

Data Submission Pre-Rave & Rave

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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

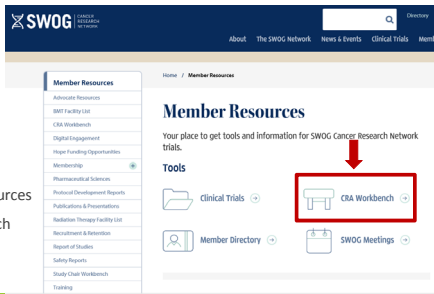
Pre-Rave

CRA Workbench: Overview

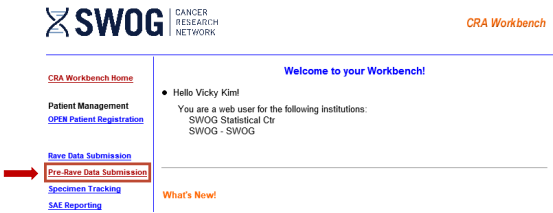
- Access
- Organization
- Data Submission
- Amending Data
- Query Resolution

CRA Workbench: Access

- SWOG.org
- Member Login
- Member Resources
- CRA Workbench



CRA Workbench: Access



[illegible]

CRA Workbench: Organization

Forms tab has up to 5 sub-tabs

Patient InfoFormsExpectationsQueries

BaselineOn TreatmentFollow-upQOL

Refresh This page to see updates reflected

Baseline Forms
Click to complete or amend

Date Submitted
Click to view confirmation

S1007 Prestudy Form - Randomized Study

8/31/2016
Re-generate image

CRA Workbench: Submit Data

Patient InfoFormsExpectationsQueries

BaselineOn TreatmentFollow-upQOL

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)

Reporting Period = 18 months

Reporting Period = 12 months (1 year)

Reporting Period = 6 months

S1007 Adverse Event Summary Form

9/5/2018
Re-generate image

4/24/2018
Re-generate image

12/8/2017
Re-generate image

9/18/2017
Re-generate image

SOUTHWEST ONCOLOGY GROUP

S1007 TREATMENT FORM

Patient Initials: (S, F, M)

SWOG Patient ID: 000000

SWOG Study No.: S1007

Registration Step: 2

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:

Physician:

Participating Group: Group Name/Study No./Patient ID

1 / 1

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 MONTHS, DAYS, YEARS. Exclude any blank fields or blank dates in the Comments section. Please use X in appropriate boxes. Circle AMENDED items in red and write AMENDED across the top of the form.

STATUS

Vital Status: ☒ Alive ☐ Dead Date of Last Contact or Death: 06 / 01 / 2017

Has the patient progressed per the definition in Section 10.0 of the protocol?

☒ Yes ☐ No

TREATMENT

Assigned treatment arm: ☐ Arm 1: Chemotherapy + endocrine therapy ☒ Arm 2: Endocrine therapy alone

Was the patient treated on the assigned arm during this reporting period?

☒ Yes ☐ No (specify reason in comments)

Reporting period start date:

02 / 27 / 2017

Reporting period end date:

06 / 27 / 2017

Weight:

55 / 0 kg

Has the patient received any chemotherapy during this reporting period?

☒ No ☐ Yes, chemotherapy continuing ☐ Yes, chemotherapy completed (submit S1007 Chemotherapy Form regardless of patient's treatment arm)

Editable Version

Submitted successfully on 3/26/2015 6:40:34 AM. Thank you, [Linda L. Smith](#).
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

Patient Initials: (L, F, M)

SWOG Patient ID: SWOG Study No.: S1007 Registration Step: 2

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

Physician

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: ☒ 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? ☒ No (submit Follow Up Form and Off Treatment Notice)

TREATMENT

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

Was the patient treated on the assigned arm during this reporting period? ☒ 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: 06 / 27 / 2017

Weight: 65 - 90

Has the patient received any chemotherapy during this reporting period?
☒ 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, [Linda L. Smith](#).
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, [Linda L. Smith](#).
The data on this form is not amendable online. Please print and fax a copy to the SWOG Statistical Center with clear corrections.

