

Fall 2020 SWOG ONCOLOGY RESEARCH PROFESSIONALS CMTE & SITE OPERATIONS MEETING – VIRTUAL

SUMMARY

Date: September 23, 2020

Time: 3:30 – 5:00 pm CT

Agenda:

[Open & Welcome](#) — Connie Szczepanek

[NCI Updates](#) — Grace Mishkin

SWOG Updates

- [Group Chair's Office and Study Finance](#) — Casey Dawson, Pat Mize, Kyle Theige
- [Operations & Membership](#) — Dana Sparks, Connie Barnes
- [Statistics and Data Management Center](#) — Rodney Sutter, Phyllis Goodman
- [Quality Assurance](#) — Elaine Armstrong

Thoughts on Life — All

Closing Announcements — Connie Szczepanek

Additional Information

[Chat Box Comments](#)

[Q&A Box](#)

0:00:00



Open & Welcome

0:02:39

Connie Szczepanek welcomed the group to the meeting.



0:03:29



0:03:32

Szczepanek reviewed the logistics and etiquette of the virtual meeting.

- Noted all on the call were muted by default and questions could be submitted through the Chat function
- Also reminded group there is no formal CE credit for attending this session

Logistics Details

- Today's session is being recorded. Please keep your phone on mute to help with sound quality.
- Questions can be submitted all throughout the meeting via the CHAT icon at the bottom floating bar (chat box will appear at right hand corner of the screen). We will present them to the speakers during the Q&A segments during the meeting.
- The slides and a recording of the presentations will be posted on the SWOG website within a few weeks.
- Although there are no formal CE credits for this meeting, you may print a copy of the agenda to reflect your attendance.

0:04:14

Szczepanek presented the meeting agenda, as in the slide.

- Encouraged all to stay to the end of the meeting, as last segment was designed to be rewarding for heart, soul, and mind

Open & Welcome	Connie Szczepanek
NCI Updates	Grace Mishkin
SWOG Updates	
• Group Chair's Office and Study Finance	Casey Dawson Pat Mize Kyle Theige
• Operations & Membership	Dana Sparks Connie Barnes
• Statistics and Data Management Center	Rodney Sutter Phyllis Goodman
• Quality Assurance	Elaine Armstrong
Thoughts on Life	All
Closing Announcements	Connie Szczepanek

NCI Updates

0:04:58

Szczepanek introduced Grace Mishkin from the NCI.

- Supports trial operations for NCI Cancer Therapy and Evaluation program (CTEP) with focus on NCTN operations

Mishkin opened by giving the group her email address – grace.mishkin@nih.gov.

- Said her message today was primarily one of appreciation
- Many updates coming out of NCI over the last 6 months
 - Sites have kept on top of them remarkably well

NCI Updates

Grace Mishkin, RN, NCI

- Said message from NCI leadership was that sites have adapted incredibly well under very challenging circumstances
- Also expressed NCI's gratitude for commitment at sites to mission of helping advance cancer treatments
- Mishkin recognized that situation has been difficult
 - Also that NCI has added to difficulty in some cases
 - Though they are trying to make things easier to cope with

Mishkin said NCI is expanding use of delegation of tasks logs (DTLs).

- Said she has spoken with group before about these
 - Noted they had rolled them out without anticipating all of their impacts
 - But NCI continues to get feedback from FDA and other regulatory agencies that it is essential they have something of the sort in place for studies
 - Hence expansion is moving forward
 - All phase 2/3 and phase 3 studies activated starting August 2020 are required to have the DTL
 - All phase 2 and earlier trials activated October 2020 or later have to have it
 - NCI is also encouraging groups to consider adding DTL to already activated studies if there's a chance they will be used for FDA registration
 - Said using a study for new drug registration with FDA will be very difficult if there's no detailed process in place
 - Mishkin said she has not been closely involved in DTL project
 - But she knows NCI is making efforts to make process easier
 - Some details of these efforts were supposed to be released at end of summer
 - Goal was to have changes rolled out with new activation of DTLs
 - But have been delays in technical changes
 - So these improvements have not all been implemented yet
 - Said feedback from sites has been important
 - More improvement is needed, but improvements already made driven by feedback from sites on workflow issues
 - Said she and Andrea Denicoff take that feedback to the tech folks
 - Repeated her email address: grace.mishkin@nih.gov
 - Email feedback to her directly
-

- Or to program email address: NCTNprogram@mail.nih.gov
- Sites with suggestions about ways to make DTL process easier should contact her
 - More people they hear from, more they can use to get changes made
- Also encouraged feedback as improvements are rolled out

Mishkin said many sites had already activated NCI COVID, or NCAP, study.

- Been a top priority for NCI leadership
- Astounded by how quickly it has been taken up across NCTN and NCORP
- Very different trial
 - Burden much more on data collection, as there is not a treatment associated
 - Noted challenges that arise when parts of NCI not used to writing protocols are called on to write them and design case report forms
 - Thanked sites for their forbearance
- Again, said sites with questions should contact her and she can connect them with the study team
- Invited questions via the Chat box in this session as well

Group Chair's Office and Study Finance

0:14:14

Szczepanek introduced the next topic – group chair's office and study finance – and presenters.

- Casey Dawson, assistant director of administration for SWOG
- Pat Mize, grants and contracts manager
- Kyle Theige, senior grants and contracts coordinator

Dawson presented.

- Echoed Mishkin's thanks
 - Noted all SWOG offices – Group Chair's Office, Ops Office, and Hope Foundation – have been operating remotely
 - Statistics and Data Management Center also operating largely in virtual realm
-

Group Chairs Office, Study Finance, Membership

Casey Dawson, Assistant Director of Administration
Pat Mize, MBA, Grants and Contracts Manager
Kyle Theige, Senior Grants and Contracts Coordinator

- Transition has been relatively seamless
 - Thanked all for their work for SWOG and patients
 - Also invited feedback from sites
 - Said great things have come from feedback from sites and members
 - For questions on coverage analysis or anything else, emails and phone numbers are on SWOG website
 - Passed presentation to Mize and Theige
-

0:16:31

Mize presented.

- Highlighted a particular CTSU update to ensure all are aware of it

SWOG Group Chair's Office **General Updates**

Presented by:
Pat Mize, Grants & Contracts Manager
SWOG Group Chair's Office

0:16:48

- August update to CTSU website added a 1-year time limit for adding submission dates in OPEN system funding tab
 - Those fields now won't take submission dates later than that

OPEN System

- OPEN Funding Tab System Update
 - Time limit for entering biospecimen and other submission information
 - Part of the August OPEN system update and notifications
 - TIME LIMIT: One year from the submission date
-

0:17:30

Questions?

- Her office's general email address is funding@swog.org

Questions?

Contact Information
funding@swog.org

0:17:40

Theige reviewed aspects of federal site payment transition.

