

Data Quality Tools: SWOG Reports and CTSU Data Quality Portal

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SWOG Reports for Quality

- Expectation Report
 - Query Report
 - Ineligible patients
 - Patients in Follow-Up
-
- SWOG reports: We are always updating, revising let us know if you have ideas for additional reports or additional fields on current reports that could be helpful to you

Access to SWOG Reports: CRA Workbench on swog.org

SWOG CANCER RESEARCH NETWORK

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CRA Workbench

Member Resources

- Advocate Resources
- BMT Facility List
- CRA Workbench**
- Digital Engagement
- Hope Funding Opportunities
- Membership
- Pharmaceutical Sciences
- Protocol Development Reports
- Publications & Presentations
- Radiation Therapy Facility List
- Recruitment & Retention
- Report of Studies
- Safety Reports

CRA Workbench Home

Patient Management

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Resources

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For SWOG Members

- [New SWOG CRAs!](#)
- [SWOG CRP Committee](#)
- [SWOG IRB/Regulatory Procedures](#)
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• Hello Phyllis Goodmant

You are a web user for the following institutions:
SWOG Statistical Ctr
SWOG - SWOG

What's New!

02/01/2019
Monthly Expectation Report – Addition of NCI-Code for
The NCI Code for the institution following the patient has been added. This will be useful for managing patient follow-up at your site. This is more useful, please let us know and we will see what we can do.

11/20/2018
On-Study Patients Registered to S1007
Effective 12/01/2018, expectations for an Off Treatment NCI Code will be required for randomization. You will be required to submit an Off Treatment NCI Code for patients reaching the 5 year (60 months) date from randomization. If the patient is continuing on endocrine therapy, the Off Treatment NCI Code should be S1007. If the patient is continuing on endocrine therapy, please use S1007.

- **Off Treatment Reason** for patients reaching the 5 year (60 months) date from randomization.
- Please use the 5 year (60 months) date from randomization.
- If the patient is continuing on endocrine therapy, the Off Treatment NCI Code should be S1007.
- If the patient is continuing on endocrine therapy, please use S1007.

If you have any questions, please e-mail breastquestion@crn.org

06/08/2018
S1404 PK/ADA Samples
Collection of PK/ADA samples was discontinued on December 1, 2017. Unresolved PK/ADA expectations have also been deleted.

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Reports

Please select the reports you wish to display:

- [Expectation and IPR Reports](#)
- [Query Reports](#)
- [Ineligible Patients Report](#)
- [Serious Adverse Events \(SAE\) for a Given Study](#)
- [Study-wide Unblinding Report](#)
- [List of Applicable Protocols for S9808 - Long Term Follow-Up Protocol](#)
- [List of Protocols with No Required Follow-Up](#)
- [Accrual Reports](#)
- [S0820 \(PACES\) Potential Patients](#)

For SWOG-credited Registrations

- [SWOG-credited Registrations for a Given Date Range](#)
- [Accrual for SWOG-credited Registrations by Race and Sex](#)
- [SWOG Patients in Follow-up](#)
- [Approved SWOG Bone Marrow Transplant Facilities](#)
- [Approved SWOG Radiation Therapy Facilities](#)

hope that this will make these reports

mark from

5b.

ite PPD Clicks.

Expectations: How SWOG communicates data requirements

- 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; post-baseline specimens, QoL forms, other forms
- Posted during protocol treatment and follow-up
 - Based on the follow-up timing for patient
 - Adverse events, treatment given, tumor assessment, new study-specific forms (S1802, S1614)
- Overdue follow-up
 - Need updated last contact date

Specimen Expectations – Example

EXPECTATIONS

Filter Criteria

Show only patient #: Show only study #: Show only investigator #:

Show only registrations after: (mm/dd/yyyy) Show only items due*: Before After (mm/dd/yyyy) Disease Type: IPR:

*Within upcoming 90 days only

[Export Report Data to Excel](#)

Data Management Institution: Kaiser Perm NCORP (CA154)


3/21/2019 9:53:53 AM



Follow-up Institution: Kaiser Perm NCORP (CA154)

Patno	Initials	Study	Investigator	RegDate	Last Contact Date	Status	Due Date	Expectation Qualifier	Days Overdue	IPR
703908	C,M	S1418-2	Birhan	11/15/2018	01/29/2019	A	02/13/2019	RT breast form/Breast Radiation Therapy Form	36	
							04/19/2019	Blood submission/Green top tube, recurrence		
							04/19/2019	Blood submission/Red top tube, recurrence		
							04/19/2019	Tissue Submission/From recurrence/progression		

Specimen Tracking: Choose the Specimen




Choose Specimen

Step 2 of 3: Choose the specimen that you are logging from the list below.

