

SOURCE DOCUMENT PORTAL, CTEP-AERS AND CTSUS WEBSITE UPDATES

OISHI SYMPOSIUM

Agenda

- Source Document Portal (SDP) updates
- CTEP-AERS reminders and notifications
- CTSU Website updates



SOURCE DOCUMENT PORTAL (SDP)

SDP Updates (I)

- General Updates:
 - Improved performance
 - Added Help Topics drop down for each SDP screen
 - Resolved instances where site staff was unable to upload documents on SDP using direct link from Rave

SDP Updates (2)
















- Source Document Portal Screen:
 - Added *Document History* icon which includes details about document upload, triage, who viewed the document, and date viewed
 - Added document *Status* column

Source Document Portal									Upload Document and Details
LPO:	ALLIANCE	Protocol:	A031501	Site:	IL057	Patient:	9114173	Go	
#	LPO	Protocol	Site	Patient	Document Type	Folder Name	Status	Updated By	Updated Date
1	ALLIANCE	A031501	IL057	9114173	Computed Tomography (CT) Report	Baseline	Triaged	Pandit, Suhela S.	04-Jun-2018
2	ALLIANCE	A031501	IL057	9114173	Imaging Technique Report	Baseline	Triaged	Pandit, Suhela S.	04-Jun-2018
3	ALLIANCE	A031501	IL057	9114173	Physician And/Or Health Care Provider Report Or Clinical Note	Baseline	Triaged	Pandit, Suhela S.	30-May-2018
4	ALLIANCE	A031501	IL057	9114173	Pathology Report	Baseline	Triaged	Pandit, Suhela S.	30-May-2018
5	ALLIANCE	A031501	IL057	9114173	Magnetic Resonance Imaging (MRI) Scan Report	Baseline	Triaged	Pandit, Suhela S.	30-May-2018
6	ALLIANCE	A031501	IL057	9114173	Laboratory Test Report	Baseline	Triaged	Pandit, Suhela S.	30-May-2018
7	ALLIANCE	A031501	IL057	9114173	Laboratory Test Report	Baseline	Uploaded	Pandit, Suhela S.	30-May-2018

SDP Updates (3)

- Expected Documents Screen:
 - Added *Document History* icon
 - Added query icon for rejected documents
 - Added *Expected Date* column
 - Added *Uploaded?* column to indicate whether or not document is uploaded
 - Added *Action* column which displays
 - Blue icon to display data points to be reviewed using this document
 - Green icon to upload documents
 - Documents identified as not expected by the Lead Protocol Organization can be viewed by clicking on the *Documents Not Expected* link

Expected Documents Screen

Expected Documents								
Protocol: A031501 Site: IL057 Patient: 9114174								
Documents Not Expected								
 1 11								
#	Protocol	Site	Patient	Document Type	Visit Type	Expected Date ▲	Uploaded?	Action
1	A031501	 IL057	 9114174	Pathology Report	Baseline	21-May-2018		
2	A031501	 IL057	 9114174	 Informed Consent	Baseline	21-May-2018	Yes	
3	A031501	 IL057	 9114174	Physician And/Or Health Care Provider Report Or Clinical Note	Baseline	21-May-2018		
4	A031501	 IL057	 9114174	Laboratory Test Report 	Baseline	21-May-2018		



CTEP-AERS INTEGRATION

Data Flow: Rave to CTEP-AERS (I)

- Sites enter Adverse Event (AE) data in Rave and submit to CTEP-AERS rules engine for expedited reporting evaluation
- All AE data in Rave will be pushed to CTEP-AERS unless an AE has an open query
- CTEP-AERS returns a report recommendation to Rave (CREATE or NONE)
- A direct link is available in Rave to automatically log into CTEP-AERS if a report is recommended

Data Flow: Rave to CTEP-AERS (2)

- In CTEP-AERS, the AE data that is pushed from Rave will be viewable but not modifiable
 - Modifications to AE data will be made in Rave since it is the data source
 - Any data modified in Rave will require the rules evaluation to be run again
 - This will cause the updated data to be pushed into CTEP-AERS
 - AE Start Date and End Date/Ongoing are required in Rave for specific protocols
 - CTEP guidance for recording Adverse Event Start and End Dates in Rave is available on CTSU.org