Federal Site Payment Transition (Fall 2020 Update)

Presented by:
Kyle Theige, Grants & Contracts Coordinator
SWOG Group Chair's Office

0:17:59

Background

- Fixed price subawards for federal member site payments are now required for the NCI
- Change took effect for both NCTN and NCORP in 2019
- Nonfederal payments are *not* affected by this
 - Nonfederal payments for SWOG studies still go through purchase service agreements with SWOG-CTP

Background

- Fixed-price subawards for federal member site payments are now required by the National Cancer Institute (NCI) for Cooperative Groups
- Change takes effect:
 - **March 1, 2019** for NCTN funding
 - **August 1, 2019** for NCORP funding
- Non-federal site payments will not be affected
 - Non-federal site payments will continue to be distributed via current PSA w/ SWOG-CTP

0:18:40

What remains the same after new mandate

- Payment triggers
 - Still same enrollment
 - Entering information into OPEN
 - SWOG doesn't accept invoices
 - Unless specifically mentioned in funding memo
- Funding amounts continue to be stated in memos
 - No F&A involved
- Distribution payments processed monthly
 - Come from Theige at group chair's office
 - Accompanied by payment report emails
 - Getting notified payments are coming
 - Have breakdown of what's being paid
 - Patient ID, activity, invoice number to reconcile
- No requirement for additional financial reporting with these subawards

What Will Remain the Same

- **Federal Payments**
 - Payment Triggers: Enrollment, OPEN, or as indicated on the funding memo. **SWOG will not accept invoices** (unless specifically stated on the funding memo).
 - Funding Amounts: As stated on the study funding memo. **No F&A added.**
 - Payment Distribution: Payments will continue to be processed monthly and be accompanied by payment report email.
- **Financial/Progress Reporting**
 - SWOG will not require additional financial reporting or progress reports (at this time)

0:19:45

What has changed

- Fixed-price subawards
 - Separate subawards for NCTN and NCORP studies
 - Six-year grant cycles shown in slide in blue
 - Subaward amounts for each site vary based on past activity levels
 - If site amount is depleted over 6-year period, can create amendments to increase funding
 - Based on past activity
 - But if site becomes more active, have ways to add funding to your agreement
- Can be additional funding that doesn't fall under one of these subawards
 - If SWOG has PSA with you, it does not expire
 - Want that mechanism in place if additional funding is needed in future

What Will Change

- **Fixed-Price Subawards**
 - Separate subawards for NCTN and NCORP study activity
 - For NCTN and NCORP subawards, initial subawards will run the entire course of the grant cycle (listed below):
 - NCTN grant cycle: 3/1/2019 – 2/28/2025
 - NCORP grant cycle: 8/1/2019 – 7/31/2025
 - Subaward amounts will vary and be based on past activity levels
 - If initial amount becomes depleted, SWOG will create amendments (as necessary) to increase funding
- **Additional Funding**
 - SWOG will keep PSA's active for funding other than NCTN and NCORP
 - In other words, **current PSA will not be terminated**
 - Study Example: S1415 (PCORI funding)

0:21:03

Next step

- Summer 2019 Theige started sending NCORP and NCTN fixed price agreements to sites
- Doing in phases, as SWOG has hundreds of sites
- Based on outstanding amount
- Has executed about 100
- Are other agreements still outstanding
 - If agreement is outstanding, so are the site's payments
 - Can't process payments until paperwork is in place
- Going forward, will move to next phase next week
 - If you haven't heard from Theige, you should soon
 - Important as part of membership with SWOG to get these financial agreements in place
 - Red line in slide is the takeaway:

If you don't know if your agreement is executed, don't understand something, or have questions about federal payments, contact Theige.

The Next Step (Updated)

- Starting in the summer of 2019, NCTN and NCORP fixed-price agreements have been sent out to sites (in phases) based on outstanding capitation amounts
 - Dozens of these agreements are still outstanding (which means the payments are, too)
- Going forward...
- Continue to get more agreements sent out to sites this fall (in phases) and continue to process outstanding payments for those sites (once agreements are executed)

If unsure whether your site has received and/or executed these agreements, please contact Kyle Theige

0:22:34

Contact information

- Theige's email address
- Can also give a site his phone number
- Important to get these in place
 - Until they are in place, he has to hold funds
 - Check with staff to ensure your site is getting payments
 - If not, contact him

Questions?

- Contact Information
 - Kyle Theige, Grants & Contracts Coordinator (SWOG GCO)
 - Email: theige@ohsu.edu
 - Cell phone: by request
-

Operations & Membership

0:23:22

Szczepanek introduced Dana Sparks, director of operations and protocols.

Sparks presented some general updates.

- Said she is continuously amazed by way staff and sites keep going despite the challenges
 - Something to be proud of
- Wanted to focus on what has been accomplished during this time
- Had about day and a half notice back in March to plan for 100% telework
- Their 1 IT guy was able to rebuild and repurpose laptops they had in office to support group meeting
 - Those were for people without VPN connection to use at home
- Most of office has worked from home since March
- In July, some started working partially from office
 - Still very controlled about how many people can be there and about cleaning
- All staff have been trained on needed hardware and VPN access
- Had already planned to expand office space
 - Now have bigger office with no one there

Ops has hired people for 2 new positions, promoted 4 staff members, and supported 2 lateral staff moves

- Recruitment and hiring is difficult under any circumstances; more so now

Finally completed single sign-on linkage to fully integrate web learning management system

- Not completely done
 - Web programming still needs to be finished
 - But background programming done
 - Should be much easier to access learning and training materials
 - Should also make it easier to engage training manager Lisa Barnstrom to develop new curriculum and training opportunities
-

Operations

Dana Sparks, M.A.T., Director of Operations and Protocols

- Expecting to expand that over next 2-3 years
- If you have ideas for training that would be particularly helpful, contact Sparks or Barnstrom

Also launched new conflict management disclosure system

- Those who help investigators disclose potential conflicts of interest should be aware that new system maintains old disclosures
 - So can check and update information already in system
 - Huge time savings
- Was launched this year, and collection process was faster and more complete than in previous system
- Most found it easy to use
- Kudos to Courtney Wille who managed conflict management system and both virtual group meetings
- Lots of work and lots of flexibility needed

Have expanded ability to conduct remote audits

- Between March and September, audit team completed 130 audits
 - About 90% were remote
- Still have some onsite audits, but very few
- Now documenting standard operating procedures for remote audits
- Clear that remote audits will continue
 - Requires less travel

New version of CTCAE is now in works.

- Working with NCI to provide them updates
 - Also to provide support to sites for process improvements to integrate expedited reporting system from Medidata Rave through CTEP/AERS
 - In new reporting process, initial report goes into Rave then is transferred to CTEP/AERS system
 - Have also supported sites regarding requirements for COVID-19 expedited reporting
 - Not a ton of this, but a new process
-

Activated 6 new trials over last 6 months.

- Continue to submit new protocols
 - 7 proposed protocols now under NCI review
- Continuing to progress and do what needs to be done

As things change, SWOG want to make sure to keep all valuable things learned from this experience.

- Find ways to incorporate those processes that make things easier for sites
 - Working within grant requirements and NCTN and NCORP guidance to ensure changes are consistent with NCI
 - Also documenting details that will allow us increased flexibility
 - To help site staff
 - Hopefully to help patients too
 - Sparks noted Chuck Blanke has developed a SWOG innovation working group
 - To look at changes and ensure group is moving forward in a way that
 - Makes sense
 - Uses available technology to create best practices for the future
 - That group will meet in January to nail down recommendations
 - Will review ASCO recommendations as well
 - Also recommendations from investigators on front line in different practice settings
 - Rural
 - Community
 - Academic
 - Sparks said she was looking forward to January meeting
 - Thought that overall this experience would make SWOG protocols better and more flexible
 - Would allow SWOG to better serve site staff and patients
 - Thought group's ability to adapt to these circumstances would strengthen its ability to adapt in the future
-

Szczepanek remarked that from Sparks's report one would never know all were locked in at home and doing strange things.

- "Pandemic schmandemic"

0:36:11

Szczepanek introduced Connie Barnes, programs manager for membership.

Barnes noted her team had been busy during last 6 months.

