NCI National Clinical Trials Network
a National Cancer Institute program

Clinical Trials Monitoring Branch Audit Guidelines

Targeted Source Data Verification & the Site Audit Portal

Transcript:

Clinical Trials Monitoring Branch Audit Guidelines - Targeted Source Data Verification and Site Audit Portal: This module provides an overview of the processes surrounding the use of targeted source data verification (TSDV) in Medidata Rave, as well as information on the Site Audit Portal (SAP). Note that this module does not include step-by-step instructions for conducting TSDV but will tell you where those instructions are available in later screens.

Introduction to Targeted Source Data Verification

- Source data verification (SDV) is the process where submitted data is compared to source documentation to ensure accuracy.
- Many NCI trials are set up for SDV to be conducted and documented *electronically within Medidata Rave*, the application where site staff enter and manage patient data and auditors review data.
- *Targeted* SDV (TSDV) is a process whereby only datapoints considered to be the most important are selected for verification in Rave.

Transcript:

Introduction to Targeted Source Data Verification: An important part of the patient case review component of a site audit is source data verification, or SDV, where submitted data are compared to source documentation to ensure accuracy.

Many NCI trials are set up for this process to be conducted and documented electronically within Medidata Rave, the application where site staff enter and manage patient data and auditors review data.

Targeted SDV, or TSDV, is a process whereby only datapoints considered to be the most important are selected for verification in Rave.

Introduction to TSDV (cont.)

- The TSDV process is accomplished through integrations between several NCI systems, including:
  - The Clinical Trials Monitoring Branch Audit Information System (CTMB-AIS), where auditing organization staff set up and manage audits;
  - Medidata Rave; and
  - The Site Audit Portal (SAP) on the Cancer Trials Support Unit (CTSU) website.

Transcript:

The TSDV process is accomplished through integrations between several NCI systems, including the Clinical Trials Monitoring Branch Audit Information System (CTMB-AIS), where auditing organization staff set up and manage audits, Medidata Rave, which contains a TSDV module, and the Site Audit Portal (SAP) on the Cancer Trials Support Unit (CTSU) website, at www.CTSU.org.

Introduction to the SAP

The SAP:

- Allows auditors to view information for audits with which they are associated;
- Manages auditor roles and audit activity for studies in Rave;
- Provides deep links for auditors to access patient data in Rave, site Delegation of Tasks Logs (DTLs), and source documents in the Source Document Portal (SDP) (for remote audits); and
- Records TSDV activity performed in Rave.

Transcript:

Introduction to the SAP: The SAP serves as a location where you can view information on your audits. It manages auditor roles and activity and provides direct access to patient data in Rave, applicable Delegation of Tasks Logs (DTLs), and patient source documentation in the CTSU Source Document Portal (SDP) when necessary for remote audits. It offers a single platform that records TSDV activity performed in Rave and helps to manage all steps in the audit process behind the scenes.

Who Can Access the SAP?

To access the SAP:

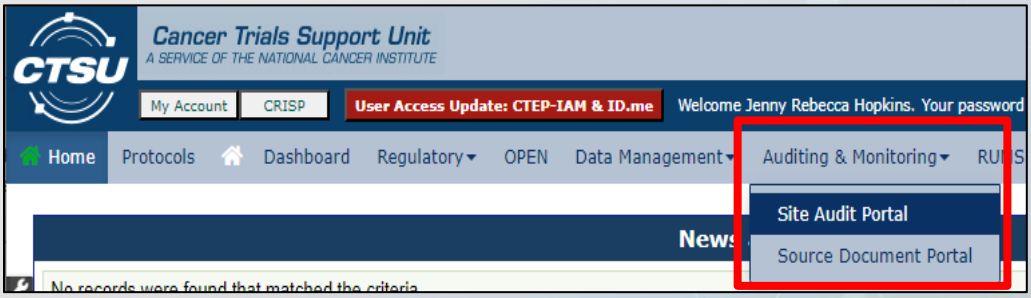
- You must work directly for an auditing organization or Lead Protocol Organization (LPO) and have the *Auditor* role on the CTSU operations roster at that LPO -or-
- If you are not directly employed by an LPO you must be assigned to an audit as a volunteer auditor.

