data, 1 site with open queries, and 1 site with overdue data. They all happen to be the same 'test site'.*

▽ Task Summary: Study	Sites
▽ ⚠ NonConformant Data	1 ▭
TEST_SITE	
1	
▷ 🍊 Requiring Coding	0 ▭
▷ 🌐 Requiring Translation	0 ▭
▽ ❓ Open Queries	1 ▭
TEST_SITE	
1	
▷ ⦾ Answered Queries	0 ▭
▽ ☐ Sticky Notes	0 ▭
▷ ⦿ Requiring Review	0 ▭
▽ ⏱ Overdue Data	1 ▭
TEST_SITE	
1	
▷ 🟢 Ready for Entry Lock	1 ▭
▷ 🔒 Ready for Data Lock	1 ▭
▷ ❓ Cancel Queries	1 ▭

▽ Task Summary: Site	Subjects
▷ ⚠ NonConformant Data	1 ▭
▷ 🍊 Requiring Coding	0 ▭
▷ 🌐 Requiring Translation	0 ▭
▷ ❓ Open Queries	1 ▭
▷ ⦾ Answered Queries	0 ▭
▷ ☐ Sticky Notes	0 ▭
▷ ⦿ Requiring Review	0 ▭
▷ ⏱ Overdue Data	12 ▭
▷ 🟢 Ready for Entry Lock	13 ▭
▷ 🔒 Ready for Data Lock	13 ▭
▷ ❓ Cancel Queries	5 ▭

The Task Summary on a **site level** displays the number of subjects within the site on the selected study that contains the selected item. *In this example, this site on this selected study has 1 patient with non-conformant data, 1 patient with an open query, and 12 patients with overdue data.*

Navigation Tips -Task Summary

Task Summary: Subject	Pages
⚠ NonConformant Data	1
Baseline-Supporting Documentation: Baseline 1	
▷ Requiring Coding	0
▷ Requiring Translation	0
▽ Open Queries	0
▷ Answered Queries	0
▽ Sticky Notes	0
▷ Requiring Review	0
▽ Overdue Data	2
Baseline-Supporting Documentation: Baseline	
Survival and Disease Status Follow-Up 02-Patient Status: Survival and Disease Status Follow-Up/Event Monitoring 1	
▷ Ready for Entry Lock	21
▷ Ready for Data Lock	21
▽ Cancel Queries	0

The Task Summary section on the **subject level** displays the number of forms within the subject that contains the selected item.

In this example, this patient has 1 form with non-conformant data (Baseline Supporting Documents), and 2 forms that are overdue (Baseline supporting documents, and Survival and Disease Follow-up 02).

A collapse ▽ or expand ▷ icon next to the Task Summary label gives the user an option to expand or collapse the entire list.

Navigation Tips -Task Summary

- The Task Summary contains task categories, the relevant icon for each task category, and the total number of tasks pending for the current user in that category, based on user role and privileges.

Icon	Task	Description
⚠️	Non-conformant Data	Includes subjects with forms that have non-conformant data.
❓	Open Queries	Includes subjects with forms where at least one field on the form has an open query that is unanswered.
🕐	Overdue Data	Includes subjects with forms that have data with an overdue status.
🟨	Sticky Notes	Includes subjects with forms where at least one field on the form has a sticky note that is pending acknowledgement.

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Utilizing Your Task Summary Non-Conformant Data

- System-generated queries indicating data does not fit the format designated for that data field.
  - Top of the query hierarchy
  - User is unable to provide a 'query response' to non-conformant data issues
  - The issue causing non-conformant data is not specified in the system-generated query
    - Contact data management for assistance if reason for non-conformance is not immediately clear.

Utilizing Your Task Summary Non-Conformant Data

- Examples of non-conformant data queries:
  - Invalid dates (In this example, the date was saved with no month)

    Primary tumor diagnosis date
    ? Data entered is non-conformant (invalid format). Please correct.
    Opened To Site from System (12 Oct 2017) ☐ Cancel
    Entry Error ∨ 01 ... ∨ 2015

  - Letters entered in a numerical only field (In this example, the site tried to indicate the year as unknown by entering UNK)

    Year of diagnosis
    ? Data entered is non-conformant (invalid format). Please correct.
    Opened To Site from System (12 Oct 2017) ☐ Cancel
    Entry Error ∨ UNK ⚠

    - What we would want instead is the data field saved blank/unanswered and your response of unknown to be put in the query response box:

      Year of diagnosis
      ? If "Asthma" is Yes, then "Year of diagnosis" is required. Please complete.
      Opened To Site from System (12 Oct 2017) ☐ Cancel
      ↻ Unknown
      Entry Error ∨ ❓

Utilizing Your Task Summary Non-Conformant Data

- More examples of non-conformant data queries:
  - Decimal points where only whole numbers are allowed:

Height
? Data entered is non-conformant (invalid format). Please correct.
Opened To Site from System (12 Oct 2017) ☐ Cancel
Entry Error ▾ 101.58 cm ⏶ ⚠

  - Special Characters where only numbers or letters are allowed

Maximum diameter *(of tumor from pathology report)*
? Data entered is non-conformant (invalid format). Please correct.
Opened To Site from System (12 Oct 2017) ☐ Cancel
Entry Error ▾ >4cm cm ⏶ ⚠

  - Entering free-text when a drop-down menu is provided

Is the patient enrolled in a targeted therapy trial from the following list?
Entry Error ▾ Yes
A081105
E4512
EA5142
None
CG (Cancer Genetics) indicator of tissue adequacy for EGFR genotyping *(derived field)* ?
BCR (Biospecimen Core Resource) indicator of tissue and blood adequacy for

Is the patient enrolled in a targeted therapy trial from the following list?
Entry Error ▾ Yes ▾ ⚠

  - Other examples include
    - Too many characters entered in a free-text field, and more.

