


**SWOG** Supporting Cancer Research

## Data Submission

Pre-Rave (Legacy) and Rave Studies

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 Cancer Research and Biostatistics



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## 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



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## Pre-Rave

### Overview

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



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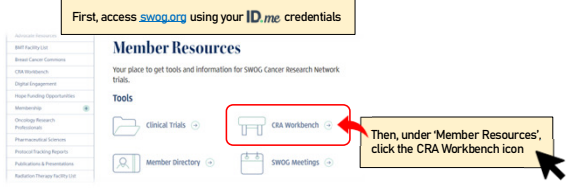
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## Pre-Rave

### Accessing the CRA Workbench

First, access [swog.org](http://swog.org) using your [ID.me](#) credentials



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

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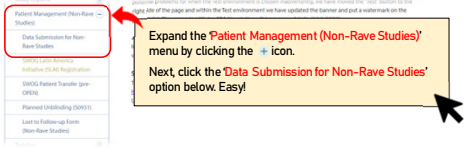
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## Pre-Rave

### Navigation 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!

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## Pre-Rave


### Patient Lookup Menu

[CRA Workbench Home](#)

Look up 1-4 specific patients

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

- Search for one patient, or up to four
- This is your SEARCH function to help you narrow down your results



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### Pre-Rave

#### Patient Registration Step Selection

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!

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### Pre-Rave

#### Patient Info

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

**Patient Info** Forms Expectations Queries

You have outstanding queries requiring your response! Please click on the 'Queries' tab above.

Registration Date: 4/17/2014  
 Registering Institution: [input] Following Institution: [input]  
 Registering Investigator: [input] Following Investigator: [input]

Status: Active Last Contact Date: 10/26/2023  
 Refresh this page to see updates reflected.

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### Pre-Rave

#### Forms: Baseline

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

**Patient Info** **Forms** Expectations Queries

**Baseline** On Treatment Follow-up QOL COVID-19

Refresh This page to see updates reflected

Baseline Forms  
 Click to complete or amend

Date Submitted  
 Click to view confirmation

S1007 Presudy Form - Randomized Study 5/12/2015

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### Pre-Rave

#### Forms: On Treatment

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

**Patient Info** **Forms** Expectations Queries

**Baseline** **On Treatment** Follow-up QOL COVID-19

Refresh This page to see updates reflected

On Treatment Forms  
 Click to complete or amend

S1007 Treatment Form  
 Baseline Period = 0.0 months (L case) 5/22/2023  
 Baseline Period = 0.0 months (R case) 5/22/2023  
 Baseline Period = 2.0 months 5/22/2023  
 Baseline Period = 2.0 months (L case) 5/22/2023  
 Baseline Period = 2.0 months (R case) 5/22/2023  
 Baseline Period = 4.0 months 5/22/2023  
 Baseline Period = 4.0 months (L case) 5/22/2023  
 Baseline Period = 4.0 months (R case) 5/22/2023  
 S1007 Adverse Event Summary Form 5/22/2023  
 S1007 Observation Form 5/22/2023  
 S1007 Radiation Therapy Form 5/22/2023

View previously submitted forms only

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

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### Pre-Rave

#### Forms: Follow-Up

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

**Patient Info** **Forms** Expectations Queries

**Baseline** **On Treatment** **Follow-up** QOL COVID-19

Refresh This page to see updates reflected

Follow-up Forms  
 Click to complete or amend

S1007 Follow-up Form  
 Date of Evaluation = 12/15/2023 12/15/2023  
 Date of Evaluation = 12/15/2023 12/15/2023  
 Date of Evaluation = 12/15/2023 12/15/2023  
 Initial of Death

Follow-up Form (Do not use these links to submit new data. These should only be used to edit or amend previously submitted forms.)  
 S1007 Supplementary Follow-up Form (Do not use these links to submit new data. These should only be used to edit or amend previously submitted forms.)

These links have been inactivated!

