Theradex Specimen Tracking System (STS) User Guide
Version 5 (December 2023)

THERADEX ONCOLOGY

Contents

Not all features described are present in older versions of STS.

Access

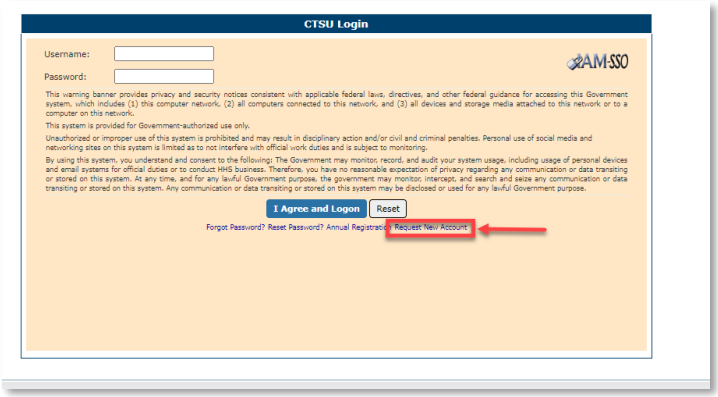
Access to your study in Rave is overseen by CTSU and is granted based on the role assignment in the roster (and protocol DTL if applicable) for your site. You will need to contact your site's RSS or DTL administrator to request the addition of your name on the roster. Information on new Rave accounts is in the protocol (section 4 for protocols that use the newest CTEP template). Please contact the CTSU Help Desk for more assistance CTSUContact@Westat.com

The Theradex Specimen Tracking System is integrated within a study in Rave. Contact your RSS or DTL site administrator or CTSU to ensure you are on the site roster for your study with the role of **Rave Clinical Research Associate** (CRA) for each protocol you need to enter data. For protocols that require a DTL: A staff member who is on the roster as Rave CRA but not on the DTL will only receive an invitation of Read Only. Once they are on the DTL, CTSU will send the Rave CRA invitation.

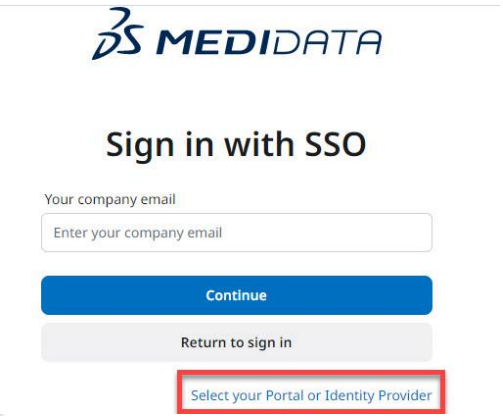
For certain older studies, Theradex will need to grant you an additional Rave role for each study named "CRA Specimen Tracking" after CTSU has sent the EDC invitation for the regular CRA role. The training required to gain access to STS can be taken through CTSU's CLASS system or via a video presentation supplied by Theradex, again depending on the study. Please contact STS.Support@theradex.com to clarify what is appropriate for your study's requirements.

CTEP-IAM and Rave Account Setup

All individuals are required to have an active CTEP-IAM account prior to being granted access to Rave. To create a CTEP-IAM account, proceed as follows:



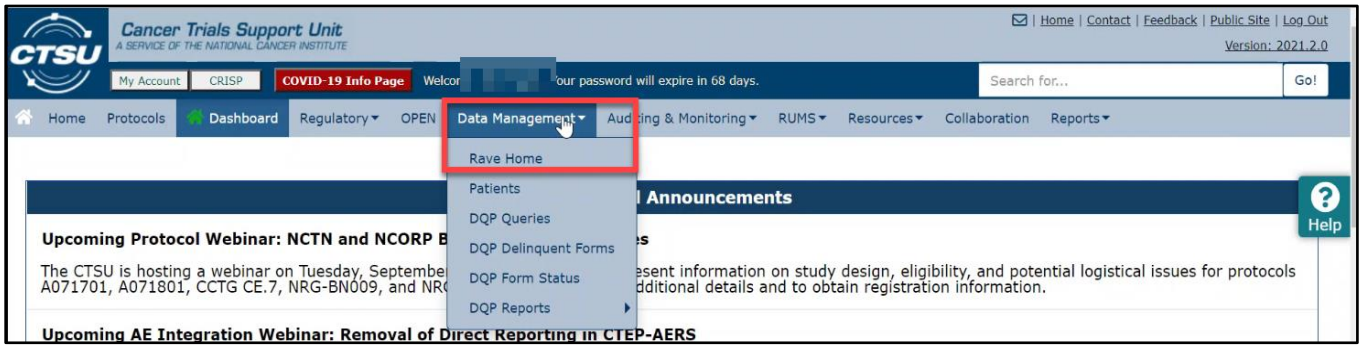
1. Go to the following URL: https://www.ctsu.org/public/default_login.aspx
2. Under the buttons, click **Request New Account**. This will take you to the CTEP-IAM page.
3. Follow the prompts to enter the required identifying information for your account. Choose the Associate Plus application
4. You will receive an authorization email in **24-48 hours**.
5. After receiving the CTEP-IAM authorization (which may take up to 48 hours), *documentation must be uploaded to the CTEP Registration and Credential Repository (RCR) to complete your registration*.
6. After these steps are completed, go to the following URL: https://login.imedidata.com/login
7. Click on **Sign in with SSO**
8. Click on **Select your Portal or Identity Provider**



9. From the menu, choose **CTEP-IAM IdP**.
10. Click **Select**
11. Login with your CTEP-IAM username and password on the resulting screen.

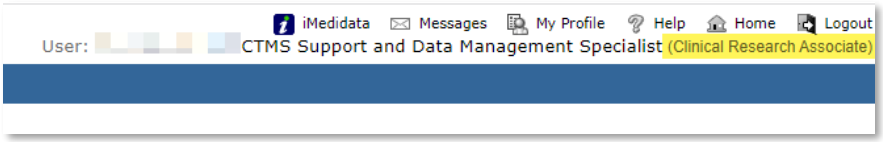
Logging in through CTSU

1. Go to the following URL: https://www.ctsu.org/Public/Default.aspx
2. Click **Log in.**
3. At the login page, enter your **CTEP-IAM Username** and **Password**
4. Click **I agree and logon**.
5. Go to the **Data Management** menu.
6. Click **Rave Home**.



Current role in Rave

After logging in to Rave and select your study. If you only have the **Clinical Research Associate** role you will see it next to your name in the top right hand corner of the website after selecting the study.



If your role is Read Only, you will not be able to enter or edit data. The CTSU Help Desk will be able to advise you further on why you do not have Clinical Research Associate access.

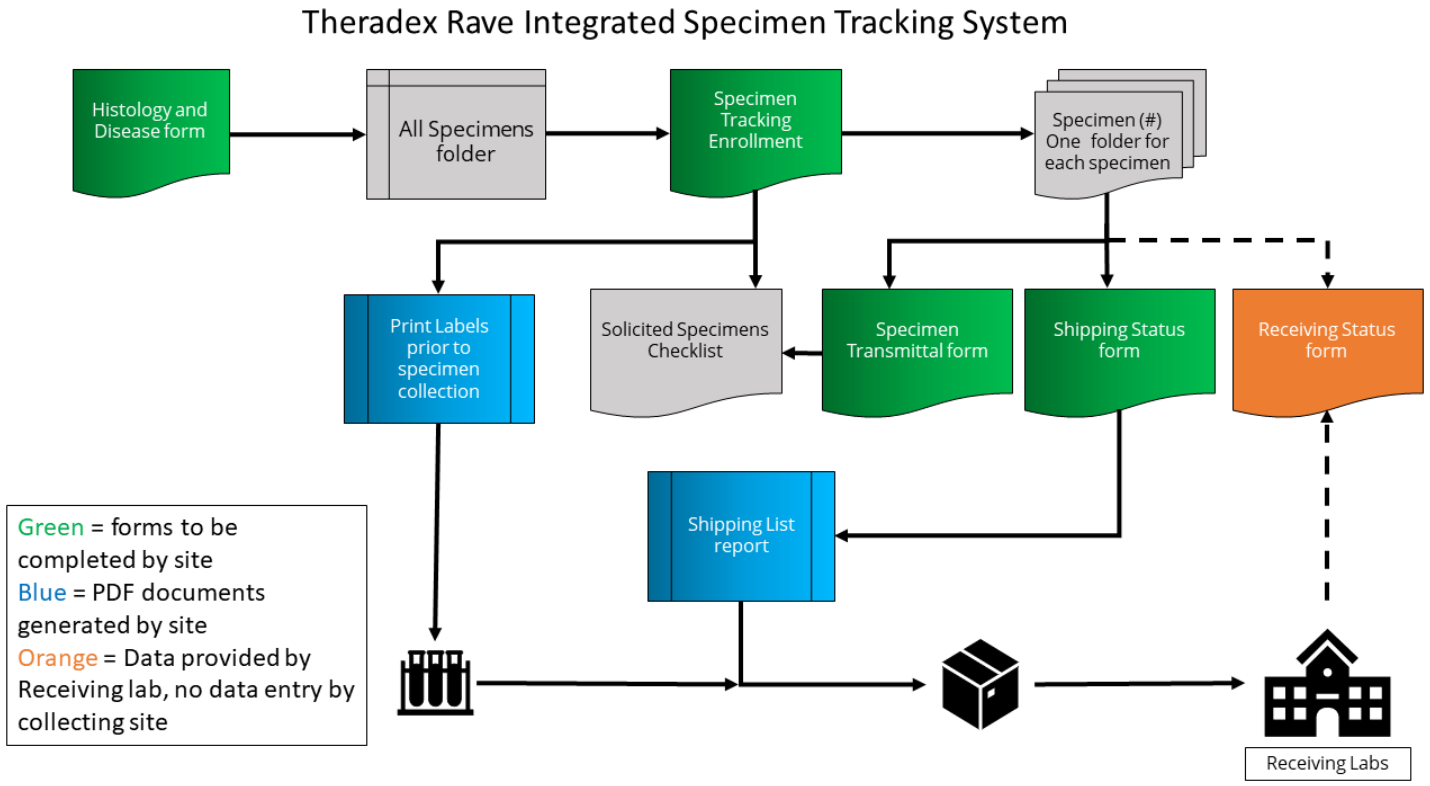
If your role is **Clinical Research Associate** and you cannot edit forms in the All Specimens folder or generate reports, contact STS support as we may need to add the **CRA Specimen Tracking** role to your account. See Access for more information.

Specimen Tracking System Overview

Specimen tracking system was initially designed in conjunction with the Biopathology Center at Nationwide Children's Hospital. In earlier protocols they were known as the ETCTN Biorepository. Currently they have an NCI contract as the EET Biobank (Early-Phase and Experimental Clinical Trials Biospecimen Bank).

The Specimen Tracking System is made up of several parts. It is important to complete all the specimen tracking forms for every specimen collected from a participant. The system's programming depends on responses on the **Histology & Disease** form found in the Enrollment folder. Be sure this form is completed before entering specimen data. The remaining forms are located in the **All Specimens** folder.

Important – If the **Histology & Disease** form is not completed, the other forms/steps of STS will not function properly



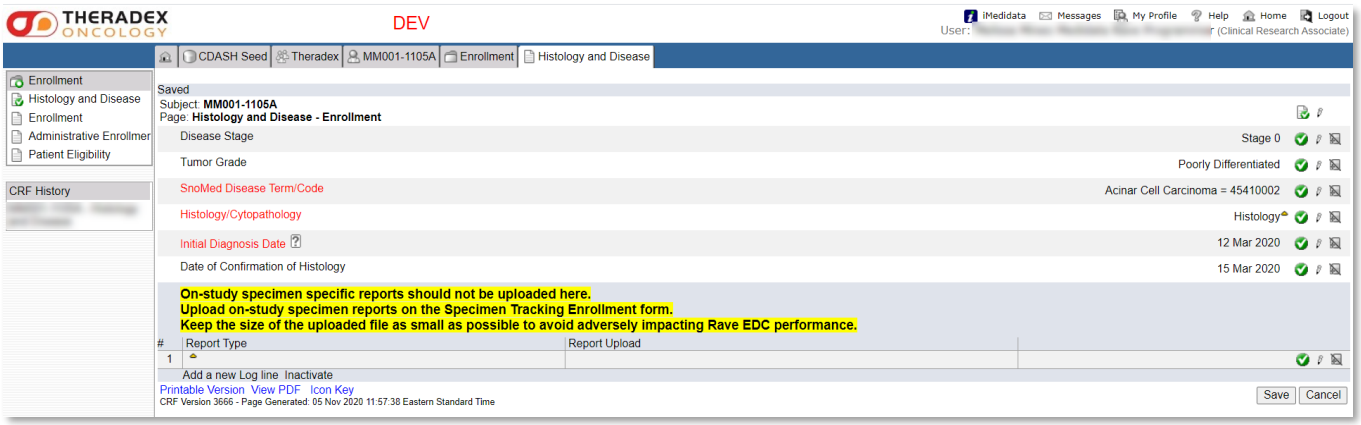
Summary of STS data entry

All steps must be completed prior to shipping the specimen. Hand delivery of specimens within the same institution is considered shipping and completion of all steps is required.

