Oncology Research Professionals (ORP) Site Operations Meeting

SWOG Spring Meeting 2023

Connie Szczepanek, RN, BSN, CCRP
Liz Edwards, BA, CCRP
Caitlin Hutchinson, MS

SWOG CANCER RESEARCH NETWORK
NCI National Clinical Trials Network
a National Cancer Institute program
NCI Community Oncology Research Program
A program of the National Cancer Institute of the National Institutes of Health

Logistics Details

- Please keep your phone on mute to help with sound quality.
- Questions can be submitted all throughout the meeting via the CHAT icon. We will present them to the speakers during the meeting.
- The presentations will be posted on the SWOG website within a few weeks.

Spring Site Operations Meeting Agenda
May 10, 5:30 – 7:30 PM PST

AGENDA	
Open, Welcome, and Announcements	Connie Szczepanek
Research Operations Updates	Jennifer Dill Connie Szczepanek
NCI Updates	Andrea Denicoff
Specimen Collection and Submission	Kae Tagtmeier
SWOG Updates	
*Group Chair's Office & Study Finance	Kyle Theige Pat Mize
*Operations & Membership	Dana Sparks
*Statistics & Data Management Center	Rodney Sutter
*Quality Assurance	Laura Gonzales
Thoughts on Life	Caitlin Hutchinson Tobi Sample
Closing Remarks	Connie Szczepanek

Although there are no formal CE credits for this meeting, you may print a copy of the agenda to reflect your attendance

(e.g.: for use with SOCRA or ACRP).

ORP Site Operations Committee

Wednesday, May 10, 2023 | 5:30 PM - 7:30 PM PT

Open, Welcome, and Announcements	Connie Szczepanek
Research Operations Updates	Jennifer Dill & Connie Szczepanek
NCI Updates	Andrea Denicoff
Specimen Collection and Submission	Kae Tegtmeier
SWOG Updates	
• Group Chair's Office & Study Finance	Casey Dawson, Pat Mize, Kyle Theige
• Operations Office & Membership	Dana Sparks
• Statistics & Data Management Center	Rodney Sutter
• Quality Assurance	Laura Gonzales
Thoughts on Life	Guest Presenter
Closing Remarks	Connie Szczepanek

I certify that I attended _____ hours of this meeting. The topics of the meeting contribute to the education and professional advancement in clinical research.

Signature_____ Date_____

Site Operations Sub-committee Chairs:
Connie Szczepanek, RN, BSN, CCRP – connie.szczepanek@crcwm.org
Liz Edwards, BA, CCRP – edwardel@ohsu.edu
Caitlin Hutchinson - caitlin.hutchinson2@va.gov

YOU are The ORP Committee!

"SWOG holds a fundamental conviction that the **O**ncology **R**esearch **P**rofessionals (ORP) play a crucial role in the successful development, implementation, and analysis of any SWOG clinical trial."

The SWOG Oncology Research Professionals (ORP) Committee & Sub-Committees

SWOG Cancer Research Network's Mission

- To significantly improve lives through cancer clinical trials and translational research.

ORP Committee Mission

- To support SWOG activities through promotion of integrity and excellence in clinical research through education, guidance, & collaborative contributions.

To get more deeply involved in the ORP Committee!

See the SWOG Website:

Member Resources / Membership / Committee Membership

https://www.swog.org/member-resources/membership/committee-membership

Key Involvement Opportunities

- Disease Specific Liaisons
- Liaisons at Large
- Education Team

Additional ORP Sessions Thursday

- Jeri & Noboru Oishi Symposium
- ORP Open Forum

ORP / CRP Research Operations Updates

SWOG Site Operations Committee Meeting

May 10, 2023

Jen Dill, BS, CCRP

Missouri Baptist Medical Center / Heartland NCORP

ALLIANCE CRP Committee Chair

Connie Szczepanek, RN, BSN, CCRP

Cancer Research Consortium of West MI NCORP

SWOG ORP Committee Chair

NCI National Clinical Trials Network
a National Cancer Institute program

NCI Community Oncology Research Program
A program of the National Cancer Institute of the National Institutes of Health

Background

Abstract 11049: National impact of the COVID-19 pandemic on clinical trial staff attrition: Results of the SWOG Cancer Research Network Survey of Oncology Research Professionals

Don S. Dizon[1], Connie M. Szczepanek[2], Daniel P. Petrylak[3], Dana B. Sparks[4], Catherine Tangen[5], Primo "Lucky" N. Lara Jr.[6], Ian M. Thompson, Jr.[7], Charles David Blanke[4]
(1) Lifespan Cancer Institute and Brown University; (2) Cancer Research Consortium of West Michigan, (3) Yale Cancer Center, (4) Oregon Health & Science University/SWOG, (5) Fred Hutchinson Cancer Research Center; (6) University of California Davis Comprehensive Cancer Center; (7) Children's Hospital of San Antonio

Background

- Considering the ongoing COVID-19 pandemic, severe staffing shortages in clinical trial staff in the United States and internationally have been anecdotally reported. However, data are lacking
- In order to better assess the scope and impact of staffing shortages, the SWOG Cancer Research Network conducted a cooperative group-wide survey of Oncology Research Professionals (ORP)

Methods:

- The survey was developed by SWOG leadership and endorsed by its Survey Subcommittee
- Exemption was granted by the Lifespan IRB (Providence, RI)
- In January 2022, the survey was distributed by the RedCap electronic data capture tool (Lifespan) to 100 Head Clinical Research Associates (CRAs) who were site-identified administrative leaders of SWOG Member and National Community Oncology Research Program Institutions

Respondent Demographics

	n (%)
Gender	
Female	69 (89.6)
Male	8 (10.4)
Year of birth (range)	
1955-1964	14 (18)
1965-1975	20 (24.9)
1976-1984	28 (35.9)
1985-1996	15 (18.3)
1996-2012	1 (1.3)
Before 1995	4 (5.13)
Ethnicity	
Hispanic	10 (12.8)
Not Hispanic	72 (87.8)
Race	
White	74 (85.1)
Black	1 (1.2)
American Indian/Alaskan	1 (1.2)
Asian	6 (6.9)

- 48% worked in an academic medical center; 20% private practice
- 22% each worked in a community hospital, health system, or an NCORP institution

CALL TO ACTION

Initiatives to recruit, train, and retain staff are urgently needed. The potential for post-pandemic persistence of this issue requires an immediate national response.

Major Findings

- **59/73 (80.8%) of CRAs report staffing shortages since the start of the COVID-19 pandemic.**

Where the shortage is being felt:

Every aspect of clinical trial processes has been impacted. On a scale of 0 (no impact) to 6 (significant impact):
- Audit activities 5 (4-5.6)
- Accrual 5 (3-5.5)
- Data transfers 4.5 (4-5)
- Sponsor visits 4.5 (3.5-5)
- Data collection 4 (3-5)
- Regulatory 4 (3.5-5)
- Screening 4 (3-5)
- Trial activation 4 (2.5-5)

Why people are leaving (lower score = more common)

Reason	Total Score (95% CI)
Better pay	34 (20.7 – 47.3)
Better opportunity	57 (46.4 – 67.6)
Better flexibility/Work from home	72 (53.7 – 90.3)
Burned out/Dissatisfied	77 (63.3 – 90.7)
Long work hours	97 (86.4 – 107.6)
Pursuit of further education	107 (89.7 – 124.3)
Leaving field altogether	116 (101.9 – 130.1)

Major Themes:

- Trials are increasingly more complex
- High levels of turnover increase the stress on existing staff
- Compensation is not keeping up with the job expectations in research
- Remaining staff are experiencing issues related to low morale

Email: don.dizon@lifespan.org

Research Operations Initiative Working Group

Amanda Dinsdale
Montana Cancer Consortium

Cassandra Gill
Medicine College of Wisconsin

Connie Szczepanek
Cancer Research Consortium of West Michigan

Cynthia Licavoli
Missouri Baptist Medical Center

Jamie Roberts
Duke

Jenna Russell
Michigan NCORP

Jennifer Anderson
Illinois CancerCare Research

Jen Dill
Missouri Baptist Medical Center

Liz Edwards
Oregon Health and Science University

Maggie So
Fred Hutchinson Cancer Research Center

Peggy Wisher
Decatur Memorial Hospital

Stephanie Couch
Alliance Foundation

Tamara Fischer
Sanford Health

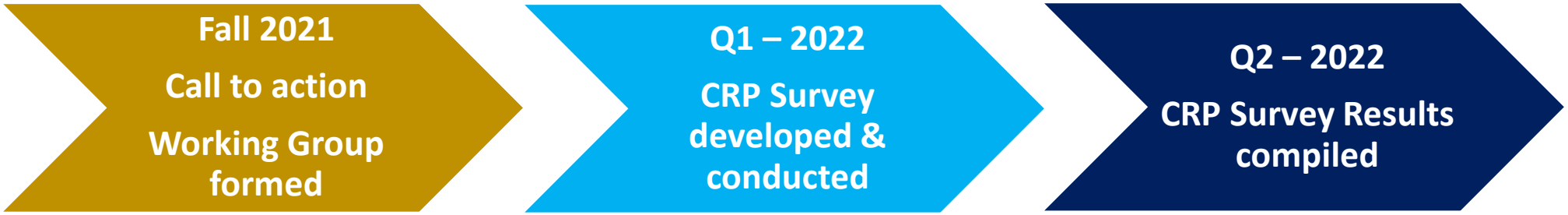
Tammie Mlodozyniec
Essentia Health Cancer Center

CRP Site Survey

- CRP Site Survey was sent to Alliance and NRG Membership Distribution lists in December 2021- January 2022; a link to the survey was also posted on the CTSU Bi-monthly Broadcast

- Goal: Elicit feedback on site's most pressing operational challenges in the following categories:
  - Regulatory
  - Administration
  - Clinical Coordination
  - Data Coordination
  - Study Activation
  - Remote Audits

Timeline and Progress



CRP Site Survey / Key Themes

- We received 566 responses and over 800 free text comments
- KEY THEMES:
  - Lack of clarity in protocols and data submission instructions
  - Inefficiencies in trial activation and duplicative work
  - Volume of complexity and required data
  - High staff turnover and subsequent onboarding of new staff
  - Inefficiencies from inaccurate reports such as DQP and Open Funding