Data Submission

5

Not Amendable Online

Older studies may have some forms that are not amendable online
Instead, print the confirmation, make changes, and fax to SDMC

****Refresh This page to see updates reflected**


Follow-up Forms <small>Click to complete or amend</small>	Date Submitted <small>Click to view confirmation</small>
On Treatment Notice	
Follow Up Form	
S0221 Supplementary Follow Up Form	
S0221 Trastuzumab Use Form	
Notice of Death	8/4/2008
S0221 AC or AC+Q Adverse Event Form	

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
g) 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)

SWOG Patient No: SWOG Study No.: S0819 Reg Step: 1 Patient Initials (L,F,M):

Patient Info

Forms

Expectations

Queries

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 800-492-4007. 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 ELIG, 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.

S0819 Data Coordinator:

Note Date	Author	Note Type	Note	
8/26/2013	LGK	REQ	Submit all pages of 10/15/09 Whole Body PETCT scan. We only received pg 2.	Resolved
8/28/2013	AH	REQ	Please submit the radiology reports for the 12/30/2009 Follow Up Tumor Assessment.	Resolved
8/28/2013	AH	REQ	12/30/2009 Follow Up Tumor Assessment: Please amend to include the Assessment Type for the skeletal mets as well.	Resolved
4/5/2012	CMM	CRA	CRA FYI, this patient progressed on 11/24/10. Pt's MBL disease increased >20% over the smallest sum seen (5.2cm on 5/31/10). Pt should have been removed from Tx at this time.	Acknowledged

QUERIES

Filter Criteria

Show only patient #

Show only study #

Show only investigator #

Disease Type: ALL

Show only ☒ Raw studies

Show only ☐ Non-Raw studies

Apply

Reset

Data Management Institution: Follow up Institution:

Patno

Initials

Investigator

Study

Rave Folder

Rave Form

Rave Field

Query Date

Author

Query

217999			S0307 - 1			7/10/2013	IS	Please submit Supplementary CRF Treatment and End of Treatment Central Examination forms.
238008			S0801 - 2			5/28/2013	IS	Please submit or scan reports for 04/05/2013.
194482			S0230 - 1			6/9/2013	IS	Please amend Ovarian Function assessment form for "Age 2". Answer yes or no for question "have the patient's menstrual periods been absent?".
194482			S0230 - 1			6/9/2013	IS	Please amend Ovarian Assessment form for "Year 2, were there any laboratory tests done?"
238602			S0931 - 1			6/24/2013	AH	The Blood Pre-cycle 1 expectation refers to the Pre-cycle 1 Whole Blood specimen. If this was not shipped into Diagnostic Training, please select N from the specimen type list (88) from the laboratory, enter the collection site, create a validated shipment, and Ship This Shipment. For questions, please call 206-652-2267. Thank you.
238602			S0931 - 1			6/24/2013	AH	Please check weight entered for Cycle 5 - Doubled from previous cycle.
238602			S0931 - 1			6/24/2013	AH	Cycle 5 Ad reporting form: Please enter the reportable events for the cycle.
240493			S1115 - 1 Baseline	Oraduloy Patient and Disease Description	Primary Tumor/Pancreas	5/28/2013	chrisan	No pancreatic dx is listed on the RTA. Is the pelvic ascites what you are referring to? If so, please explain in comments. If not, please amend site of dx, dx dx listed on RTA and Oraduloy must match and all dx present at baseline must be reported. Thank you.
240493			S1115 - 1 Baseline	Oraduloy Patient and Disease Description	Regional Lymph Node	5/28/2013	chrisan	No node dx is listed on the RTA. All dx listed on RTA and Oraduloy must match and all dx present at baseline must be reported. Thank you.

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

Welcome to iMedidata! You successfully logged in.