1. Go to **Enrollment folder** and complete the Histology & Disease form.
2. Go to the All Specimens folder.
3. Complete the Specimen Consent form, if required by your protocol.
4. Complete the Specimen Tracking Enrollment form for each specimen. In some studies, this form is labeled as Specimen Collection Initiation,
5. Complete the Print Labels form. Labels will be sent to user's email address.
   ** Some studies do not have this form. For these studies use the Specimen Label Report. **
6. Open the **Specimen (#)** folder within the All Specimens folder. The number corresponds to the log line in the Specimen Tracking Enrollment form.
7. On the **day of collection**, complete the Specimen Transmittal form. In some studies, this form is labeled as Specimen Collection Details.
8. When specimen is ready to ship, complete the Shipping Status form.
9. For each additional specimen, you can import data from the initial Shipping Status form by using Copy Shipping.
10. Print the Shipping List report to send with the specimens (see page 19). Put the shipping list report and hardcopies of relevant pathology reports in the box with the specimens.
11. Return to the Shipping Status form and click the click the checkbox to have an email alert sent to the destination that specimen is on its way. This is done one time per shipment.

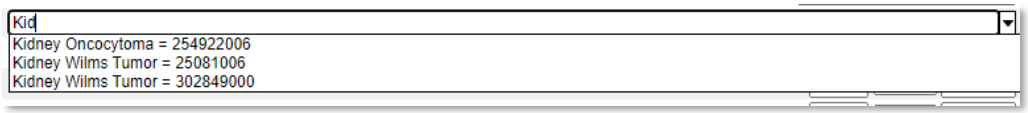
Enrollment folder - Histology & Disease form

In the Enrollment folder, confirm the **Histology & Disease** form has been completed for the participant. This is the first step in specimen tracking and *always* needs to be completed before entering specimen data. Fields in red are required fields. If not completed, fill these out.

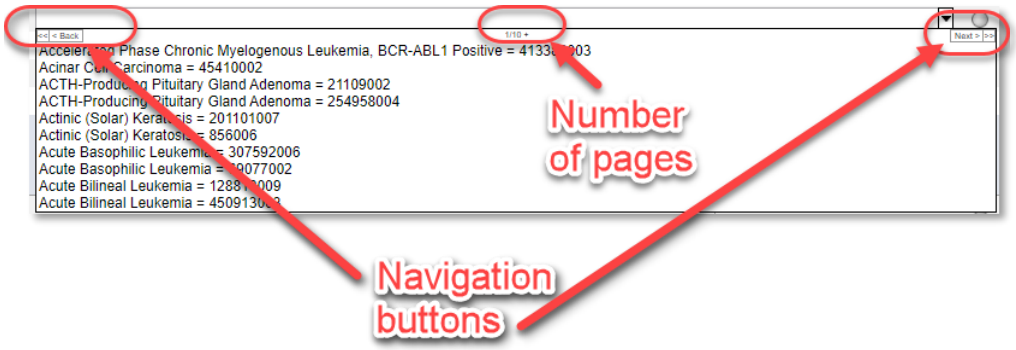


Notes:

- SNOMED Disease Term/Code is required for STS functionality
- Start typing in the box and the options will narrow based on what you type.



- If you double-click into the field an alphabetical search list populates.



- The SNOMED Disease Term/Code list is a combination of several sources. Some terms may be duplicated, select the first instance in the list.
- The EET Biobank requires the Pathology report for tissue specimens.
- The upload of pathology and other reports depends on the protocol, however if the only samples collected are blood samples, these reports are generally not needed.
- **Any report must have PHI and PPI redacted from within the report and the removed from the filename.**
- The participant ID and UPID displayed must be included in the report.
- An extra specimen label is an easy way to get add IDs onto the report before scanning.

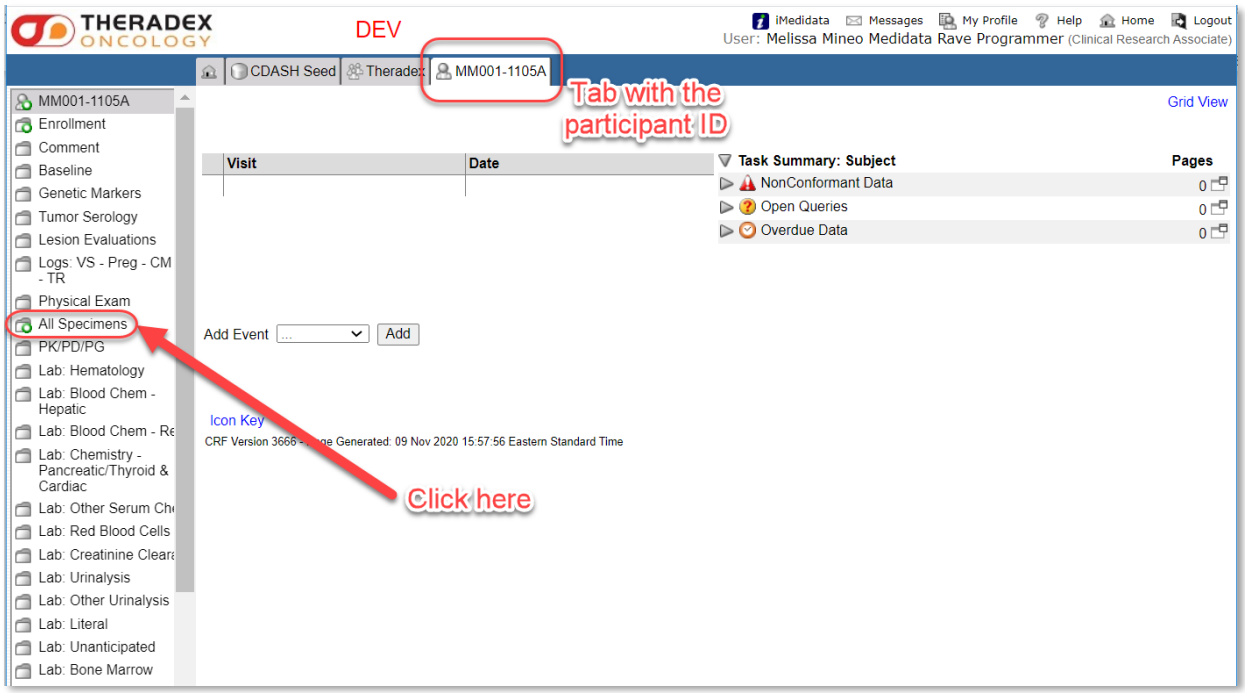
Examples of PHI/PPI

- Names
- Geographic subdivisions smaller than a state (e.g., street address, city, county, etc.).
- All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death, and all ages over 89
- Telephone numbers
- Fax numbers
- Electronic mail addresses
- Social Security numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers and serial numbers, including license plate numbers
- Device identifiers and serial numbers
- Web URLs
- Biometric identifiers, including finger or voice prints
- Full face photographic images and any comparable images
- Internet Protocol address numbers
- Any other unique identifying number characteristic or code (e.g., DNA)

All Specimens folder

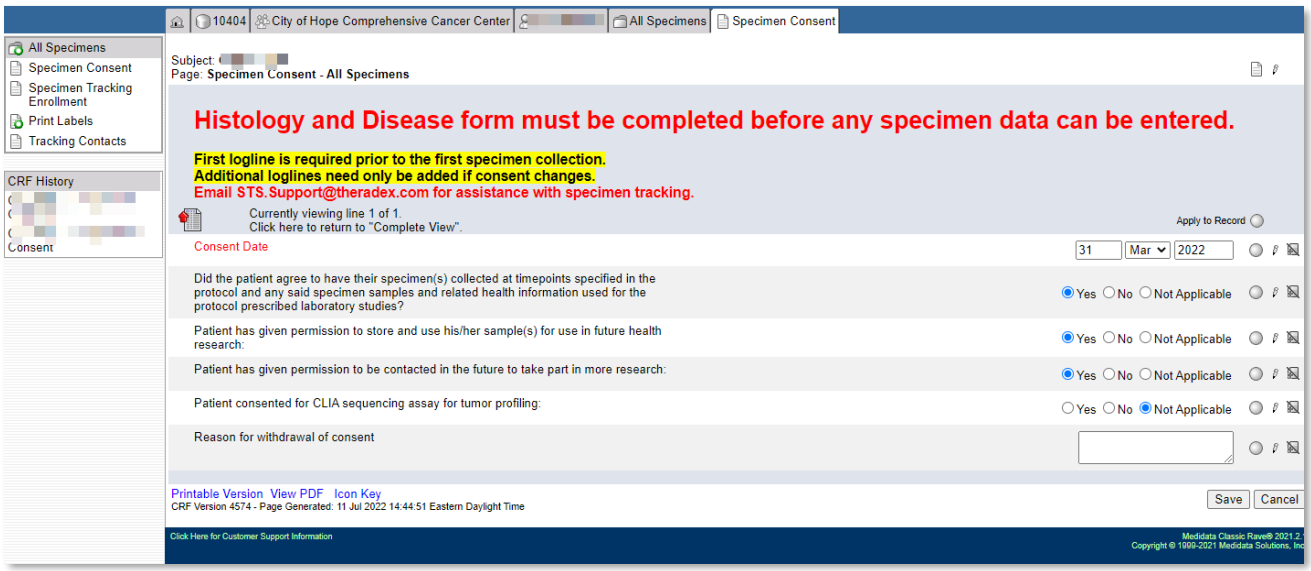
Ensure the Histology and Disease form in the Enrollment folder is complete before proceeding with any data entry.

Return to the participant level by clicking the tab with the participant ID and open the **All Specimens** folder.

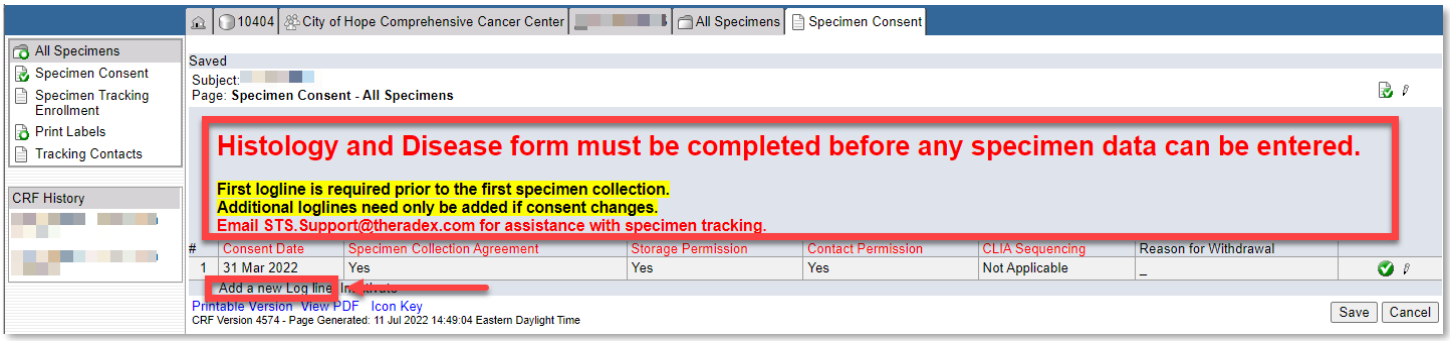


Specimen Consent form

Complete the **Specimen Consent** form as required for your study.



As you move through the STS, if you see phrases in a different size or color font, these have been placed by Theradex to help guide you in using the Specimen Tracking System.



