



**Advancing NIH Research on the Health of Women:  
A 2021 Conference**

# **NCI Clinical Trials in Gynecologic Cancer: A Changing Landscape**

**Robert S. Mannel, MD**

**Co-Chair of NRG Oncology**

**Director of OU Stephenson Cancer Center**

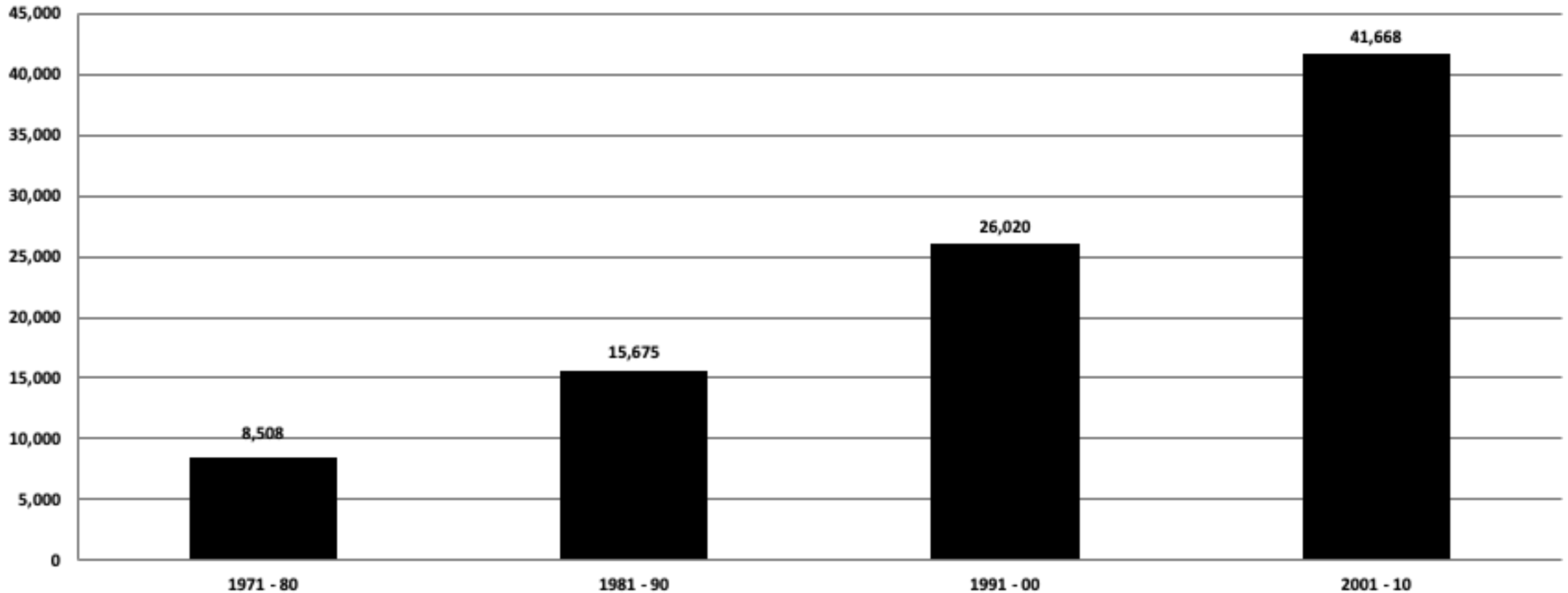
**October 20, 2021**

# A National Response to Address Gynecologic Malignancies

- 1971 – Gynecologic Oncology Group founded with support from the NCI
- Eleven founding institutions
- Includes gynecologic, radiation and medical oncology
- Rapid growth over next 40 years with over 300 member institutions nationally and internationally
- Set the worldwide standard for management of gynecologic malignancies

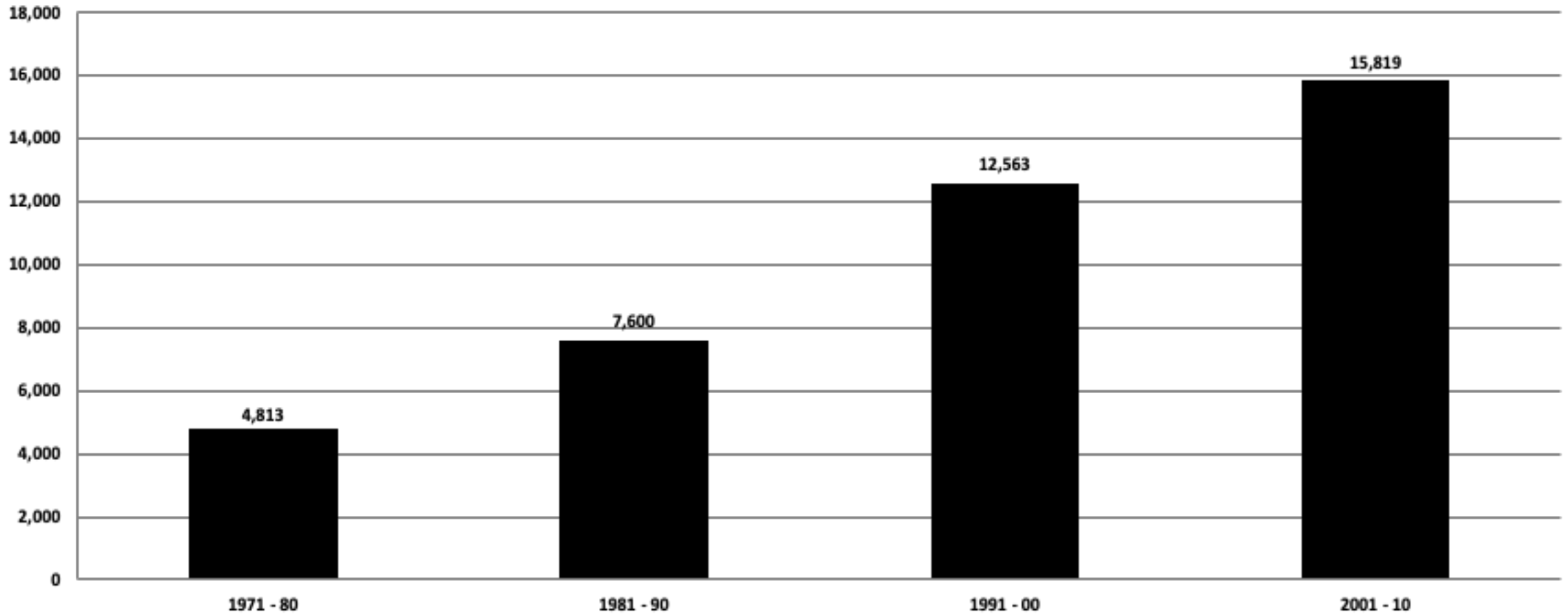
# GOG – Total accrual first 40 years

**Total Accrual**  
(Total 91,871 Patients)



# GOG Phase III Accrual – Growth over the first 40 years

**Phase III Accrual**  
(Total 40,795 Patients)



# Population, Clinical, and Scientific Impact of National Cancer Institute-Sponsored Clinical Trial Network Treatment Studies