Clicking 'S1007 Follow-up Form' will start a new Follow-up Form

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### Pre-Rave

#### Expectations

SWOG Patient No.: [input] SWOG Study No.: S1007 Reg Step: 1 Patient Initials (L.F.M): [input]

**Patient Info** **Forms** **Expectations** Queries

Expectations Report: Current Expectations All Expectations GO

Ptno	Initials	Study	CTEPID	Investigator	RegDate	Last Contact Date	Status	Due date	Expectation Qualifier	Days Overdue	IPR
					11/30/2023	02/15/2024	A	03/07/2024	Vital Status (On Treatment) Form/Period beginning 02/16/2024	1	
									Adverse Event Form/Period beginning 02/16/2024	1	

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

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**Rave Organization**

Subject Enrollment

Task	Date	Task Summary - Subject	Pages
Baseline Update (1)	15 May 2020	⚙️ Non-Certified Data	0/1
Baseline	26 Jun 2019	📄 Open Queries	0/1
Follow-up	26 Sep 2019	📄 Study Notes	0/1
Death (1)	24 Feb 2020	📄 Overview Data	0/1

Annotations: "Due dates within folders", "Tasks specific to this participant", "Drop-down menu to add certain forms", "Forms and folders".

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**Rave Organization**

SWOG LIVERPOOL ONCOLOGY FORMS

Form Version Selection

Annotations: "PAPER VERSION", "RAVE VERSION".

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**Rave Organization**

Baseline Tumor Assessment - Disease Assessment

Form Fields:

- Does the patient have non-measurable disease? (Yes/No)
- Was PET/CT imaging performed for disease assessment? (Yes/No)
- Was bone marrow biopsy performed? (Yes/No)
- Is the patient's bone marrow disease visualized only by PET scan? (Yes/No)

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**Rave Organization**

Flowchart showing relationships between forms:

- Disease Assessment (parent)
- Baseline Tumor Assessment (child)
- Follow-up Tumor Assessment (child)
- Baseline Tumor: Target Lesions (child)
- Baseline Tumor: Non-target Disease (child)
- Follow-up Tumor: Target Lesions (child)
- Follow-up Tumor: Non-target Disease (child)
- Source Documentation: Follow-up (child)

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**Rave Organization**

Rave Form Display Document

Form Name	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 (R007 3.1)	Baseline Tumor Assessment	Disease Assessment Folder	The Baseline Tumor Assessment form appears after the patient is registered in OPEN. If the form "Does the patient have target lesions" = Yes, the Baseline Tumor: Target Lesions form will appear. If "Does the patient have non-target disease" = Yes, the Baseline Tumor: Non-target Disease form will appear.
Follow-up Tumor Assessment Form (R007 3.1)	Follow-up Tumor Assessment	Follow-up Tumor Assessment Folder	The Follow-up Tumor Assessment form first appears after the Baseline Tumor Assessment form is submitted. If the form "Does the patient have target lesions" = No, the Follow-up Tumor: Target Lesions form will appear. If the form "Does the patient have non-target disease" = Yes, the Follow-up Tumor: Non-target Disease form will appear.
N/A	Source Documentation: Follow-up	Follow-up Tumor Assessment sub-folders	This form appears after the Follow-up Tumor Assessment form is updated. This form is required for the Source Documentation: Follow-up form to update the follow-up sub-folder with the form for the most appropriate.
Off Treatment Notice	Off Treatment Notice	Off Treatment Folder	This form appears after the Treatment Assessment form is submitted with "Yes the patient progressed per the definition of effect 3.0 of the protocol" = Yes or "No the patient continues to receive protocol therapy" = No. This form also appears any time by using the "Add Event" dropdown on the Subject tab.

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**Rave Organization**

Participant and Disease Description - Baseline

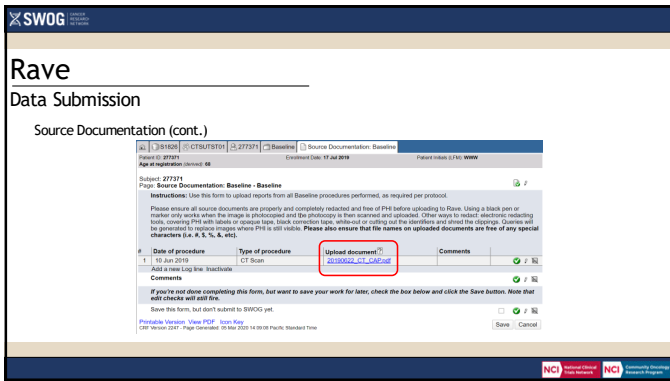
Form Fields:

- Performance Status
- Height (cm)
- Weight (kg)
- Systolic Blood Pressure (mmHg)
- Diastolic Blood Pressure (mmHg)
- What was the date of the most recent blood pressure?
- What was the date of the history and physical exam?