Apps

- Medidata Rave
- SWOG

My Information

Angela Smith (angela2)
Locale: eng
Pacific Time (US & Canada)
Account Details
iMedidata

Studies (5)

Study	Role
Medflex 561.4 (DEV)	Rave EDC
S0820 (Dev)	Rave EDC
S0820 (Test)	Rave EDC
S0931 (Dev)	Rave EDC
SWOG	Rave EDC

Tasks

- Invitations (1)
Join S1115 [accept](#) / [decline](#)
- eLearning (4)
Rave 5.6 EDC Essentials for Clinical Research Coordinators
EDC Inspection Readiness for Clinical Sites
Rave 5.6 Advanced Rave EDC for Site Users
Data Privacy Considerations for Clinical Systems

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

50020 Test Site (99999)

Subject

Advanced Search

100107

200100

200101

200102

200103

200104

200105

200106

200108

200109

200110

200111

200112

200113

200114

200115

Task Summary: Site

NonConformant Data

Open Queries

Sticky Notes

Overdue Data

Subjects

1

9

6

0

All patients this site has registered to this study

Task Summary, which shows the outstanding tasks

Icon Key

Page 1 of 1

Rave: Organization

200120

Enrollment Forms

Onstudy

Audiometry

Colonoscopy

Month 3

50020 Test Site (99999) 200120

Grid View

New Subject

Visit

Date

Enrollment Forms

Onstudy

Month 3

Task Summary: Subject

NonConformant Data

Open Queries

Sticky Notes

Overdue Data

Pages

0

0

0

0

Tasks, folders, & forms specific to this particular patient.

Add Event Add

Icon Key

CRF Version 17 - Page Generated: 04 Apr 2012 10:28:45 Pacific Daylight Time

Rave: Organization

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

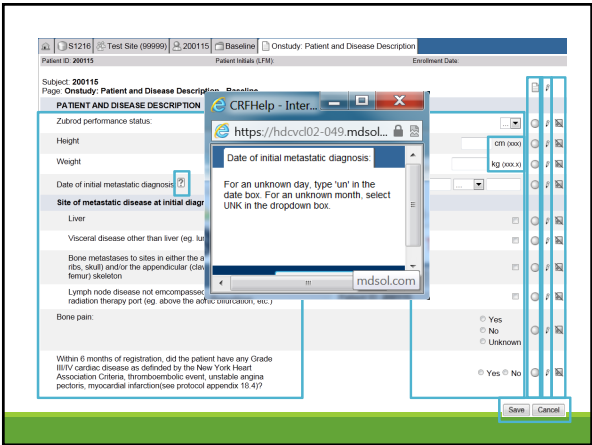
Rave allows us to show you only the folders, forms, or even parts of a form that apply to your patient.

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



Rave: 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.



- 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.

<div style="float: left; font-size: 0.8em; font-weight: normal;"> Use for non-employees SWGC Pattern # 0000 </div> <div style="float: right; text-align: right;"> SWGC 50100 COLONOSCOPY REPORT FORM SWGC Study No. 50002 </div> <div style="clear: both;"></div>		Page 2 of 2 Registration Date 11/11/2011			
(DEFINITIONS) Evidence of occurrence of adenoma? <input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, describe all adenoma found during this colonoscopy using the codes below for location, histology, and size. Attach all adenoma biopsy reports to this form to be performed (submit with this form)					
Location	Histology	Size (mm)	Location	Histology	Size (mm)
1. Cecum	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	6. Descending colon	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
2. Ascending colon	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	7. Sigmoid colon	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
3. Transverse colon	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	8. Rectum	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
4. Descending colon	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	9. Anus	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
5. Sigmoid colon	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	10. Other	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
6. Descending colon	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No			
7. Sigmoid colon	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No			
8. Rectum	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No			
9. Anus	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No			
10. Other	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No			
Comments: <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div style="width: 45%;"> 1. Polyp(s) a. Number _____ b. Location(s) _____ c. Histology _____ d. Size(s) _____ e. Polyp(s) type(s) _____ f. Other _____ </div> <div style="width: 45%;"> 2. Adenoma(s) a. Number _____ b. Location(s) _____ c. Histology _____ d. Size(s) _____ e. Polyp(s) type(s) _____ f. Other _____ </div> </div>					

