SWOG CANCER RESEARCH NETWORK

Oncology Research Professionals (ORP) Committee -- Updates Meeting

SPECIAL FOCUS:

COVID-19 Management Issues and Perspectives Related to Cancer Clinical Trials

SWOG Virtual Spring Meeting 2020

Connie Szczepanek, RN, BSN, CCRP
SWOG ORP Committee Chair
connie.szczepanek@crcwm.org

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 2 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.

AGENDA

Welcome	Connie Szczepanek
An Overview from SWOG Leadership Regarding the Impact of COVID-19 on Cancer Clinical Trials	Charles Blanke
NCI Viewpoints	Marge Good
NCI CIRB Guidance	Amanda Sly
Operations Perspectives	Dana Sparks
Q&A / Site Concerns and Issues	Speakers & Attendees
Statistics and Data Management Center Insights	Dani Weatherbee Rodney Sutter Phyllis Goodman
Quality Assurance Updates	Elaine Armstrong
Group Chairs Office, Study Finance, Membership	Casey Dawson Pat Mize Kyle Theige Connie Barnes
Q&A / Site Concerns and Issues	Speakers & Attendees
Thoughts on Life and Closing Comments	Connie Szczepanek

An Overview from SWOG Leadership Regarding the Impact of COVID-19 on Cancer Clinical Trials

Charles D. Blanke, MD, F.A.S.C.O., SWOG Group Chair

Impact of COVID-19 on Federally-funded Cancer Clinical Trials

Charles D. Blanke, M.D., F.A.S.C.O.
Chair, SWOG Cancer Research Network

Oncology Research Professionals Update Meeting
April 22, 2020

COVID-19 and Cancer: Some Numbers from Overseas

- Incidence of cancer in Chinese COVID-infected patients: 1%
  - Incidence in general population 0.29%
- % of patients with cancer with severe events*: 39
  - % of non-cancer patients with same: 8
- % of cancer in Italian patients dying: 20
- Particularly increased mortality: patients with lung, GI, metastatic cancers

*Ventilator or death

Concerns with Cancer Clinical Trials During COVID

- Volume of COVID-19 patients has overwhelmed ability to provide *any* non-emergent care (NYC)
- Laboratories and imaging facilities have closed
- Loss of personal protective equipment makes outpatient visits difficult
- Some institutions have shut down accrual to all non-COVID studies
  - Some limit accrual to studies with “immediate” benefit
    - This precludes placebo-controlled, most NCORP (societal benefit)

NCTN Clinical Trials Network Program

Accrual for "Intervention" Step in Trials by Lead NCTN Group & Week

February 3, 2020 to April 12, 2020 (CTSU Open Data)

NCTN Group	2/3 - 2/9	2/10 - 2/16	2/17 - 2/23	2/24 - 3/1	3/2 - 3/8	3/9 - 3/15	3/16 - 3/22	3/23 - 3/29	3/30 - 4/5	4/6 – 4/12	% Drop Last Week *vs* Weekly Avg 2/3-3/15
ALLIANCE	93	88	83	93	105	94	67	30	41	30	-68%
CCTG	2	5	5	4	6	3	6	4	3	4	-4%
COG	43	53	47	45	51	58	41	34	39	34	-31%
ECOG-ACRIN	45	56	47	51	45	45	43	35	27	23	-52%
NRG	44	57	44	59	45	46	49	24	29	34	-31%
SWOG	49	46	43	54	54	46	54	35	29	33	-32%
TOTAL	276	305	269	306	306	292	260	162	168	158	-46%

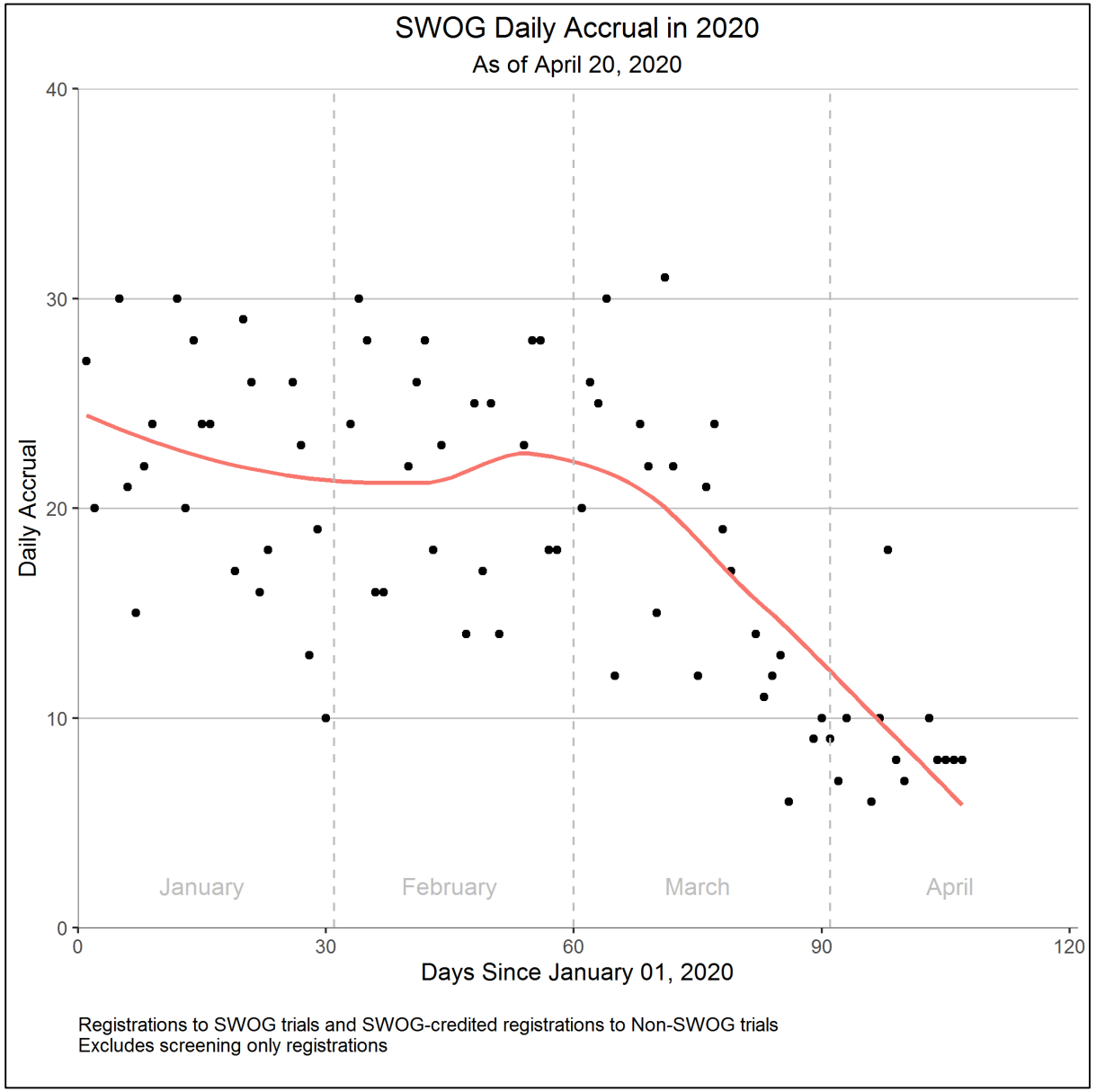
2 slides Courtesy Meg Mooney, MD

NCTN Clinical Trials Network Program

Accrual for "Screening" Step in Trials by Lead NCTN Group & Week

February 3, 2020 to April 12, 2020 (CTSU Open Data)

NCTN Group	2/3 - 2/9	2/10 - 2/16	2/17 - 2/23	2/24 - 3/1	3/2 - 3/8	3/9 - 3/15	3/16 - 3/22	3/23 - 3/29	3/30 - 4/5	4/6 – 4/12	% Drop Last Week *vs* Weekly Avg 2/3-3/15
ALLIANCE	24	22	25	28	22	27	13	7	10	7	-72%
CCTG	7	10	18	10	6	10	6	11	5	6	-41%
COG	9	14	14	9	5	9	9	5	13	12	+20%
ECOG-ACRIN	17	9	15	14	15	16	13	6	14	7	-51%
NRG	13	5	9	6	8	7	13	2	7	1	-88%
SWOG	20	28	28	23	30	24	23	21	8	20	-22%
TOTAL	90	88	109	90	86	93	77	52	57	53	-43%



Courtesy Cathy Rankin, MS

SWOG Committee-Specific Accrual Patterns

- Big drops: Breast, GI, SXQOL, (probably) Prevention, Survivorship
- Holding their own: GU, Lung, Lymphoma

NCTN Adaptations to COVID

- Patient care can be transferred to different participating study sites
- Local healthcare providers can provide continuity of care with oversight by responsible investigator
  - Treatment with non IND drugs
  - Physical exams, KPS assessments
  - Protocol-specific clinical lab tests
  - Protocol-specified radiologic imaging, EKG's, cardiac ultrasound
- NCI can ship oral IND agents directly to patients

NCTN Adaptations to COVID-19 (cont.)

