



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



Contents

Access	3
CTEP-IAM and Rave Account Setup	3
Logging in through CTSU	4
Current role in Rave	4
Specimen Tracking System Overview	5
Summary of STS data entry	6
Enrollment folder - Histology & Disease form	6
Examples of PHI/PPI	7
All Specimens folder	8
Specimen Consent form	8
Solicited Specimen Checklist	10
Specimen Tracking Enrollment form	11
Also referred to as Specimen Collection Initiation in some studies.....	11
Labels.....	13
Print Label form	13
Printing labels by manual selection	14
Printing labels by Available Protocol Timepoints	14
Specimen Label Report	16
Specimen Transmittal form	17
Also referred to as Specimen Collection Details in some studies	17
Shipping.....	19
Shipping Status form	19
Copy Shipping	20
Receiving Status form	21
Tracking Contacts form	21
Shipping List	22
Adverse Events in Specimen Collection	25
Pre-treatment Biopsy Adverse Event Presence.....	25
Adverse Events (All Specimens)	26
Expedited Reporting Evaluation (All Specimens).....	28

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

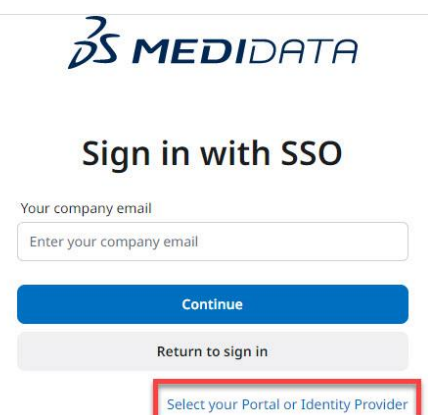
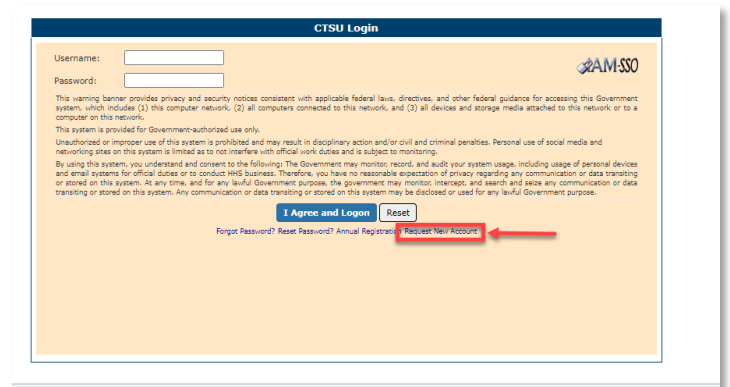
The Theradex Specimen Tracking System is integrated within a study in Rave. Contact your RSS or DTL site administrator or CTSU to ensure you are on the site roster for your study with the role of **Rave Clinical Research Associate (CRA)** for each protocol you need to enter data. For protocols that require 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.

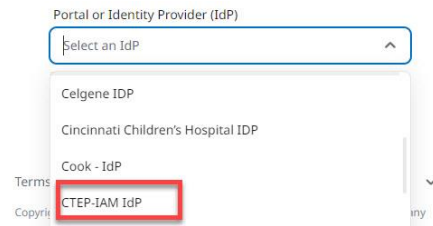
CTEP-IAM and Rave Account Setup

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**

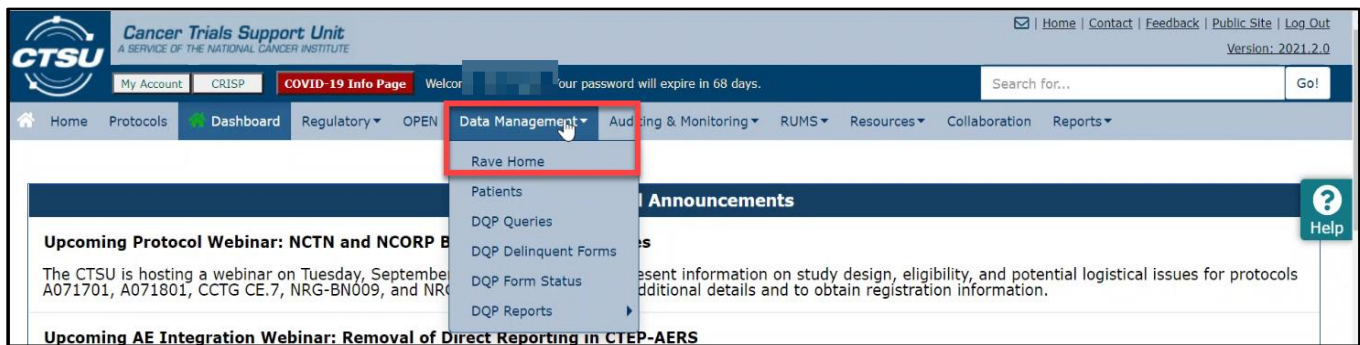


- From the menu, choose **CTEP-IAM IdP**.
- Click **Select**
- Login with your CTEP-IAM username and password on the resulting screen.



Logging in through CTSU

- Go to the following URL: <https://www.ctsuh.org/Public/Default.aspx>
- Click **Log in**.
- At the login page, enter your **CTEP-IAM Username** and **Password**
- Click **I agree and logon**.
- Go to the **Data Management** menu.
- Click **Rave Home**.

