Medidata Rave Update

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Alliance Fall Meeting Nov, 2014

Presentation Objectives

- To provide an update on the SAE Medidata Rave integration
- To highlight reports available within Medidata Rave to assist in data management
- To provide the strategy for transitioning legacy CALGB trials in long term follow-up to Medidata Rave

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Update on the Status of the SAE Integration

- The SAE integration will be piloted in trial A071102 targeted to open in December 2014
- For trial A071102, all expedited AE reporting will occur within Medidata Rave
- If you need to report an expedited AE for example on cycle 3, and have not completed your cycle 2 data entry yet, save the Patient Status Form for cycle 2 with key data entered to get the cycle 3 folder to roll out

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Example of Pt Status Form for Trial A071102

Subject: **JMR03**
Page: **Patient Status: Treatment (Intervention) - Treatment 01**

Cycle	1
SURVIVAL STATUS	
Participant vital status	Alive
Date of most recent contact	1 Feb 2000
Death date	
Date of last contact or death	01 Feb 2000
Cause of death	
If other cause of death, specify	
DISEASE STATUS	
Was disease status evaluated during this reporting period?	No
(If yes), date of most recent disease status evaluation	
(If yes), has the patient developed a first unequivocal progression that has not been previously reported?	
Date of progression *(or relapse)*	
PROTOCOL TREATMENT	
Will the patient continue protocol treatment (intervention) in the subsequent cycle?	Yes
PRO/QOL ASSESSMENT(S)	
Did the participant complete the PRO/QOL assessment(s)?	Yes
(If yes), date completed	
CONCOMITANT MEDICATIONS	

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SAE Integration

- Notice that many fields on the SAE reporting forms are derived from previously entered data.
- All derived fields will be denoted with a (derived) next to the item
- If any derived items look incorrect go to the form that the field was originally entered and correct the data at the source.

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New Adverse Event Form Used for Both Routine and to Launch Expedited AE Reporting

Form Instructions

*** red asterisk before a field denotes a required response**

Course/Cycle # (derived)

Reporting period end date (optional, user entered if known)

Start date of this course/cycle (derived)

Start date of first course/cycle (derived)

Verbatim term	Solicited (derived)	*Adverse event term (CTCAE v4.0)	MedDRA adverse event code (CTCAE v4.0) (derived)	*Adverse event evaluated this cycle?	Adverse event grade description (first 120 characters)	Adverse event (grade) grade description (full description)		Attribution to study intervention (if grade>0)		Did the adverse event result in any of the following? (Check all that apply)	None	Hospitalization	Life-threatening	Death	Disability	Congenital anomaly/birth defect	Required Intervention	Other	Adverse event ID (derived)	SAE report required by caAERs (derived)	Report ID (derived)	Date first learned (derived)	Time zone (derived)		Submitted By (derived)
Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data	Data

Add a new Log line

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Questions?