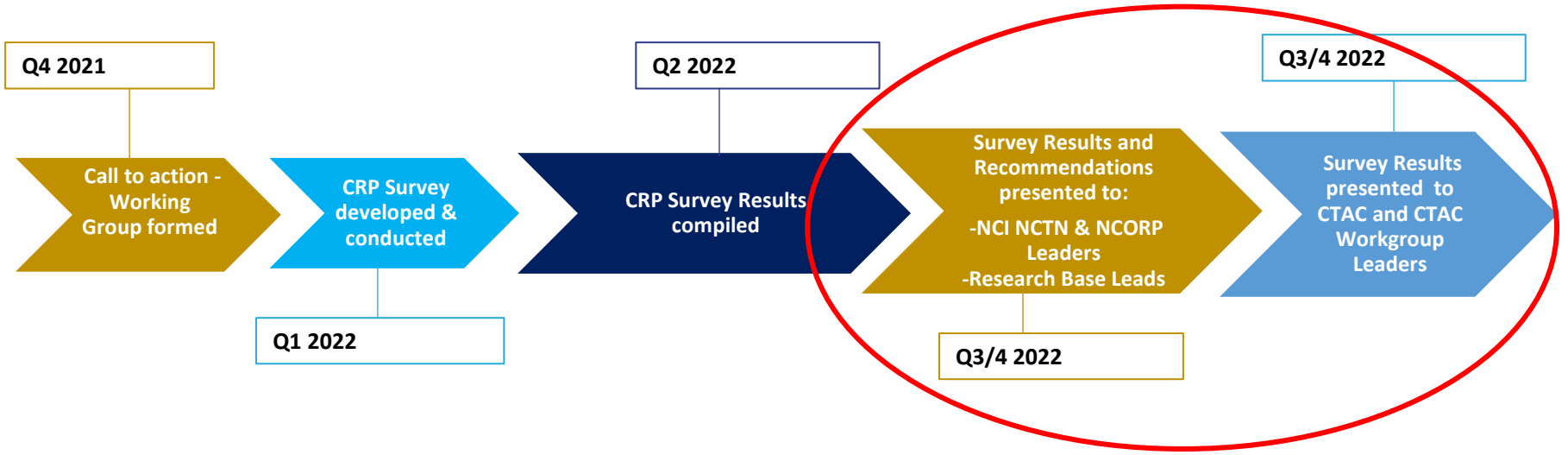
Working Group Goals

- Improve efficiencies within the existing research enterprise structure
- Identify ways to work together across the NCTN/ NCORP enterprise
- Decrease site research staff turnover through improved job satisfaction
- Improve clinical trial accessibility for rural and underserved populations

Opportunities To Increase Efficiency

1. Improve clarity of protocols and case report forms (CRFs)
2. Reduce data collection
3. Clearly label FDA Registration trials
4. Streamline regulatory and rostering processes
5. Increase audit consistency between research bases
6. Develop a Master DTL
7. Improve CTSU report accuracy
8. Improve clinical trial accessibility for underserved populations
9. Provide protocol-specific EMR treatment plans
10. Centralize CRP training

Timeline and Progress



Timing…

Picture from Google Images

Timeline and Progress

Progress

NCI Clinical Trials & Translational Research Advisory Committee (CTAC)

Recommendations For Streamlining Data Collection

Approved (11/9/2022)

https://deainfo.nci.nih.gov/advisory/ctac/1122/Meropol-Mandrekar2.pdf

Progress on Recommendations

1. Improve clarity of protocols and case report forms (CRFs) ***– In Progress***
2. Provide protocol specific EMR treatment plans ***– Now Required***
3. Centralize CRP training ***– In Progress***
4. Reduce data collection ***– Initial Steps Approved***
5. Clearly label FDA Registration trials
6. Streamline regulatory and rostering processes
7. Increase audit consistency between research bases ***– In Progress***
8. Develop a Master DTL ***– In Discussion but very complicated***
9. Improve CTSU report accuracy
10. Improve clinical trial accessibility to underserved population
11. Funding Sheet Tracked Changes posted to CTSU ***– Now Required***

Moving Forward

Reimagine ways to work ***together*** across all levels of the NCTN / NCORP enterprise

- Site
- Research Base
- NCTN / NCORP

Next Steps

- Continue to collaborate across the NCI Research Enterprise
- Continue to obtain feedback from site research staff to refine recommendations
- Continue to work with leadership to identify feasible improvements of high priority challenges

SWOG Site Operations Meeting: Updates from the NCI

Andrea Denicoff, MS, RN

Grace Mishkin, PhD, MPH

Cancer Therapy Evaluation Program (CTEP)

Division of Cancer Treatment and Diagnosis (DCTD)

NIH NATIONAL CANCER INSTITUTE

May 10, 2023

1. *Share key points from NCI leadership on adaptation to changed clinical research environment presented to NCAB in Feb. 2023*
2. *Provide updates from CTEP*

Adapting NCI's Clinical Trials System to a Changed Clinical Research Environment

James H. Doroshow, M.D.
NCI Deputy Director for Clinical and Translational Research

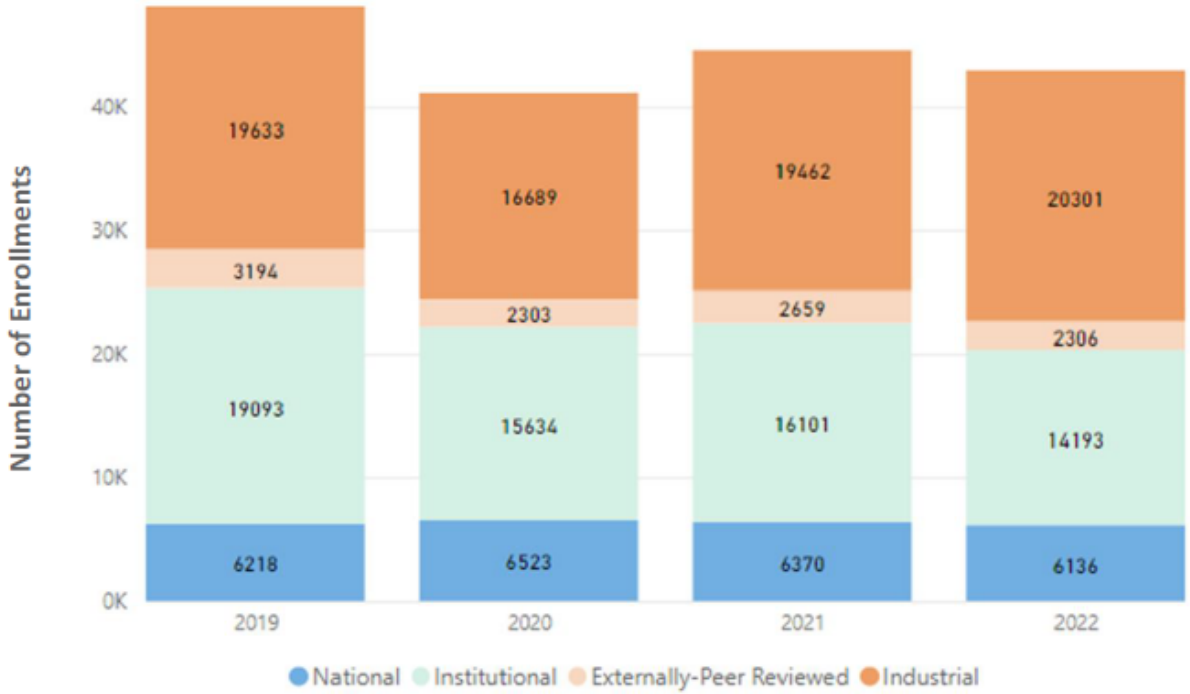
NIH NATIONAL CANCER INSTITUTE

National Cancer Advisory Board

February 9, 2023

https://deainfo.nci.nih.gov/advisory/ncab/0223/index.htm

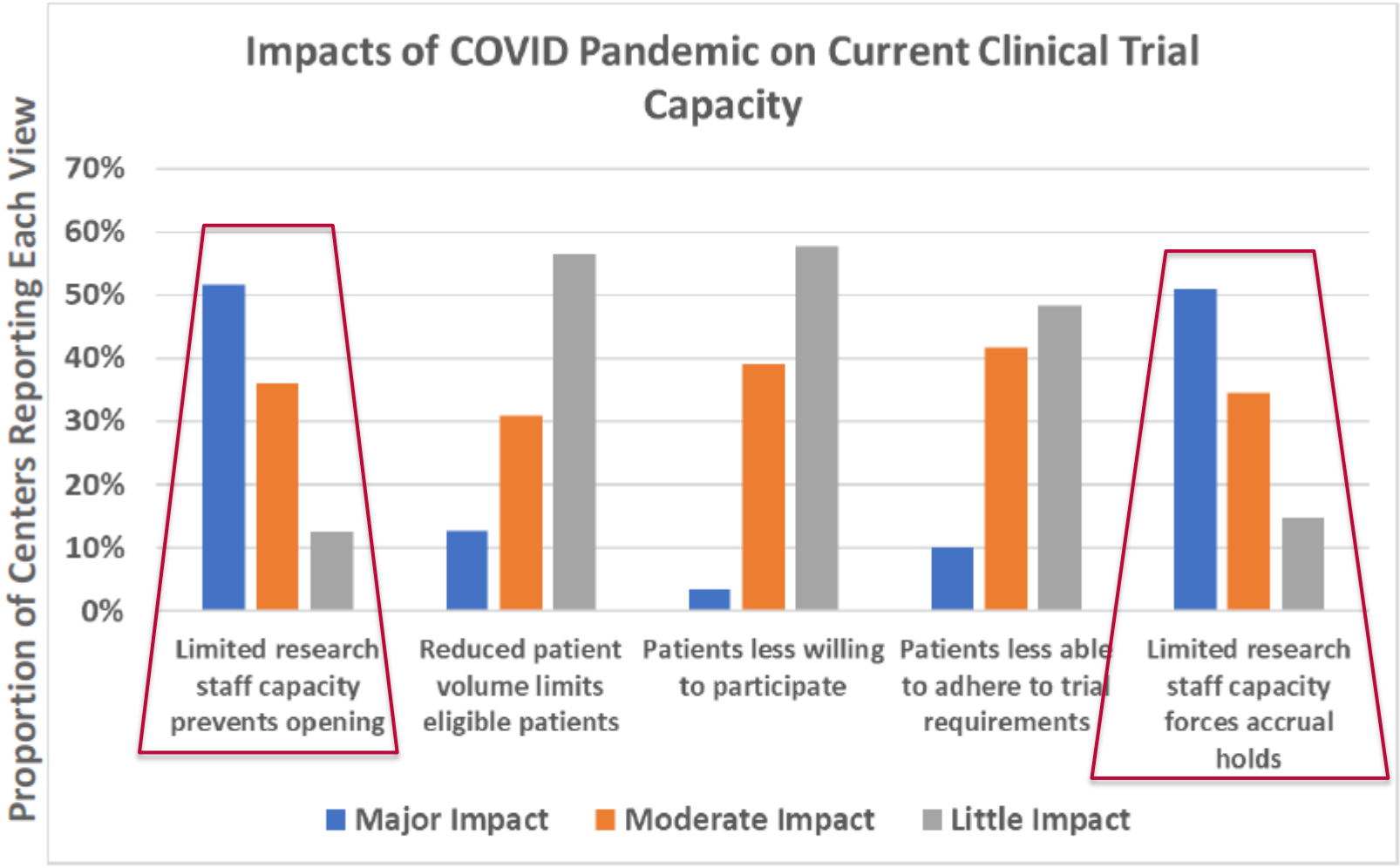
Annual Enrollment to Treatment Trials by Study Source*
NCI-Designated Cancers: 1/1/19-12/31/22