- Said she hated to tell Theige but would add more purchase service agreements to his stack
- International presence is expanding
 - Bringing Chile and Uruguay on board
 - Brazil to follow
- She also had changes in works with sites moving among membership programs

Membership

Connie Barnes, Programs Manager

Barnes had mentioned at spring meeting that SWOG would eliminate credentialing process effective September 1.

- Had to delay that to October 1 because board of governors did not meet in the spring
 - Expect to move forward after Saturday BoG meeting
 - Should simplify workloads related to credentialing documents
-

Statistics and Data Management Center

0:38:16

Szczepanek introduced Rodney Sutter, program director for therapeutic studies, and Phyllis Goodman, coordinating statistician and institutional performance guru.

Statistics and Data Management Center Insights

Rodney Sutter, Program Director, Therapeutic Studies
Phyllis Goodman, Coordinating Statistician, Institution Performance

0:38:43

Sutter said he had just a few updates on the SDMC.

SDMC Updates



Rodney Sutter, CCRP
Program Director, Therapeutic Studies
Cancer Research And Biostatistics

Phyllis Goodman, MS
Coordinating Statistician, Institution Performance
Fred Hutchinson Cancer Research Center

Statistics and Data Management Center
Seattle, WA



0:39:01

- Sutter reminded group of the quarterly SWOG CRA newsletter, launched one year ago
- Fifth edition was just released
- Has publicized it by notifying head CRAs and using the CRA listserv
 - Got feedback that the listserv is preferred, so will continue doing that
- Noted that those who had signed up for the listserv but haven't been getting these messages should check their junk mail
- Useful articles
 - Some by SDMC staff
 - Some by ORPs

CRA Newsletter



- First edition published in September, 2019
- Quarterly, posted to the CRA Workbench
- SWOG policy, expectations
- Group Meeting Information
- Form changes
- SWOG committee members
- Rave, Specimen Tracking
- COVID-related articles
- Advice columns!



- Slide shows some recent topics covered
- Started advice column from site perspective
- Autumn edition has articles from U Arizona Cancer Center and Cleveland Clinic
- Sutter encouraged anyone with advice to share to reach out

0:40:11

Sutter noted most recent version of CRA newsletter is posted to front page of CRA Workbench.

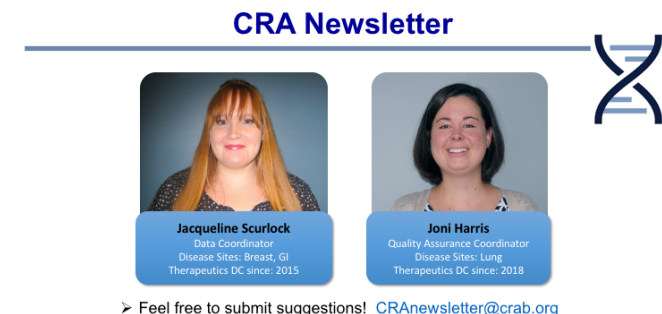
- Also a newsletter link to past editions in menu under Resources



0:40:37

Sutter recognized two SDMC staff who have taken lead in producing newsletter.

- Jacqueline Scurlock, data coordinator
- Joni Harris, quality assurance coordinator
- Both put in much effort on newsletter
- An initiative both ORP executive committee and SDMC were interested in
- They want to ensure content is useful to sites
- Reach out to CRAnewsletter@crab.org



0:41:20

Sutter spoke to the SWOG COVID-19 diagnosis and deviations form.

- Released about 3 months ago
- Many submitted online, through Rave or via CRA Workbench for pre-Rave trials
- Have heard from audit team that many have been documented on paper log at site but staff have not yet submitted in EDC
- Sutter provided tips for submitting form
 - Don't need to report deviations related to late data submission
 - Focus on documenting deviations related to patient care
 - Submit form only to report positive test results or pandemic-related deviations
- Questions about what is minor vs. major deviation for this form?
 - Use qa@swog.org email list to reach SWOG audit team

COVID-19 Deviations



- Form was released on June 26, 2020
- Many received, but auditors note many are missing
 - Tracking on paper log, not entering in the EDC
- Report deviations in regard to patient care, not data submission
- Only submit for positive test results and/or pandemic related deviations

SWOG
COVID-19 DIAGNOSIS AND PROTOCOL DEVIATIONS

Participant Identifier Study Identifier

Participant Initials (L, F, M)

Page: COVID-19 Diagnosis and Protocol Deviations

Instructions: Complete this form if the participant has tested positive for the COVID-19 virus or has any protocol deviations due to a COVID-19 diagnosis or other pandemic-related reasons. Submit this form within 15 days of knowledge of a positive COVID-19 diagnosis or protocol deviation. Amend the existing form if this participant has a second COVID-19 diagnosis or additional COVID-19 related protocol deviations not previously reported.

- Report any major deviations following the guidance of the IRB of record for the study. If unsure if an event is minor or major, contact SWOG Quality Assurance at qa@swog.org

0:42:22

- Also heard from sites overwhelmed with number of deviations they had to report before form was available
 - SWOG submits reports to CIRB summarizing deviation data
 - SWOG has prioritized studies based on their CIRB renewal date
 - Posted list in summer edition of CRA Newsletter
 - Current list provided in slide

COVID-19 Deviations



- Backlog of deviations to report?
 - We generate reports to the CIRB summarizing deviation data
 - SWOG prioritized studies based on their CIRB renewal date
 - First list provided in the CRA Newsletter (Summer Edition)

- Current priority list:

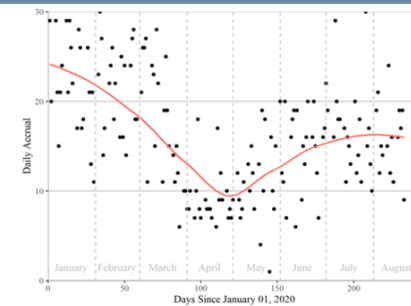
Study	CIRB Renewal Date	Need Form Entered by:
S1318	11/18/2020	09/19/2020
S1501	11/25/2020	09/25/2020
S1613	12/04/2020	10/04/2020
S1616	12/04/2020	10/04/2020
S1701	12/04/2020	10/04/2020
S1712	12/04/2020	10/04/2020
S1803	12/04/2020	10/04/2020
S1806	12/18/2020	10/18/2020
S1505	01/21/2021	11/21/2020
S1406	01/21/2021	11/21/2020
S1007	02/19/2021	12/19/2020

0:42:55

Accrual

- Sutter showed visual representation of SWOG accrual during pandemic
- Daily accrual fell to its lowest toward end of April
- Been coming back since, though not yet back to average pre-COVID
 - Getting close

SWOG Daily Accrual



0:43:20

Accrual table

- Accrual data sorted by committee
- Sutter highlighted that table has NCORP committees in top half, NCTN in lower
- Green column shows pre-COVID accrual
- To right of that in light blue is post-COVID
- Overall, accrual for NCORP committees were hit harder
- Cells in gold are months when accrual returned to pre-COVID numbers
- Committees that have fared well in accrual:
 - Palliative Care & EoL
 - GU
 - Lung
 - Lymphoma
- Table and graph in previous slide available in report of studies on swog.org