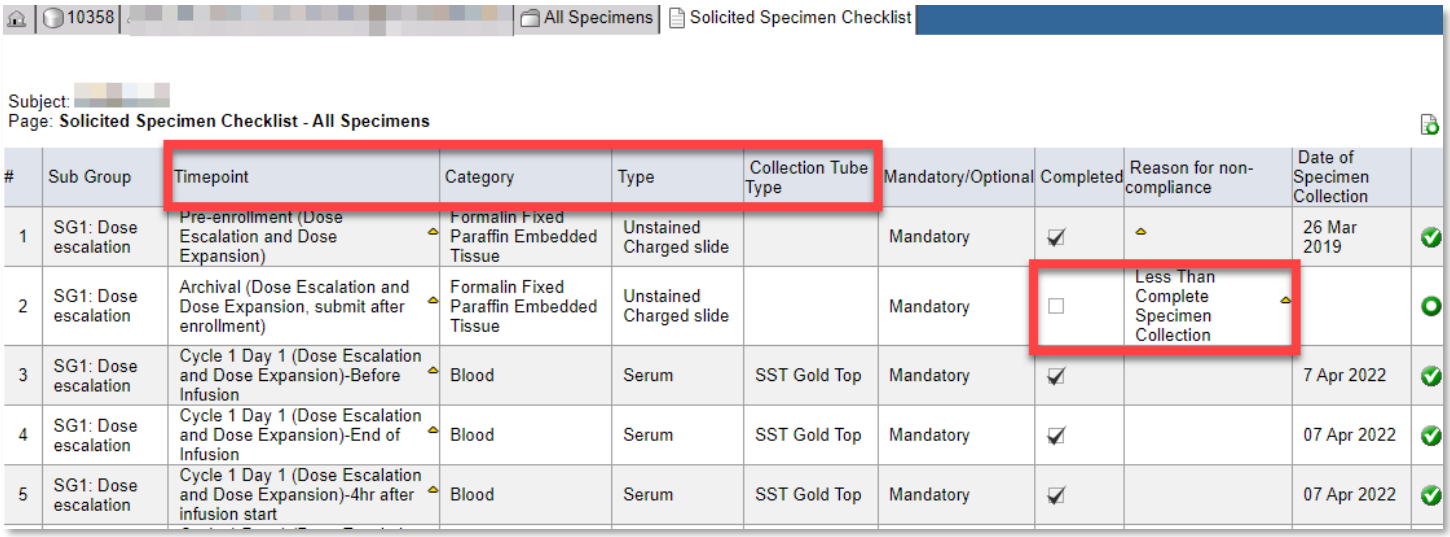
- Add a new log line for each consent change.
- Some protocols require a consent record for each timepoint of specimen collection. Therefore, add as many rows as needed.
- Participant withdrawal should be recorded on a separate log line.

Solicited Specimen Checklist

The checklist provides a summary of the specimens, timepoints, and dates of collection.

This form automatically checks entries in the Specimen Tracking Enrollment and Specimen Transmittal forms against the expected specimens for each Assessment Timepoint as defined in the protocol.

Please refer to the protocol and this form frequently to ensure compliance with your study's required specimen collections.



10358 | All Specimens | Solicited Specimen Checklist

Subject:

Page: **Solicited Specimen Checklist - All Specimens**

#	Sub Group	Timepoint	Category	Type	Collection Tube Type	Mandatory/Optional	Completed	Reason for non-compliance	Date of Specimen Collection	
1	SG1: Dose escalation	Pre-enrollment (Dose Escalation and Dose Expansion)	Formalin Fixed Paraffin Embedded Tissue	Unstained Charged slide		Mandatory	☑		26 Mar 2019	
2	SG1: Dose escalation	Archival (Dose Escalation and Dose Expansion, submit after enrollment)	Formalin Fixed Paraffin Embedded Tissue	Unstained Charged slide		Mandatory	☐	Less Than Complete Specimen Collection		
3	SG1: Dose escalation	Cycle 1 Day 1 (Dose Escalation and Dose Expansion)-Before Infusion	Blood	Serum	SST Gold Top	Mandatory	☑		7 Apr 2022	
4	SG1: Dose escalation	Cycle 1 Day 1 (Dose Escalation and Dose Expansion)-End of Infusion	Blood	Serum	SST Gold Top	Mandatory	☑		07 Apr 2022	
5	SG1: Dose escalation	Cycle 1 Day 1 (Dose Escalation and Dose Expansion)-4hr after infusion start	Blood	Serum	SST Gold Top	Mandatory	☑		07 Apr 2022	

This form is not present in all studies.

The line numbering (#) in the form does NOT correspond to the log lines in Specimen Tracking Enrollment.

To activate the Completed checkbox the **Timepoint, Category, Type**, and **Collection Tube Type** must be entered into **Specimen Tracking Enrollment** exactly as it is displayed in this form. The checkbox is activated when the **Date of Specimen Collection** is entered in the **Specimen Transmittal** form. Some studies have unique shipping needs, these must also be entered in **Shipping Status** before the form marks the specimen as completed.

If a **Mandatory** specimen was not collected or if the collected specimen differs in Category, Type, and Collection Tube Type, a system query will appear. The **Reasons for non-compliance** field will have a drop down available to record the reason the deviation from protocol occurred (ie. Less than complete collection, wrong specimen collected, or choose Other and provide a short description).

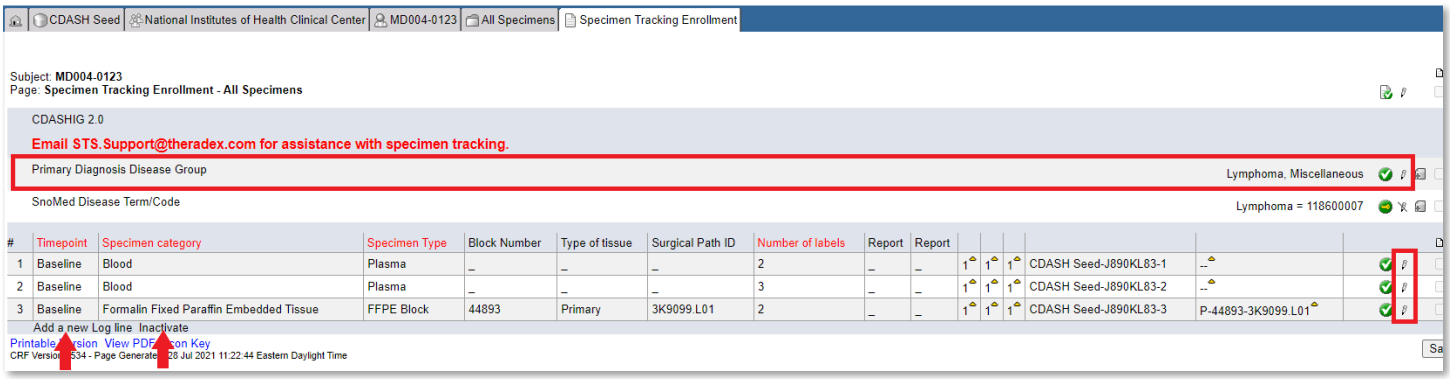
For **Optional** specimens the form will activate the Completed checkbox when collected but will not automatically issue system queries.

Specimen Tracking Enrollment form

Also referred to as **Specimen Collection Initiation** in some studies

Ensure the Histology and Disease form in the Enrollment folder is complete before proceeding with any data entry.

Each specimen type (including differences in the container) should be on a separate log line. For example, stained and unstained slides should be on two log lines. Blood collected in different tube types, even if collected at the same collection time point, would also be on separate lines. Blood in the same tube type and at the same collection time point (i.e. 2 x 3 mL blood in purple top EDTA tube, processed for plasma) should be one single line.



1. If not present, add the **Primary Diagnosis Disease Group**. On some studies this is automatically filled out. If the **SnoMed Disease Term Code** is empty, complete the Histology and Disease form in the Enrollment folder before proceeding any further.
2. If a blank line is present, use the pencil icon to edit the fields in each row. Otherwise use, Add a new Log Line.
3. Complete at minimum the required fields:
    a. Assessment Timepoint
    b. Specimen category
    c. Specimen Type
    d. Tube Type
    e. How many labels are needed? *Extra labels can be applied to redacted reports to be uploaded – whether on this form or the Histology and Disease form*
4. For **tissue specimens** you need to select the **Tissue type**.
5. Click **Save**.
6. You can edit any previously entered data by using the pencil icon. This will expand the row. After the row is expanded, use the pencil icon to right any individual field to open it for editing.

Notes:

Additional rows can be added by selecting "**Add a new Log line**" at the bottom of the screen (red arrow).

Rows can be inactivated by selecting "**Inactivate**" and entering the row number (red arrow). See note below. Inactivating a log line will remove the corresponding Specimen (#) folder.

If the inactivate function has been used in **Specimen Tracking Enrollment** form or a line is left blank, the **Specimen (#)** folder for new entries will not match at first; but will be updated to match the log line when the **Specimen Transmittal** form (or **Specimen Collection Details** form) is saved.

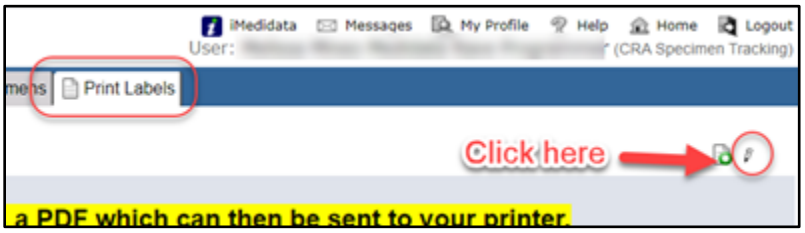
If using the **Print Labels** form, once the **Specimen Tracking Enrollment** form is saved, the number of labels cannot be updated on this form. If a change is needed to the number of labels, update on the **Print Labels** form.

Labels

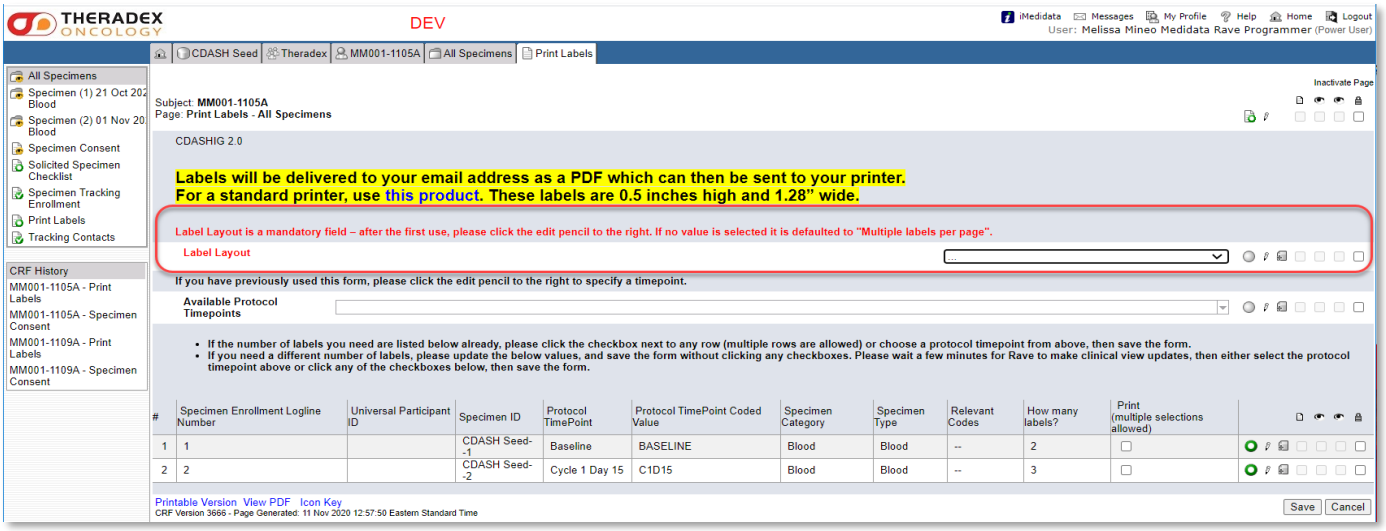
Print Label form

The label printing process has been updated for recent studies to utilize the Print Labels form. Follow the next steps for these studies. See **Specimen Label Report** *for older studies that do not include the Print Labels form.*

1. In the **All Specimens** folder, open the **Print Labels** form.



2. At the top right of the form, click on the pencil to edit.
3. Select the **Label Layout**.
   - *Multiple labels per page* (default) — for standard laser printers
   - *One label per page* — for special purpose thermal label printers

