# SWOG SDMC Update

***Statistics and Data Management Center***

**Rodney Sutter, CCRP**
**Program Director, Therapeutic Studies**
**SWOG Data Operations Center**
**Seattle, WA**

# SWOG Policy #33

- Institutional Performance Review Updates
  - Address evolving data requirements
  - Align our performance measures with the DQP
  - Bridge gaps identified in the review process

- <u>IFS (Initial Forms Set)</u>:
  - ***Expand*** to include all baseline forms, reports, ***specimens*** and source documents

- <u>Follow-Up</u>:
  - ***Consolidate*** ‘follow-up, on tx’ and ‘follow-up, off tx’ measures
  - ***Rename*** into ‘Vital Status Update’

# IPR Recommendations

- Post-baseline Forms:
  - ***Include post-baseline forms***, report or other protocol-specified document that has an outstanding expectation within the last 13 months

- Specimen Submission:
  - ***Include post-baseline specimens*** for which an expectation has been posted

*** If approved by the Board of Governors, sites will be given adequate time to respond to any additional data submission requirements. SWOG will send formal notification with details. ***

# S1404 Data Monitoring

- Outstanding Forms
- Outstanding Queries
- Refer to ‘Reports’ on CRA Workbench & the DQP

Wed 9/20/2017 8:33 AM

krystlep (Krystle Pagarigan)

**S1404-- Outstanding Data Requiring Your Attention**

To

Cc ⊞ melanomaquestion

This message was sent with High importance.

Hello,
I am reaching out regarding your site’s participation in the S1404 trial “A Phase III Randomized Trial Comparing Physician/Patient Choice of Either High Dose Interferon or Ipilimumab to MK-3475 (Pembrolizumab) in Patients with High Risk Resected Melanoma.” This is a registration-intent trial that the study sponsor will submit to the Food and Drug Administration (FDA) next year; as such, it is vital that the SWOG Data Operations Center monitor expected data more closely, and ensure all data are submitted as soon as possible.

**Your site has a total of 76 outstanding queries on S1404 as of September 19, 2017, as reported by the Data Quality Portal (DQP) on CTSU.org. This value includes queries from Data Managers, non-conformant data errors, and system queries.** Please work with your study team to ensure that this backlog of outstanding data submissions is addressed promptly as all current and future queries must be addressed and closed prior to FDA submission.

Additional information will be released in the near future regarding how S1404 preparation for FDA submission will impact sites, and an automated email will be sent frequently detailing overdue data. In the meanwhile, your site staff’s time and contributions to this important trial are greatly appreciated.

If you have questions about specific queries, please feel free to reach out to the S1404 trial Data Managers at melanomaquestion@crab.org, or call the SWOG Data Operations office in Seattle at 206-652-2267.

# Baseline Smoking Status

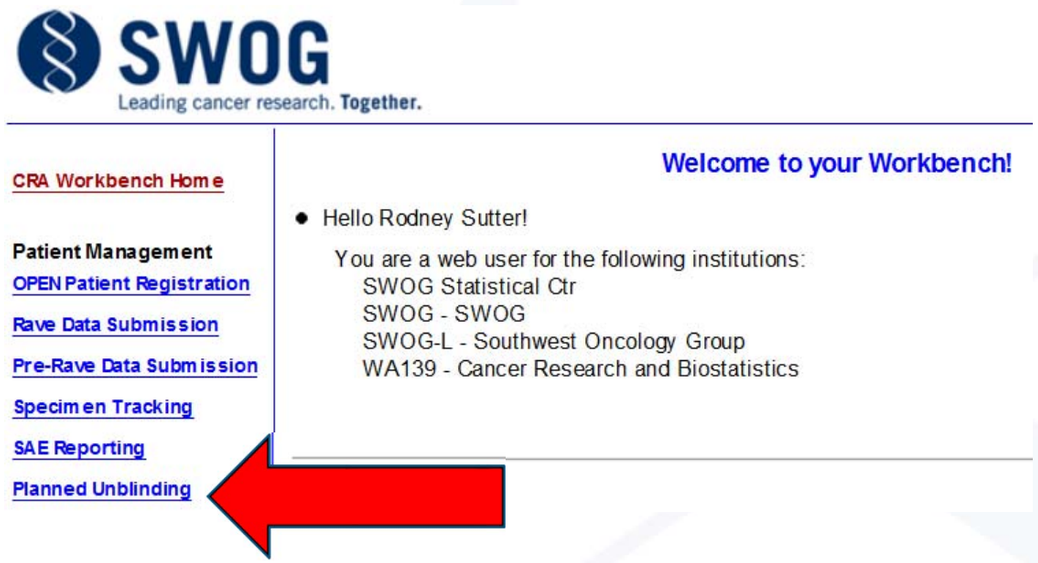
- NCI expressed interest in collecting baseline smoking status data
  - ➢ Some SWOG protocols already collect this, so we plan to incorporate for all new studies
    1. Future planning of potential prevention studies perhaps in smoking cessation
    2. Additional risk factor analyses for all studies