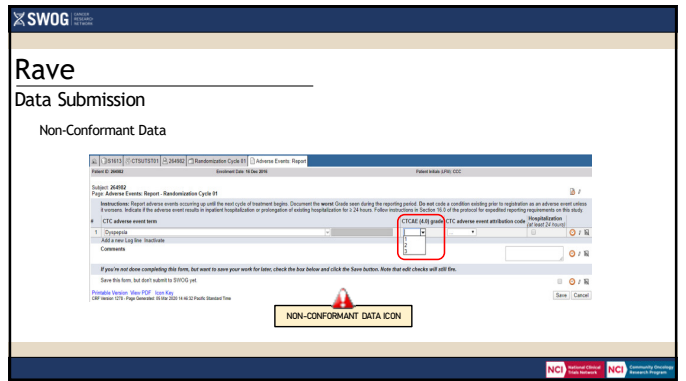
Annotations: "Status Icon", "Field Entry", "Field Labels".

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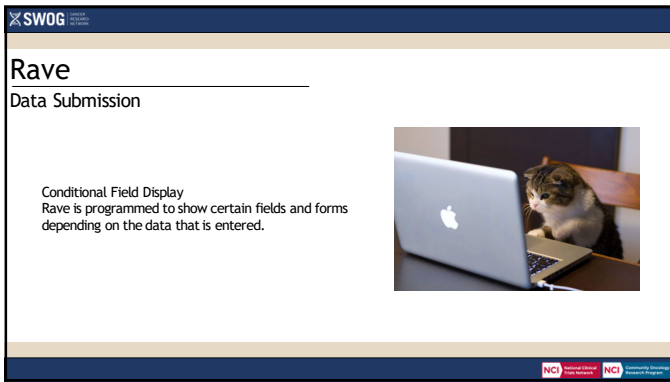




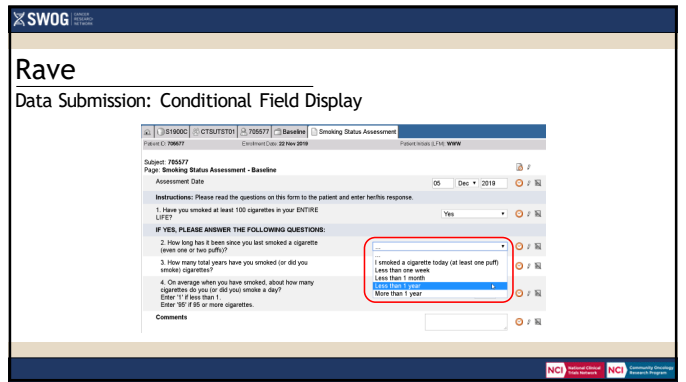
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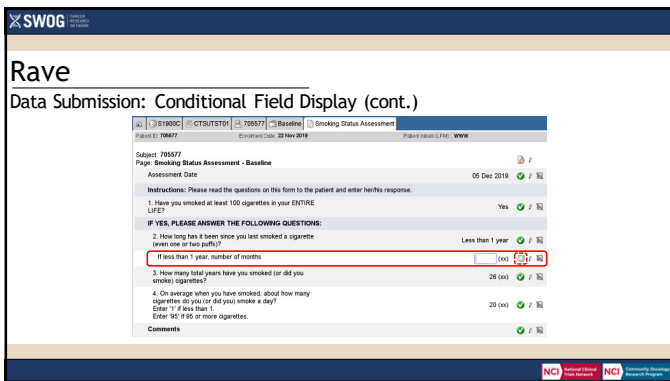
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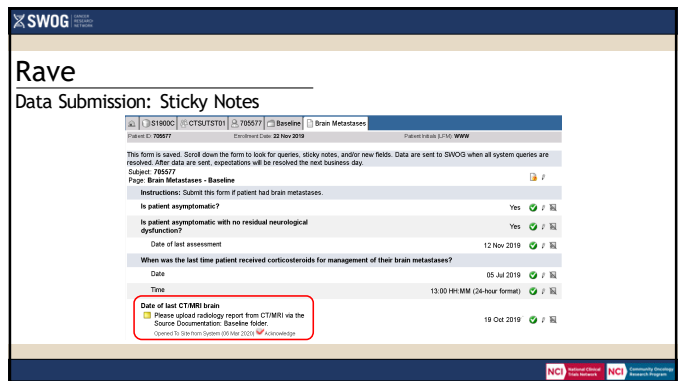
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**Rave**  
Data Submission: Query Resolution & Amending Data

