

Data Quality Tools: SWOG Expectation Reports and CTSU Data Quality Portal

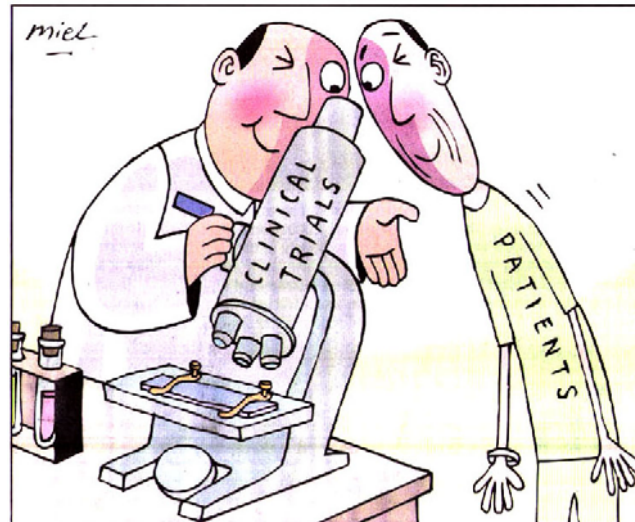
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Why Do Patients Participate on Clinical Trials?

- Advance medical knowledge
- Access to the latest treatment
- Hope for their own illness
- To make a difference
- Trust

Why Quality Data are Important

- Clinical trial participants trust us with their lives
- We need to honor their trust and participation through quality data collection
- Ensure that their data are used in the analysis



How does SWOG communicate data needs? Expectations

- Required forms, reports, specimens
- Posted at the time the patient is registered
 - Baseline forms, specimens
 - Others with a defined due date known at the time of patient registration; could be post-baseline
- Posted during protocol treatment and follow-up
 - Based on the follow-up timing for patient
 - Adverse events, treatment given, tumor assessment
- Overdue follow-up (need updated last contact date)

SWOG Reports for Quality

- Query Report
 - Includes queries from data coordinators and study chairs based on their review of the patient chart
 - Across all studies (Rave and legacy)
- Expectation Report
 - Overdue Expectations + upcoming Expectations
 - Patient follow-up reminders
 - Across all studies (Rave and legacy)

How SWOG Measures Data Quality

- Institution Performance Review (IPR)
 - Statistics used to monitor an institution's compliance to data submission requirements
 - Are required forms being submitted?
 - SWOG Policy #33
- Categories of data
 - Baseline (Initial Forms Set)
 - Follow-up
 - On Treatment – required forms, survival status update
 - Off Treatment – survival status update

Access to SWOG Reports: CRA Workbench on swog.org

The screenshot shows the SWOG website's CRA Workbench. The top navigation bar includes the SWOG logo, a search bar, and links for 'Website Survey', 'FAQs & How to use this site', 'Home', 'About Us', 'Contact Us', 'Website Index', and 'Logoff'. A 'Welcome Phyllis Goodman' message is displayed. The left sidebar contains a 'MEMBERS SECTION' with links to 'Other Sections', 'Quicklinks', 'My Favorites', 'My Protocols', 'Website Index', 'Clinical Trials', 'Membership', 'Workbenches', 'Member Roster', 'Training', 'Policies & Manuals', 'Administrative Forms', 'Minutes', 'IRB', 'QA/Audits', 'Serious Adverse Events', 'Pharmaceutical Science', 'Biospecimen Resources', 'Research Support', 'Bulletin Board', 'FAQs', 'Newsletters', 'Group Meeting', 'Young Investigators', 'Links', 'Employment', 'Contact Us', and 'Logoff'. The 'Workbenches' section is expanded, showing 'CRA Workbench', 'SC Workbench', and 'SELECT Workbench'. The 'CRA Workbench' section is highlighted with a yellow arrow. The main content area displays 'Latest SWOG News' with links to 'Spring Group Meeting Registration' and 'Modality and Discipline Travel Fund'. A yellow arrow points to the 'CRA Workbench Home' link in the 'Reports' section. The 'Reports' section is titled 'Please select the reports you wish to display:' and lists various report types: 'Expectation and IPR Reports', 'Query Reports', 'Ineligible Patients Report', 'Patients in followup', 'Registrations by Race and Sex', 'Initial Registrations', 'Registrations for a given date range', 'Serious Adverse Events (SAE) for a given study', 'List of Applicable Protocols for S9808 - Long Term Follow-Up Protocol', 'List of Protocols with No Required Follow-Up', 'Approved SWOG Bone Marrow Transplant Facilities', 'Approved SWOG Radiation Therapy Facilities', 'Accrual Reports', and 'Lab Specimen Management'. A yellow arrow points to the 'Query Reports' link. The bottom of the page features the SWOG logo and the text 'Leading cancer research. Together.'.