↑ 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 according to 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

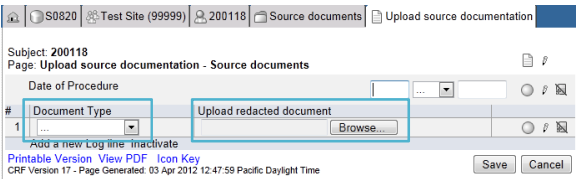
Inactivate

- 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

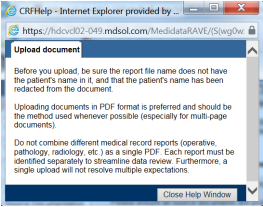
- Rave has a special field that allows the upload of electronic documents
- Add a new log line for multiple reports (if needed)



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.



Rave: Data Submission

The screenshot displays the ePRO system interface for reporting adverse events. The top navigation bar shows the user is logged in as 'Test Site (200000)' and is viewing the 'Report Cardiac (4) - Cycle 01' form. The form is titled 'Report Cardiac (4) - Cycle 01' and includes a 'Print Adverse Events Report Cardiac (4) - Cycle 01' button. The form contains a table for reporting adverse events, with columns for 'CTCAE Grade (A3, D3, group)', 'CTCAE adverse event description', 'Hospitalization (at least 24 hours)', and 'Date'. The 'Comments' section is empty. The 'Save' button is highlighted. The bottom of the form includes a 'Printable Version Using PDF' link and a 'Save' button.

Report Cardiac (4) - Cycle 01

Print Adverse Events Report Cardiac (4) - Cycle 01

Instructions: Report adverse events occurring up until the next cycle of treatment begins. Document the worst grade seen during the reporting period. Do not check a condition unless you are reporting an adverse event during 8 weeks. Include the adverse event results in reported hospitalizations in percentage of events. Hospitalization for 24 hours. Follow instructions in Section 10.2 of the protocol for reported reporting requirements on this study.

CTCAE Grade (A3, D3, group)	CTCAE adverse event description	Hospitalization (at least 24 hours)	Date

Comments

Save this form. But don't submit to ePRO yet

Printable Version Using PDF **Save**

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Rave: Data Submission

Conditional Field Display

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

S0620

CTSUTST01

240420

Supplemental Agents

Supplemental Agents

Patient ID: 240420

Patient Initials (LFM): MUU

Enrollment Date: 29 Jan 2013

Subject: 240420

Page: Supplemental Agents - Supplemental Agents

Planned assessment

Month 3

Calcium

Has the participant taken supplemental calcium since the previous visit?

☐ Yes

☒ No

☐ Unknown

Aspirin

Has the participant taken supplemental aspirin since the previous visit?

☒ Yes

☐ No

☐ Unknown

NSAIDs (other than aspirin)

Has the participant taken supplemental NSAIDs (besides aspirin) since the previous visit?

☐ Yes

☒ No

☐ Unknown

Statins

Has the participant taken statin medications since the previous visit?

☐ Yes

☒ No

☐ Unknown

S0620

CTSUTST01

240452

Supplemental Agents

Supplemental Agents Month 3

Patient ID: 240452

Patient Initials (LFM): MTS

Enrollment Date: 30 Jan 2013

Subject: 240452

Page: Supplemental Agents Month 3 - Supplemental Agents

Planned assessment

Month 3

Calcium

Has the participant taken supplemental calcium since the previous visit?

No

Aspirin

Has the participant taken supplemental aspirin since the previous visit?

Yes

If Yes, please estimate the frequency of taking each supplement since the previous visit

☐ ≤ 1 pill per week

☐ 2-5 pills per week

☐ 1 pill per day

☐ ≥ 2 pills per day

Estimated amount of aspirin per pill (?)

...

