



CTSUS UPDATES

SWOG Spring Meeting

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Agenda

- Accrual in OPEN
- Delegation of Tasks Log (DTL)
- Source Document Portal (SDP)
- Data Quality Portal (DQP)
- Roster Reminders
- Questions



OPEN ACCRUAL




















How to find accrual (and other) information using OPEN

Accrual Details - OPEN

- New accrual columns were added to the OPEN history screen
 - Step type
 - Count towards
- Each enrollment step will display on a separate row
 - Includes the step type
 - Indicates if the enrollment will be counted towards the step type






Step Type	Count Towards
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OPEN History Screen

Protocol	Site	Credit	Step	Step Type	Count Towards
 EAY131 		ECOG-ACRIN	0	SCREENING	Y
 EA8143 		ECOG-ACRIN	1	INTERVENTION	Y
 EA8143		ECOG-ACRIN	0	SCREENING	Y
 EA8143 		ECOG-ACRIN	1	INTERVENTION	Y
 EA8143		ECOG-ACRIN	0	SCREENING	Y
 EAQ171CD		ECOG-ACRIN	0	SCREENING	Y
 EAQ171CD		ECOG-ACRIN	2	INTERVENTION	N
 EAQ171CD		ECOG-ACRIN	1	INTERVENTION	Y

'i' Button in OPEN

- At-A-Glance information for the protocol
- Pop-up box includes:
 - General protocol information
 - Registration steps
 - OPEN person types
 - Funding information
 - Site enrollment information

Track #	Protocol	Site	Credit	Step
612047	 EA8143	 MN008	ECOG-ACRIN	0
612046	 At-A-Glance for Protocol Number EA8143	CRIN		1
612045	 EA8143	 MN008	ECOG-ACRIN	0

At-A-Glance Pop-Up Box

Protocol: A221602

Title: Olanzapine With or Without Fosaprepitant for the Prevention of Chemotherapy Induced Nausea and Vomiting (CINV)in Patients Receiving Highly Emetogenic Chemotherapy (HEC):

GRP Prot Status: Active

PIO Status: Active

Network Group: ALLIANCE

Legacy group:

Restrict Sites: N

Auto QA: Y

Rave study? Y

Rave Study Group: MAYO

PMB Dist? N

UUIID? ef385198-77c2-480c-91dd-18abc3090ffe

CTSU Web Post: N

Menu Date:

Study Type: G

OPEN protocol? Y

OPEN to load to Rave? N

OPEN Slot Reservation? N

OPEN Activation Date: 15-Oct-2018 12:00:00 AM EDT

OPEN to Load to caAERS? N

OPEN to Submit CDUS? Y

TRIAD Protocol? N

TRIAD Activation Date:

RT QA Flag? N

CIRB Posting Flag? Y

Financial Posting Flag? Y

CTA? N

CTA Holder

DQP Supported

Balance Study? N

DTL Required? N

Central Monitoring? N

EPRO Study? Y

Express Courier: Not Required

Monitoring Method: CDUS - Abbreviated

Site Enrollments For A221602

Count Towards Step: INTERVENTION

NCI Site Code	Enrollments
BL002	13
ME044	5
LA024	4
KY096	4
WT009	4
EW026	3
MD028	3
NY087	3
WS026	3
FL194	2
MD097	2
MD002	2
ME026	2
WS118	2
WV046	2
LA072	2
BL096	2
MD020	2
NC142	2
ME048	2
EM014	2
PA052	2
DC034	2
VT004	2
WT144	2

Top 15 Enrolling Sites For A221602 (Only INTERVENTION Step)

Legend for Donut Chart:

- AL002
- ME044
- LA024
- KY096
- WT009
- EW026
- MD028
- NY087
- WS026
- FL194
- MD097
- MD002
- ME026
- WS118
- WV046
- LA072
- BL096
- MD020
- NC142
- ME048
- EM014
- PA052
- DC034
- VT004
- WT144

Registration Steps:

Step	Description	Step Type	Required?	Load To	FIM?	Count Towards?
1	Randomization	INTERVENTION	Y	NONE	Y	Y
2	Re-Registration	INTERVENTION	N	NONE	N	N