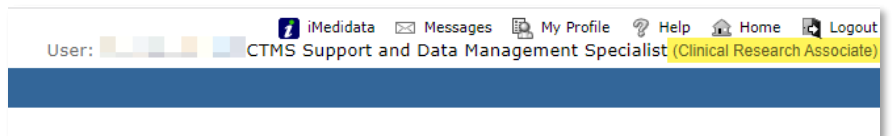


Current role in Rave

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.



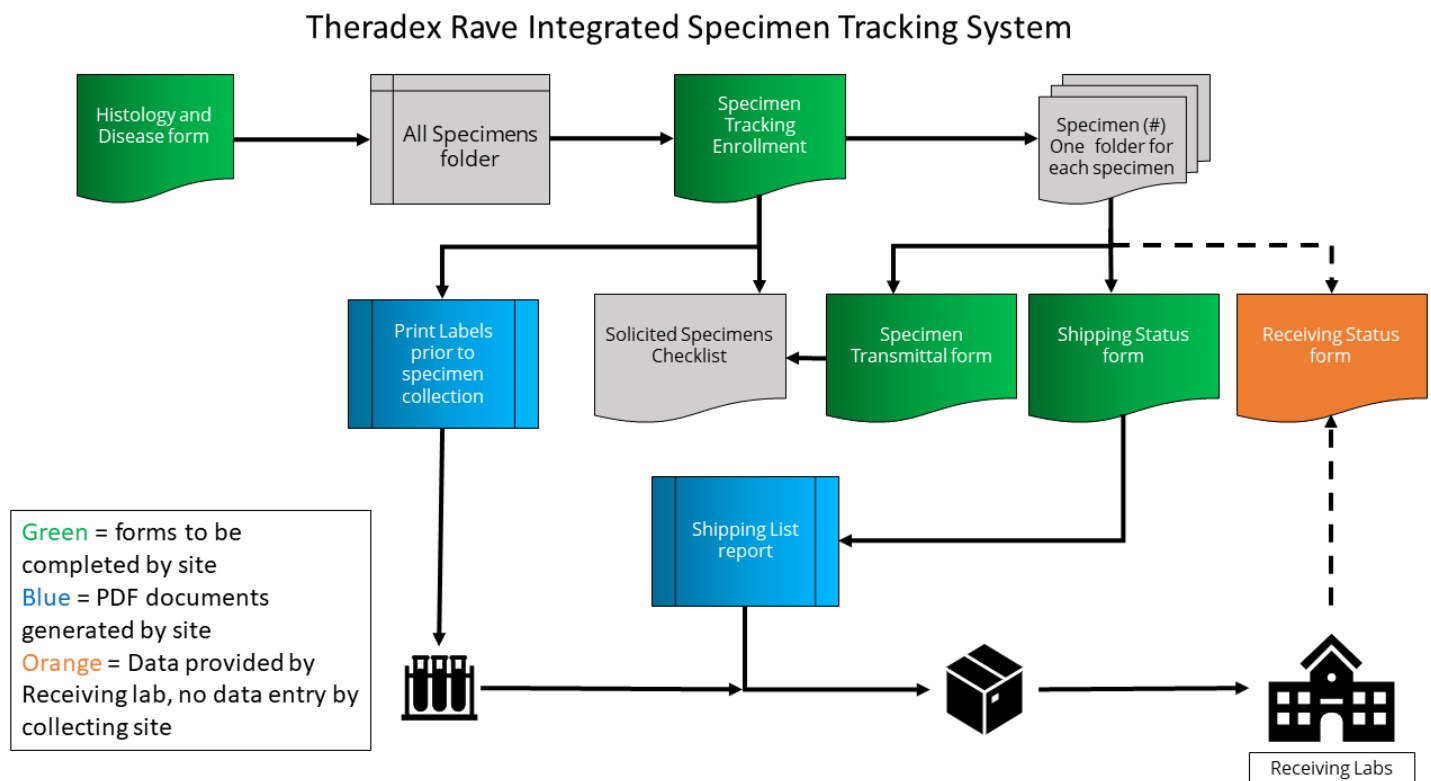
If your role is **Clinical Research Associate** and you cannot edit forms in the All Specimens folder or generate reports, contact STS support as we may need to add the **CRA Specimen Tracking** role to your account. See [Access](#) for more information.

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 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.

The screenshot shows the TheraDex Oncology web application interface. The top navigation bar includes the TheraDex Oncology logo, a 'DEV' status indicator, and user navigation links (iMedidata, Messages, My Profile, Help, Home, Logout). The main content area displays the 'Histology and Disease' form for subject MM001-1105A. The form is divided into sections: 'Disease Stage' (Stage 0), 'Tumor Grade' (Poorly Differentiated), 'SnoMed Disease Term/Code' (Acinar Cell Carcinoma = 45410002), 'Histology/Cytopathology' (Histology), 'Initial Diagnosis Date' (12 Mar 2020), and 'Date of Confirmation of Histology' (15 Mar 2020). A yellow warning box is present, stating: 'On-study specimen specific reports should not be uploaded here. Upload on-study specimen reports on the Specimen Tracking Enrollment form. Keep the size of the uploaded file as small as possible to avoid adversely impacting Rave EDC performance.' The bottom of the form features a 'Report Upload' section with a table for adding log lines and a 'Save' button.

