TIPS AND TOOLS FOR WORKING WITH THE CTSU

SWOG Group Meeting
Oishi Symposium

Jenny R. Hopkins, CTSU Assistant Project Director
Topics

• Maximizing the CTSU Website
• Rostering Tips
• Viewing Regulatory Information
• Data Quality Portal Reminders and Tips
• CTSU Dashboard
• CRISP Notifications
• General Resources
Maximizing the CTSU Website

• The CTSU has a robust website that serves as the center point for many of the activities sites perform with respect to the conduct of NCI-funded clinical trials.

• These are some tips and tricks that apply across the website, as well as some that are more context-specific.

  – The goal is to help those using the website to become more efficient and self-sufficient and minimize the need to contact the CTSU Help Desk.
Things to Look For on the Website

• Click on ? Help or Help Topics on most pages/applications to find details on their use (i.e., user guide-type content).

• Use buttons to display context-specific details.

• Use More Commands or Export to Excel buttons to export tables/grids for review and distribution.

• Use filters to focus your queries and reports.

• Use the Dashboard for information that is personalized to you and your site(s).

• Use CRISP to subscribe to email notifications.
Page-Specific Help Content

- Help Topics
  - Home Page
  - Regulatory
  - Source Document Portal
  - RUMS
  - Delegation Log

- Other help content, incl. user guides or
  - Dashboard
  - OPEN
  - Data Management, incl. DQP
  - CRISP
Person Information (Including Your Own)

Click on the My Account button to access information about your account.

Use the Person button to view affiliation and registration data (all persons).

Do you receive the Bi-Monthly Broadcast?

Expiration dates and registration type

Cancer Trials Support Unit (CTSU)

10/3/2019
Tips for Rostering in RUMS

- Review the Help Topics
  - Includes the rostering business rules and roles and access matrix (by organization)
- Use the browser filters to run reports

- Export query output to Excel
More RUMS Tips

- Find someone’s CTEP ID using the CTEP ID Search
  - Query on full or partial first and/or last name
  - City/State/Zip help to confirm

- Use the RUMS Tracking tab to view and respond to roster owner queries
Viewing Regulatory Information

Use filters to focus your search

See what is needed to obtain approval

Click on i button to view the site-protocol PI and the status of protocol requirements

<table>
<thead>
<tr>
<th>Site Number</th>
<th>Protocol Number</th>
<th>LPO</th>
<th>Protocol Status</th>
<th>IRB Type</th>
<th>IRB Approval Expiration (Days)</th>
<th>CTSU Collecting Review?</th>
<th>Member Of LPO or PO</th>
<th>Site Registration Status</th>
<th>Missing Requirements (If applicable)</th>
</tr>
</thead>
<tbody>
<tr>
<td>31</td>
<td>S1400F</td>
<td>SWOG</td>
<td>Temporarily Closed to Accrual</td>
<td>CIRB</td>
<td>275</td>
<td>Yes</td>
<td>Y</td>
<td>Pending</td>
<td>Protocol is Temporarily Closed to Accrual</td>
</tr>
<tr>
<td>32</td>
<td>S1501</td>
<td>SWOG</td>
<td>Active</td>
<td>CIRB</td>
<td>141</td>
<td>Yes</td>
<td>Y</td>
<td>Pending</td>
<td>Regs not complied [Echo Lab Validation {due 05/31/2018}]</td>
</tr>
<tr>
<td>33</td>
<td>S1600</td>
<td>SWOG</td>
<td>Active</td>
<td>CIRB</td>
<td>83</td>
<td>Yes</td>
<td>Y</td>
<td>Pending</td>
<td>Regs not complied [Site Requirements Form {due 02/21/2019}]</td>
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</tbody>
</table>

Site Number: [blank] Site Status: Pending Protocol: S1501
Principal Investigator: [blank]
Comment: [blank]

<table>
<thead>
<tr>
<th>#</th>
<th>Code</th>
<th>Description</th>
<th>Required By Date</th>
<th>Required?</th>
<th>Complied?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>IRB</td>
<td>IRB Approval</td>
<td>09/15/2017</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>2</td>
<td>SITE_QUALIFICATION</td>
<td>Echo Lab Validation</td>
<td>05/31/2018</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>
Data Quality Portal Reminders and Tips

• **DQP Access**
  – Anybody rostered to a site can view the DQP; those with Rave-related roles can link directly into Rave from the DQP.

