BOARD OF GOVERNORS MEETING REPORT
Saturday, April 9, 2022
Hybrid Meeting

Charles D. Blanke, M.D. called the meeting to order at 7:00 a.m. PT. A modified consent agenda was used for voting.

APPROVAL OF MINUTES FOR THE FALL 2021 BOARD OF GOVERNORS MEETING

The minutes of the Board of Governors meeting held virtually in fall of 2021 were presented for approval. The motion to approve the minutes as written was seconded and carried.

NEW PRINCIPAL INVESTIGATORS

Seven SWOG Investigators were recommended by SWOG institutions to serve as Principal Investigators at their institutions. Prior to the meeting, this was vetted by the Group's Professional Review Committee. The Board of Governors approved the following new investigators and the board's decision was recognized by Dr. Blanke:

1. Peng Wang, MD, PhD, University of Kentucky Markey Cancer Center, replacing Susanne M. Arnold, MD as PI. Effective January 1, 2022.

2. Haythem Yousif Ali, MD, Henry Ford Health System, replacing Ding Wang, MD, PhD as PI. Effective January 16, 2022.

3. Michaela Liedtke, MD, Stanford University School of Medicine/Standford Cancer Institute, replacing Steven E. Coutre, MD as PI. Effective December 18, 2021.

4. Tareq Al Baghdadi, MD, Michigan Cancer Research Consortium NCORP, replacing Philip J. Stella, MD as PI. Effective December 31, 2021.

5. Xinhua Zhu, MD, PhD, Northwell Health NCORP, replacing Wasif Muhammad Saif, MD as PI. Effective December 30, 2021.

6. Jesus Antonio Acosta Penaloza, MD, Instituto Nacional de Cancerologia (INC), Bogota, Colombia, replacing Juan Carlos Velasquez, MD as Co-PI. Effective February 3, 2022.

7. Patrick W. Cobb, MD, SCL Health St. Joseph Hospital, replacing Alan M. Miller, MD, PhD as PI. Effective March 17, 2022.

NEW INSTITUTIONS (MAIN MEMBER)

The following institutions have applied for and met the requirements to allow their approval by the Professional Review Committee as Probationary institutions within the Group. The Board approved.

1. Medical College of Wisconsin, Milwaukee, WI
   Principal Investigator: Razelle Kurzrock, MD, FACP

   The Medical College of Wisconsin was awarded a LAPS grant in March 2019. They currently participate with the ALLIANCE, ECOG-ACRIN and NRG.

2. Lifespan Cancer Institute, Rhode Island, Providence, RI
   Principal Investigator: Stephanie L. Graff, MD

   Rhode Island Hospital currently participates as a Main Member of the ALLIANCE, ECOG-ACRIN and NRG.

BOG MEMBERSHIP ELIGIBILITY

A list of institutions who would remain eligible for BOG membership, those who would not remain eligible and those who are newly eligible, for Member, NCORP and International membership categories was presented to the board. BC Cancer Agency and UCSD Moores CC, and Western States NCORP are newly eligible; Dayton NCORP is no longer eligible; Northwestern University and CORA NCORP remain eligible for an additional 2 years. The board approved.

MOVEMENT OF INSTITUTIONS FROM PROBATIONARY TO FULL MEMBER STATUS

The following institutions have met the acceptable institutional performance standards for registrations, acceptable quality of data, and a successful quality assurance audit to allow their progression from Probationary Member to Full Membership status within the Group. The Board approved.

1. Duke University Medical Center, Durham, NC. Harry P. Erba, MD, PhD is the Principal Investigator.

2. Salem Hospital, Salem, OR. Janelle Meyer, MD is the Principal Investigator.

3. Vanderbilt University/Ingram Cancer Center, Nashville, TN. Cathy Eng, MD is the Principal Investigator.

4. Northwell Health NCORP, Lake Success, NY. Xinhua Zhu, MD, PhD is the Principal Investigator.

MEMBERSHIP COMMITTEE APPROVALS

Dr. Jim K. Weick, Chair of the Membership Committee, reported that the committee has reviewed and approved 458 new investigators for spring of 2021 for SWOG membership as nominated. The Board approved the recommendation of the membership committee.