- Injectable CTEP IND agents must still be administered at a registered trial site
- On-site auditing visits are being re-scheduled; some remote auditing has been adopted by NCTN groups
- Alternative procedures that do not compromise safety or the integrity of the study will be considered minor deviations:
  - Must be documented in the medical record with reason (e.g.,, travel restriction)
  - Examples: study visits by telemedicine rather than in-person; delayed study visits; delayed lab or imaging tests; minimal treatment delays; biospecimen collections, allowing QOL questionnaires to be done over phone, pausing RT

NCTN Adaptations to COVID-19 (cont.)

- Major deviations may be unavoidable; must still be reported to CIRB
- NCI CIRB supports “remote” informed consent: telephone discussion in conjunction with patient signature on written document
- Semi-annual group meetings cancelled or changed to virtual
- Weekly group chairs-NCI calls scheduled
  - SWOG EAC also made weekly
- SWOG has created a COVID-19 clearinghouse on SWOG.org

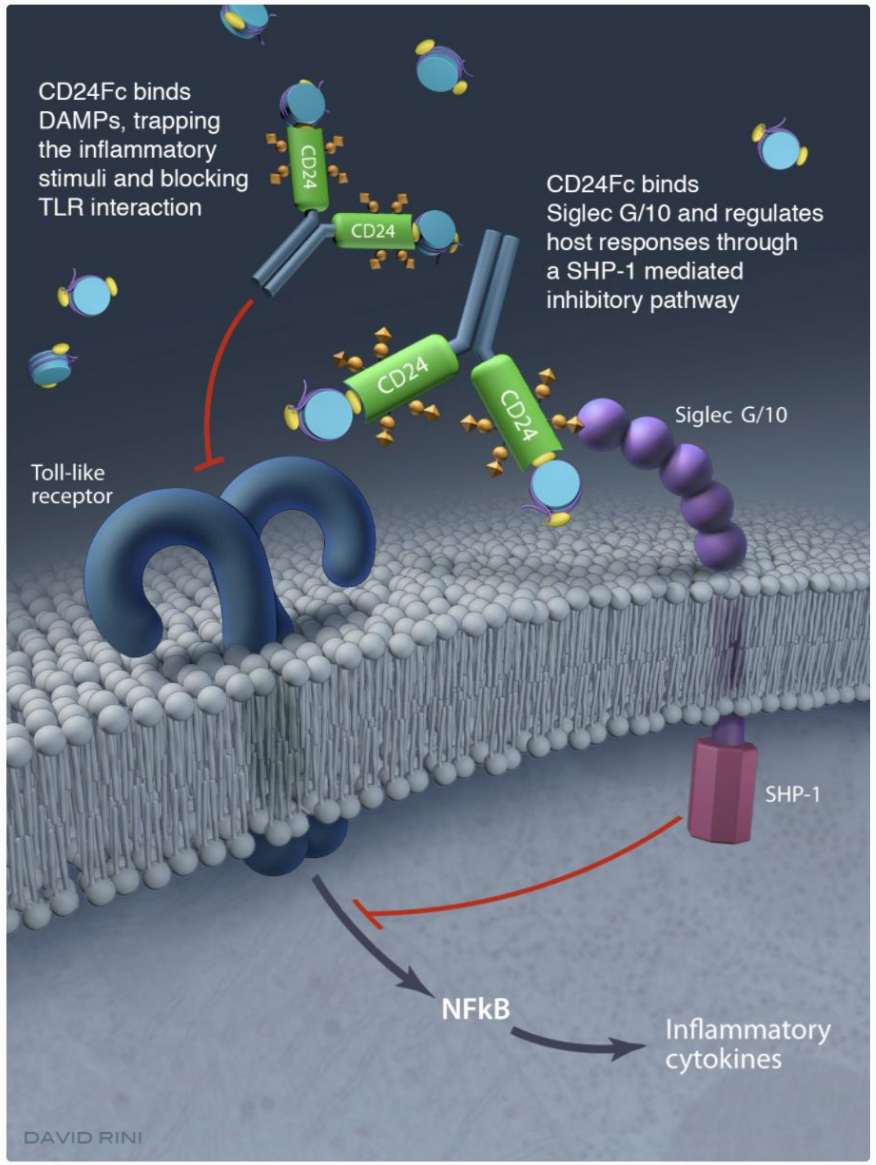
THINKING OUTSIDE THE BOX

A Randomized, Double-blind, Placebo-controlled, Multi-site, Phase III Study to Evaluate the Safety and Efficacy of CD24Fc in COVID-19 Patients with Cancer