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Utilizing Your Task Summary Overdue Data

- Target dates are set in Rave indicating when visit folders are expected, based on previous data entry and trial requirements.
  - Despite your site/local requirements for data entry, these are the timelines for data entry that will be utilized by the DM.
- NCI sets standards for timelines, designating when folders/queries are overdue for NCTN trials.
  - Visit Folders:
    - Baseline and Treatment: 15 days from target date
    - Follow-up (CFU and SFU) 30 days from target date
  - Queries
    - 15 days from date issued
- Failure to submit data in a timely manner will result in a deficiency in general data quality and will be assessed per the following time frames:
  - Lesser : ≥ 3 months, but ≤ 6 months
  - Major: > 6 months

Utilizing Your Task Summary Overdue Data

- Data generally appears overdue when it is greater than 30 Days past the indicated target date in Rave
  - Target dates can be identified via the visit calendar on the subject home page

	Visit	Date
	Baseline	18 Jan 2016
	Survival and Disease Status Follow-Up 01: 04-Jan-2016	18 Jan 2016
	Survival and Disease Status Follow-Up 02: 08-Jun-2016	02 Jul 2016
	Survival and Disease Status Follow-Up 03: 11-Jan-2017	05 Dec 2016
	Survival and Disease Status Follow-Up 04	10 Jul 2017

  - Rave only reflects overdue forms, not overdue queries
  - The overdue icon will remain until all data fields on that eCRF are up-to-date.

Utilizing Your Task Summary Sticky Notes

- Not used as often by Data Management staff, but may be used for situations in which the DM needs to communicate regarding something perhaps not directly relating to a data field or not requiring action in Rave.

  - Can be 'removed' from task summary and eCRF by site acknowledging the sticky note by checking the appropriate box and saving the form.

Not submitted reason other, specify
☐ A flag will be filed, protocol deviation for tissue nut submitted per protocol.
Opened To Site from DM (12 Oct 2017) ☑ Acknowledge

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Utilizing Your Task Summary Sticky Notes

- A system-generated sticky note is also currently being used relating to expedited AE reporting for some trials.

Sticky Note for SAE Reporting

Form Instructions ?

A delay is expected when the safety system is called for AE evaluation.
Note: Do not open more than one ticket per course/cycle in CTEP-AERS. If more than one serious adverse event occurs this course/cycle, amend the report so both events are entered on the same ticket.

Course/Cycle # *(derived)*	1 ✓
Send all AEs for evaluation	☐ ✓
Recommended action for report *(derived)* ☐ An expedited report is RECOMMENDED. If the Investigator believes an expedited report is not warranted, (e.g., per protocol, commercial agent/arm, medical judgement, etc.), edit the 'Recommended action for report' field to indicate 'NONE'. Opened To Site from System (12 Jul 2017) ☐ Acknowledge ☐ Click this link to complete the safety report	CREATE ✓
Report ID *(derived)*	REP0137486 ✓
Recommended report type *(derived)*	CTEP 10 Calendar Day SAE Report ✓
Report due by *(derived)*	Saturday, July 22, 2017 ✓

Printable Version View PDF Icon Key   Save Can

- A recommended action 'CREATE' indicates that an expedited report is expected, based on the rules set-up in CTEP-AERS for the trial.

- If the Investigator chooses not to report the recommended action, the data field would be amended to indicate 'None' instead of 'Create'.

- Sticky note must also be 'acknowledged' by checking the appropriate box.

Utilizing Your Task Summary Open Queries

- Items that require a response, clarification, and/or change in Rave
  - Open queries indicated in your task manager can be system-generated or Data Manager-generated
    - Per the NCI standard, queries should be responded to/resolved within 15 days of being issued.
    - Queries will not appear overdue in Rave if not responded to within this timeframe, but will reflect as past due in other areas like the Overdue Materials Report, DQP, or DSMB.

Query Responses

- There are two types of entry fields available with most types of queries.

Histologic grade (differentiation)
? This field is required. Please complete.
Opened To Site from System (12 Oct 2017) ☐ Cancel

Entry Error ▾
... ▾

User Response Field:
A free-text field that can be used to provide further clarification, to specify when data is not available, or to provide a response (when required) to a DM-generated query (also called query response box).

Data Entry Field:
Where data requested for that field should be provided, when available.

Common Query: Please provide your response in the data field, not in the query response box.

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

System-Generated Queries

Examples would be non-conformant data, data field is required/not required, future date entered, study-specific requirements, etc.

- Log lines with open queries will appear in light and/or dark pink on the eCRF.