- First study to implement will be S1612 (Leukemia)

# Unblinding Patients

- Emergent
  - Washington Poison Center (WPC)
  - S0820, S1202, S1207, S1222, S1416

- Planned
  - S0023, S0232, S0303, S0931, S1416 (via CRA Workbench)



# Unblinding Patients – *RAVE*

- S1416 Emergent
  - Washington Poison Center
  - *Entered in Rave* by WPC
- S1416 Planned
  - *Entered in Rave* by the CRA
- Applicable to all future blinded studies

***Effective Date TBD, stay tuned……***

# CTEP – IAM Account

- CTEP – IAM *(Identity and Access Management)*
  - https://ctepcore.nci.nih.gov/iam/index.jsp

  - Click ‘Request New Account’ (2-3 days to process)

# Website Redesign

- Release planned for November, 2017
  - Will use a single logon (SWOG plus non-SWOG)
  - Improved search function
  - Fresh photos, videos and testimonials
  - Member resources (training, GM info, tools, etc.)
  - SWOG Glossary

- In preparation:
  - Consolidated SWOG and non-SWOG versions of the CRA Workbench
  - Redesigned the structure of menu items
  - Released on 09/01/2017

SWOG
Leading cancer research. Together.

CRA Workbench

CRA Workbench Home

Patient Management
OPEN Patient Registration
Rave Data Submission
Pre-Rave Data Submission
Specimen Tracking
SAE Reporting
Planned Unblinding

Resources
Reports
ORP Manual
Tools of the Trade
Training
SWOG Group Meetings
SWOG QA/Audits
CTSU Members Page
Related Links
Join the CRA Mailing List!
Contact Us

For SWOG Members
New SWOG CRAs!
SWOG ORP Committee
SWOG IRB/Regulatory Procedures
SWOG Protocols
SWOG Roster
SWOG Patient Transfer
swog.org members area

## Welcome to your Workbench!

- Hello Rodney Sutter!

You are a web user for the following institutions:
SWOG Statistical Ctr
SWOG - SWOG
SWOG-L - Southwest Oncology Group
WA139 - Cancer Research and Biostatistics

