






**DATA SUBMISSION**  
FOR PRE-RAVE (LEGACY) AND RAVE STUDIES

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**PRE-RAVE**  
ACCESSING THE CRA WORKBENCH

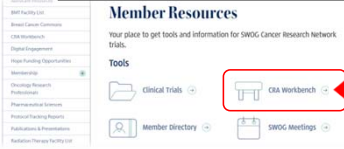




First, access [swog.org](http://swog.org) using your **CTEP-IAM** or with your **ID.me** credentials

**Member Resources**  
Your place to get tools and information for SWOG Cancer Research Network trials.

**Tools**

- Clinical Trials
- CRA Workbench**
- SWOG Meetings
- Member Directory

Then, under 'Member Resources', click the CRA Workbench icon






**DATA SUBMISSION**  
OVERVIEW

**Pre-Rave: Accessed via CRA Workbench**

- Also known as Chart Manager or the "Legacy" system
- We use this for SWOG studies activated prior to April 2012

**Medidata Rave EDC**

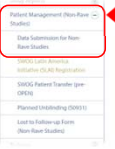




- Used for studies activated after April 2012
- Currently used for most SWOG studies

**PRE-RAVE**  
NAVIGATING TO NON-RAVE (LEGACY) STUDIES






Next, locate the 'Patient Management (Non-Rave Studies)' option in the left-hand menu

Expand the 'Patient Management (Non-Rave Studies)' menu by clicking the + icon.  
Next, click the 'Data Submission for Non-Rave Studies' option below. Easy!

**PRE-RAVE**  
OVERVIEW

- Accessing a SWOG Pre-Rave study
- Navigating Pre-Rave studies
- Pre-Rave form submission
- Pre-Rave expectations and queries

**PRE-RAVE**  
PATIENT LOOKUP MENU

Look up 1 - 4 specific patients

- Search for one patient, or up to four

Look up a list of patients by one or more of the following:

- This is your SEARCH function to help you narrow down your results

**Look up 1-4 specific patients**

SWOG Patient Number(s):

**Look up a list of patients by one or more of the following:**

Study Number:

CTEP Investigator ID:

To lookup a CTEP Investigator ID, go to [swog.org](http://swog.org), click the RAVE tab, then the CTEP ID Search tab.






CTEP Institution ID (e.g., N00003):

☐ Show only active patients

☐ Show only patients with unmet expectations

☐ Show only patients with outstanding queries

Note: Institutions that return many records can take several minutes to process.

## PRE-RAVE

### PATIENT REGISTRATION STEP SELECTION

SWOG Patient No.:  SWOG Study No.: S1007 Reg Step: 2 Patient Initials (L,F,M):

Click on the desired patient number at left

After entering the appropriate SWOG Patient Number(s)...

- Click the patient hyperlink to enter/view data for the appropriate Registration Step.
- Make sure you're selecting the appropriate step!

## PRE-RAVE

### Forms: On Treatment

SWOG Patient No.:  SWOG Study No.: S1007 Reg Step: 2 Patient Initials (L,F,M):

Click on the desired patient number at left

Clicking 'S1007 Treatment Form' will start a new treatment form

View previously submitted forms only

## PRE-RAVE

### Patient Info

SWOG Patient No.:  SWOG Study No.: S1007 Reg Step: 2 Patient Initials (L,F,M):

Click on the desired patient number at left

Registration Date: 4/17/2014

Registering Institution:

Following Institution:

Registering Investigator:

Status: Alive Last Contact Date: 10/26/2023

Refresh this page to see updates reflected.

## PRE-RAVE

### Forms: Follow-Up

SWOG Patient No.:  SWOG Study No.: S1007 Reg Step: 2 Patient Initials (L,F,M):

Click on the desired patient number at left

Clicking 'S1007 Follow Up Form' will start a new Follow Up Form

These links have been inactivated

## PRE-RAVE

### Forms: Baseline

SWOG Patient No.:  SWOG Study No.: S1007 Reg Step: 2 Patient Initials (L,F,M):

Click on the desired patient number at left

Baseline Forms

Click to complete or amend

Date Submitted

Click to view confirmation

S1007 Prestudy Form - Randomized Study 5/12/2015

## PRE-RAVE

### Expectations

SWOG Patient No.:  SWOG Study No.: S1007 Reg Step: 2 Patient Initials (L,F,M):

Click on the desired patient number at left

Expectations Report: ☐ Current Expectations ☐ All Expectations

Patient	Initials	Study	Institution	CTEP ID	Investigator	Reg Date	Last Contact Date	Status	Due date	Expectation	Days Overdue	IPR
						11/30/2023	02/15/2024	A	03/07/2024	Vital Status (On Treatment) Form/Period beginning 02/15/2024	1	

Click here for a printer-friendly version of this report.