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.

Kid
Kidney Oncocytoma = 254922006
Kidney Wilms Tumor = 25081006
Kidney Wilms Tumor = 302849000

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

Back 1/10 Next

Accelerated Phase Chronic Myelogenous Leukemia, BCR-ABL1 Positive = 41331003
 Acinar Cell Carcinoma = 45410002
 ACTH-Producing Pituitary Gland Adenoma = 21109002
 ACTH-Producing Pituitary Gland Adenoma = 254958004
 Actinic (Solar) Keratosis = 201101007
 Actinic (Solar) Keratosis = 856006
 Acute Basophilic Leukemia = 307592006
 Acute Basophilic Leukemia = 30077002
 Acute Bilineal Leukemia = 12881009
 Acute Bilineal Leukemia = 450913003

Number of pages

Navigation buttons

- 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.

The screenshot shows the THERADEx ONCOLOGY interface. The top navigation bar includes the THERADEx ONCOLOGY logo, the text 'DEV', and a user profile for 'Melissa Mineo Medidata Rave Programmer (Clinical Research Associate)'. The left sidebar lists various folders, with 'All Specimens' highlighted. The main content area shows the participant level for 'MM001-1105A'. A red box highlights the participant ID in the top navigation bar, with the text 'Tab with the participant ID' next to it. A red arrow points to the 'All Specimens' folder in the sidebar, with the text 'Click here' next to it.

Specimen Consent form

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

The screenshot shows the 'Specimen Consent' form in the THERADEx ONCOLOGY interface. The top navigation bar includes the THERADEx ONCOLOGY logo, the text 'DEV', and a user profile for 'Melissa Mineo Medidata Rave Programmer (Clinical Research Associate)'. The left sidebar lists various folders, with 'All Specimens' highlighted. The main content area shows the 'Specimen Consent' form. A red box highlights the warning message: 'Histology and Disease form must be completed before any specimen data can be entered.' The form includes fields for 'Consent Date' (31 Mar 2022), a consent statement, and a reason for withdrawal of consent. The form also includes a 'Printable Version' link and a 'View PDF' link.

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.

Saved

Subject: 10404 City of Hope Comprehensive Cancer Center

Page: Specimen Consent - All Specimens

Histology and Disease form must be completed before any specimen data can be entered.

First logline is required prior to the first specimen collection.
 Additional loglines need only be added if consent changes.
 Email STS.Support@theradex.com for assistance with specimen tracking.

#	Consent Date	Specimen Collection Agreement	Storage Permission	Contact Permission	CLIA Sequencing	Reason for Withdrawal
1	31 Mar 2022	Yes	Yes	Yes	Not Applicable	--

[Add a new Log line](#) [Printable Version](#) [View PDF](#) [Icon Key](#)

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Save Cancel

- 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.

Subject: [REDACTED]
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.

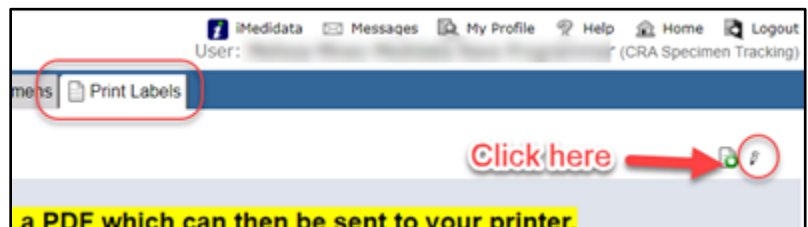
If using the **Print Labels** form, once the **Specimen Tracking Enrollment** form is saved, the number of labels cannot be updated on this form. If a change is needed to the number of labels, update on the **Print Labels** form.

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

CDASHIG 2.0

Labels will be delivered to your email address as a PDF which can then be sent to your printer. For a standard printer, use this product. These labels are 0.5 inches high and 1.28 inches wide.

Label Layout is a mandatory field – after the first use, please click the edit pencil to the right. If no value is selected it is defaulted to "Multiple labels per page".

Label Layout

If you have previously used this form, please click the edit pencil to the right to specify a timepoint.

Available Protocol Timepoints

• If the number of labels you need are listed below already, please click the checkbox next to any row (multiple rows are allowed) or choose a protocol timepoint from above, then save the form.
• If you need a different number of labels, please update the below values, and save the form without clicking any checkboxes. Please wait a few minutes for Rave to make clinical view updates, then either select the protocol timepoint above or click any of the checkboxes below, then save the form.

#	Specimen Enrollment Logline Number	Universal Participant ID	Specimen ID	Protocol TimePoint	Protocol TimePoint Coded Value	Specimen Category	Specimen Type	Relevant Codes	How many labels?	Print (multiple selections allowed)	
1	1		CDASH Seed-1	Baseline	BASLINE	Blood	Blood	--	2	☐	☐
2	2		CDASH Seed-2	Cycle 1 Day 15	C1D15	Blood	Blood	--	3	☐	☐

Printable Version View PDF Icon Key
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Save Cancel

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.

THERADEx ONCOLOGY DEV

iMedidata Messages My Profile Help Home Logout
User: Melissa Mineo Medidata Rave Programmer (CRA Specimen Tracking)

CDASH Seed Theradex MM001-1105A All Specimens Print Labels

Subject: MM001-1105A
Page: Print Labels - All Specimens

Labels will be delivered to your email address as a PDF which can then be sent to your printer. For a standard printer, use this product. These labels are 0.5 inches high and 1.28" wide.

