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The European Network of Gynecological Oncological Trial Groups

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The European Network of Gynecological Oncological Trial Groups (ENGOT) is a research network of 17 European academic gynecological cancer trial groups. ENGOT coordinates and promotes clinical trials within Europe in patients with gynecological cancer. In 2010 ENGOT published the requirements for trials between the academic ENGOT and pharmaceutical companies. This has led to a number of new ENGOT trials performed in collaboration with the industry and better coordination of gynecological cancer trials in Europe. Further goals for ENGOT are to increase translational research in ENGOT trials and to develop more trials in cervical cancer, endometrial cancer and in rare gynecological cancers.

Keywords: academic research • ENGOT • gynecological cancer

The European Network of Gynecological Oncological Trial Groups (ENGOT) is a research network of the European Society of Gynecological Oncology (ESGO) and was founded in Berlin, Germany, in October 2007. Currently, 17 European gynecological cancer trial groups are members of ENGOT (Box 1).

As a network of European national or regional clinical trial units, ENGOT coordinates and promotes clinical trials within Europe in patients with gynecological cancer. This coordination is particularly relevant for academic trials, translational research, research on rare diseases and for clinical trials sponsored by the industry to perform multinational studies in Europe. ENGOT also stimulates young investigators to be involved in clinical trials and promotes the creation of new clinical study groups in parts of Europe where ENGOT is not yet represented.

In 2010 ENGOT published the requirements for trials between the academic ENGOT and pharmaceutical companies [1]. In this paper ENGOT defined the following items: development of the protocol, statistical analysis, the ownership of the database, the development of case report forms, sponsorship of the trial, monitoring of the trial, publication rules, participation of investigators from non-European countries, appointment of the independent data monitoring committee and the standard operating procedures for trials between ENGOT and the industry. The ENGOT met four times and decided what the minimal criteria should be to classify a trial with the industry as academic. Once a consensus was reached within ENGOT, a 1-day meeting with representatives from the pharmaceutical companies with oncological products was organized. All remarks of the industry were noted and during a fifth ENGOT meeting a consensus was reached and published.

ENGOT is currently working on a roadmap for trials performed in Europe. The aim of this roadmap is to facilitate cooperation between the different ENGOT groups, to clarify the role of the leading group, to determine the publication rules, to provide templates for intergroup contracts and contracts between academic groups and the pharmaceutical industry and to determine the communication flow during ENGOT trials. All topics which will be included in the roadmap are presented in Box 2. This

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Box 1. Gynecological cancer trial groups represented in European Network of Gynecological Oncological Trial Groups.

Study (country)

- AGO (Germany)
- A-AGO (Austria)
- BGOG (Belgium)
- DGCG (Denmark)
- DGOG (The Netherlands)
- EORTC-GCG (Europe)
- GEICO (Spain)
- GINECO (France)
- HECOG (Greece)
- ICORG (Ireland)
- MANGO (Italy)
- MITO (Italy)
- NCRI (UK)
- NOGGO (Germany)
- NSGO (Scandinavia)
- SGCTG (Scotland)
- TRGOG (Turkey)

Box 2. Topics of the new roadmap for European Network of Gynecological Oncological Trial Groups trials.

- Requirements for how to become an ENGOT group
- Development of informed consent
- Case report forms
- Common data elements
- Site selection and feasibility
- Handling of regulatory affairs
- Appointments for operational tasks
- Minimal requirements for central monitoring
- Confidentiality agreements for ENGOT groups
- Template for contract between ENGOT groups and institutions
- Insurance
- Requirements for conducting substudies in an ENGOT trial
- Communication flow during the ENGOT trial
- Tasks for the leading group of an ENGOT trial

ENGOT: European Network of Gynecological Oncological Trial Groups.

will facilitate the performance of ENGOT studies and also improve the speed of starting ENGOT trials.

ENGOT has been quite successful in developing new trials in Europe (Box 3). Although ENGOT has only existed for 4 years, the network has already been able to set up 11 trials in the field of gynecological cancer. In addition, one trial (ENGOT-ov3) recently completed accrual and as of today more than 2500 patients were included in ENGOT trials. A number of other new trials are in development in ovarian, endometrial and cervical cancer and will be initiated in 2011 or 2012. Further goals for ENGOT are to increase translational research in ENGOT trials and to develop more trials in cervical cancer, endometrial cancer and rare gynecological cancers.