## PRE-RAVE

### Queries

SWOG Patient No.:  SWOG Study No.: S1007 Reg Step: 2 Patient Initials (L.F.M.):

**Patient Info Forms Expectations Checklist**

The following queries require your response as soon as possible. If the query is for an online amendable form please make those changes online. If the query is for data that is not available to amend online, please submit the requested data by fax without a cover sheet to the SWOG Data Operations Center at 855-852-4537. PLEASE NOTE: Even if you don't have corrections for every page of a form that prints out, please send ALL pages of the form and include patient initials and SWOG patient number on every page.

The query will display on both the queries tab and query report until you have responded to the request and clicked the 'Resolved' button below.

Any questions should be directed to the Data Coordinator for this study at 206-652-2267. If the Note Type says 'CRA' or 'ELG', these are for informational purposes only and do not necessarily require your response. CRA notes may be removed by clicking the 'Acknowledged' button.

Please Note: Replies written on a printout of this page are NOT acceptable documentation.

S1007 Data Coordinator: Larry G. Kaye

Note Date	Author	Note Type	Note
2/2/2024	KIM	REG	Please amend the Off Treatment Data on the Off Treatment Notice. The Off Treatment Data should be listed as 5 years from their randomization date of 4/1/2014. See Sec. 7.8.b.

**Resolved**

## RAVE

### Access

Invitations to join studies will be listed here as well as any outstanding eLearning requirements!

This is your list of studies to choose from, use the arrows at the bottom to scroll through.

## RAVE

### Overview

**medidata**

- Rave Access
- Organization
- Data Submission
- Queries
- Amending Data
- Resources

## RAVE

### Organization

- Rave is organized by study
- There are no cross-study functions, only one study can be viewed at a time
- The tabs across the top of the page increase in specificity from left to right

Home Study Participant Folder Form

AL LUNGMAP CTSUTST01 703897 Baseline Onstudy: Patient and Disease Description

Patient ID: 703897 Enrollment Date: 31 Oct 2015

Subject: 703897

Page: Onstudy: Patient and Disease Description - Baseline

## RAVE

### Access

- Invitations are sent upon initial site registration approval in the CTSU Regulatory Support System (RSS)
  - Sent to all persons with "Rave CRA" role on SWOG Roster
  - Only Head CRA's identified as "Rave CRA" by default
  - Request role modifications from Head CRA
- If necessary, make sure you're on the Delegations of Tasks Log (DTL) and that your DTL is up to date
- Logon using Rave username and password
- Accept invitations to studies
- Satisfy eLearning requirements

Questions about getting started with CTSU?  
[https://www.ctsu.org/radfile.aspx?name=/public/Getting\\_Started\\_With\\_the\\_CTSU.pdf](https://www.ctsu.org/radfile.aspx?name=/public/Getting_Started_With_the_CTSU.pdf)

## RAVE

### Organization

Participants registered to the study at this site

View patients with outstanding tasks

Helpful tool on every page

## RAVE Organization

The screenshot shows the RAVE Organization page for subject 710266. On the left is a sidebar with a list of folders including Enrollment Forms, NCI Reporting, and various assessment forms. The main area displays a table of tasks with columns for 'Task Summary - Subject', 'Due Date', and 'Pages'. Red boxes highlight the 'Due dates within folders' and 'Tasks specific to this participant' sections. A red box also highlights the 'Add Error' button and the 'Drop-down menu to add certain forms'.

## RAVE Organization

The diagram illustrates the hierarchy of RAVE forms. It starts with 'Disease Assessment' leading to 'Baseline Tumor Assessment'. This then branches into 'Follow-up Tumor Assessment' and 'Baseline Tumor: Target Lesions'. 'Baseline Tumor: Target Lesions' further branches into 'Baseline Tumor: Non-target Disease' and 'Follow-up Tumor: Target Lesions'. 'Follow-up Tumor: Target Lesions' branches into 'Follow-up Tumor: Non-target Disease' and 'Source Documentation: Follow-up'.

## RAVE Organization

The screenshot compares the 'PAPER VERSION' and 'RAVE VERSION' of the 'Baseline Tumor Assessment' form. The 'PAPER VERSION' is a standard paper form with checkboxes and text fields. The 'RAVE VERSION' is a digital form with a more structured layout, including a 'Form Entry' section and a 'Form Labels' section. Red boxes highlight the 'PAPER VERSION' and 'RAVE VERSION' labels.