SWOG Accrual by Committee

	Average Weekly Accrual									
	Pre-COVID		Post-COVID		Post-COVID		Post-COVID		Post-COVID	
	Jan 01 - Mar 15	Mar 16 - Aug 23	Overall	Mar 16 - Apr 05	Apr 06 - May 03	May 04 - May 31	Jun 01 - Jun 28	Jun 29 - Jul 26	Jul 27 - Aug 23	
NCORP Committee										
Ca Care Delivery	5.41	1.43	1.67	3	0.75	1.25	1.5	0.5		
Palliative and EOL Care	0.28	0.87	0.33	0.5	0.25	0.75	2	1.25		
Prevention and Epi	0.84	0.43	0.33	0	0	0.5	0.75	1		
Ca Survivorship	1.68	1.22	2.33	0.25	1	1	1.5	1.5		
Symp Ctrl QOL	11.2	6.35	6.33	3.75	6.25	7.25	6.5	8		
TOTAL	19.41	10.3	11	7.5	8.25	10.75	12.25	12.25		
NCTN Committee										
Breast	7.75	6.52	5.67	5.25	4.5	8	8.75	6.75		
Early Tx	1.68	0.86	1.33	1.5	0.75	1.25	0	1		
Gastrointestinal	7.65	1.35	0.33	0	0	0.75	2	4.75		
Genitourinary	13.16	12.26	14.67	12	8.75	13.25	12.75	11.75		
Leukemia	1.21	0.35	0.33	0.25	0.25	0.25	0.25	0.75		
Lung	3.73	4.28	7	3.25	3	4.5	4.75	3.75		
Lymphoma	4.2	4.83	4	4.75	4.25	5.5	4	6.25		
Melanoma	4.2	2.43	2.67	2.25	3.5	3	1.25	2		
Multiple Myeloma	4.29	2.96	3	1.5	5.25	3	2.5	2.5		
TOTAL	47.88	36.91	39	36.75	31.25	39.5	36.25	39.5		
GRAND TOTAL	67.29	46.22	50	38.25	39.5	50.25	48.5	51.75		

0:44:16

Other SDMC news

- Sutter reported that SWOG S1605 would be headed to FDA soon
 - FDA registration trial
 - Current data has been reviewed at SDMC
 - Said sites can expect increase in manual queries posted to Rave in coming months as clean up continues
- Announced recently that some trials that collect data via CRA Workbench and are still in long-term follow-up would transition to collect that data via Rave
 - Transition for breast study S0221 just completed
 - Follow-up forms for that trial now only in Rave
- Sutter noted that any documents they have sent related to COVID are available on SWOG website via the COVID-19 Clearinghouse page
 - After log-in, scroll toward bottom
 - Listed under News & Stories
- Have been updating ORP Manual and online Clinical Trials Training Course
 - CTTC will take a while longer because need to be in office to record audio
 - ORP Manual should be published soon
 - Sites will get notice when it is
- Sutter said those with training needs should reach out to Lisa Barnstrom, training manager

Other SDMC News

- S1605 – Phase II Trial of Atezolizumab in in BCG-Unresponsive Non-Muscle Invasive Bladder Cancer
 - Heading to FDA
 - Expect an increase in Queries as the study is reviewed
- S0221 (Breast) – Follow-up changed from legacy system to Rave
- COVID-19 Clearinghouse on swog.org
- ORP Manual Update
- Online Clinical Trials Training Course (CTTC) Update
- Suggestions for additional training needs?



0:46:02

Sutter turned presentation to Goodman.

Goodman noted smoke had finally cleared in Seattle.

- Said that those at Fred Hutch had been told to expect to work remotely through at least June 2021



Specimens and IPR Updates

0:46:51

Goodman provided updates on specimen collection and institutional performance review.

- Report on slide shows status of labs and repositories that get specimens from SWOG trials
- Report is posted in several places
 - CRA Workbench specimen tracking
 - COVID-19 Clearinghouse
 - CTSU website
- Goodman said they had been updating this report weekly but were now updating it less frequently
 - Because labs have settled into their new routines

Status of SWOG Repositories/Labs

Updated regularly and posted on

- SWOG CRA Workbench, Specimen Tracking System
- COVID-19 Clearinghouse on swog.org
- CTSU website



ADMIN	STUDY	LAB #	Lab Name	Lab Status as of September 9, 2020
All		200/201	Nationwide - SWOG Biospecimen Repository	Accepting and processing samples as usual.
BREAST	S1416	209	Kuhn-Hicks Laboratory	Accepting and processing samples as safely as possible. They are limited in our staff and therefore REQUEST NOTIFICATION OF ALL SPECIMEN SHIPMENTS in order to schedule appropriately.
BREAST	S1418	159	NRG Serum Bank at Baylor College of Med	Blood should be shipped Monday-Thursday only so that delivery will arrive at the NRG Oncology Serum Bank at the Baylor College of Medicine on Tuesday-Friday.
BREAST	S1418	214	Clariant/Neogenomics	Accepting specimens as usual.

0:47:23

- Table in slide provides study-specific info on specimens collected
 - Table is a summary and doesn't replace protocols for individual studies
- Goodman said if you can collect only a subset of required specimens, this table will help you decide which specimens are most critical and how to ship those specimens
- Table posted on COVID-19 Clearinghouse
 - Will be added to CRA Workbench and to CTSU

Specimen Needs for Protocols

Posted on SWOG COVID-19 Clearinghouse
Individual sample needs/priorities by committee/protocol/timepoint



ADMIN	Study	Timepoint	Specimen Type	Critical Level 1=High, 2= Medium, 3=Low	Shipping
LYMPH	S1608-1	Baseline	TISSUE - relapse biopsy; block/sections/slides	1 - for eligibility	Can be shipped AMBIENT at a later date.
		Baseline	TISSUE - diagnostic biopsy; block/sections/slides	1 - primary TM endpoints	Can be shipped AMBIENT at a later date.
		Baseline	BLOOD - Streck + red top + purple top EDTA	2 - secondary endpoints	Ship overnight same day as collection
		Baseline	BLOOD - red top vacutainer	3 - banking only	Ship overnight same day as collection
		After Cycles 3, 6; 30-month	BLOOD - Streck + red top + purple top EDTA	2 - secondary endpoints	Ship overnight same day as collection
		After Cycles 3, 6	BLOOD - red top vacutainer	3 - banking only	Ship overnight same day as collection

0:47:56

- Goodman said she reviewed data on specimen submissions as of beginning September
 - Were 736 specimens from 205 patients that had not been submitted because of COVID
- Goodman said repositories haven't noticed much of a drop, so sites are overall able to submit specimens
- Noted they can only identify nonsubmissions as due to COVID if "COVID" is specified within text describing reason specimen not submitted
 - Goodman said site could just say "COVID" or could specify longer reason
 - Some example of reasons are shown in slide
- Goodman said that even if a site indicates a deviation in specimen submission on a COVID-19 deviation form, it still needs to use that function in Specimen Tracking to resolve the specimen expectation

Unsubmitted Specimens – COVID-19

- N=736 specimens from 205 patients on 23 studies ranging from 1 to 166 specimens per study
- Surprisingly low.
- Please be sure to include COVID in reason, e.g.
 - COVID-19 or CoVID-19 or COVID
 - Due to COVID-19 modified site operations, specimens couldn't be collected
 - Due to COVID-19 MD did not want patient coming in for bloods
 - Virtual appt. because of COVID-19
 - Not submitted due to COVID-19. No research staff on site to collect
- Need "Notify that Specimen Cannot be Submitted" in Specimen Tracking even if noted on the COVID-19 Deviation Form



0:49:04

- Now collecting COVID-19 deviations data on new form
- As of early September, were total of 1,037 deviations noted
 - One-third due to phone or virtual visits
 - Next largest category is late or missed study procedure
 - Then late or missed study visit or specimen collection
 - Very small number were called major
 - Goodman suspected some of these were incorrectly coded
 - Elaine Armstrong and her team will review these to ensure categorized correctly
 - Most deviations were on studies where patients were still actively getting treatment
- As Sutter had said, any data collected on log before form was available still needs to be submitted on this form
 - It's the only way they can consolidate data for CIRB review

