CTSU Updates

SWOG Spring Meeting
April 2019

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CTSU Deputy Project Director
Agenda

• Accrual in OPEN
• Delegation of Tasks Log (DTL)
• Source Document Portal (SDP)
• Data Quality Portal (DQP)
• CIRB Use Requirements
• 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
OPEN History Screen

<table>
<thead>
<tr>
<th>Protocol</th>
<th>Site</th>
<th>Credit</th>
<th>Step</th>
<th>Step Type</th>
<th>Count Towards</th>
</tr>
</thead>
<tbody>
<tr>
<td>EAY131</td>
<td></td>
<td>ECOG-ACRIN</td>
<td>0</td>
<td>SCREENING</td>
<td>Y</td>
</tr>
<tr>
<td>EA8143</td>
<td></td>
<td>ECOG-ACRIN</td>
<td>1</td>
<td>INTERVENTION</td>
<td>Y</td>
</tr>
<tr>
<td>EA8143</td>
<td></td>
<td>ECOG-ACRIN</td>
<td>0</td>
<td>SCREENING</td>
<td>Y</td>
</tr>
<tr>
<td>EA8143</td>
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<td>ECOG-ACRIN</td>
<td>1</td>
<td>INTERVENTION</td>
<td>Y</td>
</tr>
<tr>
<td>EA8143</td>
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<td>ECOG-ACRIN</td>
<td>0</td>
<td>SCREENING</td>
<td>Y</td>
</tr>
<tr>
<td>EAQ171CD</td>
<td></td>
<td>ECOG-ACRIN</td>
<td>0</td>
<td>SCREENING</td>
<td>Y</td>
</tr>
<tr>
<td>EAQ171CD</td>
<td></td>
<td>ECOG-ACRIN</td>
<td>2</td>
<td>INTERVENTION</td>
<td>N</td>
</tr>
<tr>
<td>EAQ171CD</td>
<td></td>
<td>ECOG-ACRIN</td>
<td>1</td>
<td>INTERVENTION</td>
<td>Y</td>
</tr>
</tbody>
</table>
‘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
At-A-Glance Pop-Up Box

**Protocol:** A221602

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

**Group Status:**
- Active

**Network Group:** ALLIANCE

**Restrict Sites:** N

- **Auto QA:** Y
- **Rave study:** Y
- **Rave Study Group:** MAYO
- **PMB Dist:** N

**UUID:** 9f385196-77c2-4890-c91d-81a0300f0e

**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 caER:** 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

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### Site Enrollments for A221602

<table>
<thead>
<tr>
<th>Site Enrollments</th>
<th>Count Towards Steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site 1</td>
<td>10</td>
</tr>
<tr>
<td>Site 2</td>
<td>8</td>
</tr>
<tr>
<td>Site 3</td>
<td>4</td>
</tr>
<tr>
<td>Site 4</td>
<td>2</td>
</tr>
</tbody>
</table>

**Top 18 Enrolling Sites for A221602 (Only INTERVENTION Steps)**

#### Registration Steps:

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
<th>Step Type</th>
<th>Required?</th>
<th>Load To</th>
<th>FIM?</th>
<th>Count Towards?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Randomization</td>
<td>INTERVENTION</td>
<td>Y</td>
<td>NONE</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>2</td>
<td>Re-Registration</td>
<td>INTERVENTION</td>
<td>N</td>
<td>NONE</td>
<td>N</td>
<td>N</td>
</tr>
</tbody>
</table>

#### Open Person Types:

<table>
<thead>
<tr>
<th>Person Type</th>
<th>Registration Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consenting Person</td>
<td>Non-Physician Investigator</td>
</tr>
<tr>
<td>Consenting Person</td>
<td>Investigator</td>
</tr>
<tr>
<td>Consenting Person</td>
<td>Associate Plus</td>
</tr>
<tr>
<td>Credit Investigator</td>
<td>Investigator</td>
</tr>
<tr>
<td>Site Registrar</td>
<td>Non-Physician Investigator</td>
</tr>
<tr>
<td>Site Registrar</td>
<td>Associate Plus</td>
</tr>
<tr>
<td>Site Registrar</td>
<td>Investigator</td>
</tr>
<tr>
<td>Site Registrar</td>
<td>Investigator</td>
</tr>
<tr>
<td>Site Registrar</td>
<td>Investigator</td>
</tr>
</tbody>
</table>
DELEGATION OF TASKS LOG (DTL)

