Data Submission Pre-Rave & Rave

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SWOG STATISTICS AND DATA MANAGEMENT CENTER (SDMC)

Overview

Pre-Rave: CRA Workbench
- Also known as Chart Manager or the Legacy System
- Used for studies activated prior to April 2012
- Currently in use for 29 SWOG studies

Rave
- Used for studies activated after April 2012
- Currently in use for 58 SWOG studies

Pre-Rave

CRA Workbench: Overview

Access

Organization

Data Submission

Amending Data

Query Resolution

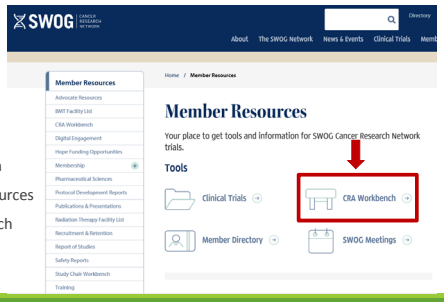
CRA Workbench: Access

SWOG.org

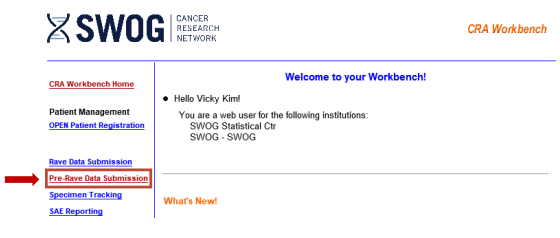
Member Login

Member Resources

CRA Workbench



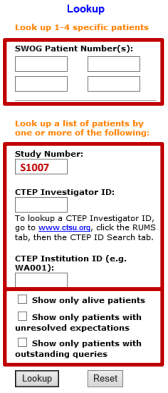
CRA Workbench: Access



Up to 4 specific patients

List of patients
- By Study
- By following CTEP investigator ID
- By CTEP institution ID

Filters
- Only show alive patients
- Only show patients with unresolved expectations
- Only show patients with outstanding queries

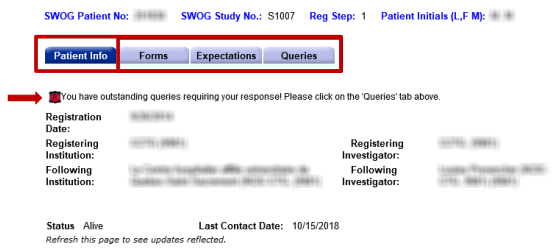


Lookup results
- Select individual patient chart

Arranged by patient number

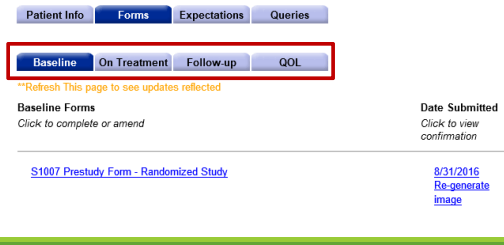
CRA Workbench: Organization

Default tab = Patient Info

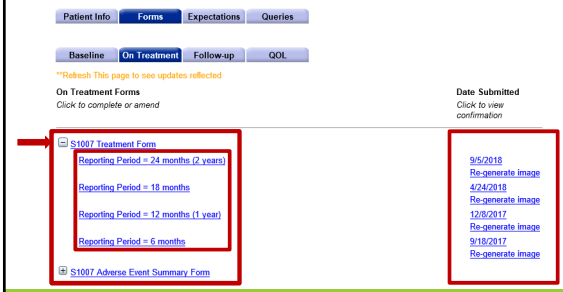


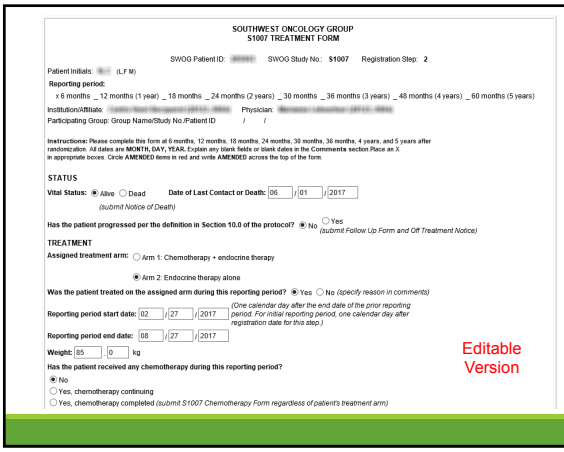
CRA Workbench: Organization

Forms tab has up to 5 sub-tabs



CRA Workbench: Submit Data





Submitted successfully on 2/26/2019 5:49:34 AM. Thank you, [redacted]
The data on this form may be amended by selecting the editable version of the form from the respective Forms tab.