Show: Registration Step = Specimen/Material Type = Lab =
 Submission Timepoint =

Show: Registration Step = Specimen/Material Type = Lab =
 Submission Timepoint =

Study Number: S1418

Registration Step	Submission Timepoint	Specimen or Material Type	Material Requirements	Lab
2	Relapse/recurrence	Tissue from distant site Blocks Paraffin-embedded core biopsies	Only option	201 - SWOG Specimen Repository Columbus, OH
2	Relapse/recurrence	Blood Whole Blood Red top tube, 5 ml whole blood	Only option	201 - SWOG Specimen Repository Columbus, OH
2	Relapse/recurrence	Blood Whole Blood Green top tube, 5 ml whole blood	Only option	201 - SWOG Specimen Repository Columbus, OH

2	Week 55	Blood Whole Blood BAHO Lavender top tube, 7.5 ml peripheral blood	Only option	159 - NRG Serum Bank at Baylor College of Med Houston, TX
2	Month 18	Blood Whole Blood BAHO Lavender top tube, 7.5 ml peripheral blood	Only option	159 - NRG Serum Bank at Baylor College of Med Houston, TX
2	Baseline	Blood Whole Blood Green top tube, 5 ml whole blood	Only option	201 - SWOG Specimen Repository Columbus, OH
2	Week 13	Blood Whole Blood Green top tube, 5 ml whole blood	Only option	201 - SWOG Specimen Repository Columbus, OH
				201 - SWOG Specimen Repository

Notes on specimens

- Specimens that can't be submitted → “Notify that Specimen Cannot be Submitted”

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[Chooser](#)
[Log a Specimen](#)
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This is the test Web site
All pages with headers in **green** act against the test database and should be used for practice only.

Welcome to the SWOG Specimen Tracking Website

You are logged in as a user for AR006 - University of Arkansas for Medical Sciences

Important Announcements:

- **Specimen Tracking Updates:** A number of updates have been made to Specimen Tracking with the goal of improving the interface of this tool for CRAs. Changes made to the "Log a Specimen" page include (1) a filter tool at the top of the page which can focus the specimen choices to your needs (2) the addition of the city and state to the Lab and (3) the addition of a column "Material Requirement" indicating if the material type is the only option, preferred or alternate. Changes to "Specimen Manager" include the addition of the specimens which could not be submitted with a checkbox filter tool.
- [Training module with demo](#) for using the Specimen Tracking System.

- If a specimen isn't logged, the expectation won't get resolved even if it has been received by the biorepository
 - Log the specimen retroactively
- If a specimen was logged in but the wrong type of specimen was chosen
 - Contact the Statistical Center

How SWOG Measures Data Quality?