## RAVE Organization

### Rave Form Display Document

- Found on [ctsu.org](https://ctsu.org) study page in the **Master Forms Set**
- Lists all forms and when they appear

Paper Form	What is the form called in Rave?	Where can I find the form in Rave?	When does the form show up in Rave?
Baseline Tumor Assessment Form (BCTF 1.0)	Baseline Tumor Assessment	Disease Assessment	The Baseline Tumor Assessment form appears after the patient is registered in RAVE. If an RAVE form "Does the patient have target lesions?" is Yes, the Baseline Tumor: Target Lesions form will appear. If the patient has non-target disease, the Baseline Tumor: Non-target Disease form will appear.
Follow-up Tumor Assessment Form (FCTF 1.0)	Follow-up Tumor Assessment	Follow-up Tumor Assessment	The Follow-up Tumor Assessment form first appears after the Baseline Tumor Assessment form is submitted. If an RAVE form "Does the patient have target lesions?" is Yes, the Follow-up Tumor: Target Lesions form will appear. If an RAVE form "Does the patient have non-target disease?" is Yes, the Follow-up Tumor: Non-target Disease form will appear.
Source Documentation: Follow-up	Source Documentation: Follow-up	Source Documentation: Follow-up	The Source Documentation: Follow-up form is submitted after the Follow-up Tumor Assessment form is submitted. The form can be added to the "Add Form" dropdown on the subject page.

## RAVE Organization

The screenshot shows the RAVE Organization page for subject 710266. On the left is a sidebar with a list of folders including Enrollment Forms, NCI Reporting, and various assessment forms. The main area displays a table of tasks with columns for 'Task Summary - Subject', 'Due Date', and 'Pages'. Red boxes highlight the 'Due dates within folders' and 'Tasks specific to this participant' sections. A red box also highlights the 'Add Error' button and the 'Drop-down menu to add certain forms'.

## RAVE Organization

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## RAVE

### Data Submission

Source Documentation (cont.)

Instructions: Use this form to upload copies from all Baseline procedures performed, as required per protocol.

Please ensure all source documents are properly and completely redacted and free of PHI before uploading to Rave. Using a black pen or marker only write what the image is photographed and the physician's name and/or initials. Other words to include: date/time, location, meeting notes, covering PHI with white or opaque tape, black correction tape, white-out or cutting out the identifying and other the vignette. Quotes will be generated by software longer when PHI is still visible. Please also ensure that the names on uploaded documents are free of any special characters (i.e., &, %, & #, & #, & #).

#	Date of procedure	Type of procedure	Upload document?	Comments
1	10 Jan 2019	CT Scan	<input checked="" type="checkbox"/>	

If you're not done completing this form, but want to save your work for later, click the Save button and click the Save button. Note that you can only save this form, but don't submit to SWOG yet.

Save this form, but don't submit to SWOG yet.

Print Version View PDF Save Key

SWOG Version 2.0.1.1 Page Generated: 10 Nov 2018 10:00:00 Pacific Standard Time

Save Cancel

## RAVE

### Data Submission: Conditional Field Display

Instructions: Please read the questions on this form to the patient and enter her/his response.

1. Have you smoked at least 100 cigarettes in your ENTIRE LIFE? Yes ☒ No ☐

If YES, PLEASE ANSWER THE FOLLOWING QUESTIONS:

2. How long has it been since you last smoked a cigarette (even one or two puffs)?

3. How many total years have you smoked (or did you smoke) cigarettes?

4. On average when you have smoked, about how many cigarettes do you (or did you) smoke a day? Enter "1" if less than 1. Enter "50" if 50 or more cigarettes.

Comments

## RAVE

### Data Submission

Non-Conformant Data

Instructions: Use this form to upload copies from all Baseline procedures performed, as required per protocol.

Please ensure all source documents are properly and completely redacted and free of PHI before uploading to Rave. Using a black pen or marker only write what the image is photographed and the physician's name and/or initials. Other words to include: date/time, location, meeting notes, covering PHI with white or opaque tape, black correction tape, white-out or cutting out the identifying and other the vignette. Quotes will be generated by software longer when PHI is still visible. Please also ensure that the names on uploaded documents are free of any special characters (i.e., &, %, & #, & #, & #).

#	Date of procedure	Type of procedure	Upload document?	Comments
1	10 Jan 2019	CT Scan	<input checked="" type="checkbox"/>	

If you're not done completing this form, but want to save your work for later, click the Save button and click the Save button. Note that you can only save this form, but don't submit to SWOG yet.

Save this form, but don't submit to SWOG yet.