SOUTHWEST ONCOLOGY GROUP
S1007 TREATMENT FORM

SWOG Patient ID: [redacted] SWOG Study No.: S1007 Registration Step: 2

Patient Initials: [redacted] (L,F M)

Reporting period:
x 6 months _ 12 months (1 year) _ 18 months _ 24 months (2 years) _ 30 months _ 36 months (3 years) _ 48 months (4 years) _ 60 months (5 years)

Institution/Affiliate: [redacted] Physician: [redacted]
Participating Group: Group Name/Study No./Patient ID / /

Instructions: Please complete this form at 6 months, 12 months, 18 months, 24 months, 30 months, 36 months, 4 years, and 5 years after randomization. All dates are MONTH, DAY, YEAR. Explain any blank fields or blank dates in the Comments section.Place an X in appropriate boxes. Circle AMENDED items in red and write AMENDED across the top of the form.

STATUS

Vital Status: X Alive _ Dead Date of Last Contact or Death: 06 / 01 / 2017
(submit Notice of Death)

Has the patient progressed per the definition in Section 10.0 of the protocol? X No _ Yes (submit Follow Up Form and Off Treatment Notice)

TREATMENT

Assigned treatment arm: _ Arm 1: Chemotherapy + endocrine therapy
X Arm 2: Endocrine therapy alone

Was the patient treated on the assigned arm during this reporting period? X Yes _ No (specify reason in comments)

Reporting period start date: 02 / 27 / 2017 (One calendar day after the end date of the prior reporting period. For initial reporting period, one calendar day after registration date for this step.)

Reporting period end date: 08 / 27 / 2017

Weight: 85 . 0 kg

Has the patient received any chemotherapy during this reporting period?
X No
_ Yes, chemotherapy continuing
_ Yes, chemotherapy completed (submit S1007 Chemotherapy Form regardless of patient's treatment arm)

Confirmation Page

CRA Workbench: Amend Data

Patient Info | Forms | Expectations | Queries

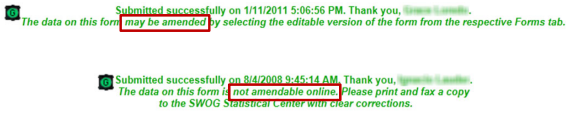
Baseline | On Treatment | Follow-up | QOL

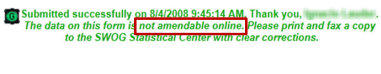
**Refresh This page to see updates reflected

On Treatment Forms *Click to complete or amend*	Date Submitted *Click to view confirmation*
S1007 Treatment Form	
Reporting Period = 24 months (2 years)	9/5/2018 Re-generate image
Reporting Period = 18 months	4/24/2018 Re-generate image
Reporting Period = 12 months (1 year)	12/8/2017 Re-generate image
Reporting Period = 6 months	9/18/2017 Re-generate image
S1007 Adverse Event Summary Form	

CRA Workbench: Amend Data

Confirmations will indicate if the data are amendable online or not

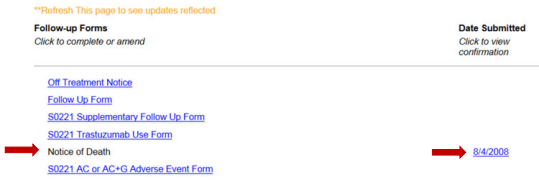

Submitted successfully on 1/11/2011 5:06:56 PM. Thank you, [redacted].
The data on this form may be amended by selecting the editable version of the form from the respective Forms tab.


Submitted successfully on 8/4/2008 9:45:14 AM. Thank you, [redacted].
The data on this form is not amendable online. Please print and fax a copy to the SWOG Statistical Center with clear corrections.

Not Amendable Online

Older studies may have some forms that are not amendable online

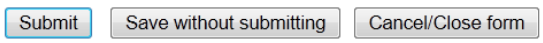
Instead, print the confirmation, make changes, and fax to SDMC



Data Submission

Complete or amend applicable fields on the form

Button options:



Edit Checks

Errors (red light) must be fixed before form can be submitted

- *Date of Last Contact or Death* is prior to the date of registration to this study and registration step.
- *Cycle Start Date* is prior to the date of registration to this study and registration step.
- *Date of Last Treatment for This Cycle* must be on or after Cycle Start Date.
- *Date of Last Treatment for This Cycle* must be on or before Date of Last Contact or Death.

Edit Checks

Warnings (yellow light) must be acknowledged before form can be submitted

Serum Creatinine Collection Date is after the registration date to this study and registration step.
Urine Protein/Creatinine Ratio is necessary for eligibility verification and should not be left blank.

Warning (s) OK as is. Explain in comments.

Edit Checks

Green light means successful submission

Submitted successfully on 2/17/2011. Thank you,
The data on this form may be amended by selecting the editable version of the form from the respective Forms tab.