Deviations Noted on COVID-19 Form

Deviation	N
Cycle Treatment Given Early or Late	24
Cycle Treatment Missed	14
Phone or Virtual Visit	341
Late or Missed Study Visit	108
Late or Missed Study Procedure	188
Late or Missed Study Lab	69
Late or Missed Imaging Procedure	43
Late or Missed QOL/PRO	59
Late or Missed Study Specimen Collection	101
Other	92
TOTAL	1037

0:50:03

CTSU notification

- Reports that CTSU pushes to sites from Data Quality Portal and Source Document Portal were restarted in August
- Slide quotes from email they sent
- Goodman has no further updates from them

CSTU Notification

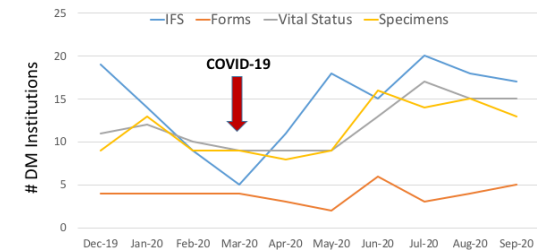
- Per notice from CTSU on August 7
Automated bi-monthly data submission notifications identifying outstanding data from the CTSU Data Quality Portal (DQP) and Source Document Portal (SDP) will be re-started this month. The notifications had been suspended in April 2020 due to the pandemic with the expectation that sites would continue to submit data as they were able

0:50:25

SWOG performance measures: Effects of pandemic

- Graph shows number of data management institutions that were out of compliance starting Dec 2019
- Before pandemic, things were steady
 - Number of sites out of compliance for submission of initial forms set was at all-time low
- When pandemic hit, noncompliance rate increased, as expected
- Because of situation, stopped sending warning emails

IPR Trends – Data Management Institutions Out of Compliance



0:51:07

- But still monitoring data submission rates and few important points to note
 - If you are able to register patient to trial, still must have all required baseline forms and documents
 - They understand systems sites use to record these may have been affected by changes in staffing, etc.
 - Understand things may be submitted later than usual
 - But still expect them to be submitted
- Initial forms sets and specimens due more than 13 months ago should no longer be outstanding
 - These were due substantially before pandemic hit

IPR Comments

- If you are able to register a patient to a trial, then you must have the required baseline forms, documents
- Systems for submitting these requirements (expectations) may have been impacted by changes in staffing, site operations
- Understand that things may be submitted later than usual, but...
- Initial Forms Sets and Specimens due more than 13 months ago
 - These should not be outstanding



0:51:50

- Slide shows data on specimens due more than 13 months
- Before pandemic, 5 sites were overdue for initial forms set, 1 overdue for specimens
- These numbers are now 18 and 19
- Items from initial forms set are almost all baseline specimens
 - If these or any post-baseline specimens are not collected, please remember to use the “Notify that a Specimen Cannot be Submitted” function in Specimen Tracking to resolve that expectation

Overdue for More than 13 Months

	Data as of March 2020	Data as of September 2020
Initial Forms Sets	5	18
Specimens	1	19



- Data from SWOG sites only
- For Initial Forms Set, everything that is more than 13 months overdue is a specimen
- If the specimen was not obtained use the “Notify that a Specimen Cannot be Submitted” function on Specimen Tracking to get the expectation resolved.

0:52:28

- Goodman said she expects SWOG will reinstitute institutional performance
- Probably first do with initial forms set
- Will give sites 1 month announcement before sending warning emails
- Pandemic has had impact on data submission, but still want to run highest quality trials possible
- Asked group to please continue to submit your data
- Goodman thanked all for hard work under difficult circumstances

Szczepanek noted that staff at SDMC has been seamless.

- Sites can get responses, find them, get help
- Good job

IPR Comments

- IFS measure will most likely be the first IPR measure to be re-instituted. You will be given a one-month heads-up.



- The pandemic has had an impact on the submission of data. We want to be sure to continue to run trials of the highest quality possible. Please submit data so that we can continue to improve lives through cancer clinical trials and translational research.

Quality Assurance

0:53:21

Szczepanek introduced Elaine Armstrong, quality assurance manager for SWOG, to present.

Armstrong said she wanted to continue topic of reporting deviations.

Quality Assurance Updates

Elaine Armstrong, MS, Quality Assurance Manager

0:54:02

- Variances for protocol requirements that have been approved by CTEP are not deviations
 - E.g., shipping investigational agents direct to patients
 - Not a deviation
- If protocol has been revised to extend timeframes, those are not deviations
 - E.g., if assessments are out of window
- Temporary variances via SWOG memos DO need to be reported
 - Not formal protocol revisions
 - So are considered deviations
- Armstrong reminded group that these deviations won't necessarily result in deficiency
 - In most cases, won't be getting a deficiency during audit
 - Primarily a way for SWOG to collect important information

Reporting Covid-19 Deviations

- Variances from protocol requirements previously approved by CTEP are not considered deviations (e.g., investigational agents shipped directly to patient).
 - Some protocols have been revised to provide extended timeframes for assessments and/or specimen and data submission for Covid-19 or other extenuating circumstances. Following these updated timeframes do not need to be reported as deviations.
 - Temporary variances distributed via memo from SWOG or the NCI must be reported as a deviation.
 - In most cases, deviations will not result in a deficiency during an audit.
-

0:55:21

Armstrong provided guidance on specifics:

- Activities performed by a local healthcare provider
 - Common now
 - Done under oversight of responsible investigator
 - Must make sure protocol requirements are followed
 - Often done even during non-pandemic times
 - E.g., patient lives 2 hours away, so have their labs done locally
 - Examples of things that could be done by a local provider:
 - Labs
 - Imaging
 - Physical exams
 - Treatment with non-investigational agents
 - Even surgery or radiation
 - These are not deviations at this time
 - But site must have process to submit required information to research site so it can submit data
 - If site cannot get data, must eventually say this is not acceptable

Reporting Covid-19 Deviations

- Activities performed by a local healthcare provider, if being provided on an intermittent/short-term basis with direct oversight by the Responsible Investigator with respect to protocol requirements and clinical care (e.g., lab tests, imaging, physical exams, treatment with non-investigational agents, other SOC therapy such as surgery or radiation if credentialing is not required) are not considered deviations. Processes must be in place to report required information to the Responsible Investigator who is responsible for ensuring data is submitted in Rave.

