

# SWOG Statistics and Data Management Center (SDMC)

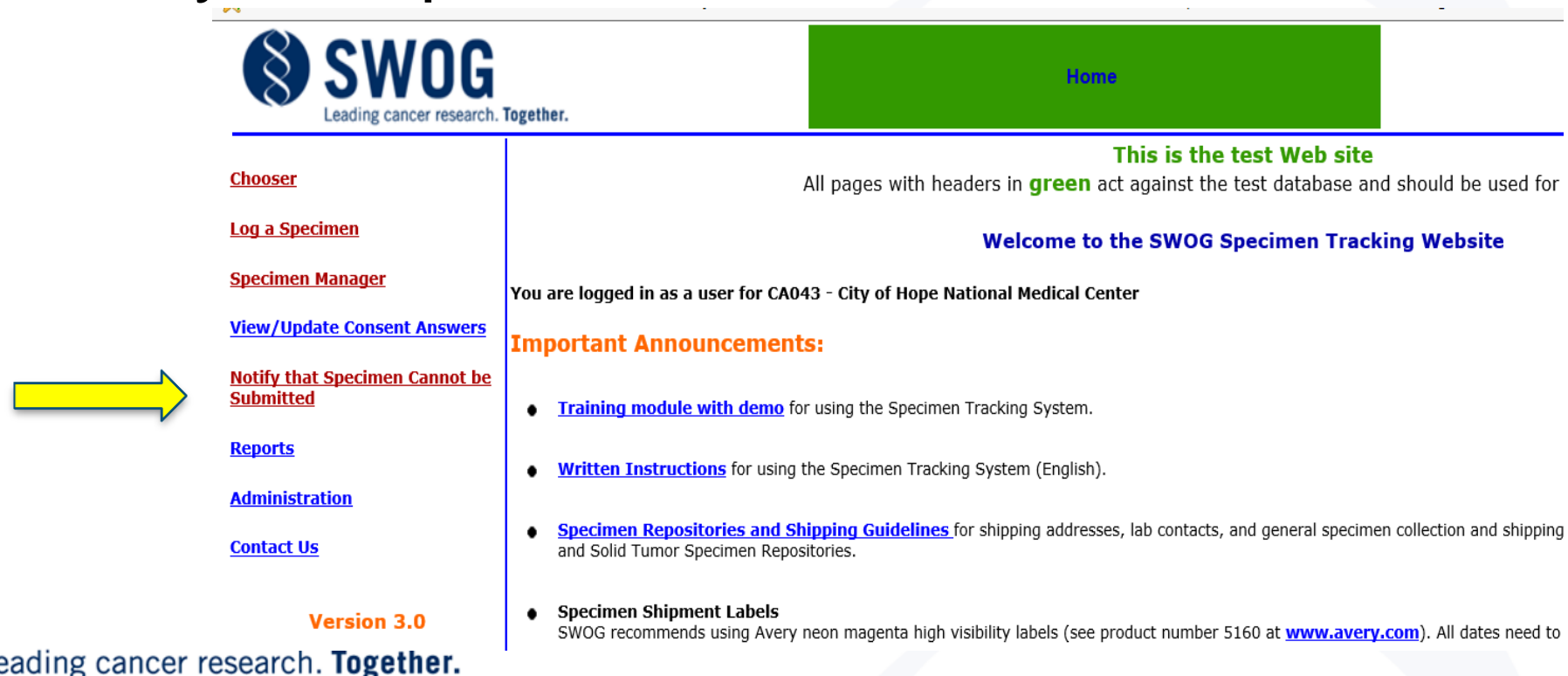
Phyllis Goodman, M.S.  
Coordinating Statistician

# Expectations and Institution Performance Review (IPR)

- Policy #33 was updated in October 2017
- Four performance categories
  - **Initial Forms Set** – measured at registration step level
  - **Vital Status Update** – combined On and Off Treatment into one measure; measured at a patient level
  - **Post-baseline forms** – new criteria; measured at form level
  - **Specimen submission** – new criteria; measured at specimen level
- IPR criteria will be enforced starting May 2018