Transcript:

Who can access the SAP: Please note that to access the SAP you must either be an employee of an auditing organization (also known as a Lead Protocol Organization or LPO) and be on the CTSU roster for that organization with the *Auditor* role, or you must be a volunteer auditor assigned to an audit. More about the different types of auditors will be covered in a few screens.

How to Access the SAP

- Log in to the CTSU members' website.
- Click on *Auditing & Monitoring* and select *Site Audit Portal* from the dropdown.

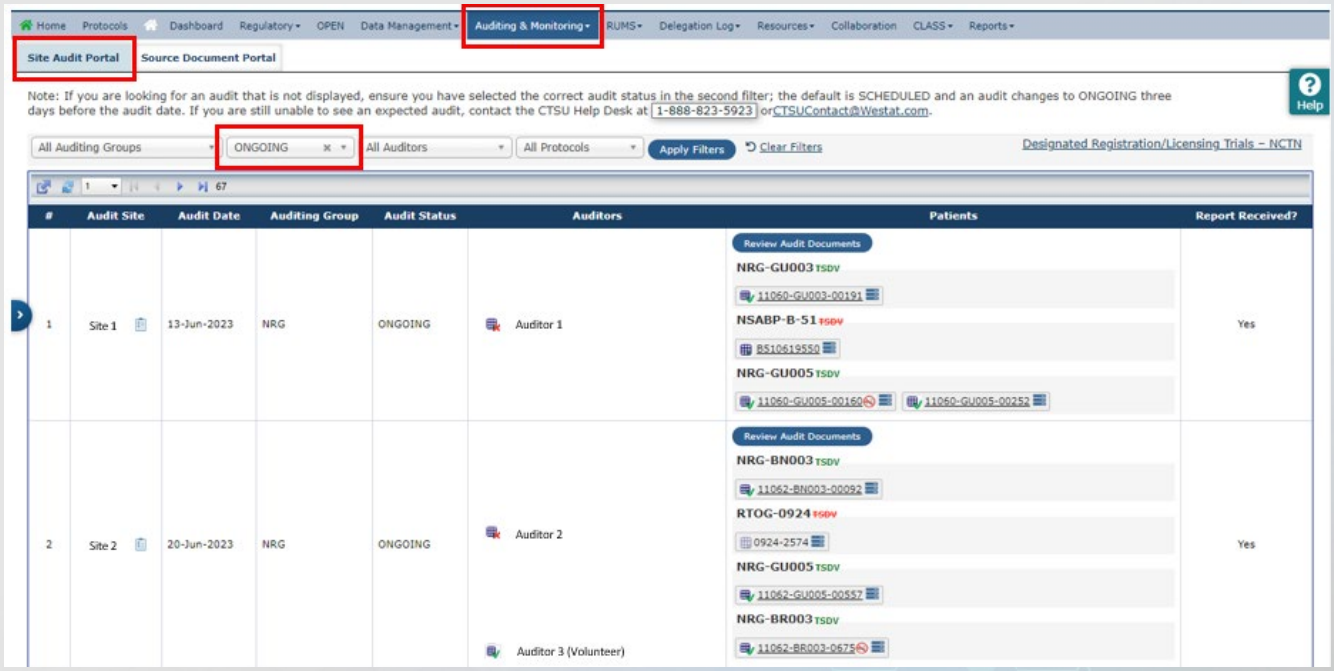


Source: Password-protected website: https://www.ctsu.org.

Transcript:

How to access the SAP: Go to the CTSU website at www.CTSU.org and log in to the members' side of the website. Click on the menu item for "Auditing & Monitoring" and choose "Site Audit Portal."

Sample SAP Screen



Source: Password-protected website: (https://www.ctsu.org).

Transcript:

Sample SAP Screen: This screen provides an example of the SAP on the CTSU website. You can select Scheduled or Ongoing from the second dropdown box (note that the default is Scheduled, and that audits shift from Scheduled to Ongoing about two days prior to the audit date). If you select Ongoing you will see the current audits in a table that displays the name or site code of the audit site, the start date for the audit, the auditing group, the audit status of Ongoing, the names of the auditors assigned to the audit, and the studies and patient cases to be reviewed. You can use the filters at the top to narrow results and can also click on the column headers to sort.

We will revisit this screen later in the training.

Pre-TSDV Activity

The main steps that take place prior to an audit that involves TSDV:

- The auditing organization notifies the site about the audit and agrees on dates.
- The auditing organization initiates the process in CTMB-AIS:
  - Schedules the audit dates; and
  - Selects the auditors, protocols, and patients for the audit (based on the CTMB Audit Guidelines).