0:56:59

Minor deviations:

- Those that don't impact patient safety or compromise study data integrity
- SWOG has best practices document that includes time windows for labs, treatments, assessments
 - If delay falls within best practices window, not a deviation
- Delays outside of window are usually minor deviations
 - E.g., single missed lab or office assessment, or single office visit
- Study visits conducted by phone or videoconference are minor deviations

Reporting Covid-19 Deviations

- **Minor deviations:** do not impact patient safety, compromise the overall integrity of the study data (ability to draw conclusions from the study data)
 - Minor delays are often addressed in the Best Practices document
 - Delays in treatment administration, study visits or follow-up assessments
 - A single missed assessment (i.e., office visit, lab procedure) or a single missed dosing
 - Study visit conducted by phone or video conference
-

0:58:03

Major deviations:

- Those that could impact patient safety, increase risk, or compromise study
- NCI has issued guidance:
 - Visits for H&P, performance status, toxicity assessment that are needed to determine eligibility *must* be done in person
 - Can't substitute telehealth
 - Missed endpoint assessment is a major deviation
 - *Multiple* missed labs or toxicity assessments add up to major deviation
 - E.g., if patient comes in for 3rd visit in row with no labs or toxicity assessments being done
 - Consider whether it's safe to keep such a patient on
 - Considered a major deviation
 - Substantial treatment delays are major
 - Few days okay, but a month is not
 - Failure to collect research specimens is a major deviation
 - Armstrong said she would consult with Goodman re prioritized list of specimens
 - See if that would inform minor vs major decision
 - Multiple missed visits while patient is on treatment is major deviation
- Armstrong said those with questions should contact her

Reporting Covid-19 Deviations

- **Major deviations:** impact on patient safety, substantially alters risk to the patient, compromises the overall integrity of the study data
 - Eligibility – no in person visit for H&P, PS, toxicity assessment, if applicable
 - Missed endpoint assessments
 - Multiple missed labs, toxicity assessments
 - Substantial treatment delays
 - Failure to collect research specimens (unless lab is closed)
 - Multiple missed visits while patient on treatment

1:00:00

Armstrong echoed Sparks: remote audits are happening.

- But said she's now in hotel room having just completed an onsite audit
- NCI Clinical Trials Monitoring Branch has approved remote audits
- Said NCI working on SOPs for these
 - Thought these would help a lot
 - Some sites are reluctant to have remote audits, but also don't want auditor on site
 - Once there's an SOP, can provide reassurance
- Armstrong noted the remote procedure is similar to the onsite

Remote audits

- NCI-CTMB has approved/endorsed remote auditing due to travel and visitor restrictions related to Covid-19
 - Audit process as similar to on site auditing as possible with communications and exit interview via email, phone or video app
 - Regulatory documents emailed or uploaded
 - Drug accountability records emailed or uploaded and pharmacy review done virtually via video app
-

- But all communications and exit interview done through technology
- Regulatory docs emailed or uploaded
- Drug accountability records also emailed or uploaded
- Been doing pharma reviews with videoconferencing app
 - Checking inventory and looking at storage conditions

1:01:29

- Armstrong said giving her office access to the site's EMR system is most efficient
 - Easier for auditor and for site
 - Otherwise site has to upload large number of documents
 - SWOG has signed privacy statements and HIPAA statements
 - Noted some sites have gone overboard and SWOG is not willing to sign their documents
 - Now getting access to many more sites than they would have 1 year earlier
- If site won't give EMR access, it needs to upload the records
 - Upload options:
 - CTSU Source Document Portal
 - Sites that have central monitoring done for registration study have used similar portal
 - Some restrictions on how you can identify documents
 - SWOG SharePoint site
 - Works pretty well, but some glitches
 - Having call on Friday to design document management for audits
 - One site had its own local document portal they gave SWOG access to
- Have several auditors always remote, so they're used to distributed work
- Most registration study audits done remotely
- Largest remote audit thus far 25–30 cases
 - Armstrong said she would be reluctant to do remote audit for really large site with 75 or 100 cases

Remote audits

- Ideally, EMR access given for the patient case review
 - If not, patient records are uploaded for review
 - Options for uploading documents into a secure portal – CTSU Source Document Portal, SWOG SharePoint site, local site portal
 - SWOG has contracted with a company to create an Audit Document Management System within the Office 365 setting to meet our audit needs
-

- None this size on schedule until after first of year
- Will work with sites and process will get easier

1:04:45

Szczepanek thanked Armstrong for her flexibility.

Armstrong added that Leanne Larson, assistant QA manager, was retiring.

- Wednesday would be her last day
- Fortunate that Vanessa Benavidez, project manager in protocol department, is replacing her
- Noted qamail@swog.org is good way to reach them because it's always up to date

Q&A

Szczepanek checked in with Caitlin Hutchinson from ORP executive operations committee re questions from the Q&A box.

Hutchinson noted few questions about remote monitoring.

- Question about whether Zoom or WebEx rather than other platforms would be options for chart review.
 - Armstrong said it was difficult to picture using Zoom or WebEx for chart review
 - Knows they have used similar technology to have someone remotely walk them through a chart
 - Would be applicable in that kind of situation, but not sure how to use them for reviewing documents
 - Hutchinson noted that in VA system they're not allowed to use Zoom because of PHI insecurity
 - But are permitted to use Microsoft Teams or WebEx
 - Her teams are preparing to upload sources not available in EMR so they can share screens both of EMR and for relevant scanned outside sources
 - Finding they have to think about workload for coordinators involved in extra steps of scanning and organizing
-

Hutchinson said another question about remote monitoring: how would planning monitoring for new studies be handled during COVID.

- Hutchinson said question might relate to SWOG 1806 or other trials that are just opened
 - How would monitoring proceed?
- Armstrong said volume of audits would probably stay same
- For registration studies, default mode would be remote
 - Easy to do 1 or 2 charts remote
- If sites say no, can look at on-site audit

1:09:53

Szczepanek moved to announcements.

Announcements & Closing Thoughts

1:09:59

Szczepanek said she hoped all were enjoying day 1 of virtual meeting.

- Just the beginning
- Two important sessions tomorrow for ORPs
 - Oishi Symposium at 1:00 CT
 - ORP Open Forums at 2:30 CT
- Szczepanek extended special thanks to Kristine Abueg, Stefanie Parker, and Deb Bergevin who worked hard to organize these

Please join these additional ORP Sessions

- **Jeri & Noboru Oishi Symposium**
Thursday, 1:00 – 2:00 PM CT
 - **ORP Open Forum**
Thursday, 2:30 – 3:30 PM CT
-

1:10:32

Szczepanek said SWOG is all about ORPs.

- Strong conviction that ORPs are the ones who make studies happen
- Several positions open for those who want to get involved
- Application process link on the website
- Also ORPExecs@swog.org email for asking questions
- Newly reconstituted membership committee
- Committee welcomes interest of anyone who wants to get more deeply involved

YOU are the ORP!

"SWOG holds a fundamental conviction that the Oncology Research Professional (ORP) plays a crucial role in the successful development, implementation, and analysis of any SWOG clinical trial. In accordance with this awareness, SWOG strives to recognize these research partners and their ideas."

The ORP Committee is accepting **Sub-Committee applications**

Join the ORP committee to help shape the educational needs and information exchange.

For more information &/or to get more deeply involved:

- See the **CRA Workbench / ORP Committee link**
- Submit a completed membership application and CV (resume or biosketch) to the ORP Membership Committee at ORPExecs@swog.org

1:11:11

Reminders

- Use CRA Workbench to find key SDMC contacts
- Next SWOG group meeting planned for spring in San Francisco

Reminders

- **Key SDMC contacts** are listed on the CRA Workbench

- **Spring 2021 SWOG Group Meeting**

April 21 – 24, 2021
Hyatt Regency San Francisco
San Francisco, California

1:11:38

- ORP's new web page just went live
- Members of executive committee can be found through this
 - Log on to SWOG website
 - Find Member Resources
 - Find page Oncology Research Professionals
- Shout out to Wendy Lawton and Annette Betley for working with Szczepanek to make this happen
- Excited about having this new venue for posting resources

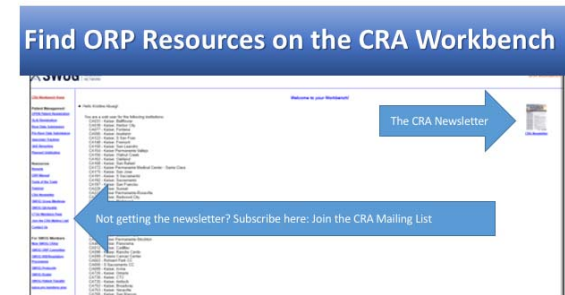
ORP Webpage

Check out our new ORP Page!