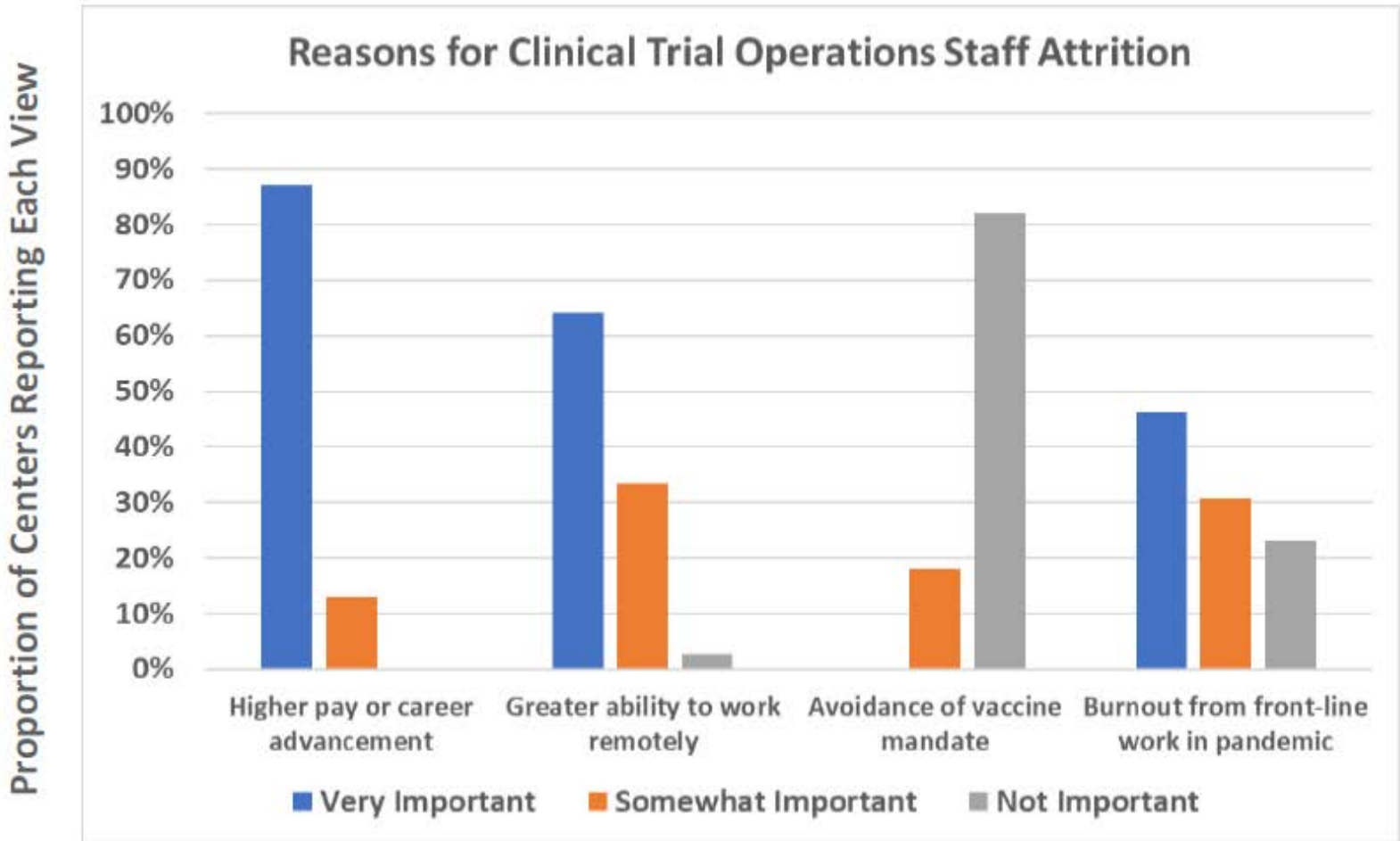
Data source: NCI's Clinical Trials Reporting Program (CTRP)

***NCI P30 Cancer Center Support Grant Data Table Guide v3.1.1**

https://cancercenters.cancer.gov/GrantsFunding/DataGuide



Respondent group for this question: all 64 clinical Cancer Centers



Respondent group for this question: the 38 clinical Cancer Centers that reported <90% pre-pandemic clinical research operations staff

NCI's 2030 Vision for Clinical Trials

Strategic Planning Working Group Report

Clinical Trials and Translational Research Advisory Committee (CTAC)

NCI Clinical Trials and Translational Research Advisory Committee Strategic Planning Working Group Overview

Re-assess strategic vision for clinical trials system for 2030 and beyond

Review and address necessary clinical trials infrastructure

Developed
15 recommendations and
3 operational initiatives

Themes:

- Trial Complexity and Cost
- Decentralized Trial Activities
- Promoting Accrual and Access
- New Data Collection Approaches
- PRO Data for Clinical Trials
- Operational Burden
- Statistical Issues
- Workforce Outreach and Training

CTEP Updates

Decentralized Trial Activities and Protocol Flexibilities

Background:

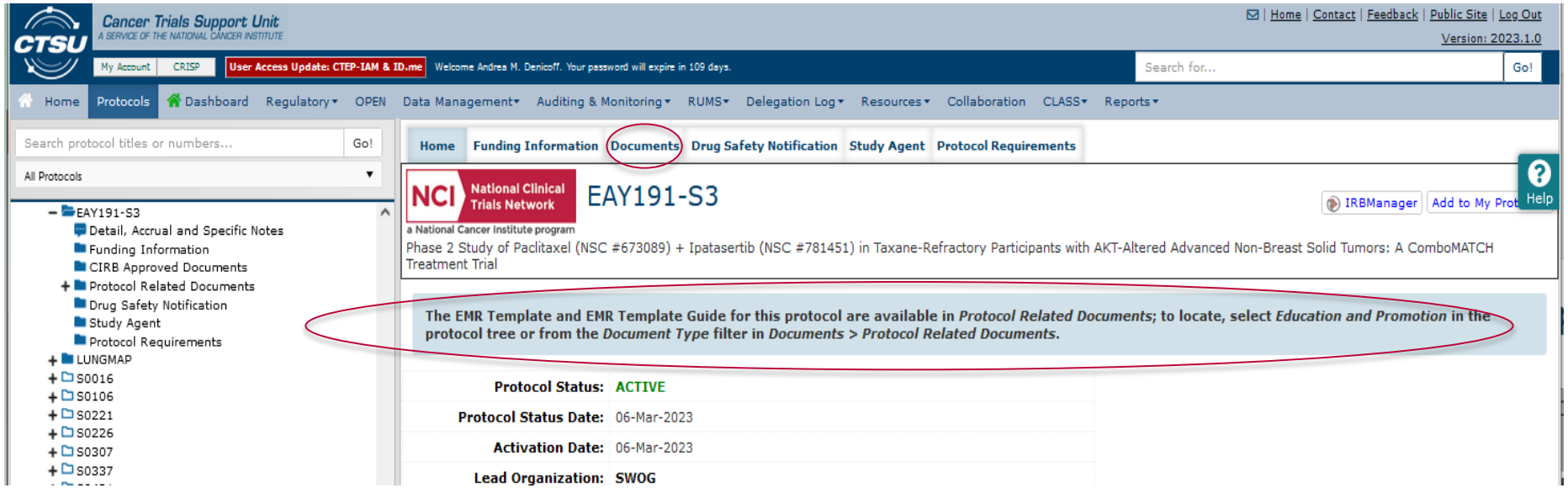
- Protocol flexibilities used during COVID had positive feedback from NCTN sites with requests to continued use
- CTAC Streamlining Clinical Trials Working Group report on decentralized trial activities

Plan:

- Trans-NCTN Working Group will develop standard language to use in NCTN protocols
  - Include protocol flexibilities and decentralized trial activities, such as remote consent, use of local labs and imaging studies, use of local health care provider to provide intermittent or short-term care
  - Consider whether any informed consent template language might be needed
  - Align standard language to fit within FDA and OHRP regulations

EMR Template Expansion

- An EMR Template is a spreadsheet to facilitate local site **E**lectronic **M**edical **R**ecord builds that includes protocol requirements for drug/agent orders and protocol elements needed for the EMR.
- For any NCTN protocol activated on or after March 13, 2023, the CTSU will draft and post an EMR template at activation.
  - All EMR templates get final review and approval by Lead NCTN Group
  - EMR templates for these studies will be updated with amendments



Shipment of Oral IND Agents

Background

- CTEP guidance for the Dispensing Pharmacy at NCTN sites to ship CTEP IND oral agents during the pandemic to maintain patient safety was a benefit for patients who lived a distance from trial site

Plan

- CTEP updated guidance to allow the shipment of CTEP IND oral agents permanently as of January 2022:
  - https://ctep.cancer.gov/content/docs/CTEP_Oral_IND_Agent_Shipment_Guideline.pdf

Remote Consent

Background

- NCI CIRB allowed the temporary use of remote consent during the COVID pandemic and site surveys reported positive benefit to sites and patients

Plan

- NCI CIRB currently updating guidance to allow remote consent to become a permanent option
  - https://ncicirb.org/content/nci-cirb-information-about-covid-19