Rave Reminders

- AE data should be entered in Rave and sent for Rules Evaluation (RE) at the time the AE is known/reported
- If the recommendation from the RE is to report, then click the direct link in Rave to access CTEP-AERS to complete the expedited reporting
 - A warning will appear when first logging into CTEP-AERS if the report was initiated in CTEP-AERS prior to reporting and RE in Rave
- AE data should be updated in Rave, not in CTEP-AERS
 - Data entered in Rave will be passed to CTEP-AERS and will only be editable in Rave
 - A field that is entered first in CTEP-AERS and then later in Rave could result in reconciliation issues as data in CTEP-AERS cannot synchronize with Rave once the expedited report has been submitted to NCI
- If entering a verbatim term in Rave, do not use special characters (e.g., &)

Site Notifications (Late RE Call)

- Anytime a modification is made to the AE form (insert, modify, delete) a query will be opened on the Expedited Reporting Evaluation form (*Send all AEs to rules evaluation*)
- If the query on the Expedited Reporting Evaluation form remains open for longer than 24 hours, an email notification is sent to the person who last modified the AE form
- The email notification states that the AEs were automatically sent to rules evaluation by the system and asks the recipient to review the recommendation on the Expedited Reporting Evaluation form

Site Notifications (Late Report Initialization)

- Anytime a recommendation to CREATE a report is generated and displayed on the Expedited Reporting Evaluation form, the site staff must initialize the report in CTEP-AERS in a timely manner
 - If the Investigator feels the recommendation is not warranted per the Protocol, override the recommendation by updating CREATE to NONE in Rave and do not initialize the report in CTEP-AERS
- If the report is not initialized, and the Investigator has not overridden the recommendation, an email notification is sent to the person who last modified the AE form
- The email notification states that there is a recommendation to report but no expedited report has been initialized in CTEP-AERS



WEBSITE UPDATES & NEW TOOLS

Home Tab (I)

- The Home page subtabs have been redesigned and moved to the center of the page
- Document Search, DSN Search, and DSN File Bucket have also been redesigned to be subtabs

The screenshot displays the CTSU Home Tab interface. At the top, a navigation bar includes links for Home, Protocols, Dashboard, Regulatory, OPEN, Data Management, Auditing & Monitoring, RUMS, Delegation Log, Resources, and Collaboration. Below this, a row of subtabs is highlighted with a red box: Protocol Updates, CIRB Updates, LPO Updates, Broadcast/Newsletter, Document Search, DSN Search, and DSN File Bucket. The main content area shows a table of updates with columns for Date, Protocol, and Update. The table lists 25 items, including action letters, amendments, and memorandums. A sidebar on the right displays tweets from the Cancer Trials Support Unit (@TheCTSU), mentioning temporary closures of trials ARST1431 and A051301.

#	Date	Protocol	Update
1	28-Aug-2018	10129	Action Letter for Olaparib (AZD2281)
2	28-Aug-2018	10129	Amendment #2
3	28-Aug-2018	9825	Action Letter for Olaparib (AZD2281)
4	28-Aug-2018	9825	Amendment #12
5	28-Aug-2018	9984	Action Letter for Olaparib (AZD2281)
6	28-Aug-2018	9984	Amendment #6
7	28-Aug-2018	10020	Action Letter for Olaparib (AZD2281)
8	28-Aug-2018	10020	Amendment #9
9	28-Aug-2018	EAQ152	Memorandum: Addendum #6 (Version Date: 06/18/18) Activation
10	28-Aug-2018	EAQ152	Memorandum: Protocol Notice: EAQ152 (COMET) Addendum #6 Activation
11	28-Aug-2018	10031	Action Letter for Olaparib (AZD2281)
12	28-Aug-2018	10031	Amendment #8
13	28-Aug-2018	ARST1431	Memorandum: Patient/Family Letter
14	28-Aug-2018	ARST1431	Memorandum: Results from EpSSG RMS 2005 and ARST0531 and Implications for ARST1431
15	28-Aug-2018	9881	Action Letter for Olaparib (AZD2281)
16	28-Aug-2018	9881	Amendment #9
17	27-Aug-2018	NRG-BR002	Memorandum: Amendment #4 and Amendment #5
18	27-Aug-2018	NRG-BN003	Memorandum: Amendment #1
19	27-Aug-2018	A041202	Memorandum: Data Cleaning
20	27-Aug-2018	10132	Memorandum: 10132 - Notice of Requirement of Site Initiation Visit Conference Call
21	27-Aug-2018	A051301	A051301 Temporary Suspension
22	24-Aug-2018	10010	Memorandum: Teleconference Minutes - 06/26/18
23	24-Aug-2018	10030	10030 Investigator Teleconference Minutes- 08/24/18
24	24-Aug-2018	10021	Memorandum: Colorectal Cancer Cohort Permanent Closure
25	24-Aug-2018	10106	Memorandum: Site Initiation Visit - Protocol Specific Requirement