Label Layout is a mandatory field – after the first use, please click the edit pencil to the right. If no value is selected it is defaulted to "Multiple labels per page".

Label Layout

If you have previously used this form, please click the edit pencil to the right to specify a timepoint.

Available Protocol Timepoints

- If the number of labels you need are listed below already, please click the checkbox next to any row (multiple rows are allowed) or choose a protocol timepoint from above, then save the form.
- If you need a different number of labels, please update the below values, and save the form without clicking any checkboxes. Please wait a few minutes for Rave to make clinical view updates, then either select the protocol timepoint above or click any of the checkboxes below, then save the form.

#	Specimen Enrollment Logline Number	Universal Participant ID	Specimen ID	Protocol TimePoint	Protocol TimePoint Coded Value	Specimen Category	Specimen Type	Relevant Codes	How many labels?	Print (multiple selections allowed)
1	1		CDASH Seed-1	Baseline	BASELINE	Blood	Blood	--	2	☐

Printable Version View PDF Icon Key
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Save Cancel

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

THERADEx ONCOLOGY DEV

iMedidata Messages My Profile Help Home Logout
User: Melissa Mineo Medidata Rave Programmer (Clinical Research Associate)

CDASH Seed Theradex MM001-1105A All Specimens Print Labels

Subject: MM001-1105A
Page: Print Labels - All Specimens

Labels will be delivered to your email address as a PDF which can then be sent to your printer. For a standard printer, use this product. These labels are 0.5 inches high and 1.28" wide.

Label Layout is a mandatory field – after the first use, please click the edit pencil to the right. If no value is selected it is defaulted to "Multiple labels per page".

Label Layout

If you have previously used this form, please click the edit pencil to the right to specify a timepoint.

Available Protocol Timepoints

- If the number of labels you need are listed below already, please click the checkbox next to any row (multiple rows are allowed) or choose a protocol timepoint from above, then save the form.
- If you need a different number of labels, please update the below values, and save the form without clicking any checkboxes. Please wait a few minutes for Rave to make clinical view updates, then either select the protocol timepoint above or click any of the checkboxes below, then save the form.

#	Specimen Enrollment Logline Number	Universal Participant ID	Specimen ID	Protocol TimePoint	Protocol TimePoint Coded Value	Specimen Category	Specimen Type	Relevant Codes	How many labels?	Print (multiple selections allowed)
1	1		CDASH Seed-1	Baseline	BASELINE	Blood	Blood	--	2	☐

Printable Version View PDF Icon Key
CRF Version 3666 - Page Generated: 11 Nov 2020 10:29:11 Eastern Standard Time

Save Cancel

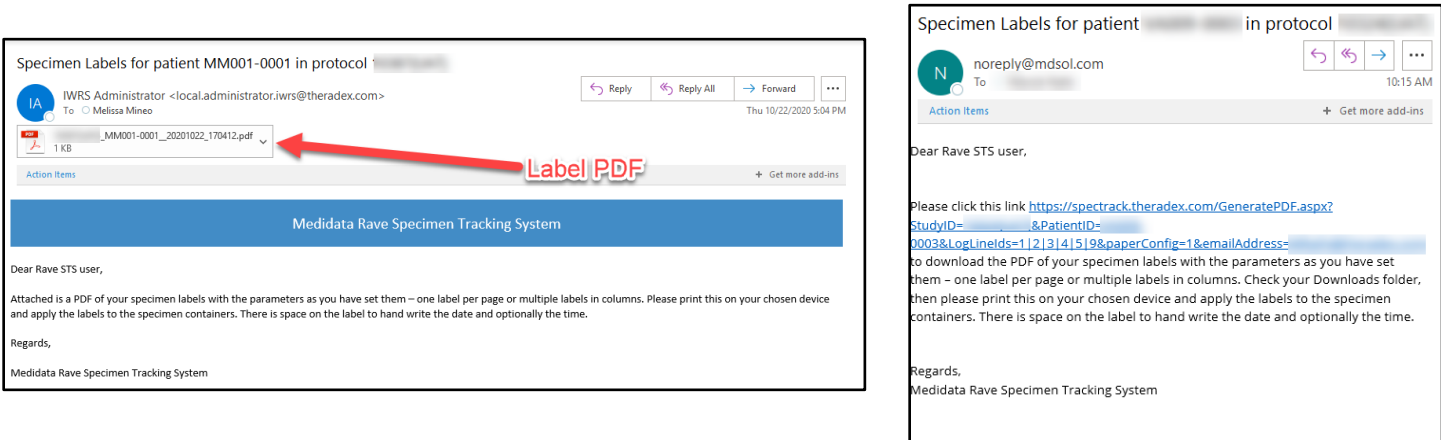
1. Select one of the **Available Protocol Timepoints** from the dropdown.
2. **Skip over** the line listing of specimens.
3. Click the **Save** button.

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.

