

Reports and Tools to Support Quality Data

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SWOG
Society for Women's Oncology
Gynecologic Cancer Research Group

NCI
National Cancer Institute
U.S. Department of Health and Human Services

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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?

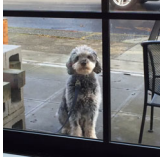
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How does SWOG facilitate data submission?

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





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When are expectations posted?



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

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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

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During protocol treatment and follow-up

- Forms for most treatment studies include
 - Adverse event, treatment, follow-up tumor 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 schedule
 - "Period beginning" is determined from patient's previous visit
- Can be conditional based on an event (e.g., progression, off treatment)

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Expectation due dates

- Current guidelines from CTSU = 15/15/30
 - Baseline data – due within 15 days of registration
 - On treatment data – due within 15 days of visit/event
 - Off treatment data – due within 30 days of visit/event
- **Always check Section 14 for data submission timelines as older studies will be different**
- Specimens (baseline and post-baseline) – Per Section 15. Typically...
 - Blood products, urine – due within 15 days except for Streck tubes which are shipped the day after collection
 - Tissue – due within 30 days of...but check protocol for actual time frame

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Vital Status Updates = Follow-up Expectations

- Frequency and length of follow-up is protocol specific
 - Continued follow-up is expected while patient is receiving treatment and after they are off-treatment
 - Dynamically posted based on patient's last follow-up
 - Protocol specific, e.g.,

The diagram illustrates a patient's follow-up schedule. It starts with 'Registration' at Year 0. 'Treatment for 2 years - Visits every 3 months' is shown from Year 0 to Year 2. 'Off Treatment' begins at Year 2. 'Off Treatment Follow-Up' is shown from Year 2 to Year 5, with a note: 'Every 6 months for 2 years, then annually'. 'Follow-Up Complete' is marked at Year 5.

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Vital Status Updates

- Time since patient's last contact
 - Calculated as days between the day the report is run and the patient's last contact date (date last known to be alive)
- Last contact date
 - Studies prior to 2019 - updated from a number of forms including the treatment, adverse event, follow-up tumor assessment forms or SWOG Follow-Up Form
- **Vital Status Update form**
 - For studies activated in 2019 or later
 - Wave of the future – now on all studies going forward

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Vital Status Form

SWOG VITAL STATUS FORM

Patient Identifier Study Identifier Registration Step



Patient Initials (L, F, M)

Instructions: Please complete this form when contact is made with the patient for any reason. **This form should be submitted prior to any other data entry related to that visit.** Date is in **DD MON YYYY** format.

Vital Status (If dead, please submit Notice of Death) Alive Dead

Date of last contact (If dead, please enter date of death)

Comments

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SWOG Reports for Quality

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

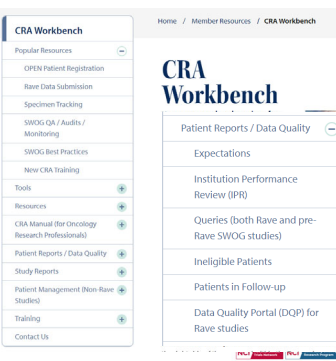






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How do I access the reports?

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

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Expectation Reports

NEWS
 5/21/2022



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 so 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	Monthly Expectation Reports	Monthly IPR Reports
UPSTATE_SWOG_...swog.NCORP	UPSTATE_SWOG_...swog.NCORP Excel	UPSTATE_SWOG_...swog.NCORP
	UPSTATE_SWOG_...swog.NCORP Excel	

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Expectation Report: 2 Versions

- 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 affect compliance (IPR) statistics

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Current Expectation Report

EXPECTATIONS



Filter Criteria

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

Registrations after: Items due: Before After (mm/dd/yyyy) **Expectation Category:** **IPR:**

Institution CTEP ID:

Data Management Institution: MUSC MU-NCORP (SC006) 2/8/2023 9:12:55 AM
 Follow-up Institution: MUSC MU-NCORP (SC006)

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Current Expectation Report

Data Management Institution: Upstate HCCRP (UPSTATE)
Follow-up Institution: Upstate HCCRP (UPSTATE) 2/9/2023 4:34:00 PM

SWOG Patient ID	Initials	Study	Institution CERP ID	Investigator	Regdate	Last Contact Date	Status	Due Date	Expectation	Days Overdue	IPR
28323	A.S.	S174-1	SC100	Shipe	11/23/2020	10/24/2022	A	01/04/2023	EORTC QLQ-C30/Week 104	36	
								01/04/2023	Events Form/Subject Toxicity Events, Week 104	36	
								01/04/2023	PRO-CTCAE/Week 104	36	
								01/04/2023	Treatment Form/Week 104	36	
29050	B.M.	S174-1	SC100	Shipe	03/17/2020	04/10/2022	A	04/28/2023	Consent Form/Questionnaire/Week 126	56	JFS
79920	J.G.	E166-2	CC24	Sumner	11/30/2022	01/17/2023	A	12/12/2022	Radiation Therapy Plan/RT Data Form Submit via TRAD	59	JFS
								12/15/2022	Eligibility Checklist/Rtg. Ctr. Source Doc. w/ Investigator Signature	56	JFS
								02/02/2023	RT Treatment Form/RT Treatment Form	7	
								02/06/2023	Concomitant 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	
									Adverse Events Form/Period beginning 01/18/2023	2	
								03/16/2023	EORTC QLQ-BLM30/Week 12		
								03/16/2023	EORTC QLQ-C30 Questionnaire/Week 12		
								03/16/2023	EQ-5D-5L Health Questionnaire/Week 12		
								03/16/2023	Quality of Life/EPRC Dowel Assessment, Week 12		