- These queries generate once the form is saved and will have the corresponding open query icon on the log line in which the query appears. *Please review eCRFs for system-generated queries once saved.
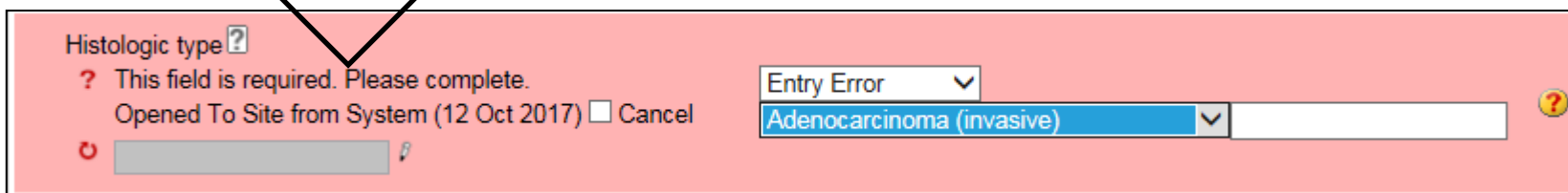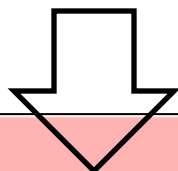
System-Generated Queries

Do not require a query response if the query can be resolved without further clarification to DM.

- Once the data is entered/issue resolved, the system-generated query box will 'shade out', indicating a response is not required, <u>as long as response is provided in the data entry field first</u> (prior to responding in user-response field).

User is now unable to type in the shaded out 'user-response field, as response is no longer required.

DM-Generated Queries

- These queries are issued upon review of the data, when further clarification or data changes are required.
  - Most often require a query response in the user-response box (often a response of 'updated' will suffice when no further clarification is need and data can be updated).

Was disease status evaluated during this reporting period?
? Please clarify why disease status was not evaluated during this reporting period. Thanks!
Opened To Site from DM (17 Oct 2017)
↻ updated

Entry Error ▾
⦿ Yes ○ No

  - Once a query response is entered/saved, the DM receives a notification in their **Answered Queries,** which prompts the DM to review the query and either close it out or re-query if additional clarification is needed.
  - Query Icon will appear on the eCRF until DM closes the query out on their end.

Query Responses

- When data changes are required, responses should be amended in the data field <u>and</u> a response should be entered in the query response box.
  - Providing only a response in the query response box will result in re-query, unless further clarification is provided.

Is the patient enrolled in a targeted therapy trial from the following list?
? This field is required. Please complete.
Opened To Site from System (17 Oct 2017)
↻ Yes, A081105

A response was entered and saved in the user-response box, but there was no data provided in the data entry field. DM will re-query.

There is no data saved in the data field.

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Query Responses

Is the patient enrolled in a targeted therapy trial from the following list?

? This field is required. Please complete.
Opened To Site from System (17 Oct 2017)

↻ Yes, A081105

? Please provide and save your response in the data field, not in the query response box. Thanks!
Opened To Site from DM (17 Oct 2017)

↻ updated

Entry Error ▾ | A081105 | × | ▾
A081105
E4512
EA5142
None

Site was re-queried to provide their response in the data entry field. A response of '*updated*' in the user-response field notifies DM of response.

Query is resolved. Data is available in the data entry field on the right side of the screen.

Is the patient enrolled in a targeted therapy trial from the following list?

? This field is required. Please complete.
Opened To Site from System (17 Oct 2017)

↻ Yes, A081105

? Please provide and save your response in the data field, not in the query response box. Thanks!
Opened To Site from DM (17 Oct 2017)

↻ updated

A081105 ✓

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Query Responses

- Sometimes responses are provided where they are not required.

Were you able to obtain any information about the patient since the last report? Yes

(If no), date of last attempt to contact patient
? If "Were you able to obtain any information about the patient since the last report?" is Yes, then "Date of last attempt to contact patient" should be blank. Please reconcile.
Opened To Site from System (17 Oct 2017)

Entry Error | 01 | Jan | 2015

Free-text fields should have data deleted and remain empty.

Drop Down menus should have the top 'empty' selection with the '…' selected.

(If no), date of last attempt to contact patient
? If "Were you able to obtain any information about the patient since the last report?" is Yes, then "Date of last attempt to contact patient" should be blank. Please reconcile.
Opened To Site from System (17 Oct 2017)

Entry Error | | … |

Were you able to obtain any information about the patient since the last report? Yes

(If no), date of last attempt to contact patient

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Query Responses

Current smoking status

INSTRUCTIONS: If the patient was smoking at baseline and has never reported quitting smoking previously, complete the following question
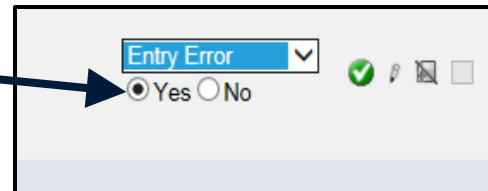
Has the patient **completely** quit smoking cigarettes since the last reported smoking status?

