



What Does SWOG Have to Offer an Early Career Investigator?

My Perspective

Cathy Tangen
Deputy Director
SWOG Statistical Center
Faculty stat: GU, Prevention

Outline



- Getting Acquainted, Steps to Take
- Potential Opportunities
- Resources and tools available on SWOG.org website
- Funding Opportunities in SWOG, The Hope Foundation
- Mentoring, Networking, Committees

Committees



1. How can an investigator join a committee?

A nomination letter from the institution Principal Investigator and a current copy of the investigator's CV must be submitted to the SWOG NOC in San Antonio at member@swog.org.

If the investigator is not yet a SWOG member, a credentialing request must be submitted either through RUMS or NCORPSYS in order to activate SWOG membership at the institution. The nomination letter from the PI and copy of the CV may be submitted simultaneously with the credentialing request.

See [SWOG Policy Memorandum #8](#) for additional information on committee membership.

2. How do I join SWOG distribution lists?

- To request to be included on the SWOG bi-monthly protocol and general updates distribution list, E-mail: member@swog.org.
- To request to be included on the SWOG CRA Quarterly Newsletter distribution list, login to the SWOG CRA Workbench and then click on the "Join the CRA Mailing list" link OR paste the following link into browser after login (<https://txwb.crab.org/TXWB/ListServe.aspx>).
- To subscribe to our weekly [Front Line](#) (the group chair's Friday blog post) or to the SWOG TM Link of the Week, contact communications@swog.org.

SWOG.org, public and private side



Public

- Meeting information
- Leadership
- Policies and Procedures
- Information about Membership
- Clinical trials, general information

Members Only

- Roster of members
- Access to trial search tool
- Protocols, CRFs, Report of Studies
- Newsletters, participate in SWOG meetings



How to Get Integrated in SWOG

- Get on email lists, invitations for regular committee (zoom) meetings
- Attend the semi-annual Group Meeting regularly
 - Disease committee open and working group, but also AYA, VA, RT, Surgery, Community Rep, DEI committees/working groups, recruitment/retention
- Introduce yourself to disease committee leadership
- Offer to help with anything
- Share your opinion
- Enter patients on NCTN trials! (crediting SWOG helps)
- Seek relationships with SWOG mentors

Upcoming Group Meetings

Spring 2024 SWOG Group Meeting

April 4-7, 2024

Hyatt Regency Seattle
Seattle, Washington



Special Sessions

Wednesday-Saturday,
April 3-6

Group Meeting

Wednesday, April 3

CRA Clinical Trials
Training Course

Thursday, April 4

Plenary I; Exhibits

Friday, April 5

Plenary II; Exhibits



Opportunities on SWOG Clinical Trials for Early Career Investigators



- Back-up study chair, answer treatment and AE questions from sites, review eligibility criteria
- Patient Reported Outcomes: sub-study chair



SWOG Champion (represent SWOG on another NCTN-group trial)

The screenshot shows a game achievement page for 'Swog Champion'. At the top left is a large image of a stone guardian statue. To its right is a banner for 'BLIZZARD GEAR' featuring two t-shirts. Below the banner is a 'Remove All Ads' button. The main content area has a breadcrumb trail: Database > Achievements > Character Achievements > Dungeons & Raids > Dragonflight Raid. The achievement title 'Swog Champion' is accompanied by a star icon. Below the title is a description: 'Defeat Volcoross after he has consumed at least 30 Sizzling Swoggers in Amirdrassil, the Dream's Hope on Normal difficulty or higher.' To the right of the title are 'Links' and 'Quick Facts' sections. The 'Quick Facts' section lists: Points: 10, Side: Both, Zone: Amirdrassil, the Dream's Hope, Icon: spell_nature_guardianward, Added in patch 10.2.0 "Guardians of the Dream", and Attained by 4% of profiles. At the bottom left, under the 'Criteria' section, it says 'Feed Volcoross 30 Sizzling Swoggers.'

Database > Achievements > Character Achievements > Dungeons & Raids > Dragonflight Raid

Swog Champion ☆

Defeat Volcoross after he has consumed at least 30 Sizzling Swoggers in Amirdrassil, the Dream's Hope on Normal difficulty or higher.

Criteria

Feed Volcoross 30 Sizzling Swoggers.

