

European Network of Gynaecological Oncological Trial groups (ENGOT)

Prof. Nicoletta Colombo, ENGOT Past Chair

ENGOT HISTORY

European Network for Gynaecological Oncological Trial Groups

Founded in Berlin 2007!

Andreas du Bois



Ignace Vergote



ENGOT mission and vision

- ENGOT is a platform that guarantees that the European spirit and culture is incorporated into the medical progress in gynaecological oncology, and that all European patients and countries can participate in an active way in clinical research and progress.
- The ultimate goal is to **bring the best treatment** to gynaecological cancer patients through the best science and **enabling every patient in every European country to access a clinical trial.**

Who we are?

- ENGOT is a **network of national and regional cooperative groups**, ENGOT coordinates and promotes clinical trials within Europe on patients with gynaecological cancer.
- This coordination is particularly relevant for academic clinical trials, translational research, research on rare diseases, and for clinical trials sponsored by the industry to perform multinational studies in Europe.
- ENGOT consists of **21 groups from 33 countries**.

ENGOT MEMBERS

engot.esgo.org



21 ENGOT
GROUPS

33 COUNTRIES



Democratic structure of ENGOT

- **ENGOT Chairs** are changed every 2 years, coming each time from a different ENGOT group.
Current ENGOT Chairs (2024-2026):



Prof. Isabelle Ray-Coquard
Clinical Chair
(GINECO, France)



Elena Biagioli
Operational Chair
(MaNGO, Italy)

- **ENGOT Assembly** open for all ENGOT members participation is held twice a year in the spring and autumn.
- **ENGOT Strategic group** is formed by groups leading the ENGOT trials.



Clinical need

WHERE DO THE ENGOT TRIALS COME FROM?

part1

Idea



Discussion and refinement

In your home study group



Find potential sponsors...