QUALITY ASSURANCE AUDIT REPORT

A total of 35 treatment audits were conducted from August 1, 2021 through January 31, 2022. Unacceptable audits included: 1 for regulatory, 1 for pharmacy and 5 for patient cases.

Potential FDA registration studies are audited on a more frequent basis. Initial audits of S1400/LUNG-MAP sub-studies are conducted within 3 months of the first registration to a sub-study at each site while initial audits of S1418, S1806 and S1914 are conducted within 6 – 9 months of their first registration. Audit results for the registration studies from August 1, 2021 through January 31, 2022 include:

- S1400/LungMap - The outcome was acceptable for all 20 audits.
- S1418 – The outcome was unacceptable for 1 out of 62 audits.
- S1605 – The outcome was unacceptable for 1 out of 4 audits. All S1605 audits are complete and no further audits are planned.
- S1806 – The outcome was unacceptable for 1 out of 20 audits.
- S1914 – The outcome was acceptable for 23 audits.

Reaudits are planned at all sites with an unacceptable audit. The audit process creates an opportunity to provide education and feedback on this issue and improvement has been noted at most reaudits. The outcome for all reaudits conducted during this audit cycle were acceptable.

Approximately 73% of audits since August 1, 2021 were conducted remotely due to visitor and travel restrictions related to Covid-19. Every attempt is made to conduct large treatment audits on site when possible due to the challenges of reviewing large number of charts remotely. There have been challenges related to this transition but an Off-site Audit Guidance has been developed and is updated as needed. In addition, the CTSU has updated and expanded its Site Audit Portal to facilitate the uploading of audit documents for sites that are unable to provide EMR access to auditors. The majority of registration study audits will continue to be conducted remotely in the future.

The QA Program continues with their current plan of careful attention to all NCI deadlines. The Quality Assurance Committee continues to work on ways to improve the audit process and provide additional educational opportunities. Protocol specific data submission guidelines have been developed for S1400/LungMAP. Special attention will be given to developing additional educational tools for the potential FDA registration studies.

COMMITTEE CHANGE

The iMATCH pilot is anticipated to launch in late spring or early summer. Subsequent projects will be developed in the Immunotherapeutics Committee. Given the longterm intent of the platform study it is recommended that the committee become a Disease and Research Committee. The board approved the movement of Immunotherapeutics from a Research Support Committee to a Disease and Research Committee.

HOPE FOUNDATION BOARD MEMBERSHIP

The board approved the nomination of Sumanta K. Pal, MD, from City of Hope Comprehensive Cancer Center, to the Hope Foundation Board of Directors.

INFORMATION ONLY

Leadership Changes

The following leadership changes were presented to the board.

Leukemia Committee: Anjali S. Advani, MD replaced Steven Coutre, MD as Vice-Chair.

Lung Committee: Jhanelle Gray, MD replaced Karen Kelly, MD as Chair.

Melanoma Committee: Roger Lo, MD, PhD replaced Hussein Tawbi, MD, PhD as Vice-Chair.

Myeloma Committee: Sikander Ailawadhi, MD replaced Brian Durie, MD as Vice-Chair.

Myeloma Committee: Jing Christine Ye, MD replaced Saad Usmani, MD as Vice-Chair.

Policy Change

Policy 49, Member Surveys, was revised to clarify, including by example, which surveys do and which do not require review by the digital engagement committee's survey subcommittee and to clarify the sequence of the reviews specified in the original policy statement.

STANDING REPORTS

Statistical Center (SDMC) Update

Group Statistician Michael LeBlanc updated the Board on a pilot project, EMR to EDC, between SWOG and nCartes. The project is designed to look at different ways to automatically collect data for EMR into the RAVE database. The system offers secure and private HIPAA-compliant application, site-specific datastore, support for structured and unstructured data, and multiple data transmission standards. The system allows the user to upload data and source documentation and it goes directly into RAVE.