Quick Facts

- Points: 10
- Side: Both
- Zone: Amirdrassil, the Dream's Hope
- Icon: spell_nature_guardianward
- Added in patch 10.2.0 "Guardians of the Dream"
- Attained by 4% of profiles

SWOG-CHAMPIONED INTERGROUP STUDIES



STUDYID Accrual	STUDY NAME	Phase	Open Date	Coop grp	SWOG/Total Accrual	Champion
EA8134 N=200	InPACT	III	9/8/2017	ECOG- ACRIN	12/82	Dr. Curtis Pettaway
EA8171 N=852	Multiparametric MRI (mpMRI) for Preop Staging and Treatment Planning for Newly-Diagnosed Pros Cancer	II	7/9/2018	ECOG- ACRIN	87/784	Dr. Michael Liss
EA8173	Pros, 18F-DCFPyL PSMA-based PET/CT for directed ablative RT in patients with biochem recur and oligometastases	II	Target 1/18	ECOG- ACRIN	Presented to prostate task force 7/17	Dr. Jing Zeng
EA8183 N=810	A Phase III Double Blinded Study of Early Intervention After RADICAL ProstaTEctomy with Androgen Deprivation Therapy with Darolutamide vs. Placebo in Men at Highest Risk of Prostate Cancer Metastasis by Genomic Stratification (ERADICATE)	III	12/09/2020 CLOSED 2/09/2023	ECOG- ACRIN	4/27	Dr. Tanya Dorff
EA8185 N=102	Phase 2 Study of Bladder- Sparing Chemoradiation with Durvalumab in Clinical Stage 3, Node Positive Bladder Cancer (INSPIRE)	II	8/25/2020 CLOSED 10/02/2023	ECOG- ACRIN	1/11	Dr. Timur Mitin & Dr. Joshua Meeks
EA8191 N=804	PET-Directed Local or Systemic Therapy Intensification in Prostate Cancer Patients with Post-Prostatectomy Biochemical Recurrence	III	10/08/2020	ECOG- ACRIN	23/209	Dr. Volkan Beylergil & Dr. Evan Yu
EA8192 N=249	Blad, High Grade UTUC, Durvalumab + Chemo Prior to Nephroureterectomy	II/III	5/06/2021	ECOG- ACRIN	2/32	Dr. Shuchi Gulati
EA8212 N=870	Intravesical BCG VeRsus Intravesical Docetaxel and GEMcitabine Treatment in BCG Naïve High Grade Non-Muscle Invasive Bladder Cancer (BRIDGE)	III	12/01/2022	ECOG- ACRIN	53/205	Dr. Sia Daneshmand & Dr. Mary Beth Westerman
GU002 N=612	Adj RT + AD Following Rad Prostatectomy +/- Adj Docetaxel	II/III	12/30/2016 CLOSED 9/06/2022	NRG	4/165	Dr. David Raben

These options are only available if you are logged in as a member

Member Resources

Your place to get tools and information for SWOG Cancer Research Network trials.

Tools

Select this



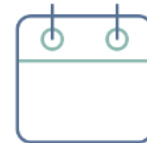
Clinical Trials →



CRA Workbench →



Member Directory →



SWOG Meetings →

Clinical Trials

Keywords/SWOG Study Number

Area of Research

SEARCH

Fewer filters



Accrual Status


Any Open Closed

Limit to SWOG Trials

All Trials SWOG Trials Only

Show only published studies

Study Type

Treatment

Study Chair

Participating Institution

Phase

Cancer Control Subcommittee

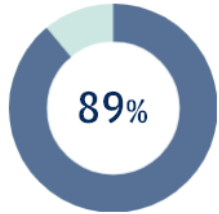
Study Sponsor

FDA Registration Trial

Uses PRO Forms

Open Phase



Accrual

S1806 SWOG Clinical Trial Number

Create a Saved List

Phase III Randomized Trial of Concurrent Chemoradiotherapy with or Without Atezolizumab in Localized Muscle Invasive Bladder Cancer.