...industry



Writing and prepare

Protocol writing and prepare study infrastructure



ENGOT GA or strategic group

Bring exposè with Lol of sponsorship for further discussion and refinement

...or public finding



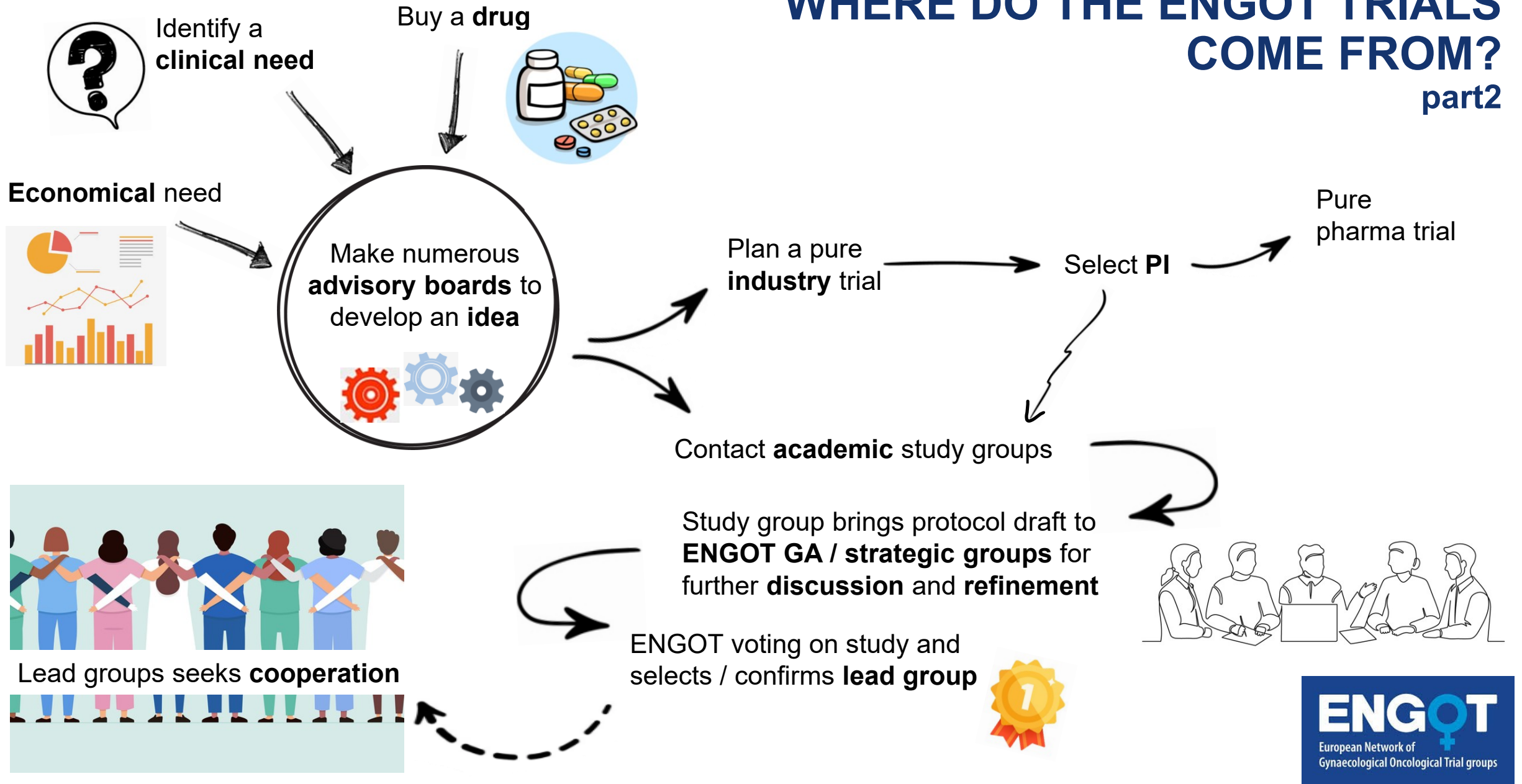
Back to ENGOT

- Final vote (number)
- Lead group
- Seeking cooperation



WHERE DO THE ENGOT TRIALS COME FROM?

part2



How do we run a trial in ENGOT?

European Network of Gynaecological Oncological Trial Groups' Requirements for Trials Between Academic Groups and Industry Partners—First Update 2015

Andreas du Bois, MD, PhD, Alexander Reuss, Eric Pujade-Lauraine, MD, Sandro Pignata, MD, Jonathan Ledermann, MD, Antonio Casado, MD, Jalid Sehouli, MD, Mansoor Mirza, MD, Nicoletta Colombo, MD, Christian Marth, MD, Els Witteveen, MD, Jose Del Campo, MD, Paula Calvert, MD, Gerassimos Aravantinos, MD, Mehmet Ali Vardar, MD, Ate G.J. van der Zee, MD, Jacob Korach, MD, Cagatay Taskiran, MD, Mathias Fehr, MD, Ros Glasspool, MD, Jacobus Pfisterer, MD, David Cibula, MD, PhD, Ignace Vergote, MD, PhD, and On behalf of the member trial groups of the European Network of Gynaecological Oncological Trial Groups (ENGOT)

Abstract: The first version of ENGOT's Requirements for Trials Between Academic Groups and Industry Partners in Europe was published 2010. This first update integrates the experiences made by the ENGOT network and the cooperative group studies while performing, analyzing, and publishing -among others - three large phase III trials. Furthermore, progress in European legislation and its impact on clinical studies in Europe have been considered in this update process.

Key Words: Academic groups, ENGOT, Requirements, Trials

Received April 14, 2015, and in revised form Month DD, YYYY.

Accepted for publication April 15, 2015.

(Int J Gynecol Cancer 2015;00: 00–00)

Roadmap for the European Network of Gynaecological Trial Groups (ENGOT) Trials

Ignace Vergote, MD, PhD, Gabriele Elser, RN, Benedicte Votan, MSc, Laura Farrelly, BSc(hons), RN, Joke De Roover, PhD, Jane Bryce, RN, MSN, Andreas du Bois, MD, PhD, and On behalf of the member trial groups of the European Network of Gynaecological Trial groups (ENGOT)

Abstract: The European Network for Gynaecological Oncological Trial groups (ENGOT) is a research network of the European Society of Gynaecological Oncology and was founded in Berlin in October 2007. Earlier, we reported on the ENGOT minimal requirements for trials between academic groups and pharmaceutical companies. In this paper, we summarize the roadmap for performing trials in the ENGOT framework. In this roadmap, we define how an ENGOT trial should be set up and discuss the following items: What are the conditions to classify a study as an ENGOT trial? What is an ENGOT protocol? How are an ENGOT protocol, informed consent (ICF), and case report form (CRF) produced? How is the center selection and feasibility performed in ENGOT trials? How are regulatory and operational tasks handled? How should a confidentiality agreement between the industry and the whole ENGOT network be negotiated? How are contracts made between the industry and ENGOT and between ENGOT groups? How are funding, insurance, and communication flow arranged in ENGOT trials? What are the requirements for conducting substudies and what are the tasks for the leading group in an ENGOT trial? A template of a confidentiality agreement, a checklist of ENGOT criteria for new study proposals, and guidelines for authorship are also provided.