---

### What's New!

**08/30/2017**

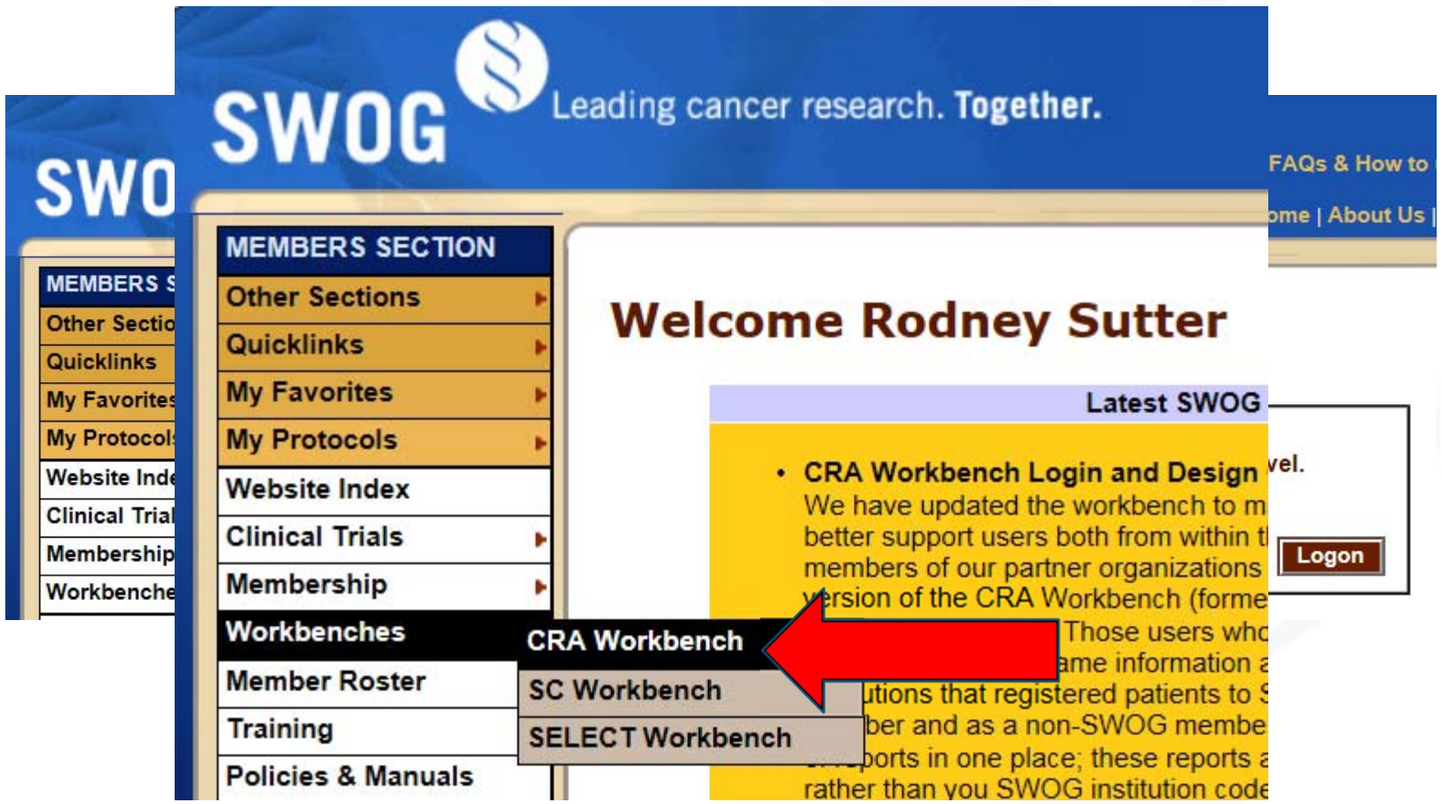
**CRA Workbench Design Change**

Welcome to the new look of your SWOG CRA Workbench! We have updated the workbench to make a number of different changes to better support users both from within the SWOG Membership, and members of our partner organizations as well. There is now only one version of the CRA Workbench (formerly there was one for SWOG and one for non-SWOG). Those users who are non-SWOG members will now have access to the same information as SWOG members. Those institutions that registered patients to SWOG studies as both a SWOG member and as a non-SWOG member, will now have access to both sets of reports in one place; these reports are now identified by your CTEP ID rather than you SWOG institution code. Some Reports will show all the data for your institution regardless of which Network Group was credited with the registration; others will be have the patients reported separately.