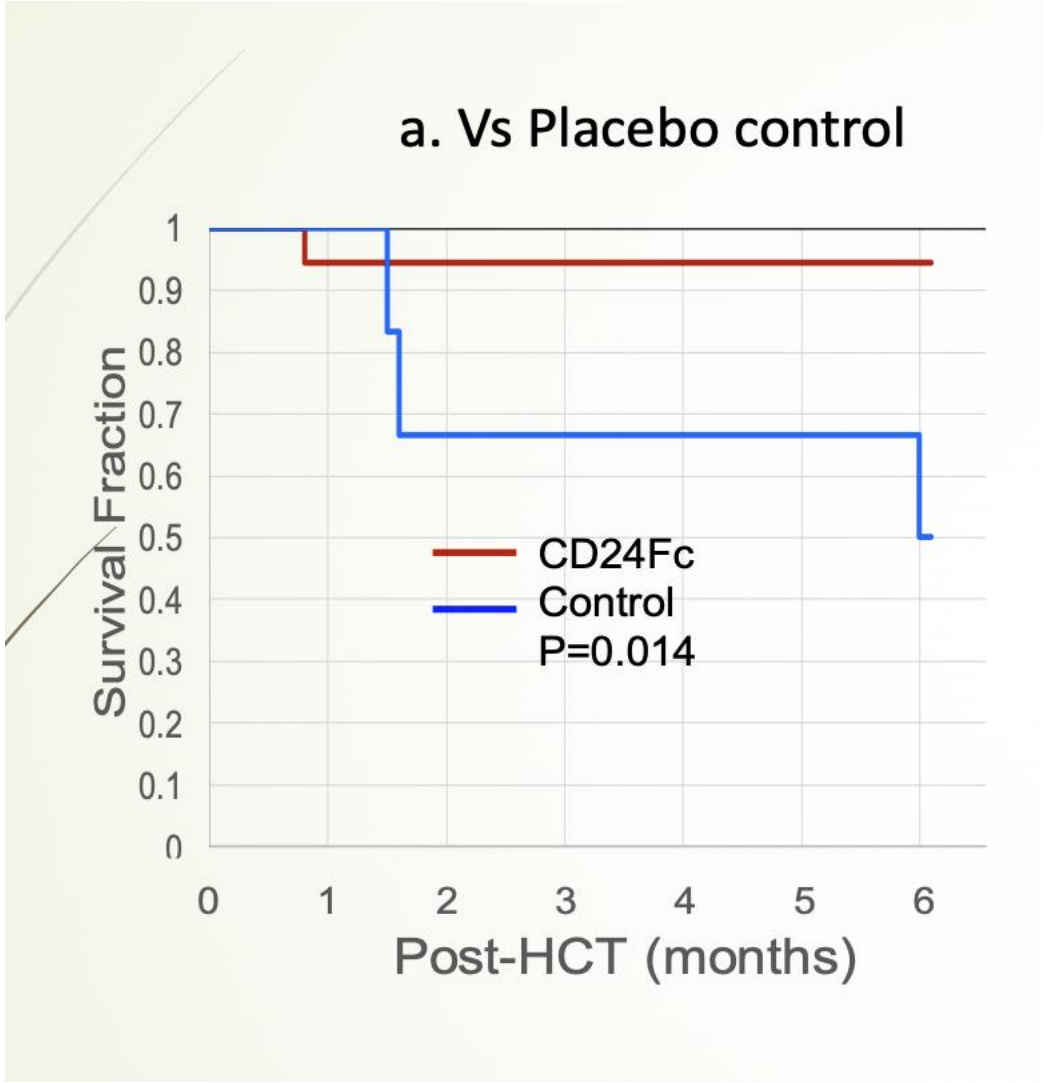
PI: Siwen Hu-Lieskovan, MD, PhD

SWOG Immunotherapy Committee

CD24Fc augments endogenous CD24 activity

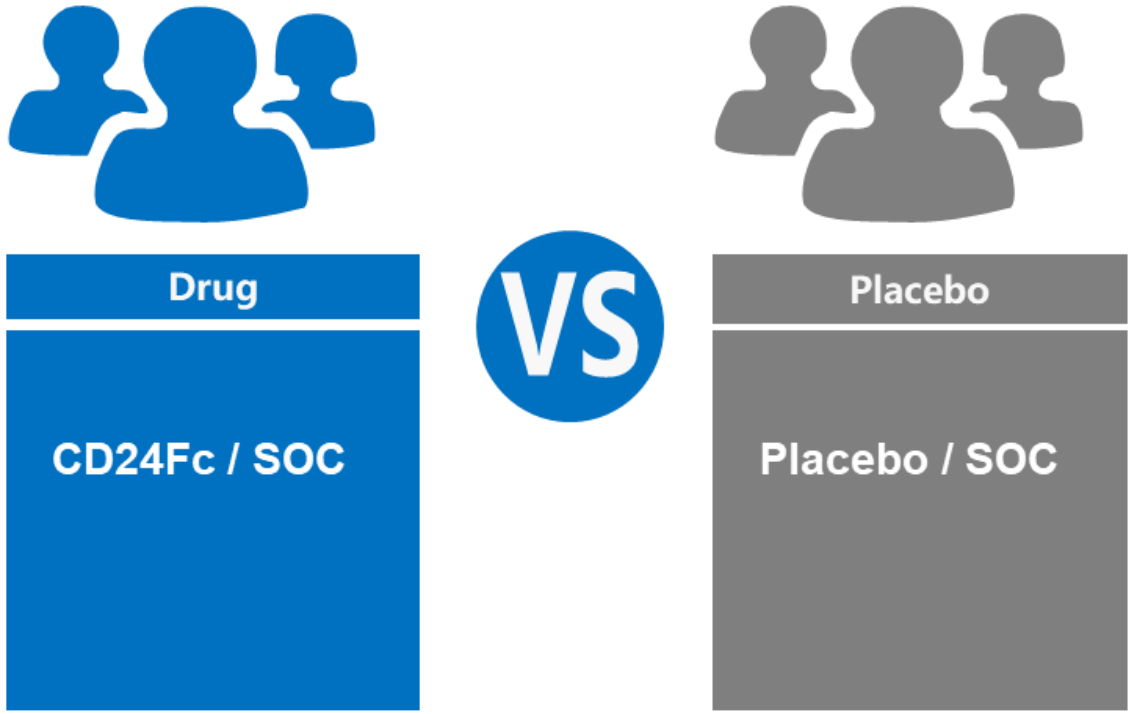


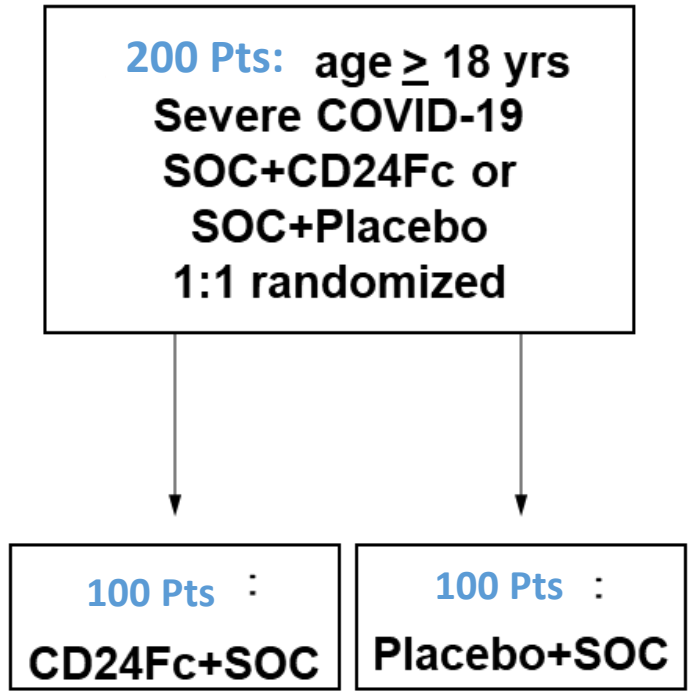
Gr III-IV GVHD-free Survival



Courtesy Oncoimmune

Phase III SAC-COVID-CANCER Clinical Trial Overview





- Randomize 1:1
- Primary endpoints: time to COVID-19 progression.
- Study duration: 3 months.

On Day 1, CD24Fc 480mg, dilute in 100ml NS, vs 100ml NS alone, i.v. infusion in 60 min.

Conclusion

- SWOG believes the best treatment is a clinical trial*

*even during the COVID pandemic

NCI Viewpoints

Marge Good, RN, MPH, Nurse Consultant / Program Director

NCI Viewpoints

SWOG ORP Meeting

April 22, 2020

NIH NATIONAL CANCER INSTITUTE

Topics/Objectives

- COVID-19-related guidance documents
- COVID-19 pandemic impact on NCTN/NCORP accrual
- NCI COVID-19 in Cancer Patients Study
- Planning ahead

NCI COVID-19 Pandemic Guidance Documents

- Interim Guidance for Clinical Trial Activities Affected by the Novel Coronavirus (3/13/20)
- Additional Guidance Regarding Alternative Procedures for Clinical Trials Supported by NCI CTEP and NCORP Affected by the Spread of the Novel Coronavirus (3/23/20)
- Updated Interim Guidance for Shipping Oral IND Agents to Clinical Trial Subjects during the COVID-19 Pandemic (3/23/20)
- CTEP/NCORP Guidance for Collection of Adverse Events Related to COVID-19 Infection (3/25/20)
- These guidelines complement and support the NCI CIRB Guidance for the novel coronavirus.