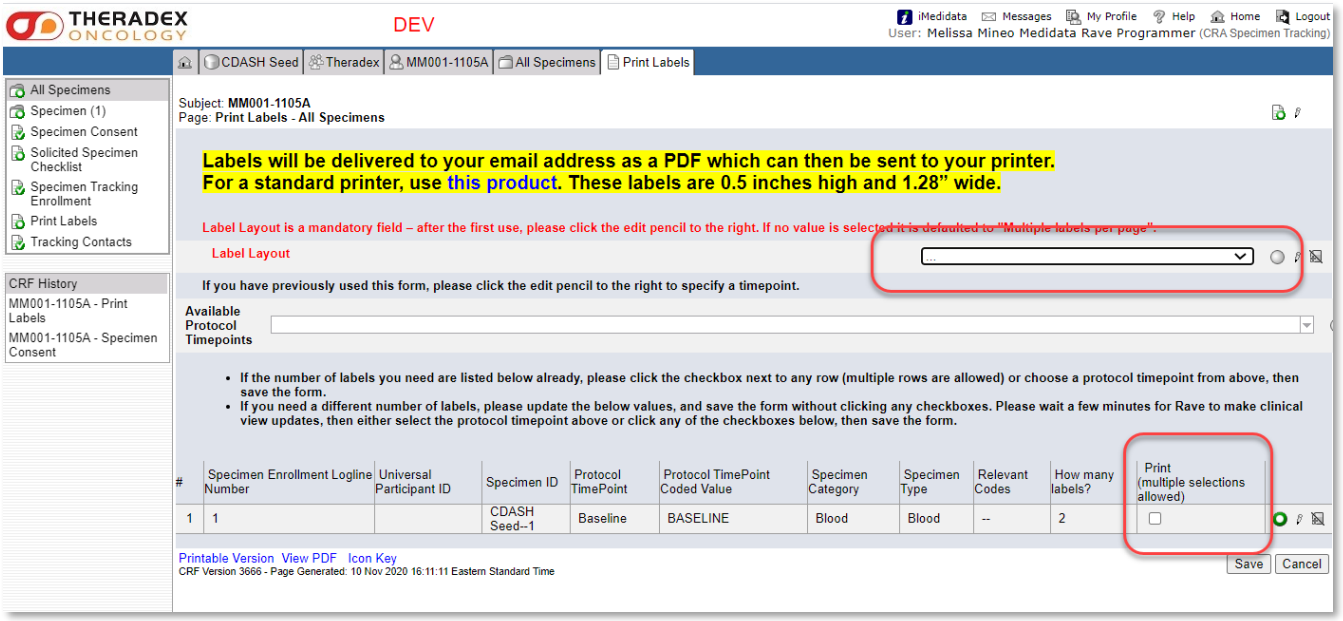


There are two ways to print labels – **CHOOSE ONE METHOD ONLY**.

- Printing labels by manual selection – the user can select individual Specimen IDs by clicking the checkbox under the column Print.

--OR--

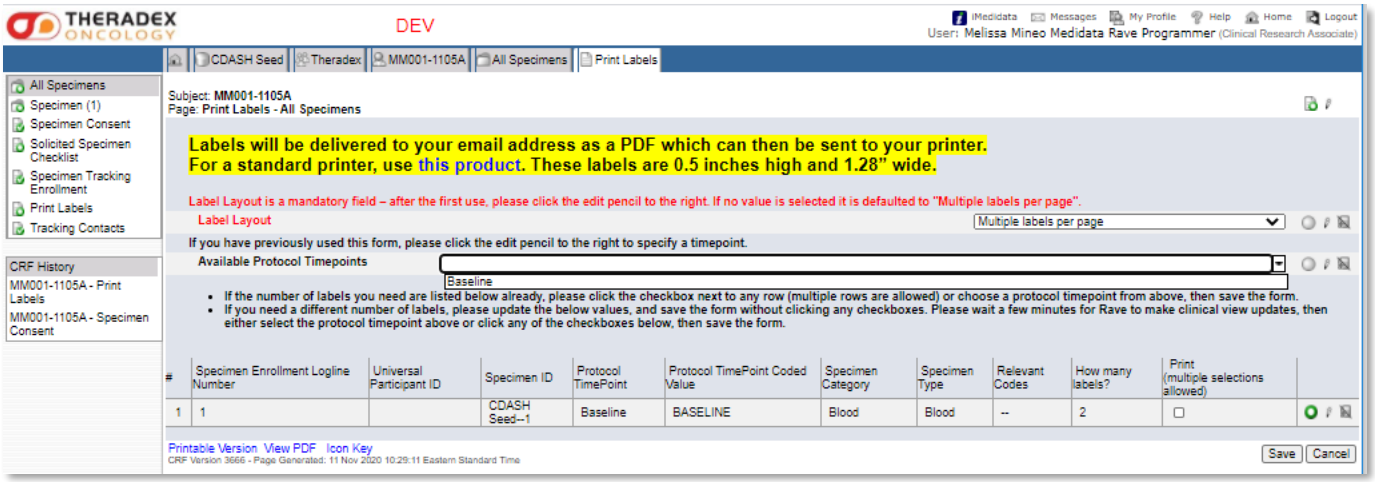
- Printing labels by Available Protocol Timepoints.



Printing labels by manual selection

1. After selecting the Label Layout **skip over** Available Protocol Timepoints
2. **How many labels** is populated with values from the **Specimen Tracking Enrollment** form. If different number of labels are needed, update the number here. This may cause a delay in label generation.
3. Click the **Print** checkbox for each needed specimen (multiple selections allowed).
4. Click **Save** button.

Printing labels by Available Protocol Timepoints



1. Select one of the **Available Protocol Timepoints** from the dropdown.
2. **Skip over** the line listing of specimens.
3. Click the **Save** button.

Once the user saves the form, the system will generate the same two emails shown above for manual selection, however these will include the timepoints that match the user selected values.

Apply labels to the specimen(s), and hand write the date and optional time on the label.

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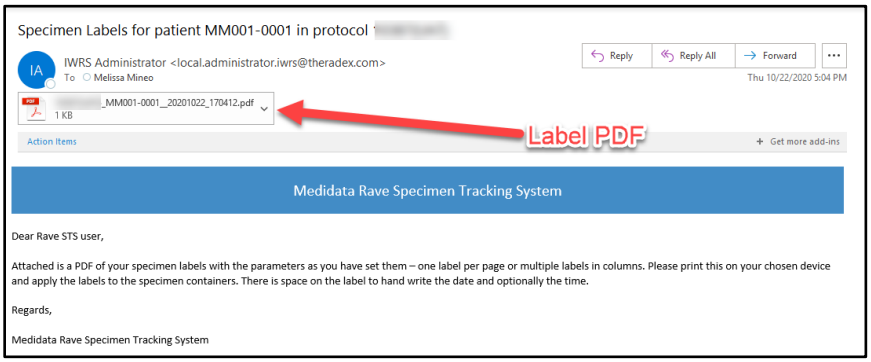
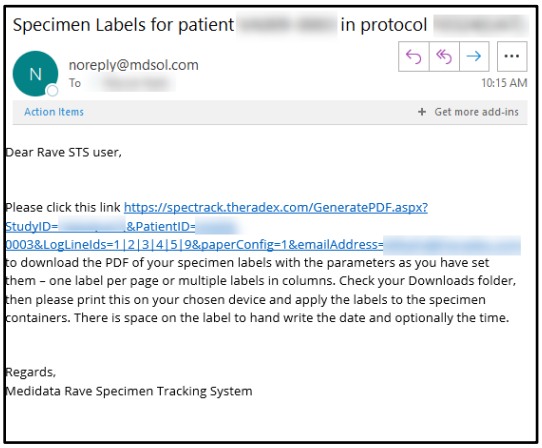
*If both protocol timepoint and the print check box are used, no email will be issued. Only **one type** should be chosen*

Once the user saves the form, two emails will be generated. One email will be sent with the actual QR Code pdf attached in the email. Open the attached pdf in Acrobat Adobe reader and follow the printing instructions. A second email will be generated and sent to the user with an active link to download the QR code pdf. User can copy / paste the link into a browser or click on the active link and pdf will be downloaded in the download folder.



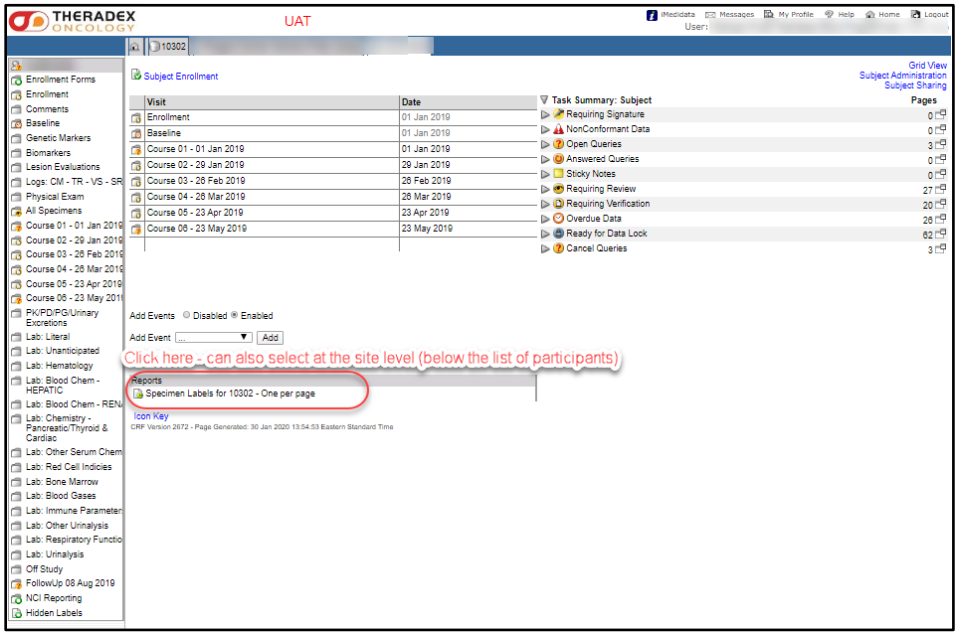


Apply labels to the specimen(s), and hand write the date and optional time on the label.

Specimen Label Report

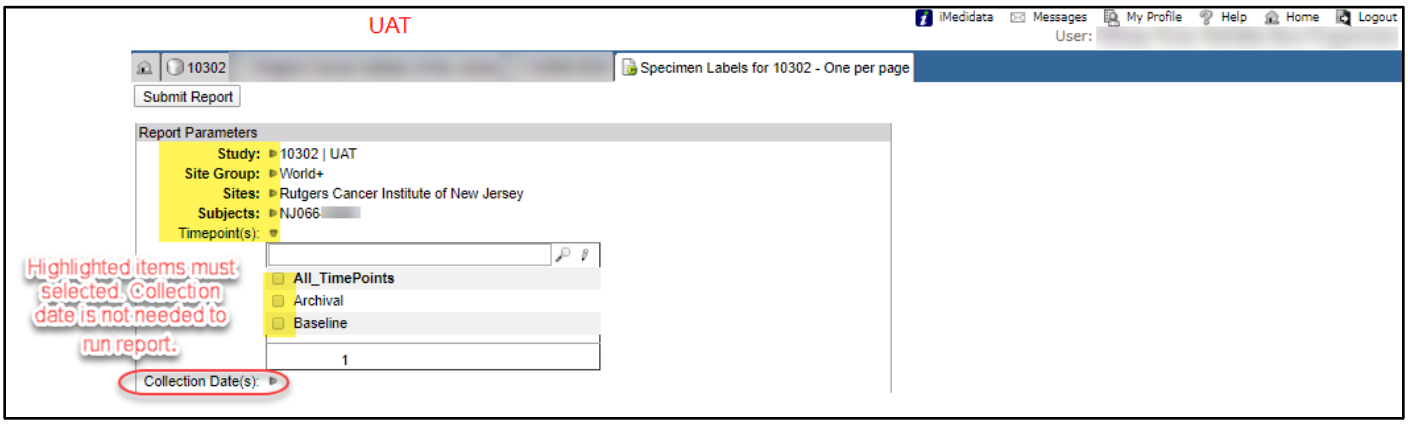
The following steps are for older versions of the STS that *do not* have the Print Labels form.