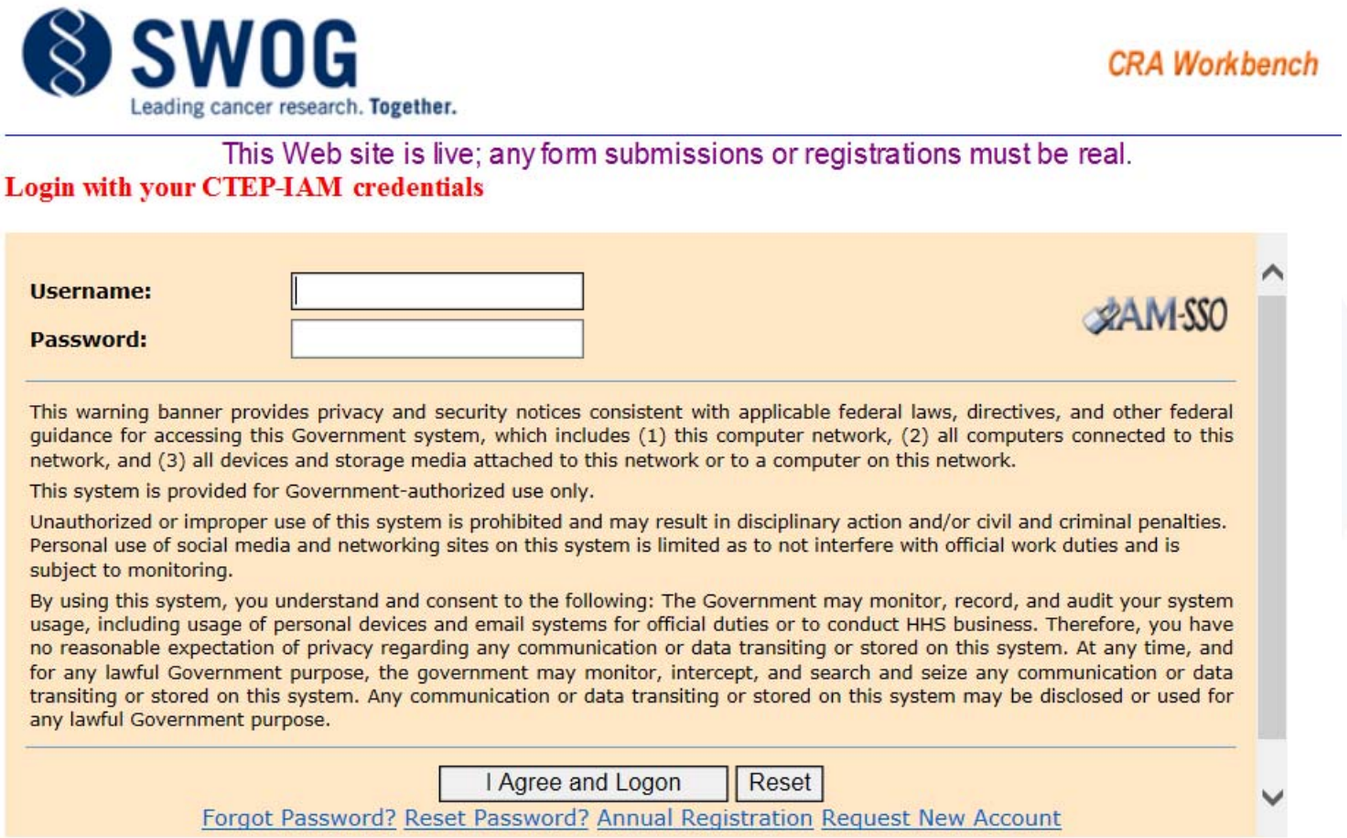
Some of the content has been shifted around or updated, but we are hopeful that everything will be easy to find.

Access is now only possible using your CTEP IAM account, and will allow us to seamlessly connect to CTSU, Rave and other applications that use that account. Please send us any feedback to technicalquestion@crab.org.

