

ORP Open Forum

Thursday, May 11, 2023 | 1:00 PM - 2:30 PM PT

Round tables discussions are back! Please join us in-person to discuss topics in a small group setting. Rotate between four 20-minute sessions of your choice to learn more about conducting SWOG trials, mitigating challenges, and implementing strategies with your facilitator and tablemates. This meeting is open to everyone and provides an opportunity to hear updates and ask questions. Please join us!

Table Schedule: please attend one table topic per session.

| Open Forum Round Tables | Session 1 1:05-1:25 | Session 2 1:25-1:45 | Session 3 1:45- 2:05 | Session 4 2:05-2:25 |
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| Table 1 | Operational Challenges Maggie Spillers Rose Ermete Connie Szczepanek | Operational Challenges Maggie Spillers Rose Ermete Connie Szczepanek | Operational Challenges Maggie Spillers Rose Ermete Connie Szczepanek | Operational Challenges Maggie Spillers Rose Ermete Connie Szczepanek |
| Table 2 | Feasibility Strategies Anthony Hicks Rachel Kitchen | Feasibility Strategies Anthony Hicks Rachel Kitchen | Feasibility Strategies Anthony Hicks Rachel Kitchen | Feasibility Strategies Anthony Hicks Rachel Kitchen |
| Table 3 | Study Implementation Nichole Mahaffey Amy Koffarnus | Study Implementation Nichole Mahaffey Amy Koffarnus | Study Implementation Nichole Mahaffey Amy Koffarnus | Study Implementation Nichole Mahaffey Amy Koffarnus |
| Table 4 | Veterans Affairs (VA) Leslie Weissenstein Caitlin Hutchinson | Veterans Affairs (VA) Leslie Weissenstein Caitlin Hutchinson | Veterans Affairs (VA) Leslie Weissenstein Caitlin Hutchinson | Veterans Affairs (VA) Leslie Weissenstein Caitlin Hutchinson |
| Table 5 | Site Reimbursement – NCA Kyle Theige Pat Mize | Site Reimbursement – NCA Kyle Theige Pat Mize | Site Reimbursement – NCA Kyle Theige Pat Mize | Site Reimbursement – NCA Kyle Theige Pat Mize |
| Table 6 | Quality Assurance & Audits Tips Laura Gonzales Dominique McReynolds | Quality Assurance & Audits Tips Laura Gonzales Dominique McReynolds | Quality Assurance & Audits Tips Laura Gonzales Dominique McReynolds | Quality Assurance & Audits Tips Laura Gonzales Dominique McReynolds |
| Table 7 | SWOG Specimens Kae Tegtmeier | SWOG Specimens Kae Tegtmeier | SWOG Specimens Kae Tegtmeier | SWOG Specimens Kae Tegtmeier |
| Table 8 | CTSU Updates Ginger Riley | CTSU Updates Ginger Riley | CTSU Updates Ginger Riley | CTSU Updates Ginger Riley |
| Table 9 | Long Term Follow-Up Ashley Tydon | Long Term Follow-Up Ashley Tydon | Long Term Follow-Up Ashley Tydon | Long Term Follow-Up Ashley Tydon |
| Table 10 | S1823 Kim Carvalho Katie Arnold | S1823 Kim Carvalho Katie Arnold | | S1900G Kevin Moralda |
| Table 11 | S1803 Hannah Hale | S1803 Hannah Hale | | S2302 PRAGMATICA-LUNG Louise Highleyman |
| Table 12 | S1826 Gabi Herbert | S1826 Gabi Herbert | | |
| Table 13 | | | Spanish-speaking CRAs Dacia Christin | Spanish-speaking CRAs Dacia Christin |

Round Table Topics

Operational Challenges Sites Face Today: Discussions will include site challenges, best practices, and resources. SWOG Staff and Site Operations leaders will be available to help answer questions, provide solutions to site challenges, and collect feedback on ways SWOG can improve communication with sites. Table Facilitators: Maggie Spillers, Quality Assurance Assistant Manager, Rose Ermete, Senior Quality Assurance Nurse Auditor, SWOG Operations Office, San Antonio TX and Connie Szczepanek, RN, BSN, CCRP, Chair, SWOG ORP Committee Director, Cancer Research Consortium of West Michigan (CRCWM)

Feasibility Strategies: Join us to continue the Oishi discussion on protocol feasibility at your site. Discussions will include strategies from lessons learned and how to help mitigate the challenges and hurdles we face today. We'll have resources, tips, and tools to improve recruitment such as the Clinical Trial Review Guide found on the CRA Workbench. Bring your questions and share what has been successful at your site. Table Facilitators: Anthony Hicks, Operations Supervisor, Cancer Research Consortium of West Michigan, and Rachel Kitchen, Senior Regulatory Affairs Coordinator, Cancer Care Network, UC Davis Comprehensive Cancer Center.

Study Implementation: Workflows! Workflows! Workflows! Tools, tips, and tricks for turning feasibility assessments into processes to support initiating a protocol in a compliant manner. Discussion will include common sticking points, communication tips with outside departments, and lessons learned from audits. Table Facilitator: Nichole Mahaffey, Ph.D., CCRP, Assistant Director of PRMS University of California Davis Health, Comprehensive Cancer Center and Amy Koffarnus, Research Administrator, CROWN Consortium.

Veterans Affairs (VA): Research at the VA is dynamic but presents numerous unique challenges. There are heightened protections for VA study participants and often other logistical barriers to getting trials open and successfully enrolling. High variability in policy, priorities and staffing across VA sites also contributes to complexity. That said, we are always stronger and more effective when we work together. Come share site-level concerns with the hope that together, we can find positive working solutions and identify common barriers to tackle together. Table Facilitators: Leslie Weissenstein, Assistant Programs Manager & VA Program Manager, SWOG Operations Office, San Antonio, TX, and Caitlin Hutchinson, Clinical Research Manager, Oncology at the Rocky Mountain Regional VAMC, University of Colorado.

