Theradex CTMS Rave User Guide Version 2.5 (September 2025)

User Guide for the Submission of the NCI/DCTD/CTEP Clinical Trials Monitoring Service Electronic Case Report Forms (eCRF) in iMedidata Rave

THERADEX ONCOLOGY

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Contact Us

CTSU Help Desk

Access and invites to the study database are overseen by CTSU. If you require access to a study or if your current access to a study suddenly changes, the **CTSU Help Desk** is your resource for these account issues. Any issues with account access should be forwarded to the CTSU Help Desk and not to Medidata. Please refer to section 4 of your protocol for more information.

Training is now integrated into the CTSU DTL application. When a new staff member is added to any study DTL, they will be enrolled in the specimen tracking training in CTSU CLASS. If the staff member will not be working on a study with a DTL, reach out to the Specimen Tracking support email below.

You can contact the CTSU Help Desk at CTSUContact@Westat.com or 1-888-823-5923; CTSU Help Desk hours are 9:00 am – 6:00 pm EST Monday-Friday (excluding holidays).

Theradex support

Rave is a common data capture application in use for many public and private studies in many different fields. As the data management center for ETCTN, we have contracted with Medidata to provide the Rave application to the network sites. **The ETCTN study databases within Rave are completely designed and maintained by Theradex**. **Any issues with forms in the study database should be forwarded to the relevant email addresses below and NOT to the Medidata Help Desk**. If assistance from Medidata is needed, a Theradex programmer or data manager will facilitate this.

When contacting Theradex, please be sure to include as much information as possible (i.e., *ETCTN Protocol number, Patient ID, Form name, Specimen ID*, *screenshot of issue*) in your communications.

Technical support:	support.ctms@theradex.com
Data Manager group:	CTMS-DM@theradex.com
Specimen Tracking support:	STS.support@theradex.com
Registration and Randomization:	support.iwrs@theradex.com; CTMS-DM@theradex.com
Main telephone:	609-799-7580
Postal address:	4365 Route 1 South Suite 101 Princeton, NJ 08540

Introduction

For over 30 years, Theradex has played a key role in monitoring early Phase Clinical trials for the NCI. The Clinical Trials Monitoring Services (CTMS) program collects Phase I and selected Phase II cancer trial data and audits the NCI-supported cancer center programs participating in these early phase trials and national cooperative group clinical trials. During the consecutive award periods of this contract, Theradex has gained significant experience in the treatment of cancer and allied diseases at the premier cancer centers in North America. Through the CTMS, Theradex has also been engaged with the leading clinical investigators involved in early clinical trials during three decades of new anti-cancer therapeutic approaches, from cytotoxic chemotherapy to immunotherapy to targeted therapies requiring genetic profiling of cancer patients.

In March 2014, the Experimental Therapeutics Clinical Trials Network (ETCTN) was launched by NCI to consolidate and integrate the conduct of all early phase clinical trials across NCI. All ETCTN protocols are monitored through Theradex's expanding CTMS program.

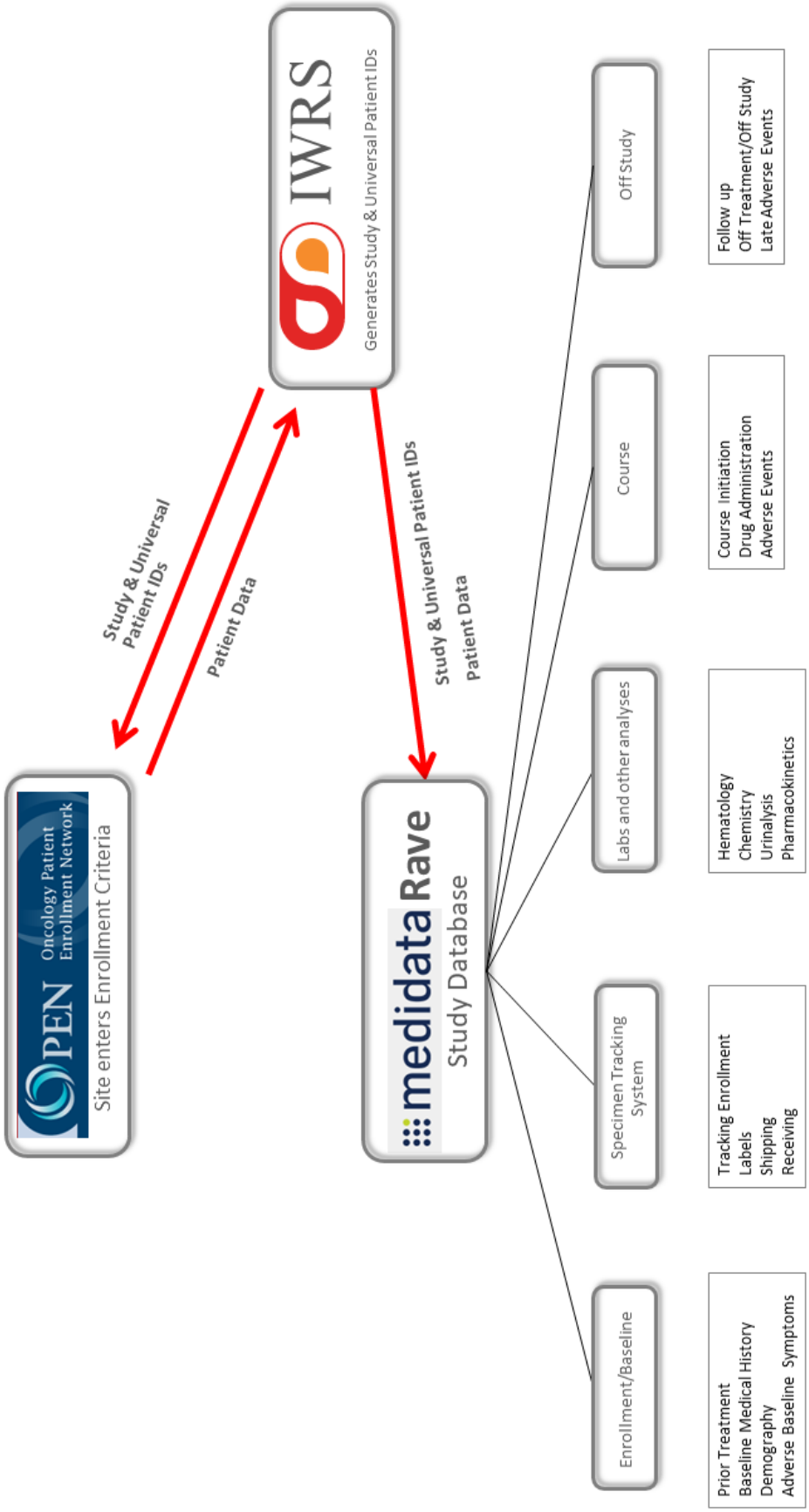
Overview

1. Access to studies and sites in Medidata Rave will be granted by invitation based on your assigned role on the roster and DTL (if applicable). Refer to protocol for detailed instructions.
2. Training in Rave (eLearning) is accessed through iMedidata, which is based on your assigned role(s) and must be completed prior to obtaining access to EDC. Once an eLearning course has been completed it does not need to be repeated for access to other studies.
3. All subjects/patients must be centrally registered prior to treatment and data entry into Rave. The selected registration system, IWRS and/or OPEN, will be determined during the set-up process. Data from the registration system will be automatically loaded into Rave to create subjects.
    a. The eCRF in Rave® are a primary set of forms that contain all the data elements required for CTMS monitoring of a study. Standard forms may be customized for a study if requested by the study team. In addition, the study team may request the creation of protocol specific custom forms.
    b. Protocol specific dictionaries in Rave will be customized to facilitate the submission of patient data, including, but not limited to, patient subgroup codes, treatment assignment codes, study drug data, pharmacokinetic and pharmacodynamics sampling schedule. The protocol specific codes for the study are provided by CTEP to the Principal Investigator at the time of protocol approval and are updated as required following approval of protocol amendments. This coding memo is loaded to the protocol portal on the CTSU website
    c. The forms are arranged in folders. The basic folders required for most studies are Enrollment, Baseline, Course folders as needed, Tumor Markers, Biomarkers, Lesion Evaluations, Physical Exam, running Logs (vitals, serology, concomitant measures, transfusions), laboratory evaluations and Off study.
    d. There are two types of forms, standard and log forms. In general, only one instance of a form is allowed in each folder. Log forms are used where multiple records are required or performed such as study drug administration, adverse events, and concomitant medications.
    e. After data entry is complete the save button, at the bottom of the data entry page, must be selected to save the data.
    f. Any required data items that are not entered or that trigger an edit check will be queried by the system.
    g. In addition to system queries, the CTMS staff may issue queries as appropriate based on the review of submitted data. These queries will be entered directly into Rave EDC.
    h. Both query types have a Text Box below the message. **Data corrections need to occur in the Data Field.** The text box is only for communication with the data manager or internal notes. A small yellow Delta symbol will appear next to the field to note the data has been changed from its initial entry.

4. Rave is usable in many, if not all, browsers. Google Chrome browser has an advantage that Microsoft Internet Explorer does not have – the ability to resize Rave text box fields. Not all browsers have been tested. The individual user may want to test several browsers to see what works best.

5. All dates are to be expressed in day/month/year (dd/mmm/yyyy) format. To avoid ambiguity, months are to be recorded using a three-letter abbreviation (i.e., Jan, Feb, Mar, etc.). Years are to be recorded as four digits (i.e., 1998).
6. In a few date fields (e.g., prior surgery) partial dates will be accepted when the specific date is not known.
    a. If the month and year are known but the day of the month is not known, for example December 2012, enter: un DEC 2012
    b. If only the year is known, then enter: un UNK 2012
    c. If the date in unknown, leave the date field blank
7. All times are to be recorded on a 24-hour clock (i.e., 13:00 should be recorded for 1:00 p.m.). Midnight should be recorded as 00:00. If a time is unknown, please leave the field empty.
8. Additional information regarding CDUS codes for groups, institutions, diseases, and adverse events can be found on the CTEP Internet Website at: http://ctep.cancer.gov or by contacting the CTEP Help Desk at ncictephelp@ctep.nci.nih.gov.
9. Additional data may be submitted on the Comments eCRF, using the appropriate form type. Comments should not be used to submit data that belongs on another case report form. Comments should contain additional information to explain and clarify data submitted on other forms and linked to that other form by the form type code selected from the list provided on the eCRF.
10. Data received is reviewed for completeness and consistency. Queries will be generated if the data submitted does not comply with data submission guidelines or if there are any questions regarding the content.

Note: Patient name and/or initials should never be entered into Rave or as part of the upload of patient de-identified documents

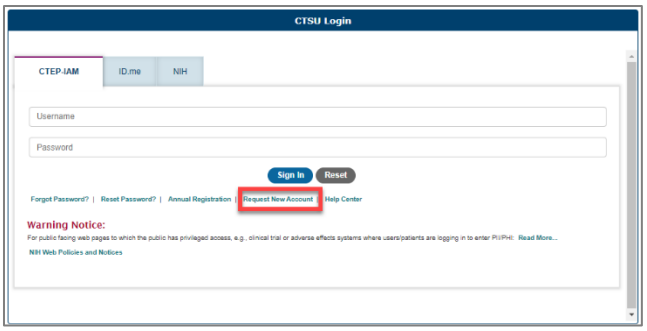

OPEN Oncology Patient Enrollment Network
Site enters Enrollment Criteria
Study & Universal Patient IDs
Patient Data
IWRS
Generates Study & Universal Patient IDs
Study & Universal Patient IDs
Patient Data
medidata Rave
Study Database
Enrollment/Baseline
Specimen Tracking System
Labs and other analyses
Course
Off Study
Prior Treatment
Baseline Medical History
Demography
Adverse Baseline Symptoms
Tracking Enrollment
Labels
Shipping
Receiving
Hematology
Chemistry
Urinalysis
Pharmacokinetics
Course Initiation
Drug Administration
Adverse Events
Follow up
Off Treatment/Off Study
Late Adverse Events

Rave Access

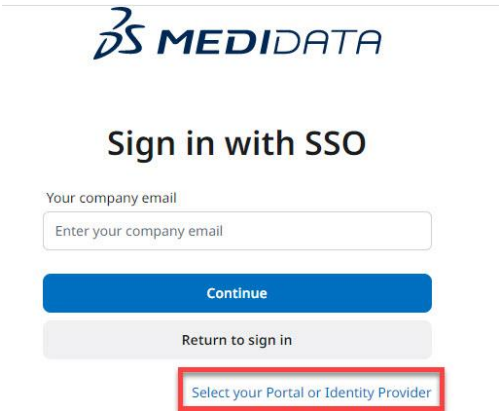
Access to your study in Rave is overseen by CTSU and is granted based on the role assignment on the roster (and protocol DTL if applicable) for your site. You will need to contact your site's RSS or DTL administrator to request the addition of your name on the roster. Information on new Rave accounts 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

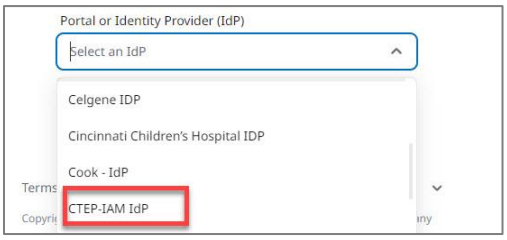
CTEP-IAM and Rave Account Setup

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://ctsu.cancer.gov/
2. Click **Log In**
3. Under the Sign In/Reset buttons, click **Request New Account**. This will take you to the CTEP-IAM page.
4. Follow the prompts to enter the required identifying information for your account. Choose the **Associate Plus** application.
5. You will receive an authorization email in **24-48 hours**.
6. 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*.
7. After these steps are completed, go to the following URL: https://login.imedidata.com/login
8. Click on **Sign in with SSO**
9. Click on **Select your Portal or Identity Provider**
10. From the menu, choose **CTEP-IAM IdP**.
11. Click **Select**
12. Login with your CTEP-IAM username and password on the resulting screen.





Log in

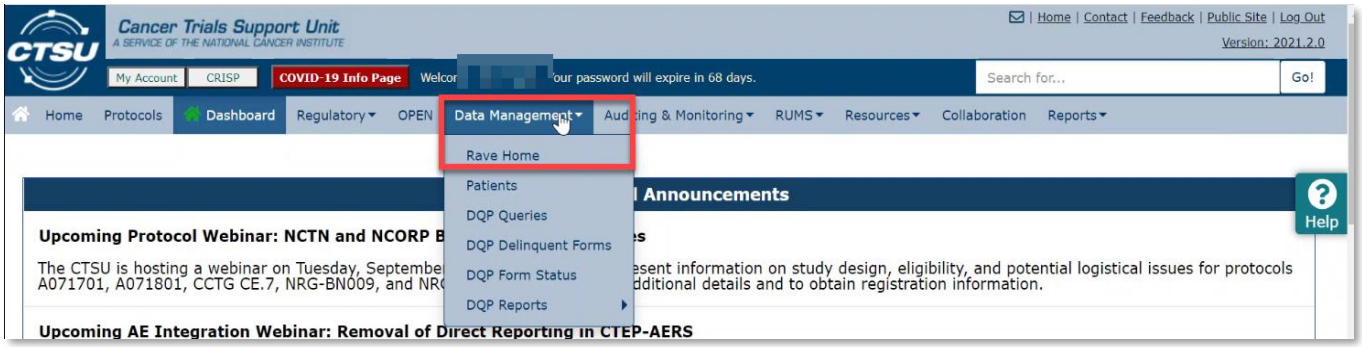
Direct URL

After linking Medidata to your CTEP-IAM SSO you can follow the steps below to login

1. Go to the following URL: https://login.imedidata.com/login
2. Click **Sign in with SSO**
3. Enter your **CTEP-IAM** or **ID.me** credentials
4. Click **Log in**

CTSU

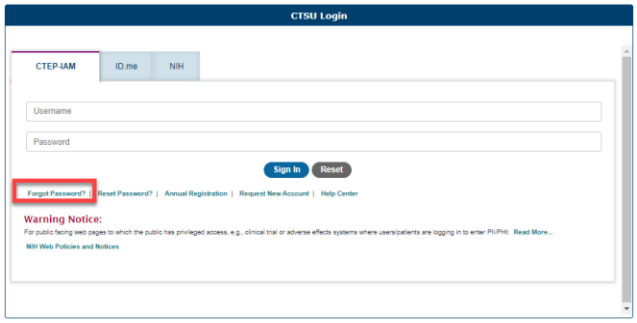
1. Go to the following URL: https://ctsu.cancer.gov/
2. Click **Log in**
3. At the login page, enter your **CTEP-IAM or ID.me Username** and **Password**
4. Click **I agree and logon**.
5. Go to the **Data Management** menu.
6. Click **Rave Home**.



Forgotten Password

If you have forgotten your password or have been locked out after five successful attempts, you can reset your password.

1. Go to the following URL: https://www.ctsu.org/public/default_login.aspx
2. Click on **Forgot username or password**
3. Follow prompts



System Time Out

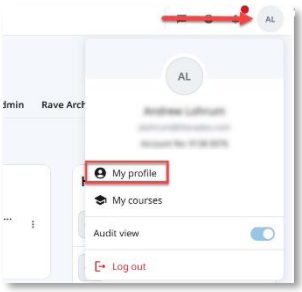
If you experience a password time out which occurs when you are logged into the system but remained idle for a set period of time, the system will prompt you to re-enter your password in order to access the system.

An interaction timeout occurs when you have been entering data into Rave and remained idle for a set period of time. The duration of inactivity in an interaction timeout is longer than a password time out. The system will prompt you to re-enter your username and password in order to access the system.

If you did not save the data you entered, any changes you made prior to an interaction timeout will be lost.

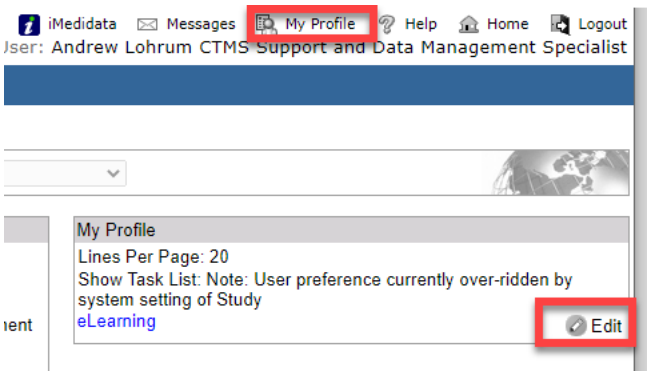
Components of the iMedidata home screen

Profile

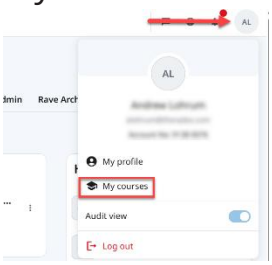


This panel allows the user to access their account and make basic edit changes to their profile such as change a password, username and telephone number. You have the ability to change the account email address – **your email address in iMedidata, CTEP-IAM, and the site roster should always match.**

Note: Further settings are available once you are logged into the Rave EDC. You will not see this menu until you follow the steps below and log into Rave EDC. Here you can set the number of log lines per page. As a log populates with records it will limit your view with this setting. By extending this you will be able to view all log lines by scrolling in lieu of multiple pages.

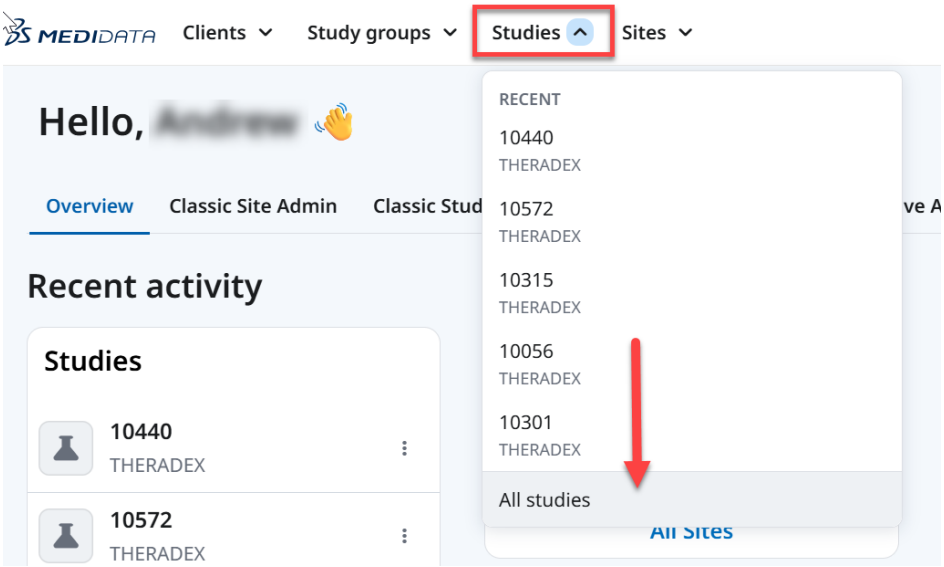


My Courses



A variety of eLearnings provide an overview of Rave EDC, Electronic Data Capture process and the roles associated with the process. If training is required, a message will appear on the Medidata homepage with a link to My Courses. After the successful completion of the course, the user is given access to the Rave study that required the training. Once an eLearning has been completed, you will not need to retake it for another study.

Studies

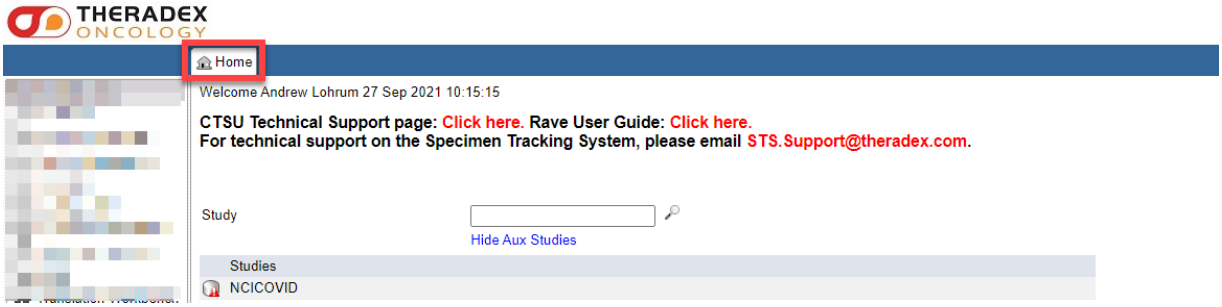


Listed under **Studies** are recently used study group links. To access a list of all studies, click **All Studies** at the bottom of the menu and use the **Search** box in the next screen to directly find the needed protocol.

The **Recent Activity** section will list the last few studies you have selected. Clicking here will take you directly to the study in the EDC.

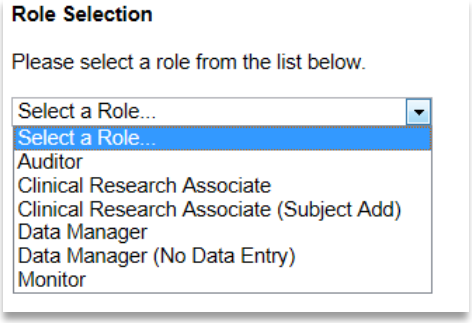
Opening to EDC Homepage

The iMedidata welcome screen allows you to access Rave directly by clicking **Rave EDC → National Cancer Institute (NCI) → Theradex** on the menu panel. Accessing Rave using this method will take you to the Rave homepage with a list of your studies after selecting your study role.



Role Selection

Most users have only been assigned one-role and will be taken directly to the Subject list after clicking Rave EDC



After clicking Rave EDC, if you hold multiple roles on a study, you will be prompted to choose the role from a drop-drown before you access the Study homepage.

Role Selection Descriptions

Clinical Research Associate or CRA: This user enters and updates clinical data in Rave. The CRA also responds to queries from Monitors, Data Managers and Theradex CTMS staff.

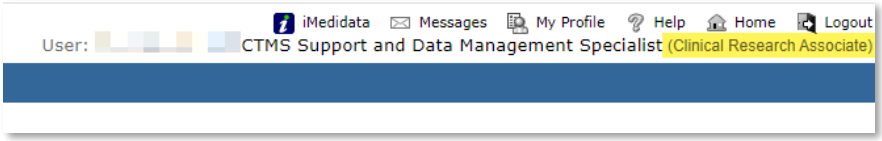
Data Manager: This user defines what will be collected in the study Case Report Forms also known as eCRF. They review data entered by the CRA and issue queries for missing or conflicting data to the CRA for resolution.

Monitor: This user works on behalf of the Sponsor. The Monitor confirms that the protocol is conducted in accordance with the clinical trial protocol, conducts on site visits and interprets Case Report Forms (eCRFs). The Monitor oversees the entire study and provides support to the site staff on using Rave EDC.

Read Only, Site Investigator and *Study Chair* may all inspect the data for review. Site Investigators and Study Chairs may also sign records.

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.

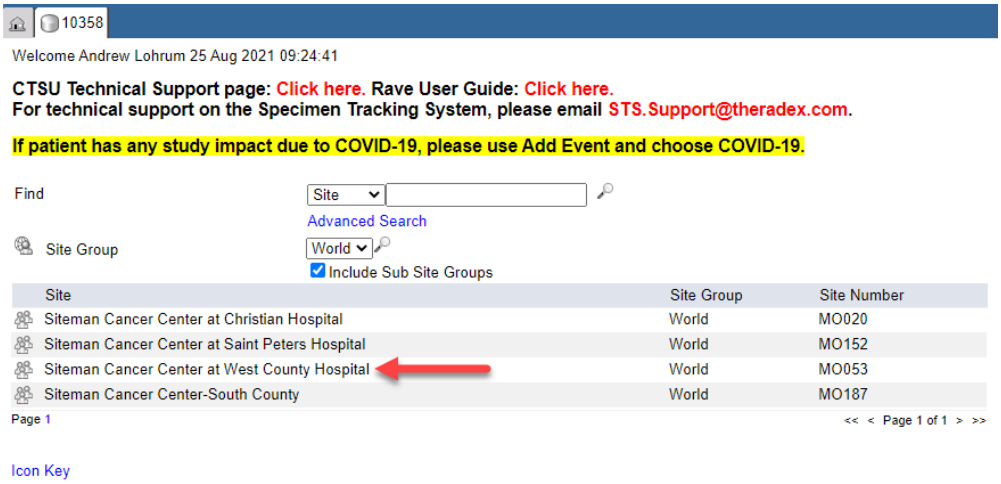


If your role is Read Only, you will not be able to enter or edit data. The CTSU Help Desk will be able to advise you further on why you do not have Clinical Research Associate access.

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.

Site Selection

This is only relevant to users that have access to more than one site. If you have access to one site, you will be taken directly to the subject list.



Click on a site name to go to the list of subjects at that site.

Site list is in alphabetical order.

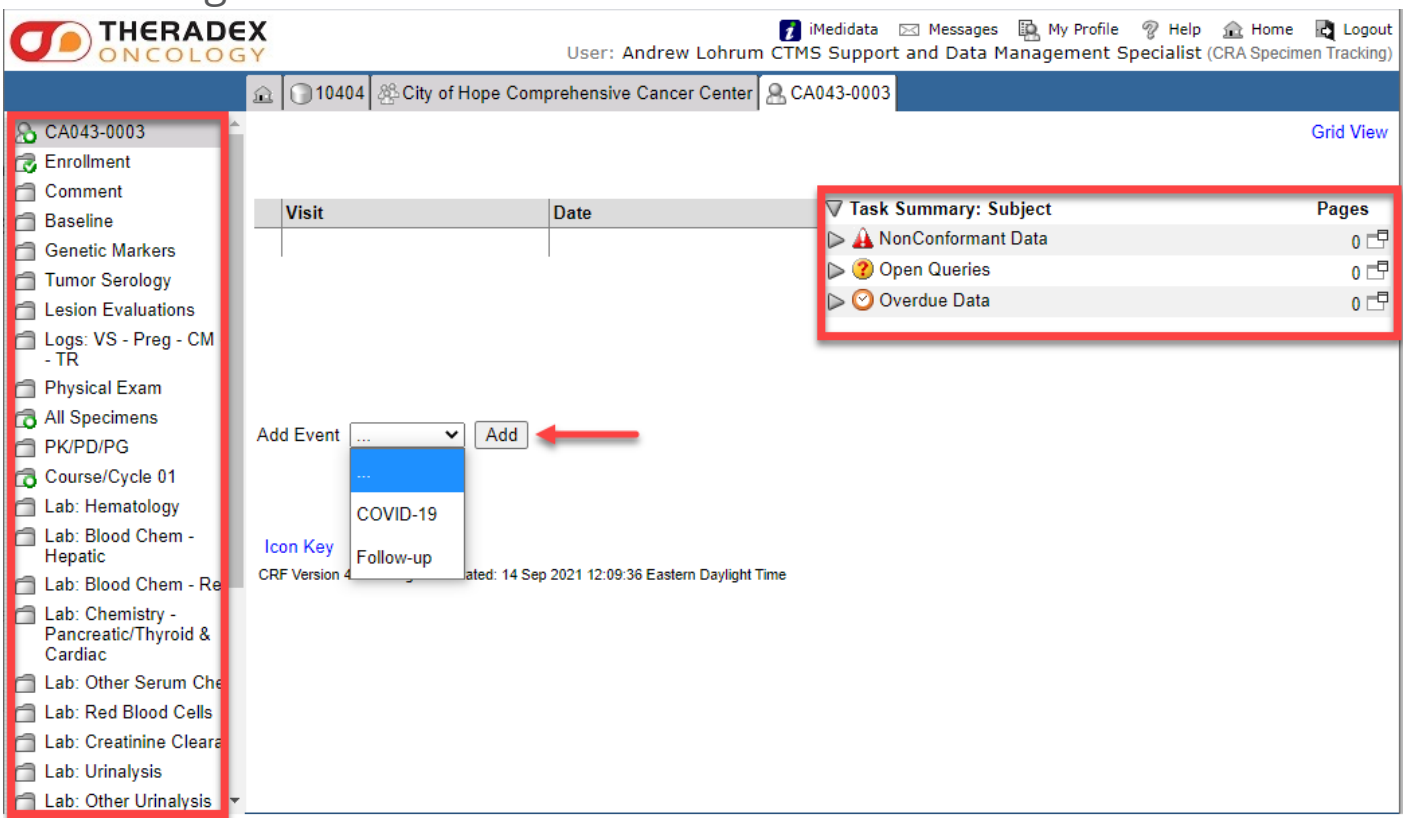
Patient List

All subjects at one site will be listed in alphabetic then numerical order by their patient ID. All subjects share the same site abbreviation, so they are listed by numerical order. The task panel to the right will highlight any data that needs your attention. A link to the Icon Key is below the subject list (see Rave Functions).

Click on a **Patient ID** to go to the Subject page.

Task Summary – The task summary will display any Nonconformant Data, Open Queries, or Overdue data for the site.

Patient Page



Folder and Form panel – The study eCRFs are organized in folders on the left side of the screen

Task Summary – The task summary will display any Nonconformant Data, Open Queries, or Overdue data for a participant.

Add Event dropdown – Options in menu are protocol dependent. Choosing an event will add a corresponding folder with forms to complete.

Example: To add a Follow up folder—

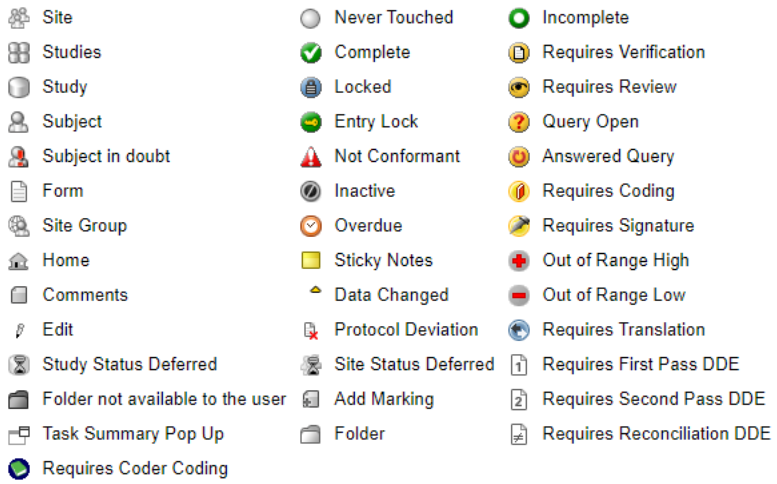
1. From the Subject page, open the **Add Event** drop down menu.
2. Select **Follow-up**.
3. Click **Add**.

Rave Functions

This section covers a selection of the most commonly used but not all available functions withing Rave. Please refer to iMedidata Help for any functions not seen here.

Icon Key

This URL is available at the bottom left of all pages in Rave. Clicking the link will load a pop up window with all of the status icons a user may encounter while using the Rave system.



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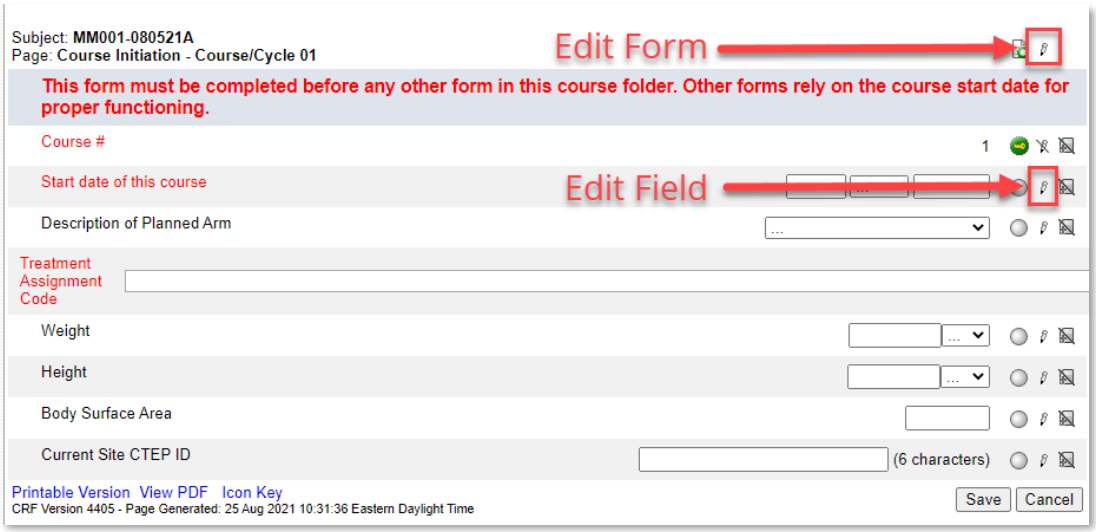
*Do not ignore **Non Conformant** errors, they are indicators of data entry errors that must be resolved. If you do not understand what the error is, please email CTMS-DM@theradex.com for assistance.*

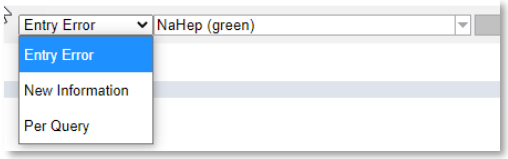
Edit Form

Clicking on the **pencil** icon at the top right of the form will open all fields for editing.



Edit Field

Clicking the edit **pencil** to the right of the field will open it for editing. If you are editing existing data, you will see the option to set to 'Entry Error', 'New Information' or 'Per query' to explain the change.



Field Format

Fields on a form will have been defined with one of several different formats. Date, time, and drop down fields are all closely regulated with regard to allowable values. Numeric and free text fields all have a prescribed length, and in the case of decimal numbers, an allowable number of fractional digits. These number and text formats are only applied after the form is saved. If the user enters a value that does not meet the prescribed format, the field will be marked as non-conformant. To aid data entry, the format of such fields is displayed to the right of the field. For text, the number of characters is listed.

Numeric Fields

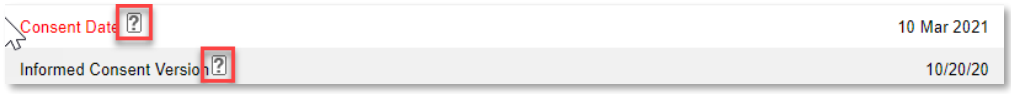
For numeric fields, the number of **digits** (and any placement of a decimal point) is displayed as a template consisting of "**d**" characters. A numeric format of **dddd** indicates that up to 4 **digits** may be entered with no decimal point. A format of ddd.dd indicates that up to three digits to the left of the decimal point and up to two digits to the right of the decimal point are allowed. See examples below:

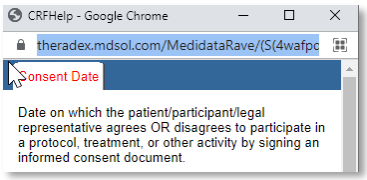
Partial Date Fields

Certain forms allow for partial dates when the either the day or month or both are unknown. '*Un*' may be substituted for the day and *'UNK'* for the month. If a partial date is allowed, these values will be available in the drop down.

Field Help

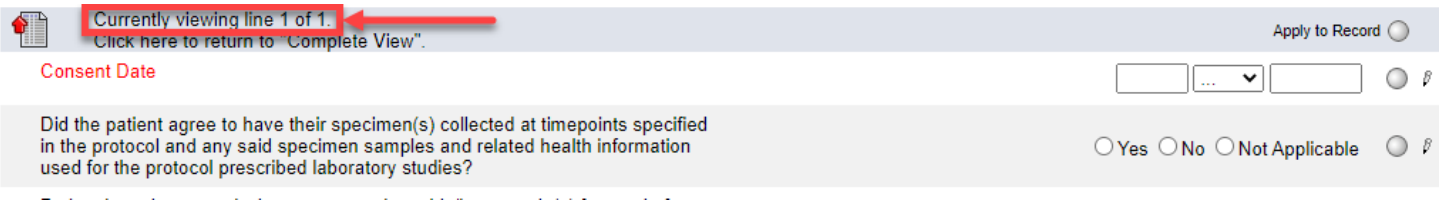
If a field displays a Help icon, the icon is there to provide further clarification of the required data. Once a Help icon has been opened, data clarification will appear in a pop-up.





New/Edit Log Line

Some eCRF are saved as a log line. A clear hint to know when a form will be saved as a log line will be listed at the top of the page. Whenever a form list displays **"Currently Viewing Line 1 of 1"**, it means the user can create multiple log lines. All log line forms offer the ability to add multiple log lines pertaining to prior treatments the subject has undergone.

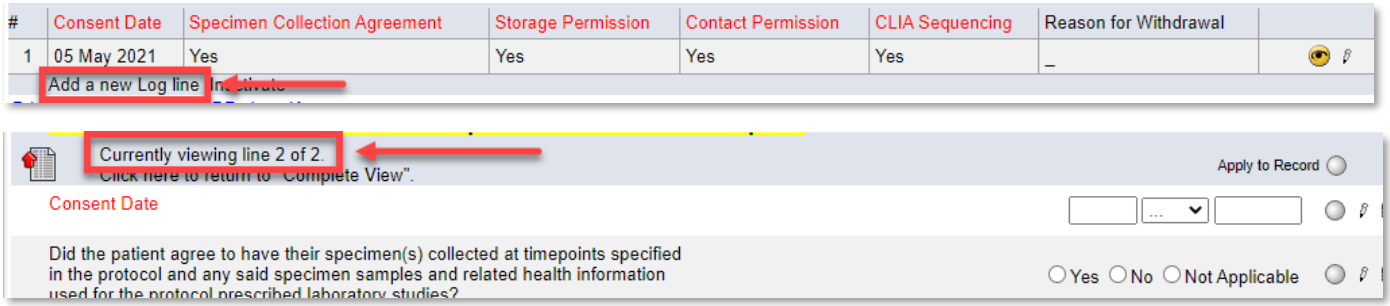


After **clicking Save**, the form will appear as a log line.

These lines can be expanded and edited by clicking on the pencil icon.

Add a New Log Line

Once the first log line has been saved, use the **Add a new Log line** function to add more forms. Click Add a new Log line under the last line in the log. A new form will appear. At the top you can confirm the log line number you are editing as **Currently Viewing**. After clicking **Save,** the completed line will appear in the log.



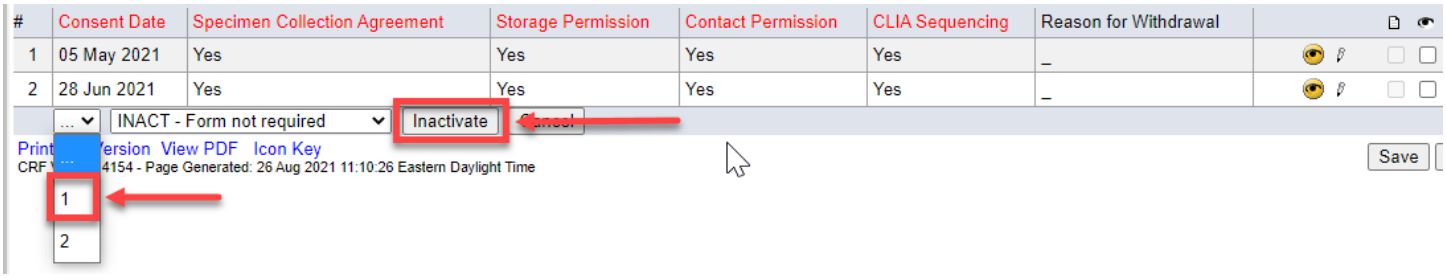
If you click **Cancel** when entering data in a new log line, Rave will save that form as an empty log line entry. To **edit** a saved log line, either **click** on the **edit pencil** on the far right of the selected line or click on any data point within the log line.

Tip: You can sort the lines by clicking on the header of an individual column. Depending on the data it will be sorted numerically or alphabetically.

Inactivate a Log Line

A saved log line cannot be deleted. If the data in a log line is not applicable or displayed as an empty line, it is recommended to inactivate the line. **Click** the **Inactivate** link at the bottom of the log.

Select the log line number from the drop down. **Click Inactivate**.

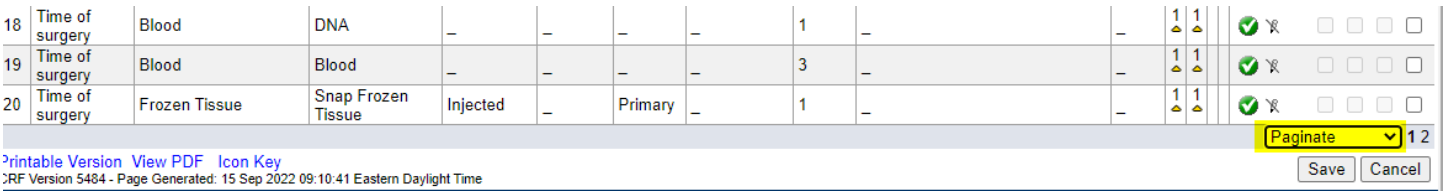


DO NOT INACTIVATE A LOG LINE WITH AN ACTIVE QUERY. For more information on resolving queries see [Queries and Edit Checks]

Reactivate a Log Line

The selected log line will then appear crossed out. Once a log line has been inactivated, the **Reactivate** function becomes available.