Other Federal Guidance Documents

- FDA
- FDA Guidance on Conduct of Clinical Trials of Medical Products during the COVID-19 Pandemic
- NIH
- Guidance for NIH-funded Clinical Trials and Human Subjects Studies Affected by COVID-19 (Notice Number: NOT-OD-20-87)
- Flexibilities Available to Applicants and Recipients of Federal Financial Assistance Affected by COVID-19 (Notice Number: NOT-OD-20-86)

COVID-19 Pandemic Accrual Impact

February – Mid-April 2020

NCTN Clinical Trials Network Program

Accrual for "Intervention" Step in Trials by Lead NCTN Group & Week

February 3, 2020 to April 5, 2020 (CTSU Open Data)

NCTN Group	2/3-2/9	2/10-2/16	2/17-2/23	2/24-3/1	3/2-3/8	3/9-3/15	3/16-3/22	3/23-3/29	3/30-4/5	% Drop Last Week *vs* Weekly Avg 2/3-3/15
ALLIANCE	93	88	83	93	105	94	67	30	41	-56%
CCTG	2	5	5	4	6	3	6	4	3	-28%
COG	43	53	47	45	51	58	41	34	39	-21%
ECOG-ACRIN	45	56	47	51	45	45	43	35	27	-44%
NRG	44	57	44	59	45	46	49	24	29	-41%
SWOG	49	46	43	54	54	46	54	35	29	-40%
TOTAL	276	305	269	306	306	292	260	162	168	-43%

NCORP Accrual for "Intervention" Step in NCORP Trials by Lead Research Base & Week February 3, 2020 to April 10, 2020 (CTSU OPEN Data & URCC/Wake Reports)

Intervention Enrollments	2/3-2/9	2/10-2/16	2/17-2/23	2/24-3/1	3/2-3/8	3/9-3/15	3/16-3/22	3/23 - 3/29	3/30 - 4/3	4/6 – 4/10	% Change Last Week vs Weekly Avg 2/3 – 3/15
ALLIANCE	16	15	4	24	9	18	8	4	2	0	-100%
COG	0	0	0	1	1	1	0	0	0	1	+230%
ECOG-ACRIN	115	140	116	118	144	124	68	3	2	5	-96%
NRG	4	3	4	1	9	4	3	0	2	1	-75%
SWOG	10	5	2	7	5	2	3	2	1	1	-80%
URCC	10	6	12	5	9	3	4	1	4	2	-60%
WAKE	15	21	19	10	14	10	2	0	2	1	-92%
TOTAL	170	190	157	166	191	162	88	10	13	11	-93%

NCORP DCP-001 Accrual by Week
February 3, 2020 to April 10, 2020 (CTSU OPEN Data)

Enrollments	2/3-2/9	2/10-2/16	2/17-2/23	2/24-3/1	3/2-3/8	3/9-3/15	3/16-3/22	3/23 - 3/29	3/30 – 4/3	4/6 – 4/10	% Change Last Week vs Weekly Avg 2/3 – 3/15
DCP-001	197	213	171	207	198	169	114	65	51	51	-72%

NCI COVID-19 in Cancer Patients Study (N-CCaPS)

Cancer-Specific efforts to study COVID-19

- **CCC19** (Rini/Warner)
  - De-identified information collected via survey
  - ALL cases of COVID-19 in patients with a current or prior history of invasive malignancy
  - Data on 30-day and 90-day outcomes
- **ASH Research Collaborative Data Hub**
  - International de-identified observational surveillance registry for outcomes of patients with COVID-19 and hematologic malignancy
  - Provide expedient public reports of aggregated data on the outcomes of patients with COVID-10 and hematologic malignancy in order to facilitate clinical decision making
  - “not intended for research purposes”
- **ASCO Survey on COVID-19 in Oncology Registry** (Launched 4/10/20)
  - Assessing pattern of symptoms and severity of COVID-19 among patients with cancer and how COVID-19 infections impact the delivery of cancer care and patient outcomes.
  - Collecting baseline and follow up data throughout the COVID-19 pandemic and into 2021.

NCI COVID-19 in Cancer Patients Study (N-CCaPS): A Longitudinal Natural History Study (Protocol # NCICOVID)

- Study Chairs: Larissa Korde (NCI) and Brian Rini (Vanderbilt)
- Trial Objectives
  - Characterize patient factors associated with COVID-19 in cancer patients undergoing treatment.
  - Describe cancer treatment modifications made in cancer patients with COVID-19.
  - Evaluate the association of COVID-19 with cancer outcomes in patient subgroups defined by clinico-pathologic characteristics.
- Biospecimen component
  - assess development of SARS CoV-2 antibodies,
  - description of the trajectory of cytokine abnormalities,
  - genome-wide association studies to define polymorphisms associated with severe COVID-19
- Plans to collect and bank research blood specimens and radiologic images
- Mid-May projected date to open on CTSU; per case accrual/credit similar to treatment trials

NCI COVID-19 in Cancer Patients Study (N-CCaPS) Participating Sites

- NCTN Sites
- NCORP Sites
- ETCTN Sites

Going Forward

Planning Ahead

- NCI Staff teleworking until May 1
  - Extension into mid-May or June?
  - Conducting virtual meetings/communication
- Future direction
  - Plans to activate new trials
  - Protocol/concept submissions
  - Encourage trial enrollment if feasible
  - Grant funding concerns

NCI CIRB Guidance

Amanda Sly, NCI CIRB, Director of Central Operations

NCI CIRB COVID-19 FAQs

APRIL 22, 2020

SWOG SPRING MEETING

AMANDA P. SLY, MS, CIP

C›I›R›B

FOR THE NATIONAL CANCER INSTITUTE

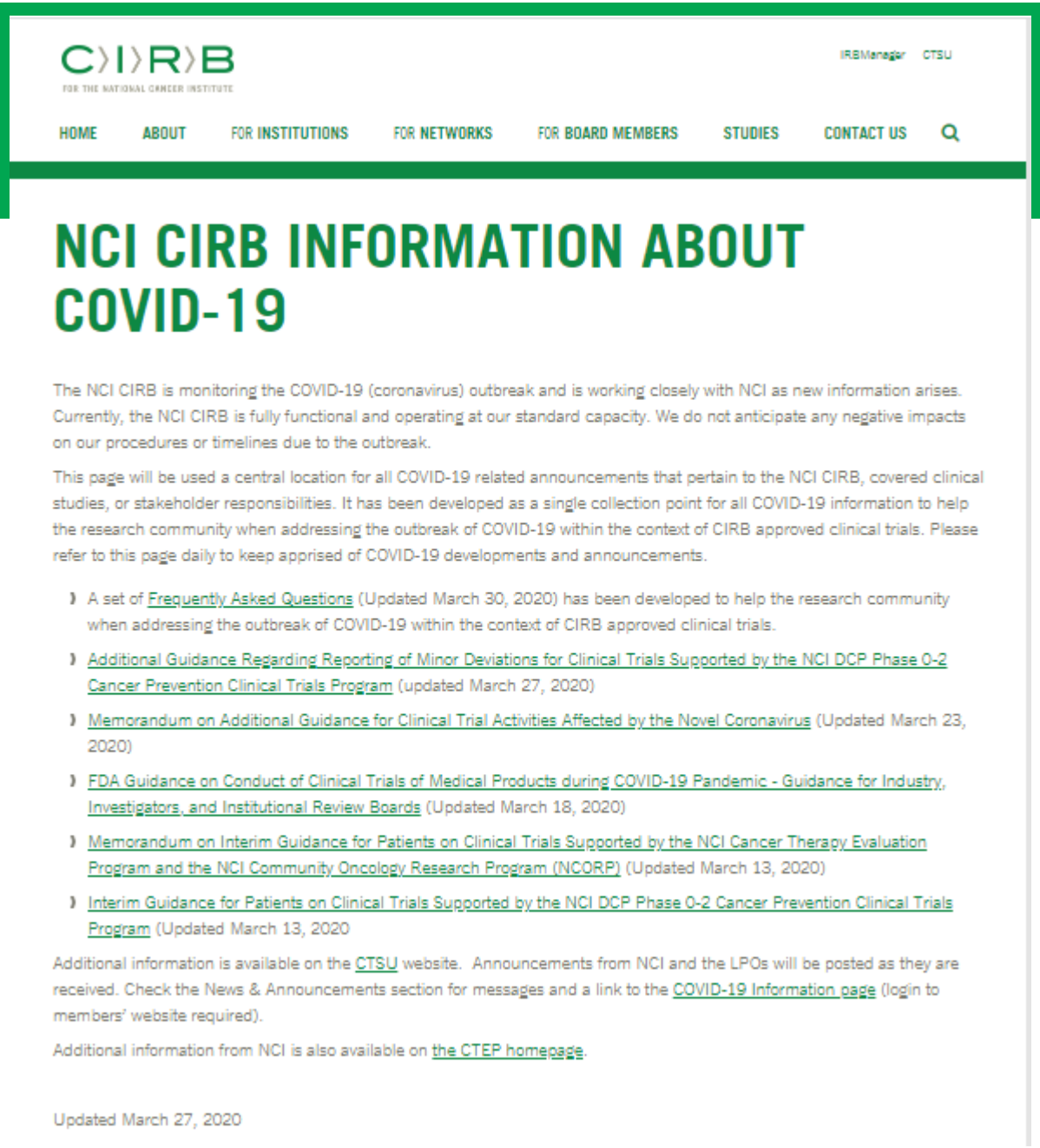
CIRB WEBSITE – COVID-19 INFORMATION

CIRB website

- www.NCICIRB.org

Homepage has a link to NCI CIRB Information about COVID-19

- Central location for all COVID-19 related communications including the CIRB's FAQ
- A single collection location for COVID-19 information