CRA Workbench: Queries

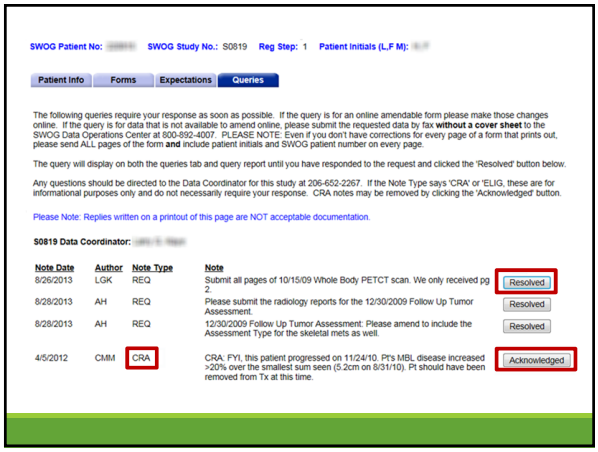
Data Coordinators evaluate submitted data for
- Eligibility
- Study compliance
- Response assessment
- Off treatment decision
- Serious adverse events (SAE)
- Death circumstances

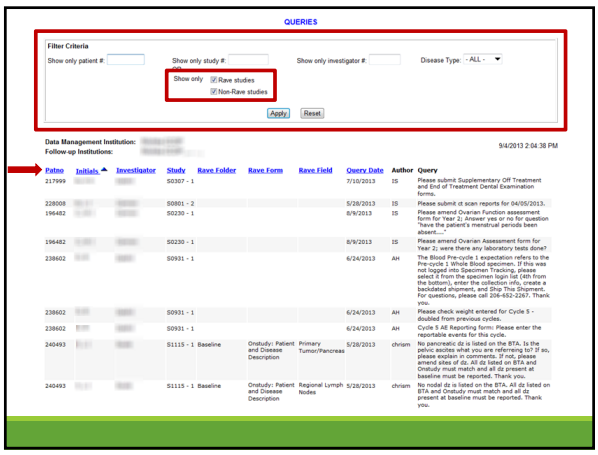
Queries are written to clarify or correct missing or inconsistent data

Query Resolution

Queries can be found in two places

- Pre-Rave Data Submission → Queries tab (patient-specific)
- Reports → Query Reports (site-specific, across all studies and patients)





Switching to Rave…

Rave

Rave: Overview

Access
Organization
Data Submission
Query Resolution/Amending Data
Resources

Rave: Access

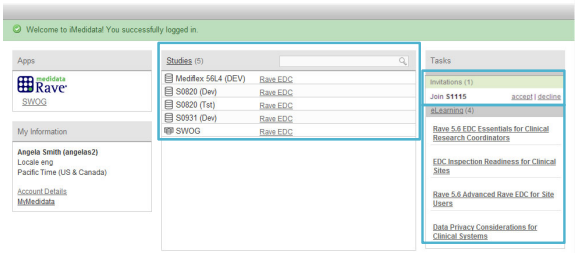
Invitations are sent to join IRB-approved study
- Sent to "Rave CRA" role on SWOG Roster
- Only Head CRAs identified as "Rave CRA" by default
- Request role modifications from Head CRA

Logon using Rave username and password

Accept invitations to studies

Satisfy eLearning requirements

Rave: Access



This is the imedidata portal to all RAVE studies you have access to, both SWOG & non-SWOG

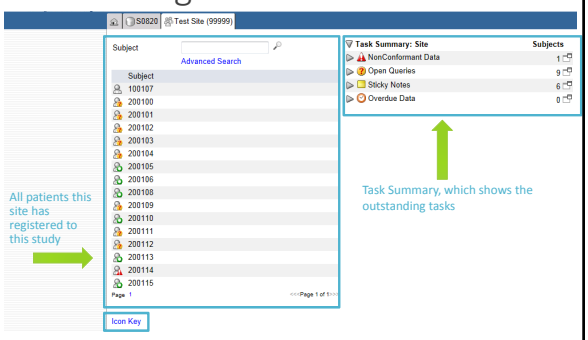
Rave: Organization

Rave is organized by study

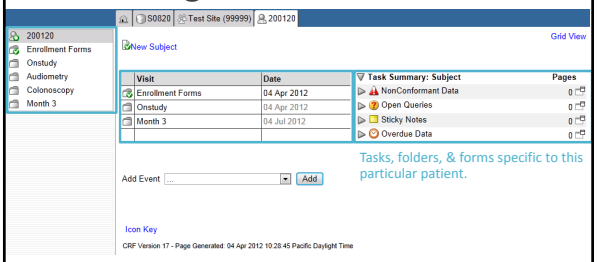
There are no cross-study reports / functions or ways to view information about more than one study at a time in RAVE.