Four studies have been configured: S1802 (GU), S1803 (myeloma), S1826 (lymphoma) and S1827 (lung). Three sites are currently participating: UC Davis, Rochester and Kansas. Benefits include fewer data entry mistakes and lower related effort and cost. UC Davis anticipates an average time savings of up to 5-15 minutes on forms that auto populate, which will save a significant amount of time over the

lifespan of a trial for data entry. A decrease in queries is also expected as nCartes will help streamline data entry consistency. Selection and addition of more studies and sites is underway.

The Hope Foundation (THF)

The Hope Foundation President Jo Horn provided financial updates of the Hope Foundation to the Board. In 2021 the Hope Foundation facilitated $3.9 million in federal grants for the SWOG Operations Office. THF had about $1.2 million in contributions in the time of COVID and gave $2.25 million to SWOG last year. The investment portfolio performed very well during COVID. The Hope endowment was up about 12.9% and SWOG-CTP monies were up about 7%. Total assets include $37 million of unrestricted funds and $27 million through CTP agency funds. They are hovering just over $64 million in total assets managed by the foundation. The grant writing workshop is May 1, NCORP Pilot grants are due June 1, impact awards deadline is July 1 and VA integration grants are due August 1.

The term for Dr. Lara is ending and Sumanta Pal, MD will be taking his place.

Conflict Management Report

Dr. Paul Okunieff reported that everything is going well. Out of almost 200 members in clinical trials leadership, headquarters or who touch primary data, only 20 reports have not been received. Due to changes in membership, rotating off committees and leaving SWOG, he feels we are basically at about 100% of forms returned. Dr. Okunieff reminded the board of the amounts that trigger a management plan or prompt removal from a protocol. $2K - $5K triggers a management plan and over $25K, if there is a conflicting protocol, prompts removal from a protocol. You can still be an author on the protocol but can't get close to the primary data. Management plans will be sent out prior to the fall 2022 meeting.

SWOG Clinical Trials Partnership (SWOG-CTP)

Dr. Kathy Albain, Vice-Chair for SWOG-CTP, provided an update on the program. She emphasized that there is confidential information from pharmaceutical companies discussed in SWOG-CTP meetings and teleconferences that should not be shared. SWOG-CTP continues to make great progress in the study development process and infrastructure for CTP. Developing a trial through CTP is a parallel process which involves the company timelines and our internal scientific timelines (including budgets, contract, statistical center input, etc.) It is that point in the process that has been a challenge in terms of unexpected delays. As a result a "Go-No Go" signoff has been created. Early on, the study team will complete a document with detailed study information and justification for developing the study through CTP. Once complete the CTP executive group will review it and either give it the green light to proceed or give it a no-go. The hope is that this will decrease the delays to keep study development moving forward on time. Dr. Albain also indicated that plain language summaries will also be created for all trials, similar to the NCTN/NCORP trials. Dr. Albain discussed some of the active industry collaborations, these include: two platform trials with Novartis, two trials with AstraZeneca, signed LOIs with Janssen, and pending industry collaborations with CNS working group, Digital Engagement committee, Immunotherapeutics committee and GI.

Diversity, Equity and Inclusion Program

Dr. Alison Caban-Holt, Chair for DEI, provided an update on the program. SWOG and The Hope Foundation, in collaboration with Genentech, launched a multi-phase, multi-year initiative to improve DEI among SWOG leadership, membership and in clinical trials. One element of that effort was bringing on Pope Consulting to give us strategy, structure, systems and practices. Dr. Caban-Holt updated the board on new roles being created in DEI: they are looking for a Vice-Chair of Diversity, Equity, Inclusion and Professional Integrity; Dr. Patricia Robinson has taken on the role of DEI Implementation Fellow; five DEI champions have been brought on to various committees; and they are developing an advisory board and DEI monitoring committee. DEI is currently working on membership profiles to include DEI elements. In addition to the data historically collected they are working on collecting age, gender identity, LGBTQ+, veteran status, geographic setting and zip code.

FUTURE GROUP MEETINGS

The next SWOG Meeting will be held October 19-22, 2022. Plans are being made for a hybrid meeting.