Open Person Types:

Person Type	Registration Type
Consenting Person	Non-Physician Investigator
Consenting Person	Investigator
Consenting Person	Associate Plus
Credit Investigator	Investigator
Site Registrar	Non-Physician Investigator
Site Registrar	Associate Plus
Site Registrar	Investigator
Treating Investigator	Investigator



DELEGATION OF TASKS LOG (DTL)

New task options – Person Minimum, Task Restrictions, Training
Documentation Required

New Task Options for DTL Templates (I)

- **Person Minimum-** assigns a minimum number of persons to a task
- **Task Restrictions-** restricts a person from being assigned certain tasks, if that person is also assigned another task on the DTL
 - Example: Cannot assign a person the Unblinded Study Personnel task and the Rave CRA task at the same site or any other site.

New Task Options for DTL Templates (2)

- **Training Documentation Required-** requires documentation of training for each person assigned to a particular task
 - Sites must upload training documentation using the site DTL
 - A reviewer will review and approve / reject documentation
 - Status of review will be available on the DTL
 - Tasks will remain in Pending status until approval occurs
 - Notification will be sent to the DTLA if documentation is rejected
 - Training documentation can be used across site DTLs

Unblinded Study Personnel Task – NRG-GY018

- **Two Person Minimum-** At least two persons must be assigned, sites cannot order drug until Pharmacy Agreements are reviewed and approved
- **Task Restrictions-** Persons assigned to this task cannot be assigned to other tasks on the DTL; except for Investigational Agent Accountability
- **Training Documentation Required:** Pharmacy Agreement must be uploaded to training documentation field on the DTL for each person assigned to this task



SOURCE DOCUMENT PORTAL (SDP)

An overview, new enhancements, and a refresher on annotations and redactions

SDP Overview

- An application on the CTSU website in Auditing & Monitoring section
- Allows the upload and storage of source documents to support activities such as Central Monitoring and Patient Eligibility Review
- Provides ability to redact Personally Identifiable Information (PII) electronically during the upload
- Currently piloted for use in Central Monitoring on several studies



SDP Enhancements

- Automatic annotation of form with study, site, and patient identifier
- Allow document type identification of *and/or*
- New document type of *Relevant Document*
- Ability for the monitor to redact PII after triaging
- Central monitoring activity report showing Rave status



Upload, Annotate, and Redact

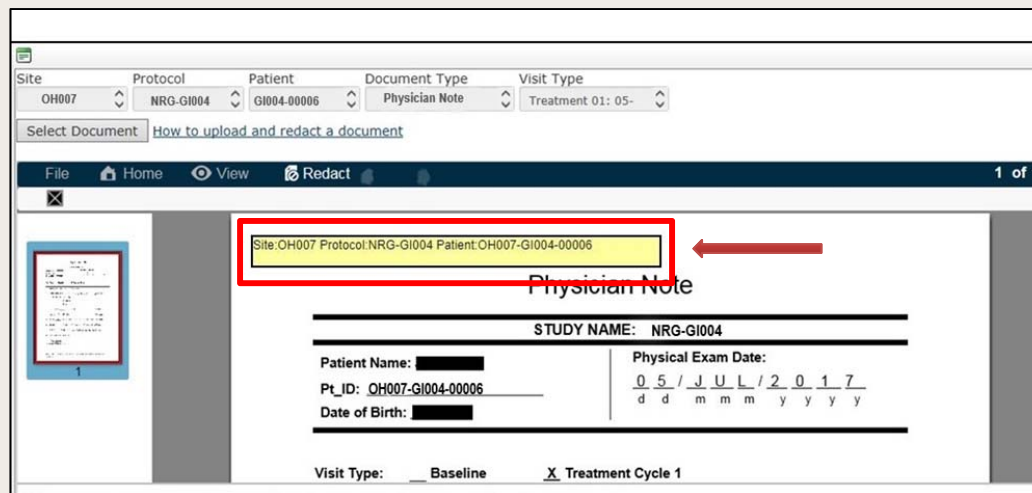
Document upload includes automatic annotation and allows redaction within the SDP