Audit Guidelines

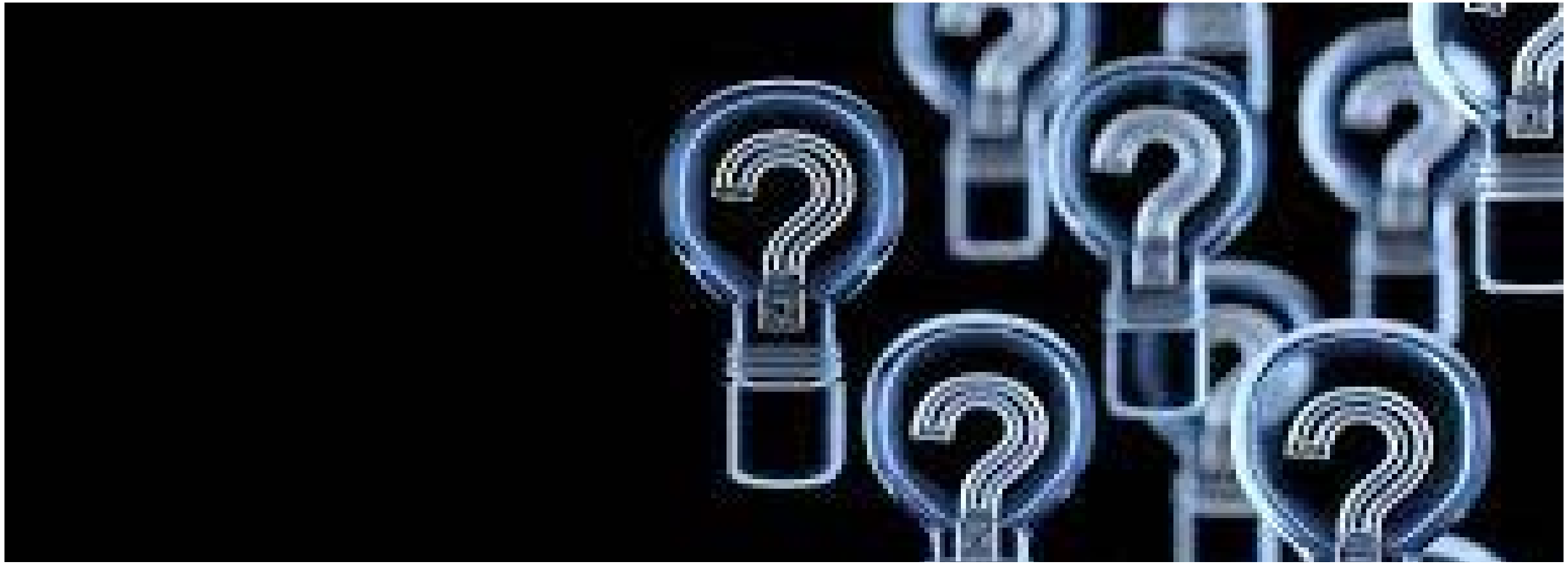
- Revised audit guidelines based on feedback from the CRP survey, effective April 10, 2023 (https://ctep.cancer.gov/branches/ctmb/clinicaltrials/docs/NCTN_Summary_of_Changes.pdf)
- **Key changes:**
  - Revisions to description of Auditable and Non-Auditable institutions
  - Clarification that, for on-site visits, auditors may be required to display a government-issued ID if all entrants are required to do so at that site
  - Added that protocols with no patient enrollment do not need to be included in the audit or informed consent review
  - Added that “Performing study-related activities without an approved DTL” is a major DTL deficiency
  - Clarified that an “Acceptable” finding would apply for Regulatory Documentation, Pharmacy, and Patient Case reviews if no follow-up is **required**, instead of saying it applies if no follow-up is **requested**
  - Clarified “Major Deficiencies” for “General Data Management Quality”:
    - Specified that unredacted data could be a major or lesser deficiency depending on the number and type of unredacted data issues
    - Added clarification for how delinquent data should be evaluated when assigning a major or lesser deficiency

NATIONAL CANCER INSTITUTE

www.cancer.gov

www.cancer.gov/espanol

Questions and Discussion



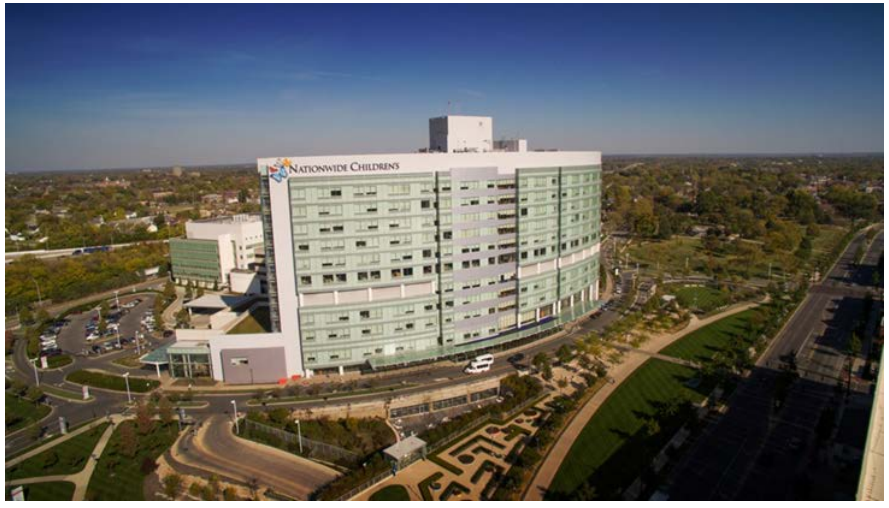
Specimen Submission to SWOG Biobank

Kae Tegtmeier
Business and Project Development Director

NATIONWIDE CHILDREN'S
When your child needs a hospital, everything matters.

Overview of the Biopathology Center (BPC)

- SWOG Biospecimen Bank is located at the Biopathology Center at the Abigail Wexner Research Institute at Nationwide Children's Hospital in Columbus, Ohio (Eastern time)
- We also bank for several other major groups and organizations:
  - Children's Oncology Group (COG)
  - NRG Oncology – Columbus
  - NCI Early-Phase and Experimental Clinical Trials (EET)
  - GOG Foundation
  - Sarcoma Alliance for Research through Collaboration (SARC)
  - Leukemia and Lymphoma Society
- College of American Pathology (CAP) accredited biorepository and clinical laboratory



Specimen Receipt at the BPC

- On an average day, the BPC receives 100-160 packages, which may contain up to 1,000 specimens for all groups!
- We receive several different specimen types for SWOG protocols:
  - FFPE tissue (blocks, slides)
  - Fresh blood, bone marrow, urine, and stool
  - Frozen processed blood products (e.g., plasma, serum, buffy coat) and urine
  - Frozen tissue
  - Tissue in Formalin (for S2101, iMATCH Pilot)
- We accept all specimen types Monday – Friday
  - Shipments of fresh blood and bone marrow may be received on Saturday for immediate processing.

SWOG Specimen Submission

- For all submissions received at the SWOG Biobank, about 30% have one or more issues
  - Over 1,700 submissions and 11,000 specimens per year
  - Require call/email/query follow-up, and a response
  - Most common: Labeling issues, too little dry ice, and quantity discrepancies
- Without required information, specimens may be unusable for downstream research
- Protocols are more complex… and the error rate has increased over the past five years

Specimen Labeling Requirements

Labeling Requirements	Additional Data for FFPE Tissue	Other Requirements
• SWOG patient ID • Patient initials • Date of specimen collection • Specimen type (whole blood, serum, etc.)	From the corresponding pathology report: • Surgical pathology ID (SPID, accession #) • Block number	• **<u>Bone Marrow:</u>** • Laterality – right (R), or left (L) • **<u>Protocol-specific requirements:</u>** • Collection time *(e.g., PK specimens)* • Tissue type – primary (P), metastatic (M), or normal (N) • Tissue slide thickness, in µm

Note: Missing information must be confirmed by the submitting institution, which can delay specimen processing, and may require a waiver. *We cannot assume any information!*

Pathology Reports and Tissue Types

- Pathology reports are **required** for formalin-fixed paraffin-embedded (FFPE) tissues – including blocks, slides, and scrolls
  - Label pathology report with the SWOG patient ID (handwritten). Do not redact initials, SPID/Accession #, or collection date.
- Before distribution, a Biobank pathologist confirms *concordance with* the institutional diagnosis
  - Quality assurance step to confirm if the tissue is acceptable for the planned research
- Biobank definitions of tissue type:
  - **Primary**: the initial source of tumor tissue, including residual tumor from the primary site. Must make biological sense for tumor type (e.g., colon cancer in colon tissue).
  - **Metastatic**: tumor tissue collected at sites separate from the primary lesion, including local and distant metastatic tumor and residual tumor from the metastatic site (e.g., lung tumor biopsy for prostate cancer)
  - **Normal**: tissue that does not contain tumor, including lymph nodes negative for tumor.

SpecTrack Tips

- All specimens sent to the Biobank must be logged in SpecTrack
- Quantity is the physical number of specimens *in that category*
  - Unstained and stained slides must be logged separately
  - Liquid specimens (fresh blood, frozen plasma) – enter number of tubes/vials sent and not the volume
- Example label on the packing list is provided as a reminder
  - Please do not cut out the example label to affix to the specimens.
  - Address label templates are available on the SWOG website or create a label with the required information.
- A printed copy of SpecTrack packing list must be included in all shipments

Resources

- SWOG Biospecimen Processing and Submission Procedures website
  - General specimen processing instructions
  - General shipping/packing guidelines
  - Specimen labeling requirements and label templates (Avery address labels)
  - Laboratory #200 and #201 addresses and contact information
  - *Note: Always refer to specific instructions in the protocol, when applicable*
- SpecTrack Packing List
  - Laboratory address
  - Labeling requirements

Share your feedback!

- Your feedback helps us improve!
- What tools or resources would be helpful?
  - FAQ page on website
  - Additional instructions on website

SWOG Group Chair's Office

Pat Mize, MBA, Grants and Contracts Manager
Kyle Theige, Senior Grants and Contracts Coordinator

SWOG Group Chair's Office
Portland, OR

ORP Open Forum

- ORP Open Forum
  - Thursday, May 11th
  - 1:00pm – 2:30pm
  - Pacific L-O (Pacific Concourse Level)
- SWOG funding team will be discussing a variety of topics, including:
  - Funding Memos
  - National Coverage Analysis (NCA's)
  - Site Payments (Federal & Non-Federal)

Goodbye (and Thank You!)

- After six wonderful years working in the Group Chairs Office, this is officially my last week at SWOG.
- THANK YOU!
- Federal Site Payments in the Interim:
  - We ask for some patience as we hire and train a new Grants & Contract Coordinator
  - Once the position is filled, any change in process or procedure will be communicated to the member sites promptly
  - Please reach out to the updated list of contacts for any and all questions (see next slide)

Site Payment Contacts

Federal Funding	Non-federal Funding
TBD SWOG Grant & Contracts Coord. FedSitePayments@swog.org	Mariela Pucci Sr Accounting Specialist, SWOG-CTP Finance@thehopefoundation.org
National Coverage Analysis (NCA) or General Funding Questions: funding@swog.org	

Operations & Membership

Dana Sparks, MAT

Director of Operations and Protocols

SWOG Operations Office
San Antonio, TX

SDMC Updates

Rodney Sutter, CCRP

Program Director, Therapeutic Studies
SWOG Statistics and Data Management Center
Seattle, WA

SWOG Q1 2023 Activations

S1900G: A Randomized Phase II Study of INC280 (Capmatinib) plus Osimertinib with or without Ramucirumab in Participants with EGFR-Mutant, MET-Amplified Stage IV or Recurrent Non-Small Cell Lung Cancer (Lung-MAP Sub-Study)

S2205: ICE COMPRESS, Randomized Trial of Limb Cryocompression versus Continuous Compression Versus Low Cyclic Compression for the Prevention of Taxane-Induced Peripheral Neuroropathy

S2302: PRAGMATICA, A prospective randomized study of Ramucirumab plus Pembrolilzumab Versus Standard of Care for Participants Previously Treated with Immunotherapy for Stage IV or Recurrent Non-Small Cell Lung Cancer

SWOG Q1 2023 Activations

EAY191-S3: COMBOMatch Phase 2 Study of Paclitaxel + Ipatasertib in Taxane-Refractory Patients with AKT-Altered Advanced Non-Breast Solid Tumors

S2114: Randomized Phase II trial of consolidation therapy following CD19 CAR T-cell treatment for Relapsed/Refractory Diffuse Large B-cell Lymphoma or Grade IIIB Follicular Lymphoma

S2010: ASPEN, Randomized Phase III Trial Comparing Active Symptom Monitoring Plus Patient Education Versus Patient Education Alone To Improve Persistence with Endocrine Therapy in Young Women With Stage I-III Breast Cancer

Please activate and enroll!