NSAIDs (other than aspirin)

Has the participant taken supplemental NSAIDs (besides aspirin) since the previous visit?

No

Statins

Has the participant taken statin medications since the previous visit?

No

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

S0820

CTSUTST01

240420

Month 3

Adverse Events: Assessment

Patient ID: 240420

Patient Initials (LFM): UUU

Enrollment Date: 29 Jan 2013

Subject: 240420

Page: Adverse Events: Assessment - Month 3

Instructions: Report all adverse events observed. Document the worst Grade seen during the reporting period. do not code a condition existing prior to registration as an adverse event unless it worsens. Indicate if the adverse event results in inpatient hospitalization or prolongation of existing hospitalization for ≥ 24 hours. Follow instructions in Section 16.0 of the protocol for expedited reporting requirements on this study.

Reporting period start date01 Mar 2013

Reporting period end date10 Mar 2013

Were adverse events assessed during most recent time period?Yes

Did the patient experience any reportable adverse events during this reporting period?Yes

Please complete AE Reporting form. Opened To Site from System (19 Mar 2013)

Acknowledge

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

S0820Test Site (99999)200113AudiometryAudiometry Assessment

This form is saved. Data are sent to SWOG when all system queries are resolved. After data are sent, expectations will be resolved the next business day.

Subject: 200113

Page: Audiometry Assessment - Audiometry

Was an Audiometry evaluation performed?Yes

Planned assessment

This field is required. Please complete. Opened To Site from System (26 Mar 2012)

Entry Error

Date of pure tone audiometryEntry Error51Mar2012

If Other, specify

Comments

Printable Version View PDF Icon Key

CRF Version 17 - Page Generated: 26 Mar 2012 10:51:16 Pacific Daylight Time

Save Cancel

System Query Example

S0820

Test Site (99999)

200115

Audiometry

Audiometry Assessment

Subject: 200115

Page: Audiometry Assessment - Audiometry

Was an Audiometry evaluation performed?

Yes

Planned assessment

This field is required. Please complete.
Opened To Site from System (28 Mar 2012)

Entry Error

Month 36

Date of pure tone audiometry

Entry Error

5

Mar

2012

If Other, specify

New Information

Per Query

Comments

Printable Version

View PDF

Icon Key

CRF Version 17 - Page Generated: 26 Mar 2012 10:48:29 Pacific Daylight Time

Save

Cancel

System Query Example

S0820

Test Site (99999)

200113

Audiometry

Audiometry Assessment (Month 36)

Subject: 200113

Page: Audiometry Assessment (Month 36) - Audiometry

Was an Audiometry evaluation performed?

Yes

Planned assessment

Month 36

Date of pure tone audiometry

15 MAR 2012

If Other, specify

Comments

Printable Version

View PDF

Icon Key

CRF Version 17 - Page Generated: 26 Mar 2012 10:57:49 Pacific Daylight Time

Save

Cancel

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

Percent of colon surface area visualized

%

Date of one-year postoperative body CT scans

...

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.

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

☒

[Printable Version](#) [View PDF](#) [Icon Key](#)

CRF Version 17 - Page Generated: 26 Mar 2012 13:49:38 Pacific Daylight Time

Save

Cancel

Percent of colon surface area visualized

40 %

Date of one-year postoperative body CT scans

28 FEB 2012

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.

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

This box must be unchecked for submission of this form to SWOG. Opened To Site from System (26 Mar 2012)

Entry Error

[Printable Version](#) [View PDF](#) [Icon Key](#)

CRF Version 17 - Page Generated: 26 Mar 2012 13:53:22 Pacific Daylight Time

Save

Cancel

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

Data Submission

20

Manual Query Example

S0820

Test Site (99999)

200113

Audiometry

Audiometry Assessment [Month 36]

Subject: 200113

Page: Audiometry Assessment [Month 36] - Audiometry

Was an Audiometry evaluation performed?

Yes

Planned assessment

Month 36

Date of pure tone audiometry

?