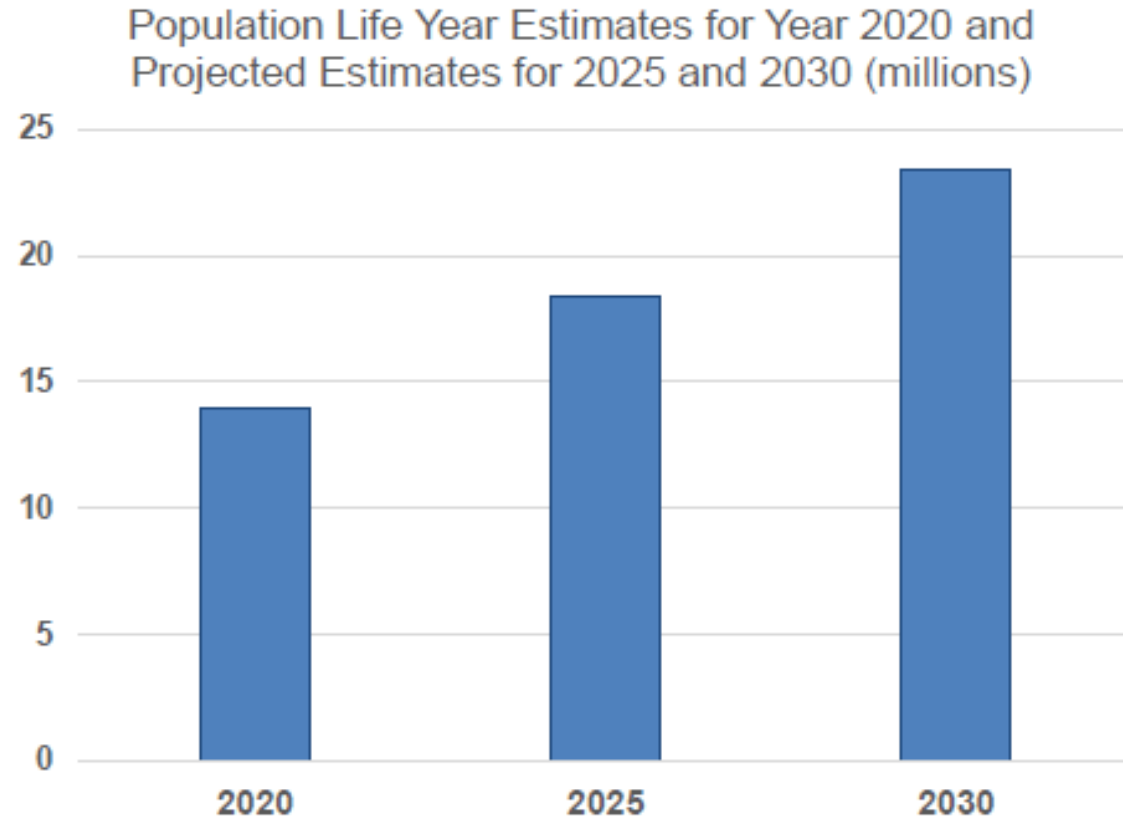
Joseph M. Unger\*, Michael LeBlanc, Monica M. Bertagnolli, Norman Wolmark, Walter J. Curran, Peter O'Dwyer, Mitchell D. Schnall, Robert Mannel, Sumithra J. Mandrekar, Joseph P. Costantino, Robert Gray, Fengmin Zhao, Fangxin Hong, Mariama Bah, Riha Vaidya, Charles D. Blanke

\* Presenting Author:

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Senior Biostatistician and Health Services Researcher, SWOG Cancer Research Network

