SWOG Statistics and Data Management Center (SDMC)

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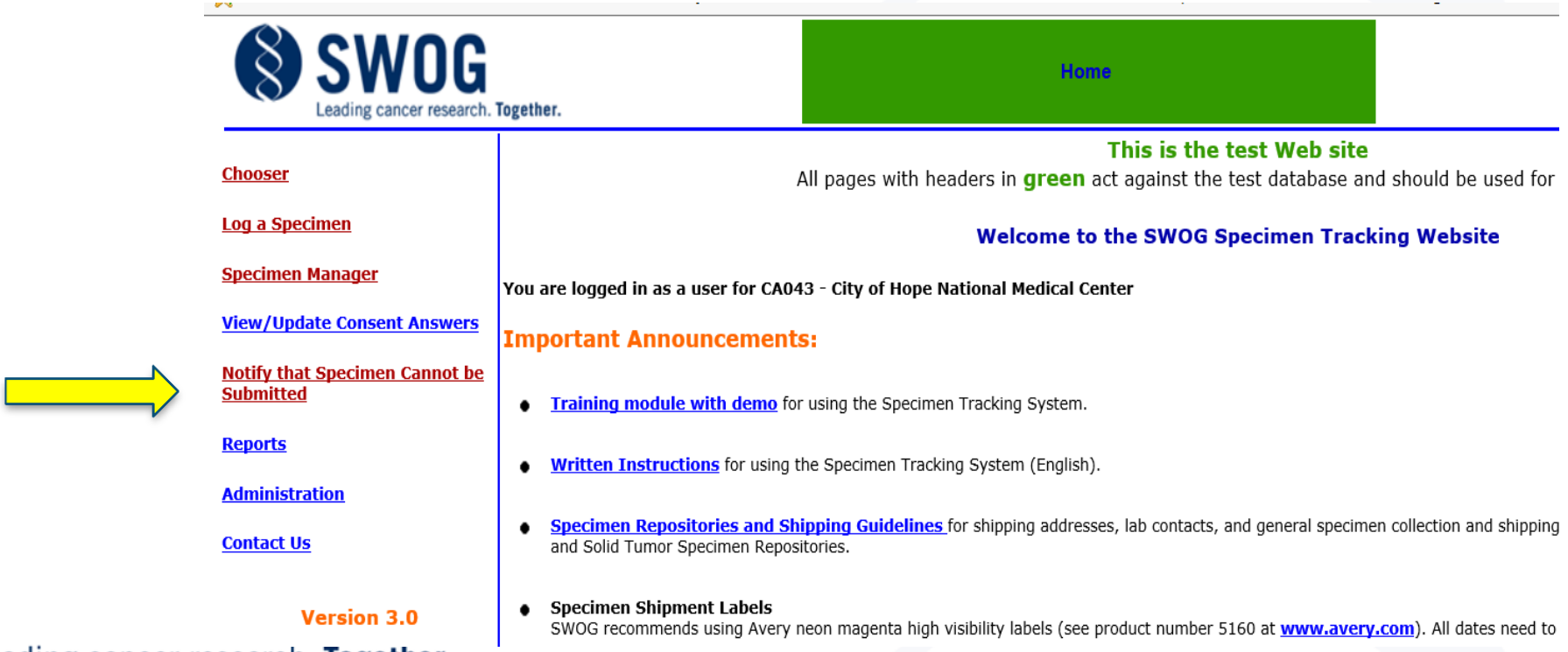
Coordinating Statistician