1. Return to the participant's main screen
2. In the Reports menu click on Specimen Labels [protocol number] link



1. In the **Report Parameters** menu, expand the **Timepoint** submenu and click to select. Alternatively, use **Collection Date(s)** if you have entered the collection date in the Specimen Transmittal form
2. Click **Submit Report**.

Apply labels to the specimen(s), and hand write the date (if not present) and optional time on the label.



Specimen Transmittal form

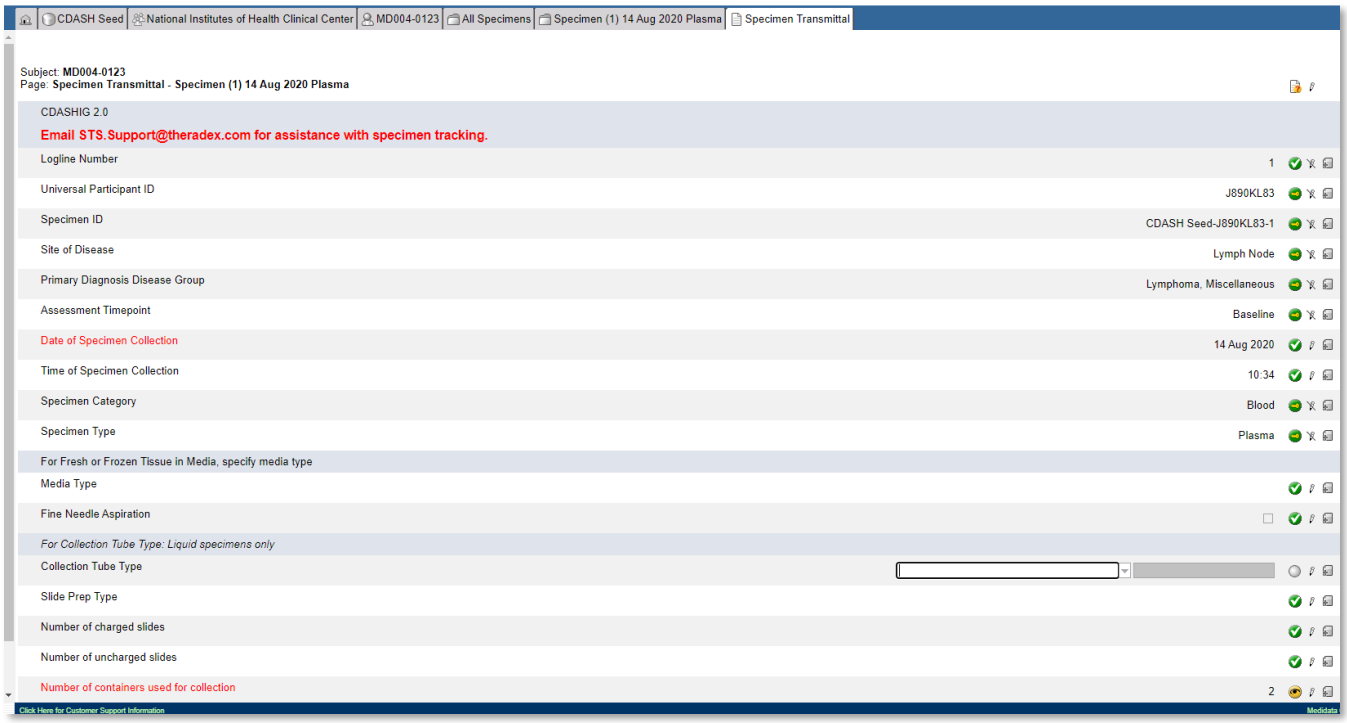
Also referred to as **Specimen Collection Details** in some studies

This form should be completed the same day as specimen collection even if the specimen is to be shipped at a later date.

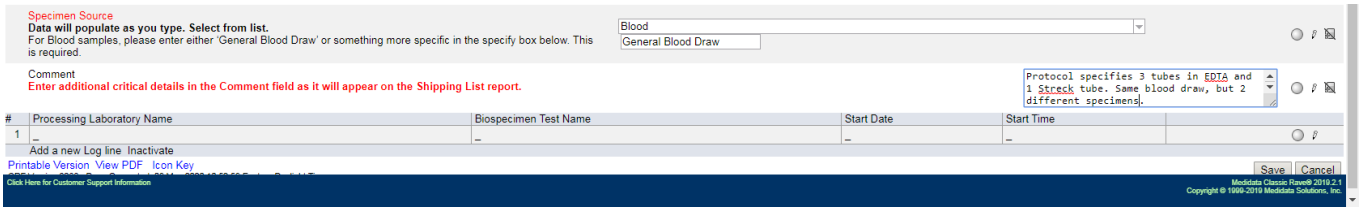
Return to the **All Specimens** folder. After adding the logline to the **Specimen Tracking Enrollment** form, a folder will have populated, **Specimen (#)** for each specimen line. Open each folder and complete the forms.

Complete **Specimen Transmittal** form for each specimen (in each specimen folder).
Required fields are in red font. Not all fields are relevant for all specimens.

If changes are needed to the **Protocol Timepoint, Specimen Category and Specimen Type**; the changes need to be made on the corresponding **Specimen Tracking Enrollment** log line.



Specimen Source: If the specimen is blood, select **Blood** from drop down. In the free text associated specify field, enter further details about the collection. If there is nothing specific, it is perfectly acceptable to simply enter "General Blood Draw"



Click **Save**. After the Specimen Transmittal form is saved, the folder name in the upper left corner will update with the Date Specimen Collected and Specimen Type.

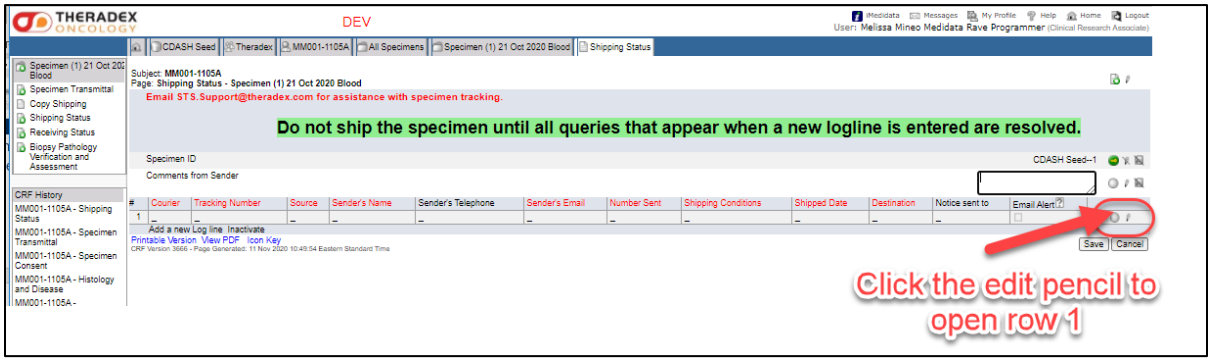
Notes:
If the **#** in the **Specimen (#)** folder name does not match the log line number. Complete the Transmittal form (enter the collection date at minimum) and the folder name will update after saving.

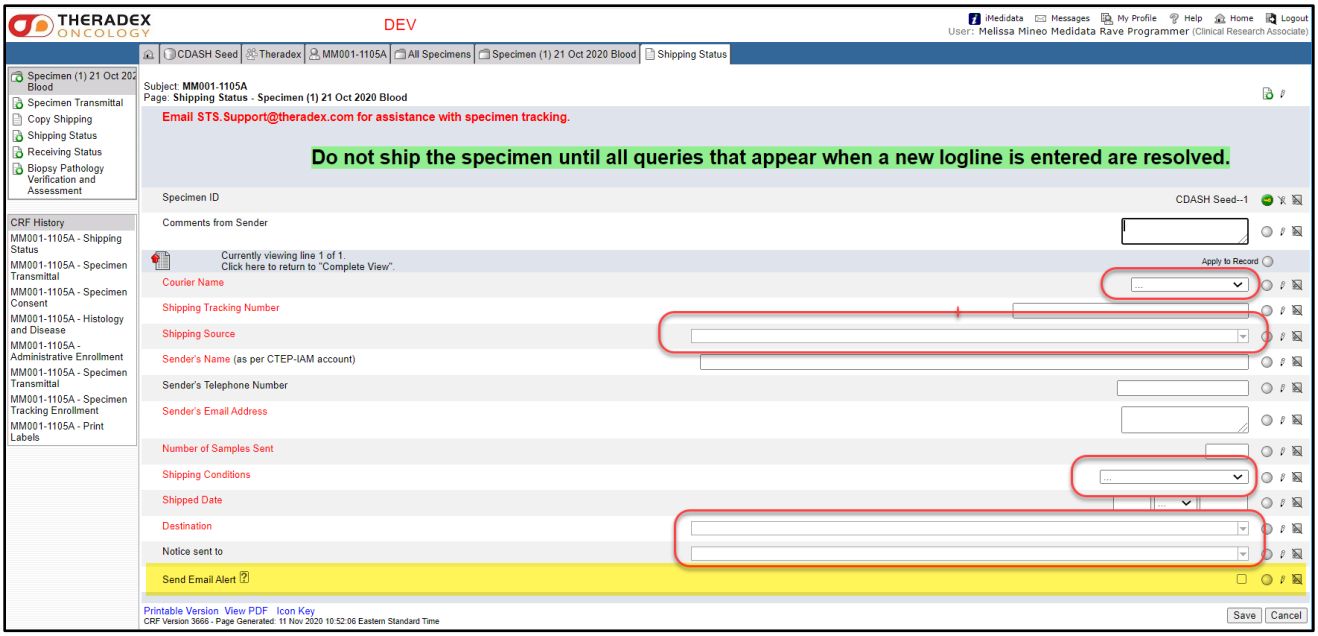
For some studies, the collection tube type is entered on this from for blood specimens.

Shipping

Shipping Status form

Complete the **Shipping Status** form for **each specimen** when it is ready to ship. The data on this form should only pertain to the specimen recorded on the Specimen Transmittal form. Once this form is completed use the **Copy Shipping** feature to help complete the Shipping Status form for other specimens on your shipment. Typically, there will only be one log line completed on this form, unless the specimens recorded on the Specimen Transmittal are being sent to different destinations. Each **Shipping Status** log line corresponds to a line item on the **Shipping List** report.





1. Click the edit pencil on the **Shipping Status** logline for the first record.
2. Complete all required fields in **red**. Please review the following notes
   Tracking Number: Be careful there are no extra spaces in the field at the beginning and end of the number. *If hand delivering to a local lab see Note below for further explanation*.
   Shipping Source: Your site. This field will have your site at the top.
   Number Sent: This number must be the same as the number of samples (of this sample type) physically put in the box to send to the lab. Do not enter the total of all samples sent.
   Destination: Choose the destination from the drop down menu. **If the drop down does not populate, go back to the Histology & Disease form and be sure it is complete**. **Do not manually enter data into this field**. **The destination must be selected from the drop down menu.**
   Notice sent to: This field changes based on the entry made in the *Destination* field above it.

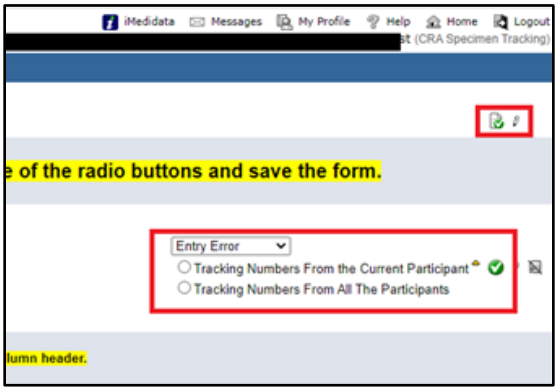
3. **Do not click** the checkbox for "Send Email Alert" at this time.
4. Click **Save**.
5. For each additional specimen included in the shipping (same tracking number) use the Copy Shipping feature to complete the Shipping Status forms, see next section.

Note:

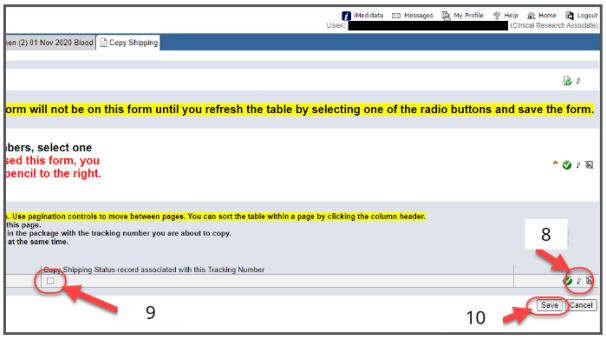
For hand delivered specimens a unique tracking number entry must be provided. Generic entries (i.e. N/A, hand delivered, dropped off) are not acceptable. An example of a unique entry can be initials and a date. Please be sure to keep the format of these entries the same *MM_15June2021* and *MM 15June2021* are not considered the same in Rave.