SWOG Leading cancer research. Together.

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Welcome Phyllis Goodman

MEMBERS SECTION

- Other Sections
- Quicklinks
- My Favorites
- My Protocols
- Website Index
- Clinical Trials
- Membership
- Workbenches**
 - CRA Workbench
 - SC Workbench
 - SELECT Workbench
- Member Roster
- Training
- Policies & Manuals
- Administrative Forms
- Minutes
- IRB
- QA/Audits
- Serious Adverse Events
- Pharmaceutical Science
- Biospecimen Resources
- Research Support
- Bulletin Board
- FAQs
- Newsletters
- Group Meeting
- Young Investigators
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Latest SWOG News

- [Spring Group Meeting Registration](#)
On-line registration for the April 29-May 1, 2010 meeting in San Francisco is now open!
- [Modality and Discipline Travel Fund](#)
If you are an investigator not specializing in medical oncology, pharmacist, radiation therapist, or biostatistician, please apply for meeting travel support from the Modality and Discipline Travel Fund. Deadline for application for spring 2010 is May 1, 2010. Learn more at <https://swog.org/Vi>

In the Members section you can build your own My Favorites and My Protocols. For help with Protocols features, go to the help pages for each bar at left. If you need help finding something, let us know. Please send any comments you would like to see, to the [Members Feedback](#) page.

CRA Workbench Home

- [Training](#)
- [SWOG Patient Registration](#)
- [OPEN Patient Registration](#)
- [Data Submission](#)
- [Save Data Submission](#)
- [SAE \(ADR\) Reporting](#)
- [IRB/Regulatory Procedures](#)
- [Specimen Tracking](#)
- [Protocols](#)
- Reports**
- [CRA Manual](#)
- [SWOG Roster](#)
- [Tools of the Trade](#)
- [Early Therapeutics Trials](#)
- [Planned Unblinding](#)
- [Patient Transfer](#)
- [New CRAs!](#)
- [ORP Committee](#)
- [Group Meetings](#)
- [WUA Administration](#)
- [Related Links](#)
- [FAQs](#)
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- [swog.org members area](#)

Reports

Please select the reports you wish to display:

- [Expectation and IPR Reports](#)
- [Query Reports](#)
- [Ineligible Patients Report](#)
- [Patients in followup](#)
- [Registrations by Race and Sex](#)
- [Initial Registrations](#)
- [Registrations for a given date range](#)
- [Serious Adverse Events \(SAE\) for a given study](#)
- [List of Applicable Protocols for S9808 - Long Term Follow-Up Protocol](#)
- [List of Protocols with No Required Follow-Up](#)
- [Approved SWOG Bone Marrow Transplant Facilities](#)
- [Approved SWOG Radiation Therapy Facilities](#)
- [Accrual Reports](#)
- [Lab Specimen Management](#)

This report is no longer available. Please use the Specimen Tracking System "Specimen Manager" page for this information.

What's new in the quality world?

- Data Quality Portal (DQP) on CTSU website
 - Overdue forms
 - Overdue queries
- Status
 - ECOG-ACRIN studies currently deployed
 - SWOG studies coming very soon

DQP – Delinquent Forms

Notice
DQP is currently being piloted for a limited number of studies. More information will be available as more studies are added.

Delinquency Aging Report Summary for LPO SWOG

Protocol	Total Delinquencies	< 15 Days	15 - 30 Days	31 - 60 Days	61 - 90 Days	> 90 Days	Last Refresh
S0820	23	-	-	1	-	22	01/20/2017 12:11 AM EST
S1204	28	15	-	1	4	8	01/20/2017 12:43 AM EST
S1312	5	1	1	-	-	3	01/19/2017 11:27 PM EST
S1313	117	31	21	16	19	30	01/20/2017 12:47 AM EST
S1314	92	19	5	13	8	47	01/20/2017 12:54 AM EST
S1316	23	6	3	3	4	7	01/19/2017 10:41 PM EST
S1318	49	1	13	12	6	17	01/19/2017 11:59 PM EST

Delinquent Forms Report Summary

Delinquency Aging Report Summary for LPO SWOG

1

22

Protocol	Total Delinquencies	< 15 Days	15 - 30 Days	31 - 60 Days	61 - 90 Days	> 90 Days
S0820	23	-	-	1	-	22
S1204	28	15	-	1	4	8
S1312						
S1313						
S1314						

S1313

Go!