Transcript:

Pre-TSDV Activity: These are the main steps involving the SAP, CTMB-AIS, and Rave that take place prior to an audit that involves TSDV.

The auditing organization notifies the site of the need for an audit and agrees on dates and then initiates the process in CTMB-AIS. The auditing organization documents the site and dates, then selects the auditors, protocols, and patients for the audit based on the CTMB Audit Guidelines.

Pre-TSDV Activity (cont.)

Additional steps that take place prior to an audit that involves TSDV:

- Applicable patients (those on a Rave study utilizing TSDV) are automatically assigned to the TSDV module Audit Tier in Rave.
- When appropriate, auditors will be invited to Rave so that they can access the patients' data during the audit.

Transcript:

Pre-TSDV Activity Continued: CTMB-AIS interfaces with Rave, so for studies that are set up for TSDV, the selected patients will be made available in Rave for TSDV, and auditors will be provided access to those patients' data in Rave in an automated fashion.

See the next screens for more information about auditor roles and access to Rave.

TSDV Activities Overview

- Details of the activities surrounding TSDV are dependent on whether an auditor has access to Rave.
- Each auditing organization has its own policy regarding which auditors will be granted access to Rave, and they specify this in CTMB-AIS when setting up each audit.
  - Check with your organization about their policy.

Transcript:

TSDV Activities Overview: Details of the activities that compose the TSDV method are dependent on whether an auditor has access to Rave. Each auditing organization has its own policy regarding which auditors will be granted access to Rave, and they specify this in CTMB-AIS when setting up each audit. If you are unsure about whether you will have access to Rave for audits, check with your organization.

TSDV Activities Overview – With Rave Access

- Auditors **with** access to Rave:
  - Access Rave and carry out TSDV by comparing source documents with the data to be verified as viewed directly in Rave itself; and
  - Record TSDV results directly in Rave.

Transcript:

TSDV Activities Overview – With access to Rave: At a very high level, an auditor with access to Rave will review all source documentation and then compare source documents with the data selected to be verified in Rave. The auditor will then record the results of that review directly in Rave.

The next screen will describe TSDV activities for auditors who do not have access to Rave.

TSDV Activities Overview – No Rave Access

- Auditors **without** access to Rave:
  - Use a Pre-SDV Workbook (an Excel file) or case report form (CRF) printouts that contain all data points that must be verified;
  - Compare source documents at the site with the data to be verified;
  - Record TSDV results in the Pre-SDV Workbook or another document; and
  - Provide the TSDV results to the Lead Auditor. The Lead Auditor or designee at the organization will need to manually enter the auditor's findings into Rave after the audit.

Transcript:

An auditor with no access to Rave needs to use a "Pre-SDV Workbook" created for them to record their patient case findings. This workbook is an Excel file that contains all data points that must be verified and can be used in hard copy or electronically. An alternative is to use printouts of case report forms (CRFs) generated from Rave.

Your organization will provide the Pre-SDV Workbook or printed CRFs. Once you document findings in the workbook or other document, the Lead Auditor or designee will manually enter your findings and activity into Rave after the audit.

It should be noted that use of the Pre-SDV Workbook is discouraged and should be used only for auditors who have not been granted access to Rave.

Auditor Roles Within the System

- You are an ***LPO Auditor*** for a specific patient case if:
  - You audit for (i.e., are employed by) the LPO for that patient's study.
- You are a ***Site Auditor*** for a specific patient case if:
  - You are a volunteer or ad hoc auditor; or
  - You audit for the credited organization, but the patient is enrolled to a study that is led by a different LPO (i.e., a cross-network auditor).

NOTE: You may be an *LPO Auditor* for one patient case and a *Site Auditor* for another patient case! (Unless you are a volunteer auditor – then you are always a *Site Auditor*.)

Transcript:

Auditor Roles Within the System: The SAP will assign you a role of either "LPO Auditor" or "Site Auditor" for each patient case chosen for an audit. Your role for a specific patient case will be "LPO Auditor" if you audit for the LPO of the study that patient is on; in other words, you are employed by the LPO. For instance, you are a SWOG employee, and you are auditing a patient on a SWOG protocol.