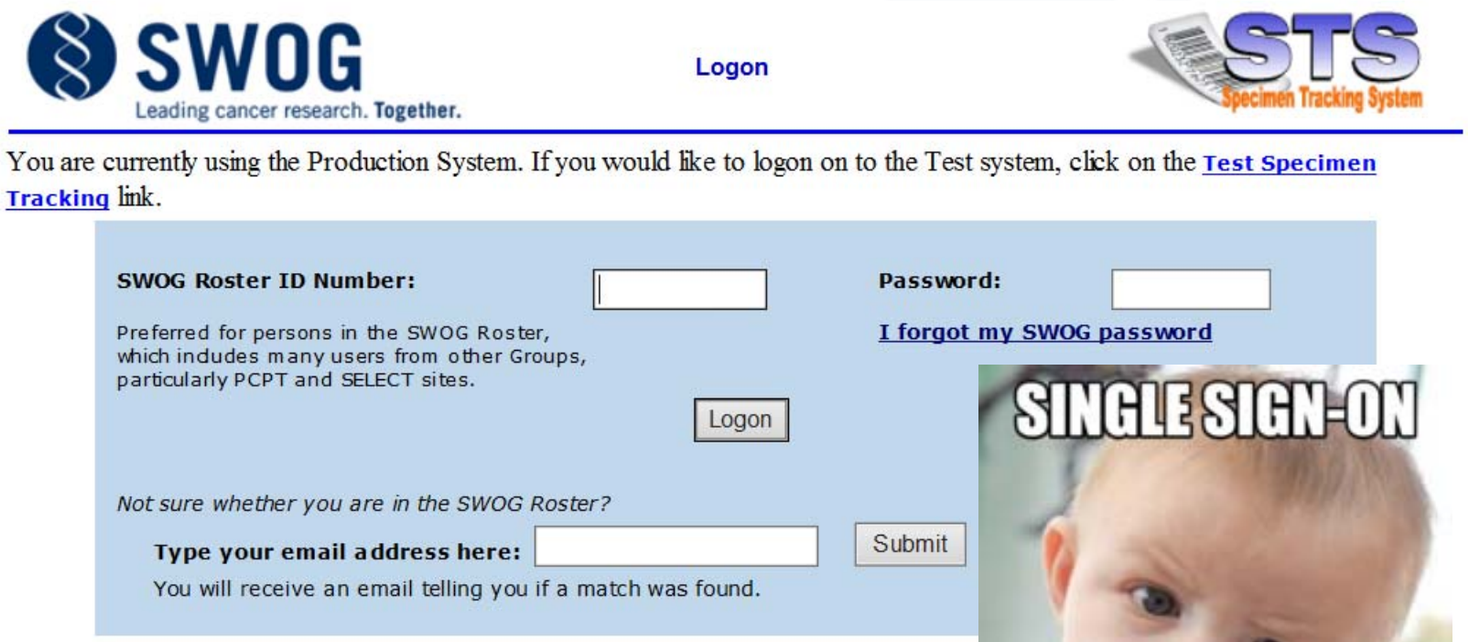
# Website Redesign



# Website Redesign



# Website Redesign



*For technical assistance, contact:*
*technicalquestion@crab.org*

# CTEP – Registration and Credential Repository Application

Message | Introduction to RCR_20170807.pdf (275 KB) | RCR Profile Checklist_AP_07JUL2017.pdf (324 KB) | Quick Reference Guide_IVR_NPIVR_AP_31JUL2017.pdf (198 KB)

**From:** RCRRegistration@nih.gov [mailto:RCRRegistration@nih.gov]
**Sent:** Thursday, August 10, 2017 11:03 PM
**To:**
**Subject:** NCI RCR Registration Reminder (60 day notification) for

Dear

Your Associate Plus (AP) registration with CTEP will expire on **09/29/2017**. With the release of CTEP's Registration and Credential Repository (RCR) application on Monday, July 31st, 2017, CTEP will no longer accept paper re-registration documents. To re-register using RCR, please login at https://ctepcore.nci.nih.gov/rcr/ using your CTEP-IAM username and password.

If you need to update your CTEP-IAM account information, please visit: https://ctepcore.nci.nih.gov/iam

Please refer to the attached documents for guidance on re-registering via RCR:

- **Introduction to RCR -** This slide deck provides an overview of CTEP's Registration and Credential Repository.
- **Registration and Credential Repository (RCR) Profile Checklist for Associate Plus (AP) -** This document provides a checklist of the information to be entered into your RCR profile to complete your NCI Biosketch and Financial Disclosure Form.
- **Quick Reference Guide for Investigators (IVRs), Non-Physician Investigators (NPIVRs), and Associate Plus (APs) -** This document will walk you through accessing RCR for the first time, creating a profile, reviewing and e-signing your registration documents, and submitting your re-registration packet to CTEP.

Once re-registered, your CTEP registration status will be updated. Your registration expiration date will be one year from the re-registration date.

If you have questions or encounter difficulties, please contact the CTEP Registration and Credential Repository (RCR) Team at RCRHelpDesk@nih.gov at any time.

****This is an automated notification from an unmonitored account. Please do not reply to this message.****

# CTEP – Registration and Credential Repository Application

- Submit the application as soon as possible
  - Human Subjects Protection Training
  - Good Clinical Practice Training

- If your registration expires, you cannot access:
  - OPEN
  - RAVE
  - TRIAD
  - CRA Workbench

# Queries in RAVE

- Marking Groups:  Site from DM, Site from Auditor, etc.
- Implement additional query tracking in RAVE vs. email

- Nationwide:
  - Queries specific to specimens submitted to the solid tumor, myeloma and lymphoma repository
  - Pilot Study – S1201

- SAEs:
  - Queries specific to missing or additional documentation specific to SAE reporting

- Clinical Monitoring:
  - Queries specific to CM review on validated studies

# Questions?

# Please Welcome,

## *Antje Hoering, PhD*

*CRAB President and CEO*

*SWOG Biostatistician – Myeloma*

**SWOG Statistics and Data Management Center**

Seattle, WA