Tips and tools for working with the CTSU

SWOG Group Meeting
Oishi Symposium
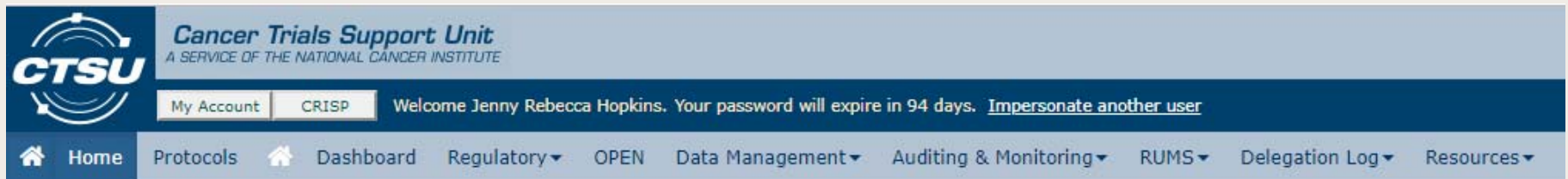
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Topics

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

- Other help content, incl. user guides or `? Help`
  - 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

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

Site Registration | Protocol Requirements | ...latory Submission | ▼

Site Number: [____]   Registration Status: Pending ▼   Protocol Status: All Protocol Statuses ▼   ...ype: **Help Topics** ▼

All IRB Types ▼

Protocol: [_____]   Pick   Go   Disclaimer

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

Site Number [____] **Site Status :** Pending **Protocol :** S1501
Principal Investigator : [____]
Comment :
Print

#	Code	Description	Required By Date	Required?	Complied?
1	IRB	IRB Approval	09/15/2017	✓	✓
2	SITE_QUALIFICATION	Echo Lab Validation	05/31/2018	✓	

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 or the Excel icon 🔲 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 [? Help].

- Use CRISP to subscribe to bi-weekly notifications from the DQP (and SDP).
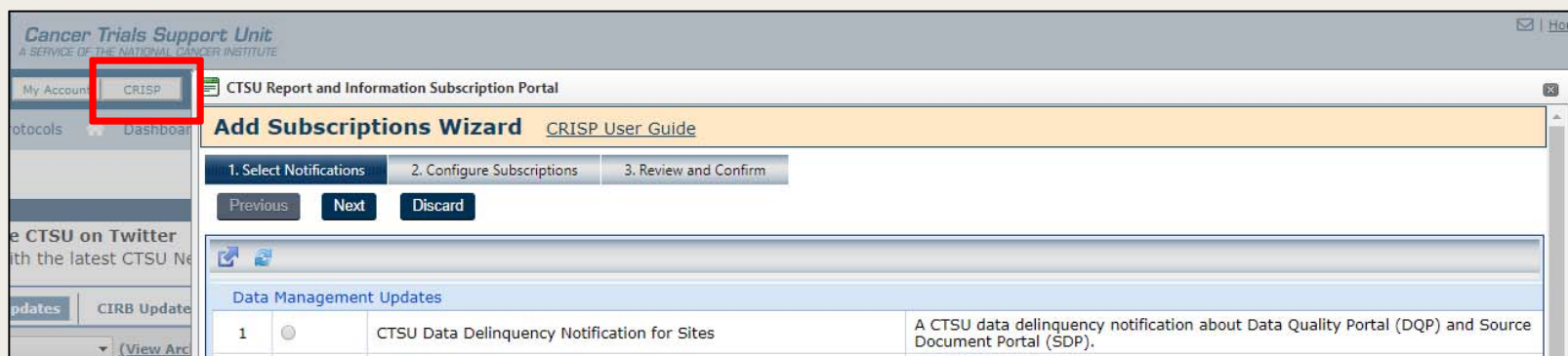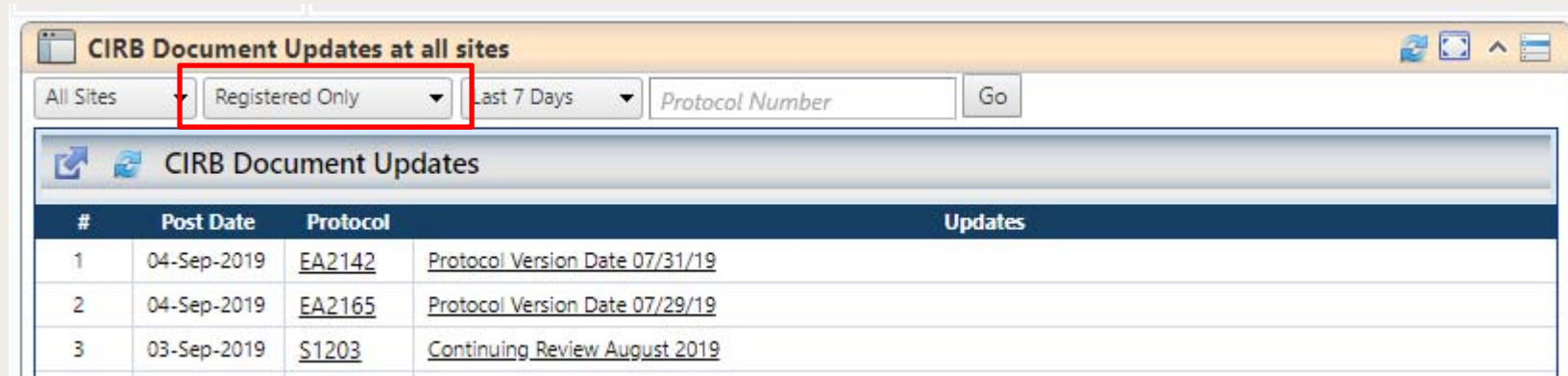
Dashboard Reminders and Tips

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

Which Studies Use Which Applications?