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Tweets by @TheCTSU

Cancer Trials Support Unit @TheCTSU
A051301 is temporarily closed to accrual effective 8/24/18. View the full memorandum in Protocol Updates on the CTSU members' homepage at ctsus.org (log in required).
Aug 27, 2018

Cancer Trials Support Unit @TheCTSU
ARST1431 is temporarily closed to accrual effective 8/22/18. View the full memorandum in Protocol Updates on the CTSU members' homepage at ctsus.org (log in required).
Aug 23, 2018

Cancer Trials Support Unit @TheCTSU
The CTSU website release 6.9.2 on 8/21/2018 includes Source Document Portal (SDP) updates/enhancements. A list of all the updates/enhancements are in the 8/22 @theCTSU Bi-Monthly Broadcast. Please visit ctsus.org, log in and click on the Broadcast/Newsletter tab.
Aug 23, 2018

Cancer Trials Support Unit Retweeted
NCI CTEP Clinical Research @NCICTEP_ClinRes

Home Tab (2)

- The CTSU Twitter feed has been added

The screenshot shows the CTSU website Home tab. The top navigation bar includes links for Home, Protocols, Dashboard, Regulatory, OPEN, Data Management, Auditing & Monitoring, RUMS, Delegation Log, Resources, and Collaboration. The main content area is titled "News and Announcements" and contains a section for "CTS National Coverage Analysis Webinar - Session 1 and 2". Below this is a "Disease Portfolio Tab" section with a table of updates.

#	Date	Protocol	Update
1	28-Aug-2018	9984	Action Letter for Olaparib (AZD2281)
2	28-Aug-2018	9984	Amendment #6
3	28-Aug-2018	10020	Action Letter for Olaparib (AZD2281)
4	28-Aug-2018	10020	Amendment #9
5	28-Aug-2018	EAQ152	Memorandum: Addendum #6 (Version Date: 06/18/18) Activation
6	28-Aug-2018	EAQ152	Memorandum: Protocol Notice: EAQ152 (COMET) Addendum #6 Activation
7	28-Aug-2018	10031	Action Letter for Olaparib (AZD2281)
8	28-Aug-2018	10031	Amendment #8
9	28-Aug-2018	ARST1431	Memorandum: Patient/Family Letter
10	28-Aug-2018	ARST1431	Memorandum: Results from EPOS5, RMS 2005 and ARST0531 and Implications for ARST1431
11	28-Aug-2018	9981	Action Letter for Olaparib (AZD2281)
12	28-Aug-2018	9981	Amendment #9
13	27-Aug-2018	NRG-BR002	Memorandum: Amendment #4 and Amendment #5
14	27-Aug-2018	NRG-BN003	Memorandum: Amendment #1
15	27-Aug-2018	A041202	Memorandum: Data Cleaning
16	27-Aug-2018	10132	Memorandum: 10132 - Notice of Requirement of Site Initiation Visit Conference Call
17	27-Aug-2018	A051301	A051301 Temporary Suspension
18	24-Aug-2018	10010	Memorandum: Teleconference Minutes - 06/26/18
19	24-Aug-2018	10030	10030 Investigator Teleconference Minutes - 08/24/18
20	24-Aug-2018	10021	Memorandum: Colorectal Cancer Cohort Permanent Closure
21	24-Aug-2018	10106	Memorandum: Site Initiation Visit - Protocol Specific Requirement
22	23-Aug-2018	51609	51609 - Memorandum: Reactivation of Cohort 16
23	23-Aug-2018	10150	Memorandum: Notice of Requirement of Site Initiation Visit Conference Call
24	23-Aug-2018	NSABP-B-55	Memorandum: NSABP-B-55 WebEx Reminder - Registration Deadline!
25	23-Aug-2018	ARST1431	Memorandum: Temporary Closure

The screenshot shows a Twitter feed titled "Tweets by @TheCTSU". It contains three tweets:

- Cancer Trials Support Unit @TheCTSU**: ARST1431 is temporarily closed to accrual effective 8/22/18. View the full memorandum in Protocol Updates on the CTSU members' homepage at ctsus.org (log in required).
Aug 23, 2018
- Cancer Trials Support Unit @TheCTSU**: The CTSU website release 6.9.2 on 8/21/2018 includes Source Document Portal (SDP) updates/enhancements. A list of all the updates/enhancements are in the 8/22 @theCTSU Bi-Monthly Broadcast. Please visit ctsus.org, log in and click on the Broadcast/Newsletter tab.
Aug 23, 2018
- NCI CTEP Clinical Research @NCICTEP_ClinRes**: Check out this newly reactivated #ancsm #immunotherapy #oncology #cancertrial (NCI: 9673) led by @CathyEngMD @MDAndersonNews and sponsored by the #NCICTEP #ETCTN. For more information, visit: bit.ly/2OWohVL.
Aug 23, 2018

- The Quick Links tab has been removed

Protocols Tab

- Study Champion information appears in the Protocols>Home subtabs

CTSU Cancer Trials Support Unit
A SERVICE OF THE NATIONAL CANCER INSTITUTE

My Notes | Home | Contact | Feedback | Public Site | Log Out
Version: 6.9.2.0

My Account | CRISP | Welcome Demetrius Williams. Your password will expire in 3 days. Impersonate another user

Search for... Go!

Home | Protocols | Dashboard | Regulatory | OPEN | Data Management | Auditing & Monitoring | RUMS | Delegation Log | Resources | Collaboration

Home | Funding Information | Documents | Drug Safety Notification | Study Agent | Protocol Requirements

NCI National Clinical Trials Network EA3163 My Notes (1) IRBManager Add to My Protocols

Phase II Randomized Trial of Neo-Adjuvant Chemotherapy Followed by Surgery and Post-Operative Radiation Versus Surgery and Post-Operative Radiation for Organ Preservation of T3 and T4a Nasal and Paranasal Sinus Squamous Cell Carcinoma (NPNSCC)

Protocol Status: ACTIVE
Protocol Status Date: 28-Mar-2018
Activation Date: 28-Mar-2018
Lead Organization: ECOG-ACRIN
NCI Program: NCTN
Phase: II
CIRB Reviewed: Yes
Country Participation:

Accrual: Target (Intervention): 134
Total (Intervention): 0 (In OPEN: 0)
As of: 28/Aug/18

Study Champions: Samuels, A. Michael **NRG** Yarbrough, Gray Wendell **SWOG** Ho, Loh Alan **ALLIANCE**

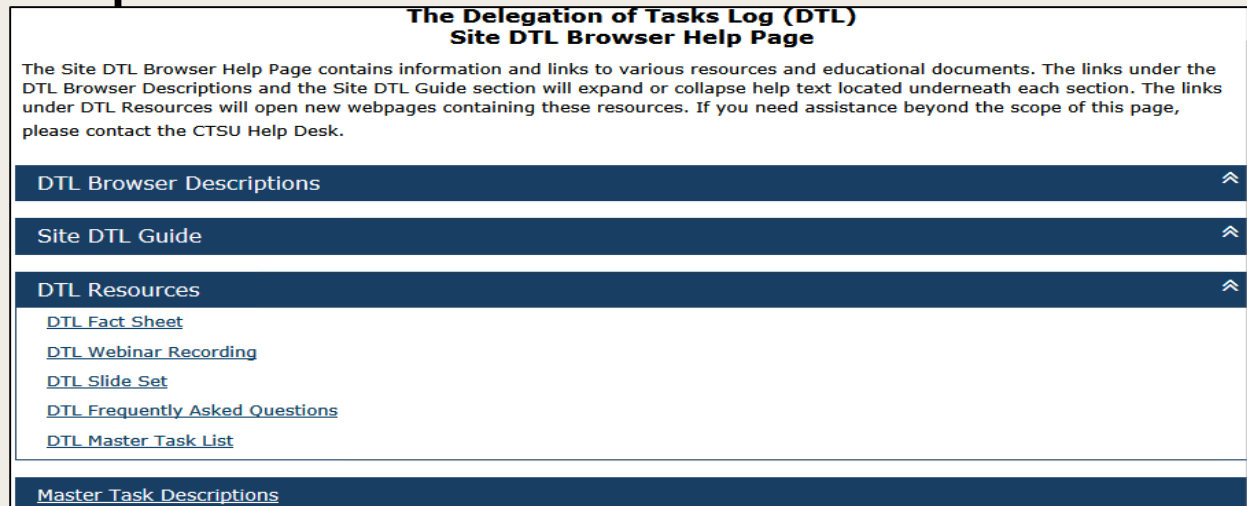
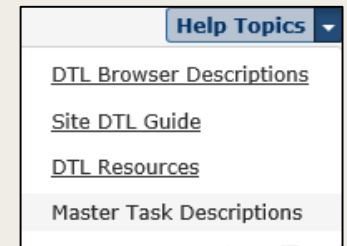
Participation: Participation Information