Your role for a specific patient case will be called "Site Auditor" if you are a volunteer auditor or if the organization being credited for that patient's enrollment is not the LPO of that study, and you are auditing it for the credited organization (the latter is also called a cross-network auditor). Think of it as being a "guest" auditor, gaining temporary rights to see that patient's data. An example would be if you work for SWOG and are auditing a patient on an Alliance protocol.

If you are a volunteer auditor, your role is "Site Auditor" no matter which study the patient is on. Otherwise, please note that you may be considered an LPO Auditor for one patient case and a Site Auditor for another patient's case.

LPO Auditor Access to Patient Data in Rave

- **LPO Auditors** are assigned to their own organization's studies in Rave by their organization.
  - This is a manual process carried out by LPO staff.
  - Once assigned to a study, an LPO Auditor will be able to view all sites for that study.
  - They will only be able to conduct audit-related tasks (e.g., verifying data in Rave) for a set amount of time around each audit.

Transcript:

LPO Auditor Access to Patient Data in Rave: An LPO Auditor will be assigned to their own organization's studies in Rave by organization staff. This is a manual process carried out by LPO staff, and once assigned to a study, they will be able to view all sites for that study. However, they will only be able to conduct audit-related tasks (e.g., verifying data in Rave) for a set amount of time around each audit.

LPO Auditor Access to Patient Data in Rave (cont.)

- If you are an LPO auditor and do not have access to patients in Rave for your organization's studies, reach out to your organization regarding that access.
  - The CTSU is not able to assist with LPO auditor access to their own studies in Rave.
- LPO Auditors are handled differently when they are auditing patients on studies not led by their own organization.

Transcript:

LPO Auditor Access to Patient Data in Rave, continued: If you are an LPO auditor approaching an audit and find you do not have access to patients in Rave for your organization's studies, reach out to your organization to obtain that access; the CTSU is not able to assist with LPO auditor access to their own studies in Rave.

Of note, LPO Auditors are handled differently when they are auditing patients on studies that aren't led by their own organization. See more about this on the following screens.

Site Auditor Access to Patient Data in Rave

- **Site Auditors** are granted access to patients' data in Rave via an automated process managed through the SAP.
- They receive invitations from iMedidata/Rave and can access *announced patients up to six weeks prior to an audit* and *unannounced patients one business day prior to an audit.*

Transcript:

Site Auditor Access to Patient Data in Rave: If you are a volunteer auditor, or a cross-network LPO auditor for a patient case, you will be granted access to that patient's data in Rave via an automated process managed through the SAP. This process includes the receipt of invitations from iMedidata/Rave up to six weeks prior to an audit for announced patients and one business day prior to an audit for unannounced patients.

Site Auditor Access to Patient Data in Rave (cont.)

- Reminder: Site Auditors include volunteer and cross-network LPO auditors.
- The email invitations go to the auditor's Cancer Therapy Evaluation Program (CTEP) account email address.
- The auditing organization must ensure that the "Rave Access" option has been selected in CTMB-AIS for anyone with the Site Auditor role.
  - If you are unable to access patients in Rave, reach out to your auditing organization first.

Transcript:

Site Auditor Access to Patient Data in Rave, continued: As a reminder, this Site Auditor process applies to both volunteer auditors and cross-network LPO auditors.

Of note, email invitations from Medidata go to the email address associated with the auditor's Cancer Therapy Evaluation Program (CTEP) account.

Note that if the "Rave Access" option for someone with the Site Auditor role has not been checked in CTMB-AIS, Rave access can not be granted until that is fixed. This is something that is handled by the auditing organization. If you don't seem to have access to audit patients in Rave but believe you should, please contact your auditing organization first.

Auditor Invitations to Rave

- **LPO Auditors** will receive invitations from Medidata whenever they are assigned to one of their LPO's studies.
  - The invitation will cover all sites conducting the study.
  - The invitation is good until the assignment is revoked by their organization.
  - No new invitation for every study prior to each separate audit.

Transcript:

The scope of auditor invitations differs depending on whether you are an LPO Auditor or a Site Auditor. (Remember, some auditors may be both during a single audit.) LPO Auditors receive invitations from Medidata when they are first assigned to one of their LPO's studies, so this may occur well before an actual audit.