S1826 – Data to FDA

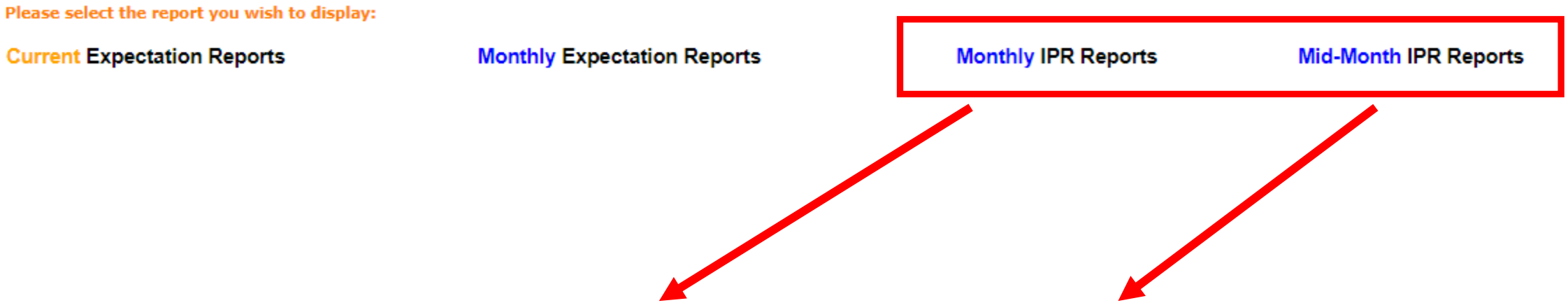
- Not officially a FDA trial, but will be sent for post-marketing analysis
- Amendment requesting uploaded images for 2 additional timepoints

- Contracting with a CRO (Avance) for assistance in:
  - Identify best contacts at each study site
  - Assist in image submission (PET/CT scans) and query resolution
  - Assist sites in resolving any missing data elements on existing CRFs
  - Assist sites in updating delegation task log (DTL)

  - No additional data will be asked for outside of uploading images at 2 additional timepoints
  - Expect an increase in queries as the study is reviewed
  - Look for upcoming funding memo related to this effort

Mid-Month IPR

- Expectation and IPR reports – 2nd of each month
- CRA suggestion to see progress



Published on the **2nd** of each month

Refreshed on the **15th** of the month to see updated calculations

Complete the ID.me Process

You now have until January 1, 2024, to register with ID.me

What you will need:

- CTEP-IAM login credentials
- Social Security Number
- Driver's License, State ID or Passport
- Smart phone with front facing camera
- Text messaging service

What you will need to do:

- Log into CTEP-IAM application
- Navigate to 'ID.me Information' and create an account
- Verify identity with proof by submitting documents
- Validate identity with a selfie
- Link ID.me credentials to CTEP-IAM account

EHR → EDC

Electronic Health Record to Electronic Data Capture

- Goal: Reduce data entry time, cost for sites & improve data quality
- Pilot successfully completed in May 2022
- nCartes is now live, more SWOG sites are signed on with more coming, and nCartes is free for SWOG trials!
- Nichole Mahaffey, the Data Research Coordinator Supervisor for lead pilot site UC Davis, summarized her experience:
  - *"UC Davis anticipates an average time saving of 5-15 minutes on forms that auto populate utilizing nCartes, saving a significant amount of time over the lifespan of a trial for data entry. Additionally, we expect a decrease in queries as nCartes will help streamline data entry consistency."*

Visit the SWOG-nCartes EHR-to-EDC table to learn more

SWOG-EHR-EDC@crab.org

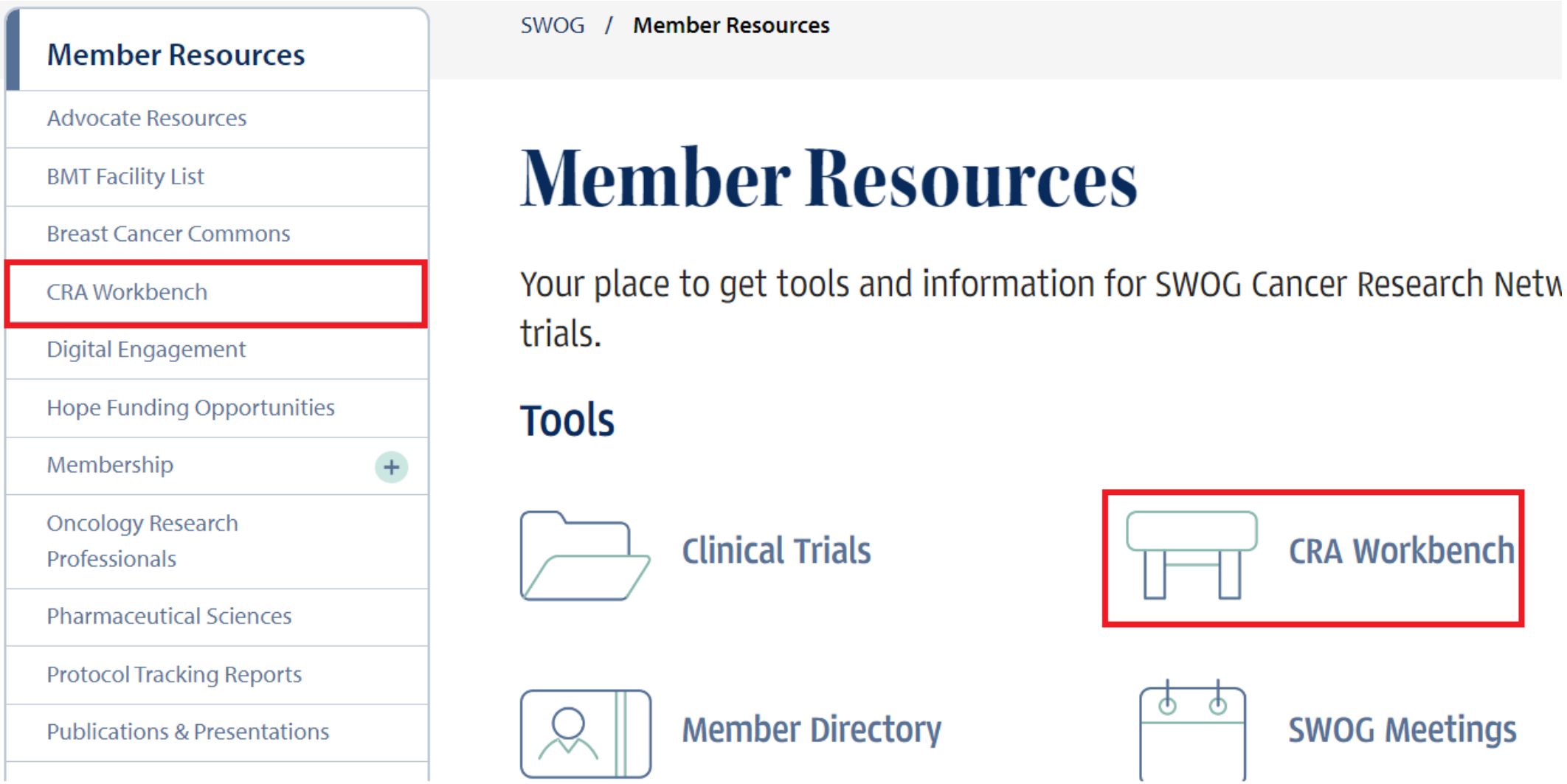
Data Management – New Staff

Pasarlai Ahmadzai
Data Coordinator
Disease Sites: Lung, Myeloma
Therapeutics DC since: 2022

Alex Rangel
Data Coordinator
Disease Sites: Lymphoma
Therapeutics DC since: 2023

Jamie Sundstrom
Recruitment and
Adherence Specialist
Since: 2023

CRA Workbench



CRA Workbench

CRA Workbench

Your resource headquarters for SWOG clinical trial patient management.

Latest CRA Newsletter

Join the CRA Mailing list

Announcements

Updates to Specimen Tracking

A couple of updates have been made to the Specimen Tracking interface. In Step 2 of Logging a Specimen, the "Filter" at the top has been updated so that now at least one key filter is required before a list of samples is displayed. We are hopeful that this will make it easier to identify and select the correct specimen. Also, to avert potential problems for when the Test environment is chosen inadvertently, we have moved the "Test" button to the right side of the page and within the Test environment we have updated the banner and put a watermark on the packing list. The upcoming Winter CRA Newsletter will have more details. [12/1/2022]

SWOG EMR to EDC Project Webinar Recording

Introductory information regarding the project being developed by the SDMC using the nCartes platform can be viewed here. See the May 27, 2022 The Front Line post for more information. [11/7/2022]

SWOG Biospecimen Bank Kit Management URL

The Kit Management URL has changed. Please make certain to update your bookmarks with the new URL: https://kits.bpc-apps.nchri.org/. If you try to access the old URL, there is no redirect as the server supporting the old URL is end of life and users will receive an error message. [8/25/2021]

CRA Newsletter – Spring Edition

- Published in April. Send your ideas! CRANewsletter@crab.org
  - Training Opportunities
  - Importance of Follow-Up
  - PMB Inventory Management System
  - Expectation Report Updates
  - SWOG Site Mentoring

Quality Assurance Updates

Laura Gonzales, BSN, MA, RN, OCN

Quality Assurance Manager

SWOG Operations Office
San Antonio, TX

Protocol Deviations

SWOG follows CIRB guidance for reportable protocol deviations:

- Potential unanticipated problem
- Continuous or serious non-compliance

https://www.ncicirb.org/Institutions/report-potential-unanticipated-problem-or-serious-or-continuing-noncompliance

Local IRB may require additional reporting

Record Retention

Record Retention Guidance: Requirements for record retention of IRB and research records

https://www.swog.org/sites/default/files/docs/2022-08/record%20retention%20guidance_%20updated%2008.22.22.pdf

Record Retention

- The report “List of Protocols with No Required Follow-up” is available on the CRA Workbench.
- It provides the date when all DHHS and FDA record retention requirements have been met group wide. After that date, records may be destroyed according to HIPAA requirements.

