

Reports and Tools to Support Quality Data

Cathy Rankin, M.S.
Coordinating Statistician
Institution Performance
SWOG Statistics and Data Management Center



When are expectations posted?

1. At the time the patient is registered
2. During protocol treatment and follow-up



What defines quality?

- NCTN Grant Submission required data on
- Timeliness
 - Were the required data forms submitted?
 - Were the required data forms submitted on time?
- Accuracy
 - We don't compare submitted data to source documents (other than audited and monitored charts) so...
 - Is the submitted data free of queries?



At patient registration

- Baseline requirements
 - Forms: On-study, Baseline abnormalities, Baseline tumor assessment, etc.
 - Source documents: Pathology/Operative reports, other source documents
 - Specimens
 - Other study-specific items (e.g., Quality of Life questionnaires, imaging)
- Defined time point post registration (e.g., Week 4)
 - Quality of Life questionnaires, other study-specific forms
 - Specimens
- Appear on the Confirmation of Registration



How does SWOG facilitate data submission?

- **Expectation System:** Identifies the submission requirements for forms, reports, specimens, patient completed forms
- Expectation = Anything that is "expected" to be submitted to the SDMC
- Protocol-specific data requirements
- May be posted conditionally based on treatment arm, stratification factor, form disease status, consent answers, etc.



During protocol treatment and follow-up

- Forms for most treatment studies include
 - Adverse event, treatment, disease assessment
- Other study-specific forms
 - e.g., S1703 Imaging/STM results, S1800D Concomitant Medications and Laboratory values, S1802 Symptomatic Local Progression
- Dynamic, time-period specific
 - Looks at next form due based on treatment or disease assessment schedule
 - "Period beginning" is determined from patient's previous visit
- Conditional based on an event (e.g., progression, off treatment)



SWOG Reports for Quality

- Expectation Report
- Query Report
- Institution Performance Review (IPR) Report
- Ineligible Patients Report



SWOG
Society for
Oncology
Clinical
Trials



NCI
National
Cancer
Institute

Expectation Reports

NEWS

2/15/2023

Updates to calculation of the Vital Status/Follow-up (FUP) and Forms (FORM)

Starting this month, there have been some updates to the calculation of the Vital Status/Follow-up (FUP) and Forms (FORM) measures. Specifically, (1) the Vital Status form now only counts in the FUP measure and (2) the denominators in the FORM measure were being counted incorrectly for some sites, this has now been fixed. You may notice slight changes in your metrics because of this change.

12/14/2022

What's included in my Expectation report?

The Expectation Report gives a list of specific data items that are either overdue or are due within the next several weeks. We had been inconsistent in the timeframe for the upcoming reports as updates were made this month regarding what shows for data due in the future.

- For **PRO Instruments**, expectations due within the upcoming **90 days** will show on the report.

- For **all other forms/specimens/source docs**, the expectation will show on the report if it is due within the upcoming **42 days**.

These changes may affect the length of your report but only because of items due in the future.

The filters at the top of the Current Expectation Report have also been renamed for clarity. You can choose to see only the Expectations counting in a specific IPR category by using the "Expectation Category" dropdown and the Expectations which are negatively impacting your IPR metrics can be identified by using the "IPR" dropdown.

Please select the report you wish to display:

Current Expectation Reports

[IPR Expectation Reports](#) [Forms Expectation Reports](#)

Monthly Expectation Reports

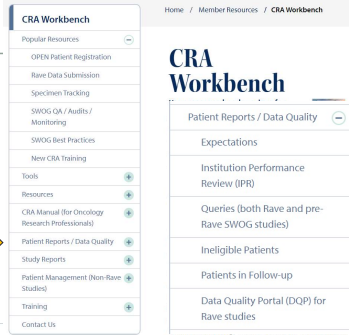
[IPR Expectation Reports](#) [Forms Expectation Reports](#)

Monthly IPR Reports

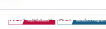
[IPR Expectation Reports](#) [Forms Expectation Reports](#)

How do I access the reports?