• **DQP Reports**
  – Aging Report Summaries
  – Delinquencies/Queries by Form
  – Rave Delinquencies/Queries
  – DQP Summary Table *(Rave Home)*
  – DQP Timeliness Reports *(Quarterly; Static)*

• **Exporting DQP reports**
  – Reports can be exported when the More Commands [icon](image) or the Excel icon [icon](image) is displayed.
More DQP Reminders and Tips

• Remember that the DQP refreshes nightly.
• Drill down to the form/field level in Rave to find delinquent forms and outstanding queries that you can’t see at the site, patient, or folder level.
• DQP User Guide
  – The DQP Site User Guide provides assistance for using the DQP and is accessible via the Help icon.
• Use CRISP to subscribe to bi-weekly notifications from the DQP (and SDP).
Dashboard Reminders and Tips

- The CTSU Dashboard contains all available data specific to each person, their associated sites, and protocols of interest. The Dashboard can be customized to suit your needs and preferences.

- Available portlets:

  - Site Accrual Report
  - In-Progress Enrollments
  - Multi-Step Enrollments
  - Rave Study Access
  - Site Registration
  - Unviewed DSNs
  - Quick Links
  - CTEP Status Notifications
  - Newly Posted Protocols
  - Protocol Accrual Summary
  - Expiring IRB Approvals
  - CTEP Profile
  - CIRB Site Approvals
  - DTLs Awaiting CI Approval
  - CIRB Document Updates
  - Site Registration Summary
  - Protocol Profile
  - Outstanding Funding
Dashboard, Cont.

- Many portlets contain information you can find elsewhere, but the dashboard allows you to see them in one place, *with your preferred filters in place.*
  - For example, you can view data only for the protocols your sites are registered for:

![CIRB Document Updates at all sites](image)

<table>
<thead>
<tr>
<th>#</th>
<th>Post Date</th>
<th>Protocol</th>
<th>Updates</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>04-Sep-2019</td>
<td>EA2142</td>
<td>Protocol Version Date 07/31/19</td>
</tr>
<tr>
<td>2</td>
<td>04-Sep-2019</td>
<td>EA2165</td>
<td>Protocol Version Date 07/29/19</td>
</tr>
<tr>
<td>3</td>
<td>03-Sep-2019</td>
<td>S1203</td>
<td>Continuing Review August 2019</td>
</tr>
</tbody>
</table>
Which Studies Use Which Applications?

- In the Dashboard (Protocol Profile Portlet)

- In an individual protocol page
CRISP Notifications

- The CTSU Report and Information Subscription Portal (CRISP) allows staff to manage automated subscription e-mail notifications in a central location.
- Some automated emails are distributed to certain individuals based on their roster roles (e.g., Primary Contacts) or other activities (e.g., the individual who uploaded something in the SDP that was then rejected), but these and other notifications can also be subscribed to via CRISP.
Available CRISP Notifications

<table>
<thead>
<tr>
<th>Add Subscriptions Wizard</th>
<th>CRISP User Guide</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Select Notifications</td>
<td>2. Configure Subscriptions</td>
</tr>
</tbody>
</table>

### Data Management Updates

1. **CTSU Data Delinquency Notification for Sites**
   - A CTSU data delinquency notification about Data Quality Portal (DQP) and Source Document Portal (SDP).

2. **CTSU Source Document Portal Notification - Documents Rejected By the Lead Protocol Organization For Site**
   - A CTSU Source Document Portal notification about rejected documents.

3. **CTSU Adverse Event Reconciliation Notification: NCI Expedited Adverse Event Report Is Recommended**
   - A CTSU Data Management AE Reconciliation Notification about AE Missing Tickets.

### Enrollment Updates

1. **Summary of Multi-step Enrollments at all Sites**
   - Provides a summary of multi-step enrollments at your selected sites.

2. **Accrual Updates for Selected Protocols at your Site**
   - Lists accrual updates for selected protocols at your site.

3. **Step change for multi-step enrollments on selected protocols**
   - Step change for multi-step enrollments on selected protocols.

### Person Roster Updates

1. **Summary of Changes to the Selected Person Rosters**
   - Lists all roster additions/withdrawals including person role changes made to the selected roster during your specified time range.

### Protocol Updates

1. **New Protocols in Your Area of Interest**
   - Lists all upcoming studies in your selected area of interest or disease category.

2. **Addition of New Protocol Versions (Summary)**

### Regulatory Updates

1. **IRB Approval Expiring In 30 Days**
   - Lists all IRB approvals due to expire within 30-days.

2. **Site Registration Status Changes**
   - Provides a summary of Site Registration Status Changes.

More notifications are in development!
General Resources

- Resources area of the website
  - CTSU Operations Information is especially useful for those new to the CTSU
  - We are working to develop orientation/overview materials
- Remember the help content for individual pages and applications!
- CTSU Help Desk
  - CTSUContact@Westat.com
  - 1-888-823-5923
Questions?
The CTSU has a table at the ORP Open Forum this afternoon, where you can ask about this content or anything else.