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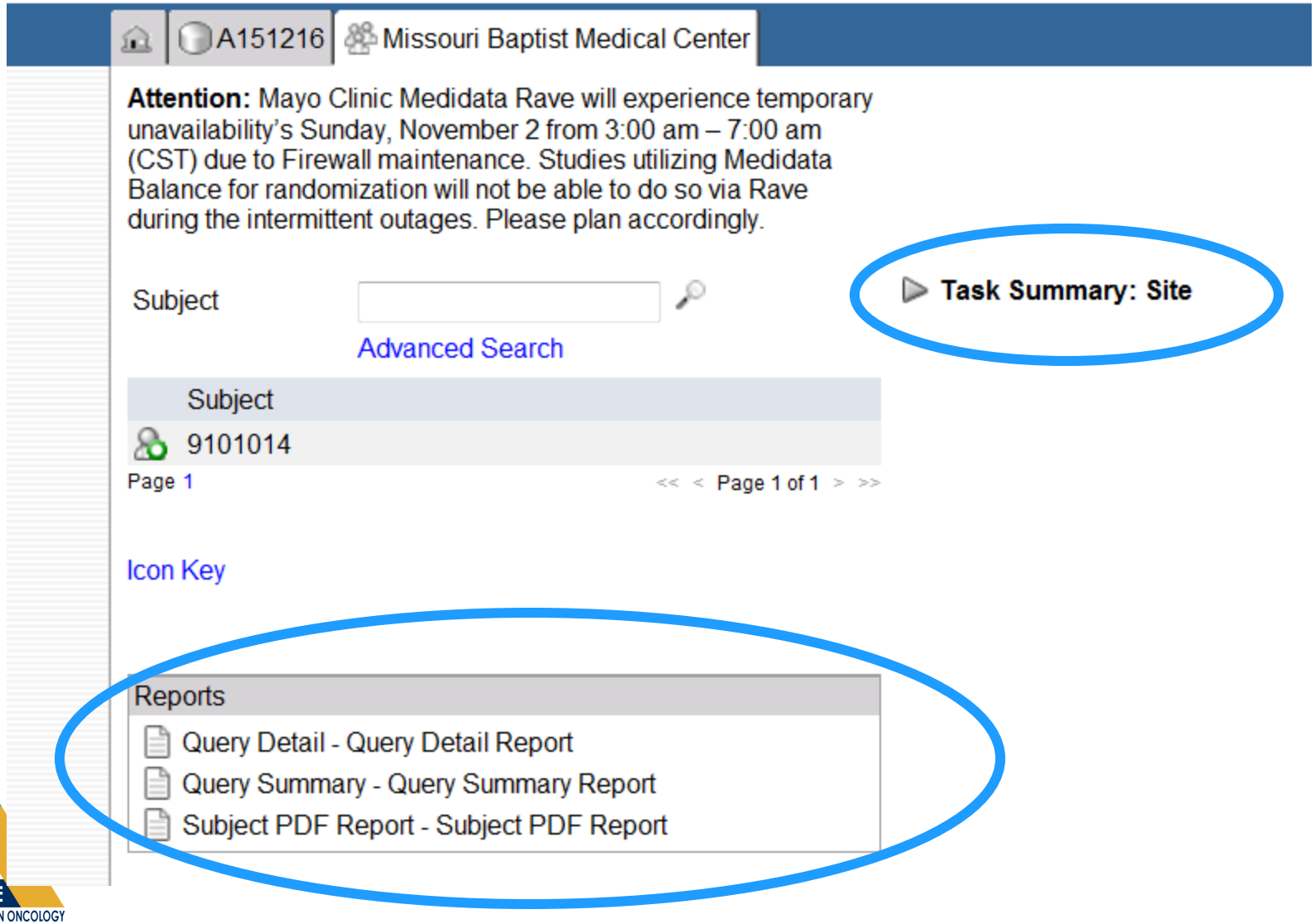
Available Reports in Rave to Assist with Data Management



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Query Summary Report

Query Summary Report for A151216 - TST

29 Oct 2014

	# Open Qrs	# Answered Qrs	# Closed Qrs	# Cancelled Qrs	# Total Qrs
Stage II Testing Round 13 - World	24	0	8	0	32
Site from System	24	0	8	0	32
A151216 - TST	24	0	8	0	32