#	Participant	Role Type	Participation Type	Start Date
1	ALLIANCE	ALL	CROSS-NETWORK	23-Jan-2018
2	NRG	ALL	CROSS-NETWORK	23-Jan-2018
3	SWOG	ALL	CROSS-NETWORK	23-Jan-2018
4	ECOG-ACRIN	ALL	LEAD	19-Jun-2017

- When persons click on a protocol link from other systems to the CTSU Members' website protocol page, messages will now display if individuals do not have privileges for accessing a protocol page or the study is invalid.

Help Topics Button

- Currently on Delegation Tab, RUMS Tab, and the Source Document Portal (SDP)
 - Select drop downs to navigate topics
 - Click button to open entire help page, sections expand and collapse
- Will eventually replace help icons on all webpages



Helpful New Tools (I)

- Translated Short Form Consents

Data Management ▾ Auditing & Monitoring ▾ RUMS ▾ Delegation Log ▾ Resources ▾ Collaboration	
Translated Short Form Consents	
#	Title
1	CIRB Approval of English and Translated Short Form Consents ★★
2	Arabic - Short Form Consent ★★
3	Arabic - Certificate of Accuracy ★★
4	Arabic - CIRB Approval Worksheet ★★
5	Creole (Haitian) - Short Form Consent ★★
6	Creole (Haitian) - Certificate of Accuracy ★★
7	Creole (Haitian) - CIRB Approval Worksheet ★★
8	English - Short Form Consent, FOR REFERENCE ONLY ★★
9	French - Short Form Consent ★★
10	French - Certificate of Accuracy ★★
11	French - CIRB Approval Worksheet ★★
12	German - Short Form Consent ★★
13	German - Certificate of Accuracy ★★
14	German - CIRB Approval Worksheet ★★
15	Italian - Short Form Consent ★★
16	Italian - Certificate of Accuracy ★★
17	Italian - CIRB Approval Worksheet ★★
18	Korean - Short Form Consent ★★
19	Korean - Certificate of Accuracy ★★
20	Korean - CIRB Approval Worksheet ★★
21	Portuguese Brazil - Short Form Consent ★★
22	Portuguese Brazil - Certificate of Accuracy ★★
23	Portuguese Brazil - CIRB Approval Worksheet ★★
24	Russian - Short Form Consent ★★
25	Russian - Certificate of Accuracy ★★
26	Russian - CIRB Approval Worksheet ★★
27	Spanish - Short Form Consent ★★
28	Spanish - Certificate of Accuracy ★★

Helpful New Tools (2)