The assignment and invitation will cover a given study across all sites and will be good until the assignment is revoked by the auditor's organization. This means that an LPO Auditor will not receive a study-specific invitation for every study prior to each separate audit, but instead, just the first time they are assigned to a given study.

The next screen addresses how Site Auditors are invited to studies for an audit.

Auditor Invitations to Rave (cont.)

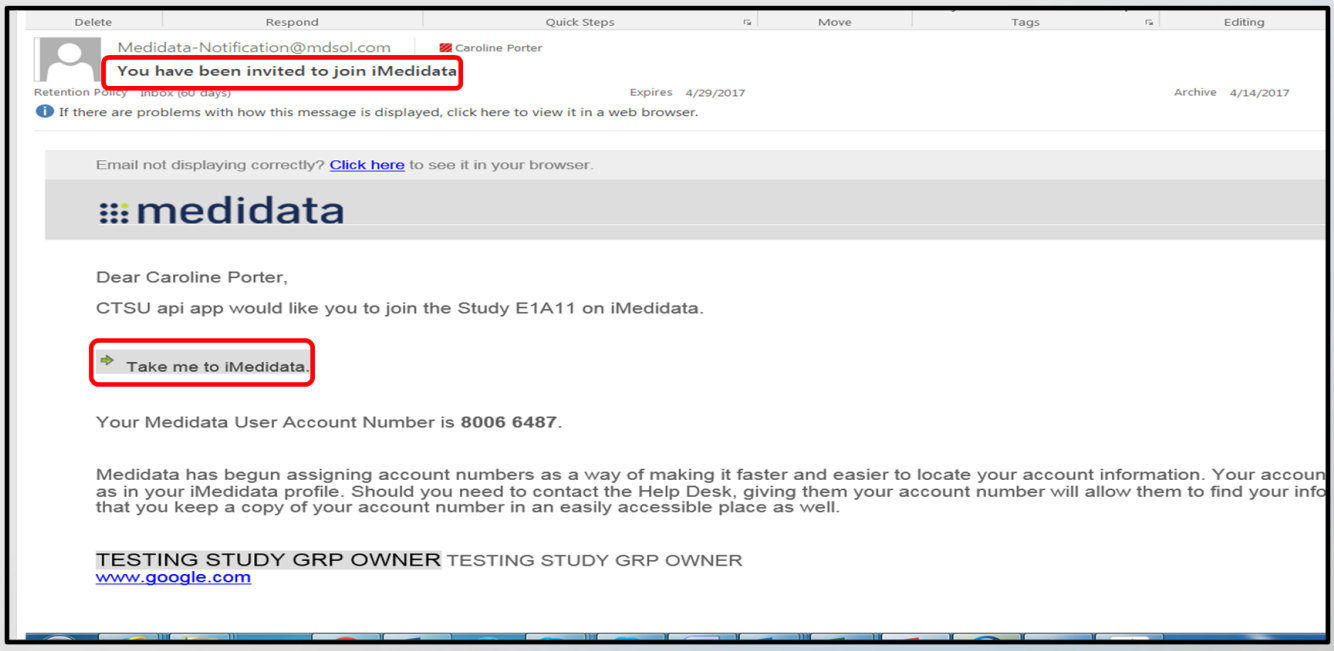
- **Site Auditors** (i.e., volunteer auditors and cross-network auditors) with Rave access will receive invitations from Medidata for the studies/sites involved in each audit.
  - Only good for that audit.

Transcript:

Site Auditors (that is, volunteer auditors and cross-network auditors) with Rave access will receive invitations from Medidata for each study and site involved in a given audit, and the invitation will only be good for that audit. A Site Auditor will receive a separate set of invitations for each audit they conduct, as each audit will involve different study and site combinations.

The next screen shows a sample invitation email.

Sample Email Invitation



Transcript:

This screen shows a sample invitation email. Remember that you may receive multiple emails if there are multiple studies being audited.

The email will come from Medidata, and the subject line will inform you that you have been invited to join iMedidata. The body of the email includes a reference to the study you are being invited to join, and there is a link that reads "Take me to iMedidata." By clicking on that link and signing into iMedidata, you will be able to access the study.

Best Practice – Pre-Audit Checks

To ensure that each audit runs smoothly, the CTSU encourages all auditors, whether they are LPO auditors or volunteer auditors, to view their audit in the SAP and test their access to Rave **in advance of the audit start date.**

- Provides time for troubleshooting.
- Report access issues to your auditing organization first.
- Reach out to the CTSU if additional investigation is required (e.g., invitations were never received for volunteer or cross-network auditors).