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HOME ABOUT FOR INSTITUTIONS FOR NETWORKS FOR BOARD MEMBERS STUDIES CONTACT US

NCI CIRB INFORMATION ABOUT COVID-19

The NCI CIRB is monitoring the COVID-19 (coronavirus) outbreak and is working closely with NCI as new information arises. Currently, the NCI CIRB is fully functional and operating at our standard capacity. We do not anticipate any negative impacts on our procedures or timelines due to the outbreak.

This page will be used a central location for all COVID-19 related announcements that pertain to the NCI CIRB, covered clinical studies, or stakeholder responsibilities. It has been developed as a single collection point for all COVID-19 information to help the research community when addressing the outbreak of COVID-19 within the context of CIRB approved clinical trials. Please refer to this page daily to keep apprised of COVID-19 developments and announcements.

- A set of Frequently Asked Questions (Updated March 30, 2020) has been developed to help the research community when addressing the outbreak of COVID-19 within the context of CIRB approved clinical trials.
- Additional Guidance Regarding Reporting of Minor Deviations for Clinical Trials Supported by the NCI DCP Phase 0-2 Cancer Prevention Clinical Trials Program (updated March 27, 2020)
- Memorandum on Additional Guidance for Clinical Trial Activities Affected by the Novel Coronavirus (Updated March 23, 2020)
- FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic - Guidance for Industry, Investigators, and Institutional Review Boards (Updated March 18, 2020)
- Memorandum on Interim Guidance for Patients on Clinical Trials Supported by the NCI Cancer Therapy Evaluation Program and the NCI Community Oncology Research Program (NCORP) (Updated March 13, 2020)
- Interim Guidance for Patients on Clinical Trials Supported by the NCI DCP Phase 0-2 Cancer Prevention Clinical Trials Program (Updated March 13, 2020

Additional information is available on the CTSU website. Announcements from NCI and the LPOs will be posted as they are received. Check the News & Announcements section for messages and a link to the COVID-19 Information page (login to members' website required).

Additional information from NCI is also available on the CTEP homepage.

Updated March 27, 2020

DEVIATIONS RELATED TO COVID-19 RESPONSE

PROTOCOL DEVIATIONS RELATED TO COVID-19

Minor protocol deviations:

- Minor protocol deviations NOT related to COVID-19 do not need to be submitted to the CIRB.
- A compiled list of all minor protocol deviations related to COVID-19 will be reported to the CIRB by the coordinating group at the time of continuing review (CR) starting on July 15.
- CIRB will update the CR Application form to request the minor protocol deviations related to COVID-19.

Major Protocol Deviations

- Utilize standard process
- Protocol deviations which are potential Serious and/or Continuing Noncompliance (SCNC) must be reported to the CIRB via the Unanticipated Problem and/or SCNC Worksheet.

HOW DO I GET MORE INFORMATION ON STANDARD PROCESSES REGARDING SUBMISSION OF NON-COMPLIANCE?

Quickguides Available on the CIRB Website

- **REPORTING AUDIT FINDINGS** provides instructions for reporting audit findings to the CIRB as potential Serious or Continuing Non-compliance (SCNC).
- **ALGORITHM TO ASSESS POTENTIAL NONCOMPLIANCE** provides an algorithm to assess whether or not an incident is reportable to the CIRB as potential Serious or Continuing Non-compliance (SCNC).
- **COMPLETING THE UNANTICIPATED PROBLEM AND/OR NONCOMPLIANCE REPORTING WORKSHEET** provides instructions for completing the Unanticipated Problem and/or the Noncompliance Reporting Worksheet.

REMOTE CONSENT

WHAT IS REMOTE CONSENT?

Remote Consent

- NCI is allowing the use of Remote Consent Procedures during the COVID-19 public emergency.
- Consent discussion is conducted by the provider via phone or video conference with the potential participant or legally authorized representative (LAR).
    - The process requires a witness.
    - The CF is signed and returned to the provider.
- Remote Consent does not require prior CIRB approval for COVID-19.
- When able, sites must update their Study Specific Worksheet (SSW) or the Signatory Institution Worksheet (SIW) to include this process.

WHAT IS REMOTE CONSENT?

Verbal Consent (uncommon)

- The participant/LAR does not sign the CF but ONLY provides consent verbally
    - Waiver of Documentation of Consent must be made for the study

Telephone consent (uncommon)

- Generally interpreted as verbal consent where confirmation of consent is obtained only via the phone.
- Scripts must be approved by the CIRB prior to utilizing telephone consent.

WHAT IS REMOTE CONSENT

Designee

- Designee may obtain consent per local policy.

Witnesses

- Witnesses are required for obtaining remote consent and the sites policy must be outlined in the SIW and/or SSW.
- The CIRB does not define who may serve as a witness; this is defined by local policy.

CIRB HELPDESK CONTACT

PHONE: 888.657.3711

NCICIRBCONTACT@EMMES.COM

HTTPS://NCICIRB.ORG

Operations Perspectives

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

Q&A / Site Concerns and Issues

Statistics and Data Management Center Insights

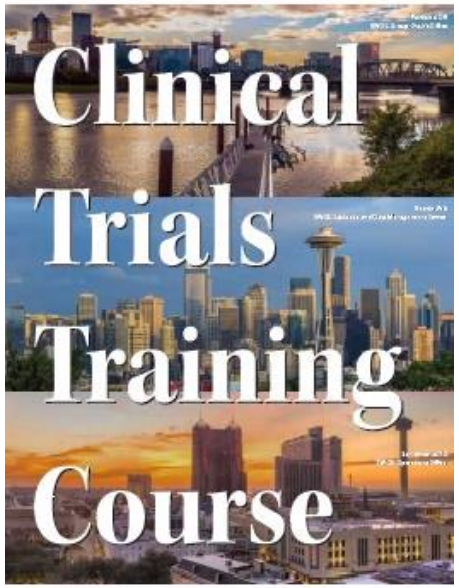
Rodney Sutter, CCRP Program Director, Therapeutic Studies
Dani Weatherbee, Application Development Project Manager
Phyllis Goodman, Coordinating Statistician Institution Performance

SDMC Updates

Rodney Sutter, CCRP Program Director, Therapeutic Studies
Dani Weatherbee, Application Development Project Manager
Phyllis Goodman, Coordinating Statistician Institution Performance

SWOG Statistics and Data Management Center
Seattle, WA

Clinical Trials Training Course



- No Virtual CTTC Planned for Spring, 2020
  - Many speakers
  - Practicum session
  - Full day
  - Online training available

- Consideration for Fall, 2020 – Chicago
  - Interest?
  - Requires approval by SWOG leadership
  - No guarantees, we will keep you posted!

NCORP Research Base Clinical Trials Workshop

SAVE THE DATE!