Multiple Page Log

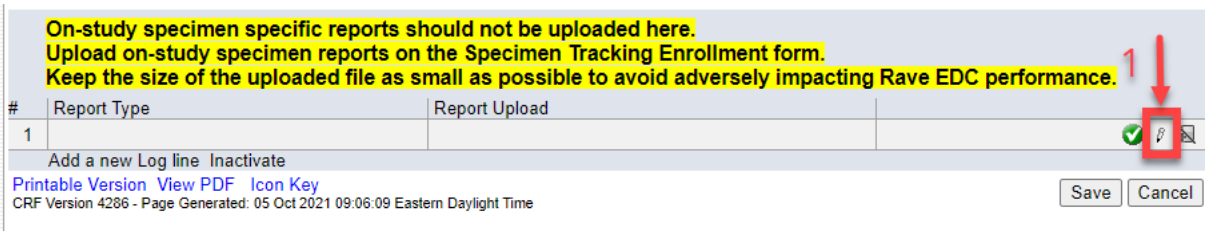


If the number of log lines exceeds the setting in your [Rave Profile], you can use the drop down at the bottom of the log to show all available lines – or – click the number to the right of the drop down to move to the next page. When sorting log lines using the header field, all lines will be included but will remain in either the paginate view or all lines view selected in the drop down.

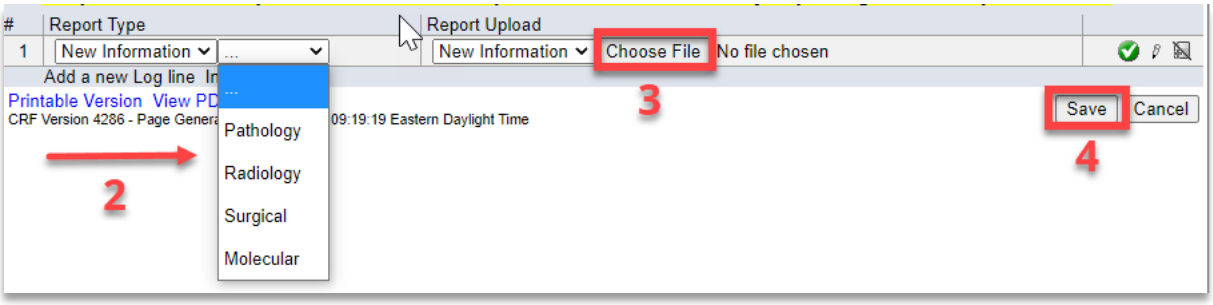
Report Upload

Several forms support the uploading of supporting documentation. Please ensure to redact all PHI and PII from the document and the filename. Be sure to include the study patient id or specimen ID in report. To prevent accidental disclosure of confidential information, please rename file as follows:

[Study Patient ID]_[report type]_date.pdf
CA043-0003_path report_01Aug2021.pdf



1. **Click** on the **Edit** pencil.
2. **Select** Report type [not on all forms].
3. Under Report Upload, **click Choose File**. In the Windows file finder, select the file and click OK.
4. **Click Save**.



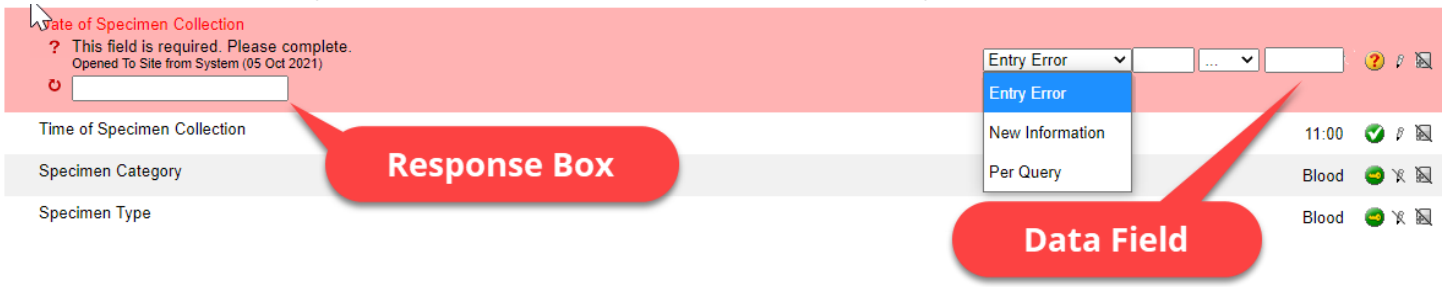
Queries and Edit Checks

There are two types of queries, System Edit Checks and Data Manager (DM) assigned queries. The query response processes for both are the same. System Edit Checks are program instructions that check the validity of data entered. Data Manager (DM) assigned queries are manually opened to request further information and/or a data change based on inconsistencies.

System Edit Checks – "To Site from System" Query

A System Edit Check can be triggered when a required field is empty or if the data entered does not match what is expected. (i.e. Numeric expected but alphabetic text or special characters are entered).

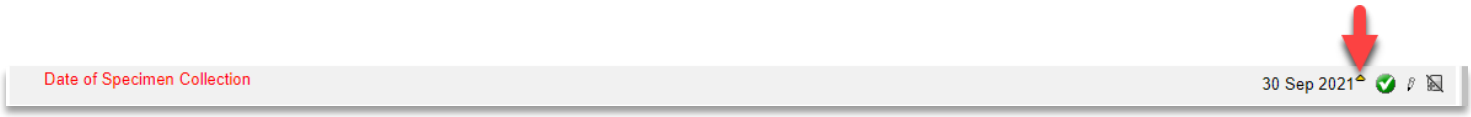
Ex. Dose is 5,000 IU. Data should be entered as 5000 as "," is not a numeric character



To correct the data:

1. **Select** the reason for the data change by using the drop-down menu.
2. **Enter** required information in the **Data Field**. If the field is not open, click the Edit pencil.
3. **[Optional] Respond** in the **Response Box** with any further information. The box will grey out if a response is not required, see below.

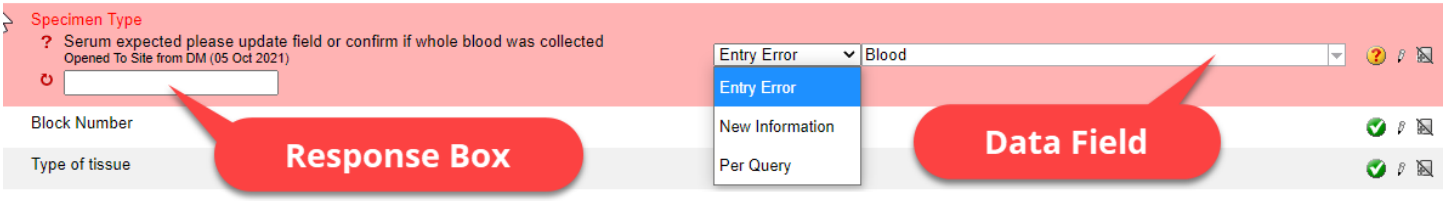
After clicking Save. The System query will clear. A small yellow Delta symbol will appear to show the data has been changed from its original entry. A full list of changes is available in the field's audit trail.



Note: Do not inactivate a log line with an active query. The response time will continue to accrue in the DQP if not resolved or canceled before inactivation.

Manual Review – "To Site from DM" Query

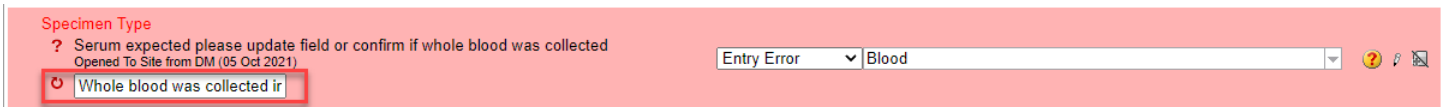
A query will be opened by a Theradex data manager if a data change and/or more information is needed.



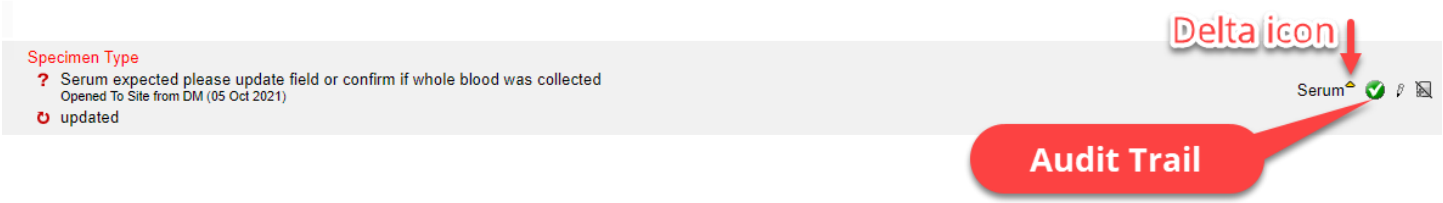
To correct the data:

1. **Select** the reason for the data change by using the drop-down menu.
2. **Enter** required information in the **Data Field**. If the field is not open, click the Edit pencil.
3. **Respond** in the **Response Box** with any further information. If the response box is greyed out, use the pencil to edit, see below. **DO NOT ENTER DATA IN THIS RESPONSE BOX. All clinical data must be entered in the Data Field on the right.**
4. **Click** Save.

If a change to the data is not needed – explanatory information can be entered into the response box on the left.



After clicking **Save**, a small yellow Delta symbol will appear to show the data has been changed from its original entry. A full record of changes is available in the field's audit trail.



Notes: Manual Review queries do not resolve automatically. The manual queries are closed after review by the CTMS data manager. It will remain highlighted in pink until it is closed but the site's response time tracked by CTSU (DQP) will not increase as long as a response has been provided.

Do not inactivate a log line with an active query. The response time will continue to accrue in the DQP if not resolved or canceled before inactivation.

CTMS Forms

The following sections contain the Folders and Electronic Case Report Forms (eCRF) for NCI/DCTD/CTEP Clinical Trials Monitoring Service studies. The content of the forms may differ than what is presented and study specific forms may be present in your database depending on the design and needs of your study. Please do not hesitate to contact your data manager for further clarification and guidance.

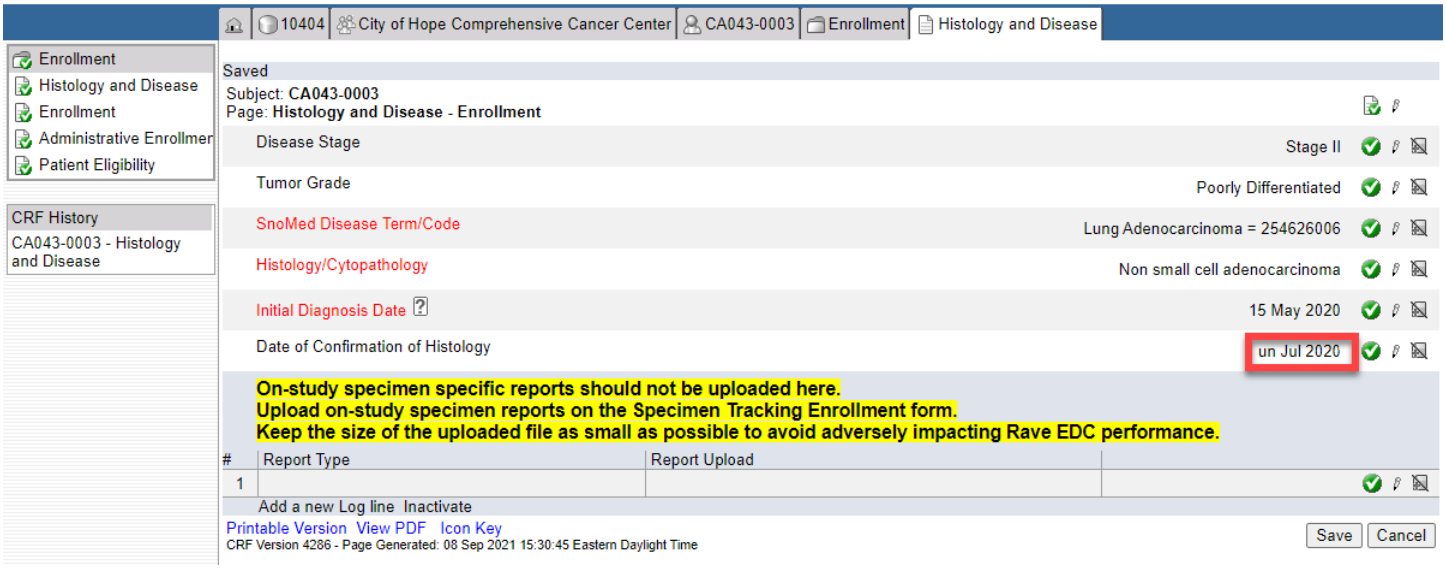
Enrollment

The following forms must be completed at the Baseline visit. Most of the forms are automatically populated by data from OPEN and IWRS. These forms are reviewed for accuracy. Any data entry errors in the forms need to be corrected in OPEN (contact: CTSUOPENFORMS@westat.com). Any discrepancies between IWRS and Rave need to be reported to CTMS-DM@theradex.com so the link between the two programs can be investigated.

Histology and Disease

Prerequisites: None. **This form should be completed before any data entry in the study database**.

Description: This form documents the disease for which the patient is being registered for the trial. The date and findings from the diagnostic biopsy are recorded here. The de-identified pathology report from the diagnostic biopsy is uploaded here. The biopsy also needs to be recorded in the Prior Treatment Summary and Surgery Supplement forms.



Fields

Disease Stage: Record the stage of disease at time of study. Options may differ depending per study. Not all diseases are staged.

Tumor Grade: Record the grade of Histology at study entry. Not all tumors are graded.

SnoMed Disease Code: Choose a **term** from the search list closest to the source documentation. You should match on the term even if the number in the medical record may differ. The menu will filter as you type. Using a code or keywords will shorten the available choices. Terms may be duplicated as this list is an amalgamation of multiple dictionaries. For duplicate terms, choose the first occurrence in the list.

Histology/Cytopathology: Interpretation of the histology at enrollment, may match the initial pathology report but might differ if disease has progressed

Initial Diagnosis Date: From medical record. Partial dates allowed, see below.

Date of Confirmation Histology: From initial pathology report. Partial dates allowed, see below.

Report Log: Upload De-identified pathology report for the initial diagnosis. Required documents differ by protocol.

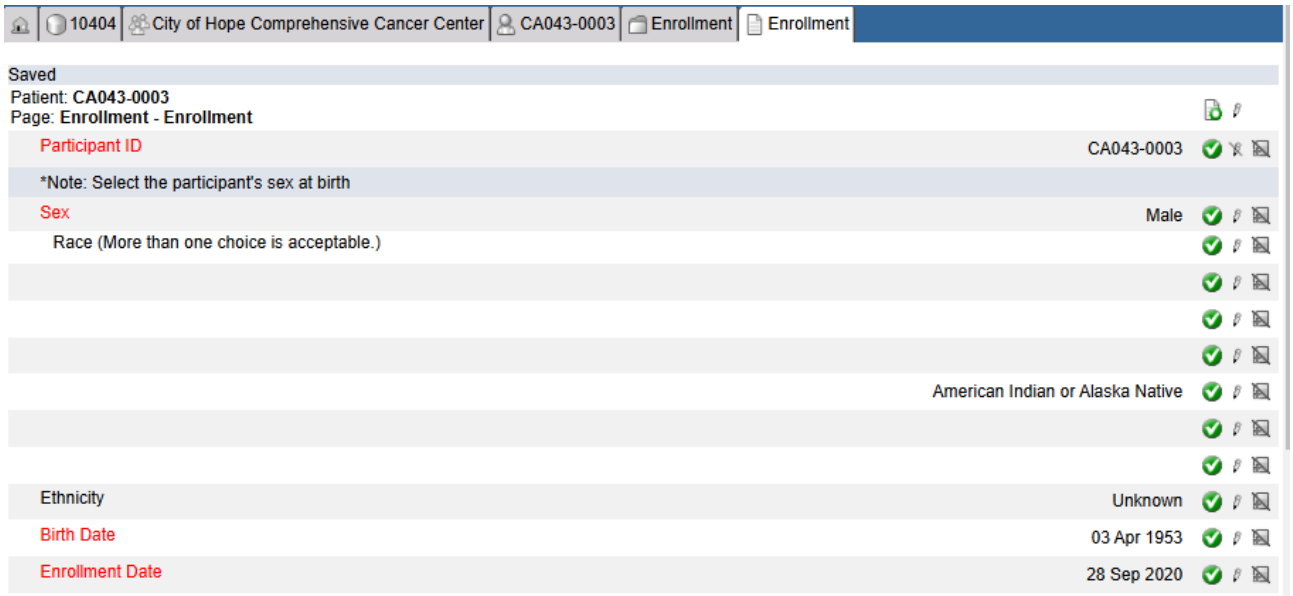
Partial Dates

If the exact date is not known; '*un*' may be substituted for the day and *'UNK'* for the month.

Enrollment

Prerequisites: None.

Description: This form auto-populates with demographic data that is entered in OPEN during registration. This form can be edited if needed and you must contact CTSU to update the data in OPEN.



Fields

Participant ID: Primary identifier issued to participant.
Sex: This is the Participant's sex at birth. Check Male or Female as appropriate.
Race: One or more of the standard NIH race categories.
Ethnicity: One or more of the standard NIH ethnicity categories.
Birth Date: Recorded in dd/mmm/yyyy format.
Enrollment Date: Date participant was registered to the study. Recorded in dd/mmm/yyyy format.
Age: For adults and children of age 5 and above, the age is given in the number of full years completed last birthday. For children less than 5, a fractional age is recorded, to indicate the number of months since their last birthday.
Weight: Recorded in kg. Use decimal places for participants under 10 kg.
Height: Recorded only in cm, to one decimal place.
Body Surface Area: Not BMI. Record participant's surface area in m2 (to two decimal places) if needed for the calculation of the study drug level. The following simple approximation may be used for persons

$$BSA(m^2) = \sqrt{\frac{Height\ \ (cm)\,x\,Weight\ \ (kg)}{3600}}$$

of "normal" height and weight:
Phase: Phase of clinical trial.

Participant Subgroup Code: Use the appropriate unique code for the identification of uniform groups of patients for separate analysis or treatment. Participant subgroup codes are provided by CTEP to the investigator at the time of protocol approval and are updated as required following approval of protocol amendments.

Enrolling Site CTEP ID: CTEP institutional code where the participant was originally registered on study.

Method of Payment: The participant's primary method of payment.

Disease Code: MedDRA disease code as assigned by CTEP.

Primary Disease Site: The primary site of the malignancy is entered using the same nomenclature as AERS. If the primary site is unknown, state "UNKNOWN". If the diagnosis is leukemia, enter LEUKEMIA, not bone marrow. If the diagnosis is lymphoma, enter LYMPHOMA, not lymph nodes. Do not give detailed descriptions. For example, do not state "anterior tibial surface of the left leg", state only leg. In the case of brain lesions, give the closest anatomical description of the originating site (e.g., frontal lobe)

Performance Status: State the performance status of the participant at the time of entry on the study. Use the performance status scale defined in the protocol.

Consent Date: Date participant signed the informed consent form (IC). Recorded in dd/mmm/yyyy format. On newer studies this field is located in the Consent form.

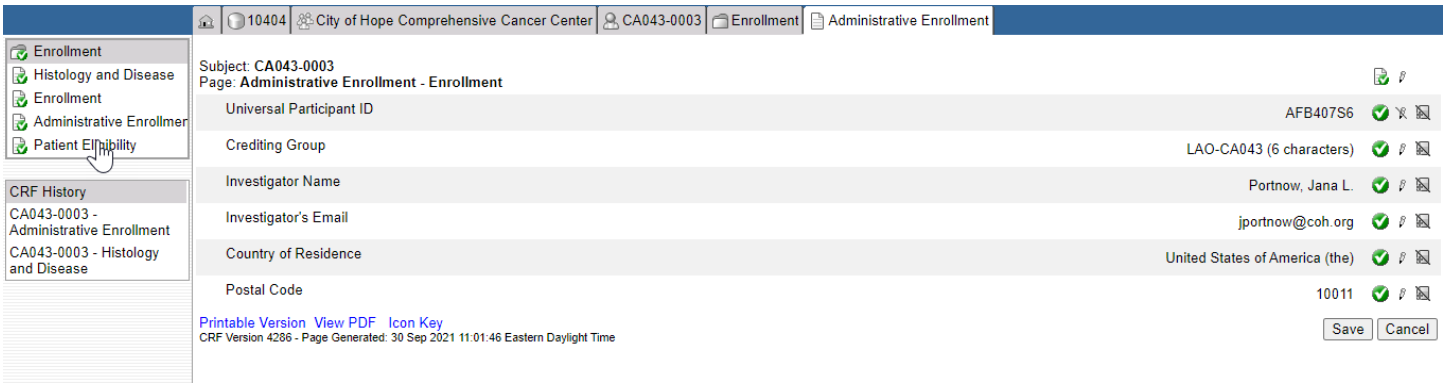
Informed Consent Version or Version Date: Version number or Date (preferred) of the IRB-approved informed consent form (IC) that was signed by the participant at the time of study entry. This data is automatically entered from OPEN but can be updated if necessary. On newer studies this field is located in the Consent form.

Treatment assignment code (TAC): The code for the participant's assigned treatment as specified by CTEP. Treatment assignment codes are provided by CTEP to the investigator at the time of protocol approval and are updated as required following approval of protocol amendments.

Administrative Enrollment

Prerequisites: None.

Description: This form auto-populates with enrollment data that is entered in OPEN during registration. This form can be edited if needed, you must contact CTSU to update the data in OPEN.



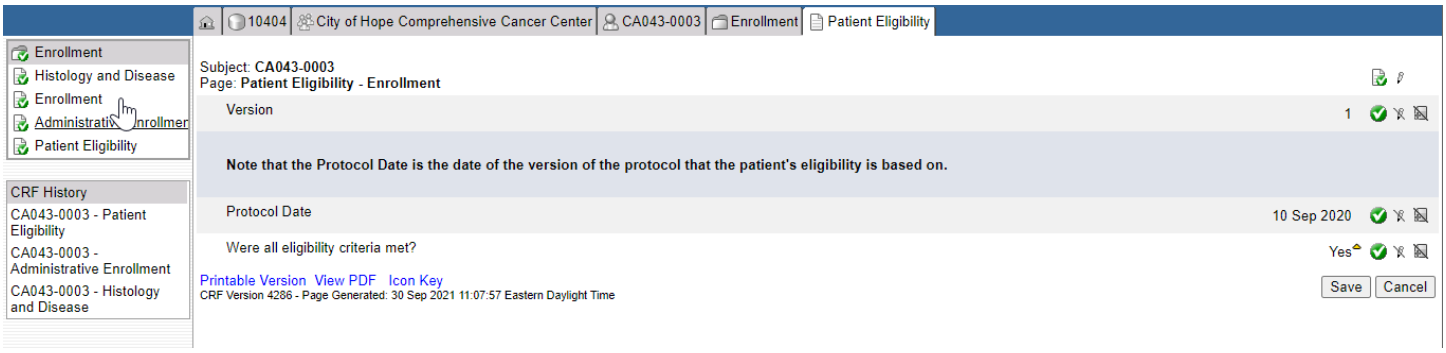
Fields

Universal Participant ID: Unique identifier issued to participant by IWRS, consistent across CTMS network trials
Crediting Group: Lead Academic Organization or Co-operative group; used for accrual counting.
Investigator Name: Name of the clinical trial principal investigator (PI).
Investigator's Email: Email address of the clinical trial principal investigator (PI).
Country of Residence: Participant's country of residence, not necessarily country of citizenship.
Postal Code: For US residents, enter the participant's 5-digit Zip code. Do not enter the last four digits of the complete nine-digit zip code to assure participant confidentiality.

Patient Eligibility

Prerequisites: None.

Description: This form auto-populates with eligibility data that is entered in OPEN during registration. This form is not editable by site users.



Fields

Version: Version number of the IRB-approved protocol that the patient's eligibility is based on.
Protocol Date: Date of the version of the protocol that the patient's eligibility is based on. Theradex staff will update the version date only when a protocol amendment has a change to the patient's eligibility.
Were all eligibility criteria met?: Based on results of eligibility checklist in OPEN.

2 Step Enrollment and Screening Failures

For single step enrollment, eligibility is resolved in OPEN. In two-step enrollment, a patient's eligibility is determined by a specimen submission and/or lab result. This requires data entry in both OPEN and Rave.

1. After completion of initial step in OPEN, the patient ID will be available in Rave on the site page. Select the patient ID and proceed to the **Enrollment** folder.
2. Review the **Enrollment** and **Admin Enrollment** forms for any obvious errors.
3. Complete the **Histology and Disease** form.
4. If a specimen is to be submitted. Proceed to complete the necessary forms in the Specimen Tracking System. See Appendix 1: Theradex Specimen Tracking System (STS)
5. Complete the second step in OPEN to either register the patient for treatment or for screen failure.
6. If patient is deemed eligible, the TAC will be assigned at this time and loaded into the Enrollment form.
7. If patient fails screening and is ineligible:
    a. If a lab result is available, record in the appropriate form.
    b. Any other data used to determine eligibility can be entered. (i.e., Genetic Marker)
    c. Complete the Off Study form. Select **Trial Screen Failure** in the **Reason** drop-down menu.

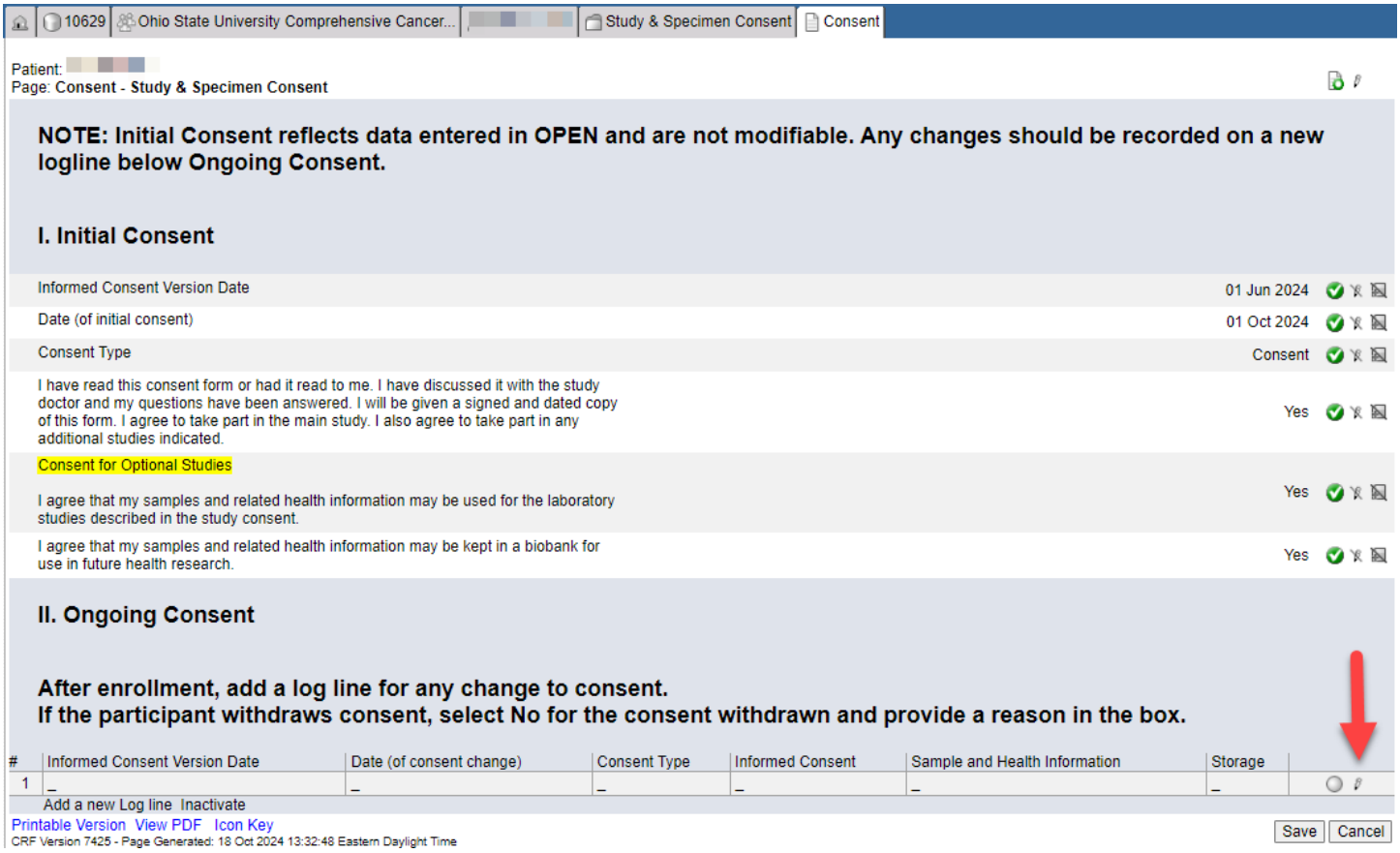
Study & Specimen Consent

Consent

Prerequisites: None.

Description: This form auto-populates with consent data that is entered in OPEN during registration. The auto populated data cannot be edited. Changes to consent are recorded in the log at the bottom of the form.

The questions which appear under **Consent for Optional Studies** are specific to each study and may differ from the screen shot below. The steps to complete the form, remain the same.



Informed Consent Version Date: The date of the IC document presented to the participant and which the patient signed.
Date (of initial consent): Date the participant signed the IC document.
Consent Type:
I have read this consent form … : Affirmative statement from IC document. Participant response captured in OPEN.
Samples for laboratory studies … : Participant affirms to have specimens collected an analyzed as described in the IC document.
Samples for future research … : Participant affirms to allow specimens to be stored and used in future research.

Change in consent

If the Patient changes their consent (including withdrawal from study) or if the patient is reconsented, use the **Edit** pencil (red arrow) to expand the log line to record this information.

II. Ongoing Consent

After enrollment, add a log line for any change to consent.
If the participant withdraws consent, select No for the consent withdrawn and provide a reason in the box.

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

Apply to Record

Informed Consent Version Date (only if patient reconsented)	...
Date (of consent change)	11 Oct 2024
Consent Type	Study Reconsent / Study Withdrawal / Optional Studies/Specimen Consent Change
I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed and dated copy of this form. I agree to take part in the main study. I also agree to take part in any additional studies indicated. **If no is selected, enter a reason.**	Yes / No
Consent for Optional Studies	
I agree that my samples and related health information may be used for the laboratory studies described in the study consent. **If no is selected, enter a reason.**	Yes / No
I agree that my samples and related health information may be kept in a biobank for use in future health research. **If no is selected, enter a reason.**	Yes / No — Patient does not want to ba

Printable Version View PDF Icon Key
CRF Version 7425 - Page Generated: 18 Oct 2024 13:47:19 Eastern Daylight Time

Save Cancel

For Study Reconsent, enter the version date of the IC document and the date of consent.

For Study Withdrawal, enter the date of consent change and select the Study Withdrawal radio button. To the right of the consent statement, select No and enter the participant's reason to withdrawal from the study. Be sure to respond to the remaining questions in the Consent for Optional Studies section.

For Optional Studies, enter the Date (of consent change), select the Optional Studies radio button, and complete the questions after Consent for Optional Studies. For No, please enter the participant's reason for withdrawal of consent for lab testing and/or storage.

II. Ongoing Consent

After enrollment, add a log line for any change to consent.
If the participant withdraws consent, select No for the consent withdrawn and provide a reason in the box.

#	Informed Consent Version Date	Date (of consent change)	Consent Type	Informed Consent	Sample and Health Information	Storage
1		11 Oct 2024	_	Yes	Yes	No (Patient does not want to bank specimens)

Add a new Log line Inactivate

Printable Version View PDF Icon Key
CRF Version 7425 - Page Generated: 18 Oct 2024 13:49:49 Eastern Daylight Time

Save Cancel

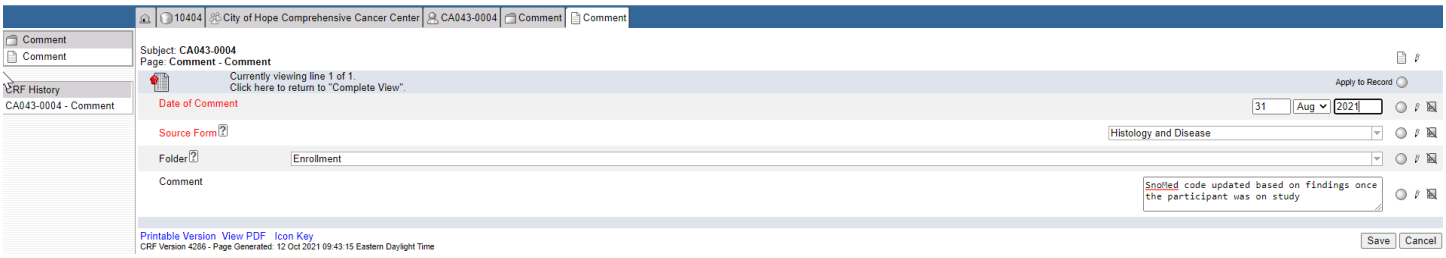
Any further changes in consent can be documented by using **Add a new Log Line** at the bottom of the form. For any erroneous entries, use the **Inactivate** function.

Comment

Comment

Prerequisites: None

Description: This form allows the users to make notations on forms as needed. Common notations include explanations for missing information, missing or irregular results, missing labs, etc. Text fields on the standard forms are limited in size, use this form to record additional information that does not fit in these fields.



Fields

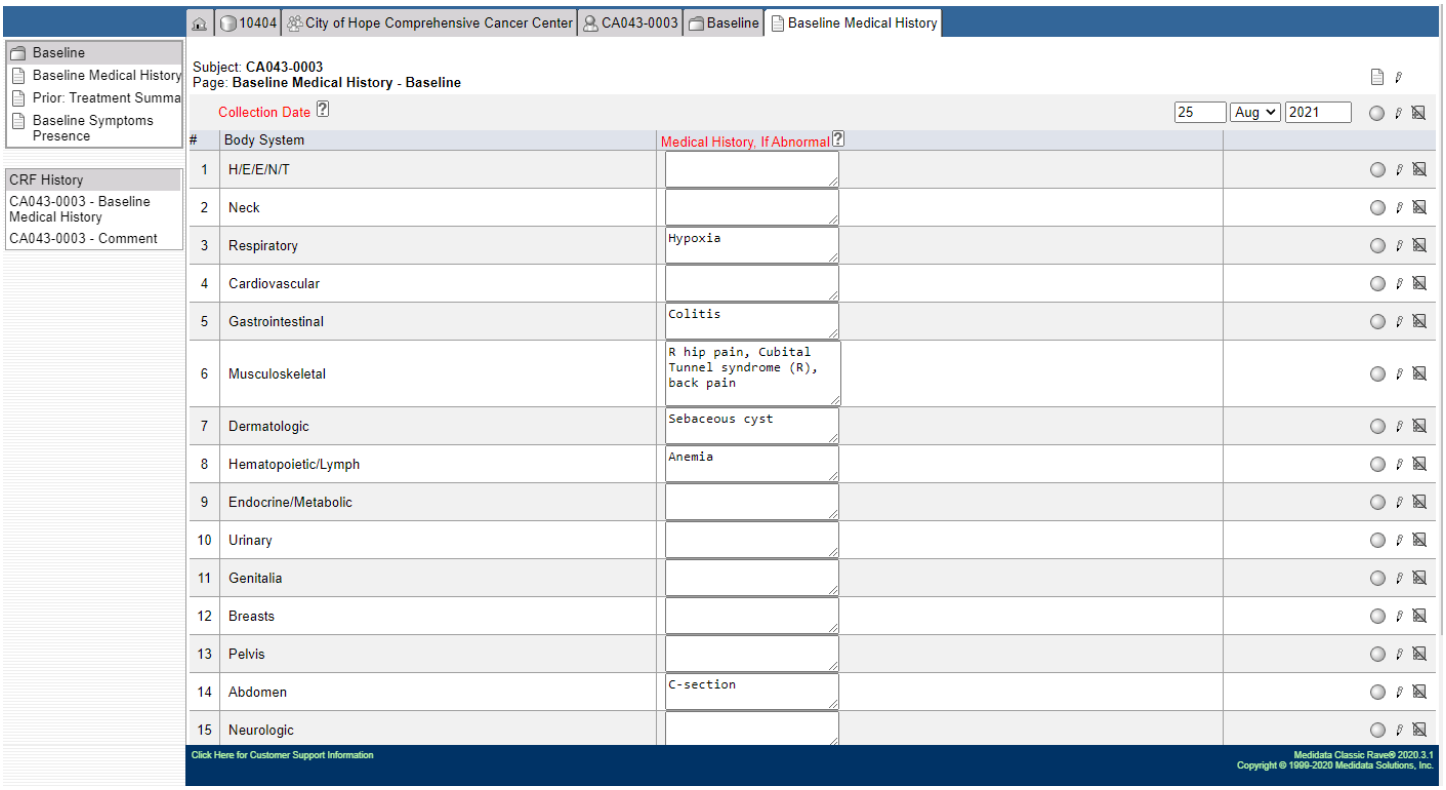
Date of Comment: The date you completed this form.
Source form: Alphabetic list of forms. Use Next and Back keys to move through the menu.
Folder: Location of the Source form.
Comment: A free text field to capture the notes that pertain to the form selected in Source form.

Baseline

Baseline Medical History

Prerequisites: None

Description: This form documents the medical history of the participant as required by protocol.



Enter the date the medical history was collected. Enter any relevant medical history in the free text fields. Click Save. After saving, the fields can be edited/updated by using the Edit pencil.

Fields

Collection Date: Enter the date the medical history was documented.
Body System: A predefined list of anatomical systems
Medical History, If Abnormal: Brief description of major medical and surgical events that occurred during the patient's lifetime.

Prior: Treatment Summary

Prerequisites: None

Description: This form documents any prior treatments or modalities. This form determines which supplementary forms will load after saving. *The supplementary forms are required, please refer to each form entry for more information*.

10404 | City of Hope Comprehensive Cancer Center | CA043-0004 | Baseline | Prior: Treatment Summary

Baseline
Baseline Medical History
Prior: Treatment Summa
Baseline Symptoms Presence

CRF History
CA043-0004 - Prior: Treatment Summary
CA043-0004 - Baseline Medical History
CA043-0003 - Prior: Treatment Summary
CA043-0003 - Baseline Medical History

Subject: CA043-0004
Page: **Prior: Treatment Summary - Baseline**

Please enter the date of the most recent prior treatments for each therapy category on this summary form. After entering all known prior therapy types, proceed to the supplemental forms to enter the details. Additional older prior treatments may be entered directly on the supplemental forms.

If you answer Yes for "Did the subject take the treatment?" please enter the date of the last dose or procedure. This date should correspond to the last dose date in the corresponding Prior Therapy, Radiation or Surgery form.

#	Therapy	Any therapy?	Date of Last Dose		
1	Single Agent Systemic Chemotherapy	No			
2	Chemotherapy, multiple agents systemic	No			
3	Chemotherapy, NOS	No			
4	Hormone Therapy	No			
5	Immunotherapy	No			
6	Bone Marrow Transplantation	No			
7	Gene Transfer	No			
8	Prior Therapy (NOS)	No			
9	Chemotherapy, non-cytotoxic	No			
10	Anti-retroviral Therapy	No			
11	Antisense Therapy	No			
12	Oncolytic Virotherapy	No			
13	Vaccine Therapy	No			
14	Stem Cell	No			
15	Surgery	Yes	18	May	2021
16	Extensive Radiation	No			
17	Limited Radiation	No			
18	Radiation (NOS)	Yes	13	Jun	2021

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Save | Cancel

Indicate if the patient has received any treatments for each prior therapy type listed by selecting Yes, No or Unknown for all questions (required). If the patient has not received any prior therapy, please select No for all of the therapies listed.

For prior treatments that are **ongoing** at the start of the study (e.g., hormone therapy), enter the date of the last dose taken prior to enrollment; the therapy should also be entered in the Concomitant Medications form, since ongoing during the study; the **start date** entered on the Concomitant Medications form should be the **same date** entered in the Prior Therapy Supplement form.

After clicking **Save**, **supplementary forms** will appear in the folder for any therapy marked with **Yes**. Older treatments must be recorded on these forms.

10404 | City of Hope Comprehensive Cancer Center | CA043-0004 | Baseline | Prior: Treatment Summary

Baseline
Baseline Medical History
Prior: Treatment Summa
Prior: Radiation Supplement
Prior: Surgery Suppleme
Baseline Symptoms Presence

CRF History
CA043-0004 - Prior: Treatment Summary
CA043-0004 - Baseline Medical History

Saved
Subject: CA043-0004
Page: **Prior: Treatment Summary - Baseline**

Please enter the date of the most recent prior treatments for each therapy category on this summary form. After entering all known prior therapy types, proceed to the supplemental forms to enter the details. Additional older prior treatments may be entered directly on the supplemental forms.

If you answer Yes for "Did the subject take the treatment?" please enter the date of the last dose or procedure. This date should correspond to the last dose date in the corresponding Prior Therapy, Radiation or Surgery form.

#	Therapy	Any therapy?	Date of Last Dose
1	Single Agent Systemic Chemotherapy	No	
2	Chemotherapy, multiple agents systemic	No	
3	Chemotherapy, NOS	No	
4	Hormone Therapy	No	

Fields

Any Therapy: Required. Select yes or no depending on the presence of this type of therapy or modality in the participant's medical record. Unknown should not be listed in the Any Therapy column; consult with the physician if unable to determine via medical record.

- *Extensive Radiation*: Therapy using ionizing radiation to a significant portion of the body (>50%), e.g. craniospinal, pelvic, or total-body.
- *Limited Radiation*: Therapy using ionizing radiation to a limited (≤ 50%) portion of the body,
- *Radiation (NOS)*: Radiation, *not otherwise specified*, but the extent is not known.

Date of Last Dose: Date of the last (i.e. most recent) dose/treatment. Corrections to this date need to be made on this form. Updated data will appear on the supplements. Partial dates allowed, see below.

Partial Dates
If the exact date is not known; '*un*' may be substituted for the day and *'UNK'* for the month.

