

RESOURCES AND REPORTS ON THE CTSU WEBSITE

Alliance Breakout Session November 3, 2017 Martha Hering

Nov. 3, 2017

Agenda

- Goals of this Presentation
- Dashboard Quick Views
- CRISP
- Accrual Reports
- Funding Information
- Regulatory Tab
- Roster Information
- Data Quality Portal
- Patients Subtab
- Other Resources

Goals

- Provide a high-level overview of resources on the CTSU website
- Demonstrate how to find resources and their uses
- Show best practices via user demonstration



Dashboard Tab

- Allows customized views of data related to associated site(s)
- May set as your landing page
- Use default profiles or customize view from a selection of portlets
- Default Profiles: Protocol, Enrollment, Regulatory and General

CTSU Report and Information Subscription Portal (CRISP)

- Allows subscriptions to a variety of e-mail alerts
- Located on main tool bar



- Includes:
 - Enrollment Updates: multi-step enrollments, accrual updates and step changes
 - Person Roster: changes at selected rosters
 - Protocol Updates: protocols in selected area of interest
 - Regulatory Updates: expiring approvals, changes site registration status, IRB approval received, registration status change on selected protocols

User Experience

DESIGN USER EXPERIENCE Are you using this?

We designed this

Accrual Reports

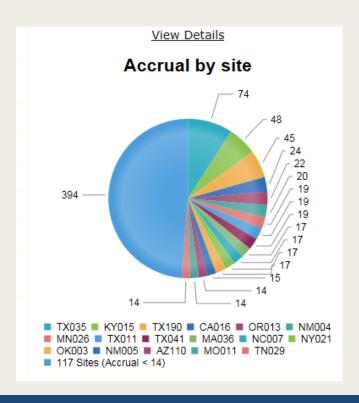
- Located at the bottom of the Protocol Browser Tree
- Categories: NCTN, ETCTN, NCORP and AYA
- Filters: protocol status and phase
- Keyword search
- Group by: study type, disease, Lead Org
- Export to: PDF, CSV or Excel or print

Limited View Reports

- Located under the Reports tab
- Limited to Lead Academic Participating Site (LAPS) sites
- Includes subtabs
 - LAPS Accrual Report: accruals to protocols under the LAPS grant
 - LAPS Budget Analysis: summary of accrual costs and percentages towards grant funding goals

Upcoming Accrual Reports

- Coming Soon Accrual Graph and Details
 - On Protocol-Specific Home Pages



| | ☑ ② Site Accrual Summary | | | | | | |
|----|--------------------------|---|----------------------------|---------------------|-----------------------|----------------------|--|
| # | Site | Site Name | Site Initial Approval Date | Accrual Total* + | Date of First Accrual | Date of Last Accrual | |
| 1 | NY016 | Memorial Sloan Kettering Cancer Center | 22-Jul-2015 | 14 | 06-Aug-2015 | 06-Jun-2017 | |
| 2 | PA075 | University of Pennsylvania/Abramson Cancer Center | 12-Feb-2016 | 9 | 12-Apr-2016 | 07-Jun-2017 | |
| 3 | 41004 | Istituto Nazionale Tumori | 14-Dec-2016 | 5 | 22-Dec-2016 | 23-May-2017 | |
| 4 | GA005 | Emory University/Winship Cancer Institute | 13-Apr-2016 | 4 | 27-Apr-2016 | 15-Feb-2017 | |
| 5 | CA824 | UCSF Medical Center-Mission Bay | 20-Nov-2015 | 3 | 10-May-2016 | 17-Apr-2017 | |
| 6 | CA011 | USC / Norris Comprehensive Cancer Center | 23-Nov-2016 | 2 | 23-Nov-2016 | 03-Mar-2017 | |
| 7 | MO011 | Washington University School of Medicine | 31-Aug-2015 | 2 | 24-Jan-2017 | 20-Mar-2017 | |
| 8 | OH007 | Ohio State University Comprehensive Cancer Center | 13-Jun-2016 | 2 | 31-Oct-2016 | 28-Dec-2016 | |
| 9 | TN024 | Saint Jude Children's Research Hospital | 18-Feb-2016 | 2 | 22-Jul-2016 | 04-Nov-2016 | |
| 10 | IL057 | University of Chicago Comprehensive Cancer Center | 28-Dec-2015 | 1 | 06-Sep-2016 | 06-Sep-2016 | |

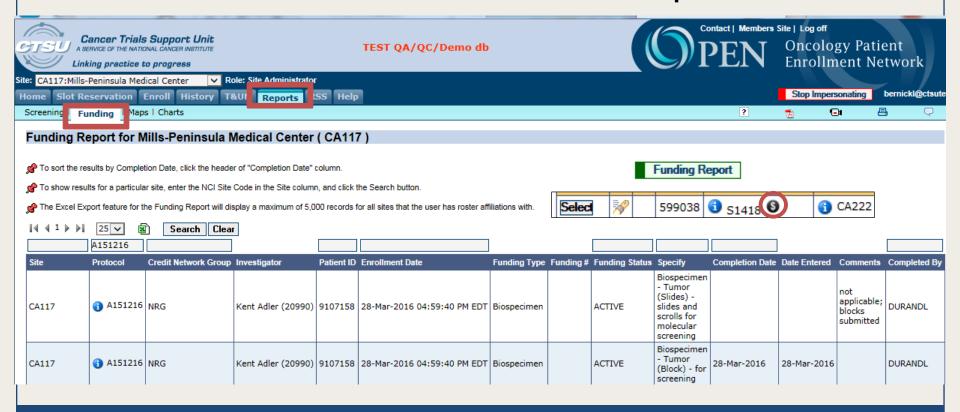
Funding Information (I)