Key Words: ENGOT, Clinical trials, Gynecologic oncology, Trial, Management, Academic

(Int J Gynecol Cancer 2013;23: 1339–1343)

Pre-requisites of a ENGOT trial

1. **One protocol developed and agreed** upon by the lead study group and the industry partner, reviewed, and approved by the trial steering committee.
2. Both the industry partner and the lead study group will agree on **1 common statistical analysis plan (SAP)** or produce their own SAPs.
 - In case of 2 different SAPs, the leading study group's SAP will be the basis for all academic publications.
3. **One database agreed** on by the lead study group and the industry partner.
4. **One case report form**
5. **50+% ENGOT centers**
6. **Center selection** by ENGOT groups in ENGOT countries
7. Lead group is responsible **for publication**

COOPERATION WITH PHARMA COMPANIES

ENGOT partnership with industry

Design of clinical trials

- Patient oriented
- Focus on unmet medical needs
- Academic participation and “validation” of clinical trials design is a plus for credibility
- Clinically-oriented translational research designs (Translational Research Group)
- Opportunity of helping in the development of the pipeline from the beginning (from Phase I/II Group to phase III design)

ENGOT partnership with industry

Apart of clinical trials ENGOT can:

- Organize Advisory Board meetings
 - Organize Steering committee meetings
 - Organize other kinds of meetings
 - Help with organization of industry symposia at congresses
-
- In case you are interested please contact the ENGOT office at engot@esgo.org

ENGOT PARTNERSHIP

engot.esgo.org



The European Network for Gynaecological Oncological Trial Groups Charta for Privileged Partnership

Christian Marth, ENGOT Chair, AGO-Austria, Andreas du Bois, ENGOT Vice-Chair, AGO Germany, Christian Schauer (AGO-Austria), Andreas du Bois (AGO-Germany), Antonio Casado (EORTC GCG), Ignace Vergote (BGOG), José Maria del Campo (GEICO), Athina Goudopoulou (HECOG), Eric Pujade-Lauraine (GINECO), Ilan Bruchim (ISGO), Nicoletta Colombo (ManGO), Sandro Pignata (MITO), Jonathan Ledermann (NCRI/MCR), Radoslav Chekerov (NOGGO), Mansoor Raza Mirza (NSGO), Anneke Westermann (DGOG), Ros Glasspool (SGTCG), Cagatay Taskiran (TSGO), Mathias Fehr (SAKK), and David Cibula (CEEGOG)



Cooperation with GOG and APGOT and more

Prof. Nicoletta Colombo

Date: 14 November 2024

GOG Foundation

- The Gynecologic Oncology Group, the earliest version of today's GOG Foundation, was **founded in 1970** and housed within the American College of Obstetricians Gynecologists.
- It later became an independent nonprofit organisation, providing a corporate home for NCI-sponsored cooperative group clinical trials.
- Since then, the GOG developed into a large organization with a robust trial portfolio that enjoyed extensive support from the gynecologic cancer research community.
- Dr **Thomas Herzog** is the current president



GOG PARTNERS



Consulting/Strategy



Clinical Trial Design



Site Management



Education

NRG ONCOLOGY

Advancing Research. Improving Lives.[™]



CTEP and other core focused items



OUR MISSION

To conduct clinical and translational research that positively impacts patients through the prevention and treatment of gynecologic malignancies



OUR VISION

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

ENGOT/GOG-F cooperation milestones

MAIN DOCUMENTS:

- **Joint ENGOT and GOG-F Requirements for Trials with Industry partners** published on [18 July 2019](#)
- **Non-disclosure agreement between ENGOT and GOG-F** signed on [19 November 2019](#)
- **ENGOT-GOG-F Publication Guidelines** developed in [April 2021](#)

REGULAR MEETINGS:

- **ENGOT-GOG-F Liaison Committee** meetings are held every 3 months



ENGOT/GOG-F liaison committee

Original Article

INTERNATIONAL JOURNAL OF
GYNECOLOGICAL CANCER

Joint ENGOT and GOG Foundation requirements for trials with industry partners

Ignace Vergote,^{a,1} Robert L. Coleman,² Sandro Pignata,³ Michael A. Bookman,⁴ Christian Marth,⁵ Thomas J. Herzog,⁶ Antonio Gonzalez Martin,⁷ Larry J. Copeland,⁸ On behalf of The European Network of Gynaecological Oncological Trial Groups (ENGOT) and The GOG Foundation, Inc

For numbered affiliations see end of article.

Correspondence to
Professor Ignace Vergote,
Gynaecological Oncology,

HIGHLIGHTS

- The European Network of Gynaecological Oncological Trial Groups (ENGOT) and The GOG Foundation present for the first time the joint requirements for trials with industry.
- Guidelines are presented for sponsorship, trial steering committee, and development of a protocol, database, and statistical plan.
- A roadmap is presented for site selection, contracts, press releases, publications, and a communication plan.