Study >> Site >> Subject >> Folders >> Forms

Rave: Organization



Rave: Organization



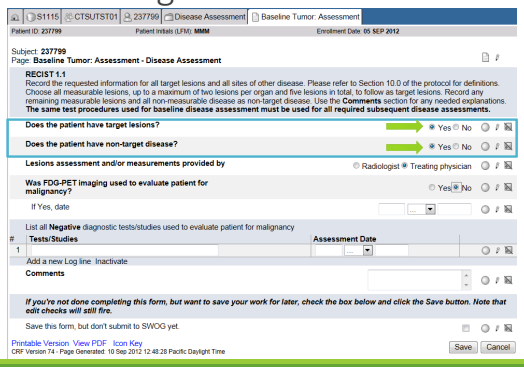
Rave: Organization

Forms in Rave will look different from their paper CRF counterparts.

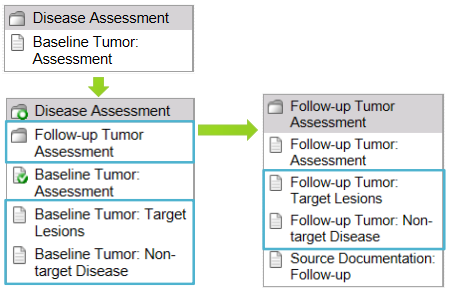
Rave allows us to show you only the folders, forms, or even parts of a form that apply to your patient.

Some Rave forms may not appear until certain questions are answered a certain way.

Rave: Organization



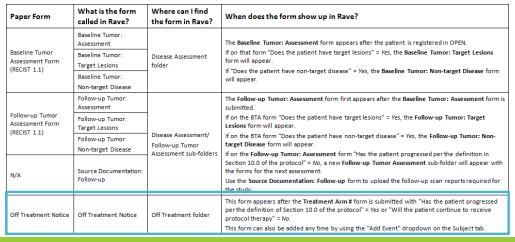
Rave: Organization



Rave: Organization

Rave Form Display document

- Found on the swog.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 (RECIST 1.1)	Baseline Tumor: Assessment Baseline Tumor: Target Lesions Baseline Tumor: Non-target Disease	Disease Assessment folder	The **Baseline Tumor: Assessment** form appears after the patient is registered in OPEN. If on that 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 (RECIST 1.1)	Follow-up Tumor: Assessment Follow-up Tumor: Target Lesions Follow-up Tumor: Non-target Disease	Disease Assessment/ Follow-up Tumor Assessment sub-folders	The **Follow-up Tumor: Assessment** form first appears after the **Baseline Tumor: Assessment** form is submitted. If on the BTA form "Does the patient have target lesions" = *Yes*, the **Follow-up Tumor: Target Lesions** form will appear. If on the BTA form "Does the patient have non-target disease" = *Yes*, the **Follow-up Tumor: Non-target Disease** form will appear. If on the **Follow-up Tumor: Assessment** form "Has the patient progressed per the definition in Section 10.0 of the protocol" = *No*, a new **Follow-up Tumor Assessment** sub-folder will appear with the forms for the next assessment. Use the **Source Documentation: Follow-up** form to upload the follow-up scan reports required for the study.
N/A	Source Documentation: Follow-up		
Off Treatment Notice	Off Treatment Notice	Off Treatment folder	This form appears after the **Treatment Arm 8** form is submitted with "Has the patient progressed per the definition of Section 10.0 of the protocol" = *Yes* or "Will the patient continue to receive protocol therapy" = *No*. This form can also be added any time by using the "Add Event" dropdown on the Subject tab.

Rave: Data Submission

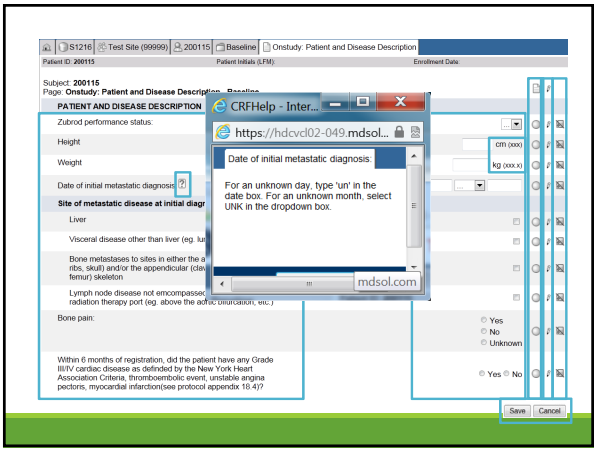
Parts of a Form

Logline Fields

Source Documentation

Conditional Field Display

Sticky Notes



Rave: Data Submission

Parts of a Form – Saving & Resolution

- After Save, static message appears at the top of the form

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.