? If "Were you able to obtain any information about the patient since the last report? " is Yes, and "Has the patient smoked 100 cigarettes (five packs) in their lifetime?" is No or "Has the patient reported quitting smoking on a previous visit?" = Yes, then "Has the patient completely quit smoking cigarettes since the last reported smoking status?" should be blank. Please reconcile.
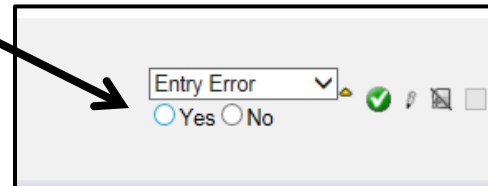
Opened To Site from System (17 Oct 2017) ☐ Cancel

Yes

To save this data field blank, click on the little black dot corresponding to a 'Yes' response to remove it.

Entry Error
⦿ Yes ◯ No

Entry Error
◯ Yes ◯ No

When saved correctly, the data field will only indicate the icon indicating data was changed, with no data present **i**n the Data Field

Current smoking status

INSTRUCTIONS: If the patient was smoking at baseline and has never reported quitting smoking previously, complete the following question

Has the patient **completely** quit smoking cigarettes since the last reported smoking status?

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Query Responses

- Please do not respond to queries with 'pending' or 'will look into', etc. as this will result in a re-query from the DM.
  - The DM cannot close out the query without resolution/clarification and are limited in the ability to track these issues outside of re-issuing a query.
    - If the query were to be closed out 'pending response', it no longer appears anywhere in the Task Manager and is no longer on the 'radar' for the DM or CRA to complete.

#	Date of assessment	Report type	Specify report type	Attachment (max file size 10 MB)	
1	01 Jan 2015	Imaging Report			✅

Attachment
❓ If "Date of assessment" or "Report type" is present, then "Attachment" is required. Please reconcile.
Opened To Site from System (17 Oct 2017)
↻ Will upload when report becomes available

Query Responses vs. Comments

- Please note that query responses in the query response boxes are not always available to the statistical team when doing their analysis.

  - If there is pertinent information that needs to be shared with and/or considered by the study team, please use the '**Comments'** section instead of in the query response box.

OTHER TOBACCO USE				
Other tobacco or nicotine products	Has the patient used other tobacco products 100 times or more in their lifetime?	Times per day	Number of years	
1	Cigar	Yes		20	✅

Times per day
If "Has the patient used other tobacco products 100 times or more in their lifetime?" is Yes, then "Times per day" is required. Please complete.
Opened To Site from System (17 Oct 2017)
↺ See Comments

2	Pipe	No			✅
3	Smokeless tobacco	No			✅
4	E-cigarettes	No			✅
5	Other (cigarillos, waterpipes, bidis, etc.)	No			✅

Comments — Patient reports smoking cigars only on special occasions over the last 20 years. Maybe 1 or 2 per year. △ ✅

Query Responses vs. Comments

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 perpindiular measurements are given △ ✓

The 'Comments' section can be used in replacement of a response, as in the previous slide, or in addition to a response, as illustrated on this slide.

Reporting Periods

- When calculating reporting periods, please note that if the patient took drug in that cycle on both the reporting period start date and end date, both dates must be accounted for in Dose (total dose).

    - For example the reporting period of June 1, 2017 to June 21, 2017 appears as 20 days on my date wheel, but if the patient took study drug for this cycles on : June 1, 2, 3, 4, 5, 6, 7 ,8 ,9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, and 21: This equals 21 days.

#	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	Entry Error 3000	mg	No	No	No	01 Jun 2017	21 Jun 2017	?

Dose
? This is a 21 day reporting period, yet only 20 days of study drug are reported, please clarify or amend. Thanks!
Opened To Site from DM (12 Oct 2017)

DATE FINDER

© Datalizer Slide Charts

START DATE

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY
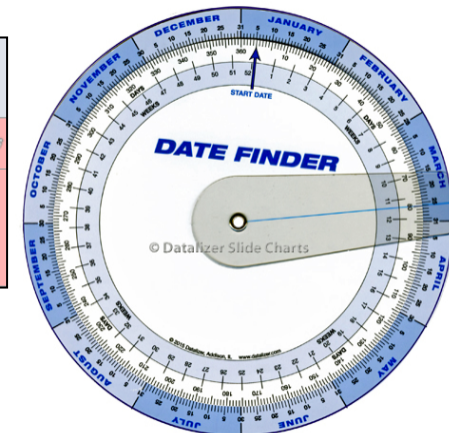
Reporting Periods

- For study drug taken orally, the dose should match the reporting period and there should be no overlap or gaps in reporting period dates.
  - Unless there were modifications/omissions/delays, the reported dose received should correspond with the reporting period for oral medications.
  - As patients typically do not take study drug for multiple cycles on the same date, treatment cycles should not overlap
    - (i.e., if June 21st is the reporting period end date of cycle 1, then cycle 2 should have a start date of June 22nd, not June 21st, as the patient did not take study drug for both cycles on this date).
  - Days still must be accounted for in which doses were not received. Unless specific to your protocol, there should be no gaps in reporting period dates between cycles/eCRFs.

Dose Modifications, Omissions, and Delays

- When any of these are reported on a Treatment form in Rave, typically another eCRF will roll out in that folder, requiring further specification once the Treatment form is saved.
  - Modification: Dose (level) reductions or escalations
  - Omissions: Doses not received
  - Discontinuations: Treatment is completely stopped
  - Delays (Hold): Treatment was held and then received at a later date during this cycle
    - Consider carefully when indicating medications as delays, as doses are often not 'made-up' later in the cycle when held. In these instances, the documentation should indicate omission(s).