*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

Theradex Oncology UAT

10302

Subject Enrollment

Visit	Date	Task Summary: Subject
Enrollment	01 Jan 2019	Requiring Signature
Baseline	01 Jan 2019	NonConformant Data
Course 01 - 01 Jan 2019	01 Jan 2019	Open Queries
Course 02 - 29 Jan 2019	29 Jan 2019	Answered Queries
Course 03 - 28 Feb 2019	28 Feb 2019	Sticky Notes
Course 04 - 28 Mar 2019	28 Mar 2019	Requiring Review
Course 05 - 23 Apr 2019	23 Apr 2019	Requiring Verification
Course 06 - 23 May 2019	23 May 2019	Overdue Data
		Ready for Data Lock
		Cancel Queries

Click here - can also select at the site level (below the list of participants)

Reports

Specimen Labels for 10302 - One per page

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.

UAT

10302

Specimen Labels for 10302 - One per page

Submit Report

Report Parameters

Study: 10302 | UAT

Site Group: World+

Sites: Rutgers Cancer Institute of New Jersey

Subjects: NJ066

Timepoint(s):

- All TimePoints
- Archival
- Baseline

Collection Date(s):

Highlighted items must be selected. Collection date is not needed to run report.

Specimen Transmittal form

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

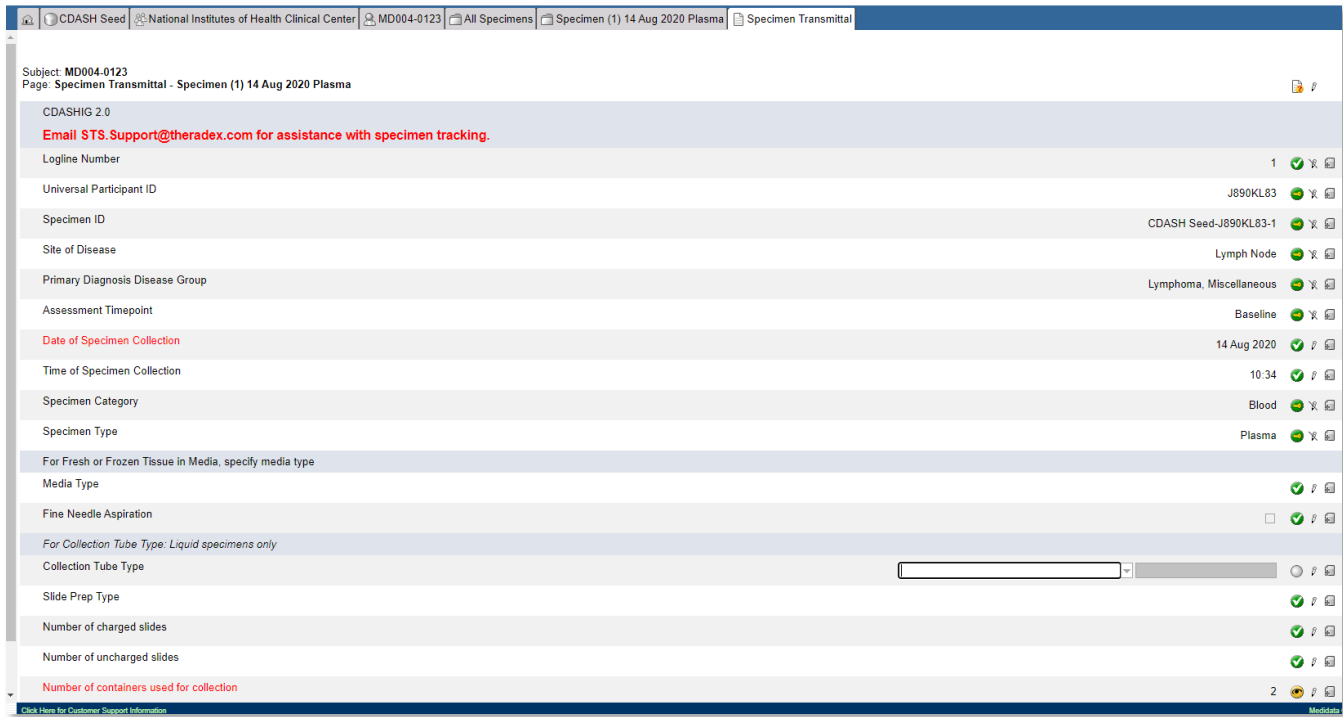


This form should be completed the same day as specimen collection even if the specimen is to be shipped at a later date.

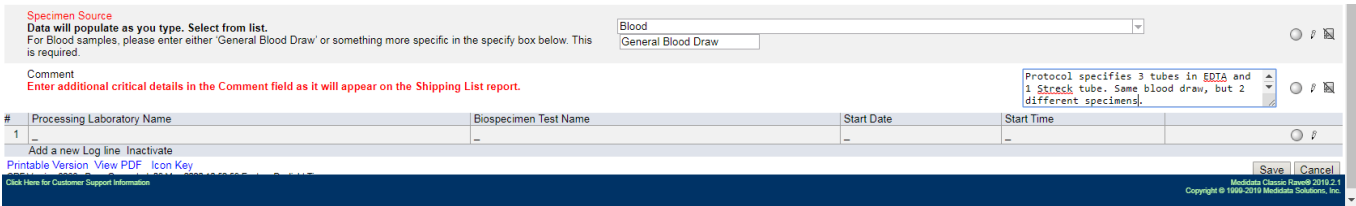
Return to the **All Specimens** folder. After adding the logline to the **Specimen Tracking Enrollment** form, a folder will have populated, **Specimen (#)** for each specimen line. Open each folder and complete the forms.

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 form 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**.

