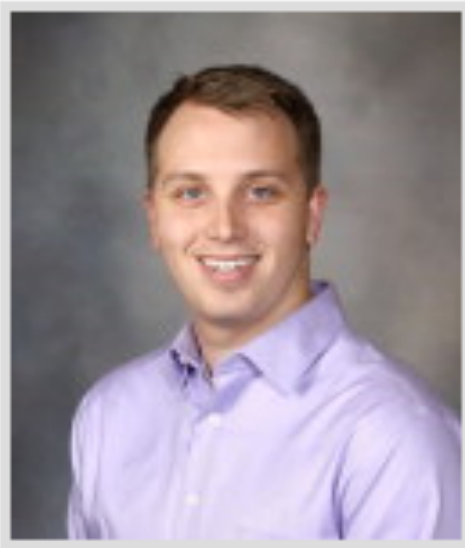# Data Management Updates

Jenny Darcy

Data Management

Alliance CRP Meeting, Thursday, November 1st, 2018

Presentation Objectives

- New staff

- Update on Ingres (JCCS) conversion project

- Final IRB closure at study termination

- Changes to the Overdue Material Report--PDF file now available

- Data freeze

- Rave tips

Data Management – New Supervisors

Aaron M. Johnson
SPV-QA SPEC II-RESEARCH

Jessica S. Krier
SPV-QA SPEC II-RESEARCH

Jarek K. Moen
SPV-QA SPEC II-RESEARCH

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Data Management – New Data Managers - Level III

Sara J. Goodman
QA SPEC III-RESEARCH

Tiffany M. Schafer
QA SPEC III-RESEARCH

Lori M. Vine
QA SPEC III-RESEARCH

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Data Management – New Data Managers – Level II

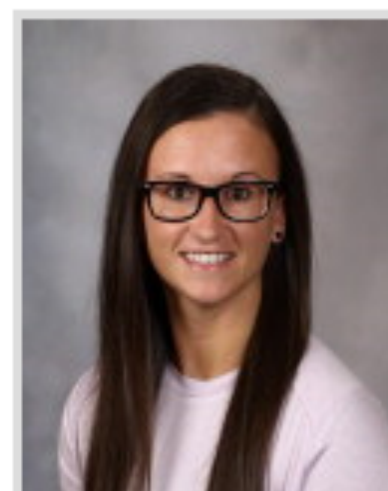Ashton L. Andersen
QA SPEC II-RESEARCH

Brandon M. Bright
QA SPEC II-RESEARCH

Zachary A. Hei
QA SPEC II-RESEARCH

Kristin L. Poe
QA SPEC II-RESEARCH

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Ingres to Rave Conversion - Retirement Target completion: December 2019

- **35** – Total Project Study Scope for the Alliance
  - **32** - Alliance Studies are targeted for Completion
    - **6** - Studies have been Terminated (Record Retention) since the start of the project in January 2018
    - **26** - Studies that will move to completed status by the end of June 2019
  - **3** - Alliance Studies remain that are targeted for Conversion to Rave
    - Alliance Studies targeted for conversion in early 2019:
      - N0577 – Full Build Conversion
      - Z1071 – Partial Build Conversion (Follow-up Only)
      - N107C – Partial Build Conversion (Follow-up Only) *

* Conversion decision pending outcome of Follow-up activity in early 2019

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IRB Closure Question

- When is the appropriate time to close a study to your IRB?
  - When the termination memo is posted on the Alliance website.

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Updated Overdue Material Update

- Updates requested by the CRP Committee at the May 2018 Alliance Meeting
- Key Updates
  - Available in both pdf and excel on the Alliance website
  - Data collapsed into 1 report regardless of number of days overdue and includes expected forms/queries in the next 30 days
  - Additional data provided including both the target and overdue form date with definitions provided on the spreadsheet
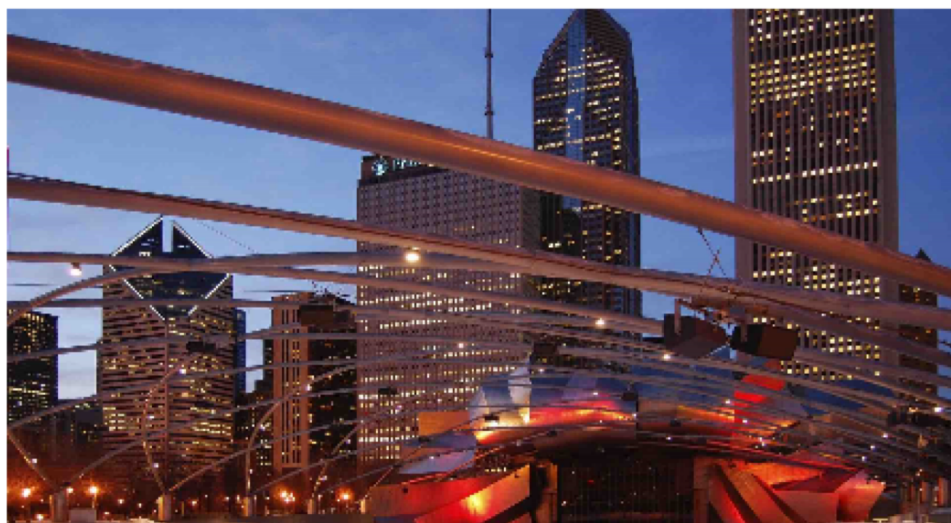- Summary report for Member PIs in development

Welcome Jennifer

ANNOUNCEMENTS

ONE WEEK AWAY AND COUNTING...
2017 Alliance Fall Group Meeting

If you haven't registered for the upcoming **2017 Alliance Fall Group Meeting** yet, now is a great time to do so. Visit the Alliance Meeting Webpage or Cvent for more details. If you have specific questions, please contact Samantha Berg, Alliance Meetings and Operations Coordinator, by e-mail sberg3@bwh.harvard.edu or phone (617) 525-3022. Also meeting agendas are now available. Presentations and other meeting materials will follow this week.