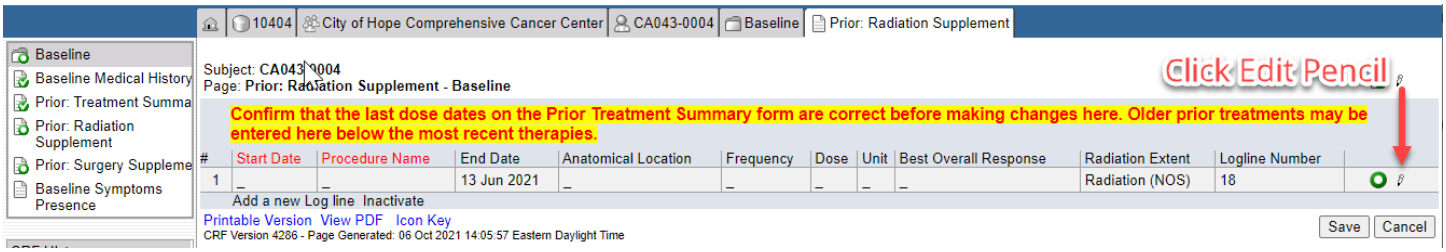
In the following supplemental forms

- Last Dose and Therapy Class auto-populate for the most recent therapies recorded in the Treatment Summary form.
- Add log lines for any older therapies:
    - Any prior stem cell toxic therapy (e.g., mitomycin C) or cardiotoxic therapy (e.g., doxorubicin or other anthracycline) if relevant to the study agent.
    - Any therapies used to determine "extensive prior therapy" if specified in protocol.
    - Any therapies restricted by the protocol eligibility criteria, either specific drugs or number of prior therapies (e.g., no more than two prior chemotherapy regimens for metastatic disease).
    - Any therapies that are clinically significant for evaluation of the current study or impact the participant's eligibility.
    - Any data (prior surgery or biopsy) to substantiate histologic diagnosis.

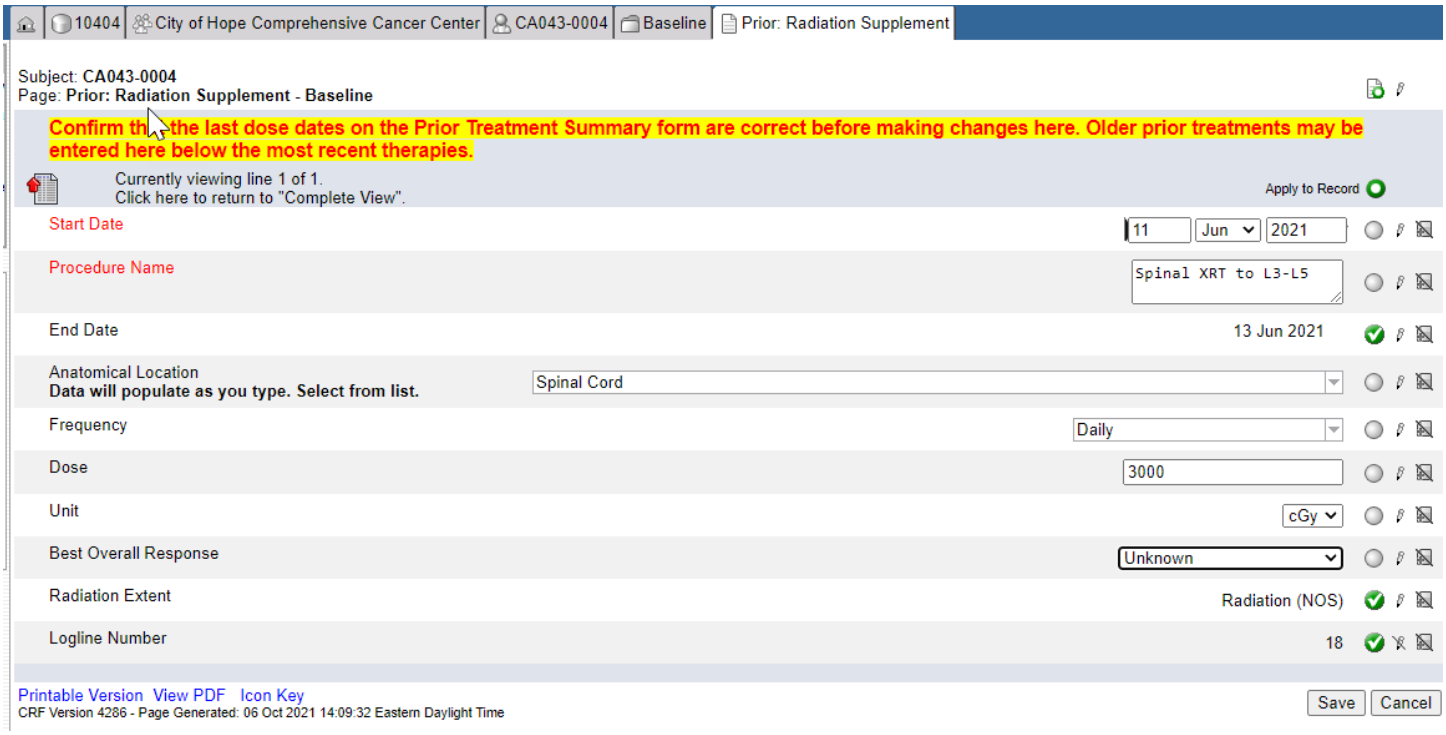
Prior: Radiation Supplement

Prerequisites: Prior Treatment Summary

Description: This form documents the specifics of any prior Radiation treatments. The most recent entry will automatically populate from the Treatment Summary form.



Click the **Edit** pencil to expand the empty log line. **End Date, Radiation Extent, and Logline Number (if present) are auto-populated from the Treatment Summary form and should not be edited.**



If **older** treatments need to be entered, use **Add a new log line**. These additional entries will have a zero in the Logline Number column as they are not linked to an entry in the Treatment Summary form.

Fields

Start Date: Give the date of the first dose of radiation therapy. Partial dates allowed, see below.
Procedure Name: State type of therapy.
End Date: Give the date of the last dose of radiation therapy. If this is the most recent therapy, the end date will be the same as the date on the Treatment Summary form.
Anatomical Location: Type to filter the options in the drop down menu.

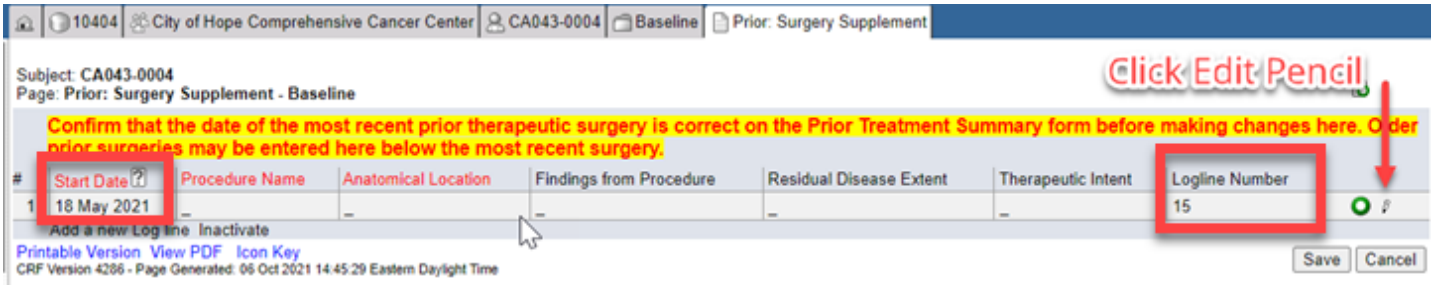
Frequency: Schedule on which radiation therapy was given
Dose and Dose Units: State the total dose the patient received during the treatment period and the dose units (e.g. cGy, Gy, or Rad).
Best Overall Response: Give the response for the irradiated site using the drop down menu.

Partial Dates
If the exact date is not known; '*un*' may be substituted for the day and *'UNK'* for the month.

Prior: Surgery Supplement (including Biopsies)

Prerequisites: Prior Treatment Summary

Description: This form documents the specifics of any prior surgical procedures for the cancer for which the participant was registered to the study. **This includes any biopsy performed to diagnose the participant**. The most recent entry will automatically populate from the Treatment Summary form.



Start Date and Logline Number (if present) are auto-populated from the Treatment Summary form and should not be edited. **Click** the **Edit** pencil to expand the empty log line and **complete** this entry before addition any additional surgeries.

If **older** surgeries need to be entered, use **Add a new log line**. These additional entries will have a zero in the Logline Number column as they are not linked to an entry in the Treatment Summary form.

Fields

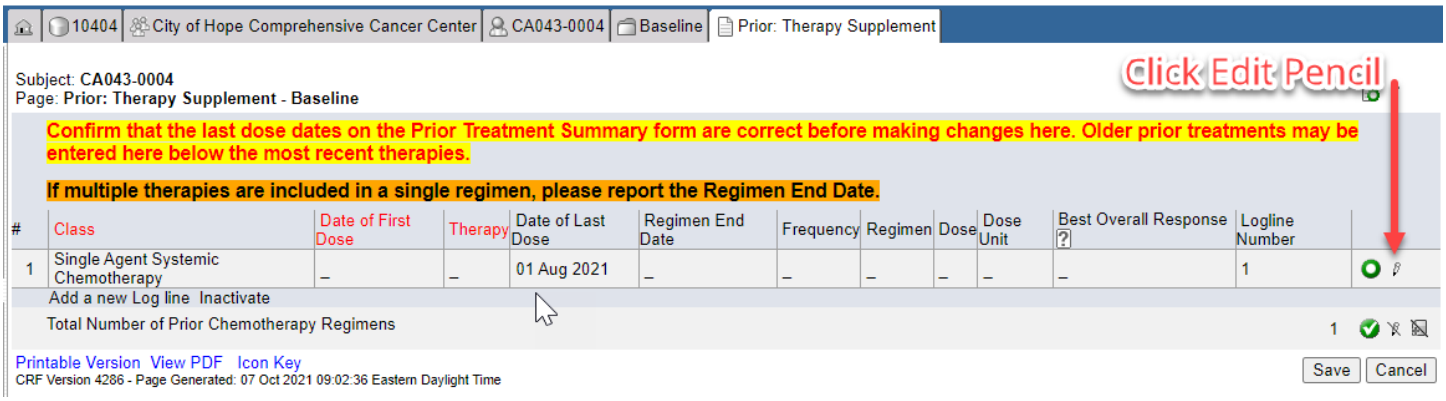
Start Date: Record the date of the surgical procedure. If this record is linked to an entry in the Treatment Summary form, it will be automatically entered. Partial dates allowed, see below.
Procedure Name: Describe the type of surgical procedure performed.
Anatomical Location: Type to filter options in the menu. Choose the best term to describe the anatomical site of the procedure.
Findings: Briefly describe the findings of the procedure.
Residual Disease Extent: Briefly state the extent of the residual disease, if any, at the conclusion of the operation.
Therapeutic Intent: If the surgical procedure was performed with therapeutic (curative) intent select Yes, if not select No.

Partial Dates
If the exact date is not known; '*un*' may be substituted for the day and *'UNK'* for the month.

Prior: Therapy Supplement

Prerequisites: Prior Treatment Summary

Description: This form documents the specifics of any prior chemotherapy treatments. The most recent entry will automatically populate from the Treatment Summary form.



Start Date and Logline Number (if present) are auto-populated from the Treatment Summary form and should not be edited.

Click the **Edit** pencil to expand the empty log line.

10404 | City of Hope Comprehensive Cancer Center | CA043-0004 | Baseline | Prior: Therapy Supplement

Subject: **CA043-0004**
Page: **Prior: Therapy Supplement - Baseline**

Confirm that the last dose dates on the Prior Treatment Summary form are correct before making changes here. Older prior treatments may be entered here below the most recent therapies.

If multiple therapies are included in a single regimen, please report the Regimen End Date.

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

Apply to Record

What is the category for the therapy?	Single Agent Systemic Chemotherapy
Date of First Dose	un / May / 2020
Therapy	Paclitaxel
Date of Last Dose	01 Aug 2021
Regimen End Date (required for systemic therapies)	01 / Aug / 2021
Frequency	Every three weeks
Intended Dose Regimen, if applicable	
Dose	175
Dose Unit	mg/m2
Best Overall Response	Unknown
Logline Number	1
Total Number of Prior Chemotherapy Regimens	1

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Save Cancel

Entries from the Summary form have the log line number linked to the entry from that form. (see above)

The **Date of Last Dose** will also auto-populate. (see above). **Do not change** the **Class** or **Date of Last Dose** on the pre-populated log lines, this data is linked to the entries on the Prior Treatment Summary form. To change this information, return to the Prior Treatment Summary form and edit there.

Chemotherapy, multiple agents systemic OR therapies with adjuvant

For multi-agent therapies, each agent should have its own entry in the log when possible. These agents should have a common regimen end date which will tie them together. If you only have an acronym to describe the therapy that would receive its own line.

Ex. FOLFOX is one entry

FOLFIRI with Avastin is two separate lines with a common **Regimen End Date**

Use **Add a New Log line** to add the Avastin.

#	Class	Date of First Dose	Therapy	Date of Last Dose	Regimen End Date	Frequency	Regimen	Dose	Dose Unit	Best Overall Response	Logline Number
1	Single Agent Systemic Chemotherapy			20 Jul 2020							1
2	Chemotherapy, multiple agents systemic	5 Jun 2021	FOLFIRI	28 Aug 2021	10 Sep 2021	Every four weeks	_	_	_	_	2
3	Immunotherapy	_	_	un May 2018	_	_	_	_	_	_	5

Add a new Log line | Inactivate

Total Number of Prior Chemotherapy Regimens 2

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Save Cancel

#	Class	Date of First Dose	Therapy	Date of Last Dose	Regimen End Date	Frequency	Regimen	Dose	Dose Unit	Best Overall Response	Logline Number
1	Single Agent Systemic Chemotherapy	_	_	20 Jul 2020	_	_	_	_	_	_	1
2	Chemotherapy, multiple agents systemic	5 Jun 2021	FOLFIRI	28 Aug 2021	10 Sep 2021	Every four weeks	_	_	_	_	2
3	Immunotherapy	_	_	un May 2018	_	_	_	_	_	_	5
4	Chemotherapy, multiple agents systemic	6 Jun 2021	Avastin	29 Aug 2021	10 Sep 2021	Every four weeks	_	_	_	_	0

If **older** therapies need to be entered, use **Add a new log line**. These additional entries will have a zero in the Logline Number column as they are not linked to an entry in the Treatment Summary form.

For any additional entries you will have to provide the **Therapy class** and **Date of Last dose**. These will not auto-populate.

Fields

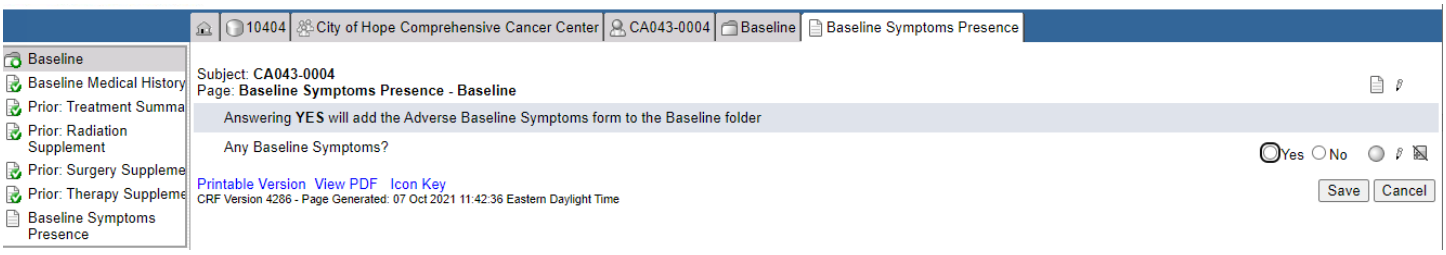
Category: Auto-filled based on entry in Treatment Summary form. This field will need to be completed for additional entries.
Date of First Dose: Enter the date of the first dose of the prior therapy. Partial dates allowed, see below.
Therapy: State the generic name of the agent that was used. In the case of a standard regimen of multiple agents, the conventional abbreviation for the regimen (i.e., MOPP, CHOP, CAF, etc.) may be used.
Date of Last Dose: Enter the date of the last dose of the prior therapy. Auto-filled based on entry in Treatment Summary form if the most recent therapy. If this needs to be changed, update the value on the Treatment Summary form. This field will need to be completed for additional entries. Partial dates allowed, see below.
Regimen End Date: Date of the last dose of the last therapy in the regimen for multi-agent systemic treatment. Partial dates allowed, see below.
Frequency: Choose frequency from drop-down list.
Intended Dose Regimen: Intended schedule or treatment plan.
Dose: State total numerical dose. Do not use a comma or other symbols in this field.
Dose Unit: Choose unit from drop-down list.
Best Overall Response: Select the best response encountered from drop down menu.

Partial Dates
If the exact date is not known; '*un*' may be substituted for the day and *'UNK'* for the month.

Baseline Symptoms Presence

Prerequisites: None

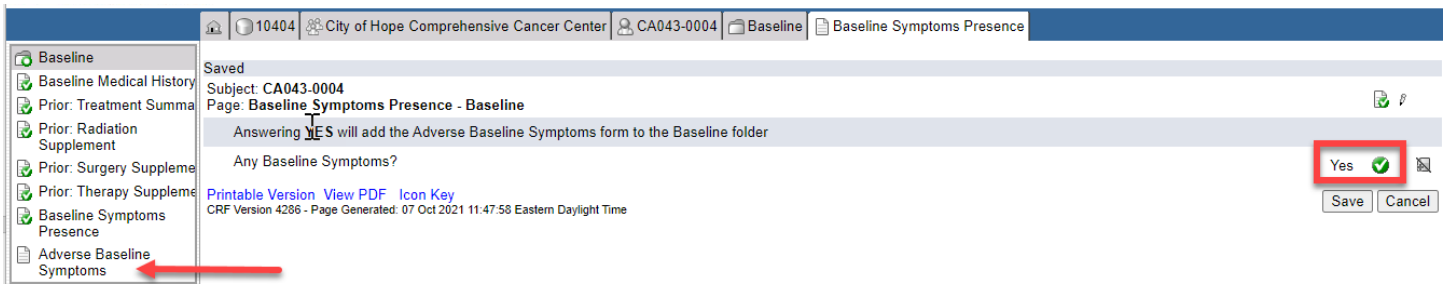
Description: This form documents the presence of symptoms at the participant's baseline or screening visit prior to taking the first does of the study agent. All baseline symptoms need to be graded based on CTCAE criteria. If the recorded grade is not permissible, please have symptom regraded. An event that is not gradable with CTCAE when the participant is screened for the study should not be recorded as a baseline symptom, add this to the Baseline Medical History form. Conditions the patient has a history of, but are not currently active, should not be entered here but added to the Baseline Medical History.



Fields

Any Baseline Symptoms?: Select **Yes** if any adverse symptoms are present at the participant's baseline or screening visit, otherwise select **No**.

Selecting **Yes** will trigger the Adverse Baseline Symptoms form. See below:



Adverse Baseline Symptoms

Prerequisites: Baseline Symptoms Presence

Description: This form documents the details of adverse symptoms present at the participant's baseline or screening visit.

10404 | City of Hope Comprehensive Cancer Center | CA043-0004 | Baseline | Adverse Baseline Symptoms

Subject: **CA043-0004**
Page: **Adverse Baseline Symptoms - Baseline**

Record Adverse Baseline Symptoms ongoing at study start

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

Apply to Record

Start Date	un UNK 2019
Unknown start date	☐
Verbatim Term	recurring frequent headaches
Event term (CTCAE v5.0) **Select term from list. If Other, enter specify in box.**	Headache
MedDRA Event Code	10019211: Nervous system disorders
What was the toxicity grade?	1
Related to Study Disease	Unknown

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Save Cancel

Fields

Start Date: Record the date that the symptom was first observed/experienced. Partial dates allowed, see below.
Unknown Start Date: If the start date is not known, click this checkbox.
Verbatim Term: Succinctly describe the symptom/adverse event. A clinical description of the actual adverse event should be entered. Record the diagnosis, e.g., flu, and not each specific symptom (e.g., chills fever, muscle aches). If pain is reported, list the anatomical location.
Event term (CTCAE v5.0): Type to filter options in the menu. Enter the CTCAE coding which was used to grade this symptom.
MedDRA Event Code: Will auto-populate after saving based on your selected CTCAE term.
What was the toxicity grade?: Select the severity from the drop down list. Grades listed are the permissible values for selected CTCAE term.
Related to Study Disease: Indicate if the symptom is related to the disease by selecting Yes or No. If unknown, select Unknown.

Partial Dates
If the exact date is not known; '*un*' may be substituted for the day and *'UNK'* for the month.

Baseline Pregnancy/Serology assays

See Pregnancy Test Log and Serology

Baseline Physical Exam

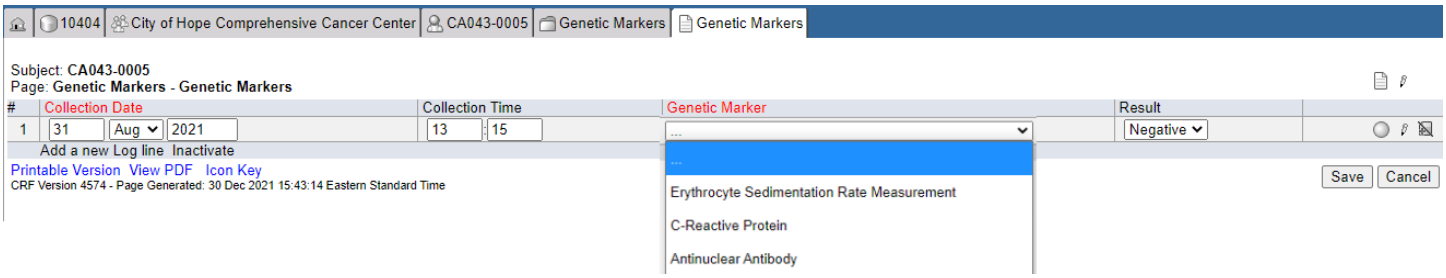
See Physical Exam

Genetic Markers

Genetic Markers

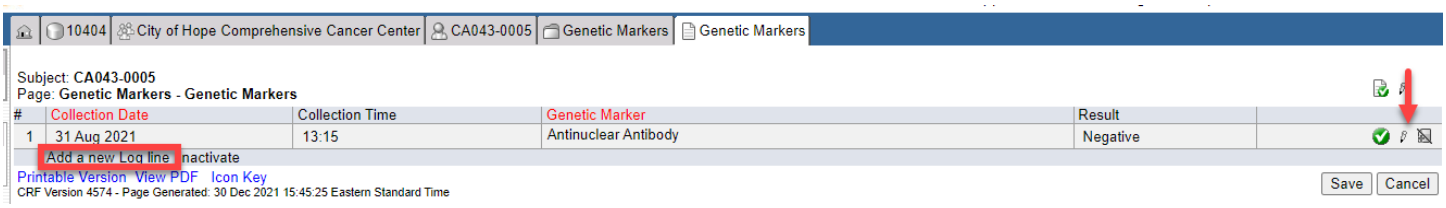
Prerequisites: None. List of Genetic Markers are protocol specific

Description: Record genetic markers for patient, usually required for eligibility. Form is customized to protocol. Dropdown items will vary.



Enter the Collection Date, Collection Time (if available), select the Genetic Marker, and select Result (if available). Values in Results fields may vary depending on protocol. Click **Save**. After saving, the fields can be edited/updated by using the Edit pencil.

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.



In some studies, an upload field is available for the redacted and deidentified report of genetic marker results.

Fields

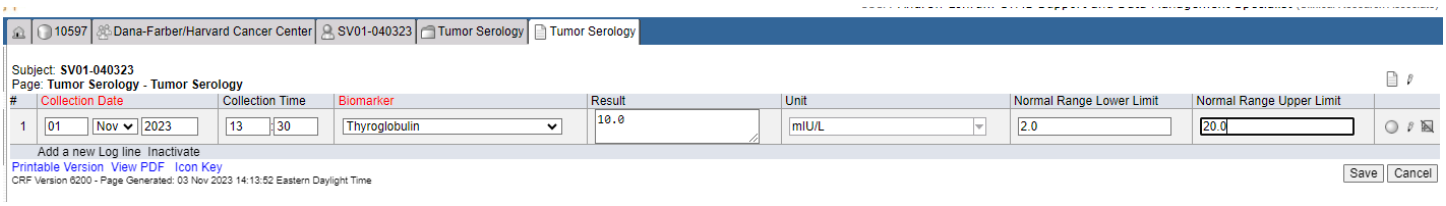
Collection Date: Date sample (tissue or blood) was collected. Partial dates are not allowed.
Collection Time: Time sample (tissue or blood) was collected
Genetic Marker: Marker that was identified during sample (tissue or blood) analysis
Result: Positive or negative for the genetic marker

Tumor Serology

Tumor Serology

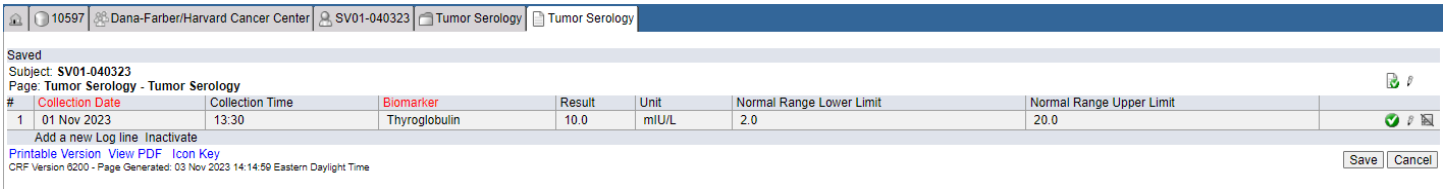
Requirements: None

Description: Predefined set of markers in serum (blood). Some cancers produce serology markers in the blood and measurements are used to assess disease.



Enter the Collection Date, Collection Time (if available), select the Biomarker, enter Result (if available), select the Unit, enter the Normal Range Lower Limit and Normal Range Upper Limit. Click **Save**. After saving, the fields can be edited/updated by using the Edit pencil.

If additional Tumor Serology records need to be entered, click on *Add a new Log line.*



Fields

Collection Date: Required. Date serum (blood) was collected
Collection Time: Time serum (blood) was collected
Biomarker: Required. Prepopulated list of biomarkers identified via serum (blood)
Result: Free text. If a numerical value is entered in this field, the **Unit** and **Normal Range** fields should also be entered.
Unit: Standard set of units
Normal Range Lower Limit: Required. Refer to lab report.
Normal Range Upper Limit: Required. Refer to lab report.

Lesion Evaluations

Baseline Lesion

Prerequisites: None

Description: This form allows the users to record and track lesions present at the Baseline visit.

10404 | City of Hope Comprehensive Cancer Center | CA043-0004 | Lesion Evaluations | Baseline Lesion

Lesion Evaluations
Baseline Lesion
New Lesion Presence

CRF History
CA043-0004 - Baseline Lesion

Subject: **CA043-0004**
Page: **Baseline Lesion - Lesion Evaluations**

On Study Lesions and Ongoing Evaluations

Note: Lesions should be sequentially numbered.
Lesion # 001

Location of the Tumor/Lesion: Soft Tissue

Description of Tumor: LL posterior neck

Previously Irradiated: No

Target Lesion: Yes

Followed for Response: Yes

Does patient have more lesions present at **baseline**? If yes, click the checkbox below to create a new blank form for the next lesion. New form is created after you enter below evaluation fields and save this form. **If any additional lesions develop after the start of protocol treatment, use the New Lesion Presence form.**

Click to add new instance of form, unclick to remove unused form. ☑

Each lesion, either observed at Baseline or during the study should be assigned a unique sequential number and never duplicated. During the course of the study this should not change and this lesion will always be recorded with this identifier.

If multiple lesions are present, use the checkbox. After the form is saved, a new blank form will be added to the folder to record this additional lesion. If a form is added in error, click the edit pencil and uncheck the box. After clicking save the blank extra form will be removed.

Next, complete the remaining portion of the form (below). This will create a log line after the form is saved.

- **All measurements must be reported in millimeters (per RECIST)**
- **The most relevant diameter should be entered first as per response criteria defined in the protocol**
- **When a lesion resolves, at each scheduled exam 0 (zero) should be entered for the measurement(s) and "Resolved" should be selected for the Evaluation Code**

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

Apply to Record

Assessment Timepoint: Baseline

Date of Tumor/Lesion Measurement: 31 Aug 2021

Method Used to Identify the Tumor/Lesion
Data will populate as you type. Select from list.: CT Scan

Most Relevant Diameter: 21.6 mm

Longest Measurement? ☐

Perpendicular Measurement: 18.9 mm

Longest Measurement? ☐

Lesion Response: Baseline

Evaluator:
- ○ Independent Assessor
- ○ Investigator
- ◉ Radiologist

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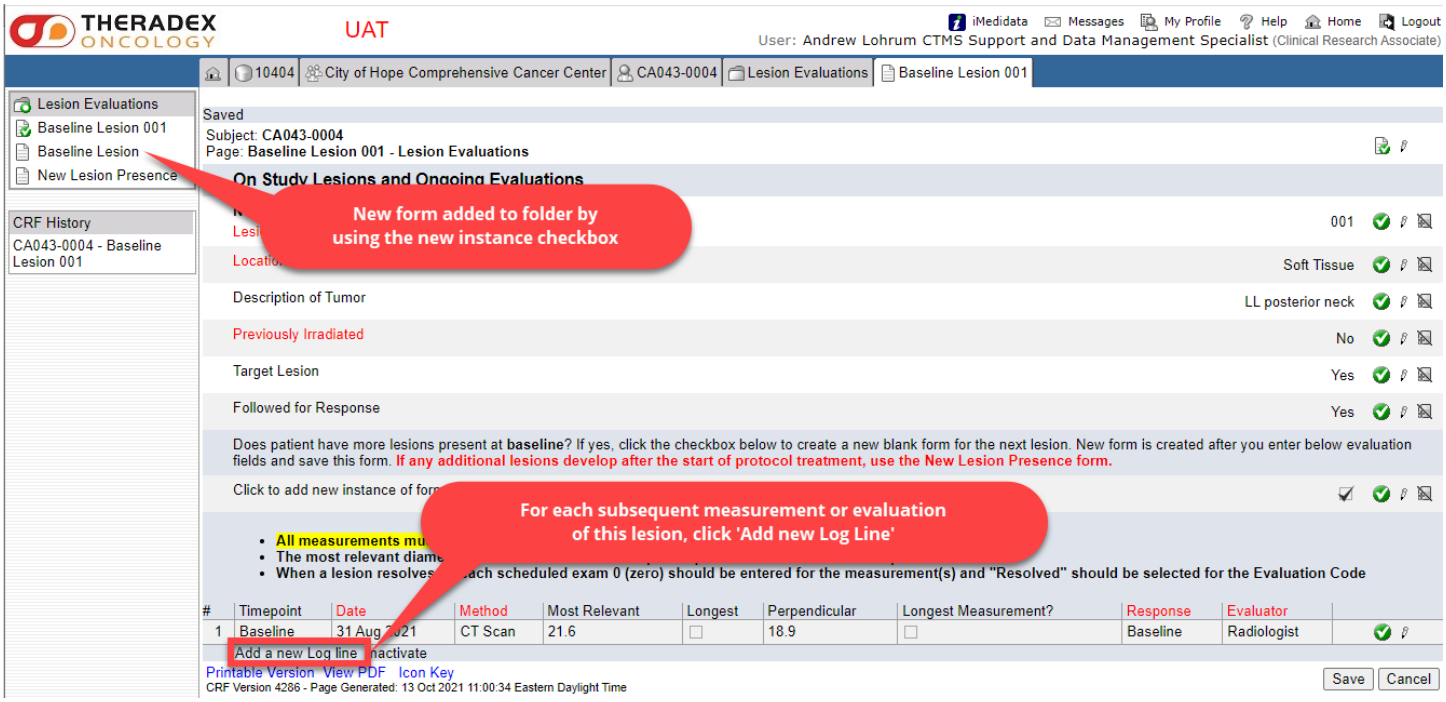
Save | Cancel

Saved form:



Proceed to the new Baseline Lesion form to record the evaluation of an additional lesion that is present at Baseline.

Fields

Lesion #: A unique sequential identifier assigned to each lesion.
Location of the Tumor/Lesion: Type in the menu and select the location of the lesion from the available options.
Description of Tumor: In this free text field, enter a description of the lesion (32 characters).
Previously Irradiated: Y/N, was this lesion treated with radiation prior to the Baseline visit.
Target Lesion: Y/N, is this lesion the target of the study therapeutic agent.
Followed for Response: Y/N, is this lesion being evaluated for response to therapeutic agent.
New Instance checkbox: If another lesion is present at the Baseline visit, click this checkbox and a new blank form will load into the folder after saving the current form. Each lesion will need a unique number to keep their evaluations separated. Do not use this feature for new lesions that appear during the study.

For the first entry, these fields are displayed and open on the form. For each additional evaluation, click Add a New Log Line and the Edit pencil in the new row to enter data in these fields.

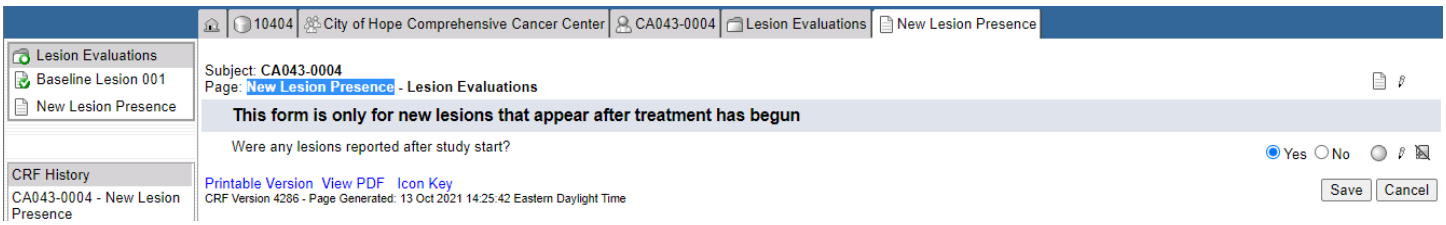
Assessment Timepoint: For the first entry, select Baseline. For each additional evaluation select the appropriate timepoint from the drop-down menu.
Date of Tumor/Lesion Measurement: Date of evaluation.

Method Used: Select the method used to measure the tumor/lesion.
Most relevant Diameter: Size in mm of the diameter of the lesion which is either the longest measurement for a lesion or shortest for a lymph node.
Longest Measurement?: Use this checkbox if the diameter measurement is the greater value of this evaluation. For lesions, this value would be selected.
Perpendicular Measurement: Size in mm perpendicular (90°) to the most relevant diameter recorded above.
Longest Measurement?: Use this checkbox if the perpendicular measurement is the greater value of this evaluation. For lymph nodes, this value would be selected.
Lesion Response: Assessment of any changes in size of the lesion/tumor.
Evaluator: Select the radio button to record whom performed the evaluation.

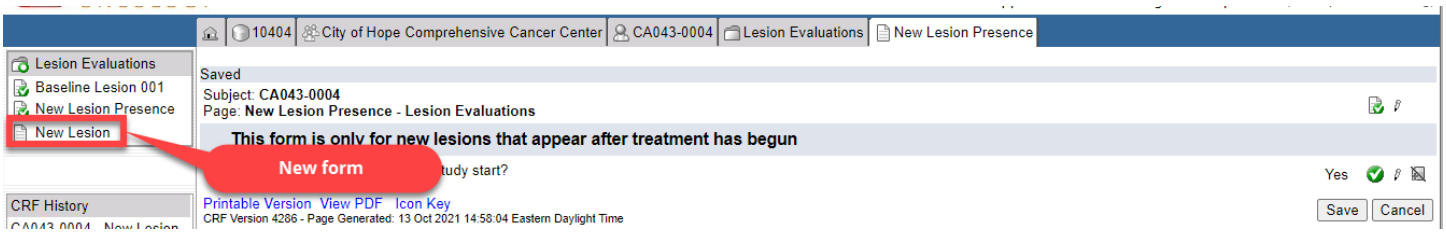
New Lesion Presence

Prerequisites: All Baseline Lesions are recorded.

Description: This form allows the users to create a new entry for lesion(s) that appear after the Baseline visit.



If a lesion appears after treatment, select **Yes** in this form and click **Save**. A new form will be loaded into the folder to record the lesion and its evaluations (see below).



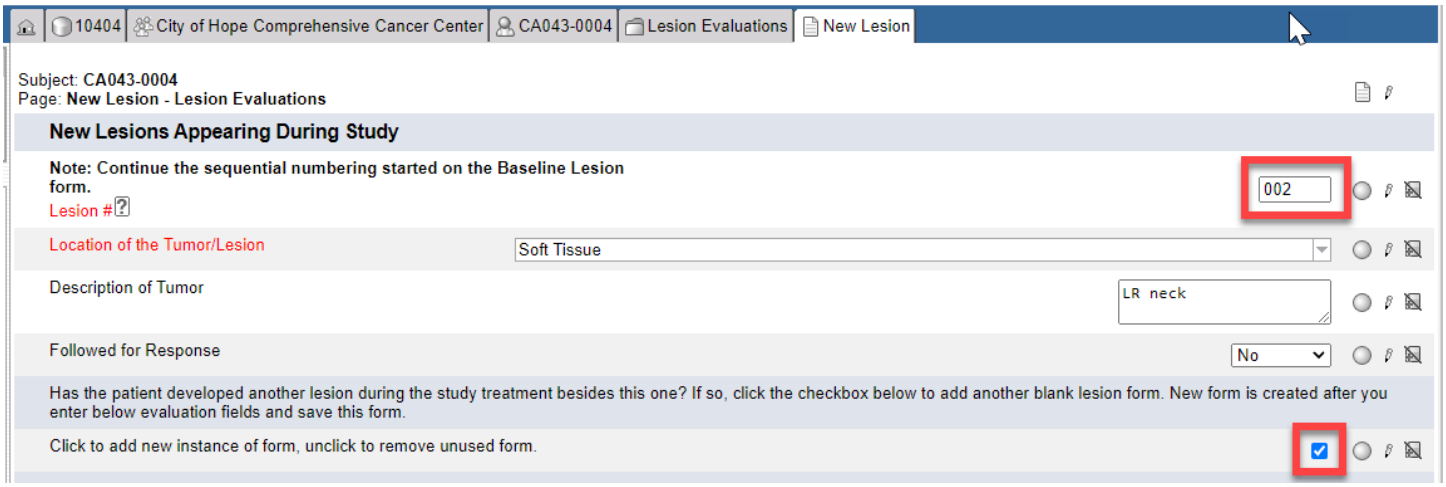
Fields

Were any lesions reported after study start? Y/N, select yes if a new lesion(s) occurs after the Baseline visit.

New Lesion

Prerequisites: New Lesion Presence

Description: This form allows the users to record and track lesions present after the Baseline visit.



Each lesion, either observed at Baseline or during the study should be assigned a unique sequential number and never duplicated. During the course of the study this should not change and this lesion will always be recorded with this identifier.

When assigning an identifier to this new lesion, you will choose the next number in numerical sequence for all lesions/tumors in the Lesion Evaluations folder. No existing numbers should be replicated or reused.

Example: If 001, 002, and 003 are used in the Baseline Lesion forms, assign 004 to the next new lesion not present at the baseline visit.

If multiple lesions are present, use the checkbox. After the form is saved, a new blank form will be added to the folder to record this additional lesion. If a form is added in error, click the edit pencil and uncheck the box. After clicking Save, the blank extra form will be removed.

Next, complete the remaining portion of the form (below). This will create a log line after the form is saved.

- All measurements must be reported in millimeters (per RECIST)
- The most relevant diameter should be entered first as per response criteria defined in the protocol
- When a lesion resolves, at each scheduled exam 0 (zero) should be entered for the measurement(s) and "Resolved" should be selected for the Evaluation Code

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

Apply to Record

Assessment Timepoint	Confirmatory scans 6 weeks following initial documentation of an objective response
Date of Tumor/Lesion Measurement	05 Sep 2021
Method Used to Identify the Tumor/Lesion	CT Scan
Most Relevant Diameter	7.3 mm
Longest Measurement	☐
Perpendicular Measurement	4.2 mm
Longest Measurement?	☐
Lesion Response	Not Examined
Evaluator	◉ Independent Assessor ○ Investigator ○ Radiologist

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Save Cancel

Saved form:

10404 | City of Hope Comprehensive Cancer Center | CA043-0004 | Lesion Evaluations | New Lesion 002

Lesion Evaluations
Baseline Lesion 001
New Lesion Presence
New Lesion 002
New Lesion

CRF History
CA043-0004 - New Lesion 002
CA043-0004 - New Lesion Presence
CA043-0004 - Baseline Lesion 001
AL011-0909 - Shipping Status
AL011-0909 - Receiving Status
AL011-0909 - Specimen Collection Details
AL011-0909 - Consent for Optional Vaccine Researcl Sub-Study
AL011-0888 - Shipping Status
AL011-0888 - Receiving Status
AL011-0888 - Copy Shipping
AL011-0888 - Specimen Collection Details

Saved
Subject: CA043-0004
Page: New Lesion 002 - Lesion Evaluations

New Lesions Appearing During Study

Note: Continue the sequential numbering started on the Baseline Lesion form. 002

Soft Tissue

LR neck

Followed for Response No

Has the patient developed another lesion during the study treatment besides this one? If so, click the checkbox below to add another blank lesion form. New form is created after you enter below evaluation fields and save this form.

Click to add new instance of form, unclick to remove unused form. ☑

New form added to folder by using the new instance checkbox

For each subsequent measurement or evaluation of this lesion, click 'Add new Log Line'

#	Assessment Timepoint	Date of Tumor/Lesion Measurement	Method Used to Identify the Tumor/Lesion	Most Relevant Diameter	Longest Measurement	Perpendicular Measurement	Longest Measurement?	Lesion Response	Evaluator
1	Confirmatory scans 6 weeks following initial documentation of an objective response	05 Sep 2021	CT Scan	7.3	☐	4.2	☐	Not Examined	Independent Assessor

Add a new Log line Inactivate

Printable Version View PDF Icon Key
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Save Cancel

Fields

Lesion #: A unique sequential identifier assigned to each lesion.
Location of the Tumor/Lesion: Type in the menu and select the location of the lesion from the available options.
Description of Tumor: In this free text field, enter a description of the lesion (32 characters).
Followed for Response: Y/N, is this lesion being evaluated for response to therapeutic agent?
New Instance checkbox: If another lesion is present after the start of the study, click this checkbox and a new blank form will load into the folder after saving the current form. Each lesion will need a unique number to keep their evaluations separate.

For the first entry, these fields are displayed and open on the form. For each additional evaluation, click Add a New Log Line and the Edit pencil in the new row to enter data in these fields.

