

SWOG-VA Partnership

AVAHO 2023

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Chair, SWOG VA Committee
Rocky Mountain Regional VA Medical Center

Presented by Michael Goodman, MD,
GU Disease Committee VA Liaison
Salisbury VA Medical Center

SWOG VA Sites



SWOG VA Partnership

- **VA Working Group (First Meeting - May 2013)**
 - Formed at the request of the SWOG Chair, Dr. Charles Blanke
 - *Dr. Blanke has been an unflinching advocate for improving VA inclusion in NCTN trials*
 - Mission:
 - Improve Veteran access to high Quality Cancer treatment by assisting local VA facilities with access, implementation, and accrual to SWOG and NCTN/NCORP trials
 - Dedicated meeting time at Fall and Spring Group Meetings
 - Significant interest but hard to navigate the various obstacles presented by VA policy, NCI policy, needed staffing

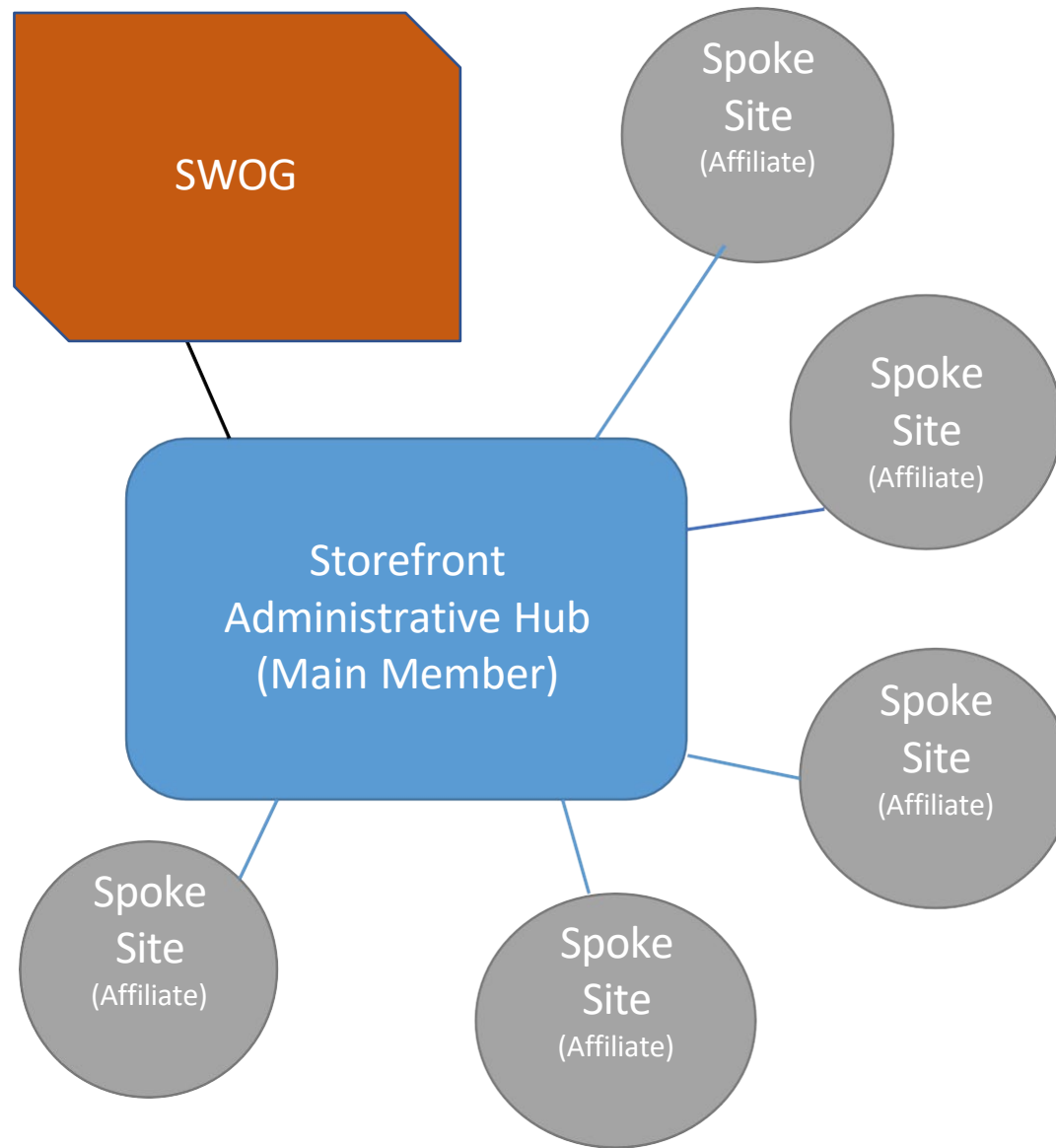
SWOG VA Partnership

- **Initial Storefront**

- Development of the VISN 1/MAVERIC SWOG Storefront (2015)
- Tremendous efforts by VISN 1 team created a unique model to allow smaller programs to participate and all sites to share resources
- Storefront Administrative site is the primary member
- Accrual from spoke sites are counted and they do not individually have to meet full member accrual goals