LIVE WEBINAR SERIES

Educational presentation followed by time for open discussion/Q&A.

Quarterly - Beginning July 2023

Hosted by SWOG Quality Assurance

Registration (Requires CTEP-IAM Login):

https://swog.exphosted.com/coursepage/85_enUS/ExpertusONE_27

Upcoming 1-Hour Sessions (Choose Your Session):	
Tuesday, July 25, 2023	12:00pm Central
Thursday, July 27, 2023	4:00pm Central

For questions, contact Maggie Spillers at mspiller@swog.org.

Questions?

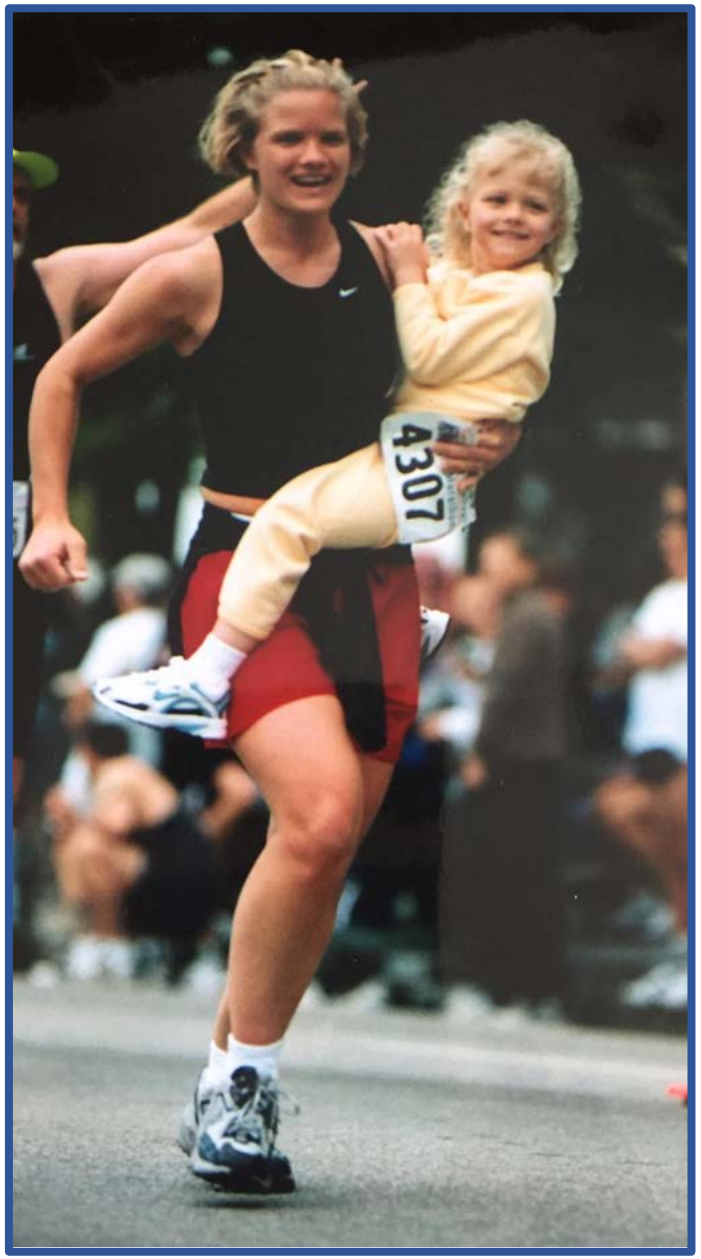
qamail@swog.org

Thoughts on Life

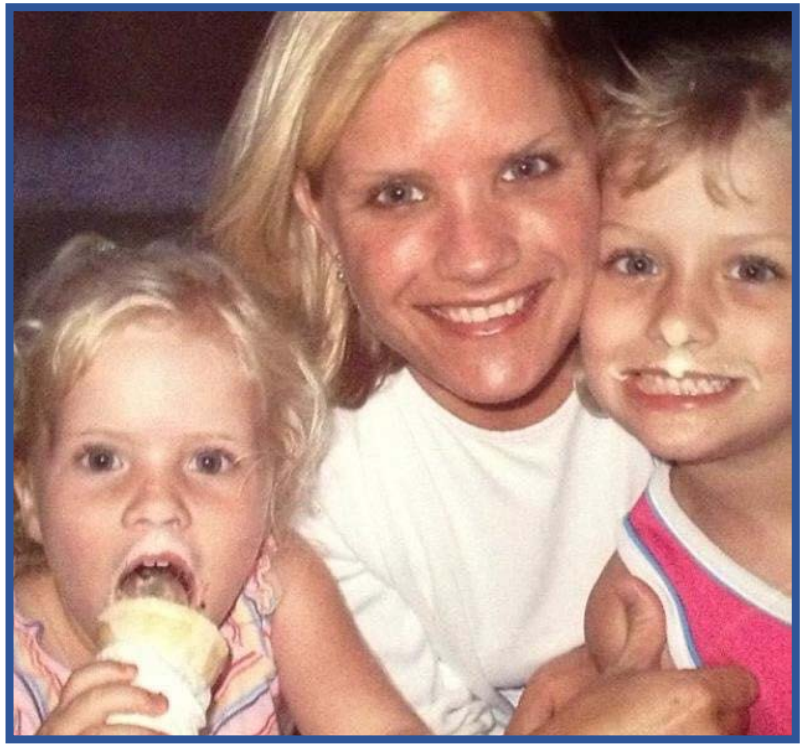
Caitlin Hutchinson

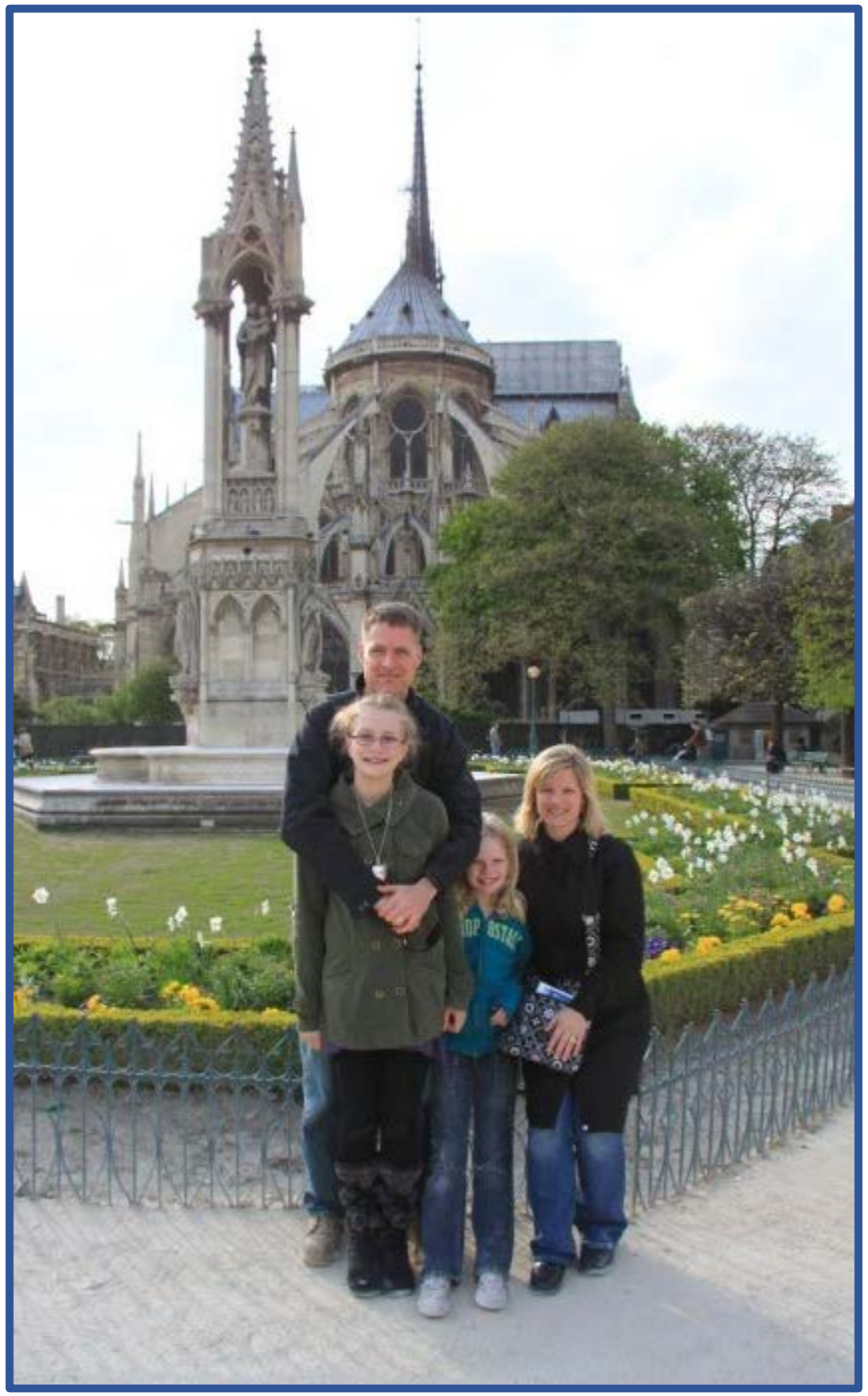
Liz Edwards

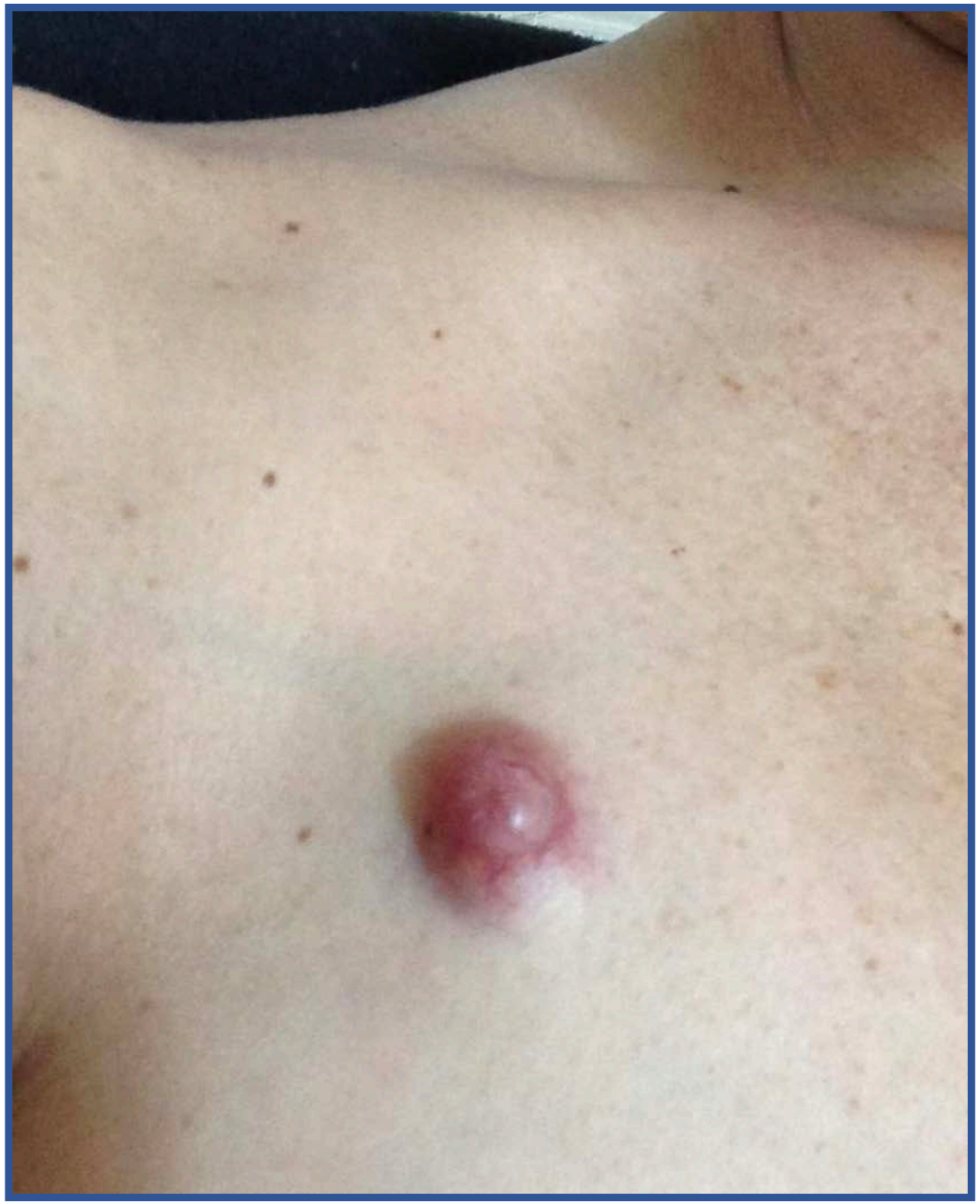
Guest Presenter: Tobi Sample

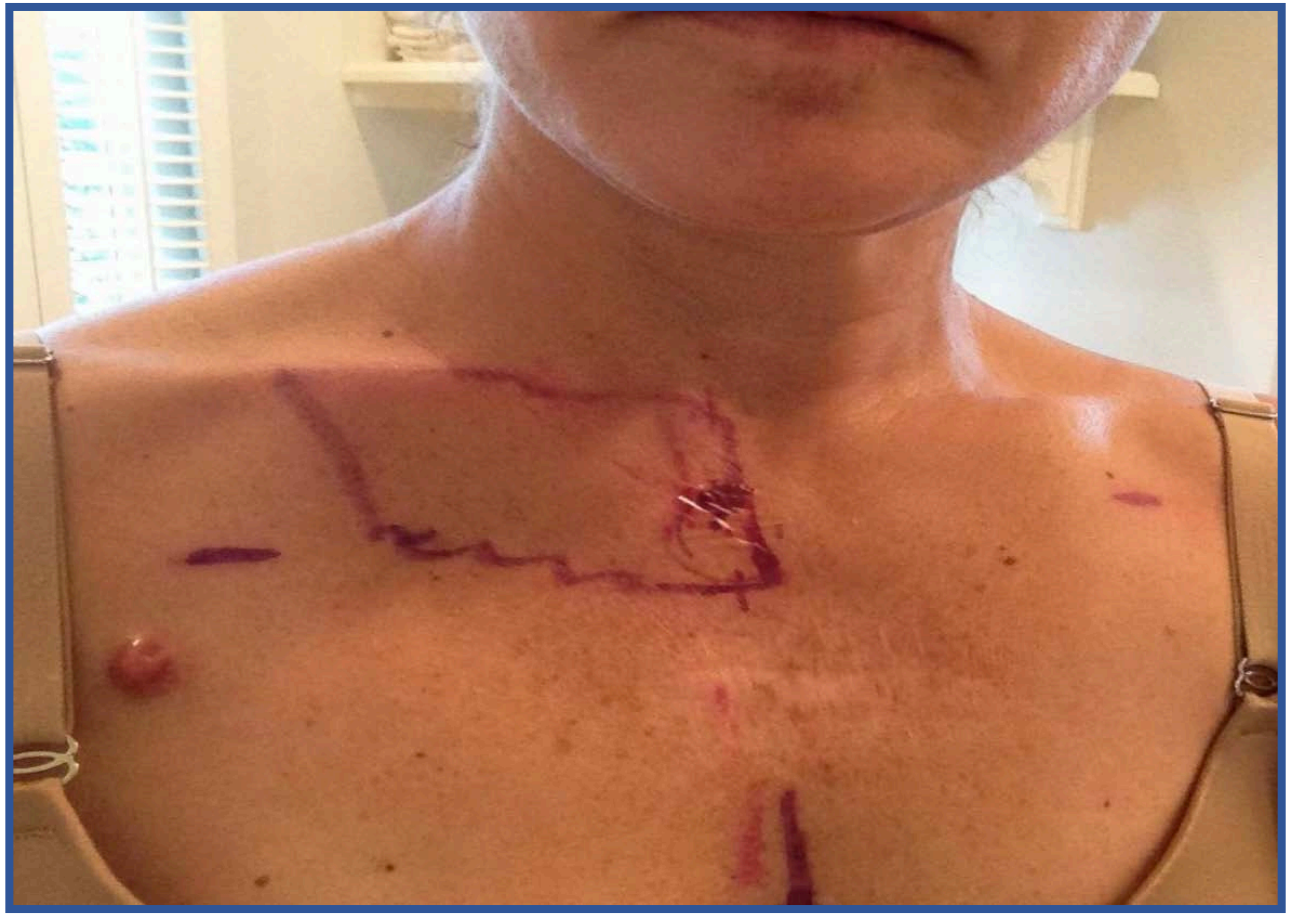

4307


ROCK 'N' ROLL
12792
SAN ANTONIO
7777
SAN ANTONIO

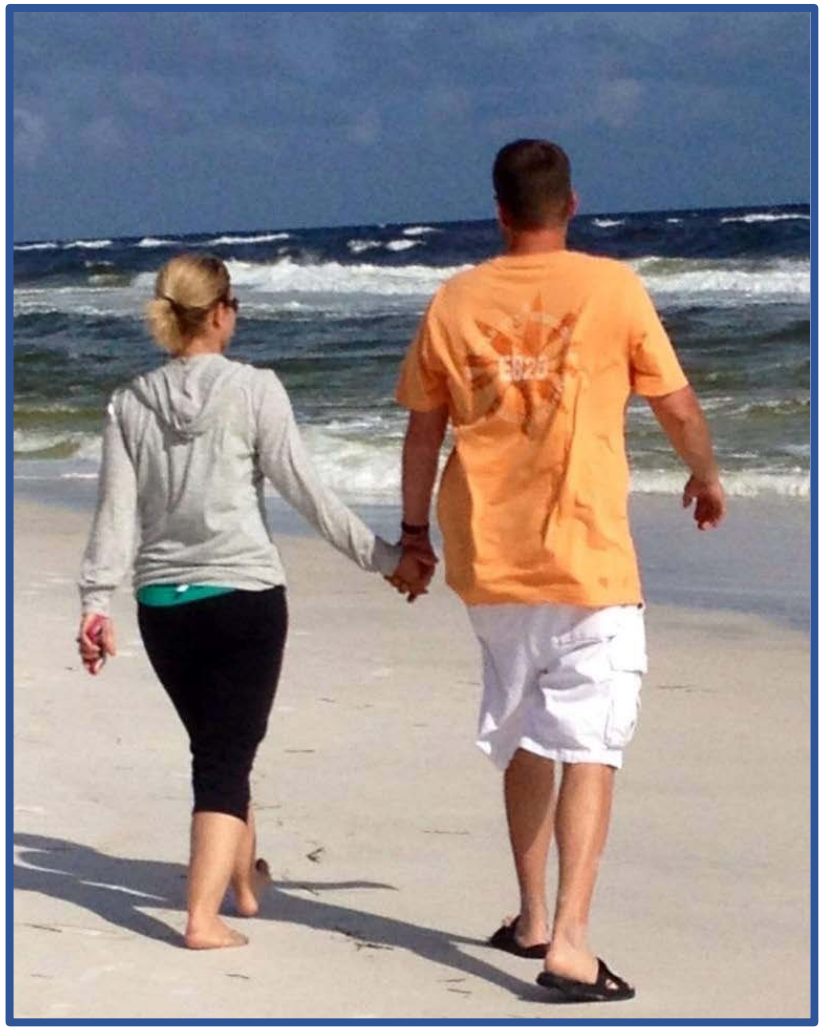