System Generated Query: This field is required. Please complete.

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**Rave**  
Data Submission: Query Resolution & Amending Data (cont.)

New Information: Data entered is non-conformant (invalid format). Please correct.

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**Rave**  
Data Submission: Query Resolution & Amending Data (cont.)

Special System Query: Save without submitting

- The bottom of every form has a "Save without submitting" checkbox
- An edit check requiring the box to be unchecked will fire a query
- Edit checks will run on other fields as well

If you're not done completing this form, but want to save your work for later, check the box below and click the Save button. Note that edit checks will still fire.

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**Rave**  
Data Submission: Query Resolution & Amending Data (cont.)

Save this form, but don't submit to SWOG yet. This box must be unchecked for submission of this form to SWOG.

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**Rave**  
Data Submission: Query Resolution & Amending Data (cont.)

DC Generated Query: Was a Smoking Status Assessment done prior to registration? If so, please amend to the date of the most recent assessment prior to registration and amend date currently entered as appropriate.

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**Rave**  
Data Submission: Manual Queries

DC Generated Query: Was a Smoking Status Assessment done prior to registration? If so, please amend to the date of the most recent assessment prior to registration and amend date currently entered as appropriate.

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### Rave

#### Data Submission: Manual Queries

Study: S1900C | CTSU/STDI | 705577 | Baseline | Smoking Status Assessment

Subject: 705577  
Page: Smoking Status Assessment - Baseline

Assessment Date:

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

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### Rave

#### Data Submission: Manual Queries

Study: S1900C | CTSU/STDI | 705577 | Baseline | Smoking Status Assessment

Subject: 705577  
Page: Smoking Status Assessment - Baseline

Assessment Date: 20 Nov 2019

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

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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

Task Summary: Site	Subjects	Task Summary: Subject	Pages
NonConformant Data	1	NonConformant Data	0
Open Queries	8	Open Queries	2
240511		Cycle-Treatment	
240525		Cycle-Adverse Events: Report	
240530		Sticky Notes	1
240533		Overdue Data	0
240543			
240545			
240526			
240596			
Sticky Notes	10		
Overdue Data	0		

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### Rave

#### CRA Workbench Reports: Query Reports

Filter Criteria: Show only patient #, Show only study #, Show only investigator #, Disease Type: ALL

Data Management Institution: VINCIA COOP (907)  
Follow-up Institution: VINCIA COOP (907)

ID	Study	Site	Baseline	Study	Report	Author	Query
240502	F.L.I.	Scale	01111 - Baseline	Study: Patient and Clinician	Report: Patient and Clinician	Author: [Name]	Query: [Text]
240503	F.L.I.	Scale	01111 - Baseline	Study: Patient and Clinician	Report: Patient and Clinician	Author: [Name]	Query: [Text]

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### Rave

#### Resources

- Link to Rave
- Link to OPEN
- Link to Specimen Tracking
- Expectation report
- IPR report
- Queries report
- Ineligible patients report
- Training slides/documents

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### Rave

#### Resources

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

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**SWOG** Survivor of War  
Oncology Group

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# Thank you!

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)  
[GYNQuestion@crab.org](mailto:GYNQuestion@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)