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Query Detail Report

Query Details Report for A091302 - TST

23 Oct 2014

Stage II Testing Round 1 - World

Subject	Folder	Form	Field	Log #	Query Status	Qry Open Date	Qry Open By	Query Text	Marking Gr. Name	Qry Respon Date	Response Text	Qry Respnded	Qry ResolvedDate	Qry ResolvedBy
BAG2	Baseline	RECIST Measurements: Baseline	ASSESSDT PID2857241_V1_0	0	Open	12 Aug 2014	System	This field is required. Please complete.	Site from System					
BAG2	Baseline	Laboratory Tests and Results: Baseline	LABDONEXX PID2838523_V1_0	1	Open	12 Aug 2014	System	This field is required. Please complete.	Site from System					
BAG2	Baseline	Laboratory Tests and Results: Baseline	LABDONEXX PID2838523_V1_0	2	Open	12 Aug 2014	System	This field is required. Please complete.	Site from System					
BAG2	Baseline	RECIST Measurements: Baseline	NTLESPRSNT PID2516415_V1_0	0	Open	12 Aug 2014	System	This field is required. Please complete.	Site from System					
BAG2	Baseline	RECIST Measurements: Baseline	TLESPRSNT PID3536672_V1_0	0	Open	12 Aug 2014	System	This field is required. Please complete.	Site from System					
BAG2	Treatment 02: Sorafenib +	RECIST Measurements	TLESXX PID4364_V3_0	1	Open	12 Aug 2014	System	At least one "Target lesion site (s)" is required. Please complete.	Site from System					
BAG2	Treatment 01: Sorafenib +	Treatment (Intervention)	TDOSEXX PID2182728_V2_0	1	Closed	12 Aug 2014	System	Data entered is non-conformant (invalid format). Please correct.	Site from System		QueryCloseBySystem		12 Aug 2014	System
BAG2	Treatment 03: Post treatment	Adverse Events: Other	TOXXX PID3125302_V1_1	1	Closed	12 Aug 2014	System	This adverse event has already been reported. Please report each event	Site from System		QueryCloseBySystem		12 Aug 2014	System

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Subject PDF Report

- Must be in Firefox to run the Subject PDF report
- If you do not want all patients or all forms for a patient, go to the site level where you can select the subject and data page (form). If selecting all, the file will be quite large
- The file will contain the complete audit trial

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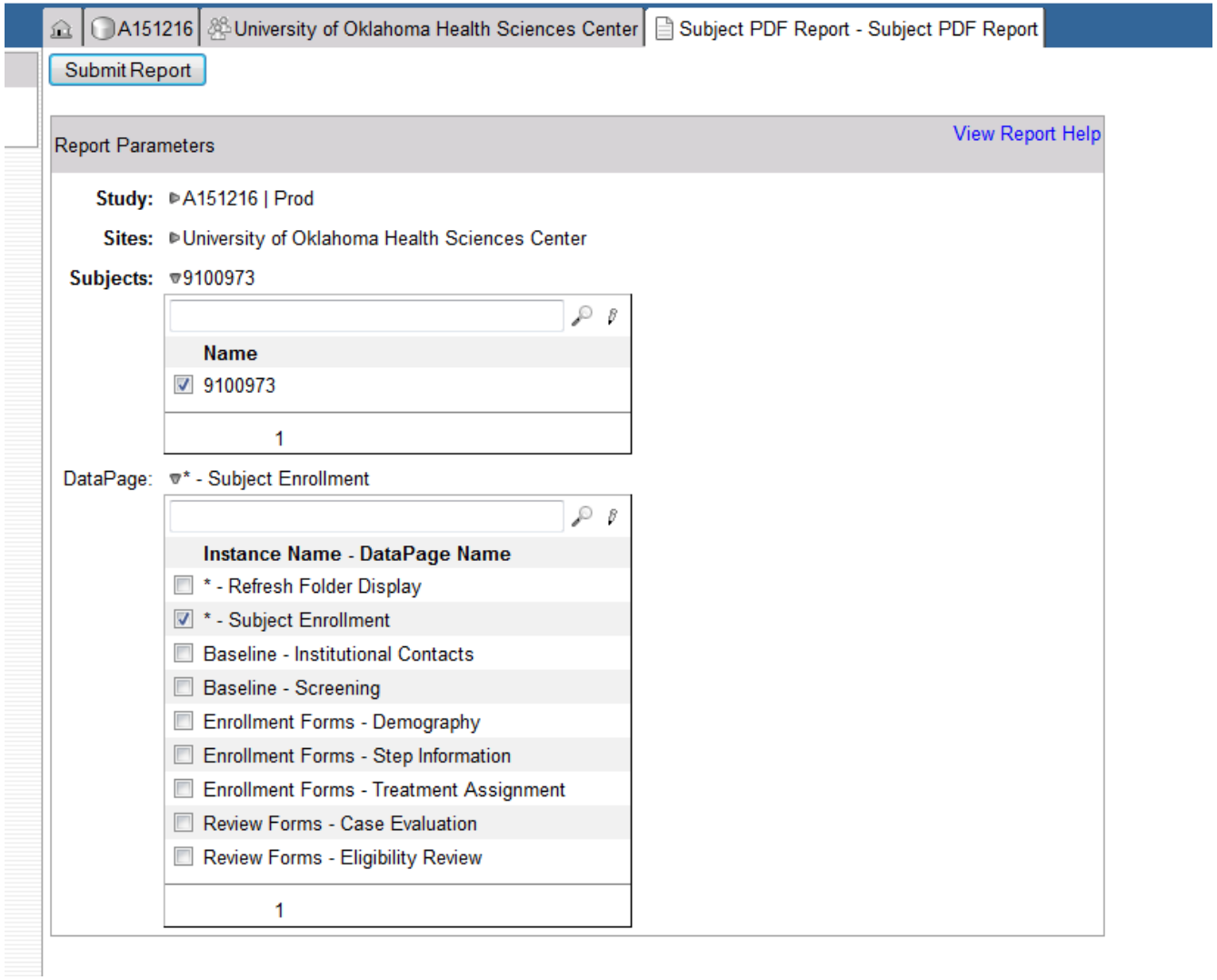
Subject PDF