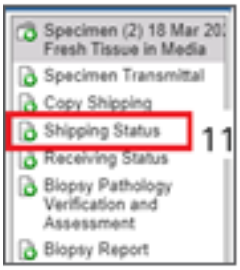
Copy Shipping

If shipping multiple specimens in the same shipment, complete the **Copy Shipping** form for subsequent samples after the **Shipping Status** form has been completed for the first sample. The **Copy Shipping** form will retrieve the information previously entered and copy it into the **Shipping Status** form for the subsequent samples. To use this form, there needs to be a tracking number entered on another sample's **Shipping Status** form. This form requires refreshing each time it is utilized.



1. Return to the **All Specimens** folder and click on the folder for the next specimen in the shipment.
2. Confirm the **Specimen Transmittal** form is complete.
3. Click on **Copy Shipping**.
4. Click the edit pencil in the top right-hand corner.
5. Select **Tracking numbers** radio button. Older versions only have a checkbox.
6. Click **Save**.
7. Find the tracking number in list. The user can sort the list by date by clicking on the Shipped Date header.
8. Click the *edit pencil for the row with the desired tracking number*.
9. Click the **Copy Shipping Status** checkbox.
10. Click **Save**.
11. Go to the **Shipping Status** form.
12. Click on the **Number sent** field; enter the value into the opened form.
13. *If this is the last specimen to be added to the shipment*, click *Send Email Alert* at this time.
14. Click **Save**.





Notes:

You must click Save after choosing one of the radio buttons – only then will the list of tracking numbers be updated.

Number sent in the Shipping Status form is the only piece of data that is not copied over as it may be different, do not forget to go to the Shipping Status form to enter this number

Remember, do not send the email alert until all specimens have been added to the relevant tracking number.

Receiving Status form

This form is used by the recipient lab only. **The sending lab should not enter or modify any data in this form.**

The number of samples listed in Shipping Status will correspond to the number of loglines in Receiving Status.

If queries are noticed on the Receiving Status form, check the **Shipping Status** form for errors (such as quantity sent) and address them on the **Shipping Status** form.

Tracking Contacts form

This form is machine controlled. **Rave Users should not enter or modify any data in this form.**

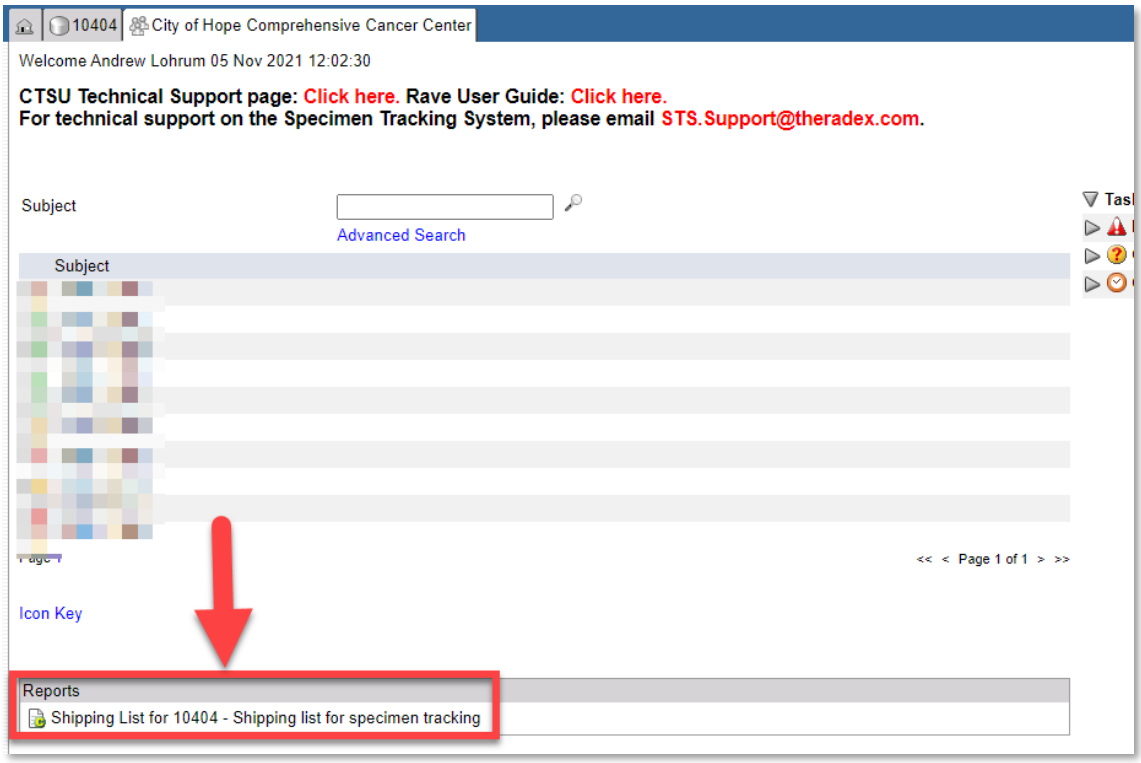
If no Destinations are present in the Shipping Status form and the Tracking Contacts form is blank. Go to the **Enrollment** folder and complete the **Histology and Disease** form.

If you believe changes are needed in this form, please contact sts.support@theradex.com.

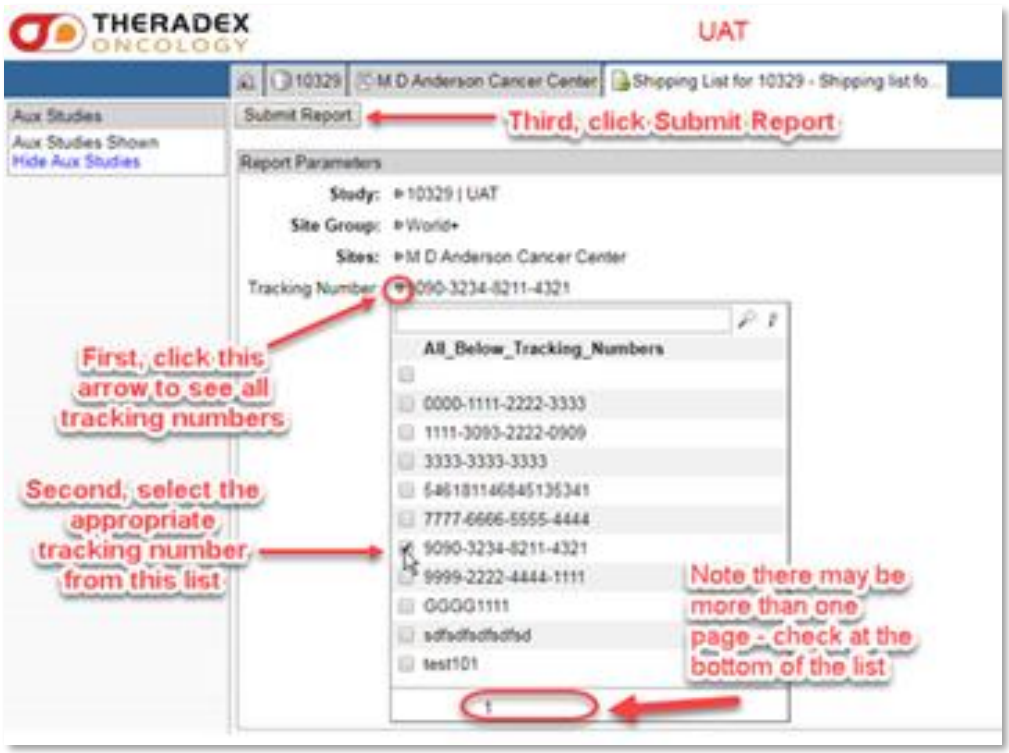
Shipping List

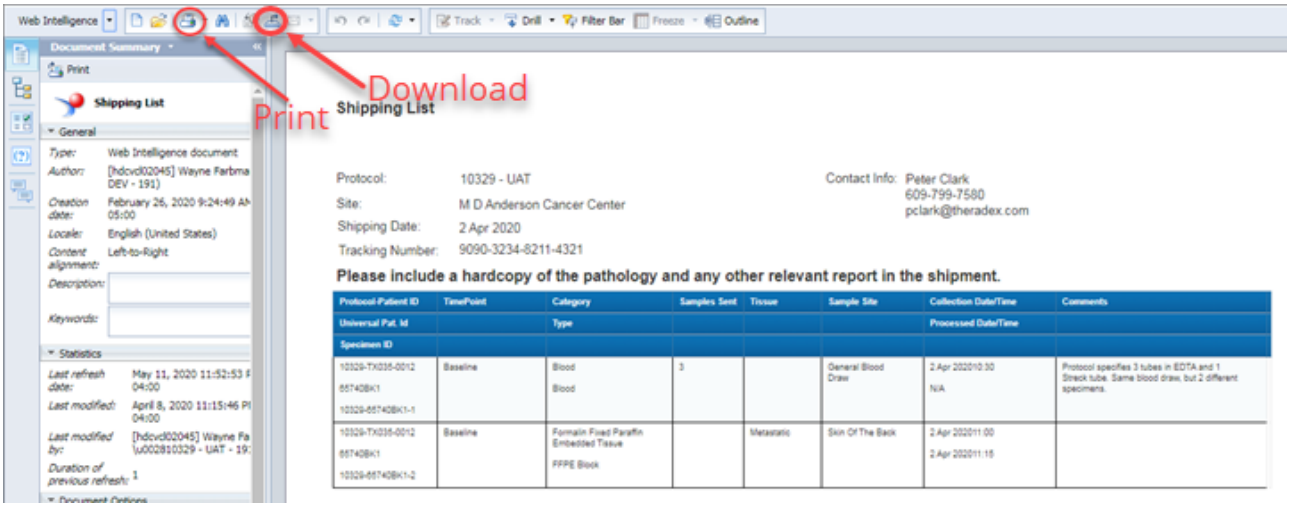
The Shipping List is indexed on the tracking number. Rave will pull entries from the Shipping Status forms with the same tracking number form and create a line in the Shipping List.

1. Click on the tab with your site name. Below the list of participants, in the **Report** box, click **Shipping List**.
2. Click on the **Tracking Number** arrow.
3. Select the tracking number from the list.
4. Click **Submit Report**.
5. Use the print icon or the download icon in the pop-up window.
6. Put shipping list report and hardcopies of relevant pathology reports in the box with the specimens.