Supporting Documents

Please be sure ALL uploaded documents are de-identified.

When 'Report Type' is prefilled with a response, these are required supporting documents and should be uploaded on their designated, prefilled log lines whenever possible. If additional documentation is being uploaded, please provide the 'type' in the log lines provided below these prefilled, required, supporting documents.

Subject: **Test01**
Page: **Supporting Documentation: Baseline - Baseline**

Cycle

#	Date of assessment	Report type	Specify report type	Attachment (max file size 10 MB)
1	[ ] [... ▼] [ ]	Operative report ▼	[ ]	[ ] Browse...
2	[ ] [... ▼] [ ]	Pathology report ▼	[ ]	[ ] Browse...
3	[ ] [... ▼] [ ]	... ▼	[ ]	[ ] Browse...
4	[ ] [... ▼] [ ]	... ▼	[ ]	[ ] Browse...
5	[ ] [... ▼] [ ]	... ▼	[ ]	[ ] Browse...
6	[ ] [... ▼] [ ]	... ▼	[ ]	[ ] Browse...
7	[ ] [... ▼] [ ]	... ▼	[ ]	[ ] Browse...
8	[ ] [... ▼] [ ]	... ▼	[ ]	[ ] Browse...
9	[ ] [... ▼] [ ]	... ▼	[ ]	[ ] Browse...
10	[ ] [... ▼] [ ]	... ▼	[ ]	[ ] Browse...

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Measurement Forms

- **Check for protocol-specific instructions for filling out the measurement form and read the help text/instructions on the measurement form.**
- In General:
    - **ALL** areas of malignant disease present at the time of registration should be documented on the measurement form as either target lesions (measurable disease) or non-target lesions (non-measurable, evaluable).
    - If the lesion fits the description in the protocol for target/measurable lesion, it must be recorded and followed as a target/measurable lesion (unless the maximum number of target lesions,or the maximum number of target lesions per organ has already been selected/recorded).
    - Check the treatment evaluation (measurement of effect) section of the protocol for definitions of target/measurable disease and non-target/non-measurable disease, acceptable measurement methods, acceptable assessment types, response criteria, and overall response criteria.

Measurement Forms

- Attempts should be made to use the same type of assessment throughout the study, follow all malignant disease, and get measurements for all target/measurable lesions.

- Once the overall objective status meets the protocol criteria of partial response (PR), it cannot be reported on a later evaluation/cycle as stable (SD).
  - It should be coded PR until it becomes complete response (CR) or progression (PD).

- Once the overall objective status meets the protocol criteria of CR, it should be coded CR until PD can be coded.
  - Exception: Not Evaluated (NE) is to be coded if not all target lesions are evaluated. This should be rare.

Measurement Forms

Look for additional, study-specific guidance relating to the overall objective status in the protocol.

Here is an example for A091401.

Alliance A091401

The overall objective status for an evaluation is determined by combining the patient's status on target lesions, target lymph nodes, non-target lesions, non-target lymph nodes, and new disease as defined in the following table:

Target Lesions & Target Lymph Nodes	Non-Target Lesions & Non-Target Lymph Nodes	New Sites of Disease	Overall Objective Status
CR	CR	No	CR
CR	Non-CR/Non-PD	No	PR
PR	CR Non-CR/Non-PD	No	PR
CR/PR	Not All Evaluated*	No	PR**
SD	CR Non-CR/Non-PD Not All Evaluated*	No	SD
Not all Evaluated	CR Non-CR/Non-PD Not All Evaluated*	No	Not Evaluated (NE)
PD	Unequivocal PD CR Non-CR/Non-PD Not All Evaluated*	Yes or No	PD
CR/PR/SD/PD/Not all Evaluated	Unequivocal PD	Yes or No	PD
CR/PR/SD/PD/Not all Evaluated	CR Non-CR/Non-PD Not All Evaluated*	Yes	PD

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Adverse Events Reporting

- The Adverse Events: Other form includes the study-specific requirements and should be reviewed prior to completion of the Adverse Events: Other form.

INSTRUCTIONS: Record grade 1 & 2 adverse events with attribution of possible, probable or definite and all grade 3, 4 and 5 adverse events regardless of attribution. (Both hematologic and non-hematologic adverse events must be graded on this form as applicable.)

- – Adverse events are being reported that are not required per protocol (i.e., Grade 1 adverse events and Grade 2 adverse events with an attribution of unrelated or unlikely).
- – AE forms in Rave should have study-specific instructions relating to trial specifications at the top of the page.

Adverse Event Reporting

- **<u>DO NOT</u>** inactivate log lines for solicited AEs.

- There is no way to reactivate these. Solicited AEs will then need to be re-entered by the person completing data entry as a new log line.

SAE Reporting Reminders

- The CTEP-AERS provides a tutorial on how to use and navigate the website:

  - https://betapps-ctep.nci.nih.gov/ctepaers/public/login

- Events reported on AdEERS <u>must</u> also be reported in Rave.