▸ **Accrual Reporting**

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- Wiki

it   View   Favorites   Tools   Help

ALGB Study and System...   📖 Lawson portal   📖 Mayo Clinic Intranet (2)   📖 Mayo Clinic Intranet   ⑤ Termination Tracker - All ...   🔵 Web Slice Gallery ▼

Jennifer Darcy(log out)

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Alliance
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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)

- PDF Report(s)
- Excel Report(s)

Delinquency Reports Legacy CALGB trials converted to Rave

- Delinquency

disclaimer   site map   contact us   careers

Updated Overdue Material Reports

- Example of the CRP excel spreadsheet

Forms and Queries Expected

Created on: October 19, 2018

Protocol	Data Manager	Data Manager Phone Number	Patient	Initials	Date On	Date of Last Contact	Material	Item	Target Date *click here for definition*	Overdue Date *click here for definition*	Days Overdue	Overdue or Expected
	Amy R. Oeltjen	(507) 538-0570	9107710	LJK	05/05/2016	11/09/2017	Rave Form	Patient Status: Clinical Follow-Up: Clinical Follow up 07	03/11/2018	04/10/2018	192	Overdue
	Tiffany Bainter	(507) 266-3551	9102244	JEM	02/24/2015	03/08/2018	Rave Form	Patient Status: Clinical Follow-Up/Observation: Clinical Follow-up 14	09/04/2018	10/04/2018	15	Overdue
	Tiffany Bainter	(507) 266-3551	9102768	CJM	04/14/2015	04/16/2018	Rave Query	On-Study: Baseline	10/01/2018	10/15/2018	4	Overdue

Data Management

- **Data Freeze Pilot (A021502 and A021501)**
- Effective August 15, 2018
- Achieve the highest data management standards
  - Provides awareness of changes to data after key reviews are completed by DM
- Key data fields to be locked after review completed
  - Eligibility
  - Case Evaluation
  - Follow-up complete
- If corrections are required post-lock
  - Sites will need to contact the Data Manager to unlock
  - Site and DM feedback to be obtained at the end of pilot

10/25/18

Rave Reminders

- Fill Patient Status forms out at the end of the cycle

- Patient Status form is what drives Rave navigation and target dates for subsequent cycles

- If you need help with folder/form roll out, contact your Data Manager

- Please update your institution contact, it allows us to query the proper contact

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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.

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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.

Primary tumor site ?
? This field is required. Please complete.
Opened To Site from System (12 Oct 2017) ☐ Cancel

Entry Error ▼
... ▼

Maximum diameter (of tumor from pathology report)
? Stage is IB (T2a, N0, M0), but the primary tumor is less than 4 cm. Please reconcile.
Opened To Site from System (12 Oct 2017) ☐ Cancel

Entry Error ▼ 3   cm⌃ ?

Primary tumor diagnosis date
? Future date has been entered. Please correct.
Opened To Site from System (12 Oct 2017) ☐ Cancel
? "Primary tumor diagnosis date" is after registration date. Please reconcile.
Opened To Site from System (12 Oct 2017) ☐ Cancel

Entry Error ▼ 01 Jan ▼ 2018
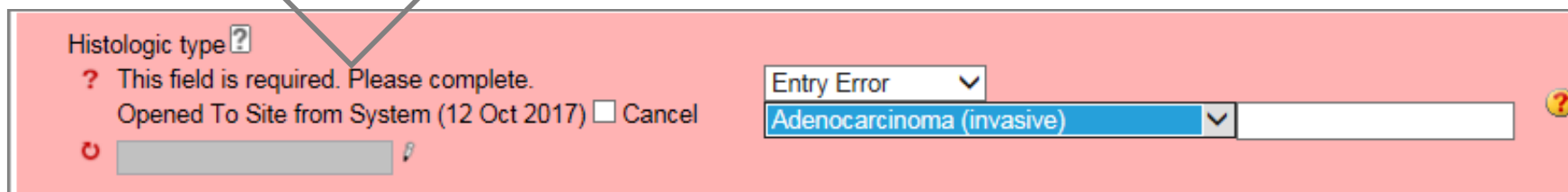
System-Generated Queries

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.
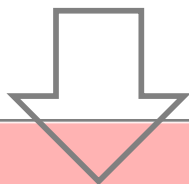
DM-Generated Queries

- 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.

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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.

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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 ⌃ ✓

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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 ∨] [   ] [... ∨] [   ]

β

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

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

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Query Responses

Current smoking status

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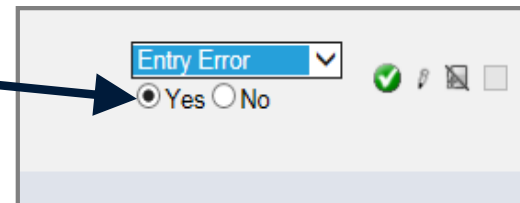
Has the patient **completely** quit smoking cigarettes since the last reported smoking status?

? 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.
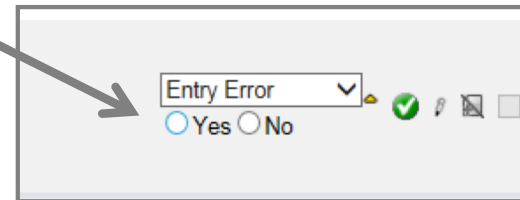
Opened To Site from System (17 Oct 2017) ☐ Cancel

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?

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.	✓

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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.

Thank you!