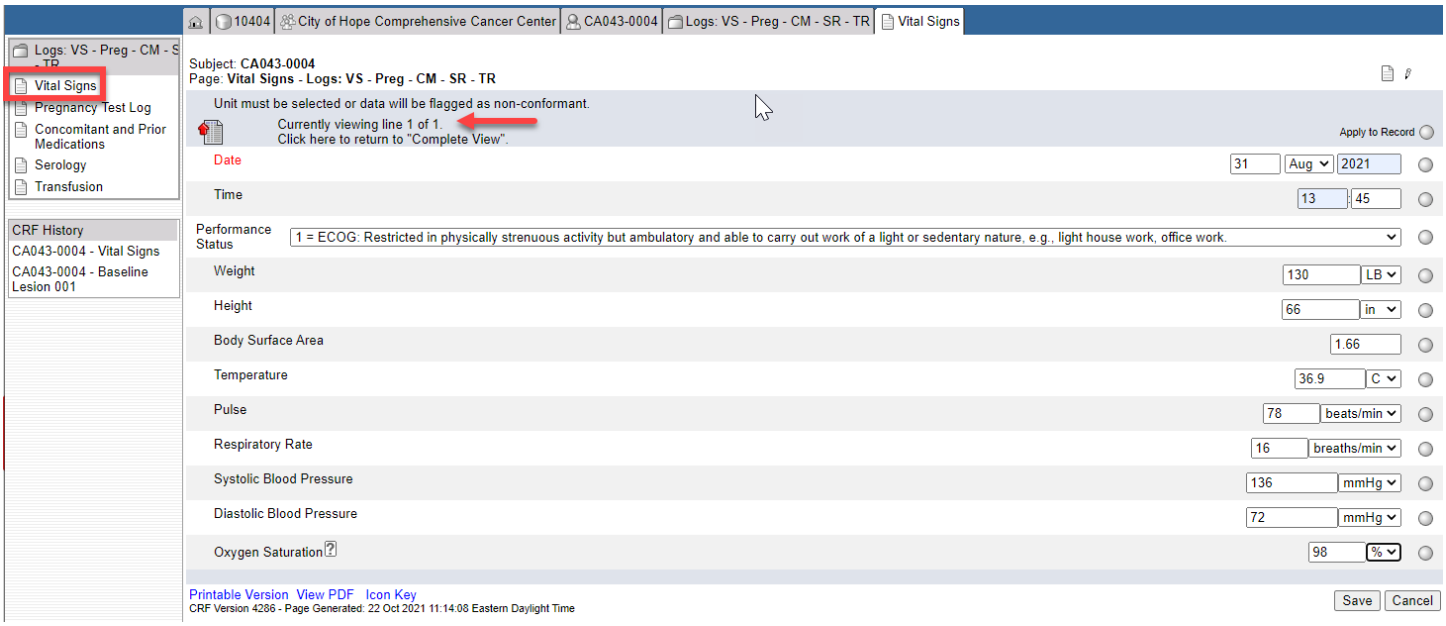
Assessment Timepoint: For the first entry, select Baseline. For each additional evaluation select the appropriate timepoint from the drop-down menu.
Date of Tumor/Lesion Measurement: Date of evaluation.
Method Used: Select the method used to measure the tumor/lesion.
Most relevant Diameter: Size in mm of the diameter of the lesion which is either the longest measurement for a lesion or shortest for a lymph node.
Longest Measurement?: Use this checkbox if the diameter measurement is the greater value of this evaluation. For lesions, this value would be selected.
Perpendicular Measurement: Size in mm perpendicular (90°) to the most relevant diameter recorded above.
Longest Measurement?: Use this checkbox if the perpendicular measurement is the greater value of this evaluation. For lymph nodes, this value would be selected.
Lesion Response: Assessment of any changes in size of the lesion/tumor.
Evaluator: Select the radio button to record whom performed the evaluation.

Logs: VS - Preg - CM - SR – TR

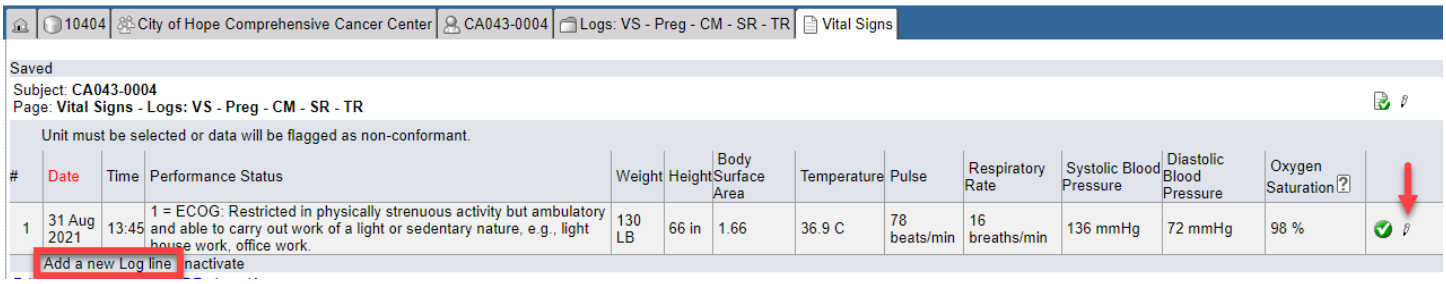
Vital Signs

Prerequisites: None

Description: This log is used to record the vital signs at each visit as required by protocol.



Enter the Date and time vitals were taken. In each filed enter the value in the text box and select the appropriate unit in the drop down. 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.



Fields

Date: Enter date vital signs were taken
Time: Time the vital signs were taken
Performance Status: Eastern Cooperative Oncology Group measure of functional status
Weight: Weight of participant in kilograms or pounds (kg or LB).
Height: Height of participant in centimeters or inches (cm or in).
Body Surface Area: Record body surface area of participant in m2.
Temperature: Temperature of participant in Celsius or Fahrenheit (C or F).
Pulse: Measured pulse rate of participant in beats per minute (beats/min).
Respiratory Rate: Observed respiratory rate of participant in breaths per minute (breaths/min).

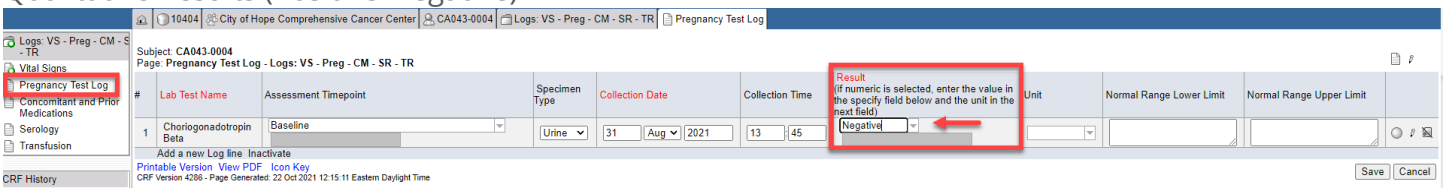
Systolic Blood Pressure: Measured systolic blood pressure in mmHg
Diastolic Blood Pressure: Measured diastolic blood pressure in mmHg
Oxygen Saturation: Measurement captured using a pulse oximeter (%). If part of blood draw, record oxygen saturation on the Blood Gases form.

Pregnancy Test Log

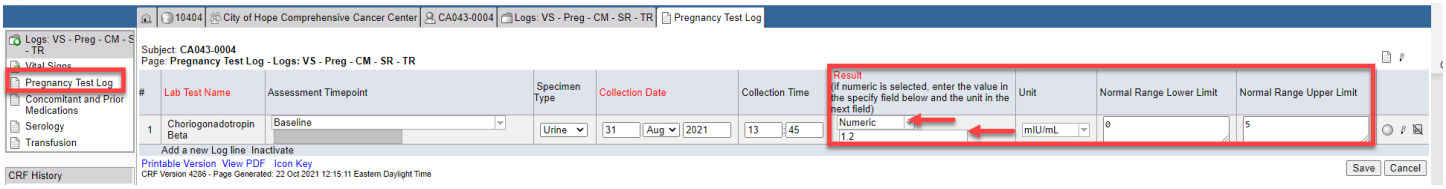
Prerequisites: None

Description: This log records the results of pregnancy tests that occur as required by protocol.

Qualitative Results (Positive/Negative)



Quantitative Results (Numerical value)



To record qualitative results, select Positive or Negative from the Results drop down menu.
For quantitative results, choose Numeric and enter the value in the open field below. Then proceed to record the unit, normal range lower limit, and normal range upper limit of the assay.

Fields

Assessment Timepoint: Protocol timepoint
Specimen Type: Indicate the sample collected for testing.
Collection Date: Date sample was collected.
Collection Time: Time sample was collected.
Result: Select Positive or Negative for qualitative test results. Select Numeric for quantitative tests, enter the numeric value in the opened box.
Unit: For quantitative tests, select reported units.
Normal Range Lower Limit: For quantitative tests, refer to lab report.
Normal Range Upper Limit: For quantitative tests, refer to lab report.

Concomitant and Prior Medications

Prerequisites: None

Description: This log records all medications administered to the participant while on study. This should also include treatments administered for adverse events.

Subject: CA043-0004
Page: Concomitant and Prior Medications - Logs: VS - Preg - CM - SR - TR

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

Apply to Record

Start Date	un Mar 2019
End Date	
Therapy	Gabapentin
Total Daily Dose	300
Unit	mg
Frequency	Twice a day
Intended Dose Regimen, if applicable	
Indication	Pain

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Save Cancel

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.

Page: Concomitant and Prior Medications - Logs: VS - Preg - CM - SR - TR

#	Start Date	End Date	Therapy	Total Daily Dose	Unit	Frequency	Intended Dose Regimen, if applicable	Indication
1	un Mar 2019	_	Gabapentin	300	mg	Twice a day	_	Pain

Add a new Log line Inactivate

#	Start Date	End Date	Therapy	Total Daily Dose	Unit	Frequency	Intended Dose Regimen, if applicable	Indication
1	un Mar 2019	_	Gabapentin	300	mg	Twice a day	_	Pain
2	un Sep 2019	09 Mar 2021	Eliquis	2.5	mg	Twice a day	_	Anticoagulation
3	un UNK 2019	_	Tylenol	1000	mg	Twice a day	_	Pain
4	un Sep 2020	_	Melatonin	10	mg	Every night	_	Insomnia
5	un Dec 2019	_	Allegra	_	Unknown	Daily	As Needed	Allergic rhinitis
6	un UNK 2018	_	B copmplex	_	Unknown	Daily	_	Supplement
7	un UNK 2018	_	Vitamin D3	2000	IU	Daily	_	Supplement

Add a new Log line Inactivate

Fields

Start Date: Date first does of medication was taken. Partial dates allowed, see below.
End Date: Date of last does of medication was taken. If participant is still continuing treatment at the end of study leave this field blank. Partial dates allowed, see below.
Therapy: Record the therapeutic agent. In case of drugs state the generic name of the drug administered. In the case of combinations such as trimethoprim/sulfamethoxazole, state the brand name (i.e., Bactrim).
Total Daily Dose: Enter the total daily dose of the agent.
Unit: Unit of agent administered. Type in the menu to filter.
Frequency: Record the frequency/schedule of drug administration.
Intended Dose Regimen: If the frequency of administration differs from the intended regimen, note the difference here.

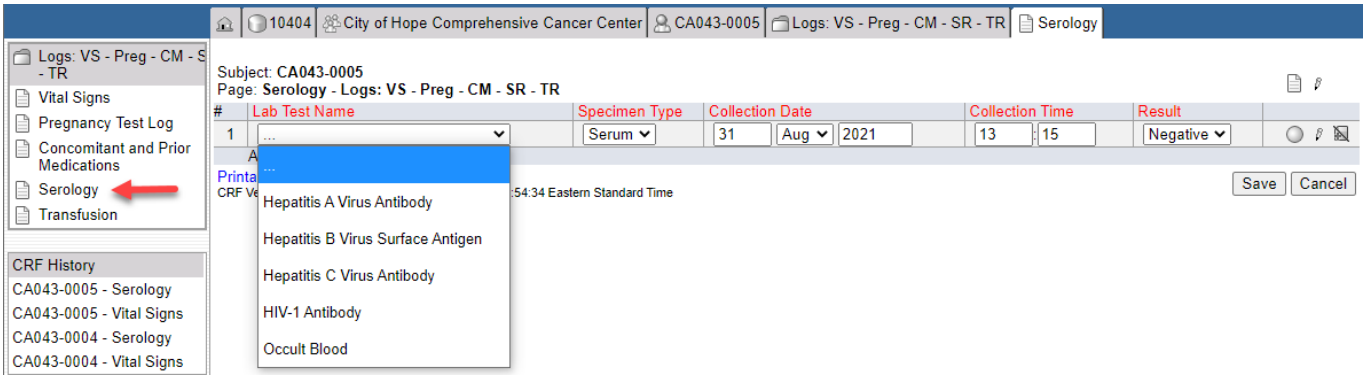
Indication: Reason drug is being administered. For example, if Bactrim is administered as a prophylactic, state "pneumocystis prophylaxis".

Partial Dates
If the exact date is not known; '*un*' may be substituted for the day and *'UNK'* for the month.

Serology

Prerequisites: None

Description: This log records the results of any serology assays performed if required to assess eligibility and while on study.



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.

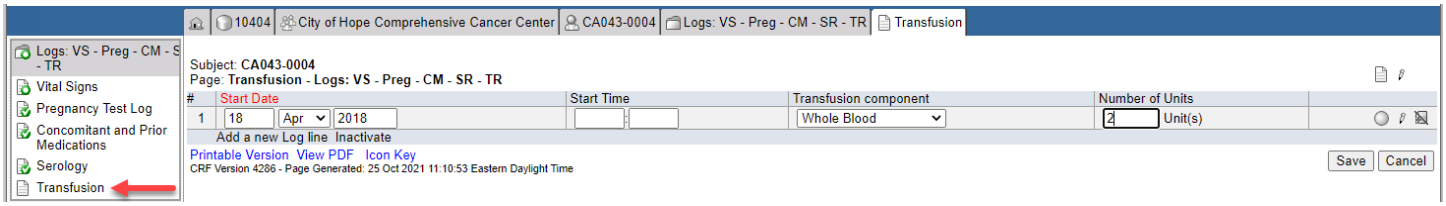
Fields

Lab Test Name: Choose the assay from the drop down menu.
Specimen Type: Select the type of specimen from the drop down menu.
Collection Date: Date sample was collected.
Collection Time: Time sample was collected.
Result: Result from lab report. Positive/Negative.

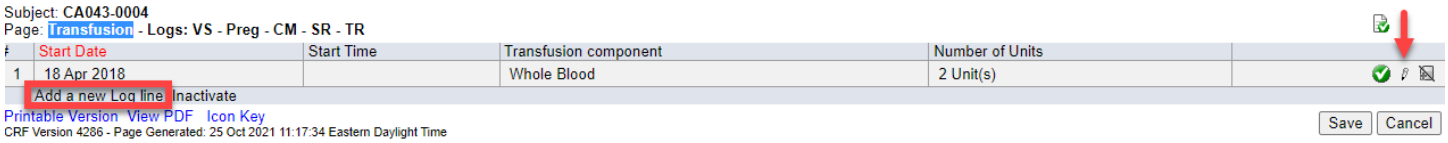
Transfusion

Prerequisites: None

Description: This log records any transfusion received by participant.



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.



Fields

Start Date: Date the transfusion was initiated.
Start Time: Time the transfusion was initiated.
Transfusion Component: Select the product from drop down menu.
Number of Units: Enter total number of units administered in the transfusion.

Physical Exam

Physical Exam

Prerequisites: None

Description: This form records the observations from a physical exam that occur at Baseline, on study, and at Follow-up.

10404 | City of Hope Comprehensive Cancer Center | CA043-0004 | Physical Exam | Physical Exam

Physical Exam
Physical Exam

CRF History
CA043-0004 - Physical Exam

Exam Date 31 Aug 2021

Click to add new instance of form, unclick to remove unused form.

#	Body System	Result	Comment if Abnormal or any change from Baseline
1	H/E/E/N/T	Normal	
2	Neck	Normal	
3	Respiratory	Normal	
4	Cardiovascular	Abnormal	Occasional PVCs
5	Gastrointestinal	Normal	
6	Musculoskeletal	Normal	
7	Dermatologic	Normal	
8	Hematopoietic/Lymph	Normal	
9	Endocrine/Metabolic	Normal	
10	Urinary	Not Evaluable	
11	Genitalia	Not Evaluable	
12	Breasts	Not Evaluable	
13	Pelvis	Not Evaluable	
14	Abdomen	Normal	
15	Neurologic	Normal	
16	Psychologic	Abnormal	Anxiety
17	Immune	Not Evaluable	
18	Other	Not Evaluable	

Add a new Log line Inactivate

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Save Cancel

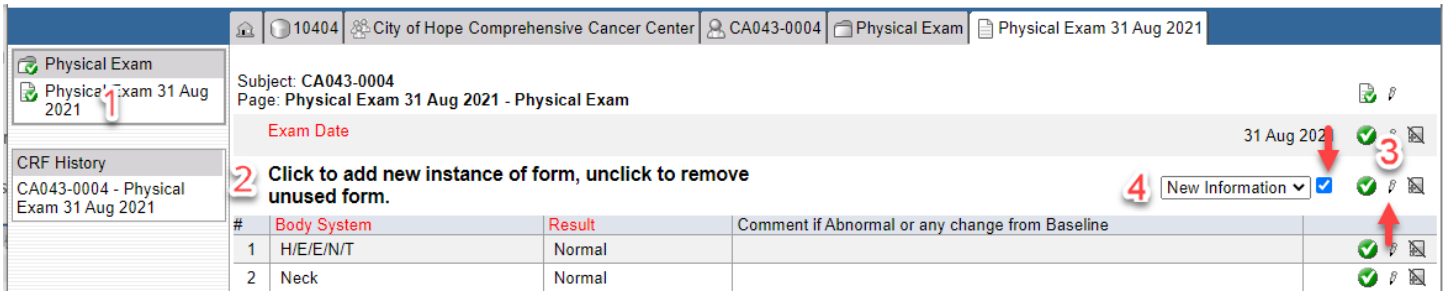
Fields

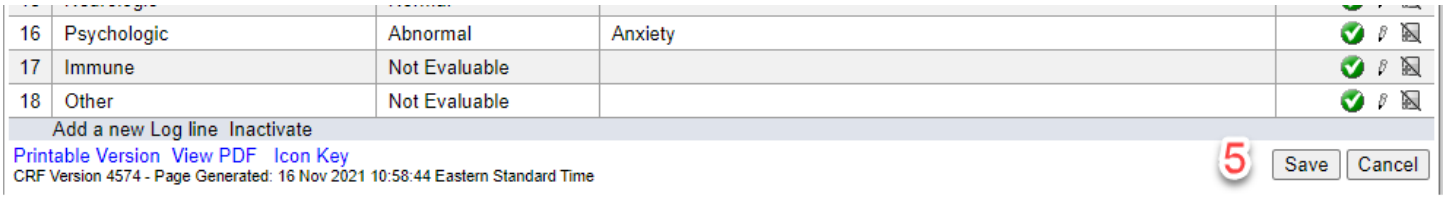
Exam Date: Record date of the physical examination.
Result: Indicate whether the findings for the particular body system were either Normal, Abnormal, or Not Evaluable (i.e. that particular body system was not examined).
Comments: If the status of a particular body system is Abnormal or has changed from baseline, give a brief description of the change.

To add a new instance of the form

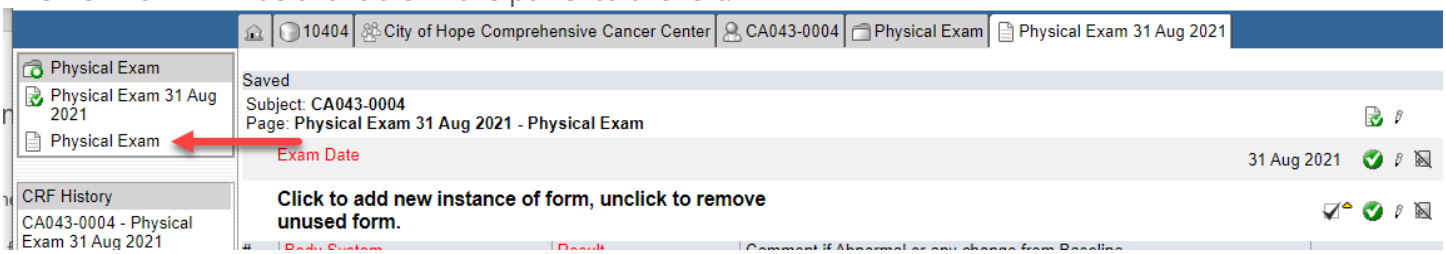
Follow these steps to add an additional blank physical exam form:

1. Go to the last completed Physical Exam form.
2. Go to the 'Click to add ...' field.
3. **Click** on the Edit Pencil.
4. **Click** the check box.
5. **Click** Save.





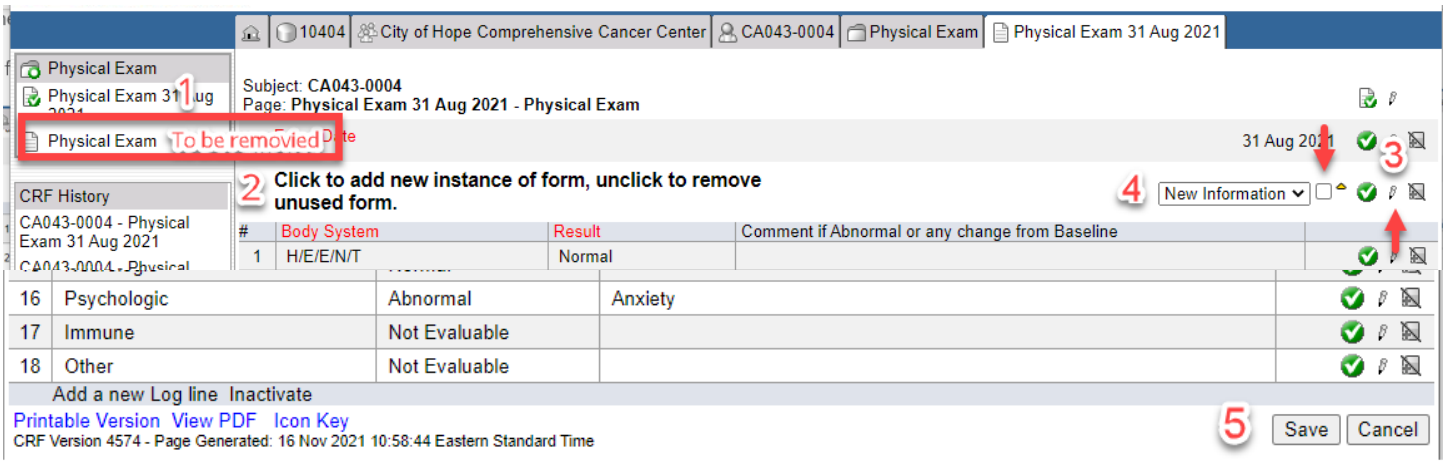
The new form will be available in the panel to the left:



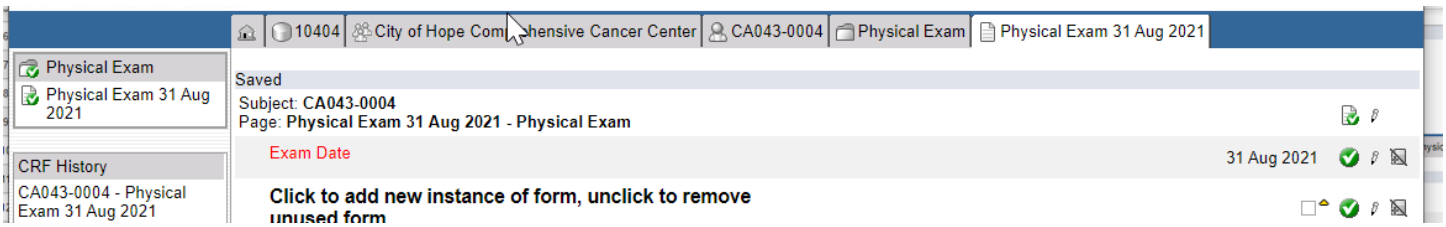
To remove an extra form

For a form that was added but not needed, the empty form can be removed following the steps below:

1. Go to the last completed Physical Exam form.
2. Go to the 'Click to add ...' field.
3. **Click** on the Edit Pencil.
4. **Click** on the checkmark, it will be removed, and the checkbox will be empty.
5. **Click** Save.



The extra form will be removed from the panel to the right:

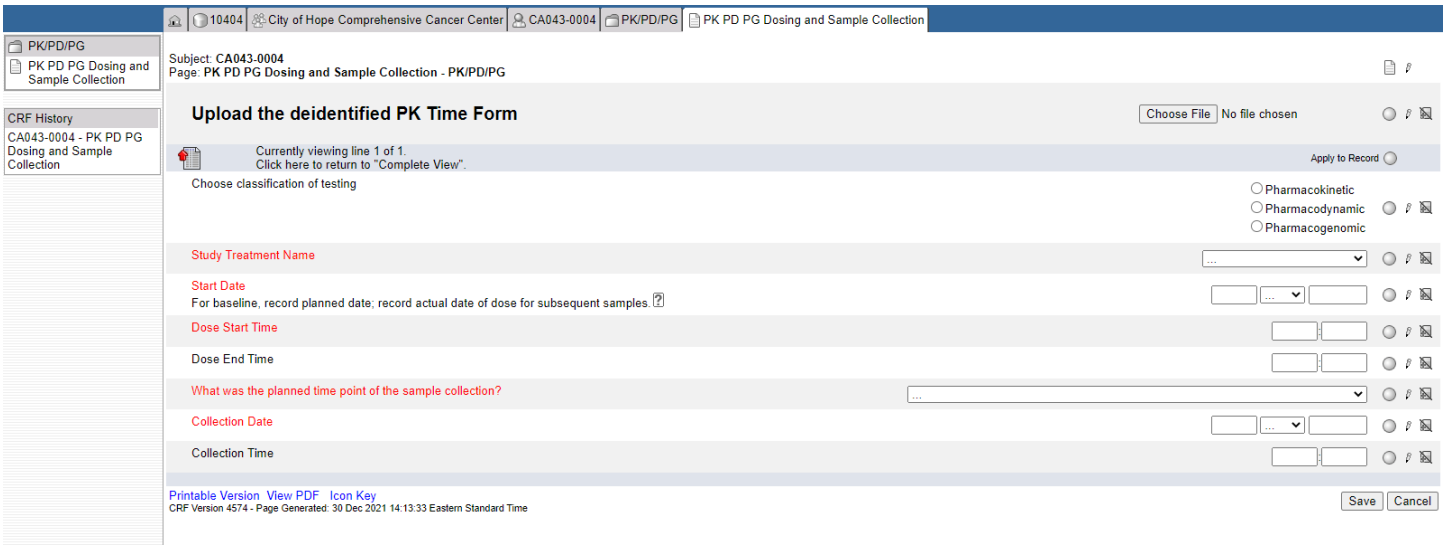


PK/PD/PG

PK PD PG Dosing and Sample Collection

Prerequisites: None

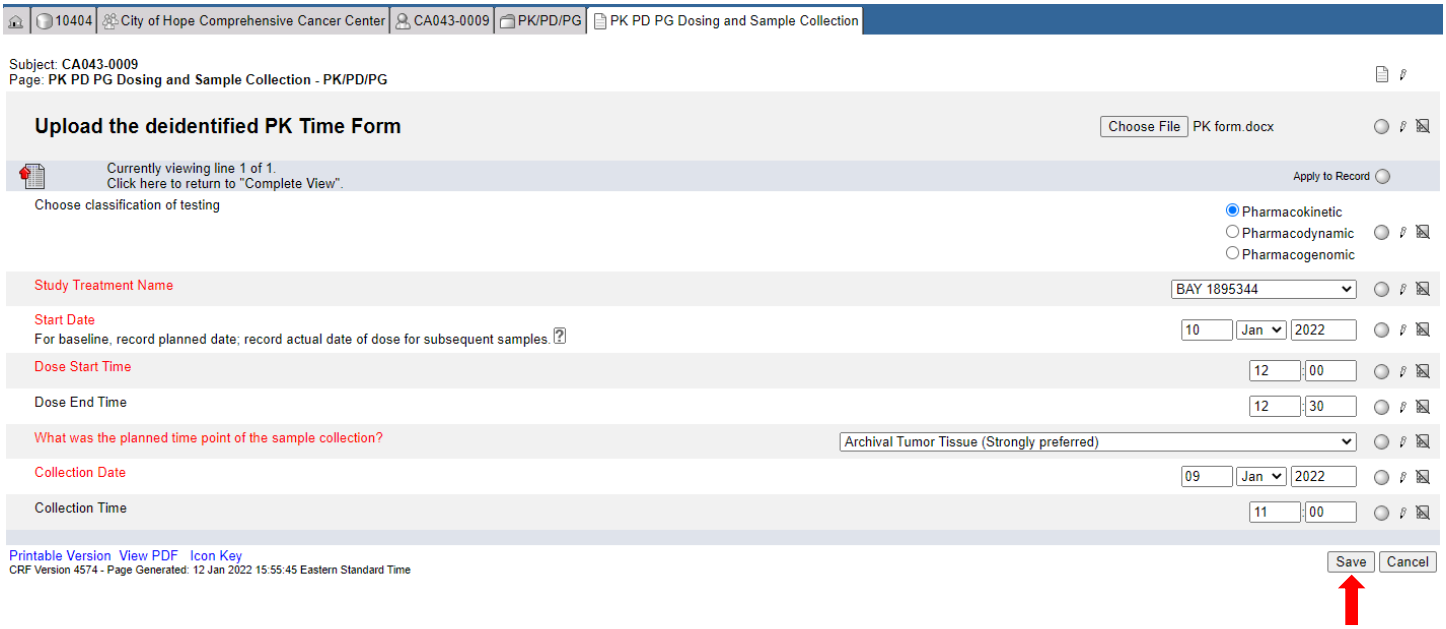
Description: This form records information on specimens that are collected for Pharmacokinetic, Pharmacodynamic, and/or Pharmacogenomic analysis.



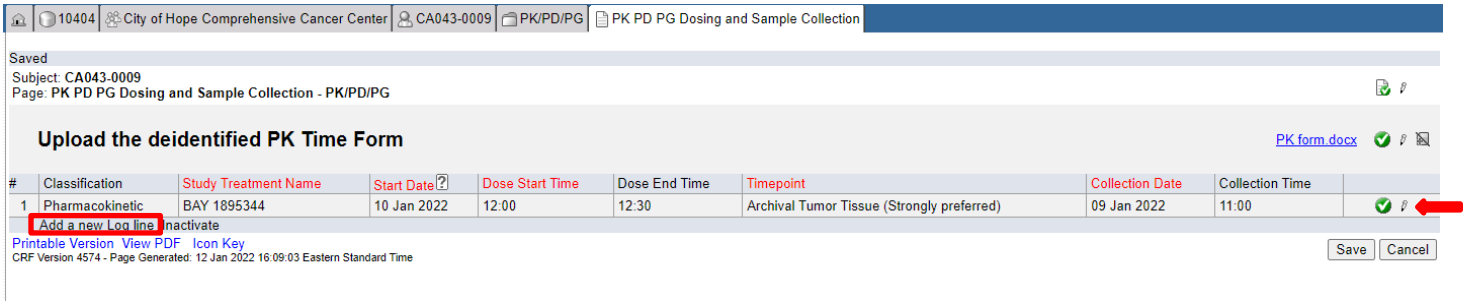
Fields

Upload the deidentified PK Time Form: Upload the PK form that contains the data collected during specimen collections. Remove all identifiers from report, including from report name.
Choose classification of testing: Select Pharmacokinetic, Pharmacodynamic, or Pharmacogenomic.
Study Treatment Name: Select the appropriate study treatment from the dropdown. If the same blood sample is being used for multiple tests, add a new a logline, and enter data for the other treatment.
Start Date: Treatment start date.
Dose Start Time: Time dose started.
Dose End Time: Time dose ended.
What was the planned time point of the sample collection?: Select the appropriate timepoint from the dropdown. There may be timepoints specific for PK and PD. Select only the timepoints that apply to the classification selected.
Collection Date: Date sample was collected.
Collection Time: Time sample was collected.

Select Choose File and Upload the deidentified PK Time Form. Choose the classification of testing. Select the Study Treatment Name. Enter the Start Date, Dose Start Time, Dose End Time (if available). **Select** the planned time point of the sample collection. **Enter** the Collection Date and Collection Time (if available). Values in Study Treatment Name and planned time point fields may vary depending on protocol. Click **Save**.



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.

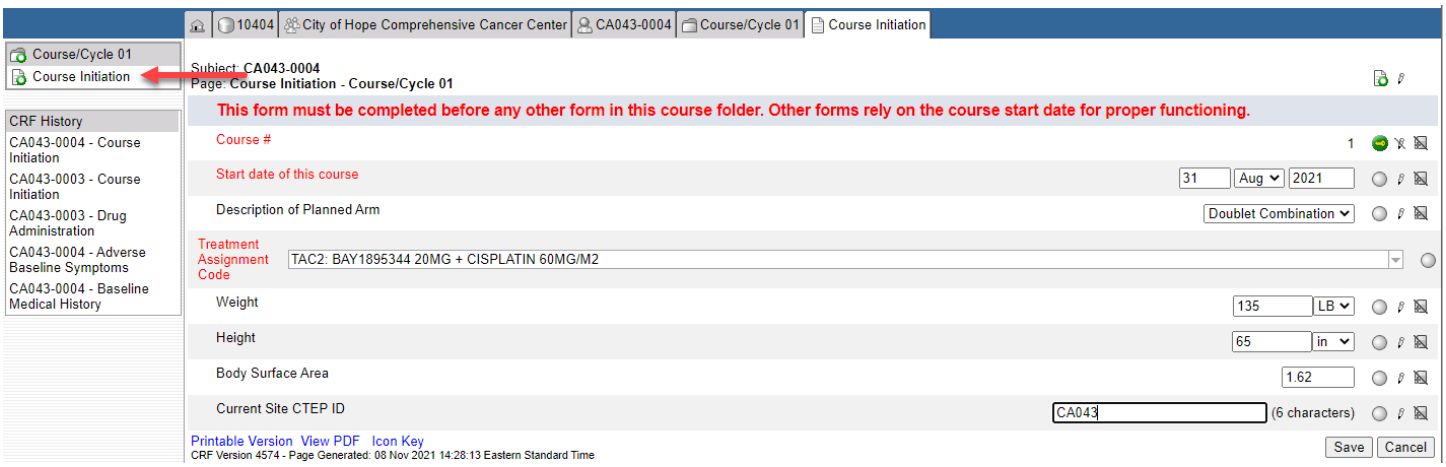


Course

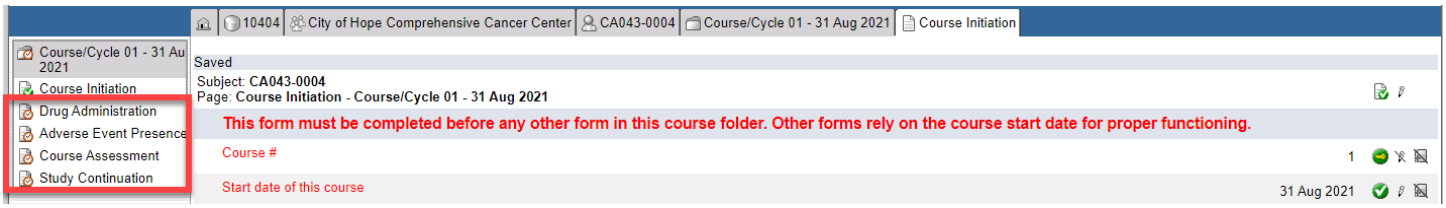
Course Initiation

Prerequisites: None

Description: This form records the course number, treatment arm, and assigned treatment of the participant. In some studies, this form is present with all associated forms for the Course/Cycle. If all forms are present, this form still **needs to be completed first**. Please refer to the red instructions at the top of the form.



After successfully saving this form, the Course folder will populate with additional forms.



Fields

Course #: The sequential number of this course of treatment (auto-populated). For cross-over protocols, at the point of cross-over the course number sequence will be modified to as specified by the study team.

Start date of this course: State the date on which this course was started. This is the **actual** date on which a protocol stipulated drug was first administered. For example, if a patient was scheduled to start the course on Aug 1 but had to reschedule and the drug was administered Aug 3, Aug 3 is the Start date of the course

Description of Planned Arm: Select the arm of the protocol-specific treatment regimen the participant is to receive from the drop-down menu.

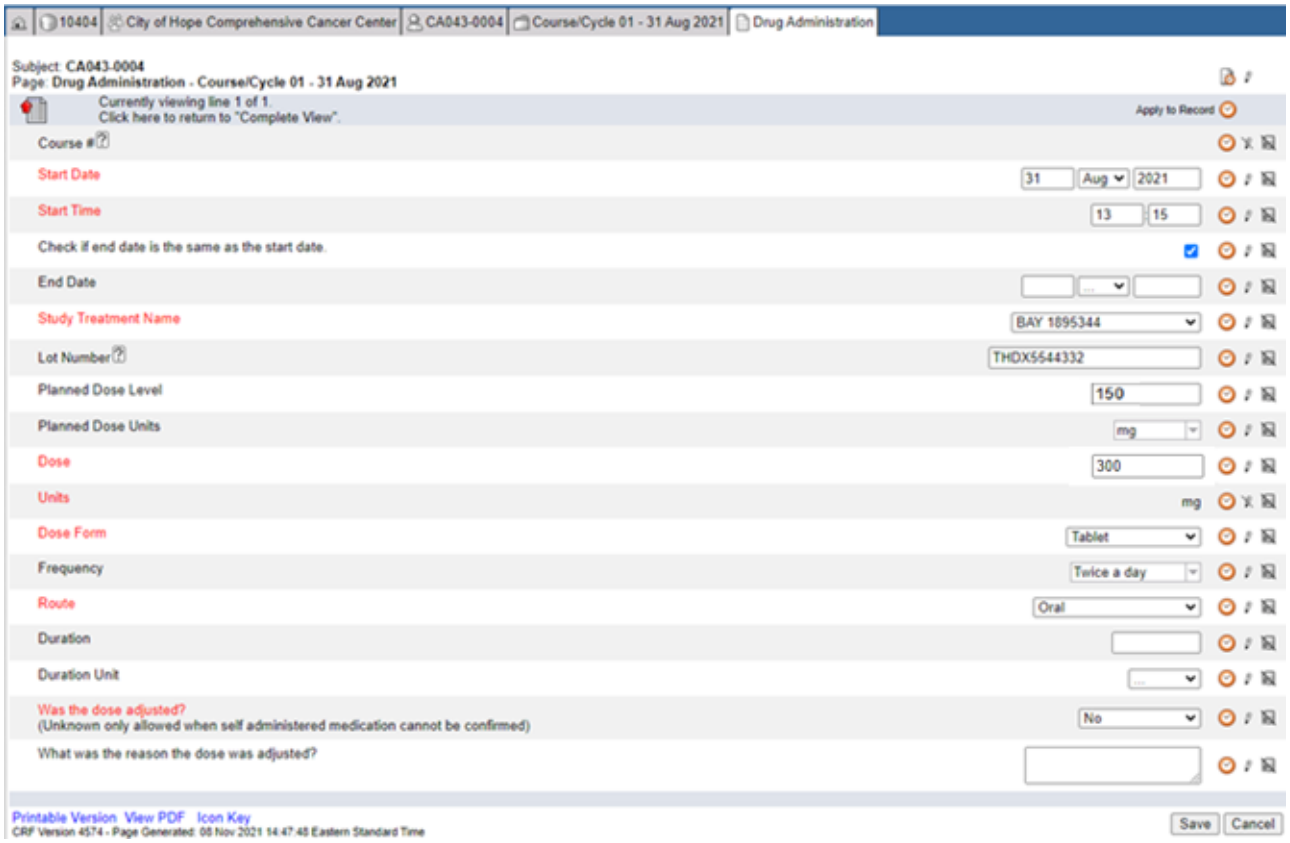
Treatment Assignment Code: Select the appropriate Treatment Assignment code for the nominal regimen and dose level of this course. Normally this will be the same TAC as specific in the Enrollment form. The TAC indicates the participant's treatment cohort, not the intended treatment from course to

course. Please note, the TAC changes if the participant is shifted to a reduced dose level due to a dose limiting toxicity (DLT) on a prior course. Other reasons for choosing a new TAC include transferring the participant to a different arm of treatment or a transfer to a higher dose level (if allowed by protocol).
Weight: Weight of participant in kilograms or pounds (kg or LB); at the start of the course.
Height: Height of participant in centimeters or inches (cm or in); at the start of the course.
Body Surface Area: Record body surface area of participant in m2.
Current Site CTEP ID: Record the unique CTEP institution code where the participant received this course of treatment.

Drug Administration

Prerequisites: Course Initiation

Description: This form is used to record the protocol defined treatment administered to the participant each cycle. *Please refer to each subsection for specific instructions based on the study agent's route of administration.*



In the example above, the protocol defines the dose as 150 mg in an oral tablet administered BID (twice daily). The Planned Dose Level is 150 mg . If the full dose is administered, the Dose level is 300 mg when calculating for the Frequency (and/or Duration). **E.g. 150 mg per dose given twice daily = 300 mg**

If the PI has lowered the total dose, the Dose, Dose Unit, and Frequency (and/or Duration) will be adjusted to the PI's instructions. The Planned Dose will remain the protocol defined amount. Be sure to answer Was the dose adjusted as Yes and enter a reason in the next field.

10404 | City of Hope Comprehensive Cancer Center | CA043-0004 | Course/Cycle 01 - 31 Aug 2021 | Drug Administration

Saved

Subject: **CA043-0004**
Page: **Drug Administration - Course/Cycle 01 - 31 Aug 2021**

#	Course #	Start Date	Start Time	Check	End Date	Treatment	Lot Number	Planned Dose Level	Planned Dose Units	Dose	Units	Form	Frequency	Route	Duration	Duration Unit	Adjusted	Reason
1	1	31 Aug 2021	13:15	☑	31 Aug 2021	BAY 1895344	THDX5544332	300	mg	300	mg	Tablet	Twice a day	Oral	–	–	No	–

Add a new Log line | Inactivate

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Save | Cancel

Use **Add a new Log line** for additional entries. See subsections below for further instructions based on study agent delivery.