  - Reported on the Adverse Events: Solicited and Adverse Events: Other forms
  - AE Grades and attributions must match on both
  - AE data should be updated in Rave, not CTEP-AERS

- Adverse Event eCRF should be completed in Rave at the time the AE is experienced.

  - AE data should not be entered in CTEP-AERS before entering in Rave

SAE Reporting Reminders

- Under the 'Patient Information' section for 'Primary Site of Disease', please list the actual primary site of disease (even if removed) and NOT the metastatic site(s).

- ALL DRUGS listed in the Treatment Assignment Code in the Course Information section must be listed.
  - Even if the patient is no longer receiving one of the specified drugs, you must list it with a 0 for Total Dose Administered this cycle, and the date the patient actually received the last dose.
    - The only time you would not list a drug, is if the patient has never started it. In this case, please make a comment to that effect.

- You will never have more than 1 AdEERS report per cycle
  - Keep amending the original report submitted for that cycle, even if the event(s) being reported now have nothing to do with the original event.

SAE Reporting

- For problems relating to <u>entering</u> an electronic report, please contact the NCI helpdesk.

    NCI Helpdesk:
    - ➢ (301)840-8202
    - ➢ ncictephelp@ctep.nci.nih.gov

- If you have questions regarding whether an event should be reported, how to report an event, etc., please contact the NCI MD Helpdesk.

    NCI <u>MD</u> Help Desk:
    - ➢ (301)897-7497 or
    - ➢ aemd@tech-res.com

Pagination

When entering data on a log line table, only a maximum number of log lines may be displayed. Pagination allows users to page through the entire list of log lines on the eCRF.

INSTRUCTIONS: Depending on your settings in Rave, this table may be paginated. If the options are available, click on Paginate and select Show All Lines or click on the numeric page numbers at the bottom right corner of the table. If these options are not available, you are already viewing the entire table.

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

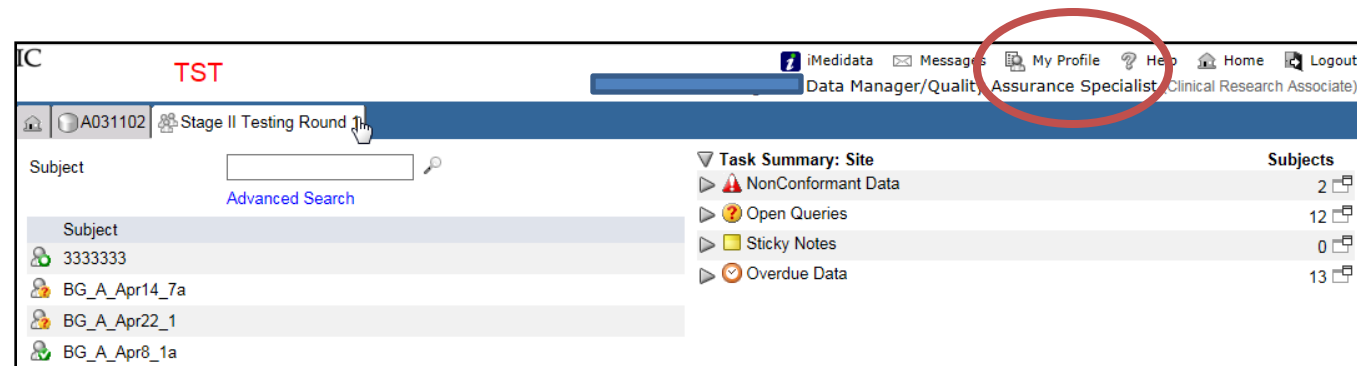CRF Version 3775 - Page Generated: 22 Apr 2015 11:58:01 Central Daylight Time

Save   Cancel

ALLIANCE
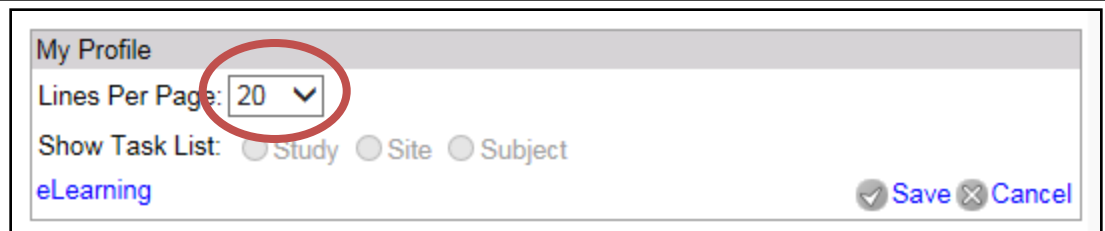FOR CLINICAL TRIALS IN ONCOLOGY
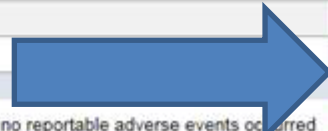
Setting Pagination Preferences

1. Navigate to **My Profile page > My Profile** section
2. Click **Edit**
3. Select a number from the dropdown (i.e,. if you select 20, the system will display 20 lines per page on lists and log forms in EDC).
4. Click **Save**

Users can select from several preset options ranging from 5 to 200 lines.

