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)
• 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>
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<tr>
<td>EA8143</td>
<td></td>
<td>ECOG-ACRIN</td>
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<td>SCREENING</td>
<td>Y</td>
</tr>
<tr>
<td>EAQ171CD</td>
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<td>ECOG-ACRIN</td>
<td>2</td>
<td>INTERVENTION</td>
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</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
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
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 if blocking information on the document
  - Moving annotations must be managed separately on each page and done *prior* to saving the document
Automatic Annotation

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
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

<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>
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<td>108</td>
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<td>5</td>
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<tr>
<td>14</td>
<td></td>
<td>-</td>
<td>-</td>
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<tr>
<td>15</td>
<td></td>
<td>29</td>
<td>219</td>
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<tr>
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<td>-</td>
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<tr>
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<td>6</td>
<td>-</td>
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<tr>
<td>18</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
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></td>
</tr>
<tr>
<td><strong>Treating, credit or drug shipment investigator in OPEN:</strong></td>
</tr>
<tr>
<td><strong>Acting as the Clinical Investigator (CI) on the site Delegation of Task Log:</strong></td>
</tr>
<tr>
<td><strong>Other role assignments:</strong></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

Because the frustration is real!

<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>
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?