# Population Impact

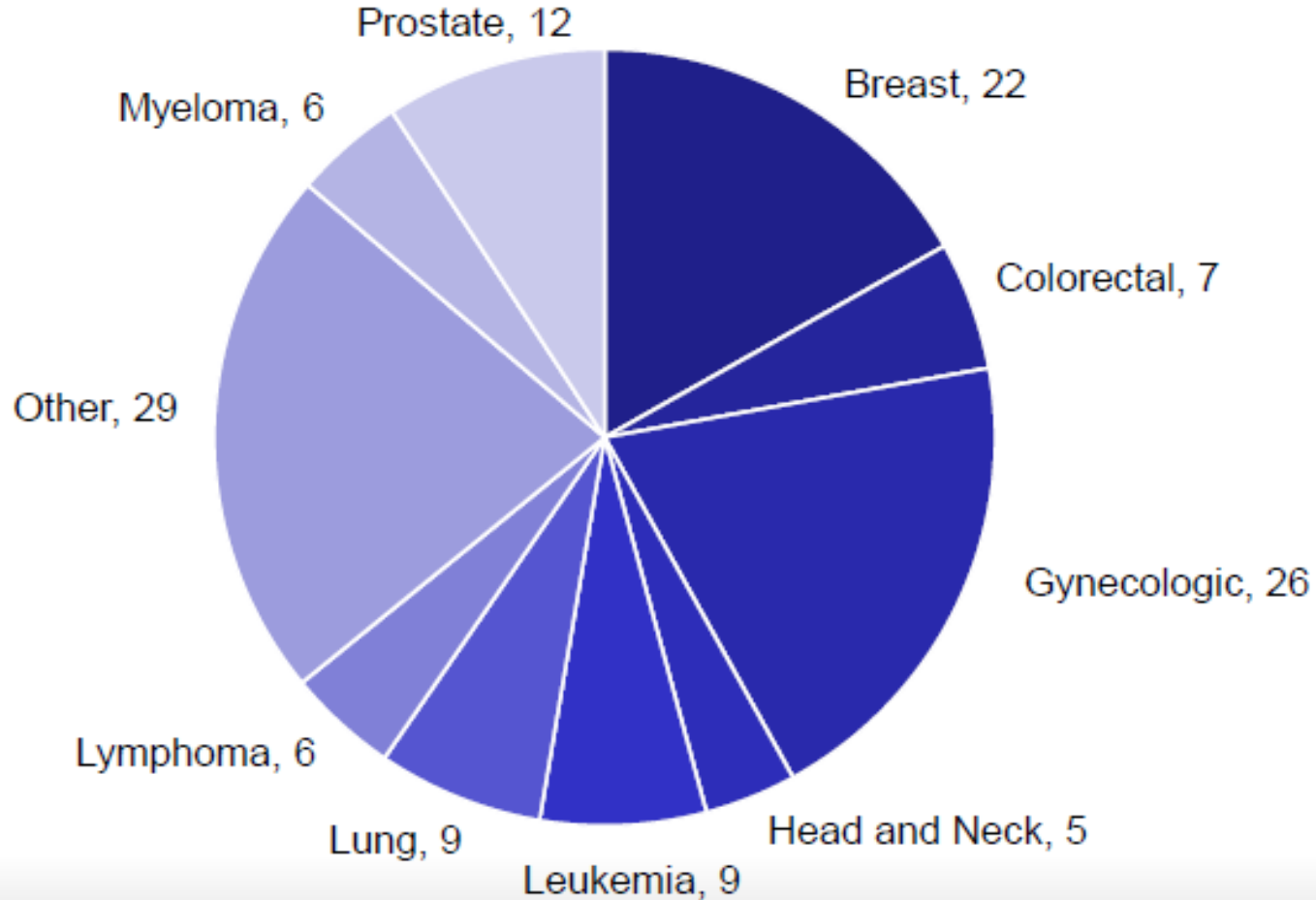


- Overall, 128 trials showed overall survival favoring the experimental arm
- These trials are estimated to have generated gains of 14.0 million life-years to patients
- Federal investment cost per life year was previously estimated at \$125/year in subset of trials\*
- Projected estimates for 2025 and 2030 increase substantially (18.4 million and 23.4 million)

