SWOG DEI Monitoring Committee

Background

Diversity, equity, and inclusion (DEI) are core principles of the SWOG Cancer Research Network. Like all DEI work, implementation of DEI principles at the clinical trial participant level requires strategy, structure, systems, and practices and the associated planning.

As part of the implementation of the methodology prepared by internal and external DEI experts, a new committee is proposed. Using funding pre-approved and provided by Genentech with the exceptional support of the Hope Foundation, a DEI Monitoring Committee which will oversee the quality of participations within the SWOG clinical trial portfolio, is proposed. The committee will function like a DSMC but will focus specifically on DEI in clinical trial participation. Criteria for reviews, the scope and outputs of those reviews, reporting, data quality, and supporting processes will be explored, clarified, and developed by the DEIMC.

DEIMC will review diversity and representativeness of trial participants at the group, committee, and subcommittee levels but will focus on feedback and modification for individual studies.

Scope

DEI Monitoring Committee (DEIMC) will evaluate results of activated and closed trials in the SWOG clinical trial portfolio and ensure SWOG leadership, investigators, and members have robust and feasible recruitment goals at the trial and committee level that support SWOG strategic plans for diversity and representativeness of clinical trial participants. The DEIMC will prepare a semi-annual report for each study for the DEII Vice Chair's approval, and that report will be delivered to the corresponding research committee's leadership for execution at the study (including the committee's DEI Champion), committee, and group levels.

Rationale

- DEI **accountability** starts with leadership and extends to study chairs and members of their study teams
- **Intentionality** to engage diverse and representative patient populations requires analysis of macro and micro drivers of results and implementation of strategies to achieve goals
- Sustained focus on **improvement**
- Improve **detection of differences** in outcomes
- **Build strong partnerships** across the diversity of the cancer community
- **Good stewardship for the public funding** that SWOG receives by distributing resources across a wide and diverse survivor population

SWOG DEI Monitoring Committee

Team Composition (and Disciplines Represented)

1. Executive Officer or Committee Chair
2. Biostatistician
3. RRC member
4. Patient Advocate member (community advocate or RRC advocate preferred to avoid COI)
5. Operations
6. External expert (Lansey, Borno, or similar)
7. Study Chair
8. Site PI

Terms and Term Limits

Members may serve up to two terms of three years. Renewal for second term contingent on both member and Committee Chair agreement. Calendar years 2022-2023 are currently funded; pending funding, a member may complete their first term in 2024 and another three-year term may be offered.

Governance

The DEIMC will vote on its chair who will serve for up to two terms of three years each, aligning with term limits for the membership.

Initial Actions (Working Group)

- Determine what, if any, relationship the DEIMC and its outputs should have to the existing DSMC which operates under SWOG *Policy 21*) and establish equivalent policy for the DEIMC if needed
- Establish charter, mission, and governance for DEI MC
- Modify/refine existing Policy 21 of the DSMC to integrate DEIMC work or create standalone DEIMC Policy
- Establish scope criteria (which trials get reviewed and which do not; note: trials must be large enough for DEIMC reviews to make sense)
- Assess Report of Studies (current reporting) with respect to fit for use and fit for purpose
- Recommend changes to data and reporting
- Define DEI MC inputs, outputs, timelines
- Establish responsibility matrix (simple RACI)
- Create report that will categorize in-scope trial diversity and representativeness thresholds as red, yellow, or green:
    - Red = significantly misses the diversity of the study population (20 percent below target?)
    - Yellow = misses study population
    - Green = reflects the study population
- Establish standards against which plans can be referenced

- Create report that will categorize in-scope trial diversity plans as red, yellow, or green:
    - Red = proposed plans appear very inadequate or are not properly resourced (people and budget)
    - Yellow = proposed countermeasures are barely adequate or resourcing is concerning (people and budget)
    - Green = proposed countermeasures are sound, properly resourced (people and budget), and likely to succeed
- Create standard agenda and requested information from underperforming studies to conduct study reviews
- Establish reasonable and appropriate timelines for countermeasures and results
- Establish reward and recognition for delivering DEI successes

Ongoing Actions (Established Committee)

- Monitor strategies structures, systems, and practices to identify opportunities for improvement
- Leverage and improve reporting on trial diversity and representativeness
- Leverage and improve trial diversity and representativeness plans
- Conduct open and closed sessions to discuss trials
- Communicate and monitor compliance to timelines for countermeasures
- Reward, recognize and highlight trials that deliver DEI successes
- Coach and mentor study teams while removing barriers to optimal DEI status
- Maintain strong relationships with DEIMC stakeholders and partners
- Document lessons learned and report macro trends and patterns to SWOG leadership, DEI Champions, and study teams

Authority

The DEIMC will provide recommendations to the DEII Vice Chair to change a study's accrual plan or to continue a study's accrual plan unchanged. In the event a change is recommended by the DEIMC, the Chair of the DEIMC will send a written report that was prepared prior to the DEIMC meeting to the DEII Vice Chair, who may seek the advice, in a confidential manner, of the Recruitment and Retention Committee Chair, DEI Champion, Study Chair, Disease Committee Chair, and/or SWOG Group Statistician.

DEII Vice Chair will act to implement the change as expeditiously as possible with support from the Study Chair, the Committee Chair, Recruitment and Retention Committee Chair, the SWOG Group Chair, and other relevant stakeholders.

In the unlikely situation that the DEII Vice Chair does not concur with the DEIMC recommendation, the DEII Vice Chair must discuss their reasons for not accepting the DEIMC recommendation with Recruitment and Retention Chair.

Estimated Effort

On average, estimated at 10 hours per semi-annual meeting (preparation, meeting time, and follow-up/report out).

Stipend

Honoraria for up to 8 members @ $1,000 each per year to cover two semi-annual reviews of the SWOG trial portfolio (funded 2022 and 2023). The honorarium does not cover travel expenses. Members will either attend meetings virtually or have their own funding to attend in-person.

Qualifications

- Experience with clinical trial accrual at the central (study team and network) and community levels, trial participant DEI strategies and tactics, and diversity of cancer subpopulations and related reporting (SEER; ACS; etc.)
- Track record of successfully working with minorities and underrepresented in clinical trials
- SWOG membership except as noted

Evaluation

- Input on contribution and advancement of DEI at SWOG from SWOG RRC Chair, DEI Champions, and SWOG stakeholders such as leadership including supported Committee Chairs, study chair partners, and members of study teams.