Site Reimbursement/National Coverage Analyses (NCA): Members of the SWOG Funding team will be present to provide information on a variety of topics including financial agreements, payment reports, funding memos, and National Coverage Analyses (NCAs). If you have questions pertaining to how a study is funded and/or where your site's funding should be coming from, please drop by the SWOG Funding table and we will work to get those questions answered. Table Facilitators: Pat Mize, MBA, Grants and Contracts Manager and Kyle Theige, Senior Grants and Contracts Coordinator, SWOG Group Chair's Office, Portland, OR.

Quality Assurance (QA) Audit Tips: Learn how to prepare for an audit and what to expect during an audit. Also, learn about best practices when conducting clinical research. Table Facilitators: Laura Gonzales, BSN, MA, RN, OCN, QA Manager and Dominique McReynolds, BSN, RN, SAE Coordinator, SWOG Operations Office, San Antonio, TX.

SWOG Specimens: Learn about best practices for submitting specimens to the SWOG Biobank, including common specimen submission issues and how to prevent them. Members from the SWOG Biobank will facilitate so bring any questions or challenges related to collecting, processing, or shipping specimens to the SWOG Biobank table! Table Facilitator: Kae Tegtmeier, Business and Project Development Director, Biopathology Center at The Research Institute at Nationwide Children's Hospital, Columbus, OH

CTSU Updates: Join us as we share updates for the Oncology Patient Enrollment Network (OPEN) Portal system and ID.me, as well as updates and information related to Aurora, RUMs, the DQP and DTL. If you have questions pertaining to any of our CTSU systems or integrations, please stop by the CTSU table to discuss. Table Facilitator: Ginger L. Riley, Senior Study Director, Clinical Trials Support Unit (CTSU)

Long Term Follow-Up: Collecting complete and accurate survival data is critical, especially for so many of our SWOG trials that involve overall survival as endpoint. We know long term follow up is challenging and not often discussed, so join us to talk about patient retention and how we help ensure the validity of the study results. Table Facilitator: Ashley Tydon, Deputy Director, Cancer Care Network, UC Davis Comprehensive Cancer Center

Let's Chat About S1823: Join us for an informal Q&A on S1823 - A Prospective Observational Cohort Study to Assess miRNA 371 for Outcome Prediction in Patients with Newly Diagnosed Germ Cell Tumors. Staff will be available to answer any questions you may have on participant eligibility, specimen submission, follow-up schedules, and updates in the recently released Revision #2 of this Prevention Committee protocol. Table Facilitators: Kim Carvalho, Data Coordinator and Katie Arnold, MS, Statistician, SWOG Statistics and Data Management Center, Seattle, WA.

S1900G – A Lung-MAP Sub-Study: Since the widespread adoption of genomic testing, EGFR mutants have been shown to represent a sizeable portion of all lung adenocarcinomas. First-line therapy usually consists of EGFR TKI's (tyrosine-kinase inhibitors) such as osimertinib, but what happens when these patients develop a resistance to TKI treatment, and aren't a good candidate for chemotherapy? A newly activated Lung-MAP sub-study, S1900G, seeks to find answers to that question, which will hopefully lead to promising chemotherapy-free treatment regimens for this vulnerable population. The SWOG SDMC is here to answer questions that you have regarding S1900G eligibility, data & specimen requirements, good data entry practices, and more. Table Facilitator: Kevin Moralda, Data Coordinator, SWOG Statistics and Data Management Center, Seattle, WA.

S1803: Anyone who has worked on S1803 knows how difficult it can be! Join one of the data coordinators for the study to gain tips and tricks to help understand and learn the requirements for sites. Please feel free to bring any general questions or concerns that you may have regarding timing of assessments, data entry, queries, specimens, and any other ideas you'd like to discuss! Table participants are encouraged to share experiences and learn from one another. Table Facilitator: Hannah Hale, Data Operations Supervisor, SWOG Data Operations Center/Cancer Research and Biostatistics (CRAB), Seattle, WA.

S2302 PRAGMATICA-LUNG: SWOG Data Coordinators will be available to answer any questions about the S2302 PRAGMATICA-LUNG trial, now accruing! We look forward to discussing the streamlined eligibility and data entry requirements for this exciting and innovative trial. Table Facilitator: Louise Highleyman, Data Coordinator, SWOG Statistics and Data Management Center, Seattle, WA.

S1826: S1826 data submission help is here! SWOG Data Operations Center staff will answer your questions about data entry on S1826, ensure that you know how to find the S1826 Data Submission Guidelines, and provide key contact information for your future questions. Table Facilitator: Gabi Herbert, Data Coordinator, SWOG Statistics and Data Management Center at Cancer Research and Biostatistics (CRAB), Seattle, WA

Spanish-Speaking CRAs: Discussion in Spanish will focus on experiences, challenges, and networking opportunities for ORPs at sites who recruit Spanish-preferring patients in the US and Latin America. If interested, participants can consider strategies to share additional resources and set up networks for mutual support. Table Facilitator: Dacia Christin, M.A., M.P.H, Project Manager and SWOG Latin America Initiative Liaison, SWOG Data Operations Center/ Cancer Research and Biostatistics, Seattle, WA.

Notes:

Handouts and supporting resources from the Open Forum session are available on the SWOG website at <https://www.swog.org/Spring-2023-ORP-Resources> or by scanning the QR code below.



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

Signature _____ Date _____

Education Sub-committee Chairs:

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