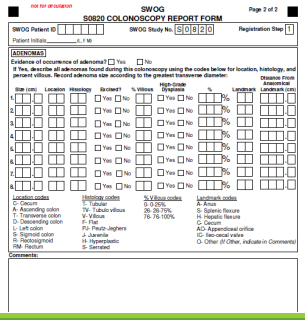
Rave: Data Submission

Logline Fields

- Used to capture data about an unknown number of events
- Can add as many loglines as needed
- Can inactivate (not delete) any added in error
- Save form after adding & completing each logline
  - Make sure there are no non-conformant data error messages on the log line after saving.

Rave: Data Submission

Paper Version:


not for circulation

SWOG

Page 2 of 2

S0820 COLONOSCOPY REPORT FORM

SWOG Patient ID ☐☐☐☐ SWOG Study No. S0820 Registration Step 1

Patient Initials_____ (L F M)

ADENOMAS

Evidence of occurrence of adenoma? ☐ Yes ☐ No

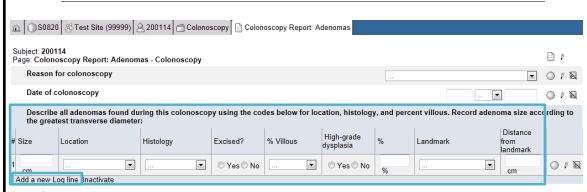
If Yes, describe all adenomas found during this colonoscopy using the codes below for location, histology, and percent villous. Record adenoma size according to the greatest transverse diameter:

	Size (cm)	Location	Histology	Excised?	% Villous	High-Grade Dysplasia	%	Landmark	Distance From Anatomical Landmark (cm)
1.				☐ Yes ☐ No		☐ Yes ☐ No	%		
2.				☐ Yes ☐ No		☐ Yes ☐ No	%		
3.				☐ Yes ☐ No		☐ Yes ☐ No	%		
4.				☐ Yes ☐ No		☐ Yes ☐ No	%		
5.				☐ Yes ☐ No		☐ Yes ☐ No	%		
6.				☐ Yes ☐ No		☐ Yes ☐ No	%		
7.				☐ Yes ☐ No		☐ Yes ☐ No	%		
8.				☐ Yes ☐ No		☐ Yes ☐ No	%		

Location codes	Histology codes	% Villous codes	Landmark codes
C- Cecum	T- Tubular	0-0.25%	A- Anus
A- Ascending colon	TV- Tubulo villous	26-26.75%	S- Splenic flexure
T- Transverse colon	V- Villous	76-76-100%	H- Hepatic flexure
D- Descending colon	F- Flat		C- Cecum
L- Left colon	PJ- Peutz-Jeghers		AO- Appendiceal orifice
S- Sigmoid colon	J- Juvenile		IC- Ileo-cecal valve
R- Rectosigmoid	H- Hyperplastic		O- Other (If Other, indicate in Comments)
RM- Rectum	S- Serrated		

Comments:

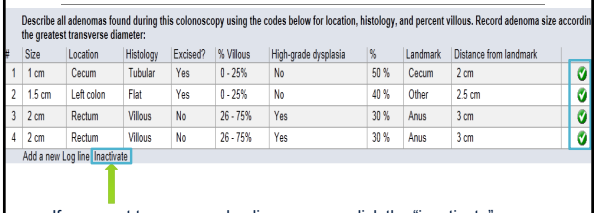
Rave: Data Submission



Only one line available to start

Click here to add lines

Rave: Data Submission


Describe all adenomas found during this colonoscopy using the codes below for location, histology, and percent villous. Record adenoma size accordin
the greatest transverse diameter:

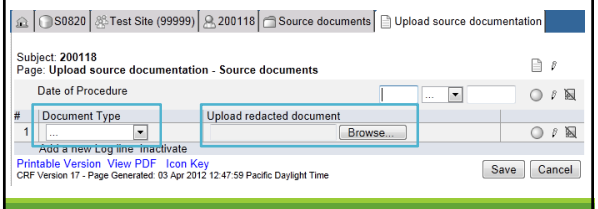
#	Size	Location	Histology	Excised?	% Villous	High-grade dysplasia	%	Landmark	Distance from landmark
1	1 cm	Cecum	Tubular	Yes	0 - 25%	No	50 %	Cecum	2 cm
2	1.5 cm	Left colon	Flat	Yes	0 - 25%	No	40 %	Other	2.5 cm
3	2 cm	Rectum	Villous	No	26 - 75%	Yes	30 %	Anus	3 cm
4	2 cm	Rectum	Villous	No	26 - 75%	Yes	30 %	Anus	3 cm

Add a new Log line | Inactivate

- If you want to remove a log line, you can click the "inactivate" button, which will prompt you to specify which line you want removed, & the data will be lined out.