Research Committee(s)	Genitourinary Cancer
Study Chair(s)	Parminder Singh, MD
Activated	04-19-2019

Closed Phase



Accrual

S1602 SWOG Clinical Trial Number

Create a Saved List

A Phase III Randomized Trial to Evaluate the Influence of BCG Strain Differences and T Cell Priming with Intradermal BCG Before Intravesical Therapy for BCG-Naïve High-Grade Non-Muscle Invasive Bladder Cancer



Status Notes	There is a monthly call for coordinators who have questions about this study. Send an email to S1602question@swog.org to be added.
Research Committee(s)	Genitourinary Cancer
Study Chair(s)	Robert Scott Svatek MD

S1602 SWOG clinical trial number

A Phase III Randomized Trial to Evaluate the Influence of BCG Strain Differences and T Cell Priming with Intradermal BCG Before Intravesical Therapy for BCG-Naïve High-Grade Non-Muscle Invasive Bladder Cancer

Create a Saved List

Email 

Print 

Download Documents

[Protocol & Model Consent Form](#) 

[Most Recent Updates Archive](#) 

Safety Reports

[BCG](#)

[BCG Tokyo-172 Strain](#)

Reports & Approvals

[ROS REPORT](#)

Closed  Phase 



Accrual

Abbreviated Title	BCG Strain Differences and BCG vaccination in High-Grade Non-Muscle Invasive Bladder Cancer
Status Notes	There is a monthly call for coordinators who have questions about this study. Send an email to S1602question@swog.org to be added.
Activated	02/07/2017
Closed	12/15/2020
Participants	ALLIANCE, ECOG-ACRIN, NRG, SWOG
Study chair(s)	Robert Scott Svatek, MD



My Account

CRISP

User Access Update: CTEP-IAM & ID.me

Welcome Catherine Marie Tangen. Your password will expire in 0 days.

Search for...

Go!

Search protocol titles or numbers...

CIRB Approved



S1602

a National Cancer Institute program

A Phase III Randomized Trial to Evaluate the Influence of BCG Strain Differences and T Cell Priming with Intradermal BCG Before Intravesical Therapy for BCG-Naive High-Grade Non-Muscle Invasive Bladder Cancer

IRBManager | Add to My Protocol | Help

CIRB Approved Documents

#	Current CIRB-approved Protocol and Consent	Post Date
1	Protocol Version Date 07/22/19	01-Oct-2019
2	Consent Form (PVD 07/22/19)	01-Oct-2019

CIRB Approved Documents

Protocol Related Documents

For assistance accessing information, refer to the [Accessibility Policy](#) to request reasonable accommodations.

- S1602
 - Detail, Accrual and Specific Notes
 - Funding Information
 - CIRB Approved Documents
 - + Protocol Related Documents
 - + Drug Safety Notification
 - Study Agent
 - Protocol Requirements
- + S1605
- + S1607
- + S1608
- + S1609
- + S1612
- + S1613
- + S1614
- + S1616
- + S1619
- + S1701
- + S1702

		Documents			
9	 Memorandum: Intradermal Supply	Supplemental Documents	01-Apr-2021	PDF	02-Apr-2021
10	 Memorandum: SWOG DSMC Meeting Minutes – October 16, 2020	Supplemental Documents	01-Dec-2020	PDF	22-Jan-2021
11	 Master Forms Set	Case Report Forms	15-Jan-2021	PDF	20-Jan-2021
12	 Memorandum: Updated Master Forms Set	Supplemental Documents	15-Jan-2021	PDF	20-Jan-2021
13	 S1602 – Accrual – January 2021	Education and Promotion	01-Jan-2021	PDF	11-Jan-2021

S1602 SWOG clinical trial number

A Phase III Randomized Trial to Evaluate the Influence of BCG Strain Differences and T Cell Priming with Intradermal BCG Before Intravesical Therapy for BCG-Naïve High-Grade Non-Muscle Invasive Bladder Cancer

Closed Phase



Accrual

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Create a Saved List

Email Print

Download Documents

Protocol & Model Consent Form

Most Recent Updates Archive

Safety Reports

BCG

BCG Tokyo-172 Strain

Reports & Approvals

ROS REPORT

S1602 Phase III - FDA Registration Trial

Coordinating Group: SWOG

A Phase III Randomized Trial to Evaluate the Influence of BCG Strain Differences and T Cell Priming with Intradermal BCG before Intravesical Therapy for BCG-Naïve High-Grade Non-Muscle Invasive Bladder Cancer

Participants:

SWOG, CTSU (Supported by Alliance, ECOG-ACRIN, NRG)

Date Activated:

02/07/2017

Study Chairs:

R Svatek, A Alva, M Woods (Alliance), V Master (NRG), J Mark (ECOG-ACRIN)

Date Closed:

12/15/2020

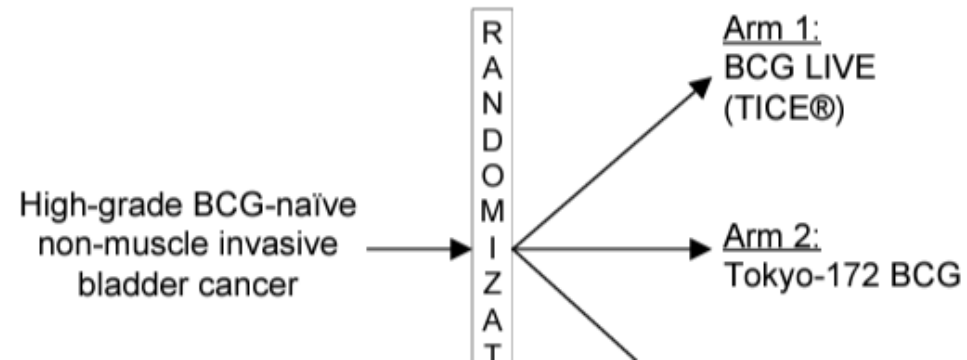
Statisticians:

C Tangen, M Plets

Data Coordinators:

T Johnson, J Jardine

SCHEMA



Research committees

Genitourinary Cancer

Treatment

BCG BCG (Tice) BCG Tokyo-172 Strain

Other Study Materials

Required S1602 Training

Eligibility Criteria 

Publication Information 

Other Clinical Trials

Most Recent Publications Listed for S1602 → Talk to the SWOG statistician

2021

The Who, What, When, Where, and Why of Bacillus Calmette-Guérin-unresponsive Bladder Cancer [Editorial]

R Li;SP Lerner;A Kamat European Urology Apr;79(4):437-439

PMid: PMID33454163

2018

Background and update for S1602 “A Phase III Randomized Trial to Evaluate the Influence of BCG Strain Differences and T Cell Priming with Intradermal BCG Before Intravesical Therapy for BCG-Naïve High-Grade Non-Muscle Invasive Bladder Cancer”

R Svatek;C Tangen;S Delacroix;W Lowrance;S Lerner European Urology Focus Jul;4(4):522-524

PMid: PMID30197040

2017

Bacillus Calmette-Gue'rin manufacturing and SWOG S1602 Intergroup clinical trial [editorial]

JJ Meeks;SP Lerner;RS Svatek Journal of Urology Mar;197(3 Pt 1):538-540; Epub 2016 Dec 16

PMid: PMID27992750 | PMC number: PMC n/a - editorial

Secondary Analysis of SWOG Data

- Two Options
- Identify your own non-SWOG statistician, fill out a data request, execute a DUA between SWOG and Hutch, get data and conduct analysis, publish in a top journal, be admired by your peers
- Propose an analysis within a SWOG committee, SWOG stats will collaborate with you and conduct the analysis, get a good publication. Resources vary by disease committee. Need to get prioritized.

SWOG Data Sharing Request

Title:

Study Chair name/address:

Clinical trial(s) from which data is requested:

Project objective(s):

Primary objective:

Secondary objective(s):

Brief Justification:

Rationale:

Background:

Significance:

Endpoints:

Primary endpoint:

Secondary endpoint(s):

Approach / Methods:

Statistical Plan:

Participating Investigator(s)/Institutions(s) – if collaborative effort:

Data Analysis performed by (and institution/address/contact information):

SWOG data requested:

Patient data from SWOG trial SXXXX. Specific variables requested are:

Expected timeline of Project Completion:

Disclosure of Conflict of Interest:

Financial support of proposal:

References:

- *Formulate an objective(s), get local stat support*
- *Ensure there is no overlap with other work*
- *Talk to disease committee and/or study leadership about your idea*
- *Complete a SWOG Data Sharing Form*
- *Send it to disease stats team for review of feasibility*
- *Request will be reviewed by SWOG execs*
- *If approved, a DUA will be executed between your Institution and SWOG for scope of work specified*
- *Stats send you data*



NATIONAL CANCER INSTITUTE
NCTN/NCORP Data Archive

[Search Single Trial Data](#)

[Search Multi Trial Data](#)

[How to Make a Request](#)
[\[PDF\]](#)

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To request data, please create an account

[Create New Account](#)