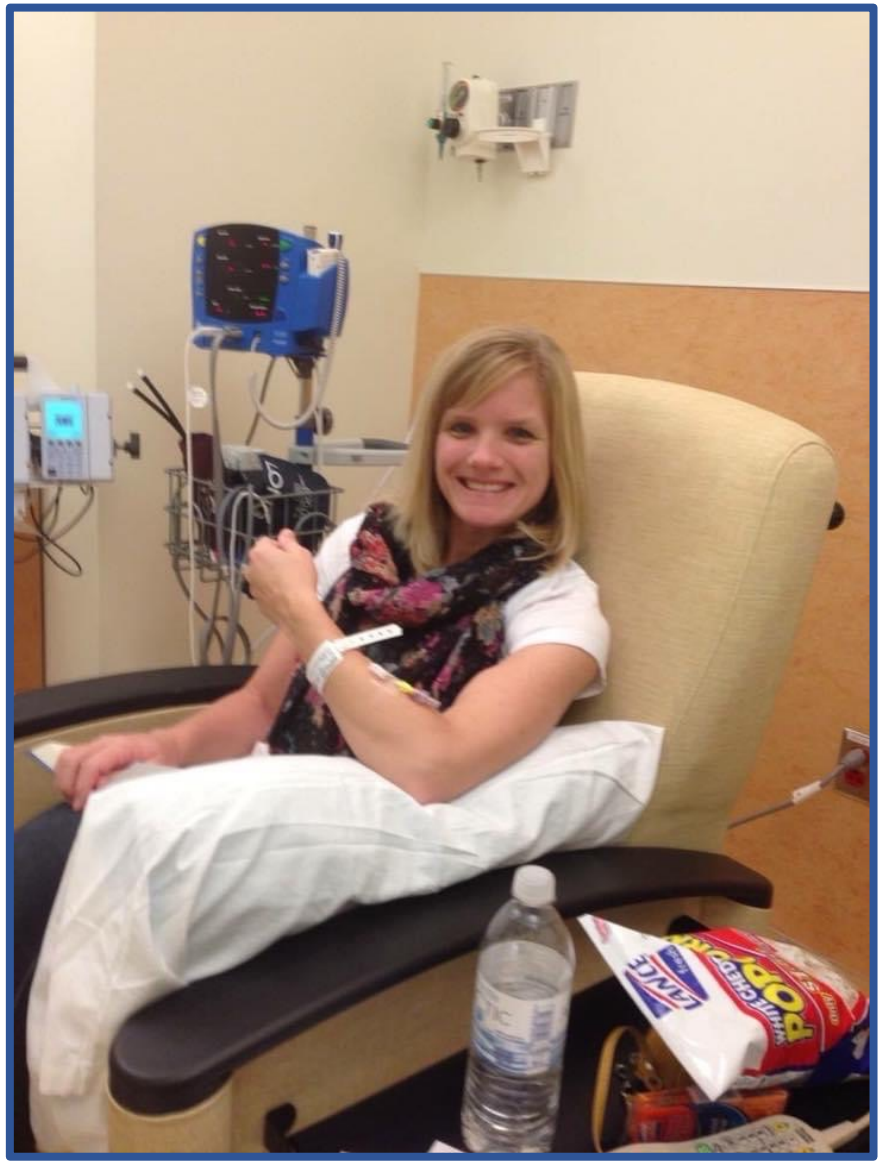






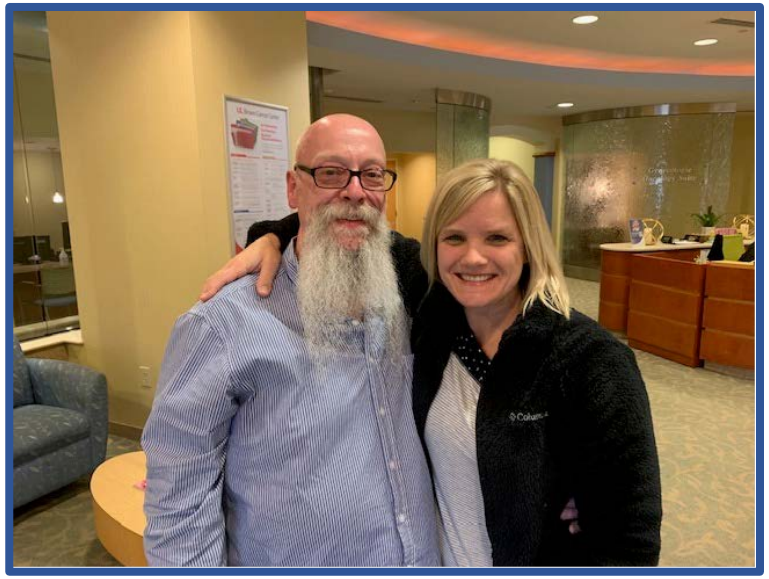

JAMES GRAHAM
BROWN CANCER CENTER
July 29th
BROWN CANCER CENTER
HERE WE COME!!






I CAN
DO ALL
THINGS


OUTRUN THE SUN
My
"Melahomies"
Honoring My Melanoma Hero
RoadID
1131
RoadID.com
EVENT




RUNNING
4 ME
AND MY
MELAHOMIES
GARY
RANDY
Stephanie
KENNY

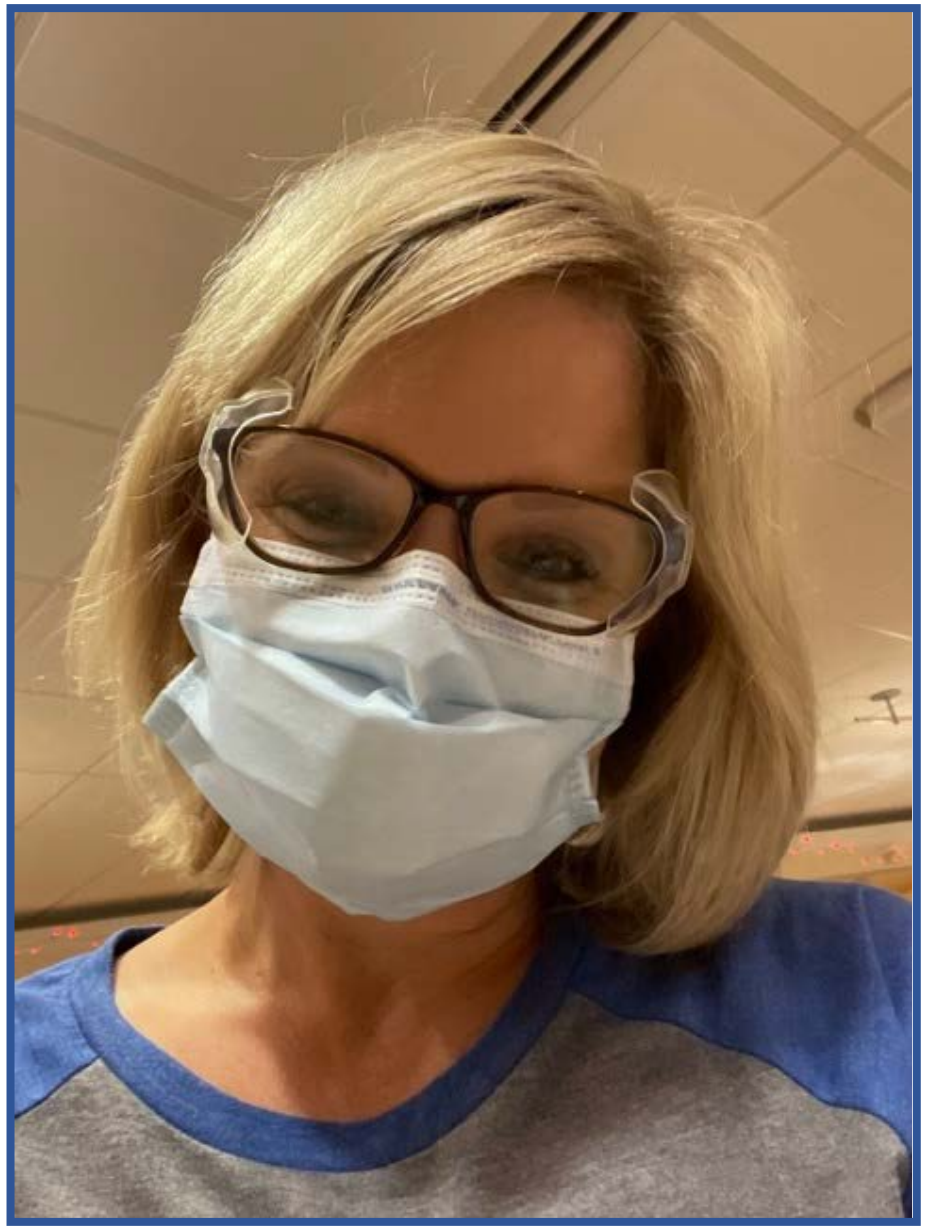

AIM


STEPS
STEPS AGAINST MELANOMA


STEPS AGAINST MELANOMA
Melanoma
Never Give Up


AIM
ARRAY

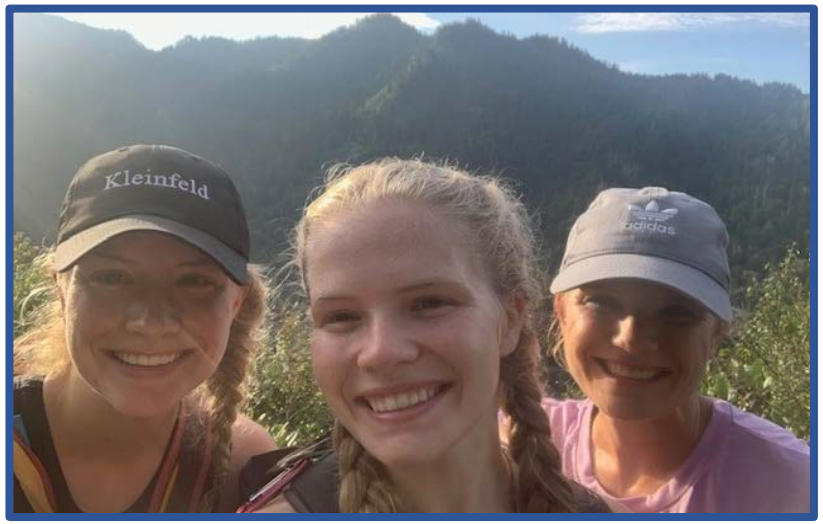

OUTRUN THE SUN
RACE AGAINST MELANOMA
INDIANAPOLIS




Mt Elbert
14,440ft
elevation


51


MOUNT KILIMANJARO
CONGRATULATIONS
YOU ARE NOW AT
PEAK, TANZANIA, 5895M/19341Ft AMSL
RICA'S HIGHEST POINT
ORLD'S HIGHEST FREE-STANDING MOUNTAIN
NE OF WORLD'S LARGEST VOLCANOES
ORLD HERITAGE AND WONDER OF AFRICA


Kleinfeld
adidas


adidas

Closing Comments

Special Thanks

- All of our Speakers
- Courtney Wille
- Site Ops Co-Chairs
  - Liz Edwards
  - Caitlin Hutchinson

Acknowledgements

ORP Executive Committee Members	
Sandy Annis	Dana Little
Deb Bergevin	Jamie Myers
Annette Betley ★	Joyce Nancarrow-Tull
Erin Cebula **	Ceil Petrowsky ★
Liz Edwards **	Lisa Stoppenhagen
Anthony Hicks	Connie Szczepanek
Caitlin Hutchinson	

SWOG CANCER RESEARCH NETWORK

NCI National Clinical Trials Network
a National Cancer Institute program

NCI Community Oncology Research Program
A program of the National Cancer Institute of the National Institutes of Health

Reminders

- **Fall 2023 SWOG Group Meeting**

  October 11-14, 2023

  Hyatt Regency Chicago

  Chicago, Illinois

Picture from Google https://www.mansiononsutter.com/wp-content/uploads/2019/03/San-Francisco-Spring-Super-Blooms.jpg