Institutional Contacts

- Found in the Baseline folder
  - To be completed at the time of patient registration
- **Update, Update, Update**
  - Use this form to identify whom the DM 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.
  - Also used to compile contact lists for upcoming trial-specific trainings or communications.
- Whenever possible, this eCRF should include <u>two different</u> contacts.
  - If you have additional contacts you want included, you can add them in the comments section.

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Add Event Drop-Down Menu

- Add-event is designed for sites to include eCRFs to the patient data that do not automatically roll-out with calendaring or responses provided on other study eCRFs.
    - Contains Withdraw of Consent, Lost to Follow-up, New Primary Tumor, and other study-specific eCRFs.
    - Found at the Subject level for each patient on trial.

CALGB to Rave Transitions

- All CALGB systems will be 'shut-down' by January 2018, with all CALGB trials either being terminated or transferred to the Rave system.
  - Transfers to Rave have already begun and will continue, in waves, over the next couple months.
  - Notifications regarding trial termination or transfer to Rave are sent via CTSU memos and bi-monthly updates.
    - Be sure you have the necessary access to receive the invitations for these trials in Rave.
  - **If you have a patient on a CALGB trial, contact data management to discuss the status of the trial and also the status of your patients on the trial.**

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

CALGB to Rave transitions

- If you try to submit new data via Teleform for trials that have been moved to Rave, you will receive an error message when trying to submit.

Form Submission Rejected

⚠ Follow-up for this study has been transitioned to Medidata Rave, therefore follow-up data will no longer be accepted via Teleform. Please submit using Rave.

Form:	C-1914 v1 (CALGB: 80802 Follow-Up and Response Form (v1))
CALGB Study:	80802

- Any hand-amended data received in the DM office after a trial's transition to Rave will be returned to the site, as the data will now need to be amended in Rave by the site staff.

CALGB to Rave Transitions

- It is VERY IMPORTANT that the **Institutional Contacts** page in Rave for all CALGB trials be completed right away upon receiving invitations.

  – Several communications regarding these converted trials may need to happen via email, as they will not function as a 'typical' Rave trial.

  – CALGB conversion trials allow for only one Institutional Contact.

    - It is important that with only one listed contact that this information be updated with change in staff.

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.

CRA

Name *(first last)*	
Email	
Phone *(example: 999-999-9999)*	
Comments	(200 characters)

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

CALGB to Rave Transitions

- Transfer to Rave essentially mirrors the old CALGB system in a new database in regards to new data submission
- Data will not appear overdue in Rave for CALGB trials, due to lack of calendaring
  - Site will know data is overdue via the Overdue Materials Report, which is derived from the patient's recent data submission.
  - Please develop an internal plan for ensuring timely data entry for these trials in Rave.
  - Work with your DM regarding questions on how to submit data for these trials in Rave.
    - This is new to us too!

CALGB to Rave Transitions: Submitting data

- All forms on CALGB trials in Rave will be 'Add Event' only.
  - No Visit Calendar with target dates
    - Sites will add forms per the protocol Data Submission Schedule (DSS) via the Add Event drop down menu.
    - Supporting documents will be uploaded in the 'Source Documents' folder
  - Queries left unresolved in the CALGB system will be manually re-issued in Rave by the DM.
  - The type/amount of previously submitted data that will transition from CALGB to Rave depends on the status of the trial and what data will be expected for entry moving forward.

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

CALGB to Rave Transitions

- Queries
  - Rave Icons will remain the same
  - Very few system-generated queries are being programmed on CALGB trials moving to Rave.
    - DM will rely more heavily on review of data and on accurate data reporting than 'typical' Rave trials.
      - The 'eyeball' icon indicating 'requires review' will be utilized more for CALGB conversion trials.

▽ ◉ Requiring Review	1
Lewis Cancer and Research Pavilion at Saint Joseph's/Candler 1	
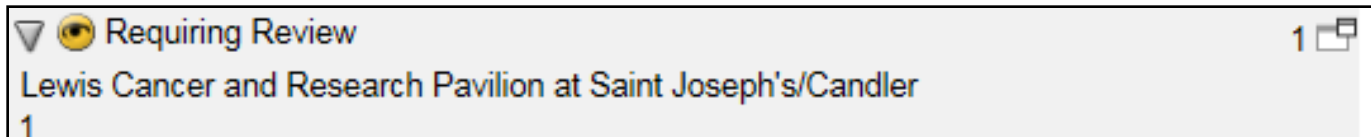
CALGB to Rave Transitions

- Supporting documents
  - New source documents will be uploaded on one eCRF in the 'Source Documents' folder.
    - Please try to provide as much clarification as possible in the data table to help easily identify the type of report that is being provided, the cycle/reporting period, etc., as these will not be 'sorted' in Rave by report type or date.
      - This can be done most easily via the 'Specify report type' data field.

INSTRUCTIONS: Use this form to submit source documents as required per protocol.