*\*Unger, LeBlanc, Blanke; JAMA Onc, 2017*

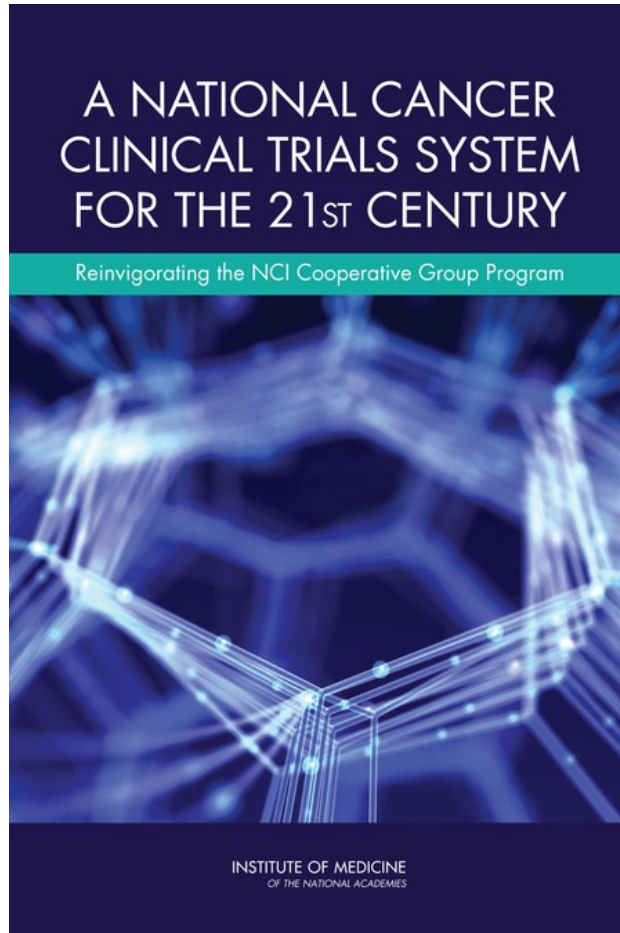
Presented by: Joseph M. Unger, PhD

# Clinical Impact



- In total, 80.4% of trials influenced care recommendations in formal guidelines

# Institute of Medicine Report (IOM)



## A NATIONAL CANCER CLINICAL TRIALS SYSTEM FOR THE 21ST CENTURY

Reinvigorating the NCI Cooperative Group Program

*Committee on Cancer Clinical Trials and the NCI  
Cooperative Group Program*

*Board on Health Care Services*

Sharyl J. Nass, Harold L. Moses, and John Mendelsohn,  
*Editors*

INSTITUTE OF MEDICINE  
OF THE NATIONAL ACADEMIES

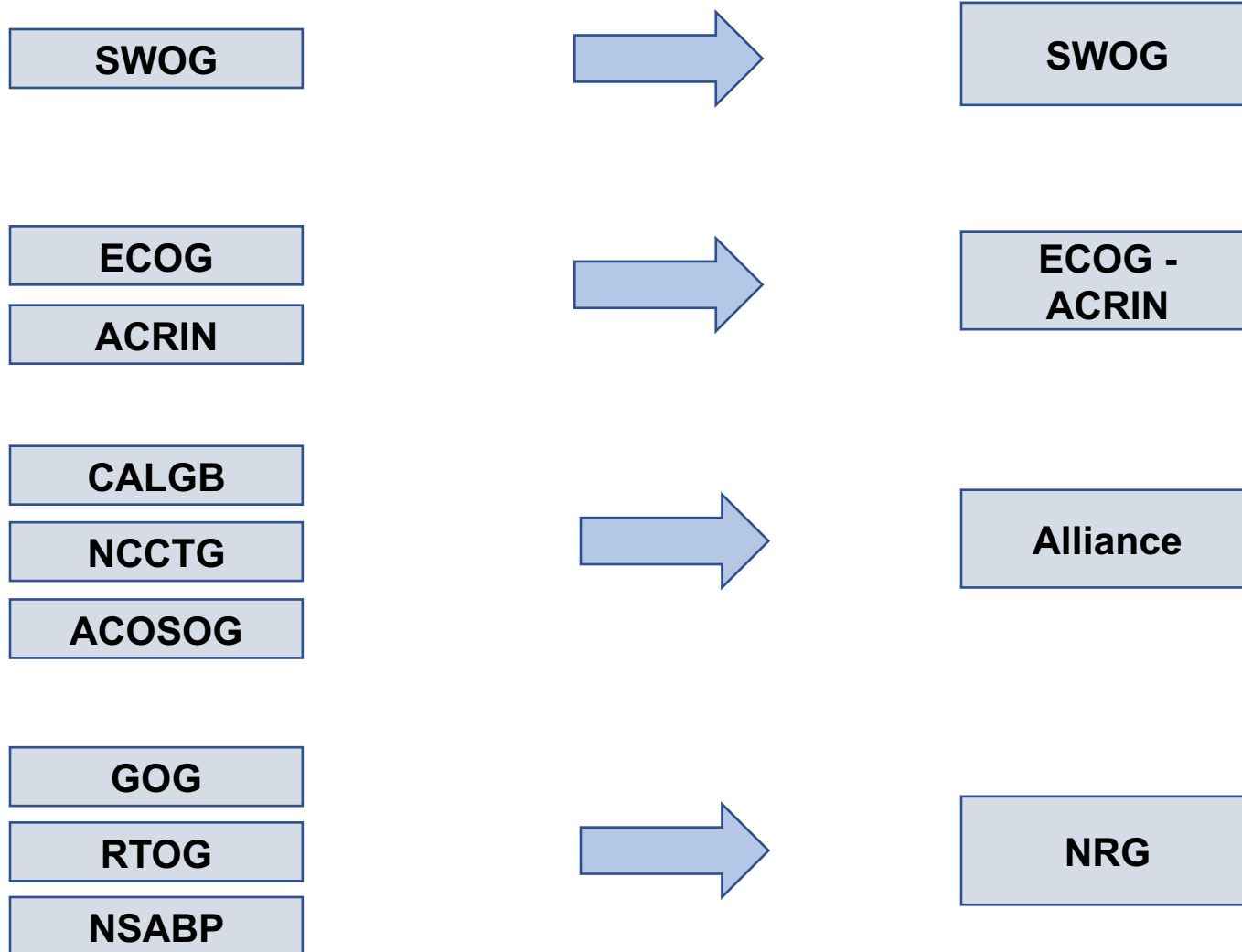
THE NATIONAL ACADEMIES PRESS  
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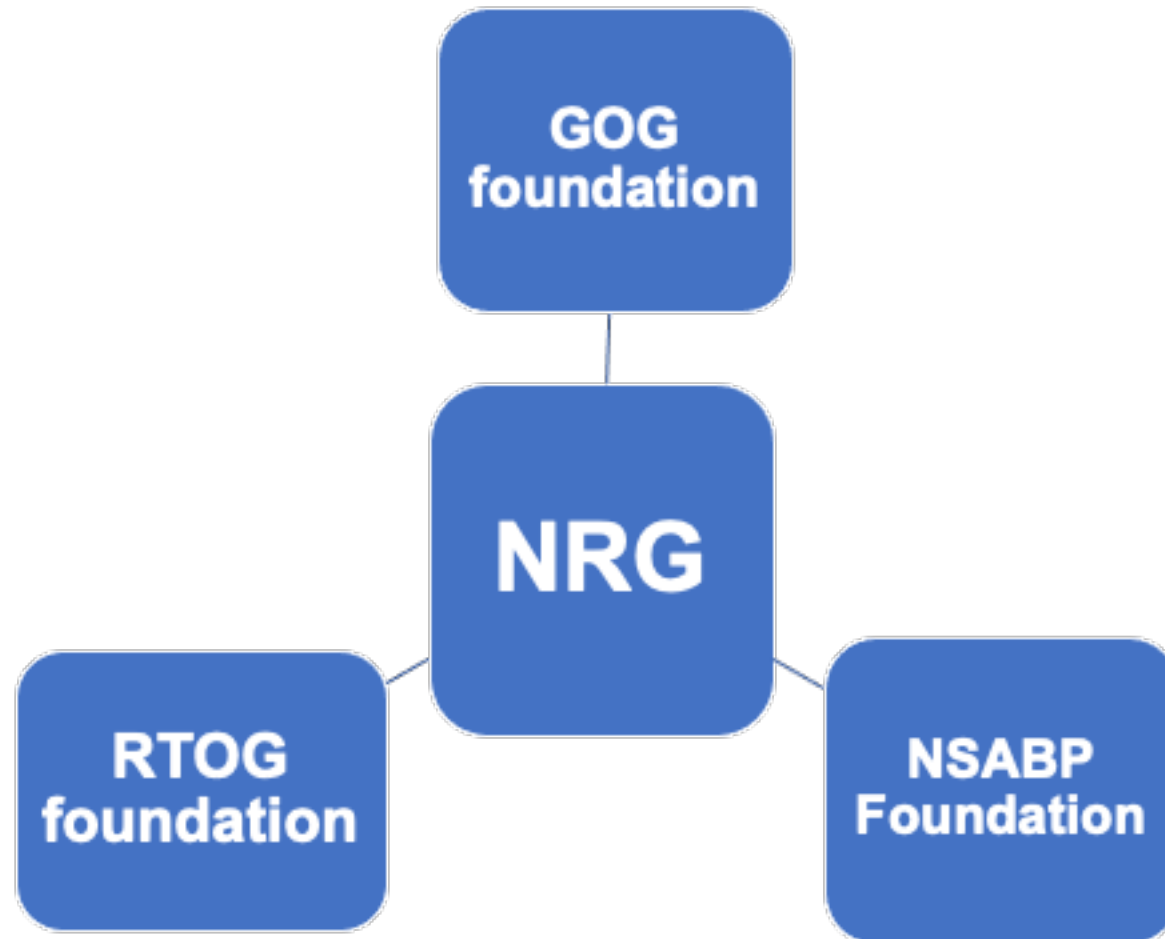
Institute of Medicine. 2010. A National Cancer Clinical Trials System for the 21st Century: Reinvigorating the NCI Cooperative Group Program. Washington, DC: The National Academies Press. <https://doi.org/10.17226/12879>.