Int J Gynecol Cancer: first published as 10.1136/ijgc-2019-001136

Gynecologic Oncology 154 (2019) 255–258



Contents lists available at ScienceDirect

Gynecologic Oncology

journal homepage: www.elsevier.com/locate/ygyno



Clinical commentary

Joint ENGOT and GOG Foundation requirements for trials with industry partners[☆]

Ignace Vergote^{a,*}, Robert L. Coleman^{b,1}, Sandro Pignata^c, Michael A. Bookman^d, Christian Marth^e, Thomas J. Herzog^f, Antonio Gonzalez-Martin^{g,2}, Larry J. Copeland^{h,2}, on behalf of the European Network of Gynaecological Oncological Trial Groups (ENGOT) and The GOG Foundation Inc.

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^b GOG-F and Gynecologic Oncology & Reproductive Medicine, University of Texas, M.D. Anderson Cancer Center, Houston, Texas, USA

^c ENGOT/MITO Istituto Nazionale Tumori IRCCS Fondazione Pascale Napoli, Italy

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^e ENGOT/A-AGO and Obstetrics and Gynecology, Innsbruck Medical University, Innsbruck, Austria

^f GOG-F and Gynecologic Oncology, University of Cincinnati, Cincinnati, Ohio, USA

^g ENGOT/GEICO and Medical Oncology, Clinica Universidad de Navarra, Madrid, Spain

^h GOG-F and Gynecologic Oncology, Ohio State University Wexner Medical Center and JamesCare Gynecologic Oncology at Mill Run, Columbus, Ohio, USA



Trials in cooperation with GOG-F

Trials done in cooperation with GOG-F (as of September 2024):

| | |
|---------------------|----|
| TOTAL: | 45 |
| Ovarian cancer: | 21 |
| Endometrial cancer: | 14 |
| Cervical cancer: | 9 |
| Basket: | 1 |

Cooperation with APGOT

APGOT
Asia-Pacific
Gynecologic Oncology
Trials Group



engot.esgo.org



Asia-Pacific Gynecologic Oncology Trials Group (APGOT)



- **Formed in 2019** with the idea of
- Performing **clinical trials highly focused on novel drugs** with good translational research **by Asia-Pacific investigators** collaborating with pharma industry.
- Attract **more trials to AP region** for the benefit of our patients