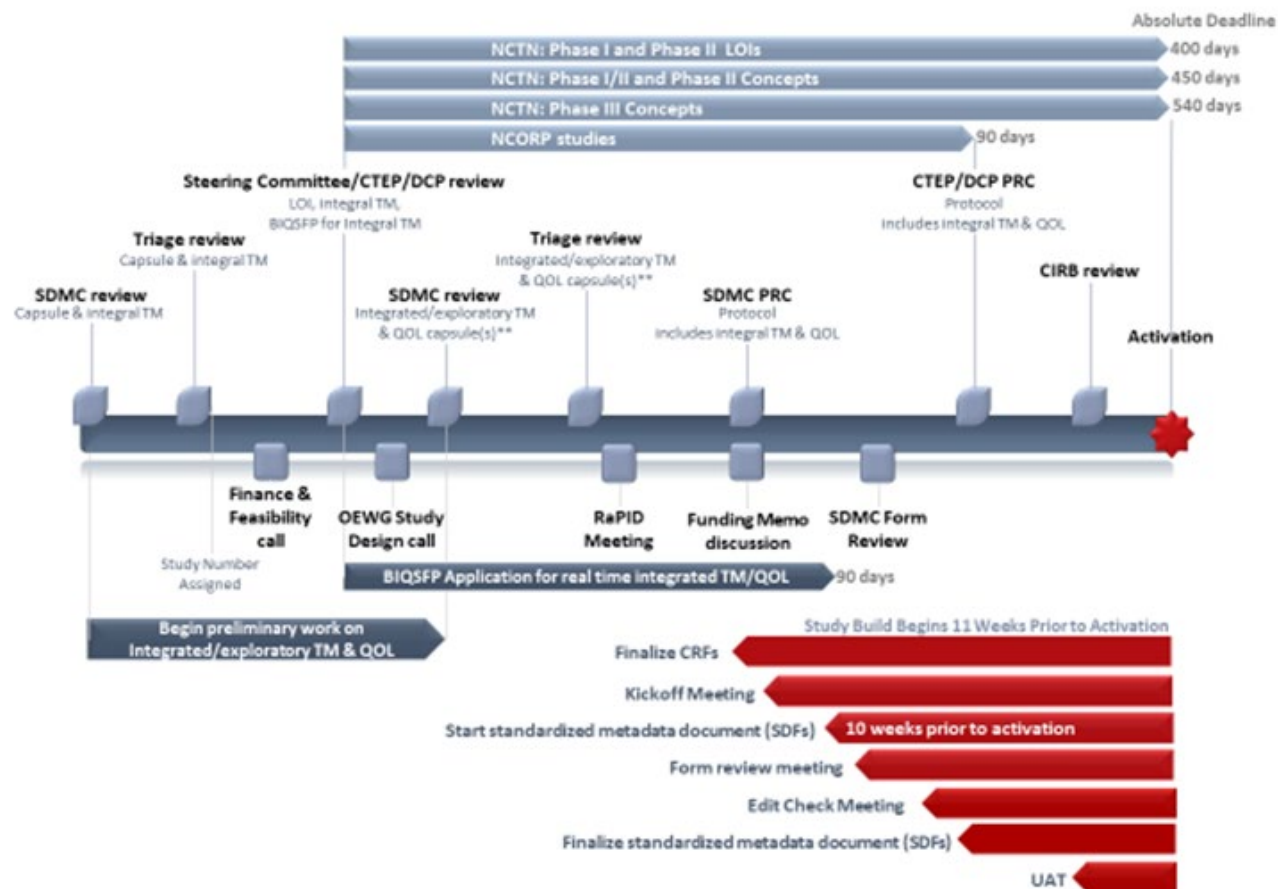
ACCESS DATA



Translational Studies

- Get to know the TM chair for your disease committee
- Statistician can help identify sample availability for a given trial.
- TM template used for applying to SWOG Execs.
- Primary (pre-specified) analyses are conducted first.
- Additional analyses on remaining samples – up for grabs
- Should be validating, “exploratory” is frowned upon by NCI
- Need a detailed stat analysis plan in the proposal
- TONS of unclaimed samples in the Nationwide Biobank!!

So you want to coordinate a clinical trial...?



4/27/22 **Anytime after concept approval. TM samples not available until 75% of accrual is reached.