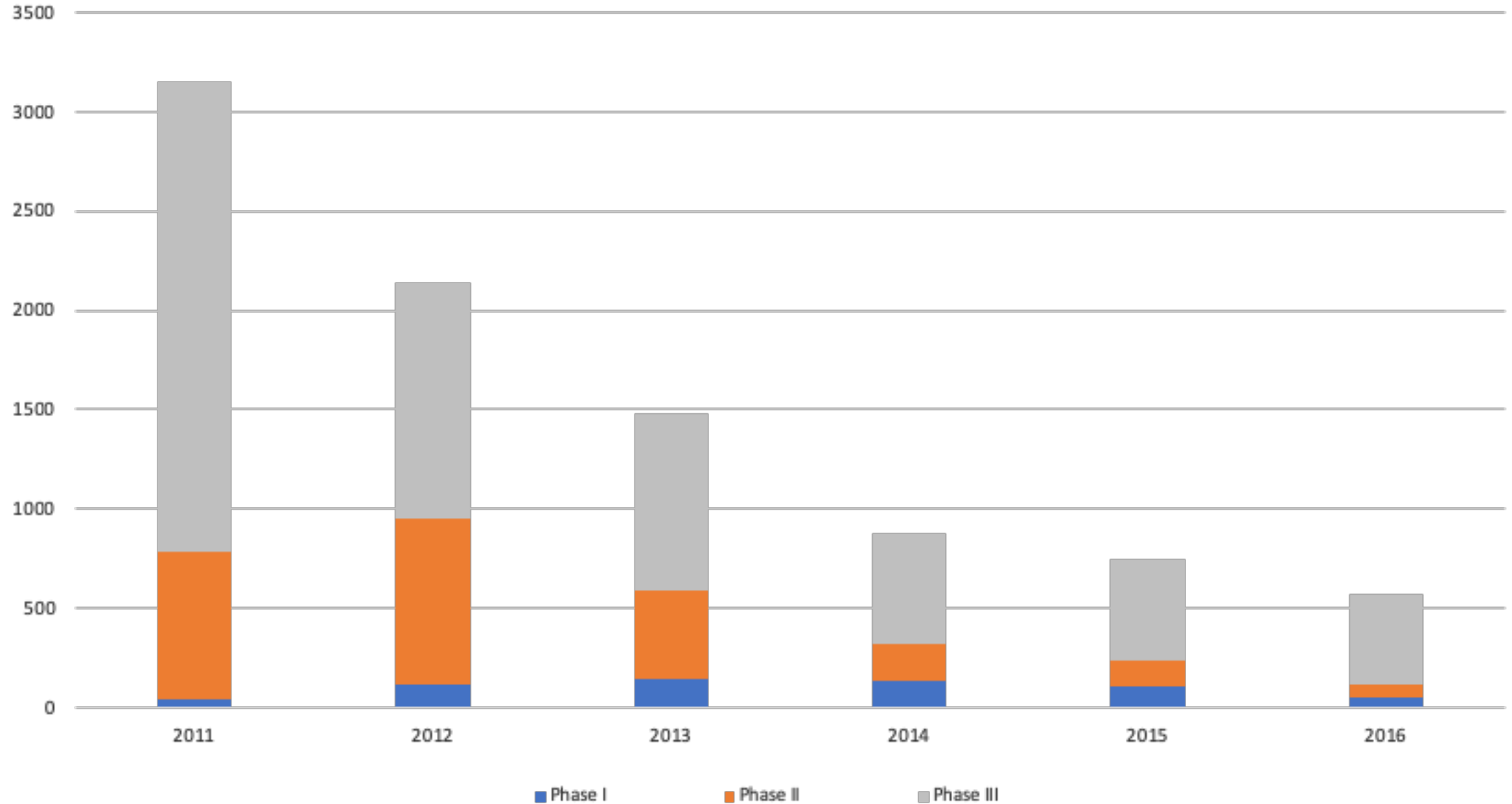
# Realignments



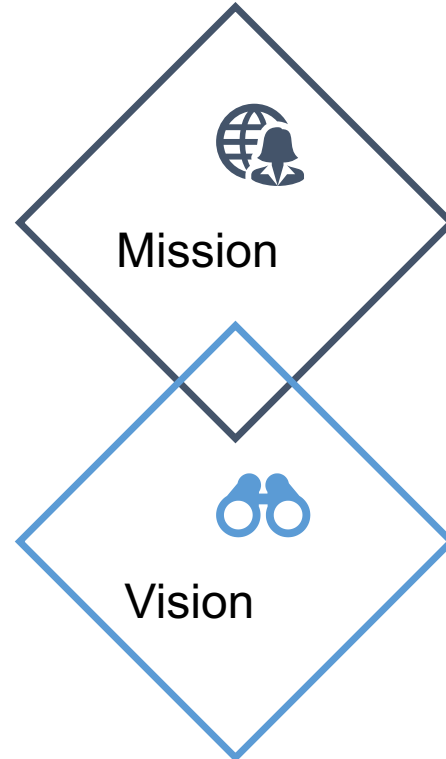
# Creation of the NRG



# Accrual to NCI GOG/NRG Phase I – III Trials



# GOG Foundation Mission/Vision



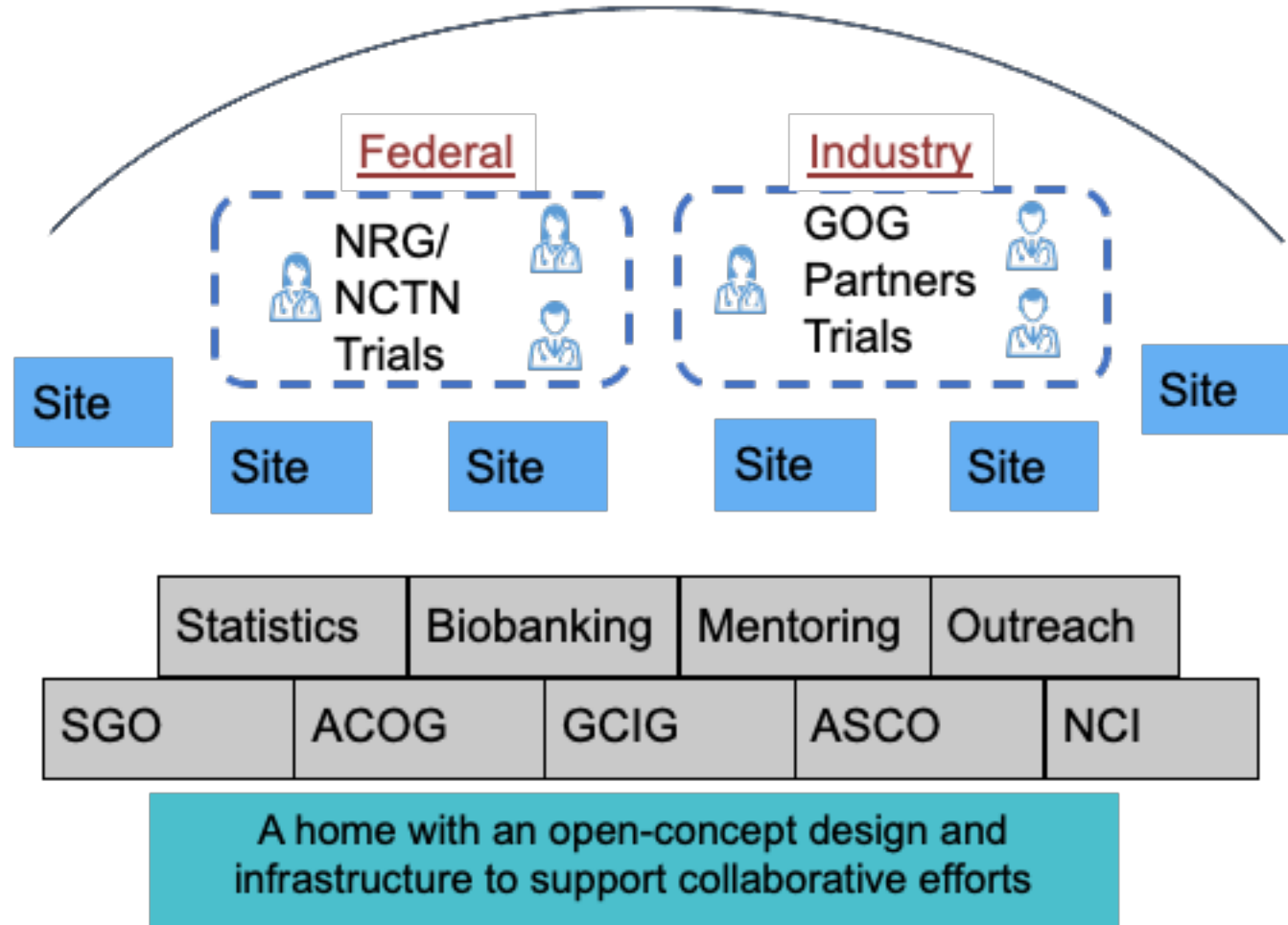
Mission