Office in Singapore

Clinical chair

- **Keiichi Fujiwara**

Operational chair

- **Yoonhee Bae**

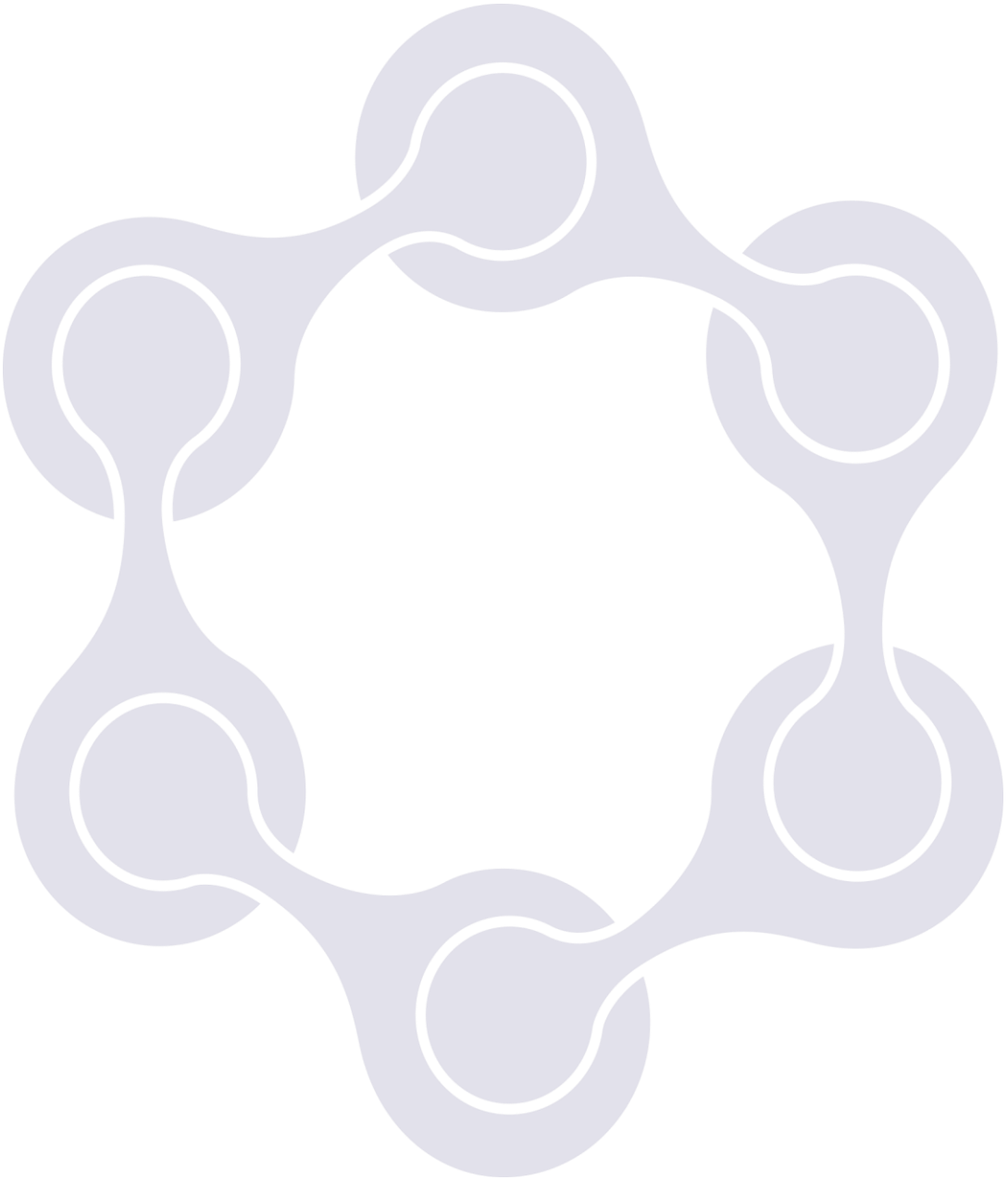
Academic groups

- GCGS (Singapore)
- KGOG (Korea)
- GOTIC (Japan)
- ANZGOG (Australia)
- Kolgotrg (India)
- SGOG (China)
- TGOG (Taiwan)
- AGOG



Trials done in cooperation with APGOT

- ENGOT-ov63/GINECO/NIRVANA
- ENGOT-ov77/GINECO/DS6000-109
- ENGOT-en13/GINECO/DOMENICA
- ENGOT-ov80/NCRI/DOVE



LACOG
LATIN AMERICAN COOPERATIVE
ONCOLOGY GROUP

LACOG MEMBERS

The **investigators** are an essential part of LACOG. We are **more than 600 members** from all over Latin America collaborating in observational studies and clinical trials. LACOG offers the possibility of Latin American investigators to develop new studies and participate in regional and international cancer trials.

ARGENTINA

38

BOLIVIA

04

BRAZIL

425

COLOMBIA

19

CHILE

12

COSTA RICA

06

CUBA

02

DOMINICAN REPUBLIC

02

ECUADOR

03

GUATEMALA

06

MEXICO

28

NICARAGUA

01

PARAGUAY

01

PERU

20

URUGUAY

04

VENEZUELA

03

TOTAL OF

620

INVESTIGATORS



LACOG INFOGRAPHIC



MEMBERS
620



COUNTRIES
17

Argentina, Brazil, Bolivia, Colombia, Chile, Costa Rica, Cuba, Dominican Republic, El Salvador, Ecuador, Guatemala, Mexico, Nicaragua, Panama, Peru, Uruguay and Venezuela



275
HOSPITALS AND
RESEARCH SITES



**MORE THAN
70**
EPIDEMIOLOGICAL
STUDIES AND
CLINICAL TRIALS



**MORE THAN
20.000**
PATIENTS
ENROLLED



**MORE THAN
135**
ABSTRACTS AND
ARTICLES
PUBLISHED



**MORE THAN
30**
EDUCATIONAL
EVENTS
PERFORMED

Infographic updated on 5/23/2024



2023 STUDY-RELATED ACTIVITIES

53
ONGOING
STUDIES

119 sites
open for recruitment
in 9 different
Latin American
countries



Argentina: 16



Brazil: 89



Colombia: 03



Chile: 02



Dom. Rep.: 01



Guatemala: 01



Mexico: 04



Peru: 02



Uruguay: 01

eCRFs
developed
6

SIV
62

Monitoring
visits
216

Signed
contracts
94

Regulatory
submissions
1271



ENGOT ACHIEVEMENTS

ENGOT achievements:

| As of Sep 2024 | |
|-------------------|------------|
| Trials per Tumour | |
| Ovarian | 92 |
| Endometrial | 29 |
| Cervical | 20 |
| Vulvar | 1 |
| Gynae basket | 10 |
| TOTAL | 152 |

| As of Sep 2024 | |
|------------------|------------|
| Trials per Model | |
| Type A | 68 |
| Type B | 5 |
| Type C | 73 |
| Type D/C | 5 |
| Type D | 1 |
| TOTAL | 152 |

| Published and presented trials as of September 2024 |
|--|
| 55 |

ENGOT patients recruitment statistics (as of March 2024)