Storefront Hub Responsibilities:

- Identifies Storefront PI and Head CRA
- Assists sites with registering and credentialing study staff
- Provide guidance for operational and logistical aspects of participating in SWOG/NCTN trials.
- Oversee the data management, registrations, regulatory data, and financial aspects (i.e., execution of SWOG and SWOG-CTI Purchase Service Agreements /Amendments / Subawards) for each site, in conjunction with the associated VA site nonprofit corporation where appropriate.
- Assure that quality control and quality assurance guidelines are met.
- Provide education to sites in the collection and shipment of specimen samples.
- Review and assess NCTN protocols for potential barriers to participation at VA sites.
- Provide support for site audits, including preparation and pre-review of audit documents to ensure compliance with SWOG policies during the formal audit, as well as follow-up to address any non-compliance or areas for improvement.
- Manage site rosters and roles through CTSU-RUMS
- Convene regular teleconferences to review new trials for feasibility and expansion and discuss emerging issues in oncology.
- Serves as the main contact for SWOG for any issues pertaining to Spoke Sites
- Responsible for ensuring Storefront recruitment targets are met by Spoke Sites



Spoke Site Responsibilities:

- Identifies PI and Head CRA for the site
- Opens trials deemed appropriate for site investigators, patient population, and resources
- Completes all site and NCI CIRB regulatory requirements
- Enroll study participants
- Completes all study visits and requirements, including data entry and query resolution
- Prepares for and completes audits, including follow up
- Participates in calls with other spoke sites and Storefront administrative hub
- Associated nonprofit corporation receives study funding for site's respective enrollments/trial activities
- Adheres to all SWOG policies and procedures

Notes:

- *All enrollments across Spoke Sites count towards one enrollment total for Storefront.*
- *Storefronts are eligible to hold a voting seat on the SWOG Board of Governors Committee after meeting specific accrual requirements.*

VA Working Group –Programs

- **VA Integration Grants (2015-2021)**

- Working Group proposed providing small “kick-starter” grants to help a local VA cancer clinical research program get started or fill a gap preventing them from being successful.
- The proposal was approved by **The HOPE Foundation** (non-profit associated with SWOG).
- Between 2015 and 2021 this funded **21 VA sites** for a total of **\$700,000**.
- Template for VA Navigate Program.

- **SWOG VA Specialist (2016)**

- A single individual located in the SWOG Operations Office (San Antonio) to provide assistance to SWOG’s VA institutions in areas of membership and regulatory processes, infrastructure development, use of the NCI CIRB, and to provide administrative support for the Working Group Chair.

VA Working Group –Programs

- **SWOG VA Workbench:**

- Launched in October 2019 on the SWOG website
- Provides a repository of resources to assist VA members in opening trials at VA sites
- <https://www.swog.org/member-resources/va-workbench>

- **VA Community Advocate:**

- Summer 2020
- Bruce Wright was recruited to serve as a liaison between veterans in promoting clinical trials as resources for viable treatment options, and SWOG researchers in ways to best design trials geared towards veterans' treatment needs

VA Working Group → Committee

- In Spring 2022 the Working Group was given **Full Committee status**
- This provides some additional benefits for the group
 - Additional Funding
 - Voting status on the SWOG Board of Governors
 - Larger voice in the strategic planning of SWOG

SWOG VA Partnership

- **VA Storefront Grant (2022+)**

- The Working Group felt the VA Integration Grant had run its course
- Requested the funds allocated by the HOPE Foundation be transitioned to a new Storefront grant in Spring of 2022
- Initially advised the request would not be considered until Fall for applications to start in 2023
- SWOG Leadership and The HOPE Foundation appreciated the approach and approved the new Storefront grant just after the Spring 2022 Group Meeting
- Request for applications in summer of 2022
 - Three applications received
- New Storefront announced November 2022
 - South Texas Healthcare System