To conduct clinical and translational research that improves the prevention of, and positively impacts women affected by, gynecologic malignancies.

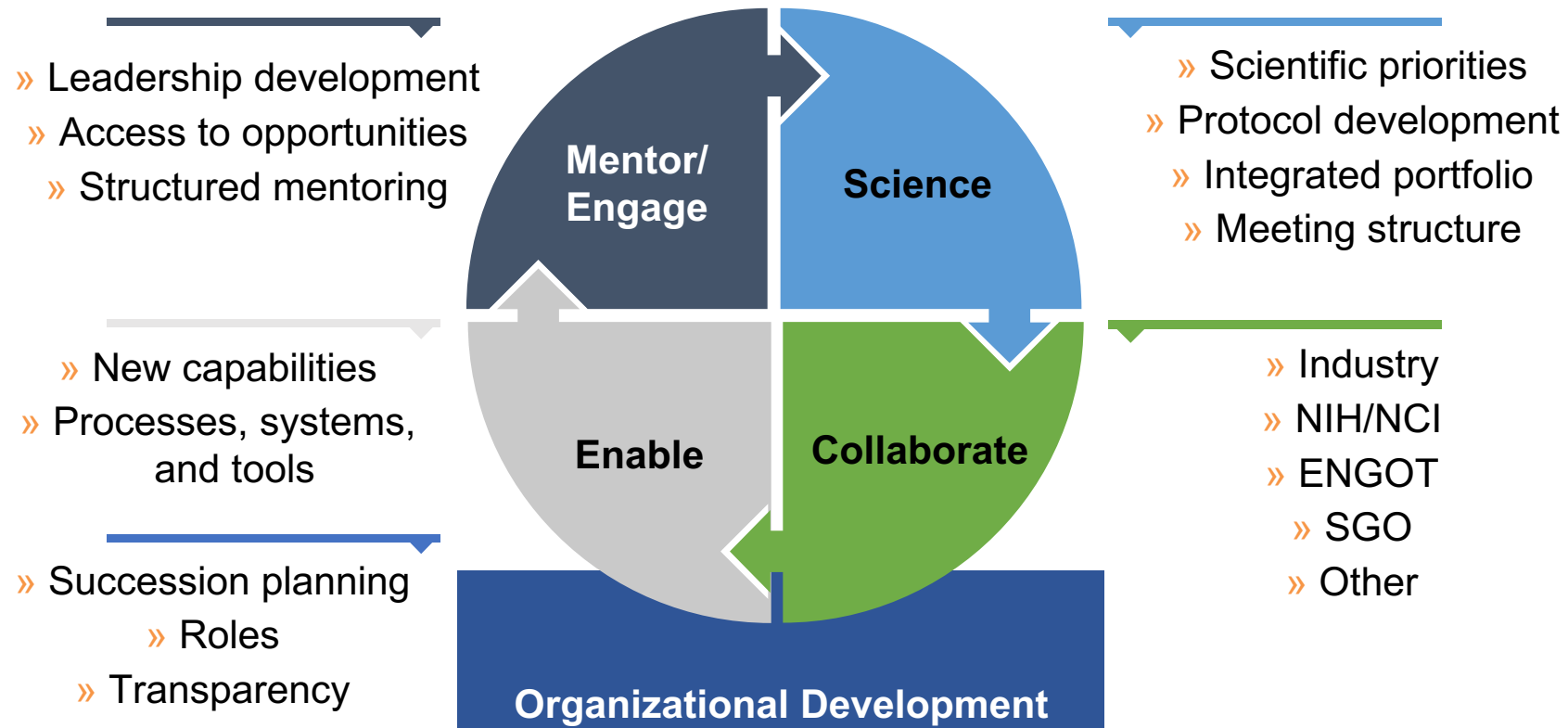
Vision

To be the premier collaborative network for transformative research in gynecologic malignancies.