- Disease Portfolios

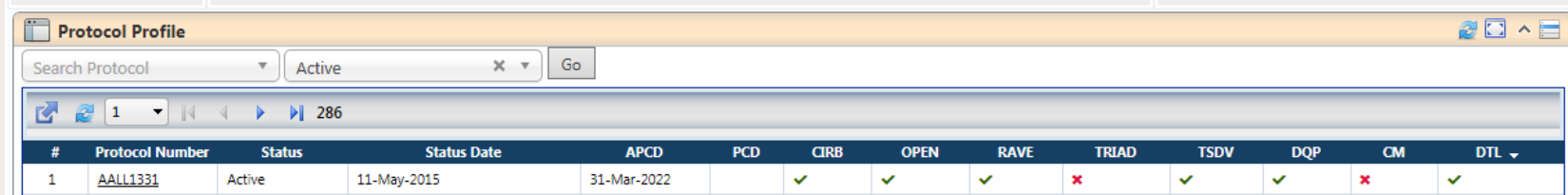
Data Management ▾ Auditing & Monitoring ▾ RUMS ▾ Delegation Log ▾ Resources ▾ Collaboration	
Disease Portfolios	
#	Title
NCTN	
1	Brain Cancer Trials Portfolio ★
2	Breast Cancer Trials Portfolio ★
3	Gastrointestinal Cancer Trials Portfolio ★
4	Genitourinary Cancer Trials Portfolio ★
5	Gynecologic Cancer Trials Portfolio ★
6	Head and Neck Cancer Trials Portfolio ★
7	Leukemia Cancer Trials Portfolio ★
8	Lung Cancer Trials Portfolio ★
9	Lymphoma Cancer Trials Portfolio ★
10	Skin (Mainly Melanoma) Cancer Trials Portfolio ★
11	Adolescent and Young Adult (AYA) Cancer Trials Portfolio ★
ETCTN	
1	Brain Cancer Trials Portfolio ★
2	Breast Cancer Trials Portfolio ★
3	Gastrointestinal Cancer Trials Portfolio ★
4	Genitourinary Cancer Trials Portfolio ★
5	Gynecologic Cancer Trials Portfolio ★
6	Head and Neck Cancer Trials Portfolio ★
7	Leukemia Cancer Trials Portfolio ★
8	Lung Cancer Trials Portfolio ★
9	Lymphoma Cancer Trials Portfolio ★
10	Myeloma Cancer Trials Portfolio ★
11	Radiation Cancer Trials Portfolio ★
12	Sarcoma Cancer Trials Portfolio ★
13	Skin and Other Melanoma Cancer Trials Portfolio ★
14	Solid Tumors Cancer Trials Portfolio ★
15	Solid Tumors Expansion Studies Cancer Trials Portfolio ★

Helpful New Tools (3)

- Changes to Org Roster “i” Button in RUMS
 - View public contact and site type
 - Instructions for updating
 - View primary contacts

Helpful New Tools (4)

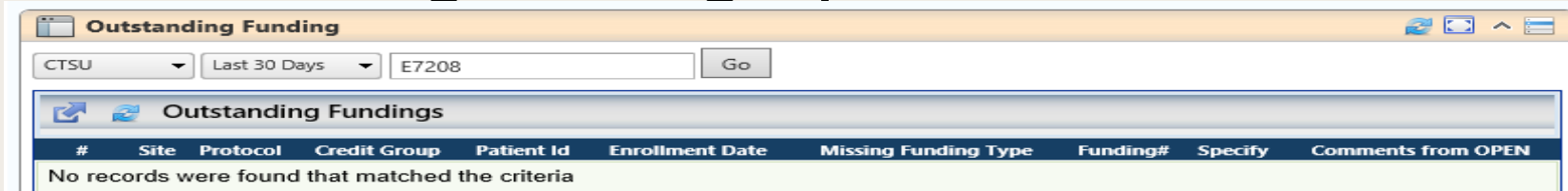
- Protocol Profile Portlet in the Dashboard (part of the protocol profile)



The screenshot shows the 'Protocol Profile' portlet. It has a search bar with 'Active' selected and a 'Go' button. Below the search bar is a table with 14 columns: #, Protocol Number, Status, Status Date, APCD, PCD, CIRB, OPEN, RAVE, TRIAD, TSDV, DQP, CM, and DTL. The table contains one row with the following data:

#	Protocol Number	Status	Status Date	APCD	PCD	CIRB	OPEN	RAVE	TRIAD	TSDV	DQP	CM	DTL
1	AALL1331	Active	11-May-2015	31-Mar-2022		✓	✓	✓	✗	✓	✓	✗	✓

- Outstanding Funding Updates



The screenshot shows the 'Outstanding Funding' portlet. It has a search bar with 'CTSU' selected, a date range of 'Last 30 Days', and a text input 'E7208'. Below the search bar is a table with 10 columns: #, Site, Protocol, Credit Group, Patient Id, Enrollment Date, Missing Funding Type, Funding#, Specify, and Comments from OPEN. The table contains one row with the following data:

#	Site	Protocol	Credit Group	Patient Id	Enrollment Date	Missing Funding Type	Funding#	Specify	Comments from OPEN
No records were found that matched the criteria									

- Subscribe to the new CRISP notification to alert you to new protocol document postings

Passwords are like your pants



- DO change them regularly
- DON'T leave them on your desk
- DON'T share them with anyone

www.bluespotcomputers.com

Please do not share your CTEP IAM password

?? Questions ??