Transcript:

Best Practice - Test Rave Access: To ensure that each audit runs smoothly, the CTSU suggests that you view your audit in the SAP as well as test out your Rave access prior to the audit start date. This will allow time if there are any issues with the audit setup or Rave access that require investigation. Report issues to your auditing organization first, and then reach out to the CTSU if necessary (for example if Rave invitations were never received for volunteer or cross-network auditors).

Required Training in Rave

- The first time an auditor accesses Rave to audit, they will be required to complete one or more eLearning modules within iMedidata, regardless of whether they are an LPO Auditor or a Site Auditor.
  - These eLearnings are separate from the module you are currently viewing.

Transcript:

Required training in Rave: The first time you access Rave to audit, you will be required to complete a one-time eLearning module within iMedidata, regardless of whether you are an LPO Auditor or a Site Auditor. Please note that this eLearning is separate from the module you are currently viewing.

Required Training in Rave (cont.)

- All auditing organizations require the *Medidata Classic Rave EDC Essentials for Clinical Research Associates (Monitor)* eLearning; it only needs to be taken once, even if auditing multiple LPOs' trials.
- Auditing organizations may also require or have as optional additional audit-related eLearnings, e.g., *Rave Query Management* or *TSDV Subject Management*.

Transcript:

Required training in Rave, continued: All LPOs require the *Rave EDC Essentials for Monitor* eLearning; this module takes about 50 minutes to complete, and only needs to be completed one time, even if auditing different LPOs' studies. LPOs may also elect to require the *Query Management* eLearning, but at this time, it is **optional** for all LPOs.

Additional Training Requirement: CTSU SDP

- Any auditor who will be participating on a remote audit that is being conducted at least in part through the CTSU SDP must take a brief training course on auditing via the SDP.
- The *Source Document Portal (SDP) for Auditors* course is available for self-enrollment in the Compliance, Learning, and SOP Solutions (CLASS) learning management system, and must be completed before an auditor can access the SDP for an audit.
- To take the training course, log in to CLASS using your CTEP credentials, go to the Catalog, locate the course, and click *Enroll*.

Transcript:

Additional Training Requirement: Source Document Portal: Any auditor who will be participating on a remote audit that is being conducted at least in part through the CTSU Source Document Portal (SDP) must take a brief training course on auditing via the SDP.

The *Source Document Portal (SDP) for Auditors* course is available for self-enrollment in the Compliance, Learning, and SOP Solutions (CLASS) learning management system, and you must complete it before you can access the SDP for an audit.

To take the training course, log in to CLASS using your CTEP credentials, go to the Catalog, locate the course, and click *Enroll*.

More Resources

- This module focuses on the interface between the SAP and Rave and does not provide step-by-step instructions on conducting TSDV in Rave.
  - Refer to the Rave eLearning, Medidata Classic Rave EDC Essentials for Clinical Research Associates (Monitor) for more detailed information.

Transcript:

Resources: This module focuses on the interface between the SAP and Rave and does not provide step-by-step instructions for conducting TSDV in Rave (e.g., how to use the checkboxes or enter queries). For more detailed information on how to conduct TSDV refer to the Rave eLearning mentioned two screens ago that all auditors must complete, *Medidata Classic Rave EDC Essentials for Clinical Research Associates (Monitor)*.