Fields

Course #: Number of the current course (cycle) of treatment (auto-populated).
Start Date: Date of drug administration.
Start Time: Start time of administration. For multiple bolus or multiple oral doses given the same day, the time of each dose must be recorded. Use Add a new Log line to create multiple entries.
Check if end date is the same ... : If the End Date of administration is the same as the Start Date, check this box.
End Date: Date of termination of drug administration.
Study Treatment Name: Select from the drop-down menu.
Lot Number: Lot number for the drug supply administered to the patient. Not required for most CTMS monitored studies.
Planned Dose Level: The daily dose level amount as specified by the protocol.
Planned Dose Units: The dose units as specified in the protocol. Select from the drop-down menu.
Dose: State the actual amount of study drug given to the participant in the time period encompassed by the duration/frequency.
Units: Select from the drop-down menu. When the dose is expressed in scientific exponential units using powers of 10 the unit will present as 10^6.
Dose Form: Select from the drop-down menu. This is the physical formulation of the study drug, such as a tablet, capsule, or intravenous solution.
Frequency: Select from the drop-down menu.
Route: The method of dose administration. Select from the drop-down menu.
Duration: Enter the numerical value of the duration.
Duration Unit: Enter the units of duration as expressed in the protocol. Select from the drop-down menu.
Was the dose adjusted?: If the administration of the study drug was different than what is defined in the protocol, select **Yes**. This will remain Yes for the first adjustment and any subsequent adjusted courses. If the patient is administered the protocol defined dose, select **No**.
What was the reason ... : If Yes, please provide further explanation for dose adjustment.

Oral Drugs

Each day's dose should be listed on a separate line when:

- PK samples are being collected during the course
- The protocol requires an oral dose to be given within a certain timeframe of another study drug (e.g., take oral drug within 5 minutes of starting an IV study drug)

- Dosing is not continuous (e.g., taken on days 2 and 5 of a course)

All doses may be entered on a single log line when dosing is continuous (e.g., BID dosing for 28 days) and the following criteria are met:

- No interruptions in dosing (no random doses missed) *see Note*
- No dose changes mid-course *see Note*
- No PKs collected
- No timing requirements in relationship to another study drug

Note: If a dose was **missed, held, or changed mid-course**, record all doses up to the timepoint when study drug was missed/held/changed on one log line then start a new log line when study drug is resumed

Intravenous (IV) Study Drug

- Record each dose on a separate log line to capture the duration of each infusion
- Continuous infusions given over more than one day can be entered on one log line

Subcutaneous (SQ), Intradermal (ID), Intramuscular (IM) Study Drug

- Record each dose on a separate log line; duration field can be left blank

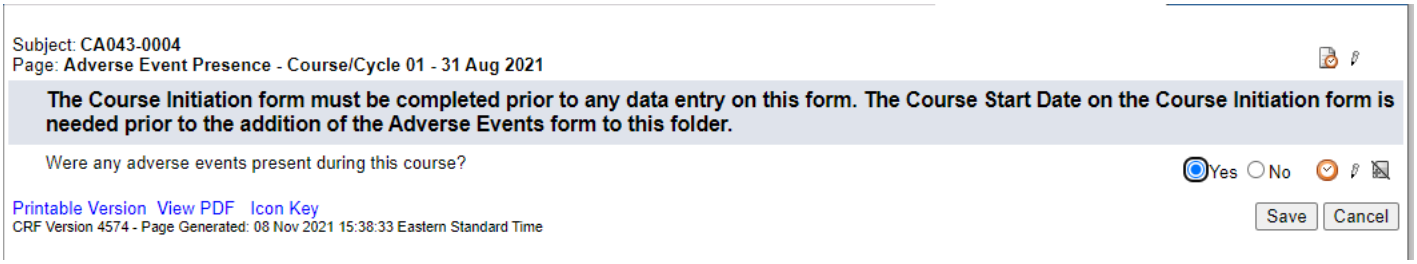
Radio labelled agents (e.g. Radium-223)

- Record each dose on a separate log line (ensure correct unit of measure is entered)
- Source documentation should be available to confirm
  - Start time
  - Duration of infusion
  - Dose infused
  - Radioactivity at timepoints required to be measured per protocol (e.g., when dose shipped from supplier, arrival at site, prior to administration, after treatment)

Adverse Event Presence

Prerequisites: Course Initiation

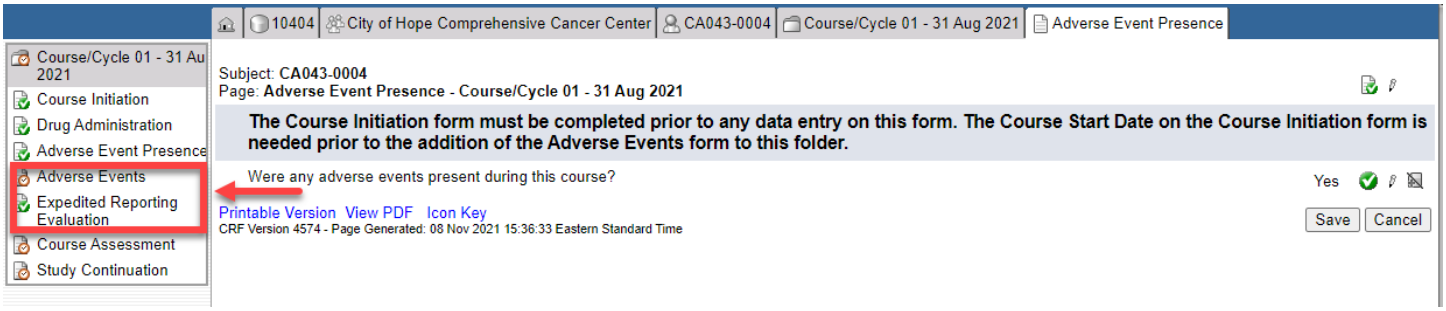
Description: This form documents the presence of Adverse Events during the course of treatment. All adverse events, regardless of severity or relationship to treatment, must be reported. Grade 2 or higher lab abnormalities should be reported both in the Lab Results and AE CRFs. Prior to completing this form, please ensure Course Initiation form is completed.



Fields

Were any adverse events present during this course?: Select **Yes** if any adverse symptoms are present at during the course of treatment, otherwise select **No**.

Selecting **Yes** will trigger the Adverse Events and Expedited Reporting Evaluation form. See below:

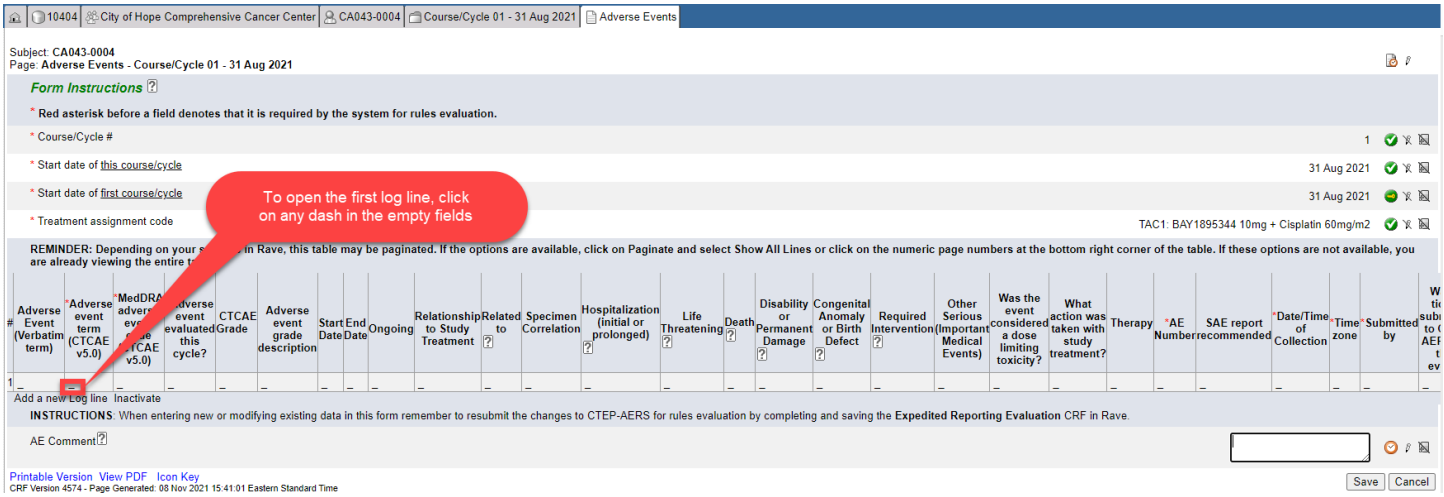


Note: If presence is changed from Yes to No, the corresponding AE form is inactive. Change to Yes to reactivate. On some older studies, the AE form will need to be manually reactivate by a data manager at Theradex. See Contact Us

Adverse Events

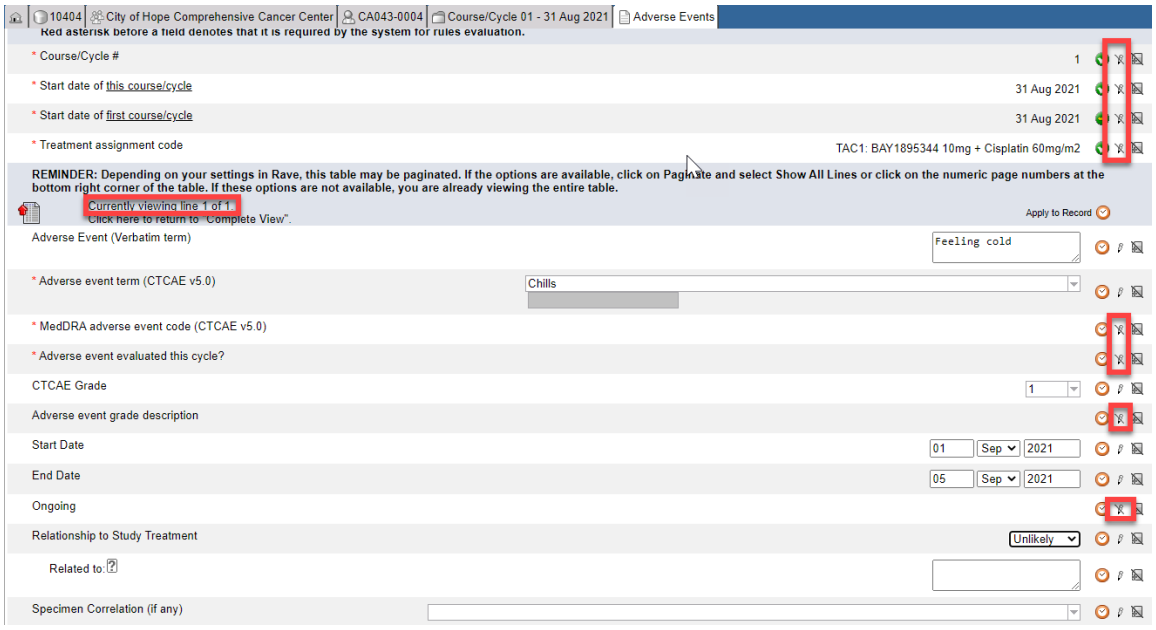
Prerequisites: Adverse Event Presence

Description: This form records the details of the Adverse Events experienced by the participant during the course in which it occurred. For example, if the Adverse Event was documented prior to the C2D1 dose then it should be reported in Course 1. Especially if it is attributable to protocol therapy based on laboratory results obtained on C2D1 (prior to administration of therapy) since it cannot be attributed to the Course 2 treatment. If the Adverse Event has no End Date, it is marked as Ongoing and will be brought into the next Course's AE form.



The header fields auto-populate with values from the Course 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 header information and several fields in the form are not open to editing. These fields will have a crossed out Edit pencil. These fields are either derived from previously entered data or will auto-populate with data based on your entries after saving the form.



10404 | City of Hope Comprehensive Cancer Center | CA043-0004 | Course/Cycle 01 - 31 Aug 2021 | Adverse Events

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?	Dose Not Changed
Therapy	None at all
* AE Number	
SAE report recommended	
* Date/Time of Collection	
* Time zone	
* Submitted by	
Was a ticket submitted to CTEP AERS for this event?	No

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

After saving, this entry will create a log line. To add additional Adverse Events, click Add a new Log line. Note the MedDRA field in the image below, 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.

10404 | City of Hope Comprehensive Cancer Center | CA043-0004 | Course/Cycle 01 - 31 Aug 2021 | Adverse Events

Course/Cycle 01 - 31 Au 2021
- Course Initiation
- Drug Administration
- Adverse Event Presence
- Adverse Events
- Expedited Reporting Evaluation
- Course Assessment
- Study Continuation

CRF History
- CA043-0004 - Adverse Events
- CA043-0004 - Expedited Reporting Evaluation
- CA043-0004 - Course Initiation

Subject: **CA043-0004**
Page: **Adverse Events - Course/Cycle 01 - 31 Aug 2021**

Form Instructions

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

* Course/Cycle #	1
* Start date of this course/cycle	31 Aug 2021
* Start date of first course/cycle	31 Aug 2021
* Treatment assignment code	TAC1: BAY1895344 10mg + Cisplatin 60mg/m2

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 (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?	W action taken st treat
1	Feeling cold	Chills	10008531: General disorders and administration site conditions	Yes	1	(1) Mild sensation of cold; shivering; chattering of teeth	01 Sep 2021	05 Sep 2021	No	Unlikely	_	_	No	No	No	No	No	No	No	No	Dose Char

Add a new Log line | Inactivate

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 4574 - Page Generated: 09 Nov 2021 15:03:00 Eastern Standard Time

Save | Cancel

Tip: You can sort the lines by clicking on the header of an individual column. For example, Clicking the Verbatim Term header will sort the lines alphabetically and gather like terms together.

IN TERM FIELDS Verbatim & Adverse Event DO NOT INCLUDE SPECIAL CHARACTERS SUCH AS SYMBOLS DASHES, COMMAS, PLUS SIGN, APOSTROPHE,

Fields

Only fields editable by the user are listed in this section.

Start Date of this Course/Cycle: This date is derived from the Course Initiation form. If blank, complete the Course Initiation form. Go back to the AE Presence form, click the pencil, change value and Save. Edit the field one more time and return to the previous answer and Save again.

Adverse Event (Verbatim term): Succinctly describe the symptom/adverse event. A clinical description of the actual adverse event should be entered. Record the diagnosis, e.g., flu, and not each specific symptom (e.g., chills fever, muscle aches). If pain is reported, list the anatomical location. **DO NOT RETYPE THE CTCAE TERM. DO NOT INCLUDE SPECIAL CHARACTERS SUCH AS SYMBOLS (DASHES, COMMAS, PLUS SIGN, APOSTROPHE, ETC.).**

Adverse event term (CTCAE v5.0): Enter the CTCAE coding which was used to grade this symptom. The menu will filter as you type. **Search carefully**. The CTEP/AERS integration relies on the use of the specific term for adverse events that are present in the menu. Choose the 'Other' option **ONLY IF** no term in the list is truly applicable. A specify box will be active when 'Other' is chosen. If active, a descriptive text of the AE must be entered. **DO NOT INCLUDE SPECIAL CHARACTERS SUCH AS SYMBOLS (DASHES, COMMAS, PLUS SIGN, APOSTROPHE, ETC.).**

THE INTEGRATION WITH CTEP-AERS WILL FAIL IF 'Other' IS CHOSEN FOR AN AE THAT HAS AN AVAILABLE CTCAE TERM

CTCAE Grade: Select the severity of the symptom from the drop down list. Only the grades allowed by the CTCAE category will be available. **If the CTCAE Grade changes during the course, enter the End Date and use Add a new Log Line to create a new entry for the new grade.**

Start Date: Record the date that the symptom was first observed/experienced. Full date required, incomplete dates will cause the integration with AERS to fail.

End Date: Record the date that the symptom was last observed/experienced. Full date required, incomplete dates will cause the integration with AERS to fail.

If no date is given, after saving the form, the Adverse Event is automatically marked **Yes** in the **Ongoing** field. The Adverse Event can be added to the next Course's Adverse Events form by confirming Yes to ongoing AEs.

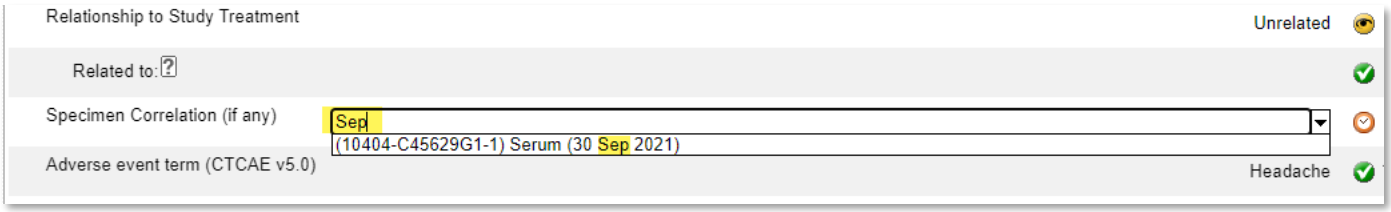
Relationship to Study Treatment: Indicate if the symptom is related to the investigative agent by selecting from the drop-down menu. For protocols that have both commercial and investigational agents, attributions should be captured in accordance with that of the investigational agent. If a study has:

- Investigational agents only – enter the overall highest attribution
- Investigational and commercial agents – enter the highest attribution for the investigational agent(s)
- Commercial agents only – enter the highest attribution for the commercial agent

Related to: Manually enter each drug name or abbreviation and their attribution.

Format: Drug Name 1 – V, Drug Name 2 - W, Disease - X, Specimen Collection (biopsy, blood draw, etc.) - Y, Other (if applicable) - Z. Where V,W,X,Y,Z are numbers that represent the attribution of the drug to the adverse event.
Attribution: **1**—Unrelated; **2**—Unlikely; **3**—Possible; **4**—Probable; **5**—Definite
Example: Triapine - 3, Lutathera - 1, Neuroendocrine Carcinoma - 1, Biopsy - 2
Specimen Correlation (if any): If the Adverse Event relates to specimen collected on study, select the Specimen ID from the drop down. In general AEs that correlate to blood draws or biopsies are physical (swelling, bruising, bleeding, infection, etc.). If the AE is related to a laboratory finding and there is no trauma from specimen collection, this field should not be used.

You can type keywords to limit the selections in the drop down menu. In the example below, "Sep" was entered to filter the list and only display specimens collected in September.



Seriousness: Indicate if the adverse event was a "serious" event by selecting Yes or No from the following categories.

- Hospitalization
- Life Threatening
- Disability or Permanent Damage
- Congenital Anomaly or Birth Defect
- Required Intervention
- Other Serious (Important Medical Events)

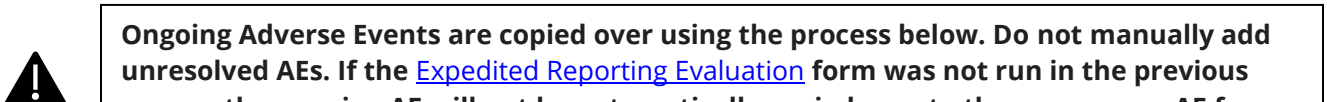
Was the event considered a dose limiting toxicity?: If the Adverse event is considered a "dose limiting toxicity" enter "Y", otherwise enter "N". Refer to the protocol for the definition of what constitutes a dose limiting toxicity for the study.
What action was taken with study treatment?: Indicate any changes made to the study regimen in response to the adverse event. "Action" refers to the decision to reduce or continue the investigational drug.
Therapy: Indicate if additional therapy is required to treat the adverse event. Any medication used to treat the event must be entered on the Concomitant Medication form.

- **Symptomatic**: any Concomitant Medication used to treat an Adverse Event. For example, antibiotics, anti-inflammatory, antiemetics, antidiarrheals, etc.
- **Supportive:** Concomitant Medications and Measures used to support the patient during the event. For example, oxygen, IV fluids, etc.
- **Vigorously Supportive Medications/Measures**: life saving measures. For example, CPR, ventilator, vasopressors, surgery, etc.

Was a ticket submitted to CTEP AERS for this event?: Indicate if the adverse event was submitted through CTEP AERS.
Comment: Enter additional comments relating to this specific adverse event, 200 character maximum.

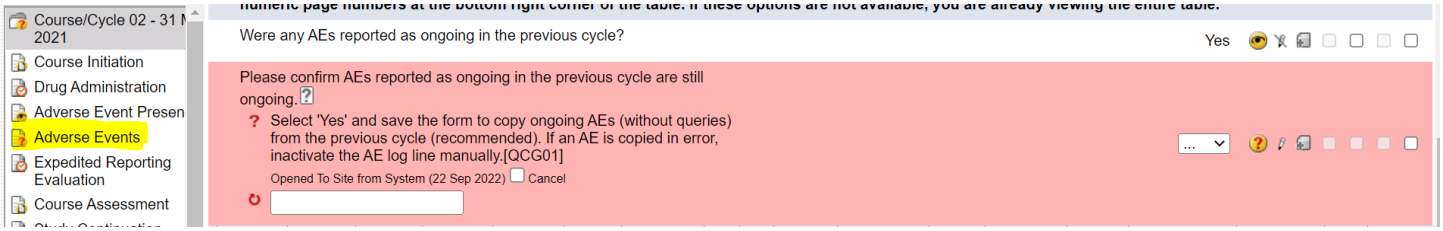
Any time Adverse Events are added or edited, the Expedited Reporting Evaluation form needs to be completed. The requirement to submit a report and the tracking of ongoing AEs requires this step to be completed.

Confirming Ongoing Adverse Events



Ongoing Adverse Events are copied over using the process below. Do not manually add unresolved AEs. If the Expedited Reporting Evaluation form was not run in the previous course, the ongoing AE will not be automatically copied over to the new course AE form.

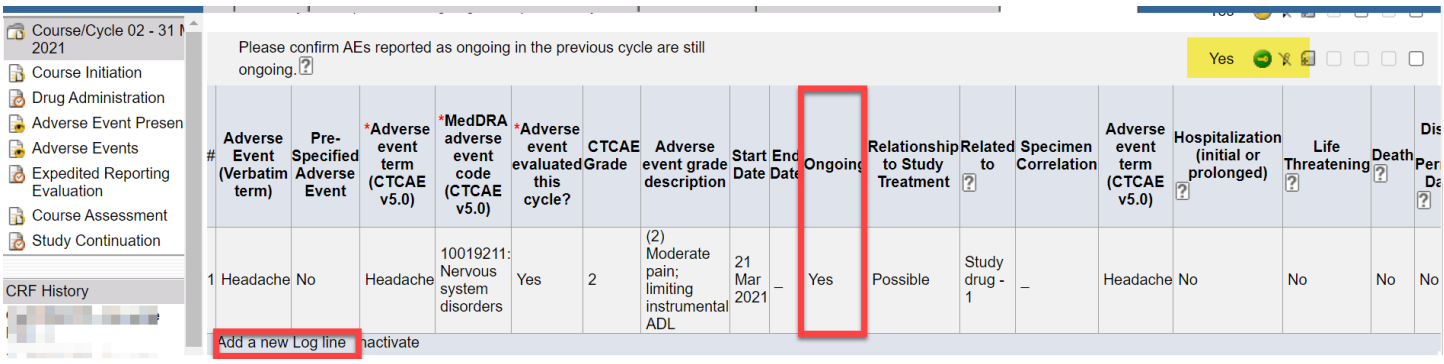
In the **next Course** folder, complete the **Course Initiation** form. Enter **Yes** in the **Adverse Event Presence** form. The **Adverse Event** form for this course will load with an automatic query (see below).



After selecting **Yes** and clicking **Save**, any adverse event from the previous course with no end date present, will be carried forward into this form. The query will resolve automatically, the **Ongoing** field will be marked to **Yes**, and the **End Date** will remain empty. If the **CTCAE Grade** changes or the adverse event stops during this course, use the edit pencil and enter the **End Date**.

If **No** is selected, the query will close after clicking Save. If No is selected and ongoing adverse events are present in prior course, the query will remain open.

Use **Add a new Log line** to add any new adverse events that occurred during this course. For **CTCAE Grade** changes, create a new entry with a **Start Date** that corresponds to the grade change.

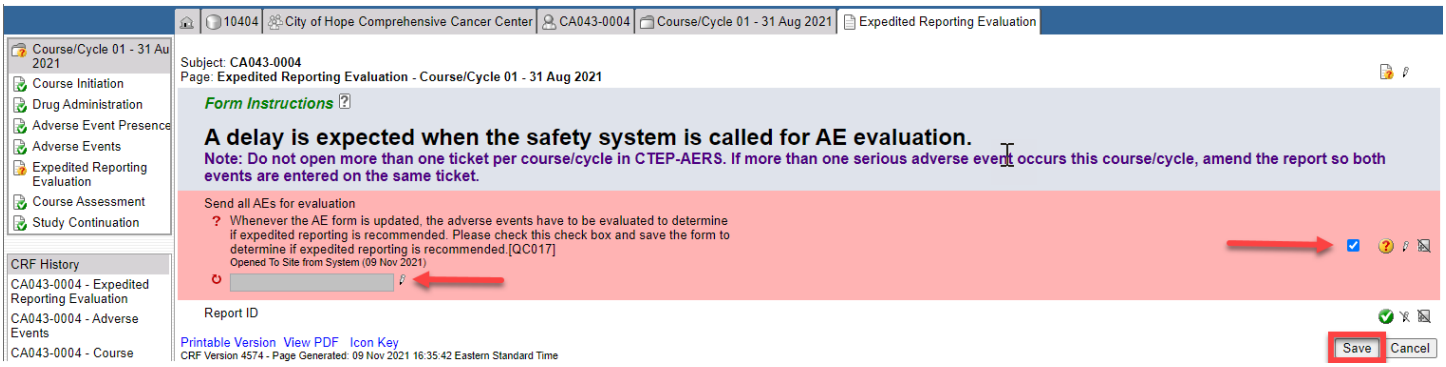


Expedited Reporting Evaluation

Prerequisites: Course Initiation and Adverse Events

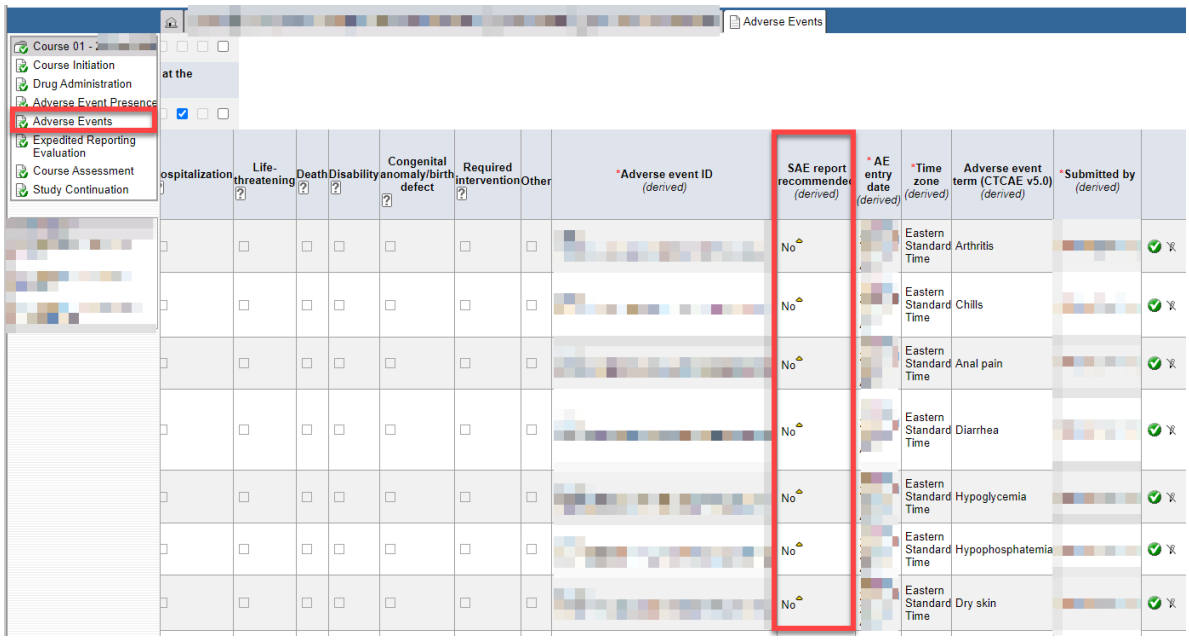
Description: This form activates the transfer of AE information to CTEP-AERS. The CTEP-AERS system will calculate if the event(s) from the course will require further reporting. The reporting recommendation will be loaded into the Adverse Event form. **The physician and the protocol determine if the AE meets the definition of an SAE; the rules evaluation is a recommendation**. A link will be present on this form to access the CTEP-AERS system.

> **<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.**

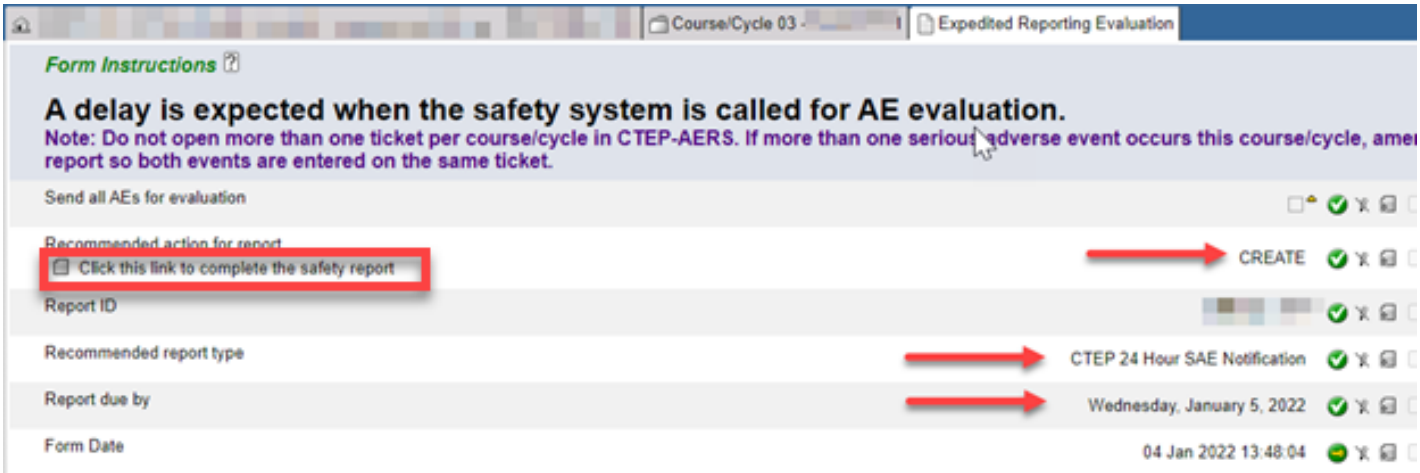


After completing the adverse events form, a query is opened on the Expedited Reporting Evaluation form. Click the checkbox and then click the Save button. Click the Edit Pencil to the right of the greyed-out response box and response to the query. A simple phrase like "Submitted" will suffice.

The SAE Report Recommendation field of the Adverse event form will be updated and the report will be available in the Expedited Reporting Evaluation form (see below).



If the CTEP-AERS calculates a report is needed (i.e. CREATE or EDIT) it will advise on the report type and due date.



Click the Link (see red box) in the completed form to complete the safety report.

If a follow up report is needed (ie. 24-Hour; 5 Calendar Days) and you do not follow up by the due date, you must submit a new ticket. You will not be able to access the report after the due by date. Please do not ignore automated email messages from AERS.

Recommended Actions

Create:

- **IS AN SAE**, click the link on the ERE eCRF to complete the safety report and submit to CTEP-AERS.

- **IS NOT AN SAE**, manually change CREATE to NONE and add a comment to the comments field on the AE eCRF regarding why the event was not submitted to CTEP-AERS.

None:

- **IS NOT AN SAE**, do nothing (AEs grade 3 and higher should have source documentation regarding if the physician considers them to be serious).

- **IS AN SAE**, do not change the recommendation, leave it as NONE; click the link on the ERE eCRF to complete the safety report and submit to CTEP-AERS.

Edit:

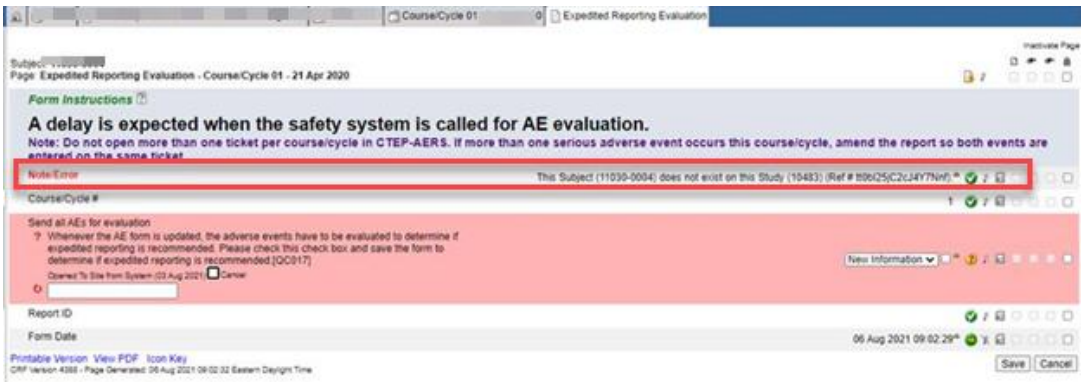
- A revision is required to the unsubmitted report and/or the AE eCRF.

Amend:

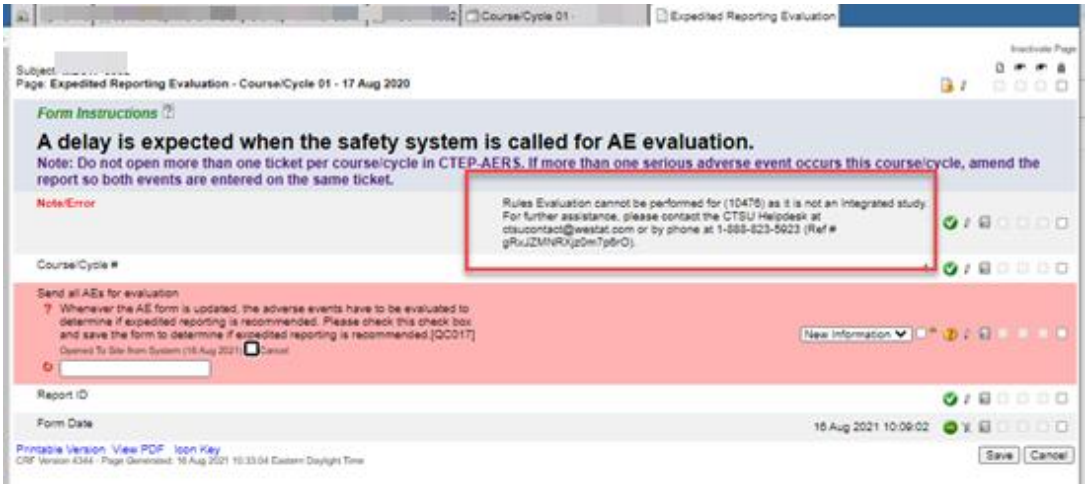
- A revision is required to the submitted report and/or the AE eCRF

AERS Integrations Errors

Sometimes the integration will produce an error. In the example below a new field, **Note/Error**, is present at the top of the form.



In the next example, we see an error stating the study is not integrated with AERS. If the study does utilize AERS, this error is indicative of an issue in communication with the CTEP-AERS system.



Please reach out to CTMS Data Management with any errors that occur in this form so they can investigate and advise. See [Contact Us]

For more information, please refer to CTSU Expedited Safety Reporting Rules Evaluation User Guide

For issues with expedited reporting in CTEP-AERS please contact the following CTEP Help Desk resources for a quick resolution.

For technical questions, contact the NCI CTEP Help Desk at: email: ncictephelp@ctep.nci.nih.gov phone: 1-888-283-7457 fax: (301) 948-2242

For medical questions, contact the AEMD Help Desk at: email: aemd@tech-res.com phone: (301) 897-7497 fax: (301) 230-0159

It is recommended to also include the CTSU help desk at: CTSUContact@Westat.com

Course Assessment

Prerequisites: Course Initiation

Description: This form records the assessment of the participant's disease during this course of treatment.

10404 | City of Hope Comprehensive Cancer Center | CA043-0004 | Course/Cycle 01 - 31 Aug 2021 | Course Assessment

Subject: **CA043-0004**
Page: **Course Assessment - Course/Cycle 01 - 31 Aug 2021**

Start Date of Course	31 Aug 2021
Response Assessment	Stable Disease
Date of Response	01 Sep 2021
Date of Progression	...
Course Disposition	Completed / Discontinued
Comment	

Printable Version View PDF Icon Key
CRF Version 4574 - Page Generated: 08 Nov 2021 16:05:41 Eastern Standard Time

Save Cancel

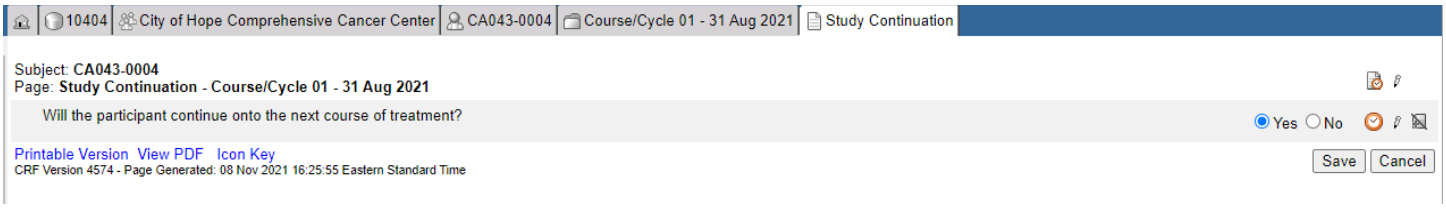
Fields

Start Date of Course: The date on which the protocol drug was first administered. This date is copied from the Course Initiation form.
Response Assessment: Select the participant's best disease state as assessed during the course. If the response is Not Evaluable, state reason in the Comment field. If the response is Not Assessed, state reason in the Comment field unless the protocol does not require an assessment during a specific course.
Date of Response: Record date the participant's disease was assessed.
Date of Progression: Record the date of the evaluation used to determine the participant's disease status of progressive disease. A date of progression may be entered if the disease progression occurred after an assessed better response.
Course Disposition: A "completed: course is one that has been conducted in accordance with the protocol in respect to length including the observation period. A course is regarded as 'discontinued' if it was shorter than specified in the protocol.
Comment: Enter any applicable comments.

Study Continuation

Prerequisites: Course Initiation

Description: The last form of the Course folder records if the participant will continue on to the next course of treatment.

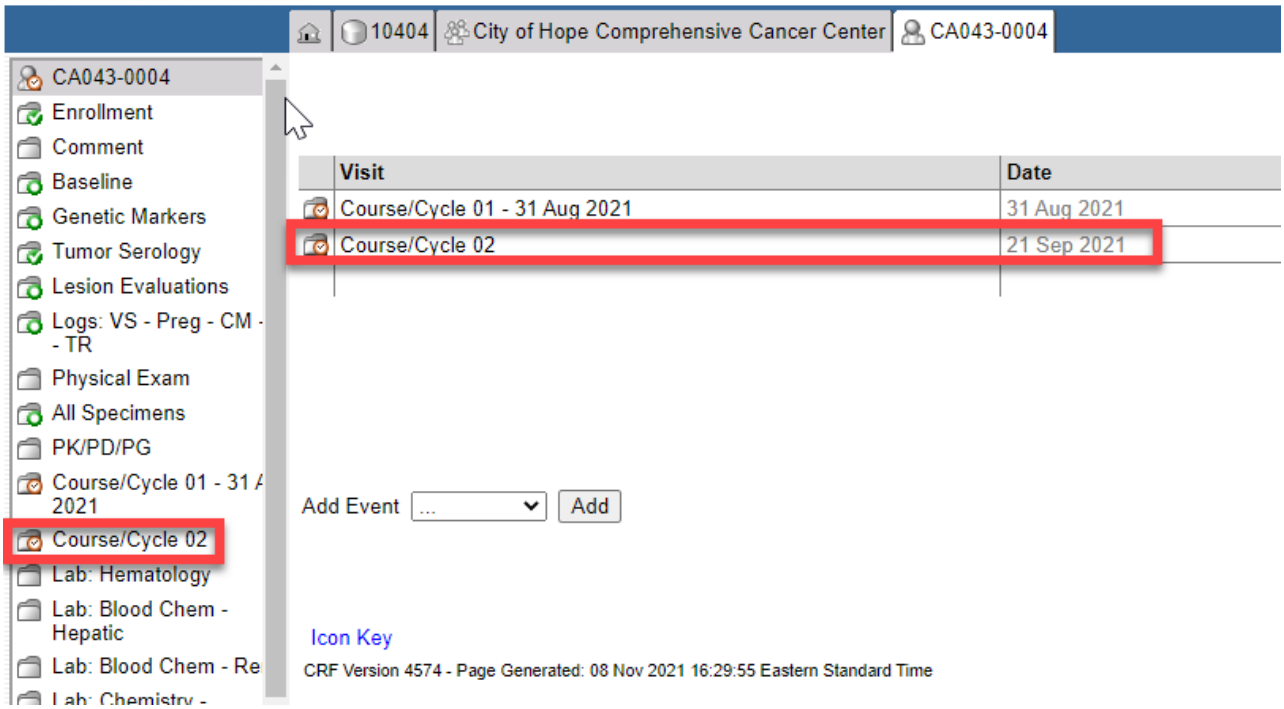


Fields

Will the participant continue … ? : If the participant will continue on the next course of treatment, select Yes. If not, select No. Ensure the decision to continue the patient on study to the next course of treatment is final before answering Yes to this question.

Selecting **Yes** will trigger a new Course folder with the next sequential number. (See below)

If Yes is chosen accidentally, changing the value in the Study Continuation form will not remove the unwanted Course folder. Contact data management at ctms-dm@theradex.com to inactivate the folder.



Study Radiation Therapy

Prerequisites: Course Initiation

Description: This form is only present in studies that have a radiation component to the experimental therapy. Please note any instructions in bold text at the top of the form.

10492 | University Health Network-Princess Margare... | Course/Cycle 01 - 01 Aug 2024 | Study Radiation Therapy

Page: **Study Radiation Therapy - Course/Cycle 01 - 01 Aug 2024**

CDASHIG 2.0

For course 1, enter weeks 1-4 of radiation. For course 2, enter weeks 5-7 of radiation.
If you need to indicate that no specific site was irradiated, please leave the "Anatomical Location" field empty.

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

Apply to Record

Start Date	02 Aug 2024
Start Time	
Procedure Name	IMRT
Type	Linear accelerator based
Anatomical Location	Hypopharynx
Frequency	Daily
Size of irradiated lesion	741 cc3
Scheduled Dose	1000
Scheduled Unit	cGy
Dose	1000
Unit	cGy
Duration	5
Duration Unit	Days

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 expand the form. To add entries, click **Add a New Log** line.

