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# **SOURCE DOCUMENT PORTAL, CTEP-AERS AND CTSU WEBSITE UPDATES**

**OISHI SYMPOSIUM**

# Agenda

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



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# **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:  Protocol:  Site:  Patient:

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

#	Protocol	Site	Patient	Document Type	Visit Type	Expected Date ▲	Uploaded?	Action
1	<a href="#">A031501</a>	<a href="#">IL057</a>	<a href="#">9114174</a>	Pathology Report	Baseline	21-May-2018		
2	<a href="#">A031501</a>	<a href="#">IL057</a>	<a href="#">9114174</a>	<a href="#">Informed Consent</a>	Baseline	21-May-2018	Yes	
3	<a href="#">A031501</a>	<a href="#">IL057</a>	<a href="#">9114174</a>	Physician And/Or Health Care Provider Report Or Clinical Note	Baseline	21-May-2018		
4	<a href="#">A031501</a>	<a href="#">IL057</a>	<a href="#">9114174</a>	Laboratory Test Report	Baseline	21-May-2018		



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# 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](http://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



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# **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 shows the CTSU Home page with a navigation bar at the top containing: Home, Protocols, Dashboard, Regulatory, OPEN, Data Management, Auditing & Monitoring, RUMS, Delegation Log, Resources, and Collaboration. Below this is a row of subtabs: Protocol Updates, CIRB Updates, LPO Updates, Broadcast/Newsletter, Document Search, DSN Search, and DSN File Bucket. The 'Protocol Updates' subtab is active, displaying a table with 662 items. The table has columns for #, Date, Protocol, and Update. The first few rows are:

#	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

At the bottom of the table, it says 'Page 1 of 27' and 'Last update: 8:07:50 PM UTC'. To the right of the table is a 'Tweets by @TheCTSU' section with three tweets from the Cancer Trials Support Unit (@TheCTSU) regarding protocol updates and website changes.

# Home Tab (2)

- The CTSU Twitter feed has been added

The screenshot shows the CTSU website home page. At the top, there are navigation tabs: Home, Protocols, Dashboard, Regulatory, OPEN, Data Management, Auditing & Monitoring, RUMS, Delegation Log, Resources, and Collaboration. Below these is a 'News and Announcements' section with a link to 'CTSUs National Coverage Analysis Webinar - Session 1 and 2'. A 'Disease Portfolio Tab' section is also visible. The main content area features a table with columns for '#', 'Date', 'Protocol', and 'Update'. A red box highlights a new 'Tweets' tab that has been added to the navigation bar.

#	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 EPSSG 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	51409	51409 - 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 for the CTSU. The top tweet is from @TheCTSUs, stating that ARST1431 is temporarily closed to accrual effective 8/22/18. The second tweet is also from @TheCTSUs, announcing a website release 6.9.2 on 8/21/2018. The third tweet is a retweet from @NCICTEP\_ClinRes, promoting a newly reactivated clinical trial (#ancsm) led by @CathyEngMD. The ETCTN logo is visible at the bottom of the feed.