- In the Dashboard (Protocol Profile Portlet)

#	Protocol Number	Status	Status Date	APCD	PCD	CIRB	OPEN	RAVE	TRIAD	TSDV	DQP	CM	DTL	CTEPAERS	EPRO
1	NRG-LU005	Active	28-May-2019	28-Dec-2026		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
2	S1800A	Active	17-May-2019	01-Feb-2023		✓	✓	✓	✓	✓	✓	✗	✓	✓	✗
3	S1803	Active	27-Jun-2019	01-Feb-2029		✓	✓	✓	✗	✓	✓	✗	✗	✓	✗
4	A031102	Active	01-Jul-2015	01-Jun-2024	16-Jan-2018	✓	✓	✓	✗	✓	✓	✗	✗	✗	✗
5	EA6134	Active	11-Apr-2016	02-Oct-2022		✓	✓	✓	✗	✓	✓	✗	✗	✗	✗
6	NSABP-B-51	Active	22-Aug-2013	31-Jul-2020		✓	✓	✓	✓	✗	✓	✗	✗	✗	✗
7	EAY131	Active	31-May-2016	30-Jun-2022		✓	✓	✓	✓	✓	✓	✗	✗	✗	✗
8	NRG-CC003	Active	09-Jan-2019	31-Jan-2022		✓	✓	✓	✓	✓	✓	✗	✗	✗	✗
9	E4512	Active	18-Aug-2014	01-May-2022		✓	✓	✓	✗	✓	✓	✗	✗	✗	✗
10	EA3161	Active	20-Jun-2019	01-Jan-2027		✓	✓	✓	✓	✓	✓	✗	✗	✓	✗

- In an individual protocol page

Supported By:	CIRB	OPEN	RAVE	IROC/TRIAD	TSDV	DQP	CM	DTL	CTEP-AERS/INTEG	ePRO
	✓	✓	✓	✗	✓	✓	✗	✗	✓	✗

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.
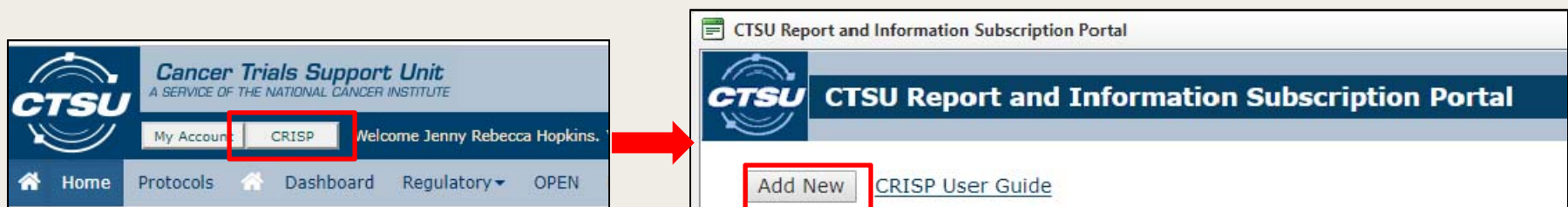
Available CRISP Notifications

Add Subscriptions Wizard CRISP User Guide

1. Select Notifications	2. Configure Subscriptions	3. Review and Confirm	

Previous | Next | Discard

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)	Notification of Additional New Protocol Versions

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
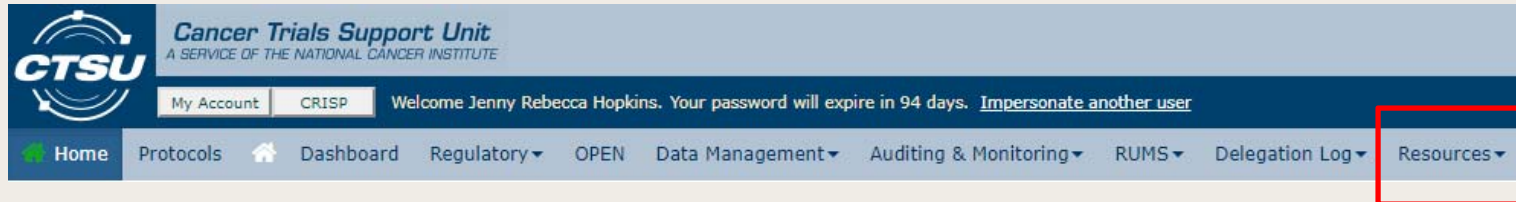
- Resources area of the website
  - CTSU Operations Information is especially useful for those new to the CTSU
  - We are working to develop orientation/overview materials
- Remember the help content for individual pages and applications!
- CTSU Help Desk
  - CTSUContact@Westat.com
  - 1-888-823-5923

Questions?

The CTSU has a table at the ORP Open Forum this afternoon, where you can ask about this content or anything else.