- Log into the SWOG Member website
 - Go to: Member Resources
 - See: Oncology Research Professionals
-

1:12:17

- Reiterated Sutter's reference to finding the CRA Newsletter on CRA Workbench



1:12:29

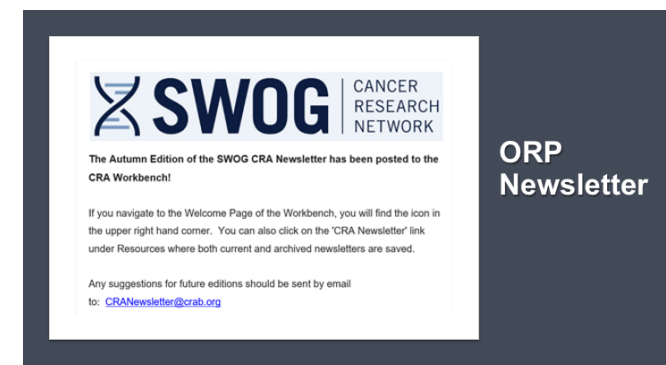
- Suggestions: submit to CRAnewsletter@crab.org



CRAnewsletter@crab.org

1:12:41

- Can subscribe to newsletter as well



1:12:49

- Szczepanek said info on scholarships for CRA travel to spring meeting would be announced in January
- Hope Foundation has been generous to ORPs

Funding Opportunity CRA and Nurse Travel Support Program

- Offered through SWOG's public charity, The Hope Foundation for Cancer Research
- Provides per traveler funding for group meeting attendance
- **Applications open early 2021 for the SWOG Spring Meeting**
- Visit tinyurl.com/CRA-NURSE

THE HOPE FOUNDATION
FOR CANCER RESEARCH

#SupportingSWOG

1:13:15

Szczepanek posted list of ORP executive committee members.

- Said they work hard throughout the year
- Said she was deeply indebted to all of them through thick and thin of COVID and beyond

Acknowledgements

ORP Executive Committee Members	
Kristine Abueg	Jamie Myers
Sandy Annis	Joyce Nancarrow-Tull
Annette Betley	Stefanie Parker
Anthony Hicks	Cecil Petrowsky
Caitlin Hutchinson	Lisa Stoppenhagen
Dana Little	Connie Szczepanek

1:13:38

- Szczepanek thanked the speakers
- Said cancer has not stopped so our work has not stopped
- Need is greater than ever
- Szczepanek also thanked Courtney Wille
 - Said world will never know how long she has gone without sleep
- Also thanked Hutchinson, new member of executive committee who volunteered to help with this session

Special Thanks

- All of our Speakers
 - Courtney Wille
 - Caitlin Hutchinson
-

1:14:27

And now for a little bit of fun ...

- And hopefully inspiration
- With help from the group

Szczepanek said she would give group 60 seconds, with some music playing, with no right or wrong answer, but asked members to submit through Q&A function something they have done or found over last 6 months that has brought them joy or is silver lining of COVID.



1:16:35

Szczepanek started, saying the photos were from her world 2 weeks earlier.

- Feeling of sand between your toes, stepping on a sharp rock, feeling the wind, flying a kite with her grands

Szczepanek said those are her joy and inspiration.

Hutchinson shared a number of postings, noting some were lovely.

- The opportunity to slow down
- Spending more quality time with my kids
- Angela [Smith?] adopted a dog and is taking long walks
- Sparks is taking joy in virtual wine tasting
 - "I know this sounds like a toss off comment, but I have an intellectual interest in wine and I've been able to explore it during this time with a great Texas winemaker"
- Katie is excited for pregnancy
- Pat says her cats join in on WebEx calls
- Hutchinson noted that quality time with dogs seemed to be a theme
- And daily meditation and appreciating even the smallest joys of the day
- Taking the ever changing times to really think about what is most important
- Keep doing the work they love doing, but finding a way to be closer to family
 - That's how moving from Tennessee to Michigan happened last month
- Hutchinson added her two cents



- She enjoys hearing her two small boys playing and laughing in the background while she's on conference calls

1:18:36

Szczepanek thanked all for sharing.

- Sometimes the hardest times in life bring forward the most beautiful things
- We've all learned a lot
- Szczepanek quoted an unknown source:
 - The most beautiful stones have been tossed by the wind, washed by the water, polished to brilliance by life's strongest storms
- Said these hardships will prepare us for the extraordinary
- Commended all for their faithfulness, dedication, and all that they do
- Hutchinson said she was looking forward to an in-person meeting in the spring

Through
hardships and
the tests of
time...



1:20:02

Meeting was adjourned.

Chat Box Comments

(Chat timestamps are aligned with video recording timestamps)

1:14:58	from Jen Dill to Host (privately):	Deepening relationship with my children
1:15:19	from Katie Minichiello to Host (privately):	Pregnancy!
1:15:26	from Bill Shea IMS Tech to Everyone:	make sure to select send to: Everyone
1:15:26	from Carey Uhlenkott to Host (privately):	Much more time with my young adult children than I ever would have had at their current ages! It's been a blessing.
1:15:27	from Kacie Simpson to Host (privately):	Spending more time with family

1:15:34	from Casey Dawson to Everyone:	Opportunity to slow down
1:15:37	from Evonne Lackey to Host (privately):	I've learned my spouse can cook....really well!!!
1:15:38	from Ingrid Tibbits to Host (privately):	Tree landscaping!
1:15:40	from Chris Pustulka to All Panelists:	Spenidng more quality time with my kids
1:15:42	from Tameka Lewis to Host & Presenter:	I have really enjoyed baking and cooking new recipes with my children. As well as planting flowers. This has helped me keep my pease.
1:15:44	from Dana Sparks to Everyone:	I have found real joy in virtual wine tastings. I know this sounds like a toss off comment, but I have an intellectual interest in wine and I've been able to explore it during this time with a great Texas winemaker.
1:15:48	from Katie Minichiello to All Panelists:	Pregnancy!
1:15:57	from Danae Campos to Host (privately):	Being able to work from home and have my lovely dog sit by my desk during stressful times
1:15:57	from Pat Mize to Everyone:	My cats joining me on webex calls
1:16:00	from Shelbi Burt to All Panelists:	I have taken the ever changing times to really think about what is most important to me. That was that I keep doing the work I love but find a way to be closer to family. That is how I ended up moving from TN to MI last month.
1:16:10	from Annette Betley to Host (privately):	being greatfull for family and friends
1:16:17	from Tameka Lewis to Host & Presenter:	Peace not Pease
1:16:23	from Tracy Maher to Host (privately):	Taking walks in my neighborhood, gettin to know my neighbors better and finding hidden parks with old growth trees that I did not know were there.
1:16:28	from Hannah Hale to All Panelists:	Quality time with my dog