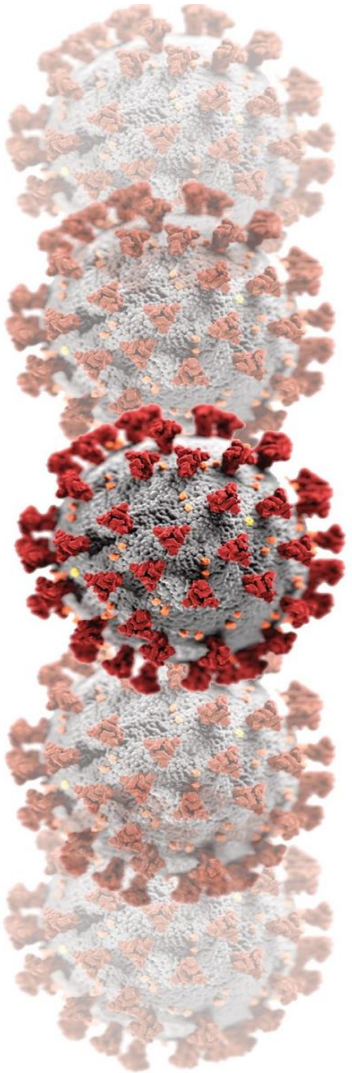
Wednesday, September 23

Fall 2020 SWOG Group Meeting

Chicago

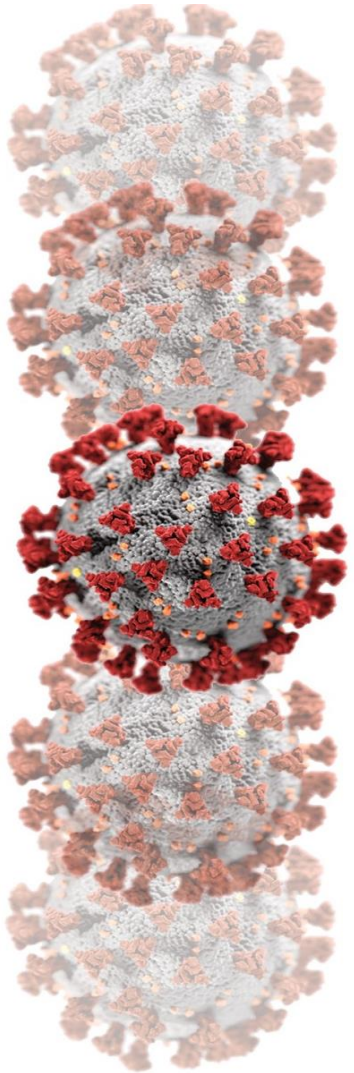
- For Clinical Research Professionals and Investigators at NCORP, Member and LAPS Institutions and Affiliates
- Studies in the following SWOG research areas will be discussed:
  - Cancer Care Delivery Research
  - Cancer Survivorship
  - Palliative and End of Life Care
  - Prevention & Epidemiology
  - Symptom Control and Quality of Life
- The workshop consists of didactic presentations and breakout sessions for information sharing
- ***New agenda and topics at each annual workshop!***

COVID-19 AE Reporting



- Positive COVID-19 Diagnosis
  - Considered an Adverse Event
  - Report on the AE form as “Infections and Infestations – Other, Specify”
  - Specify “COVID-19” as Other
  - New COVID-19 Diagnosis form is being developed and diagnoses will *also* have to be reported on this form
- Participants off protocol treatment or study intervention due to COVID-19
  - Submit the Off Treatment/Protocol Notice and specify “COVID-19” as reason off in the Comments field

SWOG COVID-19 Deviation Log



Study: _____ Site Name / CTEP ID: _____

Site Primary Investigator: _____

Patient ID	Date (*Date of planned treatment procedure, test/scan, etc. that deviated*)	Brief Summary of Deviation (*Specify the detail of the protocol deviation and justification on why it considered major/minor*)	Deviation Code*	Reason for Deviation (*COVID Outbreak vs COVID Infection*)	Major/Minor	If Major	
						Notified SWOG? If Yes, Date	Notified IRB? If Yes, Date

* Deviation Codes:

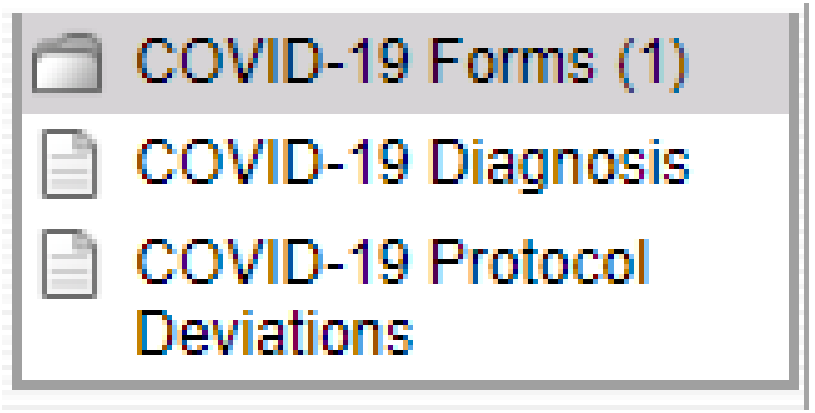
1. Cycle treatment Given Early or Late
2. Cycle of Treatment Missed
3. Phone or Virtual Visit
4. Late or Missed Study Visit
5. Late or Missed Study Procedure
6. Late or Missed Study Lab
7. Late or Missed Imaging Procedure
8. Late or Missed QOL/PRO
9. Late or Missed Study Specimen
10. Changes to Specimen Shipment Schedule
11. Other

COVID-19 Data Collection

COVID-19 Forms in Rave

Similar to the Alliance, SWOG will collect COVID-19 information within Rave.

- FOLDER: COVID-19 Forms
  - FORM: COVID-19 Diagnosis
  - FORM: COVID-19 Protocol Deviations



COVID-19 Diagnosis

Instructions: Complete this form to report that a participant has tested positive for the COVID-19 virus. A positive diagnosis is considered an adverse event and should also be reported on the Adverse Event form as "Infections and Infestations – Other, Specify" (Specify = COVID-19). Submit this form only once to report the participant's first diagnosis of the COVID-19 virus. Date is in **DD MON YYYY** format.

Instructions for documenting COVID-19 pandemic impact on other study forms:
If a participant goes off protocol treatment or permanently withdraws consent for further follow-up due to a COVID-19 diagnosis or other pandemic-related reason, submit the **Off Treatment/Protocol Notice** or **Consent Withdrawal** form (if applicable, by request through the SWOG Data Operations Center) and document the COVID-19 details in the Comments (include the text "COVID-19" in the entry). If there are any protocol deviations due to a COVID-19 diagnosis or other pandemic-related reason, submit the **COVID-19 Protocol Deviations** form.

Did the participant test positive for the COVID-19 virus? ◯ Yes ◯ No

If yes, what was the date of the first positive test? ☐☐ ☐☐☐ ☐☐☐☐

COVID-19 Protocol Deviations

Instructions: Complete this form for all protocol deviations due to a COVID-19 diagnosis or other pandemic-related reasons. Enter each protocol deviation on a separate logline in Rave as needed. Submit this form even if the deviation was reported on study-specific forms.

- 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.

Instructions for documenting COVID-19 pandemic impact on other study forms:

- All minor and major deviations should also be documented on the appropriate study form(s) (**Treatment**, **Disease Assessment**, **Adverse Event**, etc.)
  - Clearly specify in the Comments section of the study form that the deviation is due to "COVID-19 outbreak" or "COVID-19 infection."
- If the participant has a positive diagnosis of COVID-19, submit the **COVID-19 Diagnosis** form.
- A positive diagnosis is considered an adverse event and should also be reported on the **Adverse Event** form as "Infections and Infestations – Other, Specify" (Specify = COVID-19) as appropriate.
- If a participant goes off protocol treatment or study intervention due to a COVID-19 diagnosis or other pandemic-related reason, submit the **Off Treatment/Protocol Notice**.
  - Document the COVID-19 details in the Comments and include the text "COVID-19" in the entry.
- If a participant permanently withdraws consent for further follow-up due to a COVID-19 diagnosis or other pandemic-related reason, submit the **Consent Withdrawal** form if applicable.
  - The **Consent Withdrawal** form must be requested through the SWOG Data Operations Center.
  - Document the COVID-19 details in the Comments and include the text "COVID-19" in the entry.