Sender's Telephone	Sender's Email	Number Sent	Shipping Conditions	Shipped Date	Destination
	alohum@	12	Ice Pack	18 Mar 2021	EET Biobank

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.**

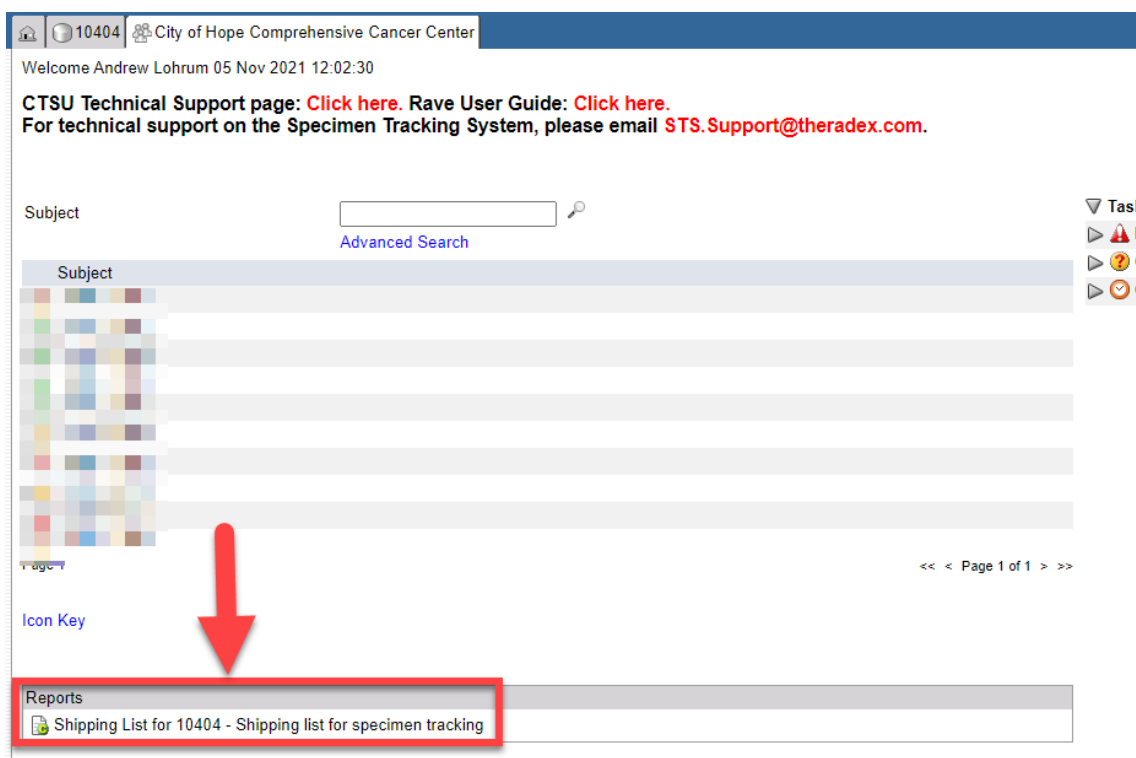
If no Destinations are present in the Shipping Status form and the Tracking Contacts form is blank. Go to the **Enrollment** folder and complete the **Histology and Disease** form.

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.

THERADEx ONCOLOGY UAT

10329 M D Anderson Cancer Center Shipping List for 10329 - Shipping list fo...

Aux Studies Submit Report Third, click Submit Report

Aux Studies Shown
Hide Aux Studies

Report Parameters

Study: 10329 | UAT
Site Group: World+
Sites: M D Anderson Cancer Center
Tracking Number: 9090-3234-8211-4321

First, click this arrow to see all tracking numbers

Second, select the appropriate tracking number from this list

Note there may be more than one page - check at the bottom of the list

All_Below_Tracking_Numbers

- ☐ 0000-1111-2222-3333
- ☐ 1111-3093-2222-0909
- ☐ 3333-3333-3333
- ☐ 646181146845135341
- ☐ 7777-6666-5555-4444
- ☒ 9090-3234-8211-4321
- ☐ 9999-2222-4444-1111
- ☐ 00001111
- ☐ eddofedofed
- ☐ test101

1

Web Intelligence Download Print Shipping List

Document Summary

Shipping List

General

Type: Web Intelligence document
Author: [hdov02045] Wayne Farba DEV - 191
Creation date: February 26, 2020 9:24:49 AM 05:00
Locale: English (United States)
Content alignment: Left-to-Right
Description:
Keywords:

Statistics

Last refresh date: May 11, 2020 11:52:53 AM 04:00
Last modified by: [hdov02045] Wayne Fa
Last modified by: [hdov02045] Wayne Fa
Duration of previous refresh: 1

Protocol: 10329 - UAT
Site: M D Anderson Cancer Center
Shipping Date: 2 Apr 2020
Tracking Number: 9090-3234-8211-4321

Contact Info: Peter Clark
609-799-7580
pclark@theradex.com

Please include a hardcopy of the pathology and any other relevant report in the shipment.