- Ovarian: 87 trials, 30 919 patients recruited
- Endometrial: 26 trials, 6 546 patients recruited
- Cervical: 20 trials, 5 032 patients recruited
- Vulvar: 1 trial, 1 719 patients recruited
- Gyneacological/basket: 9 trials, 570 patients recruited

In total: **44 786 patients recruited**

ENGOT recruits 67% involved patients compared to other groups

Standards in primary OC - who has defined it?

| Early ovarian cancer | | |
|--------------------------------|---|-------------------------|
| Surgical staging | Maggioni, EORTC/ACTION | |
| Standard chemotherapy | EORTC/ACTION | |
| Advanced ovarian cancer | | |
| Role of cytoreductive surgery | AGO metadatabase | AGO |
| Intervall-surgery | EORTC, CHORUS, TRUST | BGOG, NCRI, AGO |
| Lymphadenectomy | LION | AGO |
| Standard chemotherapy | Carboplatin/Paclitaxel (AGO-OVAR 3) TC weekly (+/- Bev) (MITO 2/ICON 8) | AGO MITO / NCRI |
| Bevacizumab | Carboplatin/Paclitaxel/Bevacizumab (ICON7) Duration of Bev maintenance (AGO-OVAR 17) | NCRI AGO |
| PARP-Inhibitors | TCB -> Bev + Olaparib (PAOLA1) TC -> Niraparib (PRIMA) TC-> Rucaparib (Athena) | GINECO GEICO NCRI |

Standards in relapsed OC - Who has defined it?

Platinum eligible relapse

| | | |
|-------------------------------------|--|---------------------------|
| Surgery for relapsed OC | DESKTOP I-III | AGO |
| Platinum vs non-platinum | MITO 8 INNOVATYON | MITO MaNGO |
| Platinum-based therapy | Carboplatin/Paclitaxel (ICON4/AGO-OVAR 2.2) Carboplatin/Gemcitabin (AGO-OVAR 2.5) Carboplatin/PLD (CALYPSO) | NCRI/AGO AGO GINECO |
| Maintenance PARP-inhibitor | Niraparib (NOVA) Olaparib (SOLO2) PARP after PARP (OREO) | NSGO GINECO GINECO |
| Bevacizumab + Platinum combinations | Carbo/Gem/Bev (OCEANS) Carbo/Pacli/Bev (GOG218) Carbo/PLD/Bev (AGO-OVAR 2.21) Bev after Bev (MITO 16b/MaNGO ov02) | AGO MITO/MaNGO |

Standards in relapsed OC - Who has defined it?

Platinum non-eligible relapse

| | | |
|--------------------------------------|-------------------------------|--------|
| Bevacizumab | Chemo + Bevacizumab (AURELIA) | GINECO |
| ADCs | Mirvetuximab (MIRASOL) | BGOG |
| Rare histologies Low grade serous | Binimetinib (MILO) | BGOG |

Standards in CC - Who has defined it?

| | | |
|---------------------|---|----------------|
| Surgical techniques | SHAPE, FERTISS, ABRAX | ENGOT, CEEGOG |
| Role of SLN | SENTIX / SENTICOL III | CEEGOG, GINECO |
| Chemotherapy | Induction Chemo (Interlace) | NCRI |
| IO | Pembrolizumab adjuvant (KN-A18) Atezolizumab (BEAT-CC) | MITO GEICO |
| ADCs | Tistoumab Vedotin (TV 301) | BGOG |

Standards in EC - Who has defined it?

| | | |
|-------------------|--|-----------------------|
| Endocrine therapy | AI+CDK 4/6 (PALEO) | NSGO |
| IO metastatic | Dostarlimab (RUBY) Atezolizumab (ATTEND) DUO-E | NSGO ManGO BGOG |

Practice changing publications



>50 publications / congress presentations of ENGOT trials (as of May 2023)