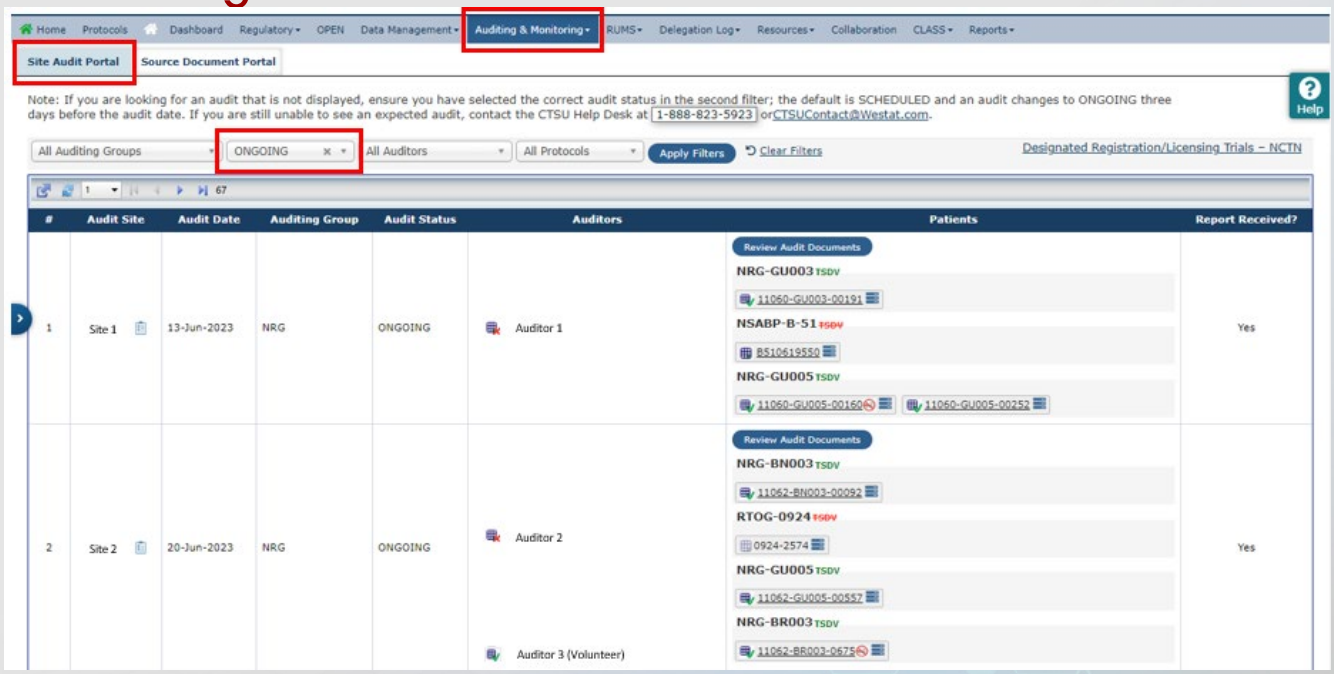
More Resources (cont.)

- Help Topics in the SAP on the CTSU website (login required to view):
  - *Instructions for Navigating the Site Audit Portal*
  - *Using Targeted Source Data Verification (TSDV) in Rave*
- Still need help? Contact the CTSU Helpdesk at 888-823-5923 or *CTSUContact@Westat.com*.

Transcript:

Resources, continued: You can also refer to two sets of Help Topics available within the SAP on the CTSU website; you can reach them by clicking the hyperlinks included on the screen (login to the website will be required). If you still need help, contact the CTSU Help Desk at 888-823-5923 or CTSUcontact@Westat.com

Accessing Rave via the SAP



Source: Password-protected website: (https://www.ctsu.org).

Transcript:

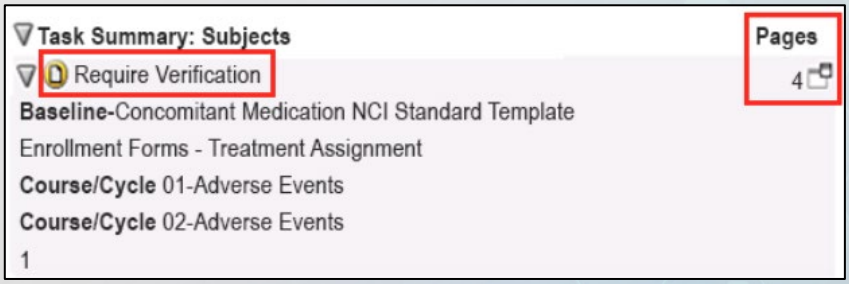
Accessing Rave via the SAP: You have been invited by Medidata to the studies needing TSDV in Rave and you are now at the audit. What now?

This is the same sample SAP screen displayed earlier. You will access Rave from here. To get to the SAP, log in to the CTSU website, click on the Auditing & Monitoring tab, then Site Auditing, then select Ongoing Audits.

Under the "Patients" column you can see the studies and patients to be reviewed at each audit. The letters TSDV are in green next to each study that is configured for TSDV in Rave (in this view, two of the three studies for Site 1and three of the four studies for Site 2 are configured for TSDV). The patient IDs are located below each study number and are clickable deep links to Rave. The SAP acts as a gateway to Rave and provides these deep links to each TSDV patient assigned to the audit. You can click on a patient's ID number in the Patients column to access that patient's data in Rave and see which data fields need to be verified.