10492 | University Health Network-Princess Margare... | 2 | Course/Cycle 01 - 01 Aug 2024 | Study Radiation Therapy

Patient:
Page: **Study Radiation Therapy - Course/Cycle 01 - 01 Aug 2024**

CDASHIG 2.0

For course 1, enter weeks 1-4 of radiation. For course 2, enter weeks 5-7 of radiation.
If you need to indicate that no specific site was irradiated, please leave the "Anatomical Location" field empty.

#	Start Date	Start Time	Procedure Name	Type	Location	Frequency	Size of irradiated lesion	Scheduled Dose	Scheduled Unit	Dose	Unit	Duration	Duration Unit
1	02 Aug 2024		IMRT	Linear accelerator based	Hypopharynx	Daily	741 cc3	1000	cGy	1000	cGy	5	Days

Add a new Log line | Inactivate

Start Date/Time: Give the date of the first dose of radiation therapy. Partial dates allowed
Procedure Name: The selections in this menu are specific to the protocol. For example: IMRT (Intensity modulated radiotherapy) or VMAT (Volumetric Modulated Arc Therapy).
Type: Select an option from the menu.
Anatomical Location: Type to filter the options in the drop down menu. If you need to indicate that no specific site was irradiated, please leave the "Anatomical Location" field empty.
Frequency: Schedule on which radiation therapy was given

Size of irradiated lesion: This is a free text field to record the size of the irradiated lesion. This can be measurement (uni- or bi-dimensional) or product of dimensions (area), depending on how it is mapped. Be sure to include units in this response.

Scheduled Dose and Scheduled Dose Units: State the intended total dose and the dose units (e.g. cGy, Gy, or Rad).

Dose and Dose Units: State the actual total dose the patient received during the treatment period and the dose units (e.g. cGy, Gy, or Rad).

Duration and Duration Units: The period of time the radiation therapy was administered. In general, this is recorded in Days. Each week of treatment is recorded as a log line

> Example: 5 days of fractions for 4 weeks would be recorded as 5 Days for the Duration and Duration Units with 4 separate log lines.

Labs

Overview

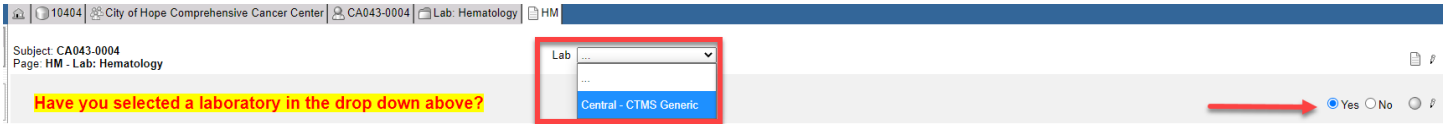
Multiple folders and forms are available in Rave to capture assay results as they are returned to the site from the testing laboratory. The assays performed will differ from study to study but the steps to record the data are the same throughout the Theradex Rave database. The forms are designed to provide multiple copies as needed to accommodate sequential laboratory evaluations.

Laboratory Abnormalities as Adverse Events

Only Grade 2 and higher laboratory abnormalities need to be reported on the Adverse Events CRFs (including adverse baseline symptoms). Grade 1 lab abnormalities must be on the Laboratory CRFs, but it is the PI's decision if they are on the AE CRFs, it is not a study requirement.

Laboratory Ranges

At the top of each form, a drop down is available to set the lab ranges for the form. This step is done each time the form is filled out. The CTMS-Generic option will load the standard lab ranges already built into the form. Choose this option unless there are others available. Institutional or local lab ranges will be available if previously submitted.



After selecting the lab from the drop down, the form will refresh and load the normal range values. The first question of the form is there to confirm this step has been performed.

Institutional Laboratory Ranges

To enter the laboratory ranges for central laboratory at the treating institution, please provide the set of ranges to CTMS-DM@theradex.com. The values provided will be entered by data management into the database and will be available in the menu above. They will be available for all studies and participants at the institution.

Local Laboratory Ranges

To enter local laboratory ranges into Rave for lab work performed outside of the treating institution. This will only apply to the specific protocol in which the participant is enrolled. Please provide a **de-identified** lab report to CTMS-DM@theradex.com. These values will be entered by data management into the database and will be available in the menu above.

10404 | City of Hope Comprehensive Cancer Center | CA043-0004 | Lab: Hematology | HM

Subject: **CA043-0004**
Page: **HM - Lab: Hematology**

Lab Central - CTMS Generic View Ranges

Have you selected a laboratory in the drop down above? Yes No

Collection Date 31 Aug 2021

Collection Time 13 : 25

Click to add new instance of form, unclick to remove unused form.

	Data	Range Status	Unit	Range
Hemoglobin	12.2		g/dL	12 - 16
Hematocrit	36.8		%	36 - 46
Leukocytes (WBC)	4.0		10^3/mm3	4.5 - 11
Neutrophils/Leukocytes			%	40 - 70
Lymphocytes/Leukocytes			%	22 - 44
Basophils/Leukocytes			%	0 - 3
Monocytes/Leukocytes			%	4 - 11
Eosinophils/Leukocytes			%	0 - 8
Neutrophils Band Form/Neutrophils			%	40 - 70
Blasts/Leukocytes			%	0 - 2
Platelets	121		10^3/mm3	150 - 350
Neutrophils (ANC)			10^3/mm3	1 - 7.5
Lymphocytes Atypical/Leukocytes			%	0 - 100
Erythrocytes (RBC)			million cells/mcL	4 - 5.2
Reticulocytes/Erythrocytes			%	0.5 - 2.5

For this example, the Hematology form is being used but the steps performed apply to all lab forms. First, choose the lab from the drop down and allow the form to load the normal range values. **Confirm** the lab was selected by choosing the Yes radio button. Enter the **Collection Date** (required) and, if available, the **Collection Time**. **Note: The collection time should be reported in a 24 hour format; 2:45 PM will be 14:45.** Skip the New Instance question for now, this is explained below. Enter the values from the lab report for the tested assay in the **Data** field. Click **Save**.

10404 | City of Hope Comprehensive Cancer Center | CA043-0004 | Lab: Hematology | HM 31 Aug 2021 13:25

Lab: Hematology
HM 31 Aug 2021 13:25

CRF History

Page: **HM 31 Aug 2021 13:25 - Lab: Hematology**

Lab Central - CTMS Generic View Ranges

Have you selected a laboratory in the drop down above? Yes

Collection Date 31 Aug 2021

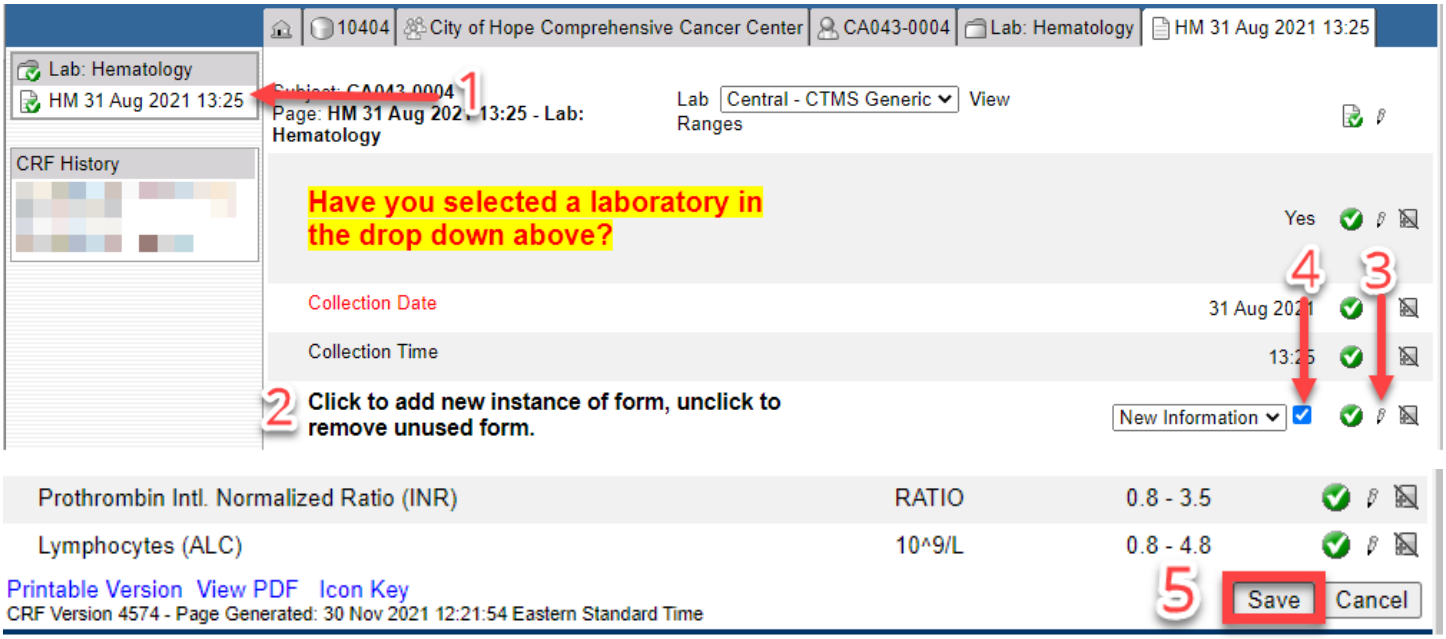
Collection Time 13:25

Click to add new instance of form, unclick to remove unused form.

	Data	Range Status	Unit	Range
Hemoglobin	12.2		g/dL	12 - 16
Hematocrit	36.8		%	36 - 46
Leukocytes (WBC)	4.0		10^3/mm3	4.5 - 11
Neutrophils/Leukocytes			%	40 - 70
Lymphocytes/Leukocytes			%	22 - 44
Basophils/Leukocytes			%	0 - 3
Monocytes/Leukocytes			%	4 - 11
Eosinophils/Leukocytes			%	0 - 8
Neutrophils Band Form/Neutrophils			%	40 - 70
Blasts/Leukocytes			%	0 - 2
Platelets	121		10^3/mm3	150 - 350
Neutrophils (ANC)			10^3/mm3	1 - 7.5

After saving, the form will appear in the folder labeled with the Collection Date and Time. Values reported that fall outside of the normal range will be flagged with an icon in the **Range Status** column.

To add a new instance of the form

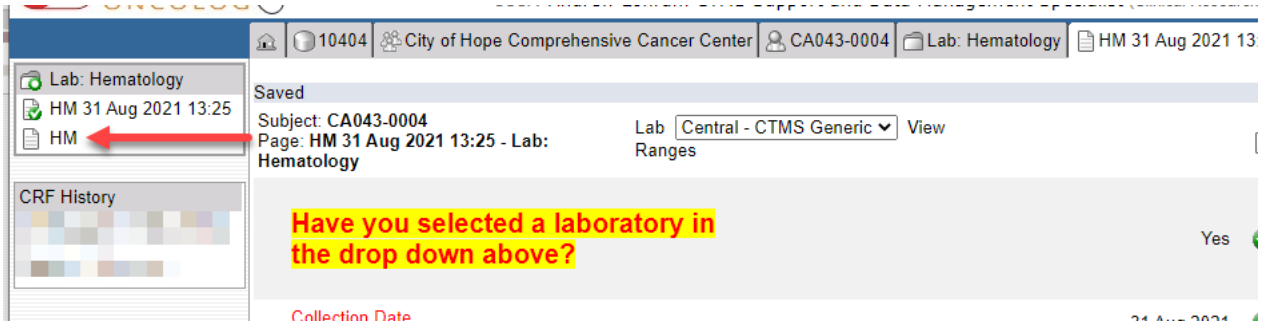


Follow these steps to add an additional blank lab form:

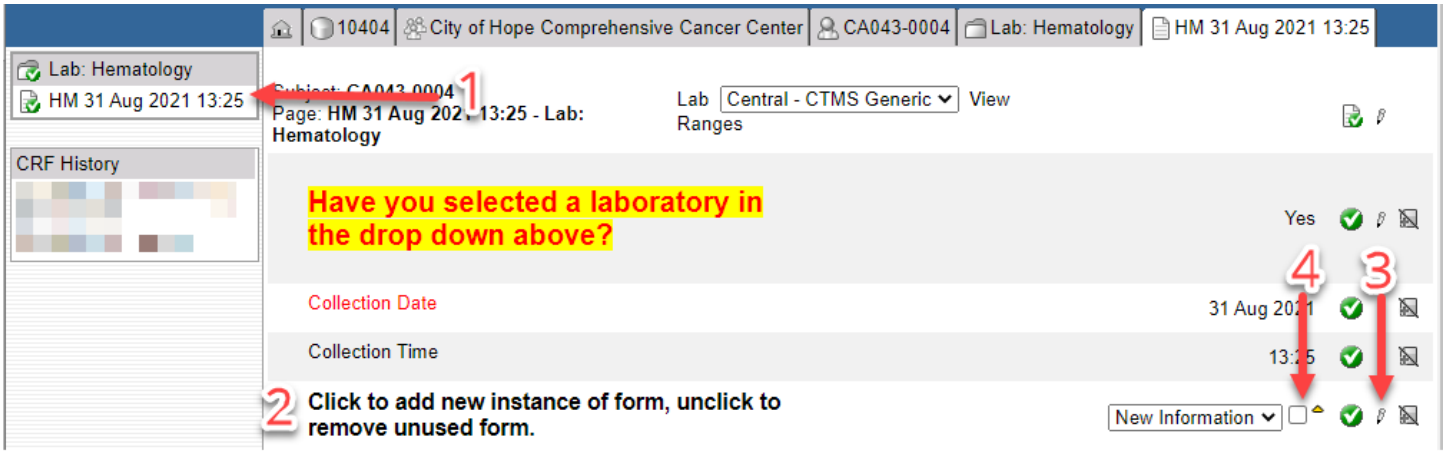
1. Go to the last completed lab form.
2. Go to the 'Click to add ...' field.
3. **Click** on the Edit Pencil.
4. **Click** the check box.
5. **Click** Save.

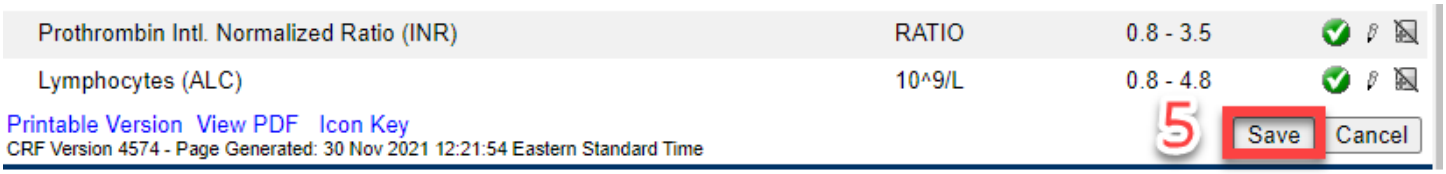
After saving, a blank form will be present in the folder.

Tip: If you expect to enter future lab data, you can check the box as part of data entry so a blank form will automatically be created for the next lab visit.



To remove an extra form

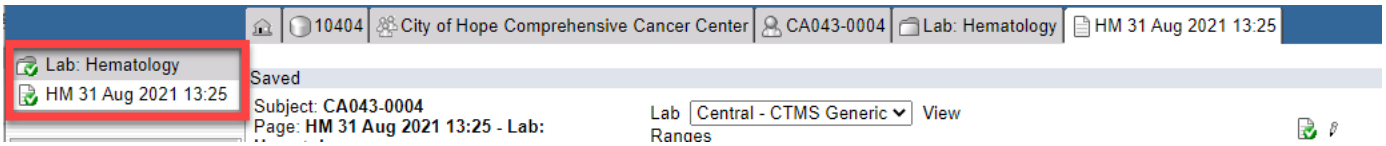




For a form that was added but not needed, the empty form can be removed following the steps below:

1. Go to the last completed lab form.
2. Go to the 'Click to add ...' field.
3. **Click** on the Edit Pencil.
4. **Click** on the checkmark, it will be removed, and the checkbox will be empty.
5. **Click** Save.

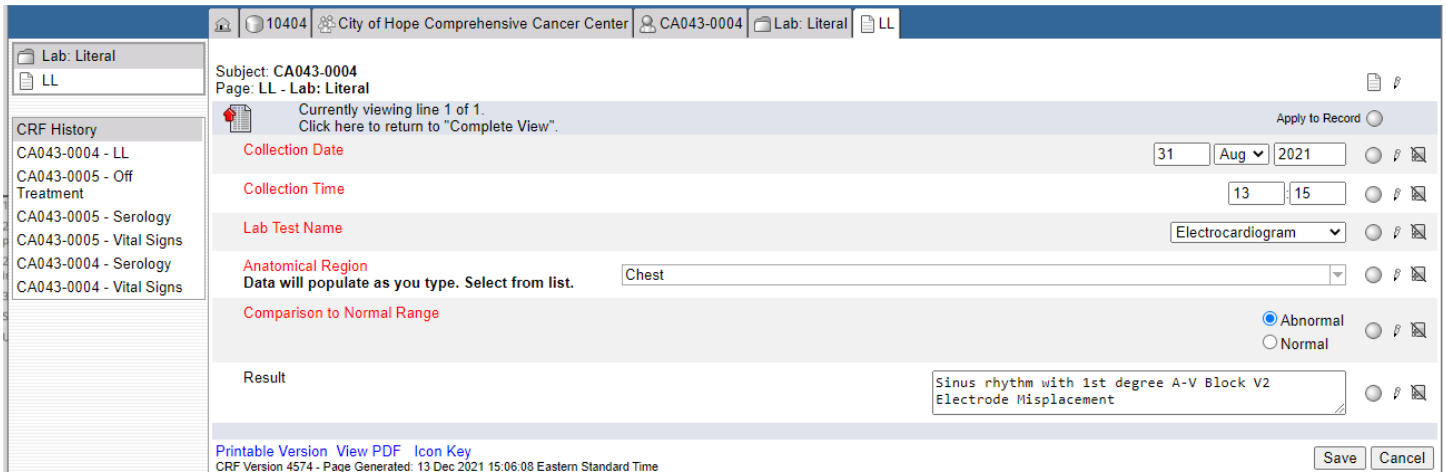
After saving the blank form will be removed. If any data entry has occurred on the extra form, you will not be able to remove it using the steps above. Please contact CTMS-DM@theradex.com for assistance.



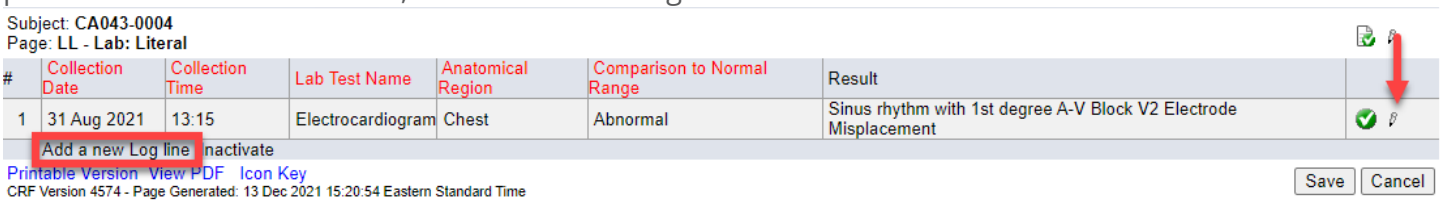
Literal Lab (LL)

Prerequisites: None

Description: This form records the date, time, and results from various assays and procedures as defined in the protocol.



After the form is saved it will appear as the first log line. The entry can be edited by clicking on the Edit pencil. To add additional labs, click Add a new Log line.



Fields

Collection Date: Date the procedure, assessment, evaluation, or scan was performed.
Collection Time: Time the procedure, assessment, evaluation, or scan was performed.
Procedure: Select a test from the drop-down menu.
Anatomical Region: Select a term from the search list. The menu will filter as you type.
Comparison to Normal Range: If results are outside the normal value for the procedure, choose Abnormal. If not, choose Normal.
Result: Enter the findings from the procedure into the free-text field.

Unanticipated (UL)

Prerequisites: None

Description: The unanticipated lab form is for test results that are not on other forms and can't be entered elsewhere on the CRFs. These may occur as standard of care or in investigating an adverse event.

10404 | City of Hope Comprehensive Cancer Center | CA043-0004 | Lab: Unanticipated | UL

Lab: Unanticipated
UL

CRF History
CA043-0004 - UL

Subject: **CA043-0004**
Page: **UL - Lab: Unanticipated**

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

Apply to Record

Collection Date	31 Aug 2021
Collection Time	13 : 15
Lab Test Name **Data will populate as you type. Select from list.**	Creatinine Clearance
Category	Urinalysis
Anatomical Region **Data will populate as you type. Select from list.**	Kidney
Comparison to Normal Range	Abnormal / Normal
Result	1.1
Unit	mL/s
Normal Range Lower Limit	1.65
Normal Range Upper Limit	2.33

Ranges required for Numeric Results

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CRF Version 4574 - Page Generated: 14 Dec 2021 16:15:41 Eastern Standard Time

Save Cancel

When completing the form not all fields will be applicable. If the results are numeric, the Upper and Lower limits of the normal range must be provided.

After the form is saved it will appear as the first log line. The entry can be edited by clicking on the Edit pencil. To add additional labs, click Add a new Log line. Each lab should be entered on its own log line, do not combine results from multiple assays.

Subject: **CA043-0004**
Page: **UL - Lab: Unanticipated**

#	Collection Date	Collection Time	Lab Test Name	Category	Anatomical Region	Comparison to Normal Range	Result	Unit	Normal Range Lower Limit	Normal Range Upper Limit
1	31 Aug 2021	13:15	Creatinine Clearance	Urinalysis	Kidney	Abnormal	1.1	mL/s	1.65	2.33

Add a new Log line | Inactivate

Ranges required for Numeric Results

Printable Version View PDF Icon Key
CRF Version 4574 - Page Generated: 14 Dec 2021 16:20:13 Eastern Standard Time

Save Cancel

Fields

Collection Date: Date sample was collected. For labs that are not based on specimen collection this will be the date the test/scan was performed.
Collection Time: Time sample was collected. For labs that are not based on specimen collection this will be the time the test/scan was performed.
Lab Test Name: Select a term from the search list. The menu will filter as you type.

Category: Select the lab test group from the menu.
Anatomical Region: Select a term from the search list. The menu will filter as you type.
Comparison to Normal Range: If results are outside the normal value for the assay or procedure, choose Abnormal. If not, choose Normal.
Result: Enter the findings from the assay or procedure into the free-text field.
Unit: For quantitative tests, select reported units.
Normal Range Lower Limit: For quantitative tests, refer to lab report.
Normal Range Upper Limit: For quantitative tests, refer to lab report.

Urinalysis Data Entry

Please refer to the chart below to enter data from a quantitative urinalysis report into Rave.

Urinalysis Data Entry	Result= numerical code		Urinalysis Data Entry	Result= numerical code
WBC	0.5=0		RBC	0.5=0
	0-5=0			0-50=0
	6-20=1			51-500=1
	21-50=2			501-1000=2
	51-100=3			1001-10,000=3
	>100=4			>10,000=4
	Occ/rare=0			Occ/rare=0
	Many=2			Many=3
	None=0			NS= None Seen=0
UGluc,Uprot, Uacetone,UBili	Neg/trace=0		TNTC= Too Numerous To Count	Enter highest amount
	Positive /small=1			
	2 or more=2			
	Large=2		Casts	Small = 1
	Mod=2			

Quantitative vs Qualitative data

Please enter 0 for negative and 1 for positive when the field in the form requires a numerical value but the lab report only provides qualitative results (i.e. Positive, Negative).

Laboratory Assay/Analyte and Associated Folder

Assay	Folder
5 Prime Nucleotidase	Other Serum Chemistries
Acid Phosphatase (ACP)	Other Serum Chemistries
Alanine Aminotransferase (ALT or SGPT)	Blood Chem - Hepatic
Albumin	Blood Chem - Hepatic
Albumin	Red Blood Cells
Albumin/Total Protein	Other Urinalysis
Aldolase	Other Serum Chemistries
Alkaline Phosphatase	Blood Chem - Hepatic
Alpha-1 Globulin	Red Blood Cells
Alpha-1 Globulin	Other Urinalysis
Alpha-2 Globulin	Red Blood Cells
Alpha-2 Globulin	Other Urinalysis
Ammonia	Blood Chem - Hepatic
Amylase	Chemistry - Pancreatic/Thyroid & Cardiac
Antiglobulin Test, Direct (Coombs)	Red Blood Cells
Antinuclear Antibodies (ANA)	Red Blood Cells
Aspartate Aminotransferase (AST or SGOT)	Blood Chem - Hepatic
Basophilic Myelocytes	Bone Marrow
Basophils/Leukocytes	Hematology
Beta Globulin	Red Blood Cells
Beta Globulin	Other Urinalysis
Bicarbonate	Blood Chem - Renal
Bicarbonate (HCO3)	Blood Gases
Bilirubin	Blood Chem - Hepatic
Bilirubin (Bile)	Urinalysis
Blasts/Leukocytes	Hematology
Bleeding Time	Red Blood Cells
Calcium	Blood Chem - Renal
Calcium	Other Urinalysis
Calcium Corrected	Blood Chem - Renal
Calcium, Ionized	Blood Chem - Renal
Child-Pugh - Total Score	Blood Chem - Hepatic
Chloride	Blood Chem - Renal
Chloride	Other Urinalysis
Cholesterol	Blood Chem - Hepatic
Clot Retraction	Red Blood Cells
Complement Total	Red Blood Cells
Copper	Other Serum Chemistries
Creatine Kinase (CK)	Other Serum Chemistries

Creatinine	Blood Chem - Renal
Creatinine	Urinalysis
Creatinine Clearance	Urinalysis
Direct Bilirubin	Blood Chem - Hepatic
Eosinophilic Myelocytes	Bone Marrow
Eosinophils/Leukocytes	Hematology
Ery. Mean Corpuscular Hemoglobin (MCH)	Red Blood Cells
Ery. Mean Corpuscular HGB Concentration (MCHC)	Red Blood Cells
Ery. Mean Corpuscular Volume (MCV)	Red Blood Cells
Erythrocyte Sedimentation Rate (ESR)	Hematology
Erythrocytes (RBC)	Hematology
Erythrocytes (RBC)	Urinalysis
Expiratory Reserve Volume	Respiratory Function
FAB Marrow Rating	Bone Marrow
Ferritin	Other Serum Chemistries
Fibrin Degradation Products (FDP)	Red Blood Cells
Fibrinogen	Red Blood Cells
Forced Expiratory Volume in 3 Seconds	Respiratory Function
Forced Vital Capacity	Respiratory Function
Functional Residual Capacity	Respiratory Function
Gamma Globulin	Red Blood Cells
Gamma Globulin	Other Urinalysis
Gamma Glutamyl Transferase (GGT)	Blood Chem - Hepatic
Globulin	Blood Chem - Hepatic
Glucose	Urinalysis
Glucose, Fasting	Chemistry - Pancreatic/Thyroid & Cardiac
Glucose, Non-Fasting	Chemistry - Pancreatic/Thyroid & Cardiac
HDL Cholesterol	Blood Chem - Hepatic
Hematocrit	Hematology
Hemoglobin	Hematology
Hemoglobin (Hgb) A1C	Chemistry - Pancreatic/Thyroid & Cardiac
Inspiratory Reserve Volume	Respiratory Function
Insulin	Chemistry - Pancreatic/Thyroid & Cardiac
Iron	Other Serum Chemistries
Iron Saturation	Other Serum Chemistries
Ketones	Urinalysis
Lactate Dehydrogenase (LDH)	Blood Chem - Hepatic
LDL Cholesterol	Blood Chem - Hepatic

Left Ventricular Ejection Fraction (LVEF)	Chemistry - Pancreatic/Thyroid & Cardiac
Leukocytes (WBC)	Hematology
Leukocytes (WBC)	Urinalysis
Lipase	Chemistry - Pancreatic/Thyroid & Cardiac
LV Ejection Time	Chemistry - Pancreatic/Thyroid & Cardiac
Lymphocytes (ALC)	Hematology
Lymphocytes Atypical/Leukocytes	Hematology
Lymphocytes/Leukocytes	Hematology
Lymphocytes/Total Cells	Bone Marrow
Magnesium	Blood Chem - Renal
Mature Plasma Cells/Total Cells	Bone Marrow
Megakaryocytes/Total Cells	Bone Marrow
Metamyelocytes/Total Cells	Bone Marrow
Methemoglobin	Blood Gases
Monocytes/Leukocytes	Hematology
Monocytes/Total Cells	Bone Marrow
Myeloblasts/Total Cells	Bone Marrow
Neutrophilic Myelocytes	Bone Marrow
Neutrophils (ANC)	Hematology
Neutrophils Band Form/Neutrophils	Hematology
Neutrophils/Leukocytes	Hematology
Normoblasts/Total Cells	Bone Marrow
Nucleated Erythrocytes (NRBC)	Red Blood Cells
Osmolality	Chemistry - Pancreatic/Thyroid & Cardiac
Osmolality	Other Urinalysis
Oxalate	Other Urinalysis
Oxygen Saturation	Blood Gases
Partial Pressure Carbon Dioxide (pCO2)	Blood Gases
Partial Pressure Oxygen (pO2)	Blood Gases
Partial Thromboplastin Time (PTT)	Hematology
Peak Expiratory Flow	Respiratory Function
pH	Urinalysis
pH	Blood Gases
Phosphate	Blood Chem - Renal
Platelets	Hematology
Polymorphic Basophils	Bone Marrow
Polymorphic Eosinophils	Bone Marrow
Polymorphic Neutrophils	Bone Marrow
Potassium	Blood Chem - Renal
Potassium	Other Urinalysis

Pre-Ejection Period	Chemistry - Pancreatic/Thyroid & Cardiac
Promyelocytes/Total Cells	Bone Marrow
Pronormoblasts/Total Cells	Bone Marrow
Protein	Red Blood Cells
Protein	Urinalysis
Protein/Creatinine	Urinalysis
Prothrombin Intl. Normalized Ratio (INR)	Hematology
Prothrombin Time (PT)	Hematology
Residual Volume	Respiratory Function
Reticulocytes/Erythrocytes	Hematology
Reticulocytes/Total Cells	Bone Marrow
Sodium	Blood Chem - Renal
Sodium	Other Urinalysis
Specific Gravity	Urinalysis
Specimen Collection Period for Urine	Urinalysis
Thrombin Time	Red Blood Cells
Thyrotropin (Thyroid Stimulating Hormone or TSH)	Chemistry - Pancreatic/Thyroid & Cardiac
Thyroxine (T4)	Chemistry - Pancreatic/Thyroid & Cardiac
Tidal Volume	Respiratory Function
Total Iron Binding Capacity	Other Serum Chemistries
Total Lung Capacity	Respiratory Function
Total Protein	Blood Chem - Hepatic
Transferrin	Other Serum Chemistries
Triglycerides	Blood Chem - Hepatic
Triiodothyronine (T3)	Chemistry - Pancreatic/Thyroid & Cardiac
Urate	Other Urinalysis
Urate (Uric Acid)	Blood Chem - Renal
Urea Nitrogen	Other Urinalysis
Urea Nitrogen (BUN)	Blood Chem - Renal
Volume	Urinalysis

Folder and Associated Laboratory Assay/Analyte

Folder	Assay
Blood Chem - Hepatic	Alanine Aminotransferase (ALT or SGPT)
Blood Chem - Hepatic	Albumin
Blood Chem - Hepatic	Alkaline Phosphatase
Blood Chem - Hepatic	Ammonia
Blood Chem - Hepatic	Aspartate Aminotransferase (AST or SGOT)
Blood Chem - Hepatic	Bilirubin
Blood Chem - Hepatic	Child-Pugh - Total Score
Blood Chem - Hepatic	Cholesterol
Blood Chem - Hepatic	Direct Bilirubin
Blood Chem - Hepatic	Gamma Glutamyl Transferase (GGT)
Blood Chem - Hepatic	Globulin
Blood Chem - Hepatic	HDL Cholesterol
Blood Chem - Hepatic	Lactate Dehydrogenase (LDH)
Blood Chem - Hepatic	LDL Cholesterol
Blood Chem - Hepatic	Total Protein
Blood Chem - Hepatic	Triglycerides
Blood Chem - Renal	Bicarbonate
Blood Chem - Renal	Calcium
Blood Chem - Renal	Calcium Corrected
Blood Chem - Renal	Calcium, Ionized
Blood Chem - Renal	Chloride
Blood Chem - Renal	Creatinine
Blood Chem - Renal	Magnesium
Blood Chem - Renal	Phosphate
Blood Chem - Renal	Potassium
Blood Chem - Renal	Sodium
Blood Chem - Renal	Urate (Uric Acid)
Blood Chem - Renal	Urea Nitrogen (BUN)
Blood Gases	Bicarbonate (HCO3)
Blood Gases	Methemoglobin
Blood Gases	Oxygen Saturation
Blood Gases	Partial Pressure Carbon Dioxide (pCO2)
Blood Gases	Partial Pressure Oxygen (pO2)
Blood Gases	pH
Bone Marrow	Basophilic Myelocytes
Bone Marrow	Eosinophilic Myelocytes
Bone Marrow	FAB Marrow Rating
Bone Marrow	Lymphocytes/Total Cells
Bone Marrow	Mature Plasma Cells/Total Cells
Bone Marrow	Megakaryocytes/Total Cells
Bone Marrow	Metamyelocytes/Total Cells
Bone Marrow	Monocytes/Total Cells

Bone Marrow	Myeloblasts/Total Cells
Bone Marrow	Neutrophilic Myelocytes
Bone Marrow	Normoblasts/Total Cells
Bone Marrow	Polymorphic Basophils
Bone Marrow	Polymorphic Eosinophils
Bone Marrow	Polymorphic Neutrophils
Bone Marrow	Promyelocytes/Total Cells
Bone Marrow	Pronormoblasts/Total Cells
Bone Marrow	Reticulocytes/Total Cells
Chemistry - Pancreatic/Thyroid & Cardiac	Amylase
Chemistry - Pancreatic/Thyroid & Cardiac	Glucose, Fasting
Chemistry - Pancreatic/Thyroid & Cardiac	Glucose, Non-Fasting
Chemistry - Pancreatic/Thyroid & Cardiac	Hemoglobin (Hgb) A1C
Chemistry - Pancreatic/Thyroid & Cardiac	Insulin
Chemistry - Pancreatic/Thyroid & Cardiac	Left Ventricular Ejection Fraction (LVEF)
Chemistry - Pancreatic/Thyroid & Cardiac	Lipase
Chemistry - Pancreatic/Thyroid & Cardiac	LV Ejection Time
Chemistry - Pancreatic/Thyroid & Cardiac	Osmolality
Chemistry - Pancreatic/Thyroid & Cardiac	Pre-Ejection Period
Chemistry - Pancreatic/Thyroid & Cardiac	Thyrotropin (Thyroid Stimulating Hormone or TSH)
Chemistry - Pancreatic/Thyroid & Cardiac	Thyroxine (T4)
Chemistry - Pancreatic/Thyroid & Cardiac	Triiodothyronine (T3)
Hematology	Basophils/Leukocytes
Hematology	Blasts/Leukocytes
Hematology	Eosinophils/Leukocytes
Hematology	Erythrocyte Sedimentation Rate (ESR)
Hematology	Erythrocytes (RBC)
Hematology	Hematocrit
Hematology	Hemoglobin
Hematology	Leukocytes (WBC)
Hematology	Lymphocytes (ALC)
Hematology	Lymphocytes Atypical/Leukocytes

Hematology	Lymphocytes/Leukocytes
Hematology	Monocytes/Leukocytes
Hematology	Neutrophils (ANC)
Hematology	Neutrophils Band Form/Neutrophils
Hematology	Neutrophils/Leukocytes
Hematology	Partial Thromboplastin Time (PTT)
Hematology	Platelets
Hematology	Prothrombin Intl. Normalized Ratio (INR)
Hematology	Prothrombin Time (PT)
Hematology	Reticulocytes/Erythrocytes
Other Serum Chemistries	5 Prime Nucleotidase
Other Serum Chemistries	Acid Phosphatase (ACP)
Other Serum Chemistries	Aldolase
Other Serum Chemistries	Copper
Other Serum Chemistries	Creatine Kinase (CK)
Other Serum Chemistries	Ferritin
Other Serum Chemistries	Iron
Other Serum Chemistries	Iron Saturation
Other Serum Chemistries	Total Iron Binding Capacity
Other Serum Chemistries	Transferrin
Other Urinalysis	Albumin/Total Protein
Other Urinalysis	Alpha-1 Globulin
Other Urinalysis	Alpha-2 Globulin
Other Urinalysis	Beta Globulin
Other Urinalysis	Calcium
Other Urinalysis	Chloride
Other Urinalysis	Gamma Globulin
Other Urinalysis	Osmolality
Other Urinalysis	Oxalate
Other Urinalysis	Potassium
Other Urinalysis	Sodium
Other Urinalysis	Urate
Other Urinalysis	Urea Nitrogen
Red Blood Cells	Albumin
Red Blood Cells	Alpha-1 Globulin
Red Blood Cells	Alpha-2 Globulin
Red Blood Cells	Antiglobulin Test, Direct (Coombs)
Red Blood Cells	Antinuclear Antibodies (ANA)
Red Blood Cells	Beta Globulin
Red Blood Cells	Bleeding Time
Red Blood Cells	Clot Retraction
Red Blood Cells	Complement Total
Red Blood Cells	Ery. Mean Corpuscular Hemoglobin (MCH)
Red Blood Cells	Ery. Mean Corpuscular HGB Concentration (MCHC)

Red Blood Cells	Ery. Mean Corpuscular Volume (MCV)
Red Blood Cells	Fibrin Degradation Products (FDP)
Red Blood Cells	Fibrinogen
Red Blood Cells	Gamma Globulin
Red Blood Cells	Nucleated Erythrocytes (NRBC)
Red Blood Cells	Protein
Red Blood Cells	Thrombin Time
Respiratory Function	Expiratory Reserve Volume
Respiratory Function	Forced Expiratory Volume in 3 Seconds
Respiratory Function	Forced Vital Capacity
Respiratory Function	Functional Residual Capacity
Respiratory Function	Inspiratory Reserve Volume
Respiratory Function	Peak Expiratory Flow
Respiratory Function	Residual Volume
Respiratory Function	Tidal Volume
Respiratory Function	Total Lung Capacity
Urinalysis	Bilirubin (Bile)
Urinalysis	Creatinine
Urinalysis	Creatinine Clearance
Urinalysis	Erythrocytes (RBC)
Urinalysis	Glucose
Urinalysis	Ketones
Urinalysis	Leukocytes (WBC)
Urinalysis	pH
Urinalysis	Protein
Urinalysis	Protein/Creatinine
Urinalysis	Specific Gravity
Urinalysis	Specimen Collection Period for Urine
Urinalysis	Volume

Off Treatment

Off Treatment

Prerequisites: None

Description: This form will record the date participant was taken off treatment, their response, and if they will move to another treatment on study or to Follow-up.

Subject: **CA043-0005**
Page: **Off Treatment - Off Treatment**

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

Apply to Record

What was the last treatment given?	TAC1: BAY1895344 10MG + CISPLATIN 60MG/M2
Off Treatment Date	21 Sep 2021
Reason	Adverse Event
If Other, specify	
Best Overall Response	Stable Disease
Date of Response	21 Sep 2021
Date of Progression	
Will the participant continue onto a different treatment on this protocol?	Yes No
Will the participant continue to Follow-up?	Yes No

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Save Cancel

After the form is saved it will appear as the first log line. If the participant is continuing on to another treatment, when that new treatment ends, record it here using Add a new Log line.

10404 | City of Hope Comprehensive Cancer Center | CA043-0004 | Off Treatment | Off Treatment

Saved
Subject: **CA043-0004**
Page: **Off Treatment - Off Treatment**

#	What was the last treatment given?	Off Treatment Date	Reason	If Other, specify	Best Overall Response	Date of Response	Date of Progression	Will the participant continue onto another treatment on this protocol?	Will the participant continue to Follow-up?	
1	TAC1: BAY1895344 10MG + CISPLATIN 60MG/M2	21 Sep 2021	Adverse Event	_	Stable Disease	21 Sep 2021	_	No	Yes	

Add a new Log line Inactivate

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Save Cancel

Fields

What was the last treatment given?: Select the Treatment Assignment Code for the last cycle of treatment given to the participant.
Off Treatment Date: Record the date of the last course completed, including follow up and observation. If the treating physician decides the patient needs to be taken off treatment prior to completion of the last course and documents this in the medical record then the date of that decision would be considered the off treatment date.
Reason: Select reason treatment is being discontinued, a few selected terms are defined below:

- **Complete**: If the participant has completed treatment per protocol and the protocol does not specify a follow-up observation period, mark as complete. Note that a plan to continue seeing the participant for extended follow-up as a matter of medical practice does not constitute a "follow-up period" in the sense of this CRF.
- **Adverse Events**: The participant experienced any toxicity that was considered related to the study drug which prohibited further protocol treatment. Participants discontinued due to toxicity are

evaluable provided the observation period has been completed per protocol. The toxicity must be listed on the Adverse Events form.

- **Death**: The participant has died during the treatment phase. The date off treatment must coincide with the date of death. The cause of death should be listed on the Adverse Event form.
- **Progressive Disease**: The participant was taken off study for disease progression. This must be reflected by an increase in the non-measurable or measurable disease state (see Course Assessment and Extent of Disease Forms). This can be manifested as clinical deterioration. A Date of Progression must be recorded.
- **Protocol Violation**: If a major protocol violation has occurred, the reason must be stated in the Comments form.

Best Overall Response: Indicate the best overall response to treatment while on Protocol. According to RECIST and WHO guidelines this would be the best response assessed from the start of treatment until disease progression.

Ordinarily this would be the best of the responses reported on the course assessment CRFs. For example, do not enter 'Stable Disease' if the patient was assessed only with progressive disease.

Please be sure to enter the best response, not necessarily the response on the last course. For example, if the patient was assessed with a 'Partial Response' followed by a 'Less than Partial Response', enter the 'Partial Response'.

If response was not assessed at all during the protocol treatment record the best response as 'Not Assessed'; similarly, for 'Not Evaluable' and 'Too Early'.

'Stable Disease' indicates tumor growth or shrinkage relative to the baseline that is not enough to justify a 'Complete\Partial\Less than Partial Disease' response or a 'Progressive Disease' progression. An actual response that persists should continue to be assessed as a response – relative to the baseline.

Date of Response: Record date the participant's best response (not progression) was first documented.

Date of Progression: Record the date of the evaluation used to determine the participant's disease status of progressive disease. Progression is the worsening of disease following a period of stable disease or a response. Relapse is the reoccurrence of disease in a patient with no evaluable disease at enrollment (e.g., on an adjuvant treatment study). A date of progression may be entered if the disease progression occurred after an assessed better response.

This date is required if the Reason Last Course Completed is for Progressive Disease or if patient was taken off study due to disease progression.

