GOG Foundation/Partners
Program Overview 2015

Philip J. DiSaia, MD – President
GOG Foundation

Larry J. Copeland, MD – Vice President
GOG Foundation

GOG Foundation/Partners

Mission Statement

The GOG Foundation is a non-profit organization with the purpose of promoting excellence in the quality and integrity of clinical and translational research in the field of gynecologic malignancies. The Foundation is committed to maintaining the highest standards in clinical trials development, execution and distribution of results. Continuous evaluation of our processes is utilized in order to constantly improve the quality of patient care.

GOG FOUNDATION/PARTNERS PROGRAM

Basic Premise

The Partners program is based on the collaboration between the GOG Foundation and our Industry Partners' Clinical Development/Medical Affairs teams for State of the Art trial conduct in all GYN malignancies. These clinical collaborations are conducted independently of the NCI mechanism but with the same attention to Quality and Data Integrity.

GOG Foundation/Partners

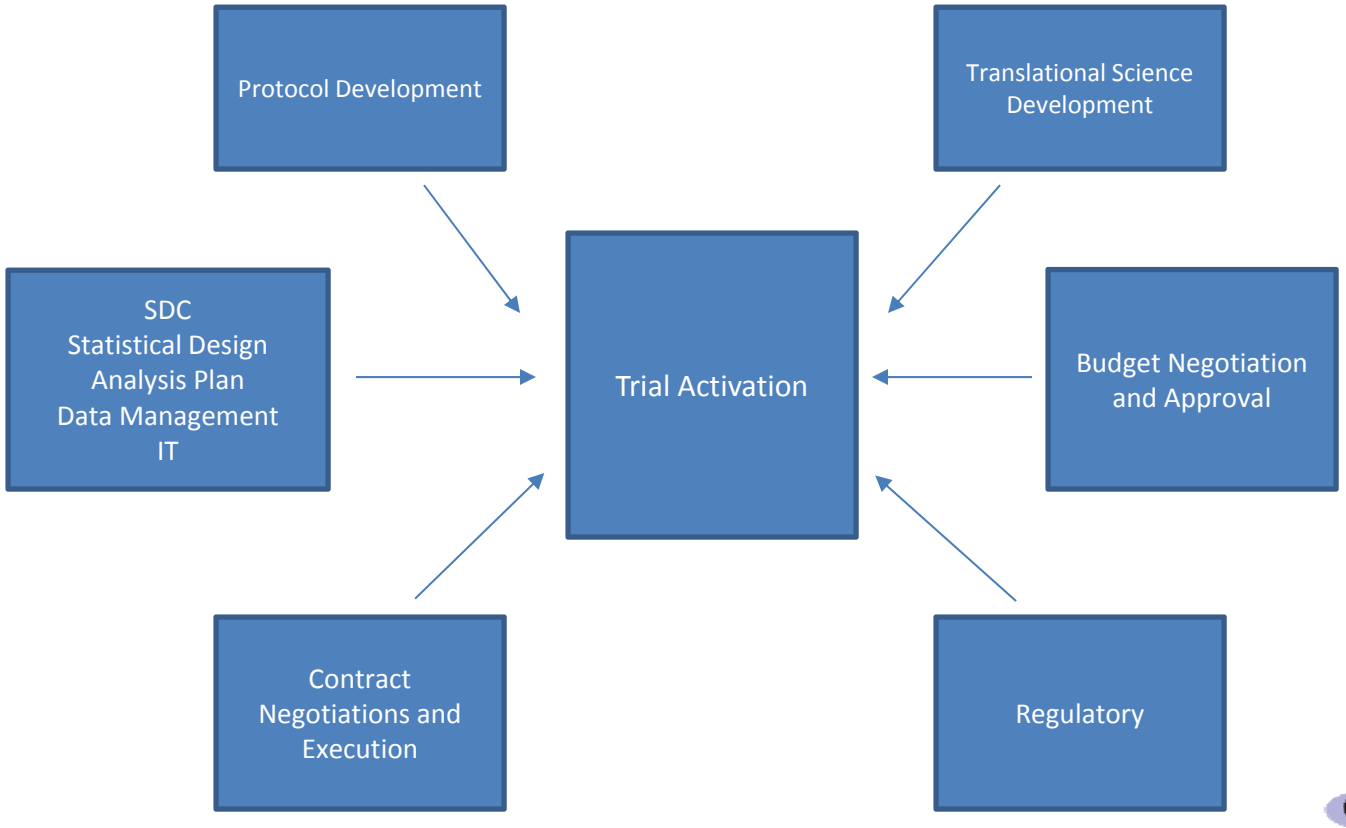
GOG FOUNDATION/PARTNERS PROGRAM

Basic Principles

- Partners collaborates with industry team to formulate the best plan for trial development and data delivery
  - GOG Administration, SDC, and Finance handle all trial aspects: design, regulatory, execution, data management, analysis and reporting
  - In special circumstances, alternative collaborations can be considered.
- Partners can fully coordinate trials with regulatory tracks.
- Study cost will depend on complexity and requirements

Basic Principles: Steps Leading To Activation

Budget, contract negotiation, regulatory (including HRC review), protocol development, SDC functions and translational science development occur in parallel with study activation as the final result.