Rave: Data Submission

Source Documentation
- Rave has a special field that allows the upload of electronic documents
- Add a new log line for multiple reports (if needed)


S0820 | Test Site (99999) | 200118 | Source documents | Upload source documentation

Subject: **200118**
Page: **Upload source documentation - Source documents**

Date of Procedure

#	Document Type	Upload redacted document
1	...	Browse...

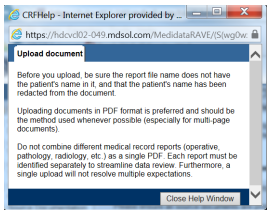
Add a new Log line Inactivate

Printable Version View PDF Icon Key
CRF Version 17 - Page Generated: 03 Apr 2012 12:47:59 Pacific Daylight Time

Save Cancel

Rave: Data Submission

Source Documentation (cont.)
- Document MUST have patient name, SSN, and address data thoroughly redacted
- Prefer PDFs
- Do not combine different documents as a single PDF.


CRFHelp - Internet Explorer provided by ...

https://hdcvcl02-049.mdsol.com/MediataRAVE/(S(wg0w

Upload document

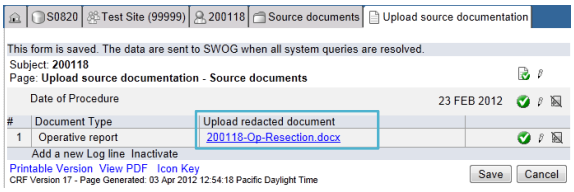
Before you upload, be sure the report file name does not have the patient's name in it, and that the patient's name has been redacted from the document.

Uploading documents in PDF format is preferred and should be the method used whenever possible (especially for multi-page documents).

Do not combine different medical record reports (operative, pathology, radiology, etc.) as a single PDF. Each report must be identified separately to streamline data review. Furthermore, a single upload will not resolve multiple expectations.

Close Help Window

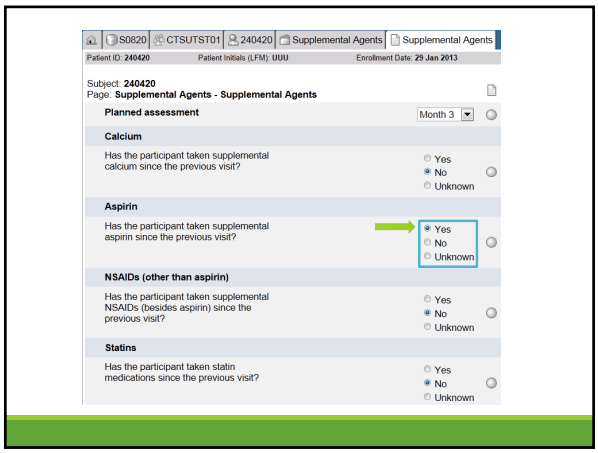
Rave: Data Submission

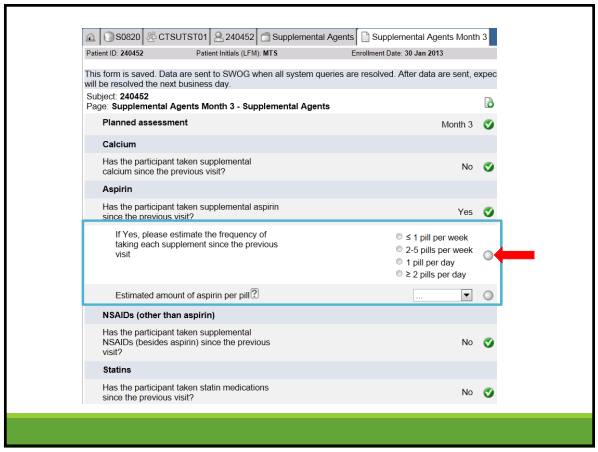


Rave: Data Submission

Conditional Field Display

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

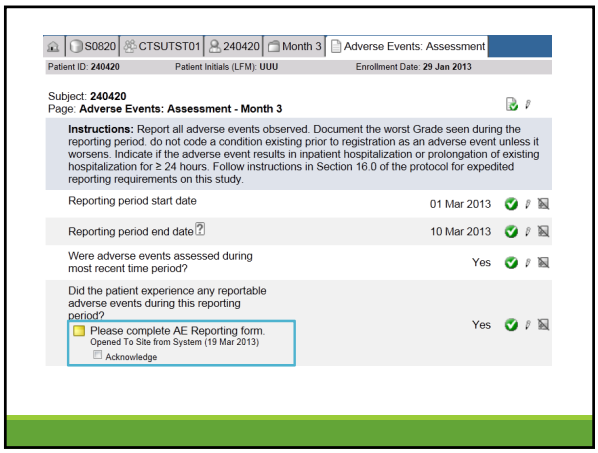




Rave: Data Submission

Sticky Notes

- Used for reminders
- Just need to check the "acknowledge" box and save the form
- Will show up in Task Summary until acknowledged
- Sticky notes do not affect green checkmarks