1:17:02	from Leslie Bechtel to Host (privately):	I have rediscovered my love for painting, and lower stress levels not commuting in rush hour traffic every day
1:17:05	from Sandi Hita to All Panelists:	daily meditation and appreciating even the smallest joys in the day
1:17:10	from Brook Wright to Host & Presenter:	spending LOTS of time with my family. We were put on lockdown with a brand new baby, and all got to bond so much since everything was canceled!
1:17:13	from Debbie Allen to Host (privately):	An opportunity to spend more time with family at home and not having to be on the go so much
1:17:13	from Anna Moseley to Host (privately):	Connecting more often with friends and family, even if virtually
1:17:22	from Roxanne Topacio to Host (privately):	I write and mail 3-5 handwritten letters each week to friends, family, current and former colleagues. Reflective and mediative practice.
1:17:31	from Leslie Weissenstein to Host (privately):	Watching the joy of life; one of our cats had kittens in April and seeing them develop was fun and endearing.
1:17:37	from Josie Faust to Host (privately):	The COVID-19 forces us to change and re-evaluate on things we do and what is important. Hope we will all change for the better including research!
1:17:58	from Leslie Weissenstein to All Panelists:	Watching the joy of life; one of our cats had kittens in April and seeing them develop was fun and endearing.
1:18:03	from Leslie Weissenstein to All Panelists:	Watching the joy of life; one of our cats had kittens in April and seeing them develop was fun and endearing.
1:18:22	from Leslie Weissenstein to All Panelists:	Watching the joy of life; one of our cats had kittens in April and seeing them develop was fun and endearing.
1:18:56	from PJay Vang to Host (privately):	Whoops I sent mine on the Questions. LOL
1:19:04	from Leslie Weissenstein to All Panelists:	Only had one batch of kittens - sorry for the duplicate messages :)

1:19:34 from Tameka Lewis to Host & Presenter: Thank you

Q&A Box Comments

-Lea Ann Bernick(bernicl@sutterhealth.org) – 0:32

Q: Need to discuss/give feedback re remote audits system

Priority: N/A--

-Lea Ann Bernick(bernicl@sutterhealth.org) – 0:33

Q: meaning I need to provide feedback

Priority: N/A-

-Caitlin Hutchinson – 0:38

A: Wonderful, I will bring this up during the Q & A-

-Caitlin Hutchinson – 0:38

A: I don't think we will have audio for the audience, what would you like me to share?-

-Bill Shea IMS Tech – 0:39

A: I can unmute Lea Ann during Q&A if you would like -

-Lea Ann Bernick(bernici@sutterhealth.org) – 0:40

Q: We need audit teams to move to CTSU portal that is not separate from the tool others are using. I can bring this up with Elaine also, but we just finished LUNG MAP audit not only could we see all the other sites PHI, but also the Hope Foundations Business

Priority: N/A-

-Caitlin Hutchinson – 0:46

A: LeaAnn, that is quite concerning indeed. I will pass this up the chain and we will follow-up-

-Lea Ann Bernick(bernici@sutterhealth.org) – 0:41

Q: documents

Priority: N/A--

-Lea Ann Bernick(bernici@sutterhealth.org) – 0:41

Q: no need to create a separate tool, when CTSU has one

Priority: N/A--

-Michelle Brockman(brockmj1@gene.com) – 1:01

Q: If a study has added Monitoring (example SWOG 1806) how are you handling it within COVID environment

Priority: N/A-

-Caitlin Hutchinson – 1:04

A: Did Elaine sufficiently answer your question?-

-Amy Koffarnus(amy.koffarnus@hshs.org) – 1:02

Q: For remote audits would the auditors be willing to view the chart via zoom with a CRA?

Priority: N/A-

-Caitlin Hutchinson – 1:04

A: Did Elaine answer your question?-

-Kelsey Bridges, UC-NCORP(kbridges@gibbscc.org) – 1:05

Q: Thank you Elaine and your team for your flexibility! We've completed 1 remote audit and it was smooth and successful.

Priority: N/A--

-Gayatri Nachaegari(gayatri.nachaegari@hci.utah.edu) - 1:08

Q: Can the CRA newsletter link be added to the email when it is sent out- instead of pointing the location only?

Priority: N/A-

-Caitlin Hutchinson - 1:10

A: Yes, we can work to include that :) Good idea!-

-Rodney Sutter - 1:18

A: The direct link may not work as users need to log on to swog.org first, but we'll look into it-

-Joyce Tull(joyce.tull@yale.edu) - 1:10

Q: Is there update on adjustments to accrual goals given the pandemic?

Priority: N/A-

-Caitlin Hutchinson - 1:10

A: I will make sure that this important question receives follow up-

-Kristine Abueg(kristine.d.abueg@kp.org) - 1:12

Q: CONnie - does the email ORPexecs@swpg.org still work?

Priority: N/A--

-Amy Koffarnus(amy.koffarnus@hshs.org) - 1:14

Q: another question no audits - for redacting PHI, has there been any talks about a program which automatically deidentifies scanned documents? Is there something like that available which sites our using or CTSU could implement as a tool?

Priority: N/A--

-Kim Turner(turnerk@genesishhealth.com) - 1:15

Q: Grandkids!!

Priority: N/A--

-Christine Magner(chrism@crab.org) - 1:15

Q: morning walks! Fresh air is the best way to start the day!

Priority: N/A--

-Joyce Tull(joyce.tull@yale.edu) - 1:15

Q: I have two new grandchildren! They help remind me of the cycle of life and give me joy everyday!

Priority: N/A-

-Phyllis Goodman - 1:15

A: (1) spending time with my kids who were home. (2) sharing in the bounty of our very productive plum tree - PLUMDEMIC 2020!-

-Michelle Brockman(brockmj1@gene.com) - 1:15

Q: Sitting side by side with my 2 dogs (polly and belle) while working.....both dogs 13 years old. They are happy I am home with them.

Priority: N/A--

-Anna Moseley(amosley@fredhutch.org) - 1:15

Q: Connecting more often with friends and family, even if virtually

Priority: N/A--

-Lea Ann Bernick(bernicl@sutterhealth.org) - 1:15

Q: Given our fires, to get that campver van sooner then later!!!! Also a safe and great way to travel during a Pandemic!

Priority: N/A--

-Kristien Lewis(lewikr@ohsu.edu) - 1:15

Q: Laughing, when there is nothing else to do. Finding one positive thing in all the negative

Priority: N/A--

-Debra Schillinger(schillinger.debra@marshfieldresearch.org) - 1:15

Q: To remember that each day is a celebration of life.

Priority: N/A--

-Christy Klepetko(cklepetko@swog.org) - 1:15

Q: Riding my trike/bike

Priority: N/A--

-Diane Liggett(dianel@crab.org) - 1:15

Q: Seeing my daughter more.

Priority: N/A--

-Janet Bogan(jbogan@med.unc.edu) - 1:15

Q: Due to Covid - I was given the opportunity to work from home and spend the last few months side-by-side with my daughter as she wrapped up (prematurely) her senior year of high school

Priority: N/A--

-Kate Bryant-Greenwood(kbryantgreenwood@cc.hawaii.edu) - 1:16

Q: Two out of 3 reg staff have adopted pets!

Priority: N/A--

-Mary Ontko(mary.ontko@daytonncorp.org) - 1:16

Q: The rare times I've been able to visit with my adult children brings me great joy!

Priority: N/A--

-Tifnee Page(tifnee.page@crcwm.org) - 1:17

Q: Spend more time with my family at safe distance!

Priority: N/A--

-PJay Vang(pajuaplai.vang@salemhealth.org) - 1:17

Q: Landing this job as a Clinical Research Coordinator at my institution.

Priority: N/A--

-Gayatri Nachaegari(gayatri.nachaegari@hci.utah.edu) - 1:17

Q: Spending time with my kid, painting and thinking about everyone in the world

Priority: N/A--

-Terah Hardcastle(thardcastle@westernstatesncorp.org) - 1:17

Q: less driving and more time outside

Priority: N/A--

-Susan Nottmeier(susan.l.nottmeier@kp.org) - 1:19

Q: great job everyone, thank you