- Navigate to the SWOG CRA Workbench via swog.org
- "Patient Reports/Data Quality" link on the left site, mid-way down



SWOG
Society for
Oncology
Clinical
Trials



NCI
National
Cancer
Institute

Current Expectation Report

EXPECTATIONS

Filter Criteria

SWOG Patient ID: Study: SWOG Investigator ID: Disease Type:

Registrations after: Items due: Expectation Category: IPR:

Institution CTEP ID: *Within upcoming 50 days only

Data Management Institution: MUSC MU-NCORP (SC008)
Follow-up Institution: MUSC MU-NCORP (SC008)

2/9/2023 8:12:05 PM



SWOG
Society for
Oncology
Clinical
Trials



NCI
National
Cancer
Institute

Expectation Report

Compilation of expectations past due *and* those due in the next 42 days (90 days for PROs)

- Monthly Report
 - Static report generated at the beginning of the month
- Current Report
 - Dynamic report that reflects up-to-the-minute database status
- Both
 - Downloadable to Excel
 - Identify overdue expectations which impact performance metrics with a code as to which metric it belongs



SWOG
Society for
Oncology
Clinical
Trials



NCI
National
Cancer
Institute

Expectation Report

Data Management Institution: Upstate NCDRP (UPSTATE)
Follow-up Institution: Upstate NCDRP (UPSTATE)

2/9/2023 4:34:00 PM

SWOG Patient ID	Initials	Study	Institution CTEP ID	Investigator	Regulate	Last Contact Date	Status	Over Due	Expectation	Days Overdue	IPR
283223	AJS	SL714-1	SC100	Siegel	11/23/2020	10/24/2022	A	01/04/2023	Events Form/Submitted neuropathy Events, Week 104	36	
286836	BLR	SL714-1	SC100	Siegel	03/17/2020	04/05/2022	A	01/04/2023	Events Form/Submitted neuropathy Events, Week 104	36	
798325	LGP	SL806-2	SC004	Humenik	11/06/2022	01/17/2023	A	01/04/2023	Events Form/Submitted neuropathy Events, Week 104	36	
								04/08/2023	Cover Sheet for Questionnaire/Week 104	36	
								12/13/2022	Radiation Therapy Plan/RT Case Form Submit via TRSAD	59	IPR
								12/13/2022	Regulatory Checklist/Reg. Case, Source Doc, No Investigator	59	IPR
								02/02/2023	Adverse Events Form/Period beginning 01/17/2023	3	
								02/06/2023	Consentment Medications Form/Period beginning 01/17/2023	3	
								02/06/2023	Laboratory Values Form/Period beginning 01/17/2023	3	
								02/06/2023	Pre-Medications Form/Period beginning 01/17/2023	3	
								02/06/2023	Adverse Events Form/Period beginning 01/17/2023	3	
								03/16/2023	SDTC QLC-BL/MS/Week 12	2	
								03/16/2023	SDTC QLC-C30 Questionnaire/Week 12	2	
								03/16/2023	EQ-SD-SL Health Questionnaire/Week 12	2	
								03/16/2023	Quality of Life/EPIC-Bond Assessment, Week 12	2	



SWOG
Society for
Oncology
Clinical
Trials



NCI
National
Cancer
Institute

Expectation Report - Details

SWOG Patient ID	Study	Due Date	Expectation	Days Overdue
296109	S2010-1	2/29/2024	Follow-up	4
294799	S2101-2	7/27/2023	Vital Status (Off Treatment) Form/Period beginning 05/05/2023	221
294799	S2101-2	4/12/2024	Vital Status/48 wks	
295876	S2001-1	1/24/2024	Adverse Events form/Period beginning 01/04/2024	40
292525	S1803-2	3/10/2024	Follow Up Tumor Assessment Form/Period beginning 01/10/2024	
298312	S2010-1	2/28/2024	Buffy Coat submission/Baseline	5
298312	S2010-1	2/28/2024	Plasma submission/Baseline	5
295678	S1931-2	1/25/2024	On-study: Lab Values	39
289143	S1501-2	1/2/2024	Echocardiogram/Week 96	62
296640	S1931-2	10/5/2023	Institution Operative Report	151
298832	S2001-1	1/24/2024	Institution Pathology Report/Confirming pancreatic adenocarcinoma	40
299091	S2010-1	6/1/2024	Cover Sheet for Questionnaires/12 wks.	
299091	S2010-1	6/1/2024	FACT/FACIT/S2010 GP5 Item and FACT-ES Subscale, 12 wks.	
299091	S2010-1	6/1/2024	Patient Completed Questionnaire/S2010 DOSE-Nonadherence, 12 wks.	