COVID-19 Protocol Deviations

- Form will be a log table. Add as many loglines as needed to capture all deviations.

Were there any protocol deviations?				◯ Yes ◯ No
If yes, what is the category of the protocol deviation?				COVID-19
Protocol Deviation Subcategory	**Protocol Deviation***	**Reason for Deviation** *(If COVID-19 Virus Infection, report first diagnosis on the COVID-19 Diagnosis form)*	**Date** *(Date of planned treatment, procedure, test/scans, assessments, follow-up, etc. that deviated)*	**Comments** *(Specify the detail of the protocol deviation and justification on why it is considered major/minor)*
◯ Major ◯ Minor	_____	◯ COVID-19 Outbreak ◯ COVID-19 Virus Infection ◯ Other	☐☐ ☐☐☐ ☐☐☐☐	_____

COVID-19 Protocol Deviations

- Protocol Deviation drop down options:

Cycle Treatment Given Early or Late
Cycle Treatment Missed
Phone or Virtual Visit
Late or Missed Study Visit
Late or Missed Study Procedure
Late or Missed Study Lab
Late or Missed Imaging Procedure
Late or Missed QOL/PRO
Late or Missed Study Specimen Collection
Changes to Specimen Shipment Schedule
Other

CDASH Updates

CDASH = Clinical Data Acquisition Standards Harmonization

Overview of CDASH Mandate

- Data must be *collected* in CDASH format
- Data must be *submitted* in SDTM format
- Required for all CTEP-IND studies activating after **3/1/2020**
  - **Will eventually include all SWOG studies for consistency**

Upcoming SWOG Studies

CDASH Studies

- **S1914 (Active!)**
- **S1929** – Spring 2020
- **S1933** – Spring 2020
- **S1925** – Spring 2020
- **S1918** – Summer 2020

Non-CDASH Studies

- S1904 – Summer 2020
- S1823 – Summer 2020
- S2000 – Summer 2020
- S1905 – Summer 2020
- S1931 – Fall 2020

CDASH Best Practices

- No “Check all that apply”, yes/no responses only
- Include “Not Done” or “Unknown” as needed
- Use data cleaning prompts
- Don’t collect the same data more than once
- Include an “Ongoing” field when applicable
- Allow for unknown dates
- Limit the use of free text responses
- *New since last group meeting*: More detailed instructions

Ongoing Improvements

- Help us help you!
  - Any and all feedback is welcome on these first studies to make certain the new forms are accurate, clear, and user-friendly.
  - Provide feedback to the SWOG Data Operations Center.

Specimen Submission Updates

New Report – Status of SWOG Repositories/Labs

Updated weekly 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 April 20, 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	Not accepting samples. DO NOT COLLECT SPECIMENS.
BREAST	S1418	214	Clarient/Neogenomics	Accepting specimens as usual.

New Report – Specimen needs for protocols

In development, will be posted very soon

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

Specimen Tracking System (STS) updates

Goal: Encourage proper labeling of specimens to reduce the queries from the Biorepository and improve on specimen processing time and quality.

- New packing list
- New label templates

SWOG Patient ID: 702480 **SWOG Study ID: S1404-1**

Summary of Contents

Blood / Serum / 1 ml serum vials from 3 10 mL whole blood tubes	Qty: 18
Tissue from Distant Site / Block / If Block available preferred	Qty: 1
Tissue from Primary Site / Unstained slides / 10 (5 micron) unstained slides	Qty: 10

WHEN PACKING THE SHIPMENT, REMEMBER THE FOLLOWING:

☐ **Include the following data for SWOG Patient ID 702480 on S1404:**

Additional form	S1404 Local Path Review Form signed by pathologist	Baseline, Pre-Randomization
Pathology report	Documenting histologic confirmation of melanoma	Baseline, Pre-Randomization

☐ **Include a copy of this Packing List (all pages)**

☐ **Note that the expected shipping temperature for the specimens in this shipment is AMBIENT**

☐ **Confirm that all specimens listed on the following page(s) are included, labeled, and that the labels include the necessary information (see "Label to Use")**

Label templates can be found at SWOG.org >> Clinical Trials >> Biospecimen Resources >> Biospecimen Processing and Submission Procedures

Shipment Information

Shipment Tracking Number: 716746091552
Comments: (None)
Merck Study Number: MK3475-053

Shipped Date: 5/18/2017
Shipped By:

SWOG Institution Head CRA:

Sent To:

Note to Recipient: Use this packing list to confirm the contents of this shipment. It is required to log receipt of this shipment in the SWOG Specimen Tracking system at https://spectrack.crab.org/logon.aspx

SWOG Patient ID: 702480	SWOG Study ID: S1404-1	Page 1 of 2

Summary of Contents

Blood / Serum / 1 ml serum vials from 3 10 mL whole blood tubes	Qty: 18
Tissue from Distant Site / Block / If Block available preferred	Qty: 1
Tissue from Primary Site / Unstained slides / 10 (5 micron) unstained slides	Qty: 10

WHEN PACKING THE SHIPMENT, REMEMBER THE FOLLOWING:

☐ **Include the following data for SWOG Patient ID 702480 on S1404:**

Additional form	S1404 Local Path Review Form signed by pathologist	Baseline, Pre-Randomization
Pathology report	Documenting histologic confirmation of melanoma	Baseline, Pre-Randomization

☐ **Include a copy of this Packing List (all pages)**

☐ **Note that the expected shipping temperature for the specimens in this shipment is AMBIENT**

☐ **Confirm that all specimens listed on the following page(s) are included, labeled, and that the labels include the necessary information (see "Label to Use")**

Label templates can be found at SWOG.org >> Clinical Trials >> Biospecimen Resources >> Biospecimen Processing and Submission Procedures

Shipped Date: 5/18/2017

Shipped By:

SWOG Institution Head CRA:

Sent To:

Note to Recipient: Use this packing list to confirm the contents of this shipment. It is required to log receipt of this shipment in the SWOG Specimen Tracking system at https://spectrack.crab.org/logon.aspx

SWOG Patient ID: 702480 **SWOG Study ID: S1404-1** **Page 2 of 2**

Specimen: **Blood / Serum / 1 ml serum vials from 3 10 mL whole blood tubes**

Timepoint: Baseline, Prior to starting treatment
Date Collected: 3/21/2017 8:49AM
Quantity: 18
SWOG Specimen #: 2349827

Label to use: Standard label

Patient #: *702480*
Patient Initials: *F,ML*
Collection Date: *3/21/2017*
Specimen Type: *Serum*

Specimen: **Tissue from Distant Site / Block / If Block available preferred over USLID**

Timepoint: Baseline, Prior to starting treatment
Date Collected: 3/21/2017
Quantity: 1
SWOG Specimen #: 2349828
Surg. Path. #: 41931167
Block #: A2

Label to use: Tissue label

Patient #: *702480*
Patient Initials: *F,ML*
Collection Date: *3/21/2017*
Specimen Type: *Tissue from Distant Site/Block*
Surg Path #: *41931167*
Block #: *A2*

Specimen-specific Questions and Answers: Q1: Method used to prepare paraffin embedded tissue A1: 10% neutral buffered formalin (NBF)

Specimen: **Tissue from Primary Site / Unstained slides / 10 (5 micron) unstained slides**

Timepoint: Baseline, Prior to starting treatment
Date Collected: 3/21/2017 8:49AM
Quantity: 10
SWOG Specimen #: 2349829
Surg. Path. #: 41931168
Block #: B1
Microns: 5

Label to use: Tissue with microns label

Patient #: *702480*
Patient Initials: *F,ML*
Collection Date: *3/21/2017*
Specimen Type: *Tissue from Primary Site/Unstained slides*
Surg Path #: *41931168*
Block #: *B1* Microns: *5*