- The Quick Links tab has been removed



# Protocols Tab

- Study Champion information appears in the Protocols>Home subtabs

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

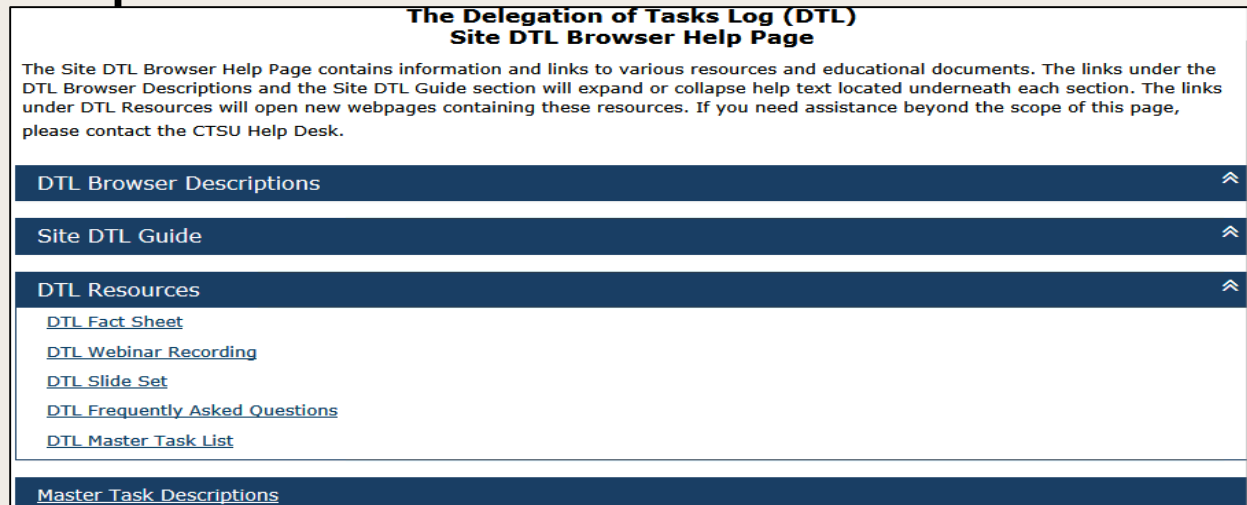
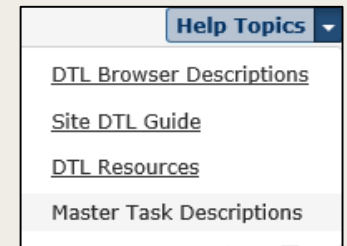
**Participation:** [Participation Information](#)

#	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

#	Title
1	<a href="#">CIRB Approval of English and Translated Short Form Consents</a> ★★
2	<a href="#">Arabic - Short Form Consent</a> ★★
3	<a href="#">Arabic - Certificate of Accuracy</a> ★★
4	<a href="#">Arabic - CIRB Approval Worksheet</a> ★★
5	<a href="#">Creole (Haitian) - Short Form Consent</a> ★★
6	<a href="#">Creole (Haitian) - Certificate of Accuracy</a> ★★
7	<a href="#">Creole (Haitian) - CIRB Approval Worksheet</a> ★★
8	<a href="#">English - Short Form Consent, FOR REFERENCE ONLY</a> ★★
9	<a href="#">French - Short Form Consent</a> ★★
10	<a href="#">French - Certificate of Accuracy</a> ★★
11	<a href="#">French - CIRB Approval Worksheet</a> ★★
12	<a href="#">German - Short Form Consent</a> ★★
13	<a href="#">German - Certificate of Accuracy</a> ★★
14	<a href="#">German - CIRB Approval Worksheet</a> ★★
15	<a href="#">Italian - Short Form Consent</a> ★★
16	<a href="#">Italian - Certificate of Accuracy</a> ★★
17	<a href="#">Italian - CIRB Approval Worksheet</a> ★★
18	<a href="#">Korean - Short Form Consent</a> ★★
19	<a href="#">Korean - Certificate of Accuracy</a> ★★
20	<a href="#">Korean - CIRB Approval Worksheet</a> ★★
21	<a href="#">Portuguese Brazil - Short Form Consent</a> ★★
22	<a href="#">Portuguese Brazil - Certificate of Accuracy</a> ★★
23	<a href="#">Portuguese Brazil - CIRB Approval Worksheet</a> ★★
24	<a href="#">Russian - Short Form Consent</a> ★★
25	<a href="#">Russian - Certificate of Accuracy</a> ★★
26	<a href="#">Russian - CIRB Approval Worksheet</a> ★★
27	<a href="#">Spanish - Short Form Consent</a> ★★
28	<a href="#">Spanish - Certificate of Accuracy</a> ★★

# Helpful New Tools (2)

- Disease Portfolios

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

# 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)

#	Protocol Number	Status	Status Date	APCD	PCD	CIRB	OPEN	RAVE	TRIAD	TSDV	DQP	CM	DTL
1	<a href="#">AALL1331</a>	Active	11-May-2015	31-Mar-2022		✓	✓	✓	✗	✓	✓	✗	✓

- Outstanding Funding Updates

#	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](http://www.bluespotcomputers.com)

**Please do not share your CTEP IAM password**

# ?? Questions ??