Incubating a Trial Idea

- Initial presentation – floating the concept
- Right fit for NCTN?
- Prioritizing within a committee,
can take a few years to move forward
- Feasibility? SWOG's prior experience?
- Complexity? Community participation?
- Investigator reaches out to stats team for initial
pass at design considerations
- Include young investigators as part of the team

Basic Design Considerations

(iterative process with study team)



- Target population: impacts accrual rate, generalizability of results, event rate
- Endpoint: Survival, PFS, response -> impacts event rate, duration of trial, sample size
- Treatment effect: The bigger the hypothesized difference between arms -> the smaller sample size, clinically meaningful difference
- Trial duration: potential relevance
Clinically meaningful vs. Pragmatic

Median OS	Sample size
12 vs 18 mo	200/arm
12 vs. 16 mo	400/arm
12 vs. 15 mo	600/arm



NCI Task Force Review – Site specific

- NCI Concept Template is used
- SWOG is staking its claim to a research area
- NCTN disease-specific expertise to review “rough” concept
- Ensure best science, review for overlap with NCTN and pharma
- Other suggestions (TM specimen collection, PROs, imaging)
- Trying to get to “We’re supportive of submitting to the Steering Committee”
- Back and forth, less formal than Steering Committee

PS Task Force membership is a good career opportunity

Statistical Review (aka PRC)



- Weekly meeting in Seattle
- Standards, consistency, clarity
- Statistical principles for design and analysis plans
- Logistical flow of study
- Burden on site and patients
- Shared SWOG knowledge, don't reinvent the wheel



SWOG Executive Review (aka “Triage”)

- Weekly, Monday mornings
- Leaders from all SWOG offices, GCO, Ops, Stats, E.O.s, Advocates
- Is trial scientifically sound? Acceptability of randomization?
- Good use of SWOG resources?
- Fit in disease committee portfolio?
- Burden on sites and patients (e.g., PROs, TM sample collection)
- Extra resources needed? (e.g., FDA registration)
- Rejections are rare, but plenty of review comments



NCI Steering Committee – Clock starts!

- Polished concept submitted, most logistics, funding worked out
- Formal review with national leaders from NCTN and NCI
- Medical, RT, surgical oncologists, TM experts, advocates, biostatisticians
- Open and closed session
- Unusual to get approved on first try (approve vs. revise and resubmit vs. disapproved)
- SWOG rule: Only 3 on the clock at any given time

Concept Approved by Steering Committee



- “clock starts”
- The fun begins at a fast pace for a lot of people!
- Statistical Team and Operations Office will help with each new step
 - Writing protocol, developing forms, building study in RAVE, testing
 - Monitoring the trial, study chair evaluation forms
 - Stats prepare DSMC reports every six months
 - Abstracts, papers

FUNDING!!

Career Engagement Award	SWOG BOG Travel Support
Committee Meeting Funds	SWOG Early Exploration & Development (SEED) Fund
CRA/Nurse Travel Support Program	SWOG/Hope Foundation Impact Award
Dr. Charles A. Coltman, Jr. Fellowship Program	SWOG Trial Support (STrS)
Early Stage Investigator Training Course	Trial-Specific Education Funds
The John Crowley, PhD Award	VA Storefront Support Program
NCORP Pilot Grant Program	Virtual Grant Writing Workshop
Secondary Data Analysis	Nicholas Vogelzang SWOG GU Scholarship

- Scientific merit
- Level of engagement in SWOG
- Mentor availability

Early Stage Investigator Training Course (ESITC)	Multi-day educational intensive in protocol development, trial management, and statistical analysis	Any early career SWOG investigator; includes travel support ; see application for details
Dr. Charles A. Coltman Jr. Fellowship Program	\$50,000 x 2 years' salary support - To ensure protected time for new investigators from SWOG-affiliated institutions to pursue mentored clinical research initiatives	Junior faculty* at SWOG member or affiliated institution; see application for details ; includes travel support

Early Stage Investigator Training Course (ESITC):

The ESITC gives new investigators the opportunity to work 1-on-1 with SWOG's most experienced leaders to develop a rigorous, relevant, and feasible SWOG trial* concept to launch within the NCI's National Clinical Trials Network. (*could be TM or complex data analysis)

Involves intensive mentorship and an online course, culminates in a 3-day workshop with SWOG leaders

Course plays a central role in fostering new leadership and ensuring the longevity and legacy of SWOG

Participants are expected to have previous experience within SWOG or make a future commitment to do so. 4 to 6 early stage investigators are selected each year.

All costs for the workshop including travel, ground transportation, meals, lodging, materials, and the workshop itself will be free of charge

Deadline to apply: May 1, 2024

2024 course dates: typically mid to late September in Seattle

Get to know your SWOG statisticians

- Happy to meet F2F to discuss potential collaborations
- Guide you through the process of requesting data, samples, conducting analyses, writing abstracts and papers
- Help you navigate a large, complex organization
- Work with you to design a scientifically sound, feasible clinical trial design and support it from initial idea to final publication
- In return, you need to be patient with SWOG's finite resources