

## Reports and Tools to Support Quality Data

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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 evaluate data timeliness?

**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.



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## Expectations can be posted...

- At the time the patient is registered
- 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 timepoint specific forms
- Specimens

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## During protocol treatment and follow-up

### Forms for most treatment studies include

- Adverse event, treatment, disease assessment, follow-up

### Other study-specific forms

- Concomitant Medications, Laboratory Values, Symptomatic Local Progression

### Dynamic, recurring 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)

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### Expectation due dates


Current guidelines from CTSU = 15/30/60

- Baseline data – due within 15 days of registration
- On treatment data – due within 30 days of visit
- Off treatment data – due within 60 days of visit

**Always check Section 14 for data submission timelines as not consistent**

Specimens follow Section 15. Typically...

- Blood products, urine – due within 15 days except for Streck tubes which are shipped overnight
- Tissue – due within 30 days of...*but check protocol for actual timeframe*



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### Categories of Expectations

**Initial Forms Sets (IFS)**  
Expectations “associated with” patient registration that are needed to assess eligibility


- Forms, images, questionnaires – per Section 14
- Specimens need to confirm eligibility, for treatment assignment or stratification or for future endpoint determination

**Post Baseline Forms**  
Any form, source document, participant-completed questionnaire due during the course of the trial  
Does NOT include the Vital Status Form (I’ll explain below)

**Vital Status Updates**

**Specimens**

- Except those noted above in IFS





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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; at study specific time-points


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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)

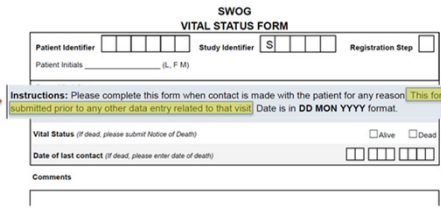

**Last contact date**  
*Studies prior to 2019* - updated from a number of forms including the treatment, adverse event, follow-up tumor assessment forms or SWOG Follow-Up Form

**Vital Status Form**  
For studies activated in 2019 or later



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### Vital Status Form

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### Specimen Expectations


**Baseline specimens include**

- Those needed to assess eligibility, stratification or future endpoint determination (included in the IFS measure)
- Those needed for banking or future TM studies

**Other Specimens**

- Fixed time point (e.g., Cycle 2, Day 1) posted at registration
- Based on an event (e.g., progression) posted conditionally

Specimens for which the patient opts out will not have expectations posted



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## SWOG Reports for Quality

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

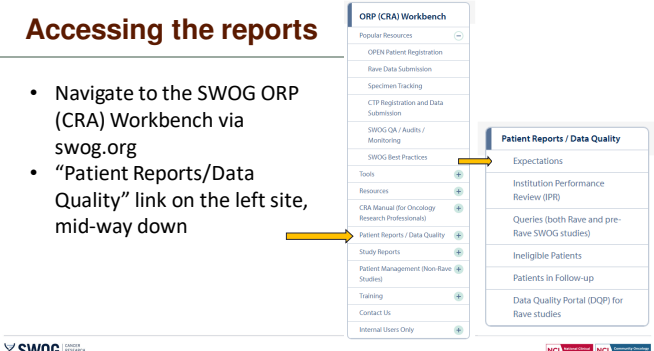







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## Accessing the reports

- Navigate to the SWOG ORP (CRA) Workbench via [swog.org](http://swog.org)
- “Patient Reports/Data Quality” link on the left site, mid-way down



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## 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

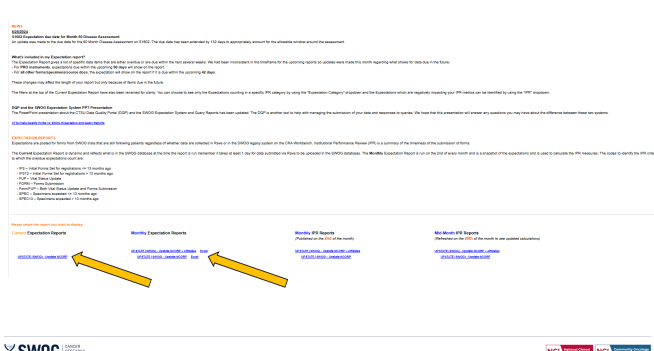
**Both**



- Downloadable to Excel
- Identify overdue expectations which impact performance metrics with a code as to which metric it belongs



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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) (mm/dd/yyyy) (mm/dd/yyyy)