VOLUME 32 • NUMBER 13 • MAY 1, 2014

JOURNAL OF CLINICAL ONCOLOGY

ORIGINAL REPORT

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

A Phase 3 Trial of Bevacizumab in Ovarian Cancer

Timothy J. Perren, M.D., Ann Marie Swart, M.D., Jacobus Pfisterer, M.D., Jonathan A. Ledermann, M.D., Eric Pujade-Lauraine, M.D., Gunnar Kristensen, M.D., Mark S. Carey, M.D., Philip Beale, M.D., Andrés Cervantes, M.D., Christian Kurzeder, M.D., Andreas du Bois, M.D., Jalid Sehouli, M.D., Rainer Kimmig, M.D., Anne Stähle, M.D., Fiona Collinson, M.D., Sharadah Essapen, M.D., Charlie Gourley, M.D., Alain Lortholary, M.D., Frédéric Selle, M.D., Mansoor R. Mirza, M.D., Arto Leminen, M.D., Marie Plante, M.D., Dan Stark, M.D., Wendi Qian, Ph.D., Mahesh K.B. Parmar, Ph.D., and Amit M. Oza, M.D., for the ICON7 Investigators*

Bevacizumab Combined With Chemotherapy for Platinum-Resistant Recurrent Ovarian Cancer: The AURELIA Open-Label Randomized Phase III Trial

Eric Pujade-Lauraine, Felix Hilpert, Béatrice Weber, Alexander Reuss, Andres Poveda, Gunnar Kristensen, Roberto Sorio, Ignace Vergote, Petronella Witteveen, Aristotelis Bamias, Deolinda Pereira, Pauline Wimberger, Ana Oaknin, Mansoor Raza Mirza, Philippe Follana, David Bollag, and Isabelle Ray-Coquard

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Niraparib Maintenance Therapy in Platinum-Sensitive, Recurrent Ovarian Cancer

M.R. Mirza, B.J. Monk, J. Herrstedt, A.M. Oza, S. Mahner, A. Redondo, M. Fabbro, J.A. Ledermann, D. Lorusso, I. Vergote, N.E. Ben-Baruch, C. Marth, R. Mađry, R.D. Christensen, J.S. Berek, A. Dørum, A.V. Tinker, A. du Bois, A. González-Martín, P. Follana, B. Benigno, P. Rosenberg, L. Gilbert, B.J. Rimel, J. Buscema, J.P. Balsler, S. Agarwal, and U.A. Matulonis, for the ENGOT-OV16/NOVA Investigators*

ORIGINAL ARTICLE

A Randomized Trial of Lymphadenectomy in Patients with Advanced Ovarian Neoplasms

P. Harter, J. Sehouli, D. Lorusso, A. Reuss, I. Vergote, C. Marth, J.-W. Kim, F. Raspagliesi, B. Lampe, G. Aletti, W. Meier, D. Cibula, A. Mustea, S. Mahner, I.B. Runnebaum, B. Schmalfeldt, A. Burges, R. Kimmig, G. Scambia, S. Gregg, F. Hilpert, A. Hasenburg, P. Hillemanns, G. Giorda, I. von Leffern, C. Schade-Brittinger, U. Wagner, and A. du Bois

ORIGINAL ARTICLE

Niraparib in Patients with Newly Diagnosed Advanced Ovarian Cancer

A. González-Martín, B. Pothuri, I. Vergote, R. DePont Christensen, W. Graybill, M.R. Mirza, C. McCormick, D. Lorusso, P. Hoskins, G. Freyer, K. Baumann, K. Jardon, A. Redondo, R.G. Moore, C. Vulsteke, R.E. O'Ceirbhail, B. Lund, F. Backes, P. Barretina-Ginesta, A.F. Haggerty, M.J. Rubio-Pérez, M.S. Shahin, G. Mangili, W.H. Bradley, I. Bruchim, K. Sun, I.A. Malinowska, Y. Li, D. Gupta, and B.J. Monk, for the PRIMA/ENGOT-OV26/GOG-3012 Investigators*



Olaparib tablets as maintenance therapy in platinum-sensitive, relapsed ovarian cancer mutation (SOLO2/ENGOT-Ov21): a double-blind randomised, placebo-controlled, phase 3 trial

Eric Pujade-Lauraine, Jonathan A Ledermann, Frédéric Selle, Val Gebski, Richard T Penson, Amit M Oza, Ja Andrés Poveda, Sandro Pignata, Michael Friedlander, Nicoletta Colombo, Philipp Harter, Keiichi Fujiwara, Joyce Liu, Elizabeth S Lowe, Ralph Bloomfield, Patricia Pautier, the SOLO2/ENGOT-Ov21 investigators*

ENGOT INITIATIVES



ENGOT active initiatives

Translational
Research
(Biobank)

Rare Tumours

Early Drug
Development
(Phase I/II)

Gyneacological
Cancer Academy
(GCA)

Future Lead
Investigators
(FLI)

Gynaecological Cancer Academy workshop (GCA)

- Educational programme aiming at the development of next generation of leaders within the clinical trial community.
- Young investigators learn how to design a trial, cooperate and conduct an analysis within the ENGOT framework.
- 13 GCA editions since 2013
- Current workshop: **November 13-15, 2024**, Stresa, Italy
- Expected outcome: research ideas that will be further developed.