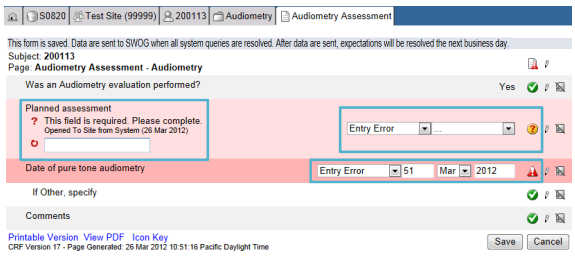


Rave: Query Resolution/ Amending Data

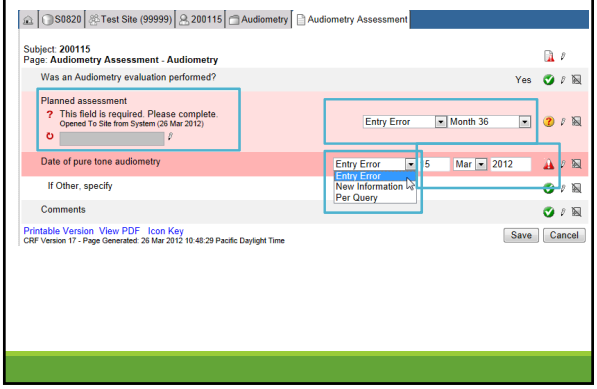
System queries are generated by Rave

- If no response box present, must change data to resolve
- If response box present, may type response rather than changing the data
- All system queries must be resolved before the data are sent to SWOG
  - Expectations resolved by next business day