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



Expectation and IPR Reports

- 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

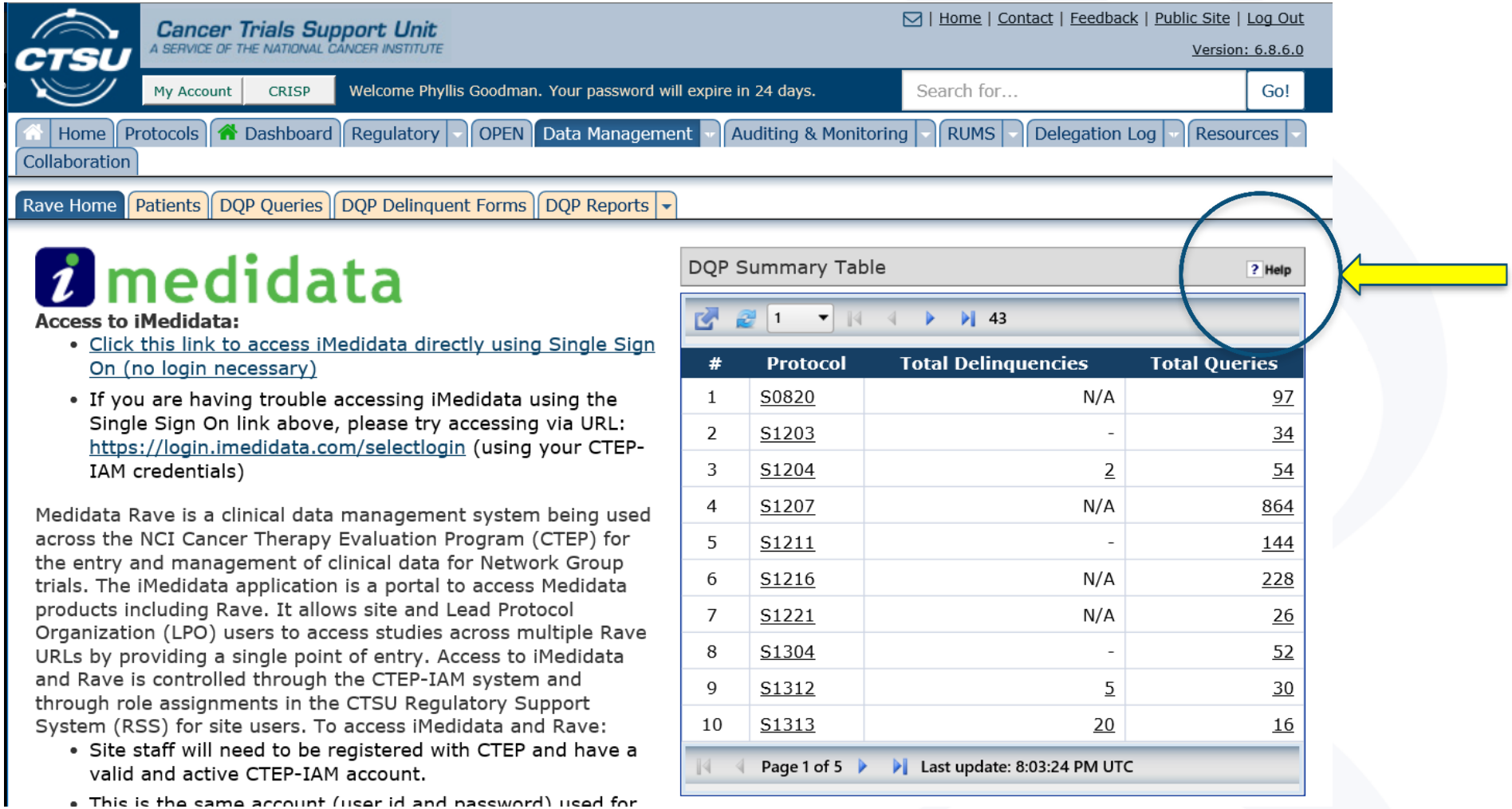
CTSU Data Delinquency Notifications Update:

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.

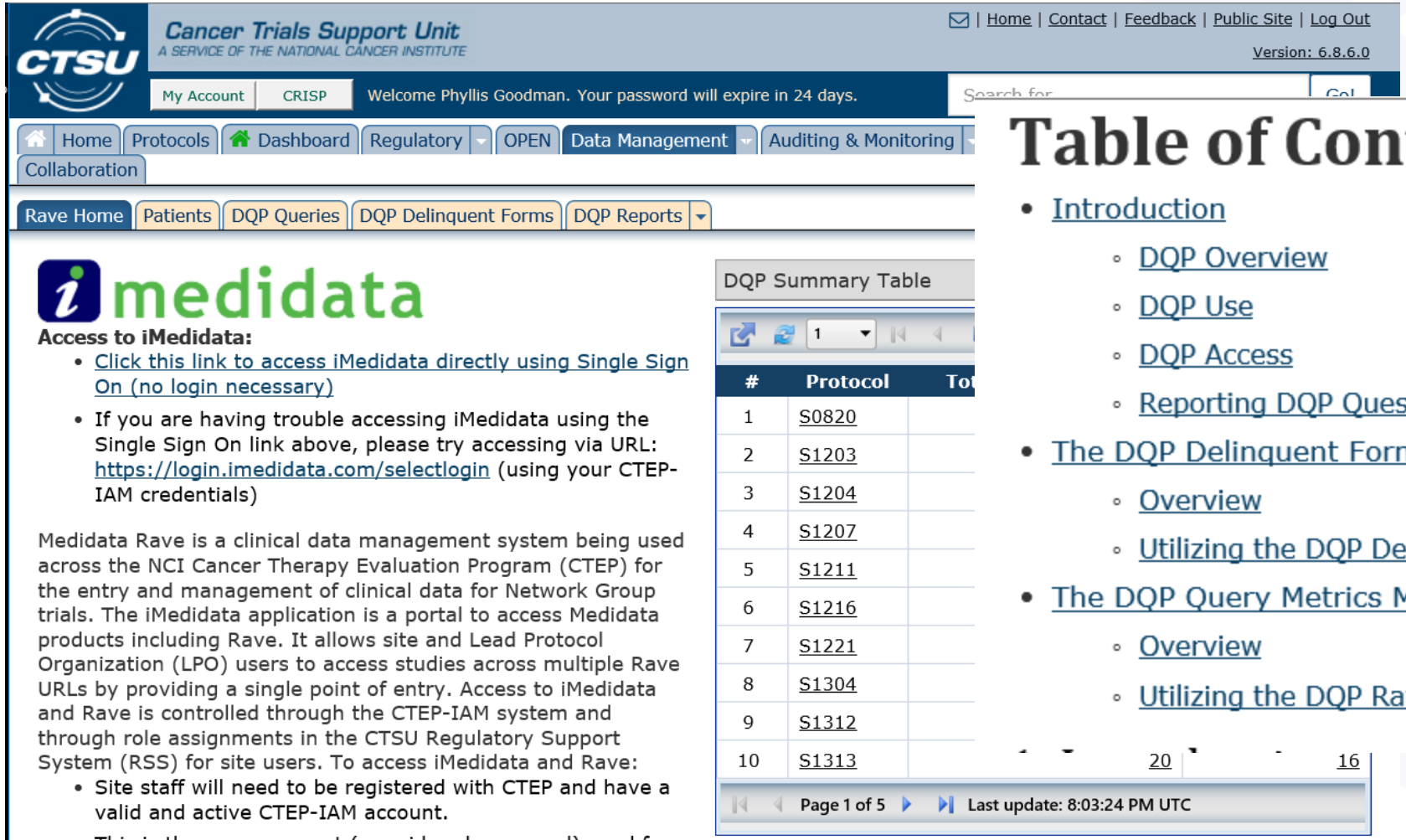
Recipients will be able to unsubscribe and re-subscribe to these notifications via the CTSU Report and Information Subscription Portal (CRISP) on the CTSU website; likewise, site staff who would like to receive the delinquency notifications can subscribe via CRISP.