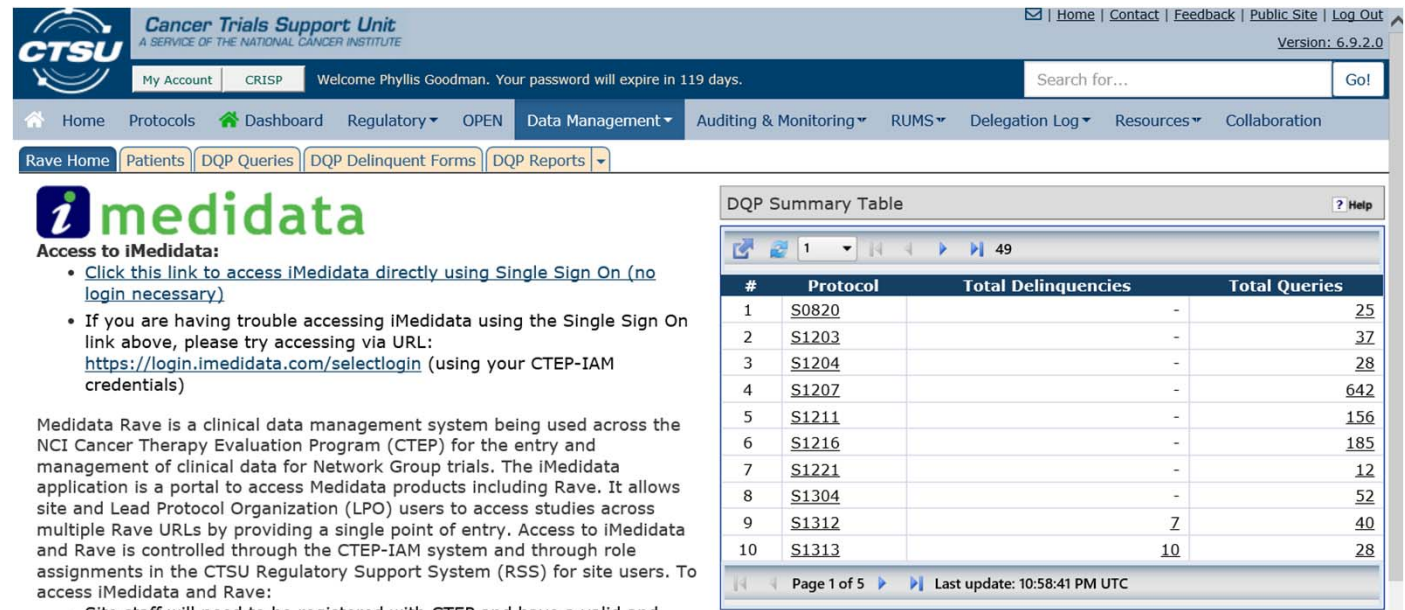
- Institution Performance Review (IPR)
 - Statistics used to monitor an institution's compliance to data submission requirements
 - Are required forms being submitted?
 - SWOG Policy #33
- Categories of data – updated November 2017
 - Baseline (Initial Forms Set)
 - Post-baseline forms submission
 - Vital status updates (Follow-up)
 - Specimen submission

IPR metrics – As of April 2, 2019

93 SWOG LAPS/Members/NCORP sites	Initial Forms Set (IFS)	Post-Baseline Forms	Follow-Up	Post-Baseline Specimens
Compliance level	≤10% patient registrations overdue	≤5% forms overdue	≤15% patients overdue	≤10% specimens overdue
Mean % overdue	108/3150 (3.4%)	315/53,464 (0.6%)	485/9,405 (5.2%)	118/3,683 (3.2%)
Number of sites at 0% overdue	59	40	28	64
Total # of sites over the compliance level	4	1	5	5

What's new(ish) in the quality world?

- Data Quality Portal (DQP) on CTSU website
 - Overdue forms
 - Overdue queries



CTSU Cancer Trials Support Unit
A SERVICE OF THE NATIONAL CANCER INSTITUTE

My Account | CRISP | Welcome Phyllis Goodman. Your password will expire in 119 days. | Search for... | Go!

Home | Protocols | Dashboard | Regulatory | OPEN | Data Management | Auditing & Monitoring | RUMS | Delegation Log | Resources | Collaboration

Rave Home | Patients | DQP Queries | DQP Delinquent Forms | DQP Reports

i medidata

Access to iMedidata:

- Click this link to access iMedidata directly using Single Sign On (no login necessary)
- If you are having trouble accessing iMedidata using the Single Sign On link above, please try accessing via URL: <https://login.imedidata.com/selectlogin> (using your CTEP-IAM credentials)

Medidata Rave is a clinical data management system being used across the NCI Cancer Therapy Evaluation Program (CTEP) for the entry and management of clinical data for Network Group trials. The iMedidata application is a portal to access Medidata products including Rave. It allows site and Lead Protocol Organization (LPO) users to access studies across multiple Rave URLs by providing a single point of entry. Access to iMedidata and Rave is controlled through the CTEP-IAM system and through role assignments in the CTSU Regulatory Support System (RSS) for site users. To access iMedidata and Rave:

- Site staff will need to be registered with CTEP and have a valid and

DQP Summary Table

#	Protocol	Total Delinquencies	Total Queries
1	S0820	-	25
2	S1203	-	37
3	S1204	-	28
4	S1207	-	642
5	S1211	-	156
6	S1216	-	185
7	S1221	-	12
8	S1304	-	52
9	S1312	7	40
10	S1313	10	28

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Expectation Report vs. DQP Delinquency Report

	Expectation Report	DQP
What's posted	Overdue and upcoming items due within next 90 days	Overdue forms only
Overdue definition	> 60 days from day expectation is due, doesn't take into account treatment delays	Based on target date + maximum treatment delay; overdue if > 15 days late
How to access	SWOG CRA Workbench; dynamic report updated in real time*	CTSU; updated nightly

* Data submitted in Rave are applied to the SWOG database overnight.