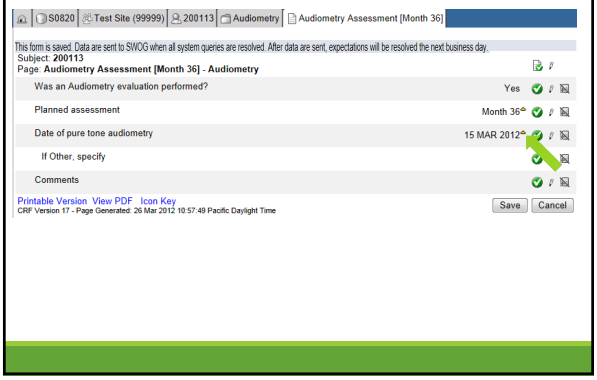
System Query Example



System Query Example



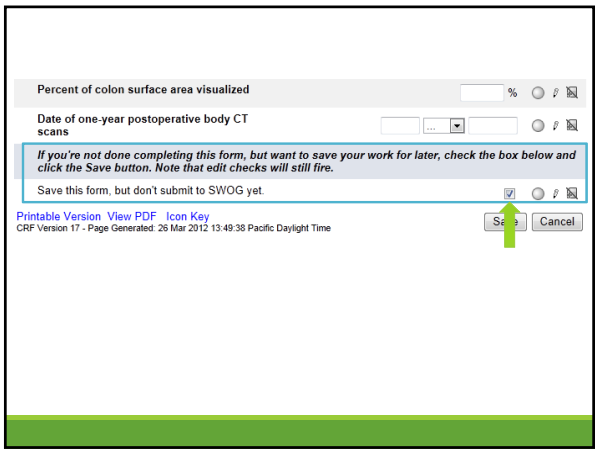
System Query Example

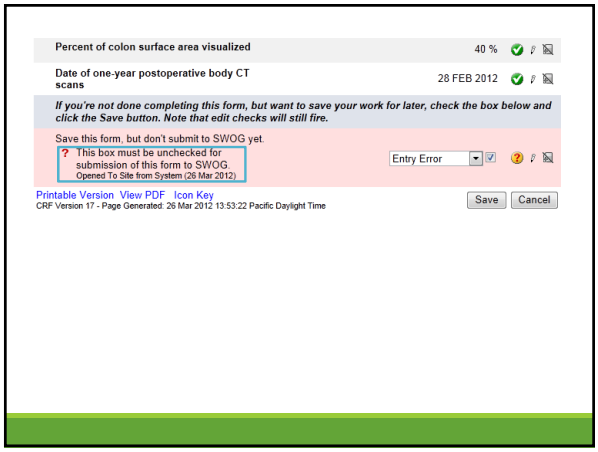


Rave: Query Resolution/ Amending Data

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



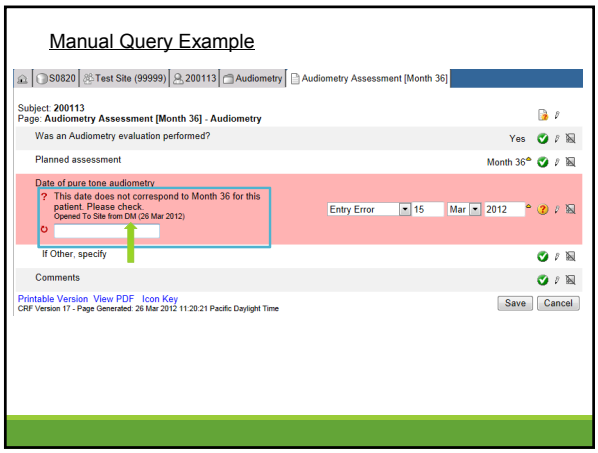


Rave: Query Resolution/ Amending Data

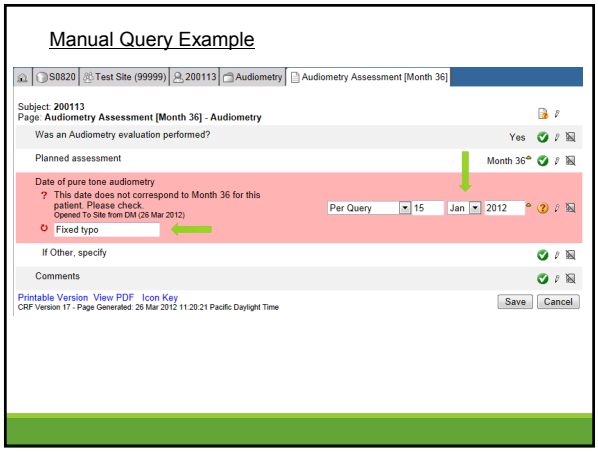
Manual queries are written by a Data Coordinator

- If no response box present, must change data to resolve
- If response box present, must TYPE response instead of, or in addition to, changing data

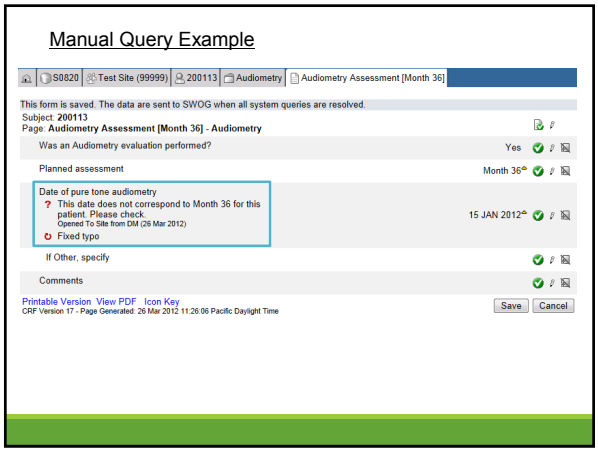
Manual Query Example



Manual Query Example



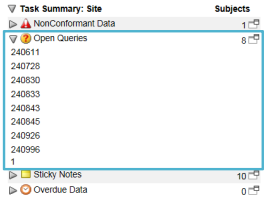
Manual Query Example

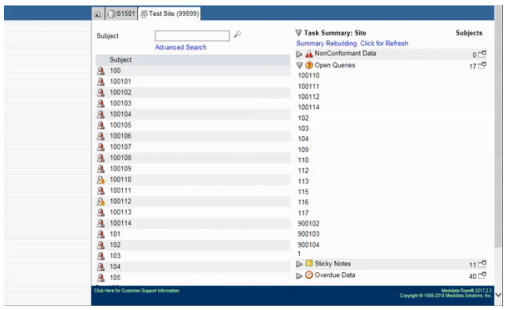


Rave: Query Resolution/ Amending Data

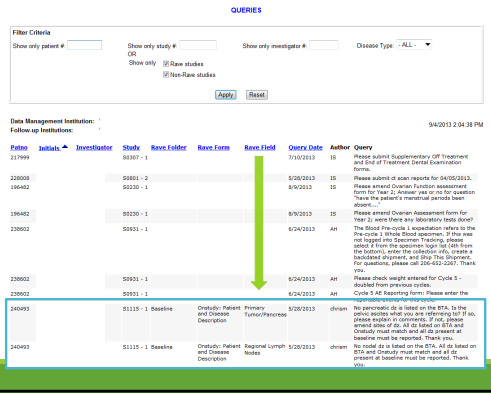
Both system queries and manual queries will be listed in the Task Summary

- Study Level
- Site Level
- Subject Level





CRA Workbench Reports >> Query Reports



Rave: Resources

CRA Workbench

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

Rave Studies NO
- Data/Form Submission
- Query resolution

Rave: Resources

CTSU Help Desk
- 9:30am – 8:30pm ET
- 1-888-823-5923
- 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

Questions?

SWOG Statistics and Data Management Center (Seattle, WA)
- (206) 652-2267