- Upload source documents as PDF (represents a single patient and visit)
- Automatically annotated with study, site, and patient identifier
- Redact PII using redaction tool
- Save document

**Note: Once an uploaded document is saved, the redacted fields and annotations are burned onto the document and cannot be changed. To make changes to a saved document you must delete the document and upload it again.*

Automatic Annotation

- Displayed at time of document upload
- Cannot be deleted but can be hidden from view
- Can be moved if the default position is blocking information on the document
 - Moving annotations must be managed separately on each page and done **prior** to saving the document



Automatic Annotation

The screenshot displays a document viewer interface with the following elements:

- Header:** Site (OH007), Protocol (NRG-GI004), Patient (OH007-), Document Type (Select Docume...), Visit Type (Enrollment Forms).
- Toolbar:** File, Home, View, Annotate, Redact. A red box highlights the **Show/Hide Annotation** button.
- Document Content:** A yellow annotation box at the top of the page contains the text: **Site:OH007 Protocol:NRG-GI004 Patient:OH007-GI004-00006**. A red box highlights this annotation.
- Document Preview:** A thumbnail of the document is shown on the left side.
- Document Text:** Radiology Report, Patient Name: [REDACTED], MRN: 123456, Sex: [REDACTED] DOB: [REDACTED], Assessment Date: 4/29/2017, Reason For Exam: Metastasis.

Uncheck box prior to selecting document to turn off annotation feature

Check box to hide annotation on page

Annotation shows Site, Protocol, Patient on each page of document

Redact PII

- Select **Redact**
- Click and drag cursor over PII to redact
- After review and PII redaction, save the document
- Check the verify checkbox at the bottom left of the Document Upload screen to confirm all PII was redacted
- Click *Save Document* to complete the upload

The screenshot shows a web interface for document upload. At the top, there is a navigation bar with 'File', 'Home', 'View', and 'Redact' (highlighted with a red box). Below the navigation bar, there is a 'Physician Note' form. The form contains the following information: 'STUDY NAME: NRG-GI004', 'Patient Name: [REDACTED]', 'Pt_ID: OH007-GI004-00006', 'Date of Birth: [REDACTED]', and 'Physical Exam Date: 05 / JUL / 2017' (with 'd d m m m y y y y' below it). At the bottom of the form, there is a 'Visit Type' section with 'Baseline' and 'X Treatment Cycle 1'. At the bottom left of the form, there is a checkbox labeled 'I verify that all personally identifiable information on this document has been redacted.' and a 'Save Document' button (highlighted with a red box).



DATA QUALITY PORTAL (DQP) AWARENESS

Available DQP Reports

- DQP Summary Table
- Aging Report Summary
- Rave Delinquencies/Queries by Form
- Rave Delinquencies/Queries
- DQP Timeliness Reports




DQP Summary Table

- Located in Data Management > Rave Home Page
- Provides summary counts of total delinquencies and total queries for each protocol
 - “-” = there are no delinquent forms or queries for the protocol
 - “n/a” = Rave calendaring is not used by the LPO for the protocol, no delinquent form information is available

#	Protocol	Total Delinquencies	Total Queries
11		<u>72</u>	<u>65</u>
12		<u>1</u>	<u>108</u>
13		-	<u>5</u>
14		-	-
15		<u>29</u>	<u>219</u>
16		-	-
17		<u>6</u>	-
18		<u>18</u>	<u>54</u>
19		<u>96</u>	<u>242</u>
20		<u>9</u>	<u>102</u>

DQP Timeliness Reports

- Form and Query Timeliness reports are available in the DQP Reports module
- Provide metrics of expected and received forms/queries for all protocols for all sites or for a specific site the user is rostered to
- Posted quarterly to the DQP, not updated after posting