ENGOT WEBINARS FOR CLINICAL COORDINATORS

engot.esgo.org



- 6 webinars held between May and November 2021
- Educational event for clinical project managers
- The topics were concentrated on organizational aspects of the clinical trials but also on the scientific content related to single tumour types

How to select a lead group for an ENGOT trial ?



The lead group is appointed/confirmed by the ENGOT assembly

Pre-requisite: Study Group wants to lead the study and has the capability and experience to lead a major trial (eg. Co-lead) and/or has collaborated in multiple ENGOT trials

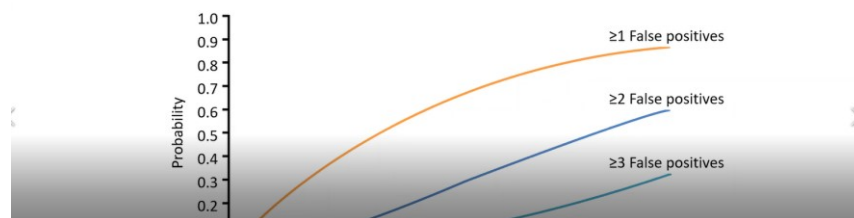
Strong factors to be considered (in declining order):

- A group/PI initiated the idea and developed it

STATISTICS AND MEDICINE

The Challenge of Subgroup Analyses — Reporting without Distorting

Stephen W. Lagakos, Ph.D.



White Paper in budgeting a trial



ENGOT decided it was crucial to establish guidelines for budgeting a trial, ensuring every Clinical Trial within ENGOT has an appropriate budget and that ENGOT requirements to industry are the same independently of the group/country.

This white paper focuses on Models A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T, U, V, W, X, Y, Z. **Lead ENGOT Group (LEG) and who is the funding partner.** Nowadays nearly all trials are funded by industry. Pure academic trials without industry funding are not covered here although they are also important.

First step:

Contract with pharmaceutical industry



Main - content: **legal entity description**, provision of financial support, provision of IMP, **Data ownership, Reports, SAE and SUSAR Reporting, Right to audit, Publication rights**
Keep in mind:

- **Save your idea**; before you present your data to the industry be sure that they sign at least a CDA (Confidentiality Disclosure Agreement).
- A **letter of intent (LOI)** should be signed by industry
- Calculate the **workload** for all the reports and additional tasks the contract partner is expecting from you. A detailed list of **roles and responsibilities** will help you to keep the overview
- Data will be used for **registrational purposes**. A higher workload and more financial support is needed.

ENGOT SUPPORT OF PATIENTS

ENGOT-ENGAGE webinar on clinical trials

- Educational event for patients, representatives of Patient advocacy groups
- 5 webinars held in 2022/2023, all recorded and still available
- The topics were presented to patients in a simpler/lay language

The screenshot displays a Zoom webinar interface. The main content is a PowerPoint slide titled "Type of clinical trials" with a sub-section "Adaptive trials". The slide features a flowchart illustrating the process of an adaptive trial. It starts with "All Patients" being stratified into "Subgroup S" (including one-third of enrolled patients) and "Subgroup T" (including two-thirds of enrolled patients). Each subgroup is randomized to either "Treatment (50%)" or "Control (50%)", resulting in n_0 patients and d_0 events in each. An "Interim Analysis" is conducted. Three decision paths are shown: 1) "If no response in both groups, stop for futility" (leading to a red box); 2) "If response in both groups, continue as planned with both subgroups" (leading to an orange box for "Final Analysis" labeled "Perform a closed test of subgroup S"); 3) "If response only in subgroup S, continue with subgroup S only (drop subgroup T) and randomly assign all remaining patients to subgroup S and increase the number of events" (leading to the same orange box). The slide is attributed to "Bhatt, Nejm, 2016". The Zoom interface shows a video call with four participants on the right, a taskbar at the bottom with the time 18:15 on 02/09/2019, and a YouTube player interface at the bottom with the video title "Clinical Trial Webinar" and 67 subscribers.

<https://engot.esgo.org/>



ENGOT
European Network of
Gynaecological Oncological Trial groups

ENGOT MEETING
9-10 March, 2023
Milan, Italy

ENGOT
European Network of
Gynaecological Oncological Trial groups

A large, abstract graphic consisting of many thin, overlapping blue lines that form a wavy, ribbon-like shape across the top half of the slide. The lines are more densely packed in some areas, creating a sense of depth and movement.

THANK YOU!

ENGOT

European Network of
Gynaecological Oncological Trial groups

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