Query Report

- Queries posted by Stat Center Data Coordinators, Central Monitors, QA team, Biorepository based on their review of the data
- Rave – System queries included in a separate section
- Recently added as IPR component of site performance
- Located in the Patient Reports link on CRA Workbench

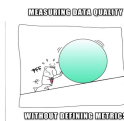
Patient Reports / Data Quality
Expectations
Institution Performance Review (IPR)
Queries (both Rave and pre-Rave SWOG studies)
Ineligible Patients
Patients in Follow-up
Data Quality Portal (DQP) for Rave studies

Specimen Tracking – Log a Specimen

Registration Step	Submission Timepoint	Specimen or Material Type	Material Requirements	Lab
1	Week 1 Induction	Blood Serum 1 mL aliquots into 2 mL cryovials	Only option	201 - SWOG Specimen Repository Columbus, OH
1	Week 1 Induction	SUPERNATANT: ~20 mL urine before BCG instillation	Only option	201 - SWOG Specimen Repository Columbus, OH
1	Week 1 Induction	PELLET: ~2-4 mL urine before BCG instillation	Only option	201 - SWOG Specimen Repository Columbus, OH
1	Week 1 Induction	UNTOUCHED: ~20 mL urine before BCG instillation	Only option	201 - SWOG Specimen Repository Columbus, OH

Institution Performance Review (IPR)

- Statistics used to monitor and measure an institution's compliance with data submission requirements
 - Are required forms being submitted?
- SWOG Policy #33: Compliance guidelines
- The IPR report is run monthly and contains the compliance rates (percentages) for each category
- Posted on the SWOG CRA Workbench and mailed to the PI and Lead ORP of the LAPS/Member/NCORP



Specimen Expectations

- If a specimen cannot be collected
 - "Notify that Specimen Cannot be Submitted" function on Specimen Tracking resolves the expectation

[Home](#)
[Link a Specimen](#)
[Specimen Manager](#)
[View/Update Consent/Assent](#)
[Notify that Specimen Cannot be Submitted](#)
[Reports](#)
[Administration](#)
[Contact Us](#)

Version: 3.0.0

Tracking Compliance: IPR Report

- Five categories
 - Initial Forms Set:** expectations "associated with" patient registration data needed to evaluate eligibility; includes specimens needed to evaluate eligibility, treatment or stratification assignment and future endpoint determination
 - Post-baseline forms** submission
 - Vital status updates** (patient follow-up)
 - Specimens:** all others not covered above
 - Queries:** unresolved queries > 15 days after posted
- Overdue items contributing to the IPR categories are identified on the Expectation Report in the IPR column with a code
 - Categories and definitions on "Expectation and IPR Reports" page

Expectation Report – IPR column

SWOG Patient ID	Study	Due Date	Expectation	Days Overdue	IPR
296109	S2010-1	2/29/2024	Follow-up	4	
294799	S2101-2	7/27/2023	Vital Status (Off Treatment) Form/Period beginning 05/05/2023	221	FUP
294799	S2101-2	4/12/2024	Vital Status/48 wks.		
295876	S2001-1	1/24/2024	Adverse Events form/Period beginning 01/04/2024	40	
292525	S1803-2	3/10/2024	Follow Up Tumor Assessment Form/Period beginning 01/10/2024		
298312	S2010-1	2/28/2024	Buffy Coat submission/Baseline	5	
298312	S2010-1	2/28/2024	Plasma submission/Baseline	5	
295678	S1931-2	1/25/2024	On-study: Lab Values	39	IFS
289143	S1501-2	1/2/2024	Echocardiogram/Week 96	62	FORM
296640	S1931-2	10/5/2023	Institution Operative Report	151	FORM
298832	S2001-1	1/24/2024	Institution Pathology Report/Confirming pancreatic adenocarcinoma	40	IFS
299091	S2010-1	6/1/2024	Cover Sheet for Questionnaires/12 wks.		
299091	S2010-1	6/1/2024	FACT/FACIT/S2010 GP5 Item and FACT-ES Subscale, 12 wks.		
299091	S2010-1	6/1/2024	Patient Completed Questionnaire/S2010 DOSE-Nonadherence, 12 wks.		

Compliance Levels (cont.)

• Out of compliance if...

- **Post-baseline specimens**: >10% of **SPECIMENS** are > 30 days overdue or there are any specimens > 13 months overdue
- **Query Resolution**: > 5% of the **QUERIES** posted in the last 13 months are unresolved or any query > 13 months ago is still unresolved

Striving for 0% across the board!

IPR Statistics and Report

SWOG Institution Performance Review Statistics			
Data as of 8/10/2025			
For patients credited to SWOG			
A. Registration steps lacking submission of Initial Forms Set			
A1. Registrations within last 13 months	3 / 55	5.45%	
A2. Registrations more than 13 months ago	0		
B. Overdue Vital Status Updates	8 / 141	5.67%	
C. Expected forms (post-baseline) not submitted	52 / 1424	3.65%	
D. Expected specimens (post-baseline) not submitted			
D1. Specimens expected in the last 13 months	14 / 173	8.09%	
D2. Specimens expected more than 13 months ago	0		
E. Responsiveness to Queries			
E1. Queries posted in the last 13 months	5 / 65	7.69% *	
E2. Queries posted more than 13 months ago	0		

*Indicates out of compliance

Consequence of poor performance

• Two Consecutive Months

- If an institution remains out of compliance on any measure for two consecutive months, a **warning email** is sent to the PI and Head CRA

• Three Consecutive Months

- The institution is at **risk of suspension** with loss of registration privileges. If not corrected within 1 month, the institution may be suspended

Compliance Levels

• Out of compliance if...