Expectation Report vs. DQP Delinquency Report (continued)

	Expectation Report	DQP
Which studies	All Rave studies + all pre-Rave studies	Rave studies WITH calendaring*
What's included	Forms, specimens, anything else for which and expectation has been created	Forms, source document uploads and anything that has be calendared within Rave
On-study form	One form for older studies; newer studies may be > 1 form/expectation	May be more than one form
Specimens	Included	Not included
Source documents	One expectation for each type of source doc at a given timepoint	One form (with log lines) which includes all relevant source docs

DQP Delinquent Forms – As of April 15, 2019

Total delinquencies	< 15 days	15-30 days	31-60 days	61 – 90 days	>90 days
1534	597 (39%)	277 (18%)	243 (16%)	125 (8%)	292 (19%)

Form Type	Number of Delinquent Forms
Baseline	352
Quality of Life	52
Disease Assessment	385
Follow-Up	299
Other	446
Total	1534

Common Questions I Get

- How come I see XXX on the SWOG Expectation Report but it isn't overdue in Rave?
 - Form forced into Rave without updating appropriate data fields in SWOG database (e.g., last contact date)
 - QoL Coversheets that trigger roll out of forms in Rave not answered appropriately
 - Was QoL form complete?
 - Yes → Appropriate form rolls out in Rave; when completed and submitted, expectation resolves
 - No → Form doesn't roll out in Rave; expectation resolves
 - Blank → System query but if answered with text rather than Y/N, form doesn't roll out (so it won't look overdue in Rave), expectation doesn't get resolved
 - Source documents uploaded with the wrong "Type of Procedure"
 - Data point which triggered expectation resolution was amended
 - Not a calendared study

Not Calendared vs. Calendared

Calendaring – Rave function for defining when forms are due

- You will not see overdue forms on studies that aren't calendared
- You will still see outstanding queries regardless of calendaring

Not calendared: Visit area is blank: S0820, S1207, S1216, S1221



Patient ID: 241551 Patient Initials (LFM): QPB Enrollment Date: 01 Apr 2013

Subject Enrollment [Grid View](#)

Visit	Date	Task Summary: Subject	Pages
		NonConformant Data	0
		Open Queries	1
		Sticky Notes	1
		Overdue Data	0

Calendared: Visit area has visits/cycles and dates forms are due: All other Rave studies



Patient ID: 251427 Patient Initials (LFM): LCI Enrollment Date: 28 Oct 2016

Subject Enrollment [Grid View](#)

Visit	Date	Task Summary: Subject	Pages
Baseline	28 Oct 2016	NonConformant Data	0
Disease Assessment	28 Oct 2016	Open Queries	1
Follow-up Tumor Assessment 2016-12-19	19 Dec 2016	Sticky Notes	0
Cycle 01	03 Nov 2016	Overdue Data	0
Cycle 02	25 Nov 2016		
Cycle 03	14 Dec 2016		
Off Treatment (1)	21 Dec 2016		
Follow-up	22 Feb 2017		

SWOG Query Report vs. DQP Queries

	SWOG Query Report	DQP Queries
Which studies	All Rave studies + all pre Rave studies	All Rave studies
What's included	Queries from Data Coordinators, Auditors/Monitors and Biorepository	Queries from Data Coordinators, Auditors/Monitors and Biorepository Medidata Rave System queries + non-conformant data
Overdue definition	Don't currently measure	Calculated from date posted; overdue if > 15 days since posted
How to access	SWOG CRA Workbench	CTSU

DQP Queries – As of April 15, 2019

Total queries	< 15 days	15-30 days	31-60 days	61 – 90 days	>90 days
3410	1265 (37%)	465 (13%)	493 (14%)	330 (10%)	857 (25%)

Query Type	Number
Site from System	1111
Site from DM (<i>Stat Center Data Coordinators</i>)	2238
Site from Monitor	2
Site from Specialist (<i>Biorepository</i>)	10
Non-conformant	49
Total	3410

DQP Comments

- Delinquent Forms
 - Complements our Expectation and IPR reports
 - If there are inconsistencies, work towards the SWOG reports as that is how site performance is currently measured
- Overdue queries
 - One missing lab value → multiple queries (value, units, ULN, LLN, sample collection date)
 - Partially completed forms → missing data queries
 - “Ghost queries” – query on a log line or form that was subsequently deleted → contact Statistical Center
- If you find an inconsistency, contact me
- We see DQP as a tool; we don’t know NCI’s long term plan for use

Thank you!