Starting the TSDV Process

1. Start at the source: Review the source documents for the patient.
2. From the Ongoing Audits screen in the SAP, click on the patient ID requiring review.
3. You will review forms and fields requiring TSDV from the Subject Level in Rave for that patient: Task Summary: Subject → Requiring Verification.



Source: Password-protected website: (https://login.imedidata.com/selectlogin).

Transcript:

Starting the TSDV process: Each auditor has their own standard approach, but generally, the first step in TSDV should be review of a patient's source documentation for protocol compliance, safety, and effectiveness. Then, from within the audit record in the SAP, you will click on that patient's ID number.

This will bring up Rave in a separate window. When you are ready to check the source against the data to be verified in Rave, look at the Subject Level Rave page for that patient. That is the view that automatically appears when you click on the patient ID; part of that view is shown on the screen here. On the page you will see the Task Summary for the subject, and under "Requiring Verification" there will be a list of the eCRFs that have data fields requiring auditor review. In the example shown on the screen, there are only four forms you need to review for this patient. You click on a form name, such as Cycle 1 Adverse Events, to go to that form.

Post-TSDV Activities (1 of 3)

After an audit, the following activities take place:

- All TSDV documentation becomes a Post-TSDV Report that can be generated from Rave by the audit team.
- The audit team (typically the Lead Auditor or designee) submits the Preliminary Report, along with the Post-TSDV Report, to CTMB via CTMB-AIS.
  - This is due within one business day of audit completion.

Transcript:

Post-TSDV activities include preparation and submission of reports. All TSDV documentation becomes a Post-TSDV report that is generated from Rave by the audit team. This report, along with the preliminary audit report, is submitted by the Lead Auditor or designee to CTMB via the CTMB-AIS within one business day of audit completion.

Post-TSDV Activities (2 of 3)

Upon submission of the Preliminary Report:

- **Volunteer auditors**' access to the patients in Rave is automatically removed.
- **LPO auditors** and **cross-network auditors** will retain access to Rave and can handle any queries.

Transcript:

Post-TSDV-related activities, continued: Upon submission of the preliminary audit report, volunteer auditors will lose access to Rave for the patients that had been selected for audit. Any remaining open queries that were created by the volunteer auditors will need to be addressed by LPO or cross-network auditors after that point.

Post-TSDV Activities (3 of 3)

Final Steps:

- The audit team will submit the Final Audit Report via CTMB-AIS per normal procedure (within 70 calendar days of Day 1 of the audit).
- **Cross-network auditors** will automatically lose access to Rave for the audited patients upon submission of the Final Audit Report.
- **LPO auditors** will lose access at that point to the *Verify* checkboxes for the audited patients.

Transcript:

Post-TSDV activities, continued: As a final step, the audit team will submit the Final Audit Report via CTMB-AIS per their normal procedure; this is due within 70 calendar days of Day 1 of the audit). At that time, cross-network auditors will lose access to Rave for the patients that had been selected for audit. LPO auditors will lose access to the Verify checkboxes for the audited patients. (They will still be able to open or close queries.)

Module Complete

- You have completed the Targeted Source Data Verification and Site Audit Portal module.
- Please exit and return to the course screen in CLASS.
- The module should now show as *Complete*.
- You can revisit completed modules in your My Courses screen.

This and the other training modules in this series were developed for the Clinical Trials Monitoring Branch of the Cancer Therapy Evaluation Program, Division of Cancer Treatment & Diagnosis, National Cancer Institute.
https://ctep.cancer.gov/branches/ctmb

This version produced: January 2024

Transcript:

Module Complete: You have completed the Targeted Source Data Verification and Site Audit Portal module. Please exit the module using the X in the upper right corner of this window, and return to the course screen in CLASS, where the module should now show as completed. You can always revisit this and other completed modules in your My Courses screen.

Note, this and the other training modules in this series were developed for the Clinical Trials Monitoring Branch of the Cancer Therapy Evaluation Program, Division of Cancer Treatment & Diagnosis, National Cancer Institute. For more information on the CTMB, visit the URL for the CTMB home page shown on the screen. This version of this individual module was produced in January 2024.