This date must be consistent with the date of progression recorded on the Course Assessment form(s).

Will the participant continue onto a different treatment on this protocol?: Select Yes if the participant will continue with another treatment cycle with a different Treatment Assignment Code (TAC). If not, select No.

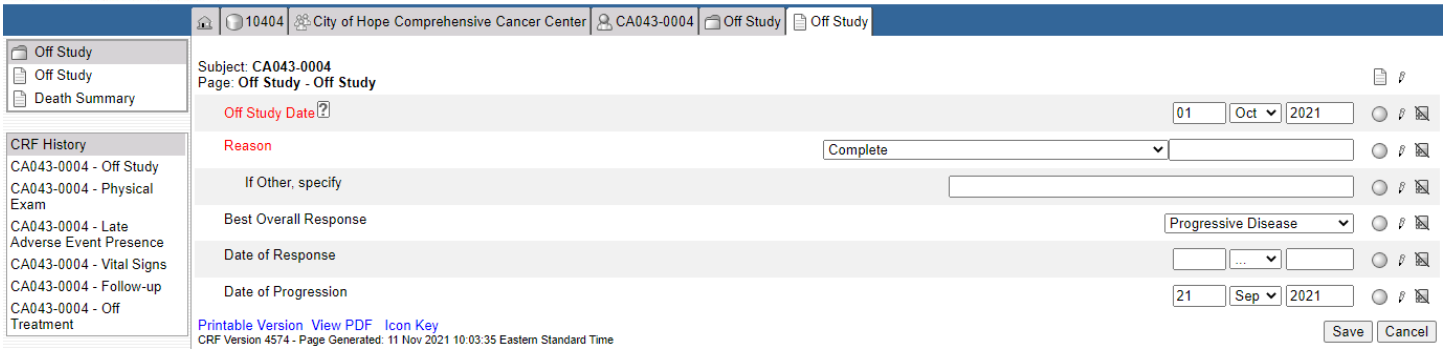
Will the participant continue to Follow-up?: Select Yes if the participant will continue to Follow-Up. after saving the form the first Follow Up folder will be available. If the participant is withdrawn completely, select No.

Off Study

Off Study

Prerequisites: If participant was treated on study, complete Off Treatment form first.

Description: This form records the date and reason a participant was removed from the study.



Fields

Off Study Date: Record the date the decision was made to remove the participant from protocol. Usually, this date is after all data is collected and any protocol follow up has been completed. However, documentation of physician (or patient) decision to be taken off study would supersede the requirement to compete protocol evaluations/follow up.

Reason: Select reason participant was removed from protocol, a few selected terms are defined below:

- **Adverse Events**: The participant experienced any toxicity that was considered related to the study drug which prohibited further protocol treatment. Participants discontinued due to toxicity are evaluable provided the observation period has been completed per protocol. The toxicity must be listed on the Adverse Events form.
- **Complete**: The patient's participation has been completed as per protocol, and the protocol does not specify a follow-up observation period. Note that a plan to continue seeing the patient for extended follow-up as a matter of medical practice does not constitute a "follow-up period" in the sense of this CRF.
- **Death**: The participant has died during the treatment phase. The date off treatment must coincide with the date of death. The cause of death should be listed on the Adverse Event form.
- **Lost to Follow-up**: Occurs when a patient does not return to the clinic or the site and all contact attempts have failed. Please follow your institution's guidelines on how many times you should reach out to a patient (generally, 3-5 times) before they are considered lost to follow-up. The Off Study Date is the date it was determined the patient was lost to follow up and no further attempts to contact the patient will be made. It may also be the date of the last (most recent) attempt to contact the patient. Each attempt at contact should be documented in the medical record.
- **Progressive Disease**: The participant was taken off study for disease progression. This must be reflected by an increase in the non-measurable or measurable disease state (see Course Assessment and Extent of Disease Forms). This can be manifested as clinical deterioration. A Date of Progression must be recorded.
- **Protocol Violation**: If a major protocol violation has occurred, the reason must be stated in the Comments form.

- **Trial Screen Failure:** During the two-step enrollment process, the patient was entered into the Rave database but was deemed ineligible due to a sample submission and/or lab result.

Best Overall Response: Indicate the best overall response to treatment while on Protocol. According to RECIST and WHO guidelines this would be the best response assessed from the start of treatment until disease progression.

Ordinarily this would be the best of the responses reported on the course assessment CRFs. For example, do not enter 'Stable Disease' if the patient was assessed only with progressive disease.

Please be sure to enter the best response, not necessarily the response on the last course. For example, if the patient was assessed with a 'Partial Response' followed by a 'Less than Partial Response', enter the 'Partial Response'.

If response was not assessed at all during the protocol treatment record the best response as 'Not Assessed; similarly, for 'Not Evaluable' and 'Too Early'.

'Stable Disease' indicates tumor growth or shrinkage relative to the baseline that is not enough to justify a 'Complete\Partial\Less than Partial Disease' response or a 'Progressive Disease' progression. An actual response that persists should continue to be assessed as a response – relative to the baseline.

Date of Response: Record date the best response was first documented.

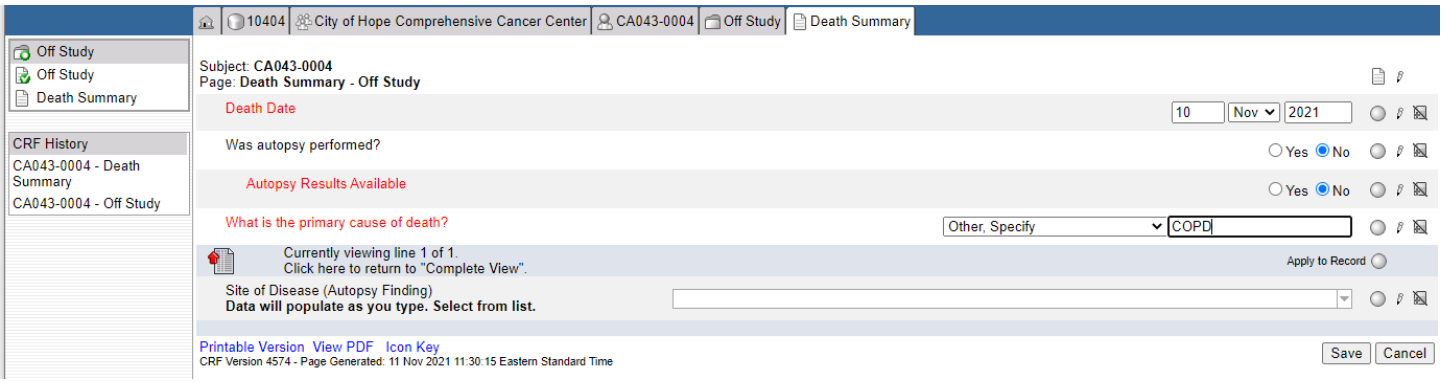
Date of Progression: Record the date of the evaluation used to determine the participant's disease status of progressive disease. A date of progression may be entered if the disease progression occurred after an assessed better response. This date is required if the Reason Last Course Completed is for Progressive Disease or if patient was taken off study due to disease progression.

This date must be consistent with the date of progression recorded on the Course Assessment form(s). Progression is the worsening of disease following a period of stable disease or a response. Relapse is the reoccurrence of disease in a patient with no evaluable disease at enrollment (e.g., on an adjuvant treatment study).

Death Summary

Prerequisites: None

Description: The form records the date and cause of death if a participant has died during the study or follow-up.



Fields

Death Date: Enter the date of death.
Was autopsy performed?: Select the appropriate box to indicate whether an autopsy was performed.
Autopsy Results Available: Select the appropriate box to indicate whether the results of an autopsy are available.
What is the primary cause of death?: If the patient died without intervening therapy specific to the disease for which the patient was put on study, this section should be completed. If "Other" is checked, give a succinct description of the cause of death.
Site of Disease (Autopsy Finding): Complete when an autopsy is performed by listing the major sites of malignant disease involvement found at the autopsy.

Follow-up

Follow-up

Prerequisites: None.

Description: This form initiates the Follow-up visit and must be completed first.

Fields

Date of Assessment: Date the participant was contacted for follow-up.
Survival Status: Select the participant's last known status from the drop-down menu.

Additional Follow-up visits can be added by using the **Add Event** function on the Subject Page.

Physical Exam

Prerequisites: Follow-up

Description: This form records the observations from a physical exam that occurs during the Follow-up visit. Follow the schedule of Physical Exams as defined in the protocol. If the Follow-up visit is in person and a Physical Exam is performed, but not required by protocol, it can still be entered in Rave.

For details on this form, see Baseline Physical Exam

Vital Signs

Prerequisites: Follow-up

Description: This form is used to record the vital signs at the follow-up assessment as required by protocol. If the Follow-up visit is in person and Vital Signs are taken, but not required by protocol, they can still be entered in Rave.

For details on this form, see VS Log

Late Adverse Event Presence

Prerequisites: Follow-up

Description: This form documents the presence of Adverse Events that occur 30 days after the patient was removed from treatment which cannot be attributed to the last treatment regimen.

If an AE occurs more than 30 days after the last dose but was definitely or probably related to the study drug, then it should be recorded within the last course and subsequently on the late adverse event form in the Follow-up folder. Please refer to the Protocol for specific AE reporting guidelines at end of treatment or during follow up.

For details on this form, see Adverse Event Presence

Adverse Events

Prerequisites: Follow-up and Late Adverse Event Presence

Description: This form documents the details of Adverse Events that occur 30 days after the patient was removed from treatment which cannot be attributed to the last treatment regimen.

If an AE occurs more than 30 days after the last dose but was definitely or probably related to the study drug, then it should be recorded within the last course and subsequently on the late adverse event form in the Follow-up folder. Please refer to the Protocol for specific AE reporting guidelines at end of treatment or during follow up.

For details on this form, see Adverse Events

Appendix 1: Theradex Specimen Tracking System (STS)

Access

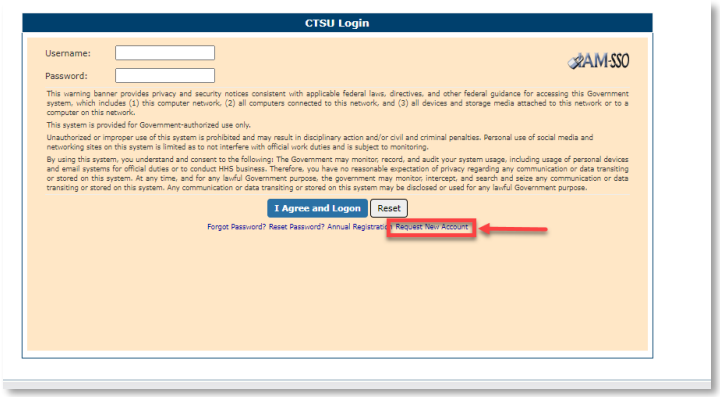
Access to your study in Rave is overseen by CTSU and is granted based on the role assignment in the roster (and protocol DTL if applicable) for your site. You will need to contact your site's RSS or DTL administrator to request the addition of your name on the roster. Information on new Rave accounts 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.

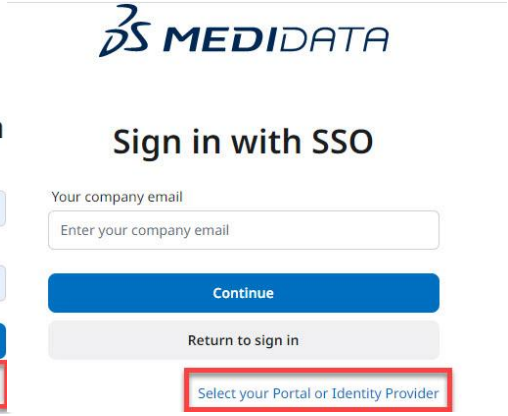
For certain older studies, Theradex will need to grant you an additional Rave role for each study named "CRA Specimen Tracking" after CTSU has sent the EDC invitation for the regular CRA role. The training required to gain access to STS can be taken through CTSU's CLASS system or via a video presentation 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

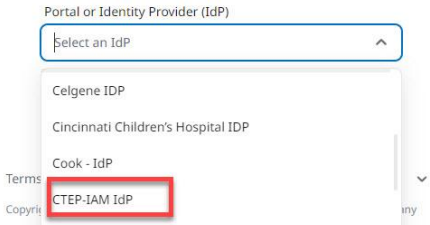
All individuals are required to have an active CTEP-IAM account prior to being granted access to Rave. To create a CTEP-IAM account, proceed as follows:



13. Go to the following URL: https://www.ctsu.org/public/default_login.aspx
14. Under the buttons, click **Request New Account**. This will take you to the CTEP-IAM page.
15. Follow the prompts to enter the required identifying information for your account. Choose the Associate Plus application
16. You will receive an authorization email in **24-48 hours**.
17. 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*.
18. After these steps are completed, go to the following URL: https://login.imedidata.com/login
19. Click on **Sign in with SSO**
20. Click on **Select your Portal or Identity Provider**

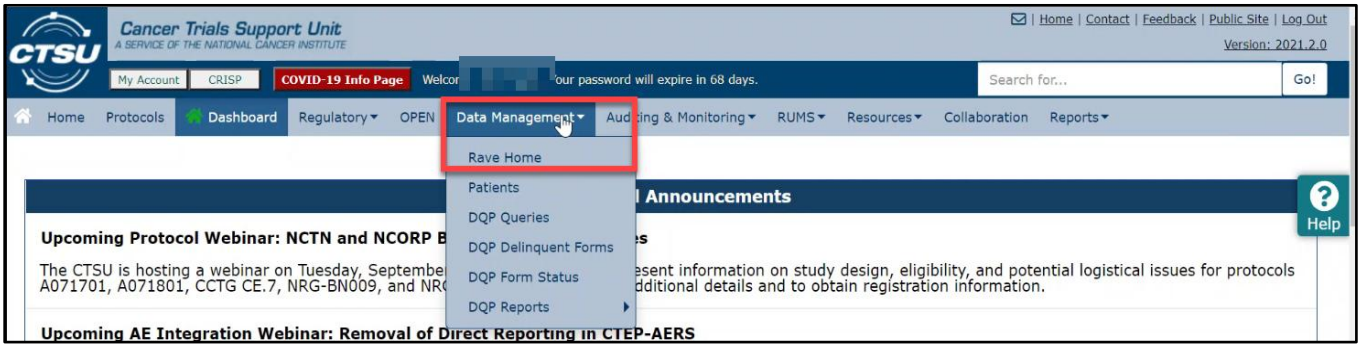


21. From the menu, choose **CTEP-IAM IdP**.
22. Click **Select**
23. Login with your CTEP-IAM username and password on the resulting screen.



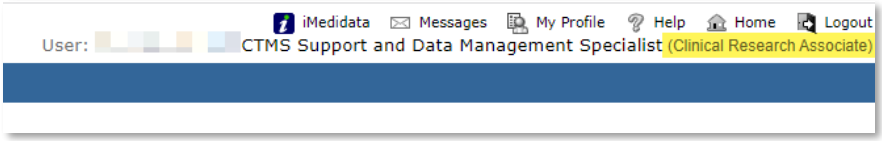
Logging in through CTSU

7. Go to the following URL: https://www.ctsu.org/Public/Default.aspx
8. Click **Log in.**
9. At the login page, enter your **CTEP-IAM Username** and **Password**
10. Click **I agree and logon**.
11. Go to the **Data Management** menu.
12. 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.

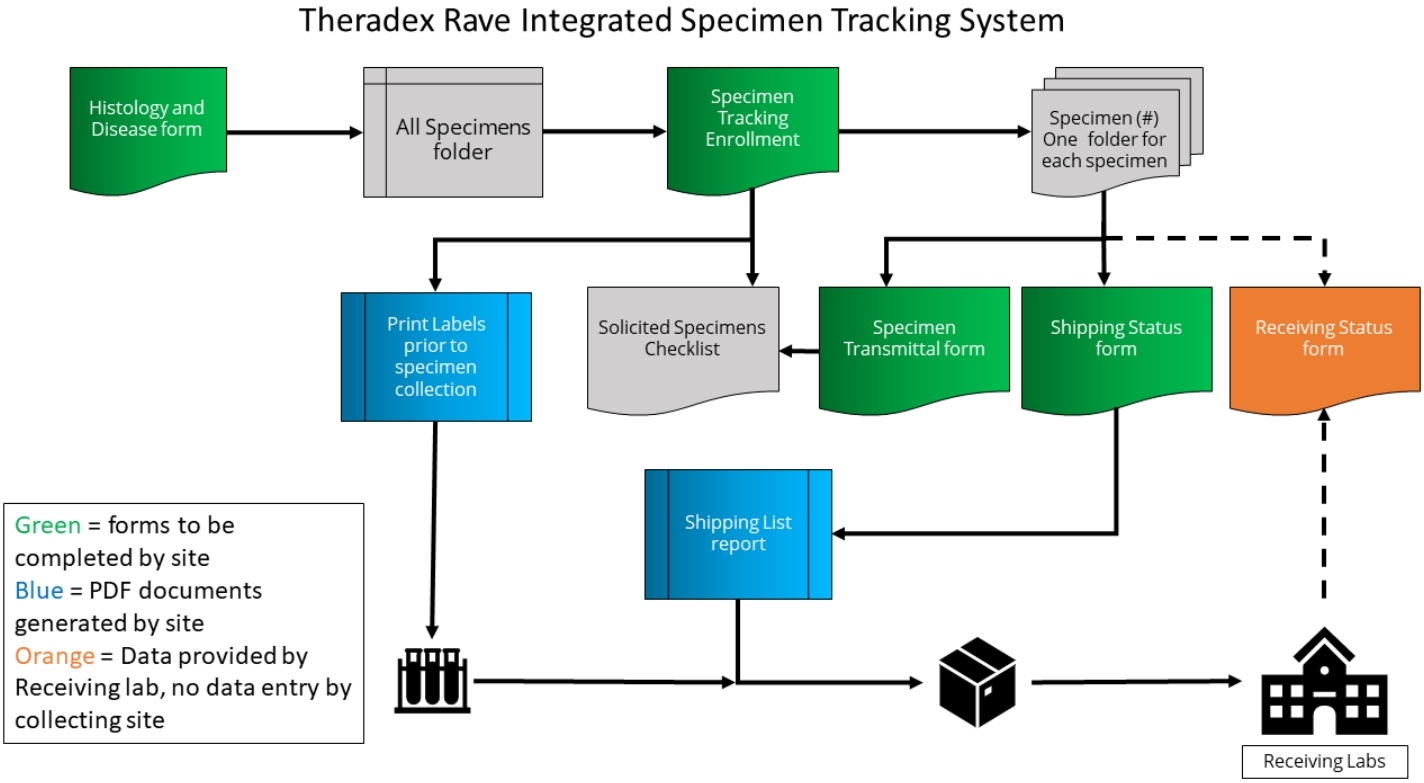
If your role is **Clinical Research Associate** and you cannot edit forms in the All Specimens folder or generate reports, contact STS support as we may need to add the **CRA Specimen Tracking** role to your account. See Access for more information.

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



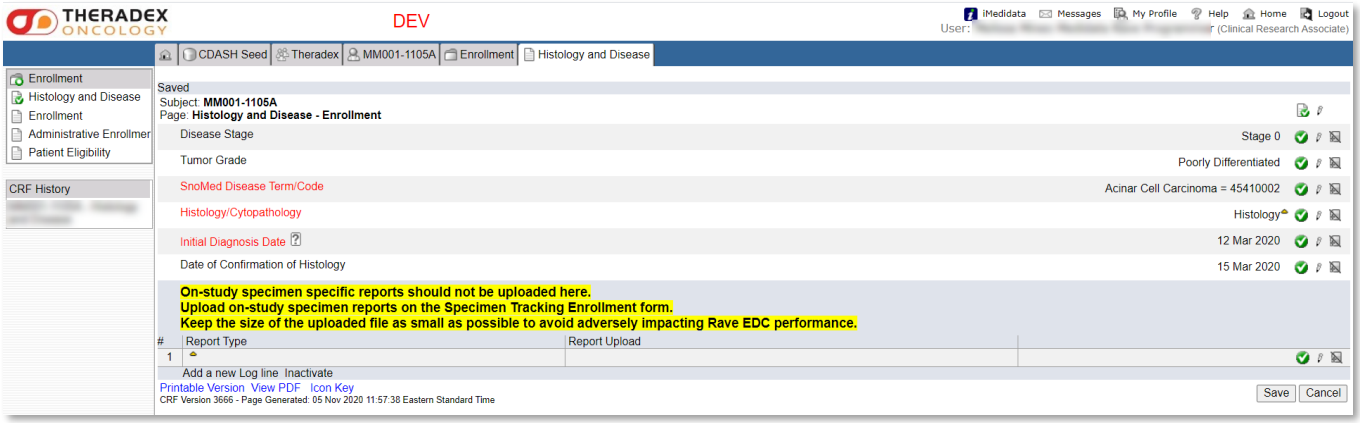
Summary of STS data entry

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.

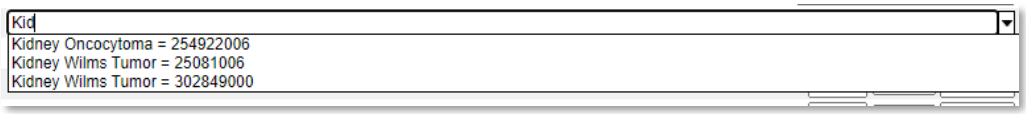
Enrollment folder - Histology & Disease form

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.

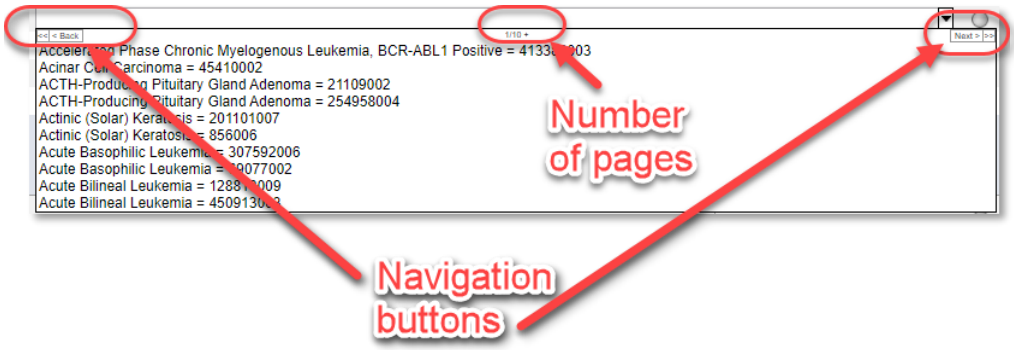


Notes:

- 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.

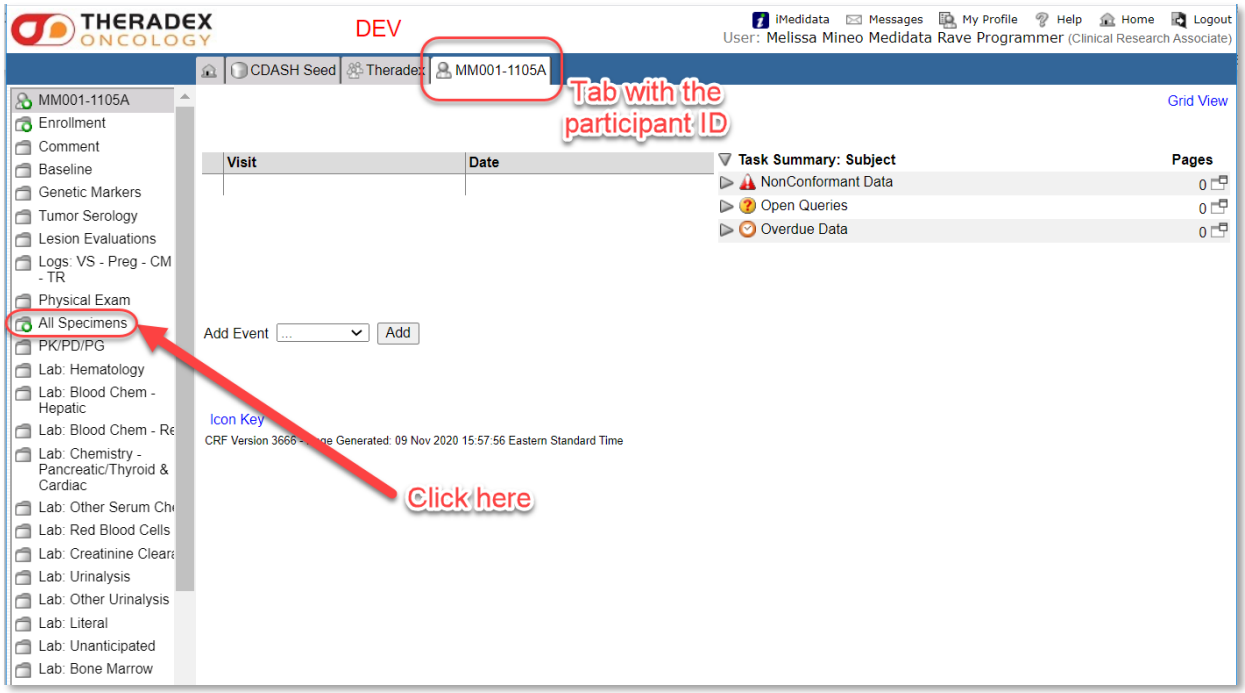
Examples of PHI/PPI

- 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

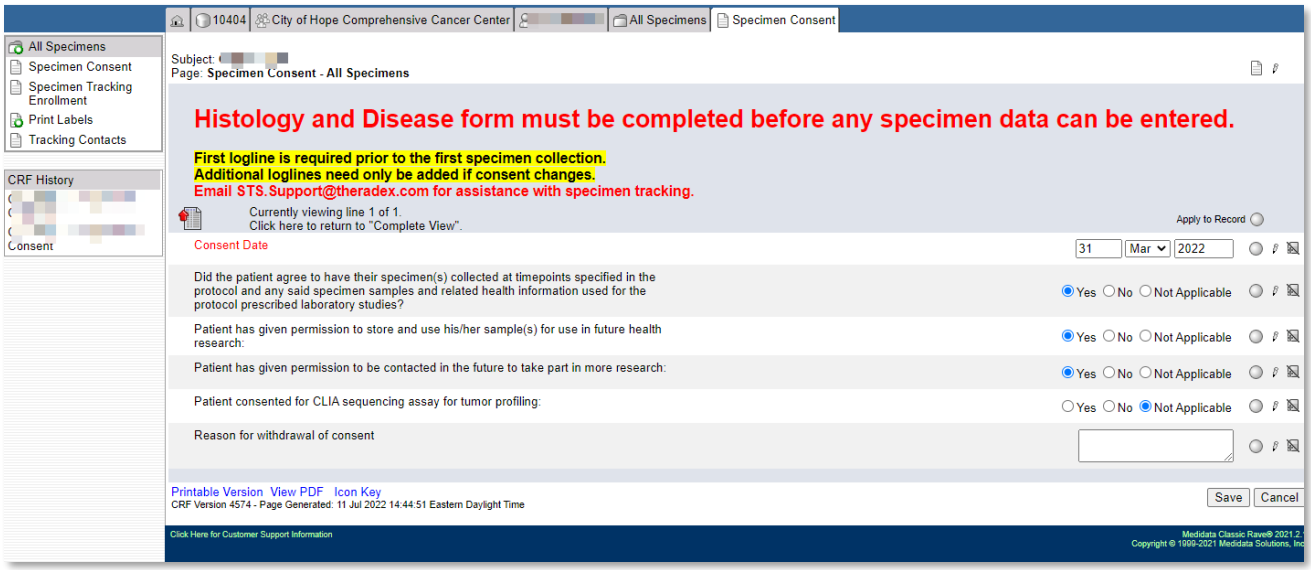
Ensure the Histology and Disease form in the Enrollment folder is complete before proceeding with any data entry.

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

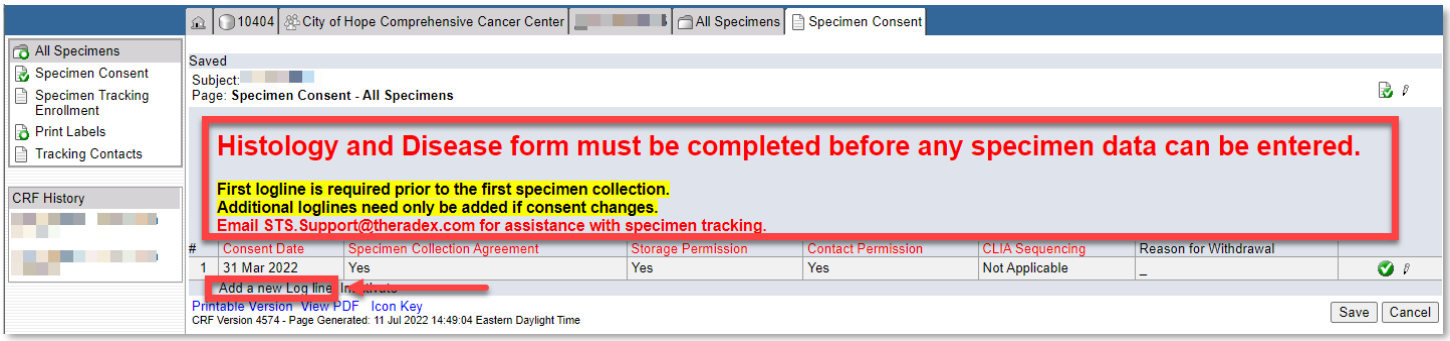


Specimen Consent form

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).

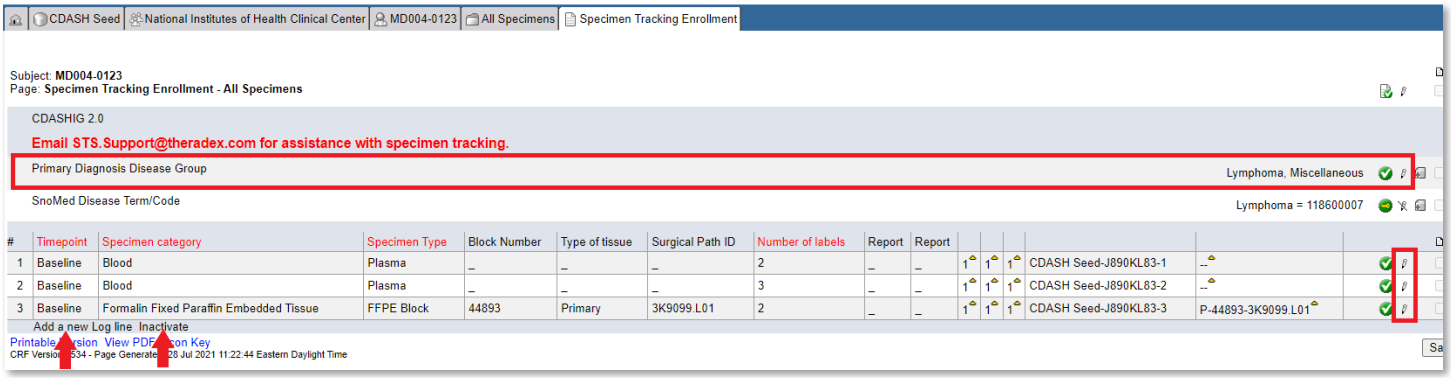
For **Optional** specimens the form will activate the Completed checkbox when collected but will not automatically issue system queries.

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.

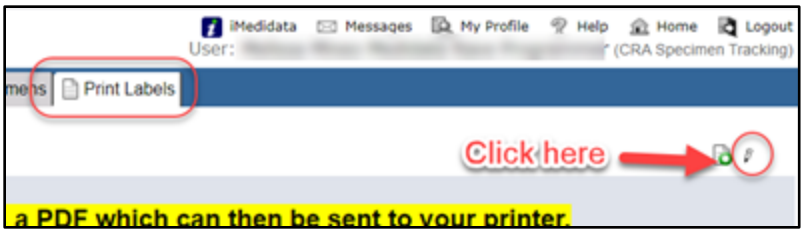
If using the **Print Labels** form, once the **Specimen Tracking Enrollment** form is saved, the number of labels cannot be updated on this form. If a change is needed to the number of labels, update on the **Print Labels** form.

Labels

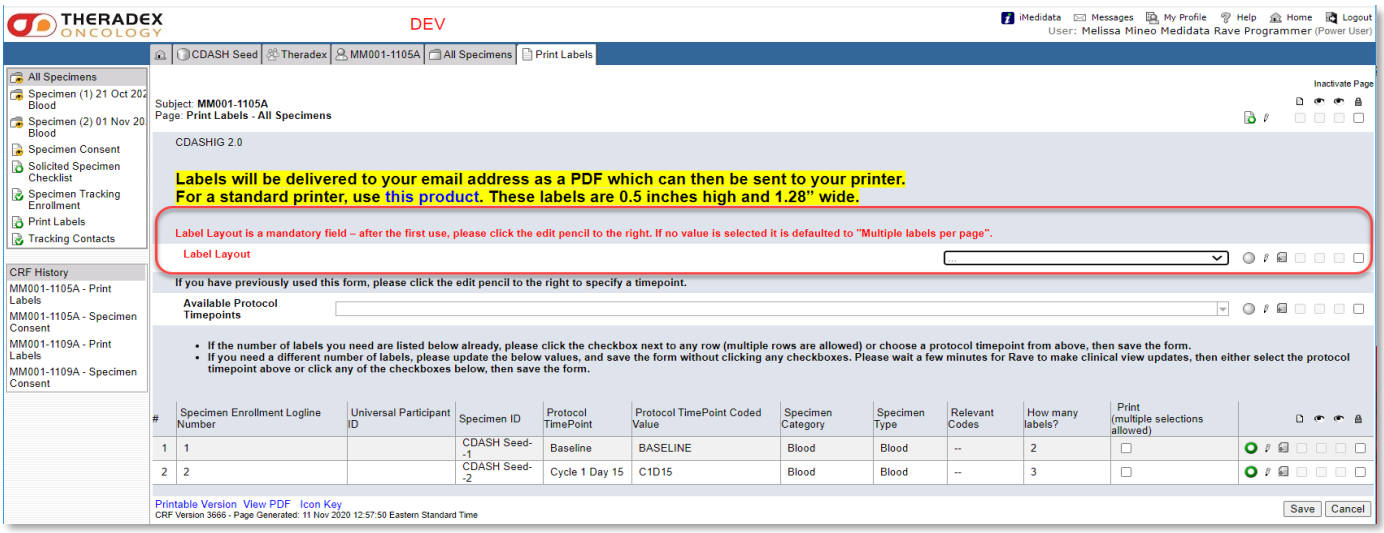
Print Label form

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

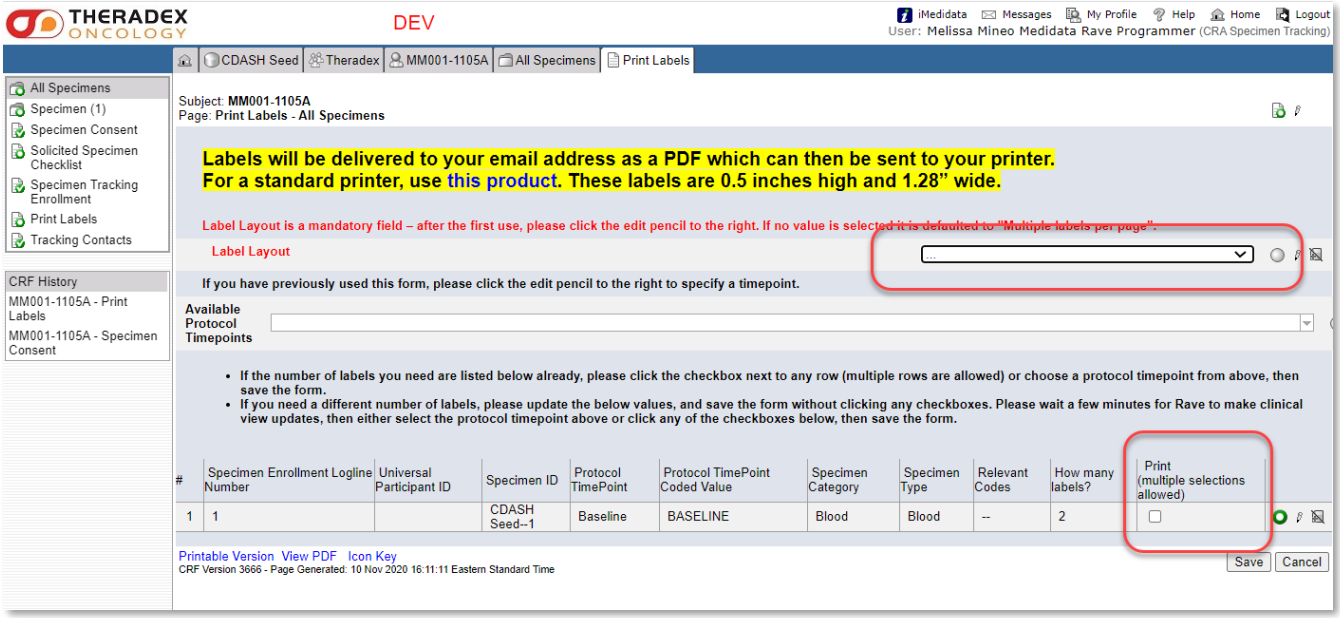


There are two ways to print labels – **CHOOSE ONE METHOD ONLY**.

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

--OR--

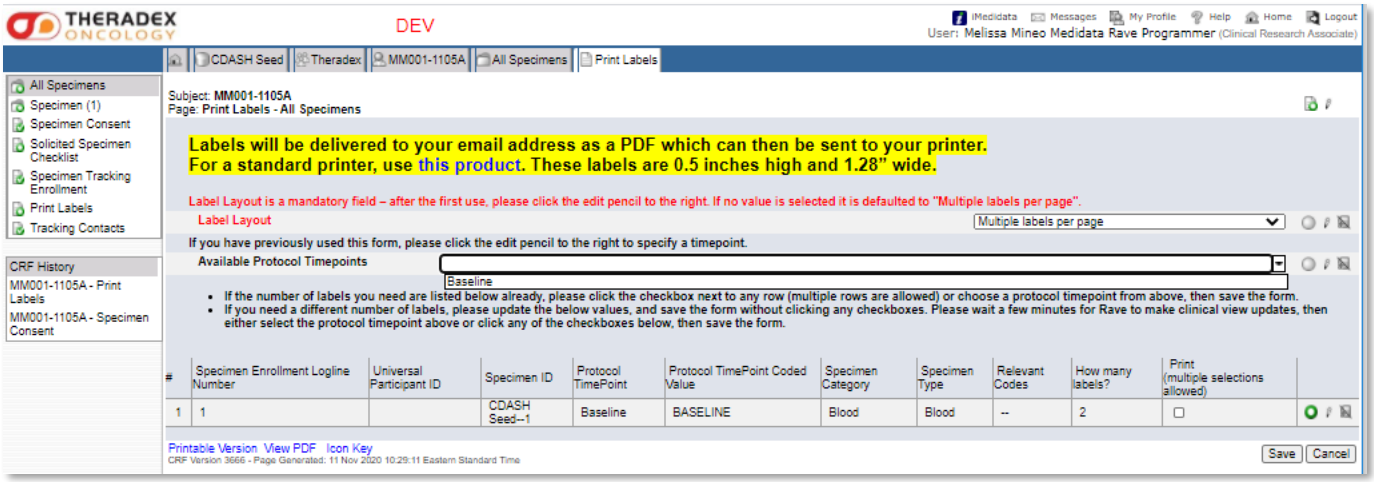
- Printing labels by Available Protocol Timepoints.



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.

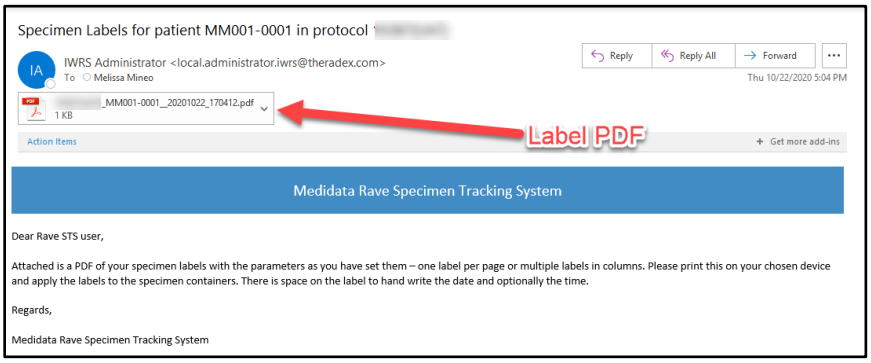
Once the user saves the form, the system will generate the same two emails shown above for manual selection, however these will include the timepoints that match the user selected values.

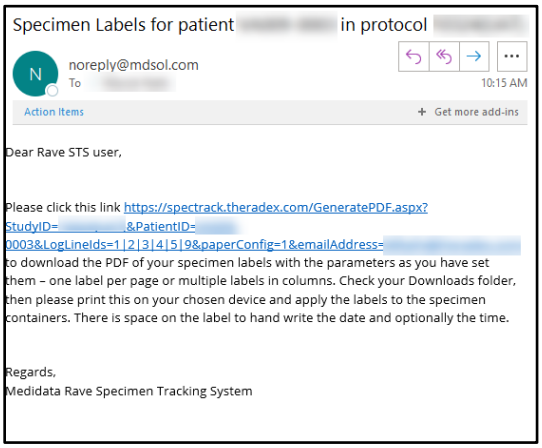
Apply labels to the specimen(s), and hand write the date and optional time on the label.

---

*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.



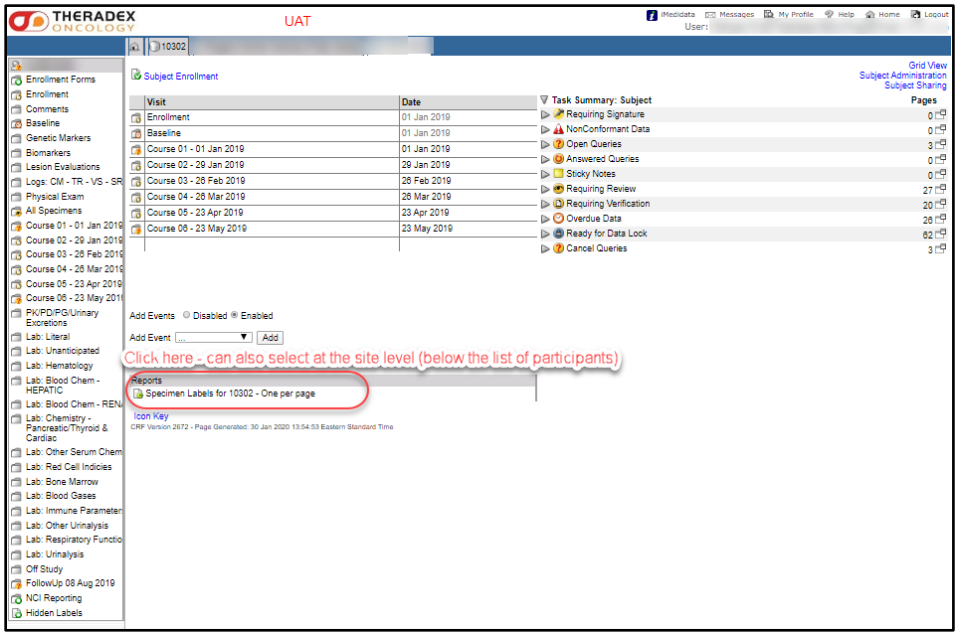


Apply labels to the specimen(s), and hand write the date and optional time on the label.