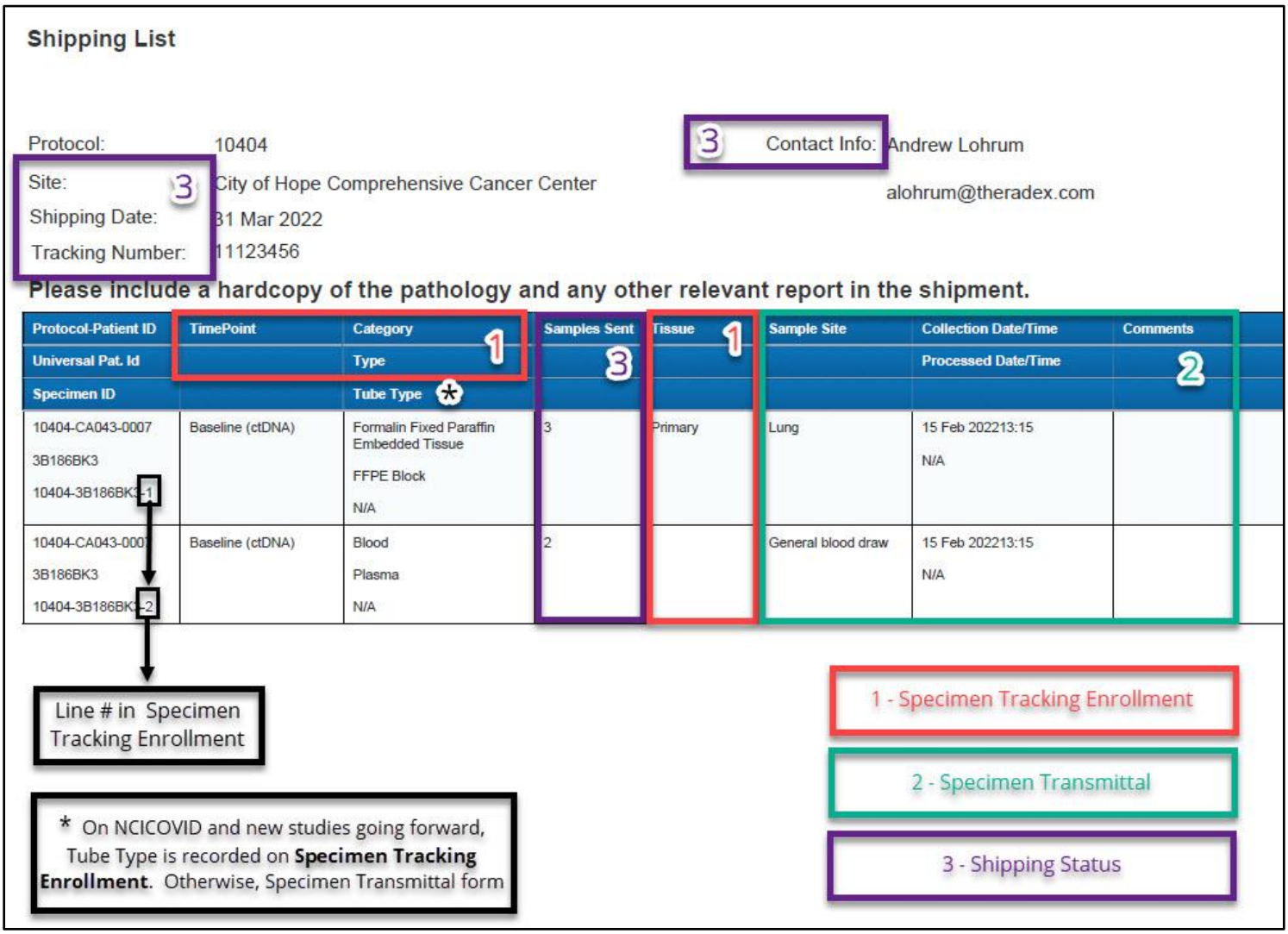
For older studies, if you do not see the Reports box on the subject page, make sure you are logged in with the **CRA Specimen Tracking** role.





NOTES:

- If the shipment includes specimens from multiple participants, the Shipping List will have a separate page for each participant.
- The Shipping List is organized by Tracking number — if items are missing check the tracking number field in Shipping Status for errors or extra spaces before or after the number.
- Double check that the specimen ID and the specimen type on the container matches the line item on the Shipping List.
- The number sent on the shipping list must correspond to the number of that specific sample that are packed in the box.
- *If any data is incorrect be sure to update the appropriate form Specimen Tracking Enrollment, Details or Shipping Status. Then regenerate the Shipping List – Corrections by hand and initialed are not acceptable. See image on next page.*

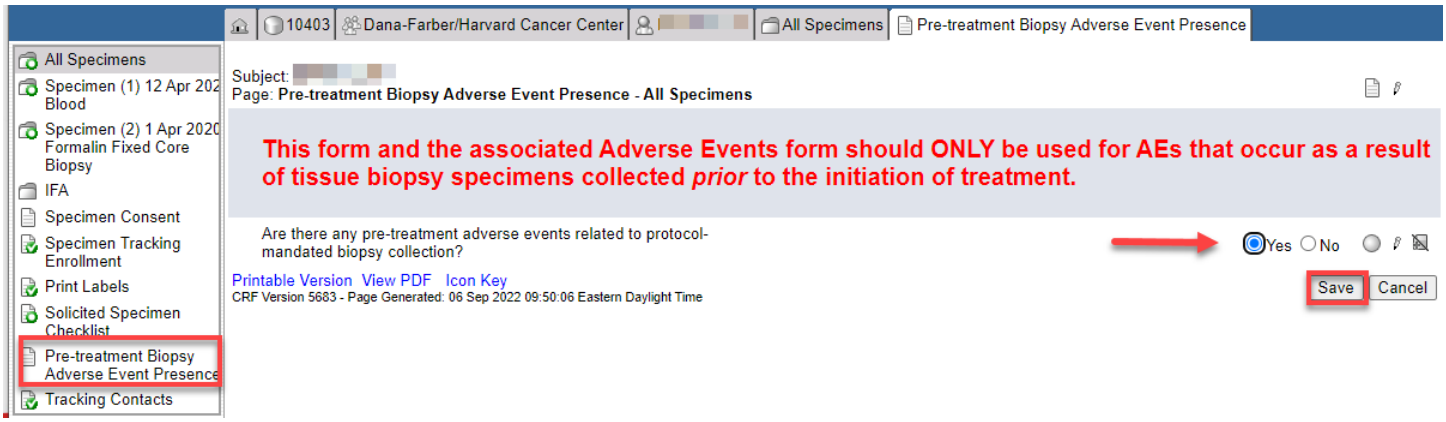

Shipping List
Protocol: 10404
Site: City of Hope Comprehensive Cancer Center
Shipping Date: 31 Mar 2022
Tracking Number: 11123456
3
Contact Info: Andrew Lohrum
alohrum@theradex.com
Please include a hardcopy of the pathology and any other relevant report in the shipment.
Protocol-Patient ID
Universal Pat. Id
Specimen ID
TimePoint
Category
Type
Tube Type
Samples Sent
Tissue
Sample Site
Collection Date/Time
Processed Date/Time
Comments
10404-CA043-0007
3B186BK3
10404-3B186BK3-1
Baseline (ctDNA)
Formalin Fixed Paraffin Embedded Tissue
FFPE Block
N/A
3
Primary
Lung
15 Feb 202213:15
N/A
10404-CA043-0007
3B186BK3
10404-3B186BK3-2
Baseline (ctDNA)
Blood
Plasma
N/A
2
General blood draw
15 Feb 202213:15
N/A
Line # in Specimen Tracking Enrollment
* On NCICOVID and new studies going forward, Tube Type is recorded on Specimen Tracking Enrollment. Otherwise, Specimen Transmittal form
1 - Specimen Tracking Enrollment
2 - Specimen Transmittal
3 - Shipping Status

Adverse Events in Specimen Collection

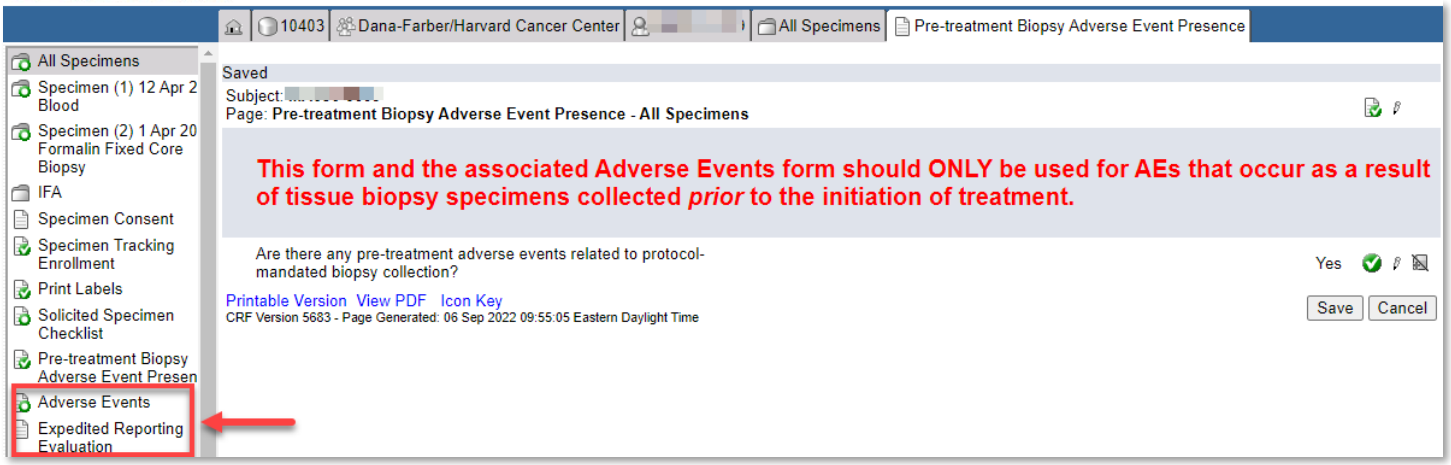
Adverse events that occur as a result of specimen collection **prior to treatment** are recorded on forms within the STS. These forms may not be present for your study.

If the event occurs during treatment, record the adverse event form in the current Course folder. See the Rave User Guide for more information.

Pre-treatment Biopsy Adverse Event Presence



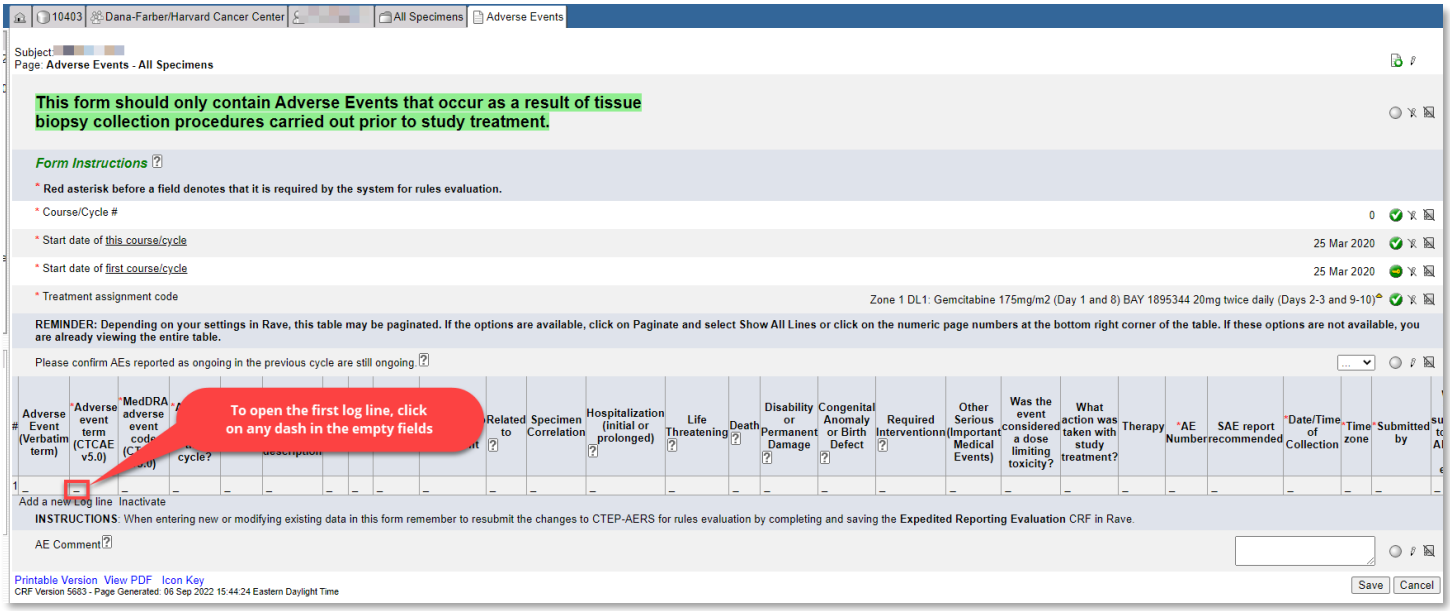
If an adverse event occurs during the collection of a tissue specimen prior to treatment, click the **Yes** radio button and then click **Save**.



After saving the form, the **Adverse Events** and **Expedited Reporting Evaluation** form will be available to collect more information.