# Specimen submission

- Specimens seem to be the biggest issue
- Two criteria: based on when specimen expected
- Notify if a Specimen Cannot be Submitted



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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

**Welcome to the SWOG Specimen Tracking Website**

You are logged in as a user for CA043 - City of Hope National Medical Center

**Important Announcements:**

- [Training module with demo](#) for using the Specimen Tracking System.
- [Written Instructions](#) for using the Specimen Tracking System (English).
- [Specimen Repositories and Shipping Guidelines](#) for shipping addresses, lab contacts, and general specimen collection and shipping and Solid Tumor Specimen Repositories.
- **Specimen Shipment Labels**  
SWOG recommends using Avery neon magenta high visibility labels (see product number 5160 at [www.avery.com](http://www.avery.com)). All dates need to

**Version 3.0**

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[View/Update Consent Answers](#)

[Notify that Specimen Cannot be Submitted](#)

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**NCI**  
National Clinical Trials Network

**NCI**  
Community Oncology Research Program

# Expectation and IPR Reports

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- Contact us if you identify any problems with your reports
  - We can explain why something is showing up *or*
  - You may have found a real problem with the report and we will investigate

# CTSU and DQP

- Bi-monthly email notifications from CTSU summary
  - DQP: Delinquent forms and queries
  - Central Monitoring Review: Missing source documents


## CTSU Data Delinquency Notifications Update:

Beginning March 15th, the CTSU will send delinquency notifications via email to site staff assigned a Primary Contact role on one or more Lead Protocol Organization (LPO) rosters. Site staff will receive these notifications twice a month, on a regular date depending on site code (i.e., A-M [plus all numeric codes] on the 1st and 15th of each month, N-Z on the 8th and 22nd). The notifications will contain summaries of delinquent forms and outstanding queries from the Data Quality Portal (DQP), and missing source documents that are required for central monitoring review.

Recipients will be able to unsubscribe and re-subscribe to these notifications via the CTSU Report and Information Subscription Portal (CRISP) on the CTSU website; likewise, site staff who would like to receive the delinquency notifications can subscribe via CRISP.

The CTSU has implemented several changes in response to feedback received regarding the initial delinquency notifications issued on February 1st, 2018. Please review the previously posted “[Update regarding CTSU Data Delinquency Notifications](#)” memo for details on the changes and for information regarding common DQP questions. The memo is located on the CTSU website under the [Resources](#) tab> CTSU Operations Information> Guidelines & Procedures.

# DQP – Accessing user's guide

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Collaboration

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

**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 active CTEP-IAM account.
- This is the same account (user id and password) used for


**DQP Summary Table** [? Help](#)

 1  43

#	Protocol	Total Delinquencies	Total Queries
1	<a href="#">S0820</a>	N/A	<a href="#">97</a>
2	<a href="#">S1203</a>	-	<a href="#">34</a>
3	<a href="#">S1204</a>	<a href="#">2</a>	<a href="#">54</a>
4	<a href="#">S1207</a>	N/A	<a href="#">864</a>
5	<a href="#">S1211</a>	-	<a href="#">144</a>
6	<a href="#">S1216</a>	N/A	<a href="#">228</a>
7	<a href="#">S1221</a>	N/A	<a href="#">26</a>
8	<a href="#">S1304</a>	-	<a href="#">52</a>
9	<a href="#">S1312</a>	<a href="#">5</a>	<a href="#">30</a>
10	<a href="#">S1313</a>	<a href="#">20</a>	<a href="#">16</a>

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# DQP – User's guide

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**medidata**

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**SWOG**

DQP Summary Table		
  1  		
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# SWOG Reports vs. CTSU DQP

- SWOG – Overdue form (Y/N), no levels based on how overdue
  - Currently, no metrics on response to queries
- Data Quality Portal (DQP) – Number of days overdue, not just presence/absence
  - Applies to both delinquent forms and response to queries



# Trials with FDA registration possibility

- S0777
  - **Pre-inspection** site visits
  - Celgene along with Elaine or Leanne
  - Sites at higher risk for FDA inspection; they have already been identified and dates set
- S1404
  - Interim analysis planned for July 2018. Intensive data clean-up and review ongoing.