Specimen Label Report

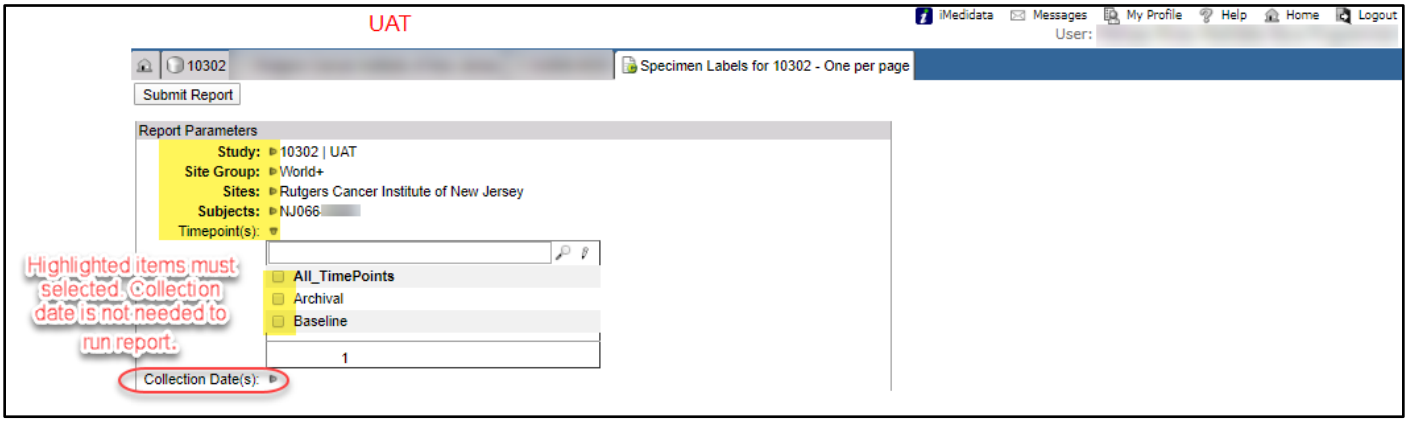
The following steps are for older versions of the STS that *do not* have the Print Labels form.

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

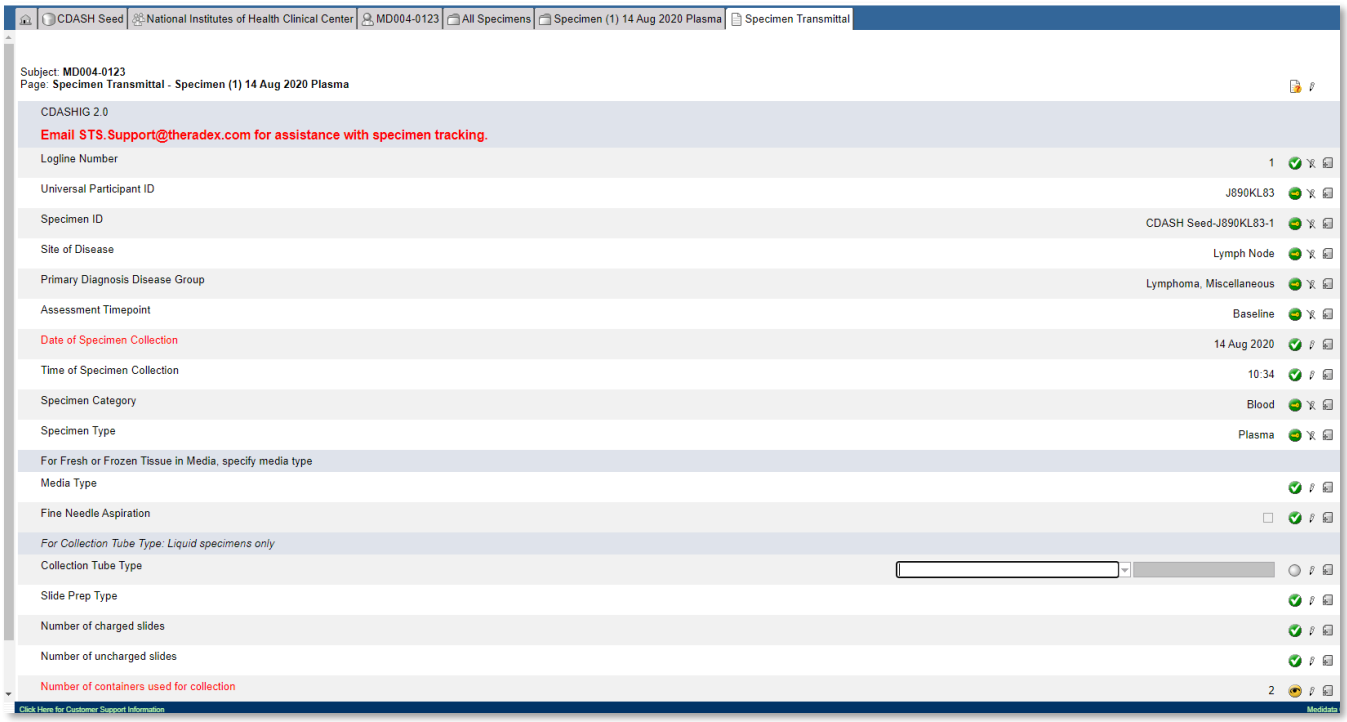
Also referred to as **Specimen Collection Details** in some studies

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

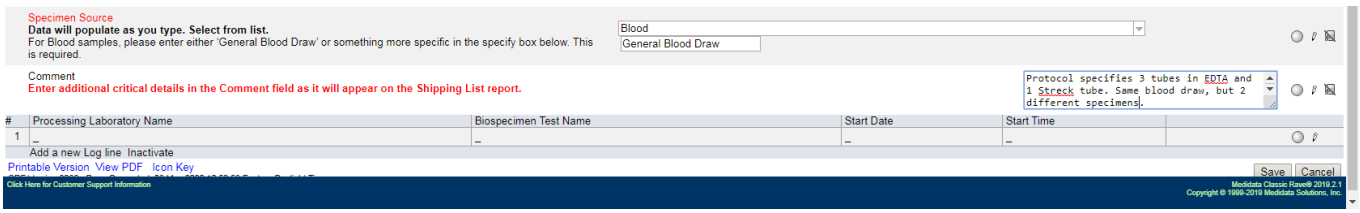
Return to the **All Specimens** folder. After adding the logline to the **Specimen Tracking Enrollment** form, a folder will have populated, **Specimen (#)** for each specimen line. Open each folder and complete the forms.

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.

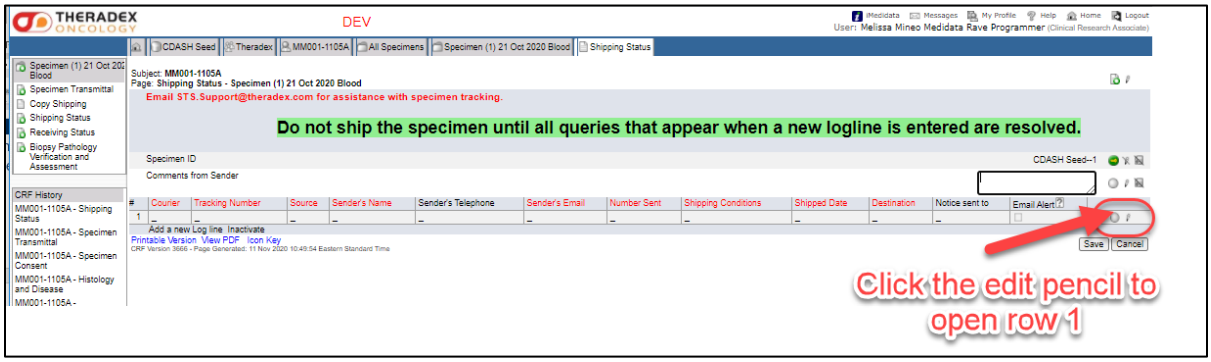
Notes:
If the **#** in the **Specimen (#)** folder name does not match the log line number. Complete the Transmittal form (enter the collection date at minimum) and the folder name will update after saving.

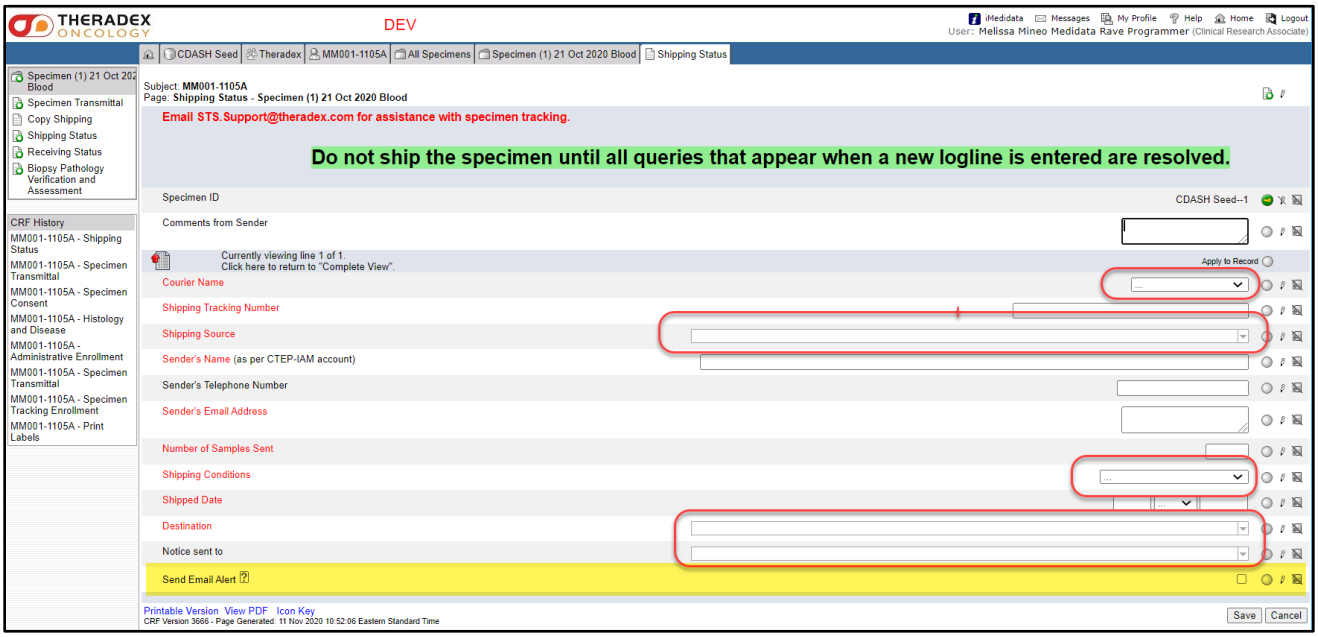
For some studies, the collection tube type is entered on this from for blood specimens.

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.

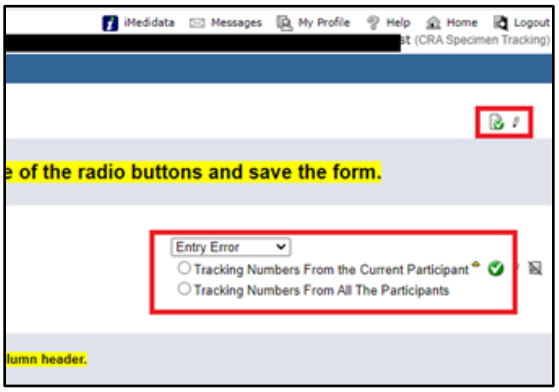
3. **Do not click** the checkbox for “Send Email Alert” at this time.
4. Click **Save**.
5. For each additional specimen included in the shipping (same tracking number) use the Copy Shipping feature to complete the Shipping Status forms, see next section.

Note:

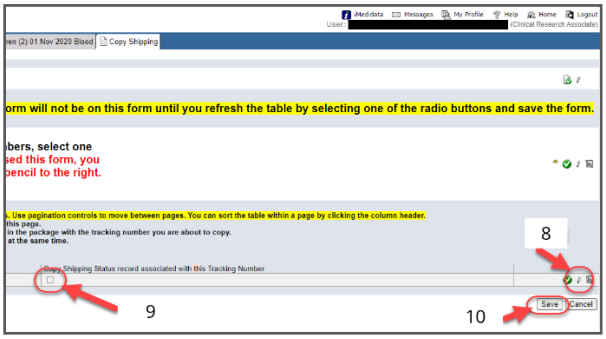
For hand delivered specimens a unique tracking number entry must be provided. Generic entries (i.e. N/A, hand delivered, dropped off) are not acceptable. An example of a unique entry can be initials and a date. Please be sure to keep the format of these entries the same *MM_15June2021* and *MM 15June2021*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

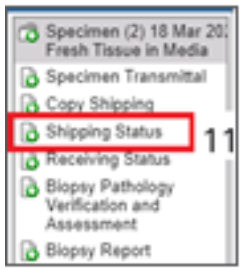
Copy Shipping

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.**

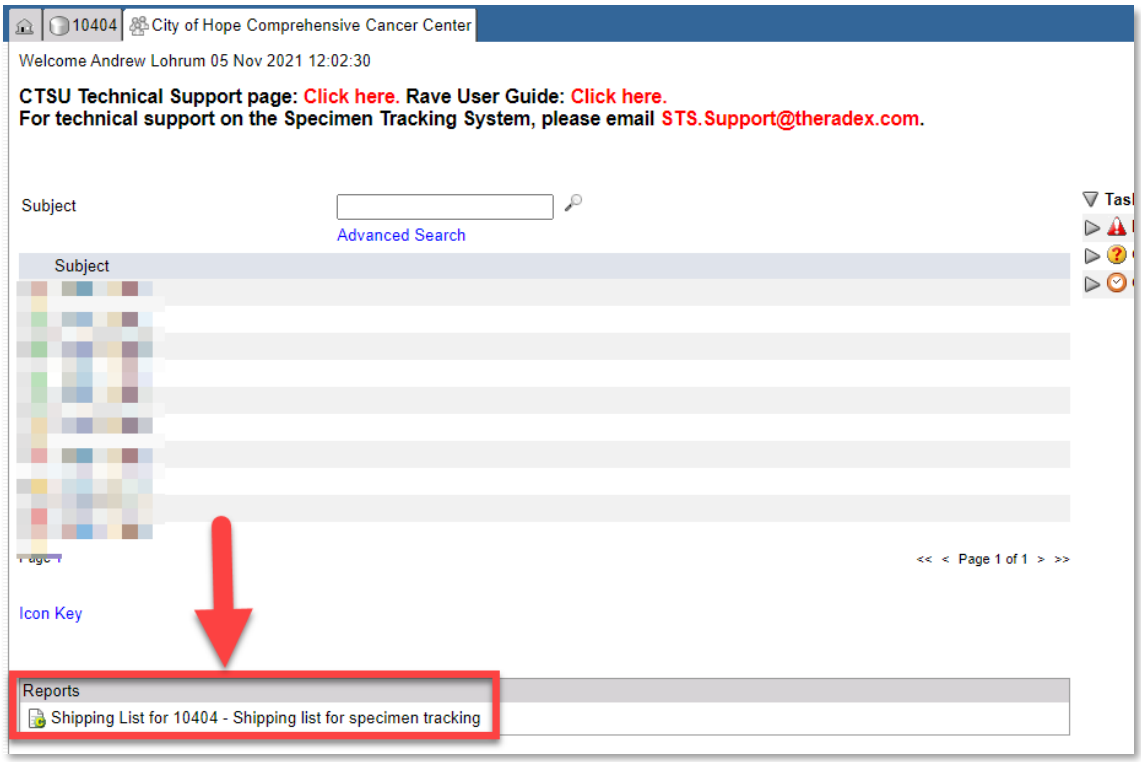
If no Destinations are present in the Shipping Status form and the Tracking Contacts form is blank. Go to the **Enrollment** folder and complete the **Histology and Disease** form.

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

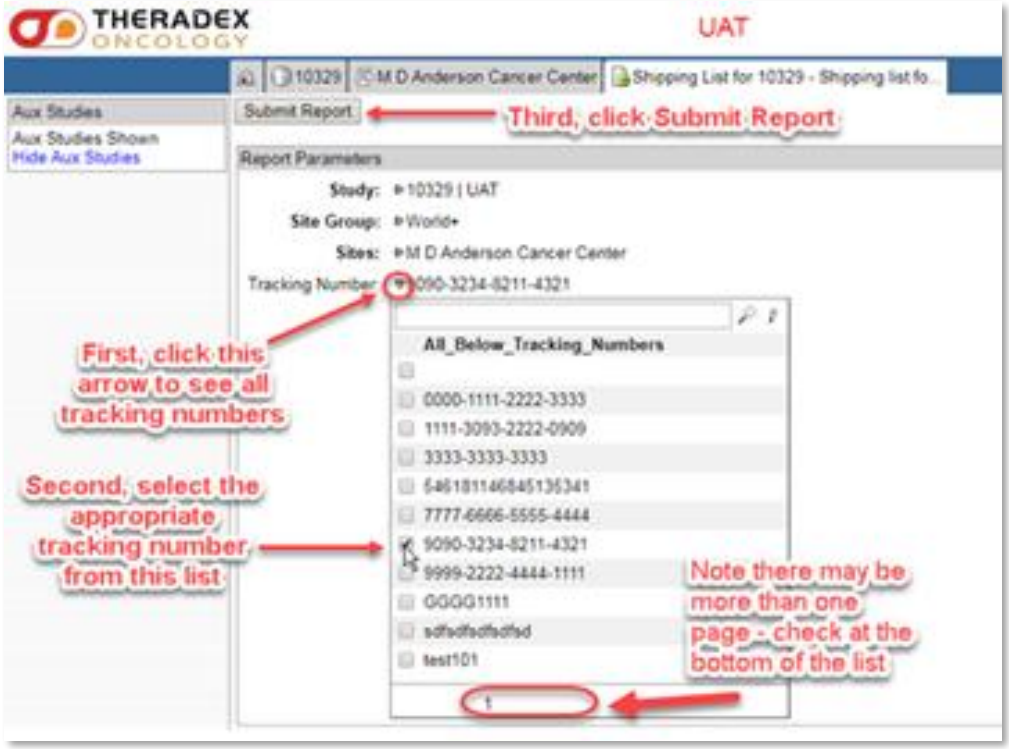
Shipping List

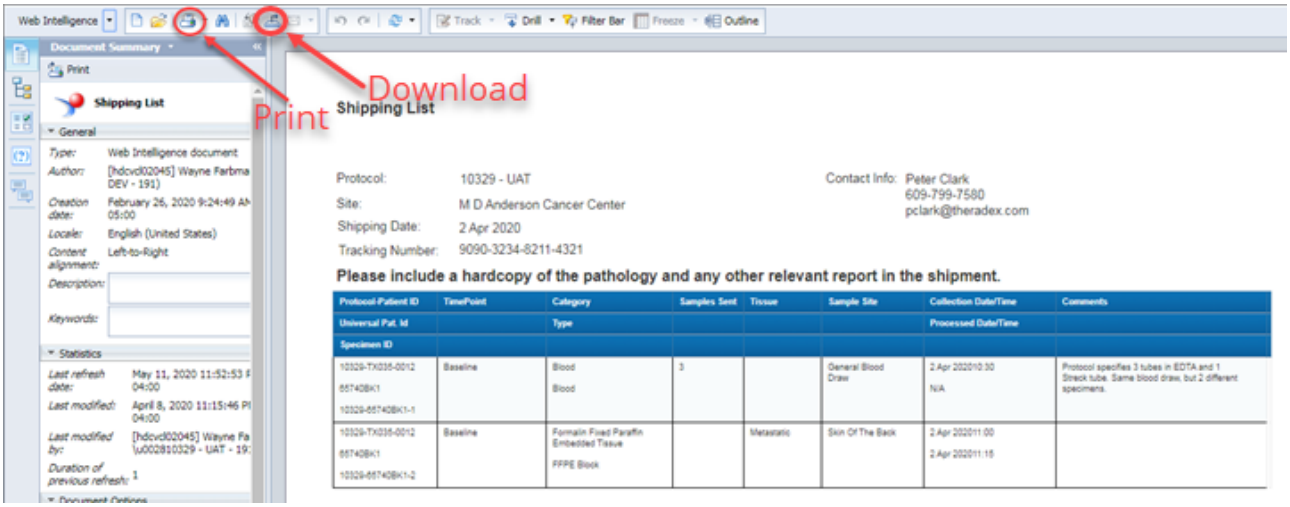
The Shipping List is indexed on the tracking number. Rave will pull entries from the Shipping Status forms with the same tracking number form and create a line in the Shipping List.

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

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

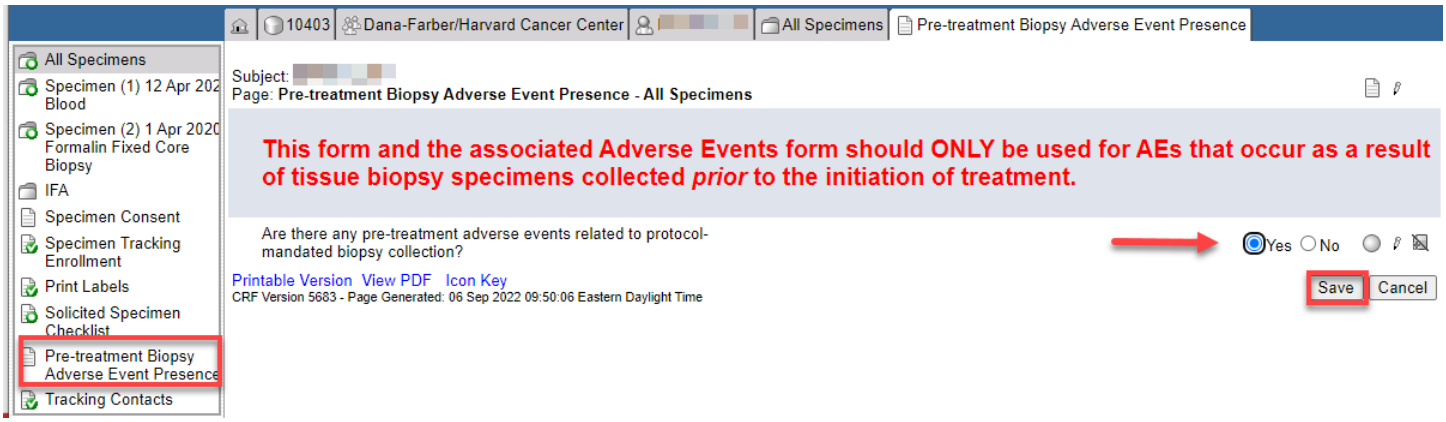
3 - Shipping Status

Adverse Events in Specimen Collection

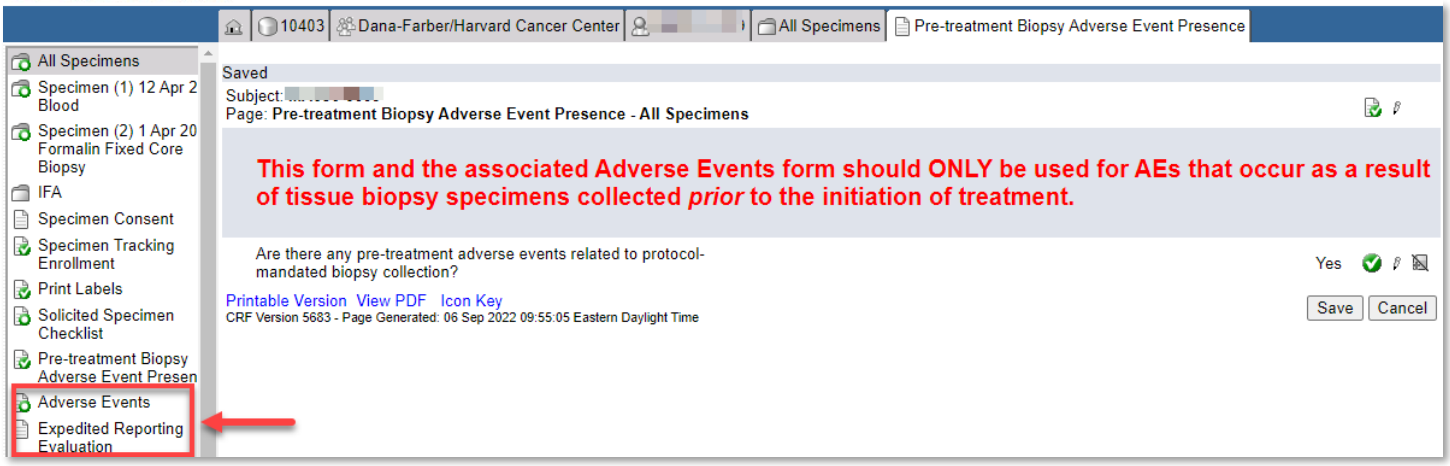
Adverse events that occur as a result of specimen collection **prior to treatment** are recorded on forms within the STS. These forms may not be present for your study.

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.

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/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.

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

To open the first log line, click on any dash in the empty fields

#	Adverse Event (Verbatim term)	*Adverse event term (CTCAE v5.0)	*MedDRA adverse event code (CTCAE v5.0)	* Adverse event evaluated this cycle?	Related to	Specimen Correlation	Hospitalization (initial or prolonged)	Life Threatening	Death	Disability or Permanent Damage	Congenital Anomaly or Birth Defect	Required Interventionn	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 line Inactivate

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 15:44:24 Eastern Daylight Time

Save Cancel

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/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.

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 Grade: 2

Adverse event grade description

Start Date: 25 Mar 2020

End Date:

Ongoing

Relationship to Study Treatment: Unrelated

Related to:

Specimen Correlation (if any): (10403-EAD5JVO2-2) 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? Not Applicable

Therapy Symptomatic

* 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 Optional

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

All Specimens
Specimen (1) 12 Apr 202 Blood
Specimen (2) 1 Apr 2020 Formalin Fixed Core Biopsy
IFA
Specimen Consent
Specimen Tracking Enrollment
Print Labels
Solicited Specimen Checklist
Pre-treatment Biopsy Adverse Event Presence
Adverse Events
Expedited Reporting Evaluation
Tracking Contacts

CRF History

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/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 (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 Interventionn	Other Serious (Important Medical Events)	Was the event considered a dose limiting toxicity?	What action was taken with study treatment?
1	Sub dermal 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)

<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

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

Subject:
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)

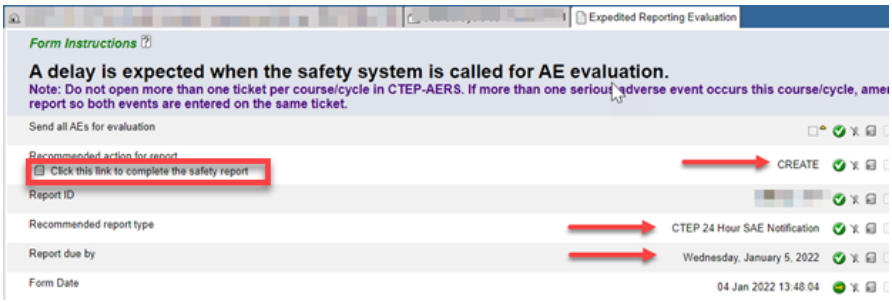
Report ID

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.

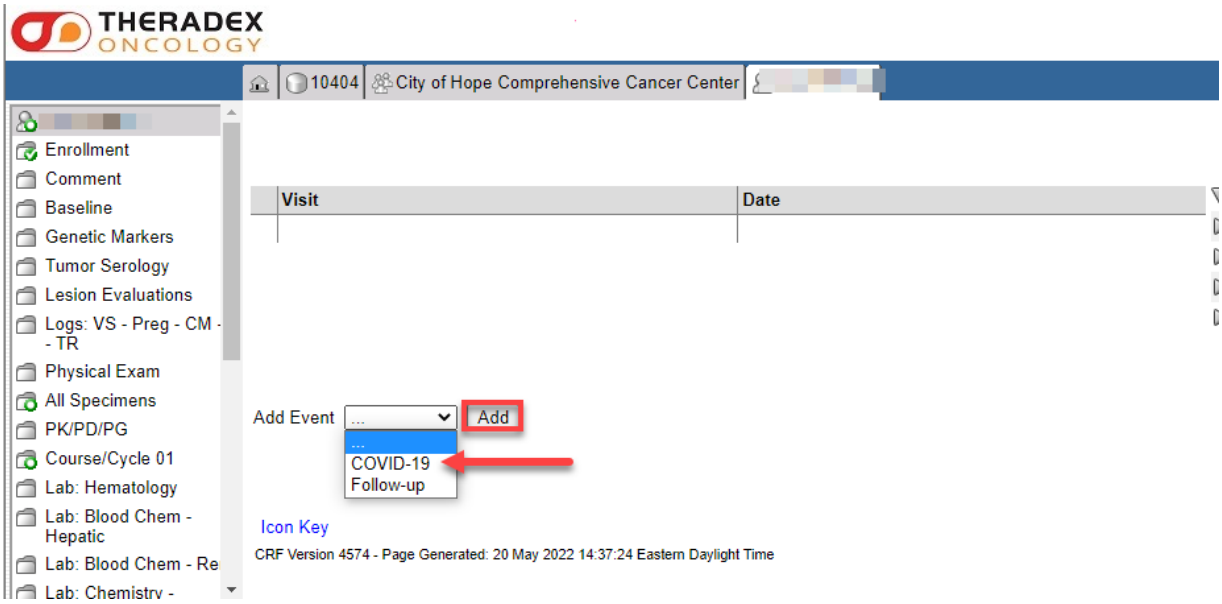
If the CTEP-AERS determines that a report is needed (ie. CREATE or EDIT) it will advise on the report type and due date. Click on the link to complete the safety report (see red box in next image).



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

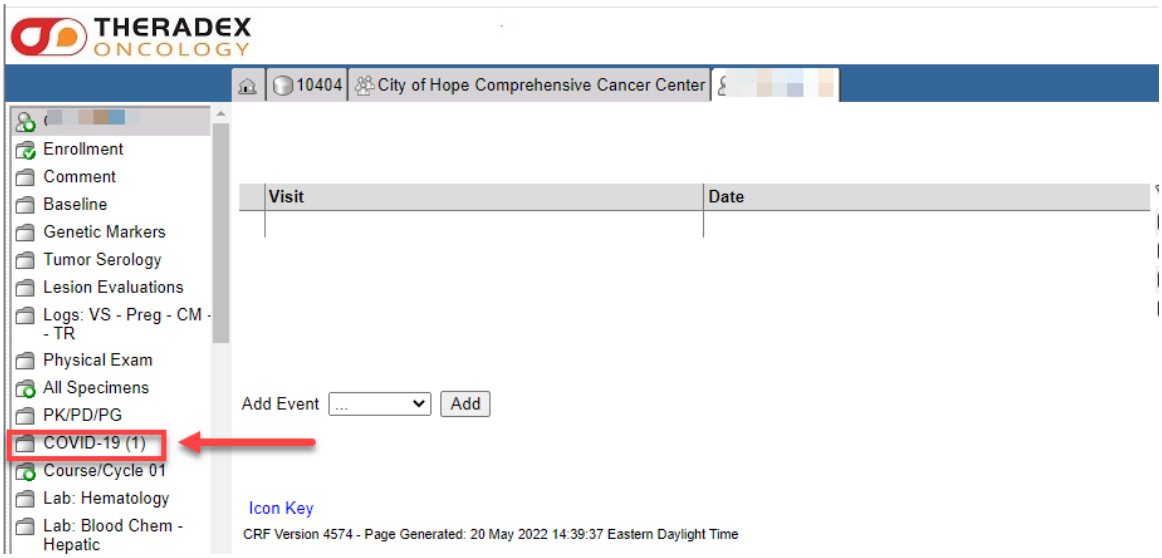
Appendix 2: Covid-19 Supplementary Forms

Add Covid-19 Event



1. Go to the subject page in Rave.
2. From the **Add Event** drop down menu, select **COVID-19**.
3. Click **Add**.

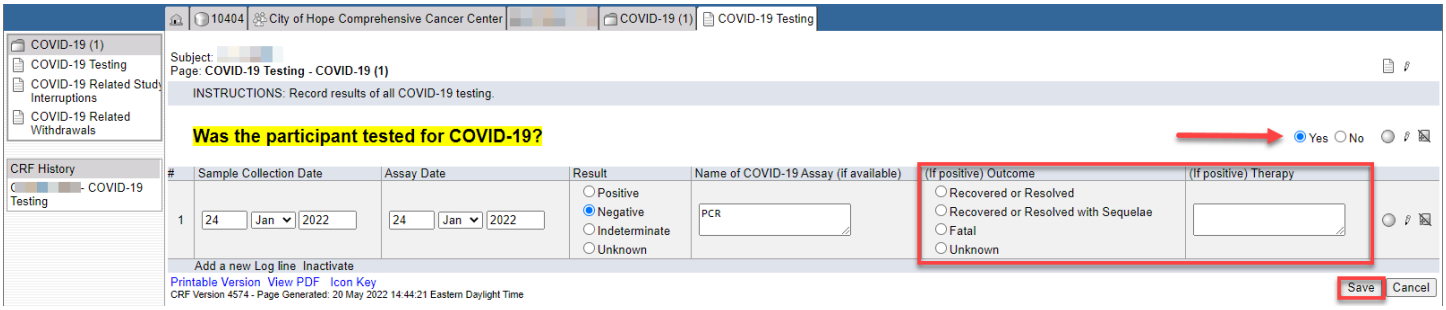
A COVID-19 folder will load in the panel with the three supplementary forms.


THERADEX
ONCOLOGY
10404
City of Hope Comprehensive Cancer Center
Enrollment
Comment
Baseline
Genetic Markers
Tumor Serology
Lesion Evaluations
Logs: VS - Preg - CM - - TR
Physical Exam
All Specimens
PK/PD/PG
COVID-19 (1)
Course/Cycle 01
Lab: Hematology
Lab: Blood Chem - Hepatic
Visit
Date
Add Event
...
Add
Icon Key
CRF Version 4574 - Page Generated: 20 May 2022 14:39:37 Eastern Daylight Time

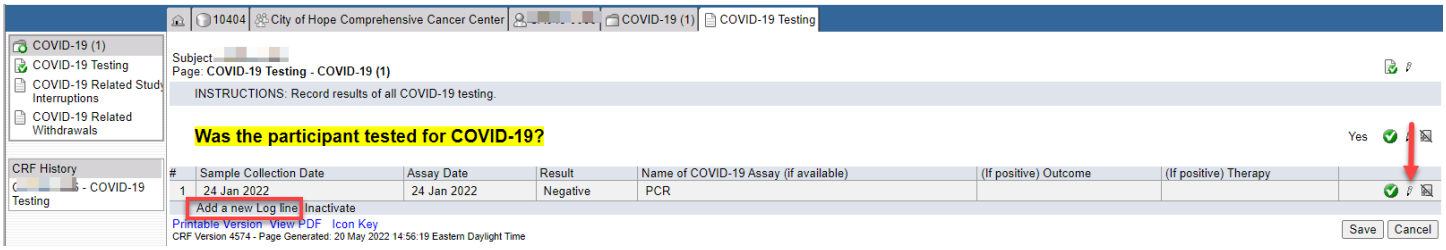
COVID-19 Testing

Requirements: None

Description: This form records all COVID-19 testing results.



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 results for additional tests, click Add a New Log line.



Fields

Was the participant tested for COVID-19?: If COVID-19 test results are available for the participant, choose Yes. If no test results are available, choose No.
Sample Collection Date: Date sample was collected.
Assay Date: Date COVID-19 assay was performed by testing lab.
Result: Select the result matching the lab report.
Name of COVID-19 Assay (if available): Transcribe commercial assay name from lab report, if available.
(If positive) Outcome: Choose from the following options -

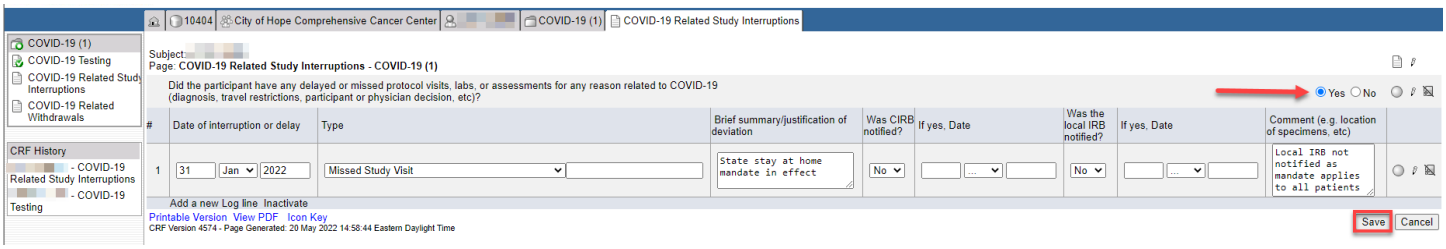
- **Recovered or Resolved**: Patient has fully recovered and exhibits no symptoms.
- **Recovered or Resolved with Sequelae**: Patient has fully recovered but still experiences some symptoms (i.e. "long COVID").
- **Fatal**: Patient is deceased as a result of their COVID-19 infection.
- **Unknown**: The state of the patient's recovery is unknown.

(If positive) Therapy: Transcribe therapy, if prescribed, from the patient's medical record.

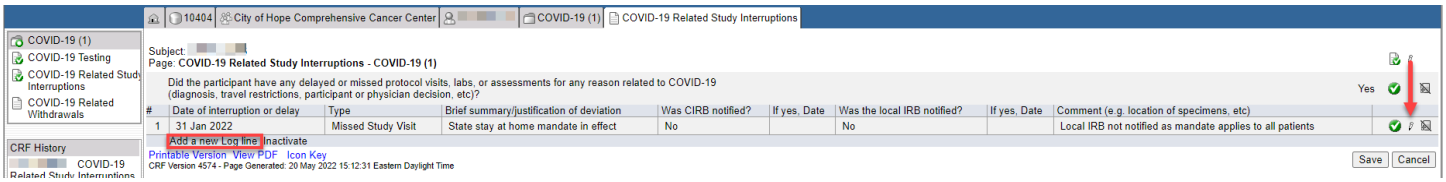
COVID-19 Related Study Interruptions

Requirements: None

Description: This form records all interruptions to the patient's protocol visits, labs, treatments, or assessments due to COVID-19.



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.



Fields

Did the participant have any delayed or missed protocol visits, labs, or assessments for any reason ...: If the patient experienced any deviation from the scheduled events of the protocol answer Yes and proceed to complete an entry in the log below, starting with the date. If not, select No.
Date of interruption or delay: Date of protocol deviation.
Type: Select the most appropriate type of deviation from the drop down menu.
Brief summary/justification of deviation: Provide a summary of protocol deviation.
Was CIRB notified?: If the Central IRB is notified of protocol deviation, enter yes. Otherwise, select No.
If yes, Date: Date CIRB was notified.
Was the local IRB notified?: If your site's local IRB is notified of protocol deviation, enter yes. Otherwise, select No.
If yes, Date: Date local IRB was notified.
Comment (e.g. location of specimens, etc.): Enter any comments relating to the study interruption.

COVID-19 Related Withdrawals

Requirements: None

Description: This form records the patient's withdrawal from protocol treatment, the study, and/or their consent for specimen use.

10404 | City of Hope Comprehensive Cancer Center | COVID-19 (1) | COVID-19 Related Withdrawals

COVID-19 (1)
COVID-19 Testing
COVID-19 Related Study Interruptions
COVID-19 Related Withdrawals

CRF History
- COVID-19 Related Withdrawals
- COVID-19 Related Study Interruptions
- COVID-19 Testing

Subject:
Page: **COVID-19 Related Withdrawals - COVID-19 (1)**

REMINDER: The Off Treatment, Off Study and/or Specimen Use Consent forms must be entered if the participant has withdrawn due to any reason related to COVID-19.

Did the participant withdraw from protocol treatment for any reason related to COVID-19 (diagnosis, travel restrictions, participant or physician decision, etc.)? — Yes / No

Off Treatment Date — 15 Feb 2022

Reason — Diagnosis of COVID-19 / Travel Restrictions / Participant Decision / Physician Decision / Other

If Other, specify

Did the participant withdraw from the study for any reason related to COVID-19 (diagnosis, travel restrictions, participant or physician decision, etc.)? — Yes / No

Off Study Date — 15 Feb 2022

Reason — Diagnosis of COVID-19 / Travel Restrictions / Participant Decision / Physician Decision / Other

If Other, specify

Did the participant withdraw consent for use of any study specimen for any reason related to COVID-19 (diagnosis, travel restrictions, participant or physician decision, etc.)? — Yes / No

Date of Withdrawal

(If Yes), Primary Reason for Withdrawing consent for specimen use for research on Study — Diagnosis of COVID-19 / Participant Decision / Other

If Other, specify

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Save Cancel

Fields

Did the participant withdraw from protocol treatment ... : If the patient has withdrawn from the assigned protocol treatment for any reason associated with the Covid-19 pandemic, select Yes. If not, select No.

If yes: **Off Treatment Date**: Date the patient discontinued assigned treatment.

Reason: Select most appropriate reason patient withdrew from treatment. If none apply, select Other.

If Other, specify: Provide a brief description of the reason patient withdrew from treatment.

Did the participant withdraw from the study ...: If the patient has withdrawn from the protocol for any reason associated with the Covid-19 pandemic, select Yes. If not, select No.

If yes: **Off Study Date**: Date the patient informed the site they wish to withdraw from the study.

Reason: Select most appropriate reason patient withdrew from the study. If none apply, select Other.

If Other, specify: Provide a brief description of the reason patient withdrew from the study.

Did the participant withdraw consent for use of any study specimen ... : If the patient has withdrawn their consent to use specimens collected on study for any reason associated with the Covid-19 pandemic, select Yes. If not, select No.

If yes: **Date of Withdrawal**: Date the patient notified the site of their withdrawal of consent.

(If Yes), Primary Reason: Select most appropriate reason patient withdrew consent for specimen use. If none apply, select Other.

If Other, specify: Provide a brief description of the reason patient withdrew consent for specimen use.