Protocol Patient ID	TimePoint	Category	Samples Sent	Tissue	Sample Site	Collection Date/Time	Comments
Universal Pat. ID		Type				Processed Date/Time	
Specimen ID							
10329-TN035-0012	Baseline	Blood	3		General Blood Draw	2 Apr 2020 10:30	Protocol specifies 3 tubes in EDTA and 1 Streck tube. Same blood draw, but 2 different specimens.
85740BK1		Blood				N/A	
10329-85740BK1-1							
10329-TN035-0012	Baseline	Formalin Fixed Paraffin Embedded Tissue		Melanotic	Skin Of The Back	2 Apr 2020 11:00	
85740BK1		FFPE Block				2 Apr 2020 11:15	
10329-85740BK1-2							

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

3

Contact Info: Andrew Lohrum

Site: 3 City of Hope Comprehensive Cancer Center

alohrum@theradex.com

Shipping Date: 31 Mar 2022

Tracking Number: 11123456

Please include a hardcopy of the pathology and any other relevant report in the shipment.

Protocol-Patient ID	TimePoint	Category	Samples Sent	Tissue	Sample Site	Collection Date/Time	Comments
Universal Pat. Id		Type	3	1		Processed Date/Time	2
Specimen ID		Tube Type *					
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

1 - Specimen Tracking Enrollment

2 - Specimen Transmittal

3 - Shipping Status

* On NCICOVID and new studies going forward, Tube Type is recorded on **Specimen Tracking Enrollment**. Otherwise, Specimen Transmittal form

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

Subject: [REDACTED]
Page: Pre-treatment Biopsy Adverse Event Presence - All Specimens

This form and the associated Adverse Events form should ONLY be used for AEs that occur as a result of tissue biopsy specimens collected prior to the initiation of treatment.

Are there any pre-treatment adverse events related to protocol-mandated biopsy collection? ☒ Yes ☐ No

[Printable Version](#) [View PDF](#) [Icon Key](#)
CRF Version 5683 - Page Generated: 06 Sep 2022 09:50:06 Eastern Daylight Time

Save **Cancel**

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

Subject: [REDACTED]
Page: Pre-treatment Biopsy Adverse Event Presence - All Specimens

This form and the associated Adverse Events form should ONLY be used for AEs that occur as a result of tissue biopsy specimens collected prior to the initiation of treatment.

Are there any pre-treatment adverse events related to protocol-mandated biopsy collection? Yes ☒ No ☐

[Printable Version](#) [View PDF](#) [Icon Key](#)
CRF Version 5683 - Page Generated: 06 Sep 2022 09:55:05 Eastern Daylight Time

Save **Cancel**

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.

10403

Dana-Farber/Harvard Cancer Center

All Specimens

Adverse Events

Subject

Page: Adverse Events - All Specimens

This form should only contain Adverse Events that occur as a result of tissue biopsy collection procedures carried out prior to study treatment.

Form Instructions

Red asterisk before a field denotes that it is required by the system for rules evaluation.

Course/Cycle #0

Start date of this course/cycle25 Mar 2020

Start date of first course/cycle25 Mar 2020

Treatment assignment codeZone 1 DL1: Gemcitabine 175mg/m2 (Day 1 and 8) BAY 1895344 20mg twice daily (Days 2-3 and 9-10)

REMINDER: Depending on your settings in Rave, this table may be paginated. If the options are available, click on Paginate and select Show All Lines or click on the numeric page numbers at the bottom right corner of the table. If these options are not available, you are already viewing the entire table.

Please confirm AEs reported as ongoing in the previous cycle are still ongoing

Adverse Event #	Adverse Event (Verbatim term)	Adverse event term (CTCAE v5.0)	MedDRA adverse event code (CTCAE v5.0)	cycle?	Related to	Specimen Correlation	Hospitalization (initial or prolonged)	Life Threatening	Death	Disability or Permanent Damage	Congenital Anomaly or Birth Defect	Required Intervention	Other Serious (Important Medical Events)	Was the event considered a dose limiting toxicity?	What action was taken with study treatment?	Therapy	AE Number	SAE report recommended	Date/Time of Collection	Time zone	Submitted by
1																					

Add a new Log lineInactivate

INSTRUCTIONS: When entering new or modifying existing data in this form remember to resubmit the changes to CTEP-AERS for rules evaluation by completing and saving the Expedited Reporting Evaluation CRF in Rave.

AE Comment

Printable VersionView PDFIcon Key

CRF Version 5683 - Page Generated: 06 Sep 2022 15:44:24 Eastern Daylight Time

SaveCancel

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.

10403

Dana-Farber/Harvard Cancer Center

All Specimens

Adverse Events

Course/Cycle #0

Start date of this course/cycle25 Mar 2020

Start date of first course/cycle25 Mar 2020

Treatment assignment codeZone 1 DL1: Gemcitabine 175mg/m2 (Day 1 and 8) BAY 1895344 20mg twice daily (Days 2-3 and 9-10)

REMINDER: Depending on your settings in Rave, this table may be paginated. If the options are available, click on Paginate and select Show All Lines or click on the numeric page numbers at the bottom right corner of the table. If these options are not available, you are already viewing the entire table.

Please confirm AEs reported as ongoing in the previous cycle are still ongoing

Currently viewing line 1 of 1. Click here to return to "Complete View".

Apply to Record

Adverse Event (Verbatim term)Sub dermal pooling of blood at biopsy site

Adverse event term (CTCAE v5.0)Hematoma

MedDRA adverse event code (CTCAE v5.0)

Adverse event evaluated this cycle?