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Current Expectation Report

Due Date	Expectation	Days Overdue	IPR
04/14/2021	Follow-up	335	FUP
05/06/2022	Off Treatment Vital Status/Period beginning 02/12/2022		
05/20/2022	Disease Assessment Form/Period beginning 02/12/2022		
04/22/2022	EORTC QLQ-BLM30/Week 104 (2 years)		
02/24/2022	Blood submission/CBALR Visit #1: SST to SWOG Bank	19	
02/24/2022	Blood submission/CBALR Visit #1: Streck tubes to SWOG Bank	19	
12/20/2021	Adverse Events Form/Period beginning 06/15/2021	85	FORM
12/20/2021	Treatment Form/Period beginning 06/15/2021	85	FORM

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Current Expectation Report

Due Date	Expectation	Days Overdue	IPR
04/14/2021	Follow-up	335	FUP
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12/20/2021	Treatment Form/Period beginning 06/15/2021	85	FORM
02/24/2022	Blood submission/CBALR Visit #1: SST to SWOG Bank	19	
02/24/2022	Blood submission/CBALR Visit #1: Streck tubes to SWOG Bank	19	

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Specimen Expectations

- Specimens for which the patient opt out will not have expectations posted
- Baseline specimens: (1) those needed to assess eligibility, stratification or future endpoint determination and (2) those needed for banking or future TM studies
- Post-baseline specimens
 - Fixed time point (e.g., month 3) posted at registration
 - Based on an event (e.g., progression) posted conditionally




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Specimen Tracking – Log a Specimen

SELECT ONE OR MORE OF THESE REQUIRED FILTERS AND CLICK APPLY TO DISPLAY SPECIMEN LIST


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	U Urine SUPERNATANT: ~20 mL urine before BCG instillation	Only option	201 - SWOG Specimen Repository Columbus, OH
1	Week 1 Induction	U Urine PELLET: ~2-4 mL urine before BCG instillation	Only option	201 - SWOG Specimen Repository Columbus, OH
1	Week 1 Induction	U Urine UNTOUCHED: ~20 mL urine before BCG instillation	Only option	201 - SWOG Specimen Repository Columbus, OH



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Specimen Expectations


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



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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 Head CRA of the LAPS/Member/NCORP



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Tracking Compliance: IPR Report

- Four categories
 - Initial Forms Set:** expectations "associated with" patient registration data; 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
- 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

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Due Date	Expectation	Days Overdue	IPR
04/14/2021	Follow-up	335	FUP
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IPR Statistics and Report

SWOG Institution Performance Review Statistics
For patients credited to SWOG
Data as of 02/02/2021

Principal Investigator:
DM Institution: 1

A. Registration steps lacking submission of Initial Forms Set		
A1. Registrations within last 13 months	7 / 90	7.78%
A2. Registrations more than 13 months ago	0	
B. Overdue Vital Status Updates	36 / 230	15.65%
C. Expected forms (post-baseline) not submitted	34 / 3009	1.13%
D. Expected specimens (post-baseline) not submitted		
D1. Specimens expected in the last 13 months	8 / 177	4.52%
D2. Specimens expected more than 13 months ago	0	



 *Indicates out of compliance

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Compliance Levels



- Out of compliance if...
 - **Initial Forms Set**: >10% of patient **REGISTRATIONS** are > 30 days 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
 - **Post-baseline specimens**: >10% of **SPECIMENS** are > 30 days overdue
- Striving for 0% across the board

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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



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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
- Not currently tied to Expectations or IPR but just as important and will be a future component of site performance
- Located in the 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



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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

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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 recruiting institution.

Filter Criteria

Show only patient # Show only CTEP investigator ID Show only patients registered since

Show only study # Show only CTEP institution ID Show only Disease Type

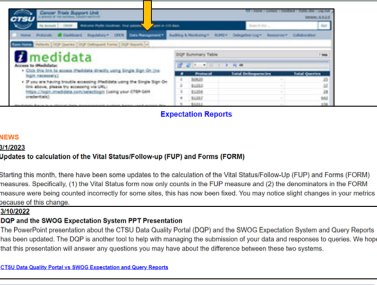
Ptcat	Initials	Registering Network Group	Registering Investigator	Registering Institution	Study	Registration Date	Ineligibility Date	Ineligibility Code	Ineligibility Reason
700835	A, J W	SWOG			51404-1	4/21/2016	7/12/2016	NI: Inelig. -staff job	Ineligible due to Oncology labs being done on 04/29/2016 and PRS/CT and CT scans being done on 04/28/2016-They were done after step 1 registration 04/21/2016
205605	A, Q	SWOG			51207-1	5/13/2016	7/15/2016	NI: ineligible	NI: Ineligible due to equivocal or positive.
207992	B, D H	SWOG			51207-1	2/2/2018	4/5/2018	NI: Inelig. -reversible	Required pretrialy block not yet submitted. <60 days.
271748	B, G L	SWOG			51609-1	3/30/2018	6/7/2018	NI: ineligible	patient ineligible (N); Patient ineligible d/o patient taking once daily combinations that use pharmacologic binders (section 2.3.2.2 of the protocol)






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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





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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

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



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Questions?