Print Version View PDF Save Key

SWOG Version 2.0.1.1 Page Generated: 10 Nov 2018 10:00:00 Pacific Standard Time

Save Cancel

NON-CONFORMANT DATA ICON

## RAVE

### Data Submission: Conditional Field Display (cont.)

Instructions: Please read the questions on this form to the patient and enter her/his response.

1. Have you smoked at least 100 cigarettes in your ENTIRE LIFE? Yes ☒ No ☐

If YES, PLEASE ANSWER THE FOLLOWING QUESTIONS:

2. How long has it been since you last smoked a cigarette (even one or two puffs)?

3. How many total years have you smoked (or did you smoke) cigarettes?

4. On average when you have smoked, about how many cigarettes do you (or did you) smoke a day? Enter "1" if less than 1. Enter "50" if 50 or more cigarettes.

Comments

## RAVE

### Data Submission

Conditional Field Display

Rave is programmed to show certain fields and forms depending on the data that is entered.

## RAVE

### Data Submission: Sticky Notes

This form is saved. Scroll down the form to look for queries, sticky notes, and/or new fields. Data are sent to SWOG when all system queries are resolved. After data are sent, expectations will be resolved the next business day.

Subject: 785677

Page: Brain Metastases - Baseline

Instructions: Submit this form if patient had brain metastases.

Is patient asymptomatic? Yes ☒ No ☐

Is patient asymptomatic with no residual neurological dysfunction? Yes ☒ No ☐

Date of last assessment: 12 Nov 2018

When was the last time patient received corticosteroids for management of their brain metastases?

Date: 05 Jul 2018

Time: 12:00 PM MDT (24-hour format)

19 Oct 2018

Sticky Note: Date of last CT/MRI brain: Please upload radiology report from CT/MRI via the Source Documentation - Baseline folder. (Optional: To view from System: 05 Nov 2018)



## RAVE

### Data Submission: Manual Queries

Assessment Date

Response to query here

## RAVE

### CRA Workbench Reports: Query Reports

## RAVE

### Data Submission: Manual Queries

## RAVE

### Resources

<p>Rave Studies <b>YES</b></p> <ul style="list-style-type: none"> <li>• Link to OPEN</li> <li>• Link to Rave</li> <li>• Link to Specimen Tracking</li> <li>• Expectation report</li> <li>• IPR report</li> <li>• Queries report</li> <li>• Ineligible patients report</li> <li>• Training slides/documents</li> </ul>	<p>Rave Studies <b>NO</b></p> <ul style="list-style-type: none"> <li>• Data/Form Submission</li> <li>• Query resolution</li> </ul>
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## RAVE

### Data Submission: Queries and Rave Task Summary

System queries and manual queries will be listed in Rave's Task Summary

- Study level
- Site level
- Subject level

## RAVE

### Resources

CTSU Help Desk  
9:30 am – 8:30 pm EST  
1-888-823-5923  
[ctsucontact@westat.com](mailto:ctsucontact@westat.com)

Multiple Resources

- Links provided in Rave at the bottom left, including CTSU contact information

Resources:

- BSA Calculator
- Calculated Creatinine Clearance Formula and Calculator
- CTEP AERS
- CTSU Technical Support**
- OPEN Patient Registration
- SWOG CRA Workbench
- SWOG Home Page
- SWOG Specimen Tracking System



 SWOG  
SOUTHERN WESTERN  
ONCOLOGY GROUP

## Thank you!

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### Questions?



SWOG Statistics and Data Management Center (Seattle, WA)  
(206) 652-2267  
[BreastQuestion@crab.org](mailto:BreastQuestion@crab.org)  
[CancerControlQuestion@crab.org](mailto:CancerControlQuestion@crab.org)  
[GIQuestion@crab.org](mailto:GIQuestion@crab.org)  
[GUQuestion@crab.org](mailto:GUQuestion@crab.org)  
[GYQuestion@crab.org](mailto:GYQuestion@crab.org)  
[LeukemiaQuestion@crab.org](mailto:LeukemiaQuestion@crab.org)  
[LungQuestion@crab.org](mailto:LungQuestion@crab.org)  
[LungMAPQuestion@crab.org](mailto:LungMAPQuestion@crab.org)  
[LymphomaQuestion@crab.org](mailto:LymphomaQuestion@crab.org)  
[MelanomaQuestion@crab.org](mailto:MelanomaQuestion@crab.org)  
[MyelomaQuestion@crab.org](mailto:MyelomaQuestion@crab.org)  
[RareTumors@crab.org](mailto:RareTumors@crab.org)

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 NCI  
Community Research  
Network Program