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Subject PDF

A151216: Stage II Testing Round 13: SLH003
Folder: Baseline
Form: On-Study
Generated On: 22 Oct 2014 21:29:24

Cycle	0

DESCRIPTION OF PRIMARY DISEASE

MedDRA disease code	Non-small cell lung cancer, NOS (10029514)
Primary tumor site	Right upper lobe lung
Histologic type	Non-small cell lung cancer NOS
Histologic grade (differentiation)	Grade I (Well differentiated)

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Subject PDF

- On-Study: Surgery (for resection of tumor)
- Supporting Documentation: Baseline
- Supporting Documentation: Baseline (1)
- Supporting Documentation: Baseline (2)
- Supporting Documentation: Baseline (3)

You will see a page in the Subject PDF report for each log line in a log line table

Subject: [illegible]LH003
Page: Supporting Documentation: Baseline - Baseline

Cycl[illegible]

#	Date of assessment	Report type	Specify report type	Attachment *(max file size 10 MB)*
1	1 Jun 2011	Operative report		EligReviewReport.pdf
2	1 Jul 2011	Pathology report		EligReviewReport.pdf
3				
4				
5				
6				
7				
8				
9				
10				

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Subject PDF-Example of Audit Trail

A151216: Stage II Testing Round 13: SLH003
Form: Subject Enrollment
Generated On: 22 Oct 2014 21:29:24

Audit	User	Time (GMT)
Patient ID User entered 'SLH003'	Shauna Hillman (448 - Hillmans6)	17 Jul 2014 19:22:00
Enrolling Site CTEP ID User entered 'MN026'	Shauna Hillman (448 - Hillmans6)	17 Jul 2014 19:22:00
Lead Organization User entered 'Alliance'	Shauna Hillman (448 - Hillmans6)	17 Jul 2014 19:22:00
Current Site CTEP ID User entered 'MN026'	Shauna Hillman (448 - Hillmans6)	17 Jul 2014 19:22:00

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Task Summary

- Use your Task Summary to navigate to tasks such as forms that need to be entered, non-conformant data and queries that need responding to
- The Task Summary is specific to your role as a Clinical Research Professional or “Read Only Role”
- If you have a “Read Only Role”, nothing will be displayed in your task summary since you have no data entry responsibilities
- The Task Summary is available at the Site or Subject level