GOG FOUNDATION/PARTNERS PROGRAM
TIMELINE GOALS

For Phases I and II trials*:*

- From original concept approval to trial activation: 4-6 months
  - Exceptionally complex trials may take longer
  - Time may vary according to complexity of study and contracting
- Accrual time depends on patient population, complexity and number of institutions

For Phase III trials*:*

- From concept approval to activation: approx. 6 months
  - Exceptionally complex trials may take longer
  - Time may vary according to complexity of study and contracting
- Accrual time depends on patient population, complexity , projected study size, number of institutions

GOG Foundation/Partners

GOG FOUNDATION/PARTNERS PROGRAM

Why GOG Foundation/Partners Rather Than CTEP?

- The Industry Partner's preference
- The Industry Partner's need for rapid development
- Agent is not within the CTEP portfolio

GOG Foundation/Partners

Why GOG Partners Rather Than Other Entities?

- Credibility and successful track record of the GOG which has set the current standard of care in gynecologic cancer
- Significant clinical and translational science expertise of the GOG in gynecologic cancers
- Dedicated expertise in statistical trial planning and data modeling in gynecologic malignancies
- Rapid trial development and execution
- Extensive network of sites (the vast majority of the gynecologic oncology community in the US)

Collaborative Strengths

- Study contract negotiation
- Protocol Development
  - Committee review
  - Coordination of the study from concept approval to termination
- Regulatory Compliance
  - IND filing and submissions
  - Drug Distribution
  - SAE reporting
  - Regulatory document collection and review
- Site Selection and feasibility

Collaborative Strengths

- Study budget negotiations
- Site study-specific contracting
  - Template distribution and negotiation
- Site study-specific budget negotiations
- Site Payments and Tracking
- Sunshine Act reporting
  - Using company specific template

Collaborative Strengths

- Close relationship with GOG Foundation Principal Investigators and Institutional CRAs
  - Longstanding (45 years), highly successful track record
  - Expertise in gynecologic cancer research
  - Unmatched experience
- Wide range of CRO functions in a research environment
- Proficient in interactions with the FDA
- Integrated into all aspects of GOG research

GOG STATISTICAL AND DATA MANAGEMENT CENTER
BIOSTATISTICS AND SCIENCE

Comprehensive Interaction

- Collaboration with Study Chair and GOG Partner
- Study design and analysis plan
- Protocol conduct
- Interim and final analyses
  - Clinical
  - Epidemiologic
  - Translational research
  - Quality of life
- Interpretation and dissemination of results
- Collaborate in FDA/EMA filing document development

GOG STATISTICAL AND DATA MANAGEMENT CENTER
DATA MANAGEMENT

Comprehensive Interaction

- Longstanding relationships with GOG investigators and SDMC infrastructure ensures experienced study team
  - Study Chair
  - Biostatistician
  - Clinical Data Coordinator
- Established network with institutional CRAs enhances data quality and timeliness
- Ongoing training and mentoring
  - New institutional CRAs
  - New study chairs
  - Study specific training workshops

GOG Foundation/Partners

GOG STATISTICAL AND DATA MANAGEMENT CENTER
DATA MANAGEMENT

Role in Protocol Conduct

- Collaborate with study team in protocol development
- CRF creation and testing
- Randomization/eligibility screening
- Management of data
  - Delinquency monitoring
  - Extensive quality control
  - Query resolution
- Toxicity and SAE monitoring
- Study Chair review

GOG Foundation/Partners

GOG STATISTICAL AND DATA MANAGEMENT CENTER
INFORMATION TECHNOLOGY

Comprehensive Capabilities

- Electronic data capture
  - Medidata Rave
  - SDC Electronic Data Entry System
- Web based patient registration
  - E-mail notification to partner
  - Electronic drug ordering capability
- Bioinformatics and data specimen tracking
- Serious adverse event portal
- Electronic data quality checks
- Help desk and issue escalation
- Software development process
- Network security and disaster recovery

GOG Foundation/Partners

GOG STATISTICAL AND DATA MANAGEMENT CENTER
Business Infrastructure – Strategic management

Additional Capabilities

- Quality Assurance and Control
  - Good Clinical Practice (GCP) regulations
  - SOPs and training
- On-site QA audits of institutional performance
- Publications – efficient processes to ensure timeliness
- Project oversight
  - Contract development
  - Oversight to ensure fulfillment of contractual obligations
  - Fiscal management

GOG FOUNDATION/PARTNERS PROGRAM

So Why Choose Partners?