Rave Delinquencies by Form

Protocol: S1313 | Aging: Total | Last Refresh: 01/20/2017 12:47 AM EST

Site Name	All Forms	Adverse Events: Assessment	Adverse Events: Report	Baseline Tumor: Assessment	Follow-up	Follow-up Tumor: Assessment	Follow-up Tumor: Non-target Disease	Follow-up Tumor: Target Lesions	Onstudy: Laboratory Values
AZ017	7	1	-	-	-	1	1	2	-
CA011	3	-	-	-	3	-	-	-	-
CA043	1	-	-	-	1	-	-	-	-
CA088	5	-	-	-	1	1	-	1	-
CA164	1	-	-	-	1	-	-	-	-
CA243	13	2	-	1	1	1	-	1	1
CT018	39	4	-	-	6	7	6	7	-
CT125	1	-	-	-	1	-	-	-	-
IL097	2	-	-	-	-	-	-	1	-
MI020	6	-	-	-	-	1	1	2	-
MO028	4	-	-	-	-	1	1	1	-
MO046	8	-	-	-	-	2	2	2	-
WA020	27	8	1	-	4	3	3	3	-
TOTAL	117	15	1	1	18	17	14	20	1

SWOG

Leading cancer research. Together.

National Clinical Trials Network

Community Oncology Research Program

Delinquencies and Queries

Rave Delinquencies
Protocol: S1313 | Site: WA020 | Form: All Forms | Aging: Total | Last Refresh: 01/20/2017 12:47 AM EST

All Patients ▼ All Folders ▼ All Forms ▼ Go! Help

Site	Patient	Folder	Form Display Name	Form	Expected Date
WA020	261877	Cycle 14	Adverse Events: Assessment	Adverse Events: Assessment	01/16/17
WA020	254467	Follow-up (1)	Follow-up	Follow-up	01/14/17
WA020	264315	Follow-up Tumor Assessment	Follow-up Tumor: Assessment	Follow-up Tumor: Assessment	01/11/17
WA020	264315	Follow-up Tumor Assessment	Follow-up Tumor: Non-target Disease	Follow-up Tumor: Non-target Disease	01/11/17
WA020	264315	Follow-up Tumor Assessment	Follow-up Tumor: Target Lesions	Follow-up Tumor: Target Lesions	01/11/17
WA020	264315	Follow-up Tumor Assessment	Source Documentation: Follow-up	Source Documentation: Follow-up	01/11/17
WA020	264277	Follow-up Tumor Assessment	Follow-up Tumor: Assessment	Follow-up Tumor: Assessment	01/07/17
WA020	264277	Follow-up Tumor Assessment	Follow-up Tumor: Non-target Disease	Follow-up Tumor: Non-target Disease	01/07/17
WA020	264277	Follow-up Tumor Assessment	Follow-up Tumor: Target Lesions	Follow-up Tumor: Target Lesions	01/07/17
WA020	264277	Follow-up Tumor Assessment	Source Documentation: Follow-up	Source Documentation: Follow-up	01/07/17

Rave Queries
Protocol: S1313 | Site: WA020 | Form: All Forms | Aging: Total | Last Refresh: 01/20/2017 12:47 AM EST

All Patients ▼ All Folders ▼ All Forms ▼ Go! Help

Site	Patient	Folder	Form Display Name	Form	Log Line	Field	Query	Date Query Opened	Marking Group
WA020	258039	Off Treatment (1)	Off Treatment Notice	Off Treatment Notice	N/A	Off treatment reason	Amend off tx reason: pt did not meet progression definition. Change to 'other: elevated tumor marker CA19-9'	01/11/2017	Site from DM
WA020	258039	Cycle 14	Adverse Events: Report	Adverse Events: Report	N/A	Comments	Submit form.	01/11/2017	Site from DM
WA020	258039	Cycle 14	Treatment	Treatment	N/A	Date of last treatment	Tx isn't given every day of the cycle. Amend last date of TX with correct end date.	01/11/2017	Site from DM

“Deep Link”

- Brings you right in to Rave
 - Either patient or form depending on where you clicked

254467
Enrollment Forms
Baseline
CA 19-9
Disease Assessment
Cycle 01
Cycle 02
Cycle 03
Cycle 04

Patient ID: 254467 Patient Initials (LFM): WSM

[Subject Enrollment](#)

Visit	Date
Baseline	24 Mar 2015
Disease Assessment	24 Mar 2015
Follow-up Tumor Assessment 2015-05-14	14 May 2015
Follow-up Tumor Assessment 2015-07-14	14 Jul 2015

LEADING CANCER RESEARCH, TOGETHER.