 Cancer Trials Support Unit <small>A SERVICE OF THE NATIONAL CANCER INSTITUTE</small> <i>Linking practice to progress</i>		Form Metrics for [REDACTED]					
Site	Protocol	Quarter (2018, Q4)				Cumulatively	Form Timeliness Metric (%) [B] / ([A] + [C])
		Total Number of Expected Forms [A]	Total Number of Forms Received On Time [B]	Total Number of Forms Received Late	Total Number of Forms Not Received	Total Number of Forms Not Received [C]	
[REDACTED]	[REDACTED]	There are no Form Metrics to Display					
		45	32	12	1	1	70%
		4	4	0	0	0	100%
		There are no Form Metrics to Display					
		5	0	5	0	0	0%
		30	30	0	0	0	100%
		2	0	2	0	0	0%
		There are no Form Metrics to Display					
		40	19	11	10	10	38%
		There are no Form Metrics to Display					
		0	0	0	0	2	
		10	5	4	1	1	45%
		4	4	0	0	0	100%
		There are no Form Metrics to Display					
		There are no Form Metrics to Display					
		There are no Form Metrics to Display					
	Totals	140	94	34	12	14	61%



ROSTER REMINDERS

Information on removing persons, site-protocol PI checks, close/transfer site checklists, and more

Hmmm...Dr. Jones left, what is the best way to remove her from our roster?



First, is Dr. Jones doing any of the following?



Site-Protocol PI:	Submit PI change request to CIRB for CIRB reviewed studies, or to the CTSU Regulatory Office for local reviewed studies
Treating, credit or drug shipment investigator in OPEN:	Use the Transfer and Update Module in OPEN to update investigator assignments
Acting as the Clinical Investigator (CI) on the site Delegation of Task Log:	Reassign the CI role
Other role assignments:	Reassign to other staff with the appropriate registration type

Next Steps

- Your site Registration Coordinator (RC) should contact the Registration and Credential Repository (RCR) Help Desk to inform them the individual has relocated or is no longer practicing
 - This should set the individual to withdrawn at all treatment sites
- Use NCORP-SYS or the Roster Update Management System (RUMS) to withdraw from individual rosters

Site-Protocol PI Checks and How To Resolve Issues



Because the frustration is real!

Check	Resolution
✓ Practice site is listed in the Site-Protocol PI's RCR profile	Update RCR to include the site
✓ IRB number is listed in the Site-Protocol PI's RCR profile	Update RCR to include the IRB number
✓ Site-Protocol PI is active with CTEP	Update RCR registration
✓ Site-Protocol PI is on a participating roster at the practice site	Add the Site-Protocol PI via NCORP-SYS or RUMS to the practice site
✓ Site-Protocol PI is the correct registration type and/or task access for the protocol	Select another investigator with the appropriate registration type
✓ Site-Protocol PI is on the Signatory roster for sites deferring to CIRB approval	Add the Site-Protocol PI to the Signatory roster in RUMS

Closing a Site - Checklist

- Determine the status of all patients
 - Off-study or transferring
- Contact Lead Protocol Organizations (LPOs) to ensure data entry/queries are complete
- Notify your network administrator (i.e., Main Member site, NCORP, or LAPS admin)
- Notify grant holder of closure
 - For LAPS contact NCTNProgram@mail.nih.gov
 - For NCORPs follow NCORP guidelines
 - Main Member sites notify affiliated NCTN Groups
- Withdraw site from CIRB Signatory (if applicable)
- Submit withdrawal of all site registration records to the CTSU Regulatory Office

Transferring a Site - Checklist

- Determine the status of all patients
 - Off-study, transferring, remaining at the site in followup or under new network
- Determine status of IRB coverage
 - Update CIRB Signatory or local IRB approvals as appropriate
 - Withdraw studies that will not remain open under new network
- Withdraw network staff via NCORP-SYS or RUMS
- Notify your network administrator (i.e., Main Member site, NCORP, or LAPS admin)
- Notify grant holder of closure
 - For LAPS contact NCTNProgram@mail.nih.gov
 - For NCORPs follow NCORP guidelines
 - Main Member sites notify affiliated NCTN Groups

More Information & Questions

- A version of this slide set with additional content will be posted to the CTSU website
 - Available in early May; will be announced in the Bi-Monthly Broadcast
 - Location: Resources >Educational Multi Media >Slide Sets
- Questions?

