

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

Phyllis Goodman, M.S.  
Coordinating Statistician  
Institution Performance  
SWOG Statistical Center



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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



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## Access to SWOG Reports: CRA Workbench on swog.org



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## 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




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## Specimen Expectations – Example

### EXPECTATIONS

Filter Criteria

Show only patient # [72360] Show only study # [S1418] Show only investigator # [ ] Disease Type [ALL] Show only registrations after [mm/dd/yyyy] Show only forms due\* [Before] [After] [mm/dd/yyyy] PK [ALL] \*Within upcoming 90 days only

Apply Reset

Export Report Data to Excel

Data Management Institution: Kaiser Perman NCCRP (CA154) 5/21/2019 9:53:53 AM

Follow-up Institution: Kaiser Perman NCCRP (CA154)

Patient	Initials	Study	Investigator	Regdate	Last Contact Date	Status	Due Date	Expectation Qualifier	Days Overdue	PK
70798	CM	S1418-2	Bhawan	5/15/2018	6/29/2019	A	6/2/2019	All based from/From 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		




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## Specimen Tracking: Choose the Specimen

SWOG logo

Registration Step = [2] Specimen/Material Type = [ ] Lab = [ ]

Submission Transport = [Radiation/recurrence]

Registration Step	Submission Transport	Specimen or Material Type	Material Requirements	Lab
2	Radiation/recurrence	<a href="#">Tissue from distant site</a> Blocks Paraffin-embedded core biopsy	Only option	201 - SWOG Specimen Repository COLUMBUS, OH
2	Radiation/recurrence	Blood White Blood Red top tube, 5 ml whole blood	Only option	201 - SWOG Specimen Repository COLUMBUS, OH
2	Radiation/recurrence	Blood White Blood Green top tube, 5 ml whole blood	Only option	201 - SWOG Specimen Repository COLUMBUS, OH




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### Notes on specimens

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



- 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

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### 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

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### 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

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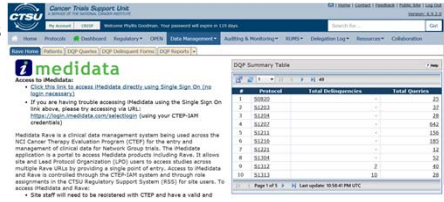
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## What's new(ish) in the quality world?

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



## 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 been 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




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### 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




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### 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

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




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### SWOG Query Report vs. DQP Queries

	SWOG Query Report	DQP
What's posted	All queries	Overdue queries
Overdue definition	Don't currently measure	Calculated from date posted; overdue if > 15 days since posted
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
How to access	SWOG CRA Workbench	CTSU
Which studies	All Rave studies + all pre Rave studies	All Rave studies

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### 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

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- ### 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
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Thank you!



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