New task options – Person Minimum, Task Restrictions, Training Documentation Required
New Task Options for DTL Templates (1)

- **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

April 2019
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
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
DATA QUALITY PORTAL (DQP) AWARENESS FAQS
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

<table>
<thead>
<tr>
<th>#</th>
<th>Protocol</th>
<th>Total Delinquencies</th>
<th>Total Queries</th>
</tr>
</thead>
<tbody>
<tr>
<td>11</td>
<td></td>
<td>72</td>
<td>65</td>
</tr>
<tr>
<td>12</td>
<td></td>
<td>1</td>
<td>108</td>
</tr>
<tr>
<td>13</td>
<td></td>
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<td>14</td>
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<td>15</td>
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<td>19</td>
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<td>96</td>
<td>242</td>
</tr>
<tr>
<td>20</td>
<td></td>
<td>9</td>
<td>102</td>
</tr>
</tbody>
</table>
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.
DQP FAQ #1

Why is my form still specified as delinquent on the DQP after I already entered it in Rave?

To be considered as received, data entry must be complete and all initial Site from System and Non Conformant queries on a form must be answered.

Allow 24 hours since a DQP system refresh runs on a nightly basis to remove received forms from the DQP.

If your form is still listed as delinquent on the DQP after the nightly refresh, and all initial Site from System and Non Conformant queries have been answered, contact the data manager for the organization leading the study.
Should this date be removed?
Ginger Riley, 3/26/2019
Why does the DQP say I have delinquent forms/queries, but are there no delinquent forms/queries specified in the Rave Task Summary?

Delinquent (or Overdue, as per Rave) forms and queries may not always be displayed in the Site or Patient Rave Task Summary or at the Rave folder level.

The CTSU recommends to always review your delinquent forms and queries in Rave at the form/field level, as delinquent forms and queries requiring site management are always displayed at the Rave form/field level.
Should this date be removed?

Ginger Riley, 3/26/2019
CIRB Requirement

• All U.S. sites participating on trials through the NCTN and NCORP must be or must become members of the NCI CIRB to continue to enroll patients on trials.

• The requirements is based on the NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research (NOT-OD-16-094).

• The implementation date of this policy was March 1, 2019.

• Sites not members of the CIRB at that point were Suspended.
  – This affects their participation on all trials, even those not covered by the CIRB.
  – Sites not joining the CIRB can continue to treat and follow previously-enrolled patients, but cannot enroll new ones.

• All new NCTN and NCORP studies will be covered by the CIRB.
Implementation of the Policy

Flow Chart for Implementation of NIH Single IRB Policy for NCTN & NCORP

Is Site a Member of the NCI CIRB on 3/1/2019?

Yes

NCTN or NCORP Trial Activated On/After March 1, 2019

Site must use the NCI CIRB as the IRB of Record (all these trials will have been reviewed by the NCI CIRB)

NCTN or NCORP Trial Activated Prior to March 1, 2019

Trial never reviewed by NCI CIRB

Site must use Local IRB as IRB of Record

Trial reviewed by NCI CIRB & opened by site prior to 3/1/19

Site should continue to use the existing IRB of Record (Local or NCI CIRB)

Trial reviewed by NCI CIRB but opened by site on/after 3/1/19

Site must use the NCI CIRB as the IRB of Record

Site Status Suspended

No enrollment of new patients to ANY trial is allowed, but treatment and follow-up data on previously enrolled patients will continue to be provided. A site may enroll new patients to trials once it becomes a member of the NCI CIRB
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?

<table>
<thead>
<tr>
<th>First, is Dr. Jones doing any of the following?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Site-Protocol PI:</strong> Submit PI change request to CIRB for CIRB reviewed studies, or to the CTSU Regulatory Office for local reviewed studies</td>
</tr>
<tr>
<td><strong>Treating, credit or drug shipment investigator in OPEN:</strong> Use the Transfer and Update Module in OPEN to update investigator assignments</td>
</tr>
<tr>
<td><strong>Acting as the Clinical Investigator (CI) on the site Delegation of Task Log:</strong> Reassign the CI role</td>
</tr>
<tr>
<td><strong>Other role assignments:</strong> Reassign to other staff with the appropriate registration type</td>
</tr>
</tbody>
</table>
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

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

Because the frustration is real!
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?