Shipment Contact Information

Shipped By:

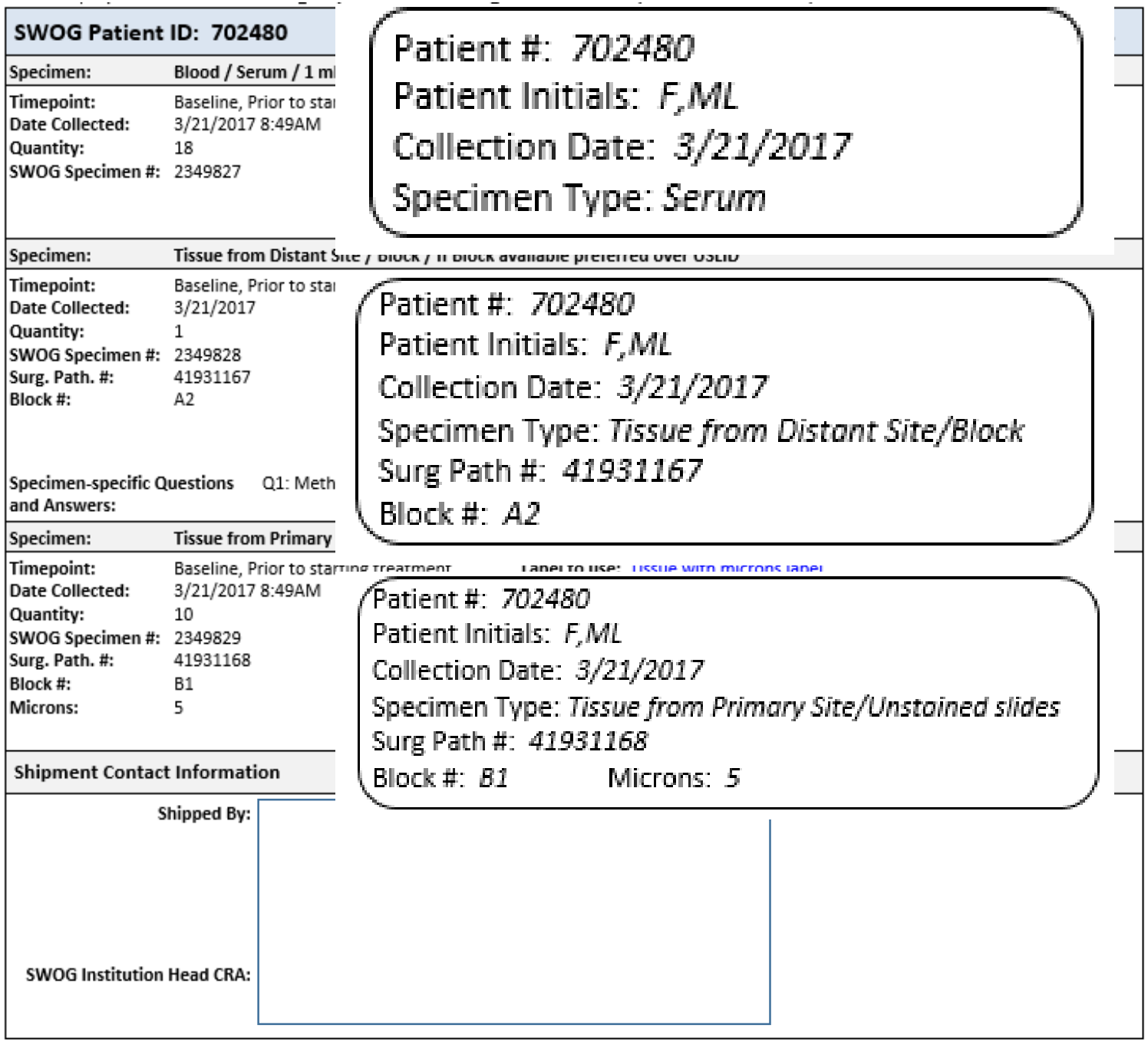
SWOG Institution Head CRA:

New label templates

- Standard – blood products, urine
- Tissue label
- Tissue label with microns

Information on label populated by data collected in Specimen Tracking System

Don't need to use the template provided BUT the information on the label needs to include what is shown on the packing list



New label templates

- Standard – blood products, urine
- Tissue label
- Tissue label with microns

Information on label populated by data collected in Specimen Tracking System

Don’t need to use the template provided <u>BUT</u> the information on the label needs to include what is shown on the packing list

Institution Performance Review - SWOG

- SWOG reports
  - Current Expectation reports are still running and accessible on CRA Workbench
  - Monthly Expectation and IPR reports are still being sent to Head CRA and PI but…
  - Due to COVID-19 pandemic, IPR enforcement (warnings/suspensions) has been put on hold

- Please …
  - Continue to enter data as you are able
  - Collect and ship samples as appropriate and able. If you can't ship a specimen, please use the "Notify that specimen cannot be submitted" function and include "COVID-19" in the reason

CTSU Quality Reports

- Automated bi-monthly data submission notifications identifying outstanding data in the Data Quality Portal (DQP) and Source Document Portal (SDP) are currently suspended

- Submission status will continue to be kept up to date and can be viewed directly in the DQP and SDP

Quality Assurance Updates

Elaine Armstrong, MS, Quality Assurance Manager

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
Connie Barnes, Programs Manager

Federal Site Payment Transition
(Spring 2020 Update)

Presented by:

Kyle Theige, Senior Grants & Contracts Coordinator

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

Update: Spring 2020

- **NCTN Fixed-Price Agreements**
  - Phase I sent out in May 2019 (did *not* include LAPS or NCORP sites)
  - Phase II (agreements for LAPS and NCORP sites) coming later this spring

- **NCORP Fixed-Price Agreements**
  - Phase I sent out in March 2020 (select sites based on outstanding payment amounts)
  - Phase II (agreements to any other sites performing activity on NCORP studies) coming this summer

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

Contact Information

- Email
  - theige@ohsu.edu
- Office Phone
  - 503-494-5514
- Cell Phone
  - By Request

Membership

Connie Barnes, Programs Manager

Q&A / Site Concerns and Issues

Closing Comments

Reminders

- The ORP Committee is accepting Sub-Committee applications

  For more Information:

  See the ***CRA Workbench / ORP Committee link*** or

  Email the Membership Committee at ***ORPExecs@swog.org***

- Key SDMC contacts are also listed on the CRA Workbench
- Please plan to attend the **Fall 2020 SWOG Group Meeting**

  September 23-26, 2020

  Hyatt Regency Chicago,

  Chicago, Illinois

Fall Funding Opportunity

CRA and Nurse Travel Support Program

- Offered through SWOG's public charity, The Hope Foundation for Cancer Research
- Provides coverage up to $1,500 per traveler for fall 2020 group meeting
- **Apply by July 1, 2020**
- Visit **tinyurl.com/CRA-NURSE**

THE HOPE FOUNDATION
FOR CANCER RESEARCH

#SupportingSWOG

Acknowledgements

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

Special Thanks

- Dr. Charles Blanke
- All of our Speakers
- Casey Dawson
- Whitney Leslie
- Courtney Wille

Thoughts

"Decreasing the burden of disease and human suffering largely are achieved through clinical trials, even during the COVID era. Along with new studies to test COVID vaccines and drugs, network oncology research will continue.

Now, perhaps more than ever, this work is vital."

NCTN Chairs Guest Editorial, The Cancer Letter, Vol. 46 - No. 15, April 10, 2020

History Will Remember by Donna Ashworth

History will remember when the world stopped
And the flights stayed on the ground
And the cars parked in the street
And the trains didn't run.
History will remember when the schools closed
and the children stayed indoors
And the medical staff walked towards the fire
And they didn't run.
History will remember when the people sang
On their balconies, in isolation
But so very much together
In courage and song.

History will remember when the people fought
for their old and their weak
Protected the vulnerable
By doing nothing at all.
History will remember when the virus left
And the houses opened
And the people came out
And hugged and kissed
And started again.
Kinder than before.