# Trials with FDA registration possibility

- S1605 (bladder)
  - Presented at Oishi tomorrow
  - Complex (and confusing!) eligibility criteria
  - Sites are encouraged to contact study chairs PRIOR to registering a patient
    - ✓ Ensure patient meets the definition of BCG-refractory
    - ✓ Patient has had all of required TURBT, re-TURBT, scan, cystoscopies, cytology etc.; criteria differ depending on CIS only vs. Ta/T1 vs. T1
  - Refer to February 15, 2018 memo and Registration note in OPEN



February 15, 2018

TO: ALL NATIONAL CLINICAL TRIALS NETWORK (NCTN) MEMBERS IN THE U.S.; CTSU

FROM: Nicki Trevino, Protocol Coordinator (E-mail: ntrevino@swog.org)

RE: **S1605**, "Phase II Trial of Atezolizumab in BCG-Unresponsive Non-Muscle Invasive Bladder Cancer." Study Chairs: Drs. P. Black, P. Singh, and S. Lerner.

**GROUP CHAIR'S OFFICE**

Charles D. Blanke, MD  
CHAIR

3181 SW Sam Jackson Pk Rd  
MC: L586  
Portland, OR 97239

503-494-5586  
503-346-8038 FAX

**OPERATIONS OFFICE**

4201 Medical Dr  
Suite 250  
San Antonio, TX 78229

210-614-8808  
210-614-0006 FAX

**STATISTICAL CENTER**

1730 Minor Ave  
Suite 1900  
Seattle, WA 98101

206-652-2267  
206-342-1616 FAX

1100 Fairview Ave North  
M3-C102  
PO Box 19024  
Seattle, WA 98109

206-667-4623  
206-667-4408 FAX

**MEMORANDUM**

Study Chair: Peter C.V. Black, M.D.  
Phone number: 605/875-5003  
E-mail: pblack@mail.ubc.ca

**IRB Review Requirements**  
(v) No review required

**MEMORANDUM**

The purpose of this memorandum is to inform sites of the following message from the study chairs:

Dear NCTN Trial Sites,

We would like to thank you for enrolling patients in **S1605**. Since the eligibility criteria are complex and quite different from many other trials in other cancers, we would like to offer you the opportunity to discuss all potential trial patients with one of the study chairs prior to registration in **S1605**. Drs. Peter Black (pblack@mail.ubc.ca; cell 604-916-1522) or Parminder Singh (Singh.Parminder@mayo.edu; cell 917-816-8595) would be happy to review any patient with you or one of your team by e-mail or telephone. We cannot mandate such a review but we would strongly encourage you to take advantage of this opportunity so that we can ensure optimal adherence to the trial criteria. We would review with you source documentation including especially the BCG history and the pathology and operative reports. Ideally this would happen before patient consent so that the patient does not develop false expectations.

Please do not hesitate to reach out!

Peter & Parminder

# Other Trials with FDA registration possibility

- Current
  - S1418 (breast)
    - Delegation of Tasks Log (DTL): In order for sites to continue participation, a signed DTL is required by April 15, 2018. Sites without a signed DTL on April 15<sup>th</sup> will revert to pending status.
  - S1400x - Lung-MAP substudies
- Future that will include monitoring
  - S1800A (new Lung-MAP study)
  - S1806 (bladder)

# Ideas for tools from SDMC?

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- Focus on data quality
  - Timeliness
  - Query resolution
  - Anything else?
- Contact me at [pgoodman@fredhutch.org](mailto:pgoodman@fredhutch.org)