VA Committee – Current Activities

- **VA Liaisons on SWOG Disease Committees**

- **Lung:** Cheryl M. Czerlanis MD, Hines-VA Med Ctr & Chao Hui Huang, MD, VAMC Kansas City
- **Myeloma:** Tom Chauncey, MD, Puget Sound
- **Breast:** Sarah Colonna, MD, VAMC Salt Lake City
- **GU:** Michael Goodman, MD, Salisbury VA
- **Leukemia:** Tsewang Tashi, MD, VAMC Salt Lake City
- **Lymphoma:** Helen Ma, MD, VAMC Long Beach
- **SCQOL:** Yeun-Hee Park, MD, VAMC Bronx
- Cancer Care Delivery - Open
- Cancer Survivorship - Open
- Early Therapeutics - Open
- Gastrointestinal - Open
- Melanoma - Open
- Palliative & End of Life - Open
- Prevention & Epidemiology – Open

VA Committee – Current Activities

- Highlighting Current SWOG studies for VA

S2209: A Phase III Randomized Trial for Newly Diagnosed Multiple Myeloma Patients Considered Frail or Ineligible for Stem Cell Transplant Comparing Frontline Regimen Bortezomib-Lenalidomide-Dexamethasone-Lite (VRd-Lite) with Daratumumab-Lenalidomide-Dexamethasone (DRd) Followed by Len+/-Dara (R+/-D) Maintenance

S2200: “A Phase II Randomized Trial of Cabozantinib (NSC #761968) with or Without Atezolizumab (NSC #783608) in Patients with Advanced Papillary Renal Cell Carcinoma (PAPMET2)”

S2409, “PRISM: A Multicohort **P**recision **S**CLC Subtype **M**aintenance Phase II Trial of Durvalumab Versus Biomarker-Directed Novel Agents in Combination with Durvalumab in Extensive Stage Small Cell Lung Cancer (ES-SCLC)”

S2302 “PRAGMATICA-LUNG: A Prospective Randomized Study of Ramucirumab (LY3009806; NSC 749128) Plus Pembrolizumab (MK-3475; NSC 776864) Versus Standard of Care for Participants Previously Treated with Immunotherapy for Stage IV or Recurrent Non-Small Cell Lung Cancer”

VA Committee – Current Activities

- **SWOG VA Program Development Team**

- Establishing and expanding the team
- Provide ideas and guidance for the continued success of the SWOG VA Committee efforts and help new research coordinators learn about SWOG

- **Committee Operational Abilities**

- Working in sync with new trial development to assist with VA site participation from the beginning.
 - e.g. Disease Committee Liaisons, Protocol Development team
- Providing training to VA sites to help with trial activation
 - Example: National Cost Analysis (NCA) training: Learn to access the NCA in CTSU to help address any local questions about usual care costs

- **Development of a Shared Resource for Studies and Operations specific to VA**

- Sharing forms and applications
- Avoid duplication of effort /assist coordinators

- **Participation in AVAHO**

SWOG VA Acknowledgements

- **SWOG Leadership**

- Dr. Charles Blanke, SWOG Chair

- **SWOG VA Program Development Team**

- Sara Schiller – formerly with MAVERIC in Boston, unfortunately no longer with VA
 - Sara's efforts in developing the working group/committee is unmatched
- Connie Barnes – SWOG Operations Office –
 - There from the beginning keeping us on point!
- Tiffin Despres - SWOG Operations Office – First active SWOG VA Specialist (now in another position)
 - A catalyst for our progress
- Leslie Weissenstein - SWOG Operations Office – Current SWOG VA Specialist –
 - Picking up where Tiffin left off
- Sharon Palmer – SWOG Operations – Protocol Project Manager –
 - Adding another key layer to the program to improve protocol development and activation focusing on VA needs
- Lacy Teegerstrom – SWOG Operations – Membership –
 - Assisting with VA membership issues

SWOG VA Acknowledgements

- **SWOG VA Program Development Team (continued)**
 - Annette Betley – University of Michigan – Coordinator – Retired
 - Provided key perspective from coordinator with a University affiliate
 - Jessica McDermott - Rocky Mountain Regional VA – Investigator
 - Perspective of an active NCTN investigator
 - Caitlin Hutchinson – Rocky Mountain Regional VA – Coordinator
 - Perspective of an active clinical trial coordinator
 - Megan Page– Providence VA Medical Center
 - Perspective of an active clinical research coordinator
 - John Prentiss – John L. McClellan Memorial Veteran’s Hospital
 - Perspective of an active clinical research coordinator
 - Laura Gonzales – SWOG QA Manager and
 - Tinas Rosas - SWOG QA Nurse Auditor
 - Both provide information and insight to assure VA programs

SWOG VA Acknowledgements

- **The HOPE Foundation**

- Jo Horn
 - President & CEO
- Morgan Cox
 - Manages grant applications and awards

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