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



DQP – User's guide



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SWOG Reports vs. CTSU DQP

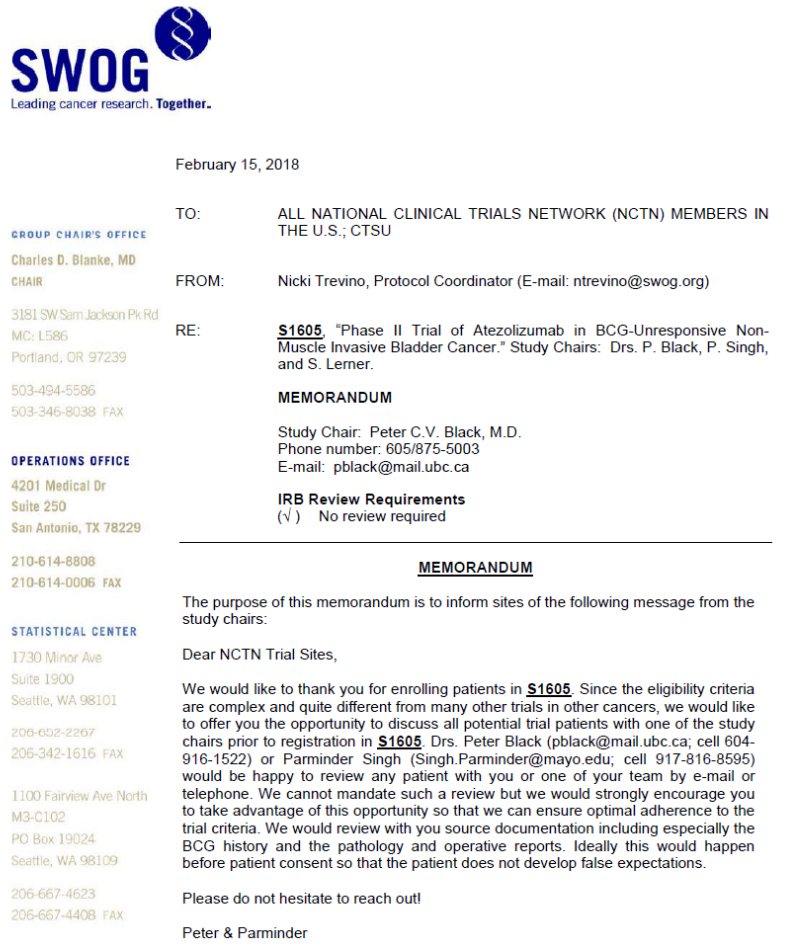
- SWOG – Overdue form (Y/N), no levels based on how overdue
  - Currently, no metrics on response to queries
- Data Quality Portal (DQP) – Number of days overdue, not just presence/absence
  - Applies to both delinquent forms and response to queries

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



SWOG
Leading cancer research. Together.

February 15, 2018

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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.

MEMORANDUM

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

IRB Review Requirements
(√) 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 15th 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?

- Focus on data quality
  - Timeliness
  - Query resolution
  - Anything else?
- Contact me at pgoodman@fredhutch.org