S1313 University of Washington Medical Center 264277

Patient ID: 264277 Patient Initials (LFM): CSA

Subject: 264277
Page: Follow-up Tumor: Assessment - Follow-up Tumor Assessment

Instructions: Record all requested information applicable to this assessment.

Was disease status evaluated during this reporting period?

Assessment date
(Date 1st scan was done this reporting period. Enter planned assessment date.)

New Lesions

#	Site	Assessment type
1		

Add a new Log line Inactivate

Symptomatic deterioration?
(Global deterioration of health without objective evidence of progression.)

Symptomatic deterioration assessment date

Has the patient progressed or relapsed (per the definition in the Section 2 of the protocol)?

Comments

If you're not done completing this form, but want to save your work:

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

[Printable Version](#) [View PDF](#) [Icon Key](#)
CRF Version 1334 - Page Generated: 20 Jan 2017 16:25:23 Pacific Standard Time

Expectation Report vs. DQP Delinquency Report

	Expectation Report	DQP
What's posted?	Overdue and upcoming within defined timeframe.	Overdue only.
What's included	Forms, specimens; anything else for which an expectation has been created (images, uploaded reports).	Forms, source document uploads and anything that has been "calendared" within Rave. Does NOT include specimens.
Overdue definition (Treatment forms)	> 60 days from day expectation is due; doesn't take into treatment delays.	Based on expected date + max treatment delay.
How to access	CRA Workbench; dynamic report updated in real time.	CTSU. Updated nightly.
Which studies	All Rave studies All legacy studies	Rave studies WITH calendaring (10 don't have calendaring)

SWOG Query Report vs. DQP Queries

	SWOG Query Report	DQP
What's posted?	Queries from Data Coordinators	Queries from Data Coordinators Queries from Auditors/Monitors Medidata Rave System queries + non-conformant data
Overdue definition	Don't currently measure.	Calculated from date posted. Due within 15 days.
How to access	SWOG CRA Workbench	CTSU
Which studies?	All Rave studies + All legacy studies	All Rave studies

DQP Comments

- Delinquent Forms
 - Complements our Expectation and IPR reports
- Overdue queries
 - One missing lab value → multiple queries (value, units, ULN, LLN, sample collection date)
 - Partially completed forms → missing data queries
- We currently see DQP as a tool; we don't know NCI's long term plan for use

S1404: Quality Data Goal

- At the time the data are given to Merck for their FDA submission, the number of delinquent forms and overdue queries need to be 0. That's right, 0!
- As of April 16, 2017

	Total	< 15 Days	15-30 Days	31-60 Days	61-90 Days	> 90 Days
Delinquent Forms	1858	566	472	439	151	230
Overdue Queries	2612	902	491	710	163	346

IPR plans

- Restructuring to be more in line with how Rave DQP works
- Revised categories
 - Initial Forms Set
 - Vital Status Update (on and off treatment combined)
 - Calculated from last contact date
 - Form submission (post-baseline) **New!**
 - Will include all forms (treatment, AE, FUTA, QoL, etc.)
 - Post-baseline specimen submission **New!**

Planned implementation

- Plan to run the 2 versions concurrently for a few months to assess impact
- Will give sites a few months to resolve newly delinquent cases due to revised definitions
- Revision to SWOG Policy #33
 - Needs to be approved by Board of Governors

Old vs. New: IFS

	Old	New (planned)
Initial Forms Set	Limited forms included in measure; forms necessary to review eligibility	Much expanded list of forms to be included; forms necessary to review eligibility and to assess endpoints
	<ul style="list-style-type: none">• Patients registered in ≤ 13 months ago (compliance $\leq 10\%$ overdue)• Patients registered > 13 months ago (compliance = 0 patients overdue)	<ul style="list-style-type: none">• Patients registered in ≤ 13 months ago (compliance $\leq 10\%$ overdue)• Patients registered > 13 months ago (compliance = 0 patients overdue)

Old vs. New: Follow-Up and Forms

	Old	New (planned)
Follow-Up (Vital status update)	<p>Two measures</p> <ul style="list-style-type: none"> • Patients On Treatment (compliance level \leq 15% overdue) • Patients Off Treatment (compliance level \leq 20% overdue) • Denominator= Patients with last known status of Alive 	<p>One measure</p> <ul style="list-style-type: none"> • All patients combined (compliance level \leq 15% overdue) • Denominator= Patients with last known status of Alive
Submission of Forms	None	<p>Overdue post-baseline forms</p> <ul style="list-style-type: none"> • Denominator = All forms submitted in last 13 months + any currently overdue forms

Thank you!