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Task Summary

- Site Level

One patient from this site has non-conformant data

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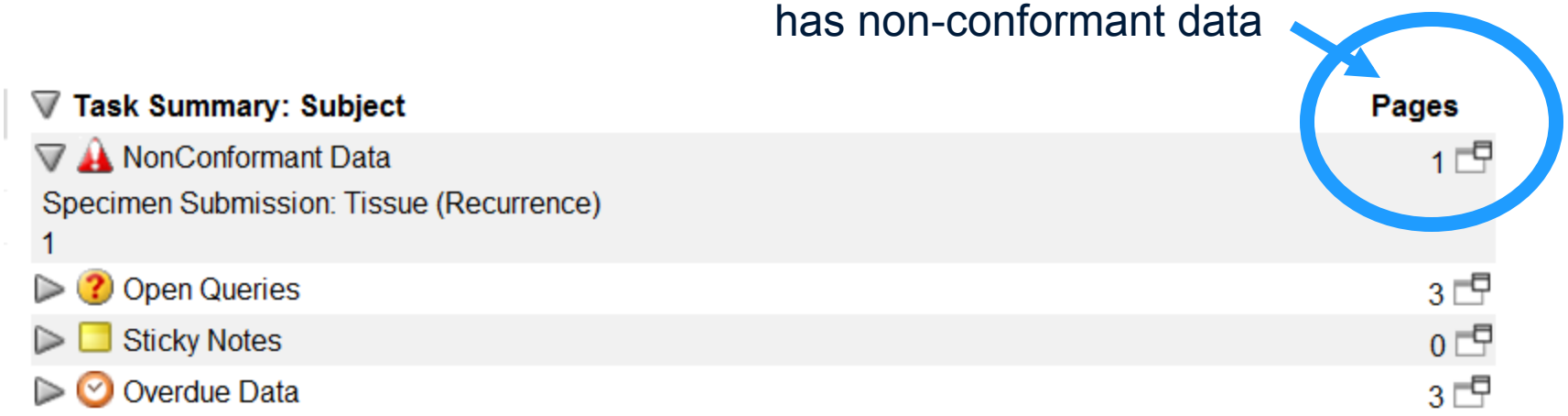
Task Summary

- Subject Level

One form from this subject has non-conformant data



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Questions

- Update on entry of AEs grades: Medidata is testing a patch to speed up the dynamic population of grades.
  - Target completion date: Jan 2015.
  - Meanwhile, save the form then enter in edit mode for faster response time. See May 2014 meeting presentation for detail
- For Rave questions, contact the Study Specific Data Manager found on the contact page of the protocol

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Transition of Long Term Follow-up for Legacy CALGB Trials from Teleform to Medidata Rave

- First trial: CALGB 140202, transition on October 31, 2014
- Future trials will be batched and transitioned quarterly
- At this time, only trials in long term follow-up are being transitioned to Rave
- All data elements and collection time points remain the same just the data collection mechanism is different (Rave versus Teleform)

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Transition of Long Term Follow-up for Legacy CALGB Trials from Teleform to Medidata Rave

- Next five trials to transition
  - 10404
  - 50303
  - 50604
  - 40603
  - 10801
- Communications go out to study personnel 1 month, and 1 week prior to transition

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Transition of Long Term Follow-up for Legacy CALGB Trials from Teleform to Medidata Rave

- The “Patient Status: Transition to Rave” form located in the “Summary of Teleform Data” folder
  - will summarize the current patient status at the time of the Rave transition
  - will be present for all patients even patients that no longer need follow-up
  - is a “read only” form
- If there are any questions about the data displayed on this form contact the Study Data Manager

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Transition of Teleform to Rave

- Follow-up status can be determined by reviewing the "Initial Follow-up in Rave" Section on the Patient Status: Transition to Rave Form
- This field will be derived for you
  - Example 1

  - Example 2

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Questions?

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