CTCAE Grade2

Adverse event grade description

Start Date25 Mar 2020

End Date

Ongoing

Relationship to Study TreatmentUnrelated

Related to

Specimen Correlation (if any)(10403-EAD5JV02-2) Formalin Fixed Core Biopsy (1 Apr 2020)

Seriousness - entry of each is required

Hospitalization (initial or prolonged)? ☐ Yes ☒ No

Life Threatening? ☐ Yes ☒ No

Death? ☐ Yes ☒ No

Disability or Permanent Damage? ☐ Yes ☒ No

Congenital Anomaly or Birth Defect? ☐ Yes ☒ No

Required Intervention? ☐ Yes ☒ No

Other Serious (Important Medical Events) ☐ Yes ☒ No

Was the event considered a dose limiting toxicity? ☐ No

What action was taken with study treatment?

Therapy

* AE Number

SAE report recommended

* Date/Time of Collection

* Time zone

* Submitted by

Was a ticket submitted to CTEP AERS for this event? ☐ Yes

INSTRUCTIONS: When entering new or modifying existing data in this form remember to resubmit the changes to CTEP-AERS for rules evaluation by completing and saving the Expedited Reporting Evaluation CRF in Rave.

AE Comment

Printable Version View PDF Icon Key

CRF Version 5683 - Page Generated: 06 Sep 2022 15:49:05 Eastern Daylight Time

Save Cancel

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.

10403 Dana-Farber/Harvard Cancer Center All Specimens Adverse Events

Subject: [Redacted]
Page: Adverse Events - All Specimens

This form should only contain Adverse Events that occur as a result of tissue biopsy collection procedures carried out prior to study treatment.

Form Instructions ?

- * Red asterisk before a field denotes that it is required by the system for rules evaluation.
- * Course/Cycle # 0
- * Start date of this course/cycle 25 Mar 2020
- * Start date of first course/cycle 25 Mar 2020
- * Treatment assignment code Zone 1 DL1: Gemcitabine 175mg/m2 (Day 1 and 8) BAY 1895344 20mg twice daily (Days 2-3 and 9-10)

REMINDER: Depending on your settings in Rave, this table may be paginated. If the options are available, click on Paginate and select Show All Lines or click on the numeric page numbers at the bottom right corner of the table. If these options are not available, you are already viewing the entire table.

Adverse Event #	Adverse Event (Verbatim term)	*Adverse event term (CTCAE v5.0)	*MedDRA adverse event code (CTCAE v5.0)	Adverse event evaluated this cycle?	CTCAE Grade	Adverse event grade description	Start Date	End Date	Ongoing	Relationship to Study Treatment	Related to ?	Specimen Correlation	Hospitalization (initial or prolonged)	Life Threatening	Death	Disability or Permanent Damage	Congenital Anomaly or Birth Defect	Required Intervention	Other Serious (Important Medical Events)	Was the event considered a dose limiting toxicity?	What action was taken with study treatment?
1	Subdermal pooling of blood at biopsy site	Hematoma	10019428 Vascular disorders	Yes	2	(2) Minimally invasive evacuation or aspiration indicated	25 Mar 2020	-	Yes	Unrelated	-	(10403-EAD5JVO2-2) Formalin Fixed Core Biopsy (1 Apr 2020)	No	No	No	No	No	No	No	No	Not Applicable

Add a new Log line Inactivate

Expedited Reporting Evaluation (All Specimens)



Whenever the AE form is updated, 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

10403 Dana-Farber/Harvard Cancer Center All Specimens Expedited Reporting Evaluation

Subject: [Redacted]
Page: Expedited Reporting Evaluation - All Specimens

Form Instructions ?

A delay is expected when the safety system is called for AE evaluation.

Note: Do not open more than one ticket per course/cycle in CTEP-AERS. If more than one serious adverse event occurs this course/cycle, amend the report so both events are entered on the same ticket.

Send all AEs for evaluation

Whenever the AE form is updated, the adverse events have to be evaluated to determine if expedited reporting is recommended. Please check this check box and save the form to determine if expedited reporting is recommended [QC017]
Opened To Site from System (06 Sep 2022)

Report ID

Printable Version View PDF Icon Key
CRF Version 5683 - Page Generated: 06 Sep 2022 16:12:55 Eastern Daylight Time

Save Cancel

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).

The screenshot shows a web browser window with the title "Expedited Reporting Evaluation". The page content includes:

- Form Instructions** (with a help icon):
 - A delay is expected when the safety system is called for AE evaluation.**
 - Note:** Do not open more than one ticket per course/cycle in CTEP-AERS. If more than one serious adverse event occurs this course/cycle, amend report so both events are entered on the same ticket.
- A button: "Send all AEs for evaluation" (with a plus icon, a green checkmark, and a document icon).
- Recommended action for report**:
 - A button: "Click this link to complete the safety report" (highlighted with a red rectangle). A red arrow points from this button to a "CREATE" button (which has a green checkmark and a document icon).
- Report ID**: A text field with a dropdown arrow, a green checkmark, and a document icon.
- Recommended report type**: A text field with a dropdown arrow, a red arrow pointing to the text "CTEP 24 Hour SAE Notification", a green checkmark, and a document icon.
- Report due by**: A text field with a dropdown arrow, a red arrow pointing to the date "Wednesday, January 5, 2022", a green checkmark, and a document icon.
- Form Date**: A text field showing "04 Jan 2022 13:48:04" (with a green checkmark and a document icon).

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