- GOG Foundation/Partners is an independent entity with its own Foundation
  - NRG Oncology and CTEP have no impact on GOG Foundation/Partners
- Scientific and operational structure is that of the prior Gynecologic Oncology Group (GOG), a proven entity
  - Key organization contact individuals remain the same
  - Studies bypass NRG Oncology complicated NCI governance/sign off
- Fully capable to perform all study functions as shown in the descriptions of the three offices

GOG Foundation/Partners

GOG FOUNDATION/PARTNERS ONE ON ONE

GOALS: Meet Partners and Learn More

- Dedicated time to meet one-on-one with collaborators seeking to learn more about Partners and/or vetting early trial ideas
  - Blocks of time for 1:1 interaction at the NRG, SGO, and ASCO meeting
  - Senior Leadership of Partners will be available for each session
  - Invitation sent to ICT membership and other Pharma Collaborators
- Access to advisory boards coordinated and customized by GOG Partners for industry collaborators

For further information about Industry Collaboration Team (ICT) or to schedule a block of time for the Partners One-on-One program, please contact:

Kathy Shumaker, Director of Development

Kshumaker@gog.org or 410-721-7126

GOG Foundation/Partners

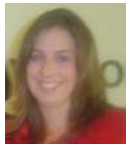
Key Contacts for Partners Concept Proposals:

- GOG Foundation/Partners contact points:
  - Overall:
    - Foundation President: Dr. Philip J. DiSaia (pjdisaia@uci.edu)
    - Vice President: Dr. Larry Copeland (larry.copeland@osumc.edu)
    - Chair of GOG Partners: Dr. Tate Thigpen (jtthigpen@att.net)
    - Co-Chair of GOG Partners: Dr. Brad Monk (bradley.monk@chw.edu)
  - Phase I-II: Developmental Therapeutics Chair: Dr. Carol Aghajanian (aghajanc@mskcc.org)
  - Phase III Trials
    - Ovary: Dr. Michael Bookman (michael.bookman@usoncology.com)
    - Cervix: Dr. Bradley Monk (bradley.monk@chw.edu)
    - Corpus: Dr. David Miller (David.Miller@utsouthwestern.edu)
    - Experimental Medicine: Dr. Michael Birrer (mbirrer@partners.org)

GOG FOUNDATION/PARTNERS PROGRAM
KEY PARTNERS CONTACTS: OPERATIONS

Scientific Leadership: Tate Thigpen, MD (jtthigpen@att.net)

Contracting
Laura Reese, Executive Director, Operations
(lreese@gog.org)



Regulatory
Katie Campbell, Director, Regulatory Affairs
(kcampbell@gog.org)

Protocol Development
Kia Neff, Director of Clinical Trials Development
(kneff@gog.org)

Budgeting
Mary Sharp, Chief Financial Officer
(msharp@gog.org)

Site Contracting
Nicole LaMack, Grants/Accounting Manager
(nlamack@gog.org)

GOG Foundation/Partners

GOG FOUNDATION/PARTNERS PROGRAM
KEY PARTNERS CONTACTS: SDC

SDC Leadership: John A. Blessing, PhD

Statistics
Mark Brady, PhD, Director, Statistics
(brady@gogstats.org)

Information Technology
Bill Elgie, Director, Information Technology
(elgie@gogstats.org)

Administration
Sally Bialy, Director, Administration
(sbialy@gogstats.org)

Data Management
Bette Stonebraker, Director, Data Management
(stonebraker@gogstats.org)

GOG FOUNDATION/PARTNERS PROGRAM

Communication Pathway for Questions from Industry

GOGPARTNERS@GOG.ORG

GOG Foundation/Partners

GOG FOUNDATION/PARTNERS

GOG OPERATIONS
Four Penn Center
1600 JFK Blvd. #1020
Philadelphia, PA 19103
215-854-0770

GOG FINANCE
2127 Espey Court
Suite 100
Crofton, MD 21114
410-721-7126

GOG SDC
Roswell Park Cancer Inst.
Elm and Carlton Streets
Buffalo, NY 14623
716-845-5702

GOG Foundation/Partners