- NCI Funding Sources
 - Lists available funds per protocols
 - Located under funding tab for each protocol

| NCI F | NCI Funding Information (other sources of funding may be available, please review the Funding Documents) | | | | | | | | |
|-------|--|----------------------------------|------------------|---|--------------|---------------|----------------|-------------------|-----------------|
| | | | | | | | Display inac | tive fund | ing also |
| | | | | | | | | | |
| # | Funding Source | Funding Type | Funding Type# | Specify | Collect Type | NCTN \$ Value | NCORP \$ Value | Funding Status | Collect in OPEN |
| 1 | DCTD-DCP | Screening for Intervention | | Pre-Registration - Step 0 | Mandatory | \$1,000.00 | \$1,000.00 | ACTIVE | No |
| 2 | DCTD-DCP | Biospecimen | 1 | Biospecimen - Whole Blood - Step 0 | Optional | \$50.00 | \$50.00 | ACTIVE | Yes |
| 3 | Other Federal | Biospecimen | 2 | Biospecimen - Tissue - Step 0:Biopsy for molecular profiling | Mandatory | \$3,000.00 | \$3,000.00 | ACTIVE | Yes |
| 4 | Other - Non Federal | Non-NCI/DCTD Funding | 2 | Other - Ophthalmologic Exams for Sub protocol H, R, S1, S2, W and Z1A | Conditional | \$250.00 | \$250.00 | ACTIVE | Yes |
| 5 | Other Federal | Biospecimen | 3 | Biospecimen - Tissue - Step 0:Re-biopsy if initial biopsy not adequate | Conditional | \$3,000.00 | \$3,000.00 | ACTIVE | Yes |
| 6 | Other - Non Federal | Non-NCI/DCTD Funding | 4 | Other - Echocardiograms for Sub protocol H, R, S1, S2, W and Z1A | Conditional | \$750.00 | \$750.00 | ACTIVE | Yes |
| 7 | DCTD-DCP | Base Intervention | | Step 1 | Mandatory | \$1,750.00 | \$2,000.00 | ACTIVE | No |
| 8 | DCTD-DCP | High Performance Intervention | | LAPS or HP NCORP - Step 1 | Mandatory | \$3,500.00 | \$3,500.00 | ACTIVE | No |
| 9 | DCTD-DCP | Biospecimen | 1 | Biospecimen - Whole Blood - Step 1: Blood Collection @ end of cycle2 or patient progress or tx discontinue prior to cycle 3 | Optional | \$50.00 | \$50.00 | ACTIVE | Yes |
| 10 | Other - Non Federal | Non-NCI/DCTD Funding | 1 | Other - Glucometer for subprotocol L | Mandatory | \$200.00 | \$200.00 | ACTIVE | Yes |

Funding Information (2)

- OPEN Funding Reports
 - Reimbursements for QOL and Biospecimens



Regulatory Tab

- Site Registration view regulatory status by site
- Protocol Requirements view protocol specific requirements (PSR) by study
- Regulatory Submissions track processing status of regulatory submissions
- CIRB Site Preferences view application of CIRB approval across affiliated sites
- Provider Association view aligned radiation/imaging providers

Roster Information

- Person and Org Roster Browser
- View persons and org rosters associated with affiliated sites for the NCTN, ETCTN, CITN, and CIRB
 - Filter on site, role, and CTEP status
- Perform following actions
 - Add/Remove role
 - Add/Remove IVR, NPIVR, AP, and A
 - Add affiliate/sub-affiliate sites to rostered swim lane

RUMS – Person Roster Browser

- Use 'i' buttons to view detailed person data
 - Practice sites, IRBs, and HSP/GCP training

| Person Name 🛦 | Registration Type | CTEP ID | CTEP Status |
|---|----------------------|---------|-------------|
| Gerbasio-Stephenson, Andrea | Associate Plus | 537552 | Active |
| 1 Hamilton, Tammy | Associate Plus | 517956 | Active |

- Future enhancements
 - Filter by Registration Type
 - NCI Registration Expiry date in Excel output

User Experience



Data Quality Portal (DQP)

- One Stop Shopping
 - Access all Rave studies
 - Direct link into Rave URLs and directly manage queries/delinquencies
 - Monitor data quality and timeliness
 - Review metrics and performance
- Standardized Experience
 - Consistent experience across LPOs and Rave studies
- Reports and other tools

DQP Metrics and Reports

- Metric Tables
 - Grid/Table layout and export features
- Metric Reports
 - Graphic layout, aging report, and totals by form and site
- Timeliness Reports
 - Quarterly updates for query and timeliness

User Experience



Additional Resources (I)

- Patient Subtab
 - Relocated from Clinical Data Tab (CDT) to Rave/DQP
 - Provides summary of all registration steps
- Study Agent Report
 - Located in Protocol Browser tree
- Tags
 - Upcoming feature which allows you to add notes to the website

Additional Resources (2)

- Other OPEN Reports
 - Screening Log enrollments
 - Accrual Maps and charts

?? Questions ??



Extra Screen Shots