This date does not correspond to Month 36 for this patient. Please check.
Opened To Site from DM (26 Mar 2012)

Entry Error

15

Mar

2012

If Other, specify

Comments

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Save

Cancel

Manual Query Example

S0820

Test Site (99999)

200113

Audiometry

Audiometry Assessment [Month 36]

Subject: 200113

Page: Audiometry Assessment [Month 36] - Audiometry

Was an Audiometry evaluation performed?

Yes

Planned assessment

Month 36

Date of pure tone audiometry

?

This date does not correspond to Month 36 for this patient. Please check.
Opened To Site from DM (26 Mar 2012)

Per Query

15

Jan

2012

If Other, specify

Comments

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Save

Cancel

Manual Query Example

S0820

Test Site (99999)

200113

Audiometry

Audiometry Assessment [Month 36]

This form is saved. The data are sent to SWOG when all system queries are resolved.

Subject: 200113

Page: Audiometry Assessment [Month 36] - Audiometry

Was an Audiometry evaluation performed?

Yes

Planned assessment

Month 36

Date of pure tone audiometry

?

This date does not correspond to Month 36 for this patient. Please check.
Opened To Site from DM (26 Mar 2012)

15 JAN 2012

If Other, specify

Comments

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Save

Cancel

Rave: Query Resolution/ Amending Data

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

- Study Level
- Site Level
- Subject Level

Task Summary: Site		Subjects
NonConformant Data		1
Open Queries		8
240811		
240728		
240830		
240833		
240843		
240845		
240926		
240996		
1		
Sickly Notes		10
Overdue Data		0

Task Summary: Site		Subjects
Summary Rebuilding. Click for Refresh		0
NonConformant Data		17
Open Queries		
100110		
100111		
100112		
100114		
102		
103		
104		
105		
110		
112		
113		
115		
116		
117		
900102		
900103		
900104		
1		
Sickly Notes		11
Overdue Data		40

CRA Workbench Reports >> Query Reports

Filter Criteria

Show only patient #

Show only study #

Show only investigator #

Discoisa Type - ALL -

OK

Show only ☒ Raw studies

☐ Non-Raw studies

Apply Reset

Follow-up Institution	Study	Case Folder	Case Form	Query Date	Author	Query
217999	80307 - 1			7/10/2013	IS	Please submit Supplementary CRF Treatment and Side of Treatment Detail Submission forms.
220008	50804 - 2			5/08/2013	IS	Please submit it when reports for 04/05/2013.
186482	80330 - 1			6/10/2013	IS	Please amend Overdue Function assessment form for Year 1. Please use the for question "Have the patient's menstrual periods been absent."
139482	80330 - 1			6/10/2013	IS	Please amend Overdue assessment form for Year 1. Have there any laboratory tests done?
238002	50931 - 1			6/24/2013	AM	The Blood Test Cycle 1 assessment refers to the pre-cycle 1 15mls blood specimen. If the was not tested the specimen training sheet, send it from the specimen sign to the from the bottom, enter the collection info, create a baseline assessment, and Stop the Specimen. For questions, please call 230-452-2057. Thank you.
220002	50931 - 1			6/24/2013	AM	Please check weight entered for Cycle 1 - divided from previous cycle.
230002	50931 - 1			6/24/2013	AM	Cycle 1 & 2 Reporting form: Please enter the appropriate date to be used on the date, so the person knows what you are referring to? If so, please enter it correctly. If not, please send date of do. It is based on B1A and Overdue must reach and all as present at baseline must be reported. Thank you.
240493	51115 - 1	Baseline	Overdue: Patient and Clinician Observation	5/28/2013	chris	No patient data is based on the B1A, all as present at baseline must be reported. Thank you.
240493	51115 - 1	Baseline	Overdue: Patient and Clinician Observation	5/28/2013	chris	No patient data is based on the B1A, all as present at baseline must be reported. Thank you.

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
- 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

Questions?

SWOG Statistics and Data Management Center (Seattle, WA)

- (206) 652-2267