- **Initial Forms Set**: >10% of patient **REGISTRATIONS** are > 30 days overdue or there are any registrations > 13 months overdue
 - All of the items associated with the Initial Forms Set must be received; a single overdue item will result in the registration being overdue
- **Post-baseline form expectation**: >5% of **FORMS** are > 60 days overdue
- **Vital Status updates** (follow-up): >15% of **PATIENTS** are > 60 days overdue

Ineligible patients report

- Eligibility determines whether patients will be included in the primary statistical analysis
- Check your ineligible patients
- Currently not a performance measure, but...
- Review your patients that are coded as ineligible
 - N = clinically ineligible
 - NI = Insufficient information
 - NR = Reversible

Patient Reports / Data Quality	
Expectations	
Institution Performance Review (IPR)	
Queries (both Rave and pre-Rave SWOG studies)	
Ineligible Patients	
Patients in Follow-up	
Data Quality Portal (DQP) for Rave studies	

Ineligible patients report

INELIGIBLE PATIENTS

The following report shows patients who have been deemed ineligible for therapeutic trials coordinated by SWOG who were registered by your institution within the last three years. Note that some of these patients may have transferred follow-up responsibility to another institution, but eligibility is credited to the registering institution.

Filter Criteria

Show only patient # Show only CTEP Investigator ID Show only patients registered since 3/6/2016

Show only study # Show only CTEP Institution ID Show only Disease Type ALL

Patient	Initials	Registering Network Group	Registering Investigator	Registering Institution	Study	Registration Date	Ineligibility Date	Ineligibility Code	Ineligibility Reason
700835	A, J W	SWOG			51404-1	4/21/2016	7/12/2016	N: Ineligibility	Ineligible due to toxicity data being done on 04/29/2016 and RECCT and CT scans being done on 04/28/2016-They were done after step 1 registration 04/11/2016.
361605	A, Q	SWOG			51207-1	5/13/2016	7/15/2016	N: Ineligible	HER2 IGH is equivocal or positive.
370902	B, D M	SWOG			51207-1	2/2/2018	4/5/2018	N: Ineligible	Required presurgery block not yet submitted - <60 days.
371148	B, G L	SWOG			51409-1	3/30/2018	4/7/2018	N: Ineligible	Patient ineligible (N): Patient ineligible-QT patient taking once daily combinations that use pharmacologic boosters (section 5.3.a.2 of the protocol)

SWOG NCI Cancer Therapy Evaluation Program NCI NCI NCI

High quality data
are essential for
good studies...
...Your efforts are
essential for high
quality data



CTSUS Reports

- Data Quality Portal (DQP)
 - Delinquent Forms
 - Queries – those from Data Coordinator as well as “System Queries” and non-conformant data
- Includes
 - All SWOG Rave studies but NOT pre-Rave studies
 - Other Network Group Rave studies

→

Expectation Reports

NEWS 3/1/2023
Updates to calculation of the Vital Status/Follow-up (FUP) and Forms (FORM)

Starting this month, there have been some updates to the calculation of the Vital Status/Follow-Up (FUP) and Forms (FORM) measures. Specifically, (1) the Vital Status form now only counts in the FUP measure and (2) the denominators in the FORM measures were being counted incorrectly for some sites, this has now been fixed. You may notice slight changes in your metrics because of this change.

3/1/2022
DQP and the SWOG Expectation System PPT Presentation
The PowerPoint presentation about the CTSU Data Quality Portal (DQP) and the SWOG Expectation System and Query Reports has been updated. The DQP is another tool to help with managing the submission of your data and responses to queries. We hope that this presentation will answer any questions you may have about the difference between these two systems.

[CTSUS Data Quality Portal vs. SWOG Expectation and Query Reports](#)

SWOG NCI Cancer Therapy Evaluation Program NCI NCI NCI

Questions?

FAQs

- Do the Auditors use these reports?
 - The auditors do have access to these reports on a case-by-case basis and can use them to support their work. They provide an overview of a site's performance. However, they are not part of the formal audit report
- Do the NCI and other Network groups have access to these reports?
 - Currently, these reports are only used by SWOG and the information is not routinely given to the NCI or other groups.
- Who should I contact if I have questions?
 - ExpectationReportQuestion@crab.org