Institution CTEP ID:  Within upcoming 90 days only

Apply | Reset

Export Report Data to Excel



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## Expectation Report

2/10/2022 4:34:00 PM

Data Management Institution: Upstate HCCORP (UHCORP) Follow-up Institution: Upstate HCCORP (UHCORP)

SWOG Patient ID	Institution	Study	Institution CTEP ID	Investigator	Reg/Date	Last Contact Date	State	Item Title	Expectation	Days Overdue	IPR
28223	A.E.S.	S174-1	SC108	Singel	11/21/2020	01/24/2022	A	02/24/2022	DOTC QOL QIPR 20, Week 104	36	
28036	B.A.H.	S174-1	SC108	Singel	03/17/2020	04/05/2022	A	04/28/2022	Cover Sheet for Questionnaire/Week 156	59	1FS
70920	S.G.P.	S1806-2	SC004	Hummelink	11/26/2022	01/17/2023	A	12/13/2022	Radiation Therapy Plan/RT Done Form Submit via TRSAD	58	1FS
								02/02/2022	RT Treatment Form/RT Treatment Form	7	
								02/06/2022	Concomitant Medications Form/Period beginning 01/17/2023	3	
								02/08/2022	Laboratory Values Form/Period beginning 01/17/2023	3	
								02/09/2022	Pre-Medications Form/Period beginning 01/17/2023	3	
									Adverse Events Form/Period beginning 01/18/2023	2	
								03/16/2022	DOTC QOL BL/MS/Week 12		
								03/16/2022	DOTC QOL CS3 Questionnaire/Week 12		
								03/16/2022	EQ-5D-5L Health Questionnaire/Week 12		
								03/16/2022	Quality of Life/EPIC Bowel Assessment, Week 12		

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### 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/FACT/S2010 GPS Item and FACT-ES Subscale, 12 wks.	
299091	S2010-1	6/1/2024	Patient Completed Questionnaire/S2010 DOSE-Nonadherence, 12 wks.	

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

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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 ORP (CRA) Workbench and mailed to the PI and Lead ORP of the LAPS/Member/NCORP

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### 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 and Query Report in the IPR column with a code

- Categories and definitions on “Expectation and IPR Reports” page

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### 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		
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295678	S1931-2	1/25/2024	On-study: Lab Values	39	IFS
289143	S1501-2	1/2/2024	Echocardiogram/Week 96	62	FORM
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299091	S2010-1	6/1/2024	FACT/FACT/S2010 GPS Item and FACT-ES Subscale, 12 wks.		
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### IPR Statistics and Report

SWOG Institution Performance Review Statistics  
Data as of 01/02/2025

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

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### 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

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### 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!

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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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### 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  Check. Was there a data entry error?
  - NI = Insufficient information  Eligibility can't be confirmed, material unavailable.
  - NR = Reversible  Missing information! Reversible if data submitted!

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 registering institution.

**Filter Criteria**

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

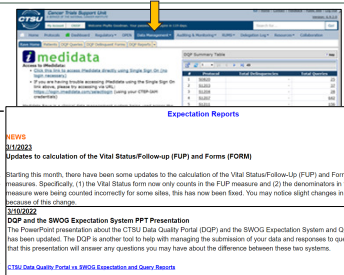
Show only study #  Show only CTEP Institution ID  Show only Disease Type

Patio	Initials	Registering Network Group	Registering Investigator	Registering Institution	Study	Registration Date	Ineligibility Date	Ineligibility Code	Ineligibility Reason
700833	A, J, W	SWOG			51404-1	4/21/2016	7/12/2016	N: Inelig_await_jud	Ineligible due to toxicity data being done on 04/20/2016 and RECIST and CT scans being done on 04/28/2016. They were done after step 1 registration 04/21/2016.
861605	A, Q	SWOG			51207-1	5/13/2016	7/15/2016	N: ineligible	HER2 ISH is equivocal or positive.
370992	B, D, H	SWOG			51207-1	2/22/2018	4/5/2018	N: Inelig_reversible	Required prestudy block not yet submitted - <60 days.
373148	B, G, L	SWOG			51609-1	3/30/2018	6/7/2018	N: ineligible	Patient ineligible (%): Patient ineligible: Q1 patient taking once daily combinations that use pharmacologic boosters (section 5.3.a.2 of the protocol)

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## CTSU 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) 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.

**3/1/2023**  
 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.

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

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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. The reports 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](mailto: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?

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