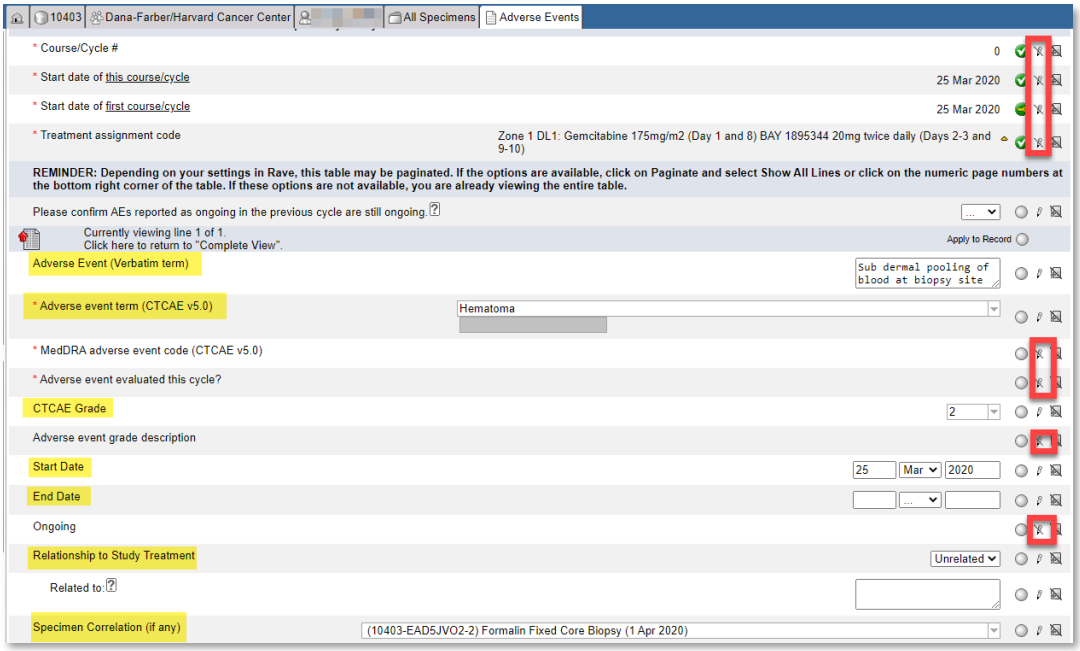
Adverse Events (All Specimens)

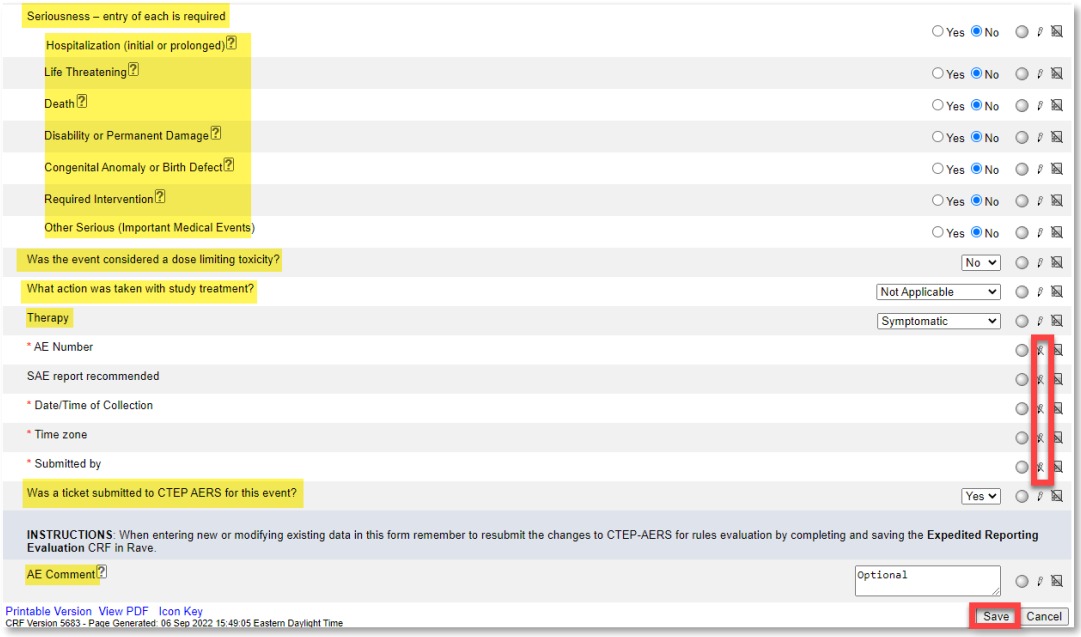
The specimen associated with the adverse event must be entered into **Specimen Tracking Enrollment** and **Specimen Transmittal** before completing this form.



The standard fields at the top of the form are auto-populated with values from the Enrollment folder. To enter the first observed adverse event, click on the dash (-) in any empty field or use the Edit pencil to expand the log line.

The auto-populated fields in the form are not open to editing. The fields are either derived from previously entered data or will auto-populate with data based on your entries after saving the form. These fields will have a crossed out Edit pencil as they cannot be edited. See red boxes below.





Succinctly describe the symptom/adverse event in the **Adverse Event (Verbatim term)** field. Do not simply retype the CTCAE term. *DO NOT INCLUDE SPECIAL CHARACTERS SUCH AS SYMBOLS (DASHES, COMMAS, PLUS SIGN, APOSTROPHE, ETC.).* Select the appropriate **CTCAE term** from the drop down menu. You can type in the menu to filter the selections. The **MedDRA code** will automatically populate after saving the form.

Choose the **CTCAE Grade** and enter the **Start** and **End dates** of the event. Enter the **Relationship to Study Treatment**.

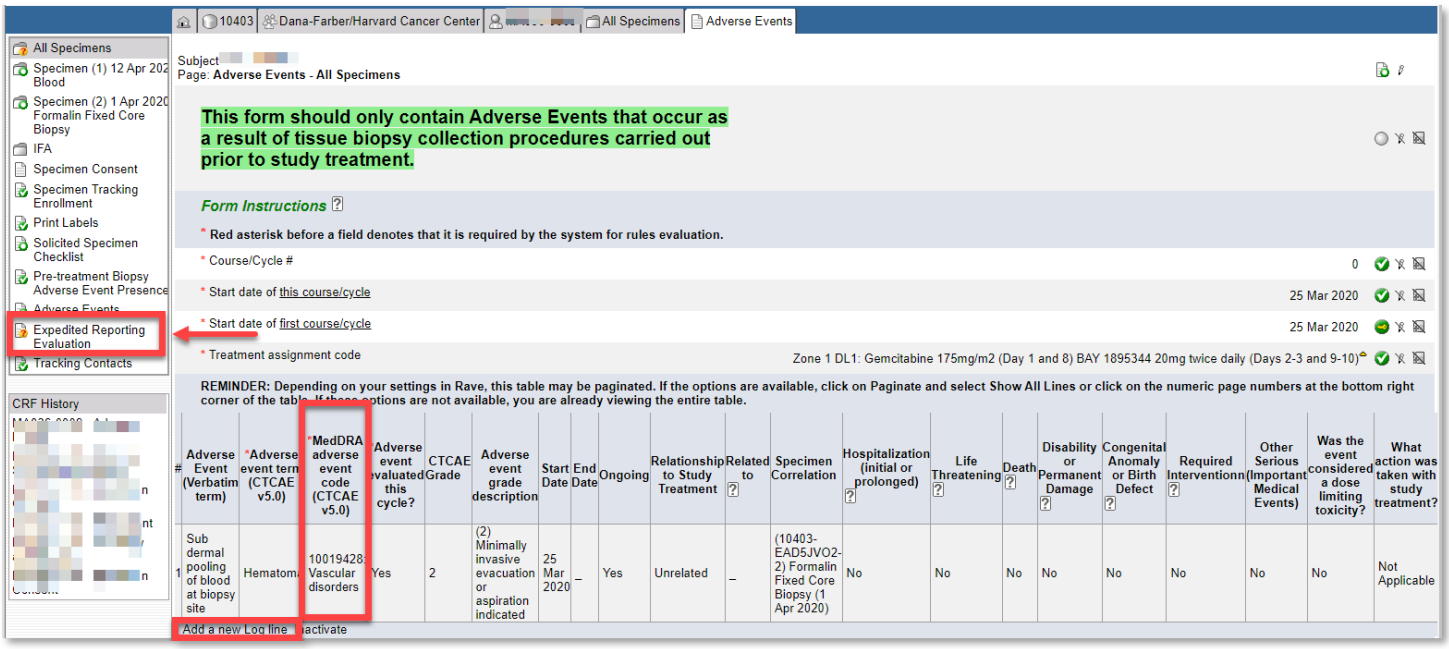
From the **Specimen Correlation (if any)** drop down, select the specimen which correlates to the adverse event. A specimen must be selected for this field, **do not leave blank**. If the drop-down is empty, the specimen must be entered into the Specimen Tracking Enrollment form and the Specimen Transmittal form must be completed prior to completion of the Adverse Events form.

Select Yes or **No** for each question pertaining to the **Seriousness** of the adverse event. Do not leave any blank.

Indicate if a ticket was submitted to **CTEP-AERS**. You can enter an optional **AE Comment**. *DO NOT INCLUDE SPECIAL CHARACTERS SUCH AS SYMBOLS (DASHES, COMMAS, PLUS SIGN, APOSTROPHE, ETC.).*

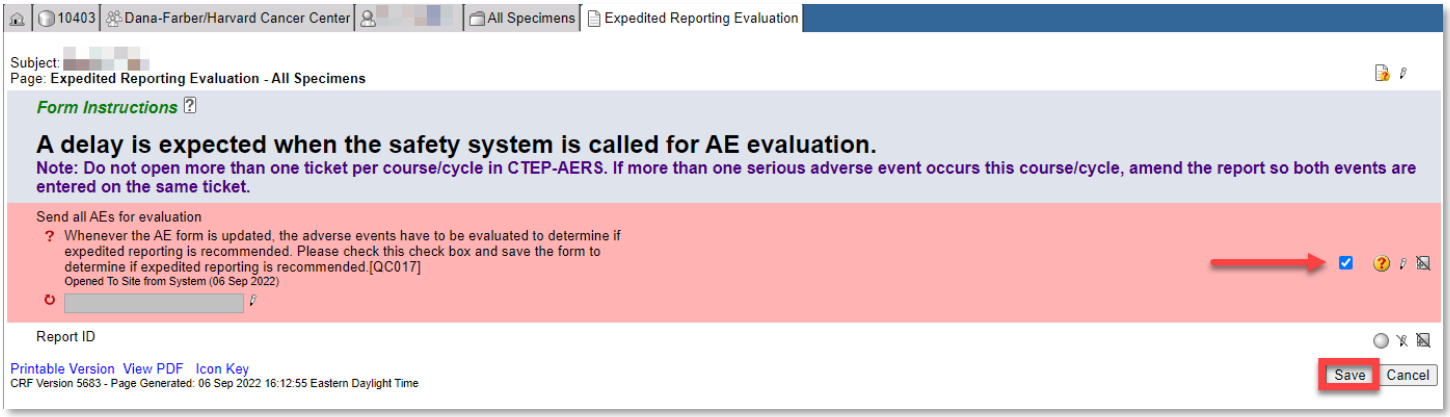
After saving, the form will create a log line. To edit the entries, use the **Edit** pencil to the right of the log line. To add entries, click **Add a New Log line**.

Note the MedDRA field in the next image, this has auto populated based on the selected CTCAE term. Also, a query has been opened on the Expedited Reporting form. This will be covered in the next section.



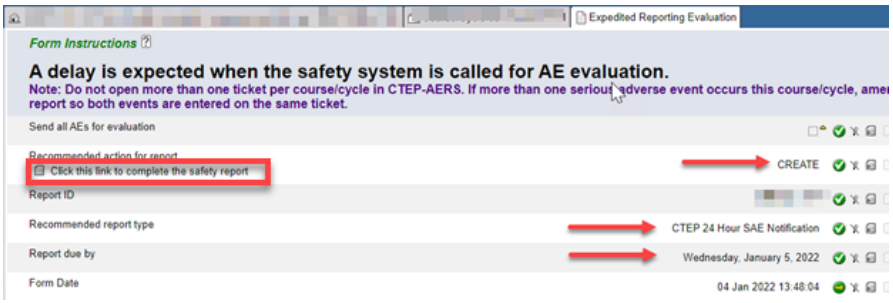
Expedited Reporting Evaluation (All Specimens)

<u>Whenever the AE form is updated</u>, the adverse events must be evaluated to determine if expedited reporting is recommended each time. Use the Send all AE's checkbox and save the form to determine if expedited reporting is recommended



After completing the adverse events form, a query is opened on the Expedited Reporting Evaluation form. **Click** the checkbox and then click the **Save** button. The query will automatically resolve when the box is checked and the form is saved.

If the CTEP-AERS determines that a report is needed (ie. CREATE or EDIT) it will advise on the report type and due date. Click on the link to complete the safety report (see red box in next image).



Please see the Adverse Events form, under the Course section, in the Rave User Guide for more information.