# GOG Foundation

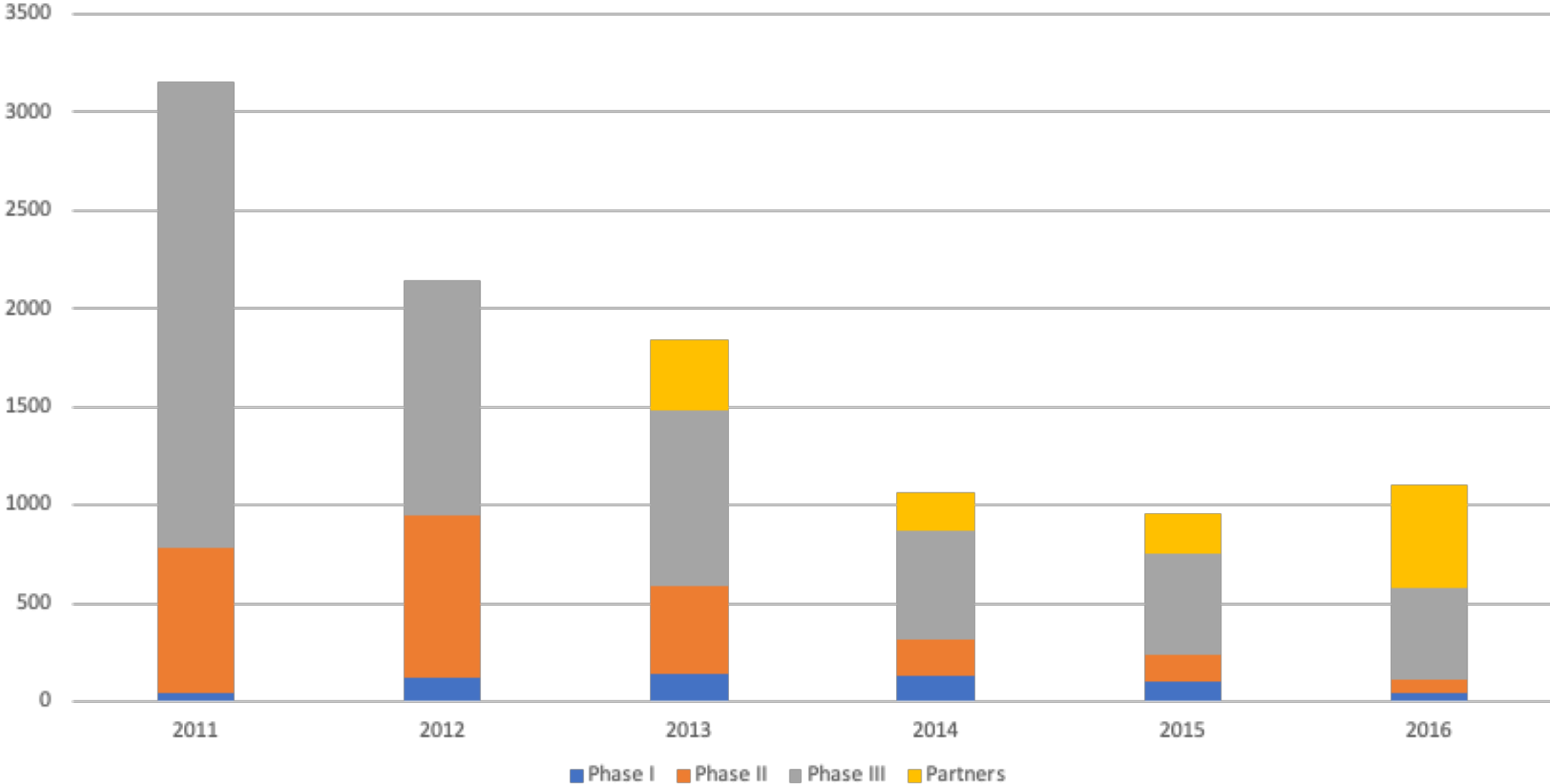


# The New GOG Foundation

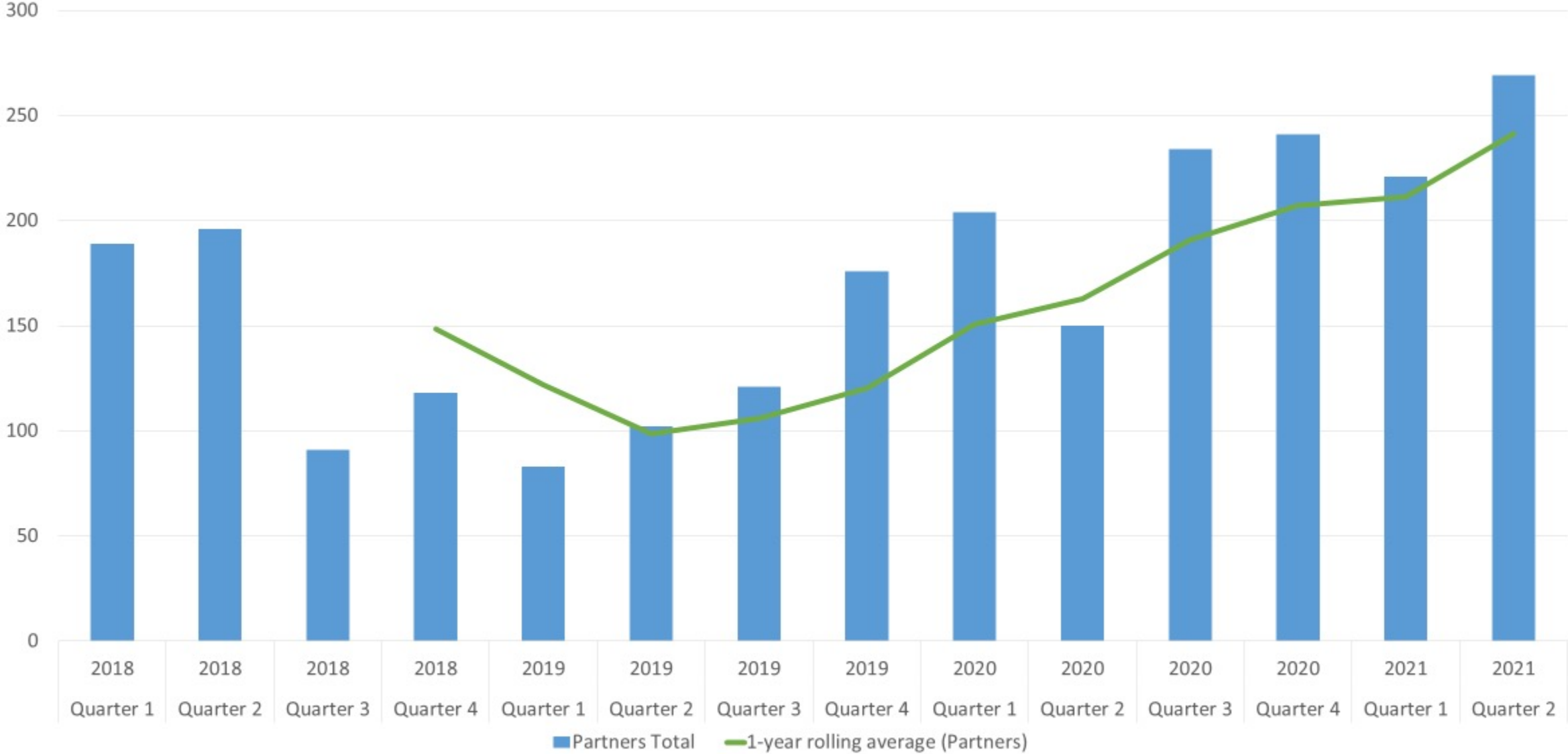


# Accrual to GOG/NRG and Partners Phase I – III Trials

Chart Title



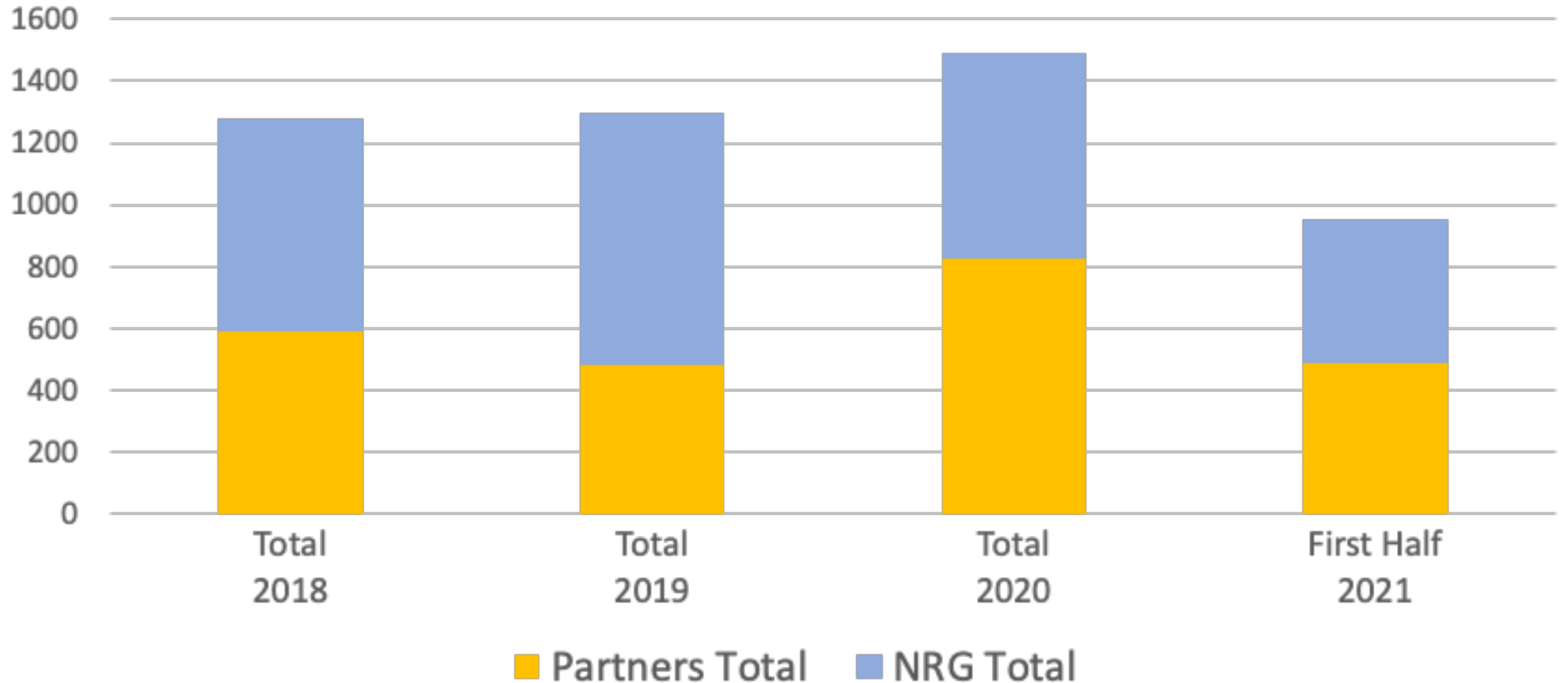
# GOG Partners Accrual



**CONFIDENTIAL**



# GOG Foundation Accrual



# Opportunities for NCI Gynecologic Cancer Clinical Trials

- Prioritize clinical research in gynecologic cancers on par with other disease sites
- Facilitate international collaboration – especially with new drugs and in rare diseases
- Facilitate real time data sharing
- Simplify layers of review to allow streamlined timelines
- Emphasize feasible research on interventions likely to be practice changing
- Support critical surgical, imaging and radiation therapy questions – trials which will not be funded by industry
- Restructure funding to adequately support trial costs