#	Date of assessment	Report type	Specify report type	Attachment (max file size 10 MB)
1	___ ... ⌄ ___	... ⌄		Browse...

Add a new Log line Inactivate

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

CALGB to Rave Transitions

- Forms that are submitted multiple times throughout the trial (i.e., AE forms, Treatment Forms, Follow-up forms, etc.) can be identified in the eCRF folder/form listing on the left side of your screen by their indicated reporting period start date, once the form has been saved with this date entered.
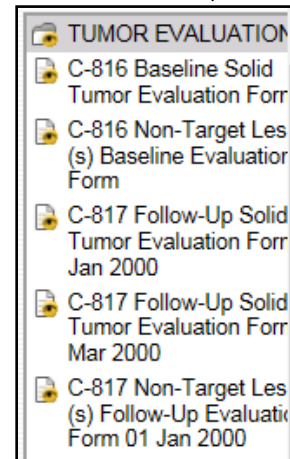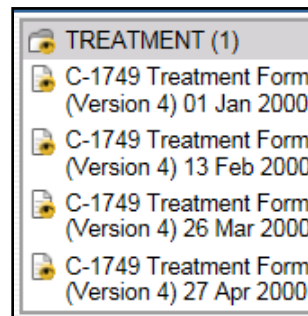
  - Forms without a reporting period start date entered will not have a date present in this list.
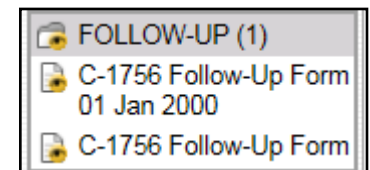
Overdue Materials Report

- Alliance members with any of the following roles can access the Overdue Materials Report:
  - Lead CRP
  - Secondary Lead CRP
  - CRP
  - DM

  Note: If a site does not select 'Alliance' for its crediting group when registering a patient, it will not find the patient's overdue list here.

Overdue Materials Report

Overdue Materials Report

Data Quality Portal (DQP)

- Found on the CTSU website under the Rave/DQP tab

- Types of DQP reports:
    - Aging Report Summary Table
        - Summary of delinquent forms and queries for each Rave protocol a site is participating in.
    - Rave Delinquencies Report
        - A complete listing of all delinquent forms or queries
    - Form Timeliness Report
        - A quarterly report that provides timeliness metrics for forms expected, received on time, received late, and not received
    - Query Timeliness Report
        - A quarterly report that provides timeliness metrics for queries issued, answered on time, answered late, and not answered

Data Quality Portal (DQP)

- Those users with Rave access can link to Rave through the DQP to access the forms relating to issues identified on the DQP, without logging in to Rave separately.
  - A Medidata Rave Icon indicates when/where deep linking to Rave is available.
- DQP is currently being piloted for a limited number of studies. More information will be available as more studies are added.

Where this icon is present, the DQP allows for "deep linking" to Rave.

Protocol Availability

- Availability on CTSU and Alliance websites depends on information listed under participating organizations. If multiple organizations are participating, they are found on both. If Alliance members only, it will only be on the Alliance website.

Participating NCTN groups:
Alliance
ECOG-ACRIN
NRG
SWOG

ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY

ALLIANCE A151216

Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST)
A screening trial for A081105, E4512 and EA5142
ClinicalTrials.gov Identifier: NCT02194738

Study Chair
Geoffrey Oxnard, MD
Lowe Center for Thoracic Oncology
Dana Farber Cancer Institute
450 Brookline Ave,
Boston, MA 02115
Tel: 617-632-6049
geoffrey_oxnard@dfci.harvard.edu

Surgical Co-chair
Dennis Wigle, MD
Mayo Clinic
Tel: 507-284-8462
wigle.dennis@mayo.edu

SWOG Co-Chair
David Gandara, M.D.
Tel: 916-734-5959
david.gandara@ucdmc.ucdavis.edu

ECOG Co-chair
Suresh Ramalingam
Tel: 404-778-7777
suresh.ramalingam@emory.edu

Disease Committee Chair
Everett Vokes, MD
Tel: 773-702-9306
evokes@medicine.bsd.uchicago.edu

Primary Statistician
Sumithra Mandrekar, PhD
Tel: 507-266-6724
mandrekar.sumithra@mayo.edu

Secondary Statistician
Shauna Hillman, MS
Tel: 507-284-1533
hillman.shauna@mayo.edu

Protocol Coordinator
Colleen Watt
Tel: 773-702-4670 Fax: 312-345-0117
cboyle@uchicago.edu

Participating NCTN groups:
Alliance
ECOG-ACRIN
NRG
SWOG

Protocol: CRFs and Data Submission Schedule (DSS)

- The DSS is no longer included as part of the protocol document.
  - The paper CRFs and DSS can be found on the CTSU and Alliance landing pages for each trial under 'Case Report Forms'.

Protocol: CRFs and DSS

BioMS

- How do I order kits?
Effective March 2016, all study kits should be ordered through BioMS.
  - (http://tinyurl.com/alliance-bioms);
    - select 'Kits requests' under 'Tasks' menu on left.

BioMS Help Desk:
  - E-mail: bioms@alliancenctn.org
  - Phone (855)-55-BIOMS; (855)-552-4667

IRB

- When can our site terminate a study with our IRB?

    - A site can terminate a study with its IRB once a termination letter is posted.

    - The data management team should not be granting permission for sites to close to their IRB. They can only confirm if data is up-to-date and if there are outstanding queries.

- Where can I find termination letters?

    – You can find termination letters within each individual study on the CTSU or Alliance websites.

        - Alliance members can use the [Study Terminations of Patient Follow-up](#) link on the Alliance website.

Questions/Feedback