In conclusion, ENGOT has succeeded in its goal to improve the collaboration between European gynecological cancer trial groups and to initiate trials. These trials have been accruing rapidly with good quality of

data. ENGOT will further focus on setting up new regional national groups, mainly in Eastern Europe where ENGOT is currently not yet represented.

Future perspective

In the coming decade innovative Phase I and II trials and large Phase III trials will be needed to establish the role of new treatment modalities in gynecological cancer. The role of academic groups in order to safeguard the scientific rationale and appropriate accrual of these trials will be essential to achieve these goals. ENGOT will play a key role in clinical and translational research in patients with gynecological cancer in Europe.

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Executive summary

- European Network of Gynecological Oncological Trial groups (ENGOT) is a research network of 17 European academic gynecological cancer trial groups.
- ENGOT coordinates and promotes clinical trials within Europe in patients with gynecological cancer.
- ENGOT developed a model for cooperation between academic research groups and the industry to perform clinical trials. In this model, amongst others, the following topics are stipulated: development of the protocol, statistical analysis, ownership of the database, sponsorship of the trial, monitoring of the trial, publication rules.
- Although ENGOT has only existed for 4 years, the network has already been able to set up 11 trials in the field of gynecological cancer. In addition, more than 2500 patients were already included in ENGOT trials.
- Further goals for ENGOT are to increase translational research in ENGOT trials and to develop more trials in cervical cancer, endometrial cancer and rare gynecological cancers.
- ENGOT will further focus on setting up new regional national groups in Eastern Europe, where ENGOT is currently not yet represented.

Box 3. Open or recently closed European Network of Gynecological Oncological Trial Groups trials.**ENGOT-OV1/MITO-8**

■ Randomized trial of pegylated liposomal doxorubicin (PLD) followed by paclitaxel–carboplatin versus paclitaxel–carboplatin followed by PLD in intermediate platin-sensitive recurrent ovarian cancer (MITO, MaNGO, BGOG, AGO). Recruitment goal: 253 patients.

ENGOT-OV2/BGOG (Trinova 3)

■ Randomized Phase III comparing paclitaxel–carboplatin with or without AMG 386 as first-line therapy in stage III or IV ovarian, peritoneal or fallopian tube cancer (BGOG, AGO, A-AGO, DGOG, GEICO, GINECO, HECOG, MaNGO, MITO, NSGO). Recruitment goal: 2000.

ENGOT-OV3/GINECO (Aurelia)

■ Randomized trial comparing chemotherapy with or without bevacizumab in recurrent platin-resistant ovarian cancer (GINECO, AGO, BGOG, DGCG, GEICO, HECOG, MITO, NSGO). The trial closed recently with 360 patients accrued.

ENGOT-OV4/NOGGO (Expression)

■ Perceptions and clinical expectations of patients with ovarian cancer: a European survey (NOGGO, AGO, BGOG, MITO, MaNGO, NCRI, GINECO, GEICO). Recruitment status: 1276 patients.

ENGOT-OV5/MaNGO (Inovatyon)

■ Phase III multicenter, randomized study of trabectedin plus PLD versus carboplatin plus PLD in patients with ovarian cancer progressing within 6–12 months of last platinum (MaNGO, AGO, BGOG, EORTC, NOGGO, NSGO, NCRI, HECOG, GEICO). Recruitment goal: 588 patients.

ENGOT-OV6/A-AGO (Trinova-2)

■ A Phase III, randomized, double-blind trial of PLD plus AMG 386 or placebo in women with recurrent, partially platinum-sensitive or platinum-resistant epithelial ovarian, primary peritoneal or fallopian tube cancer (A-AGO, AGO, BGOG, DGCG, MITO, MaNGO, NCRI). Recruitment goal: 396 patients.

ENGOT-OV9/NOGGO

■ A randomized, double-blind, placebo controlled, multicenter Phase II study to assess the efficacy and safety of sorafenib added to standard treatment with topotecan in patients with platinum-resistant recurrent ovarian cancer (NOGGO-AGO). Recruitment goal: 184 patients.

ENGOT-OV10/MITO-7

■ First-line weekly carboplatin and paclitaxel versus three-weekly carboplatin and paclitaxel in patients with ovarian cancer (MITO, MaNGO, GINECO, HECOG). Recruitment goal: 800 patients.

ENGOT-OV12/MITO-12

■ Pathway to the diagnosis of ovarian cancer: an observational, retrospective, multicenter trial (MITO, BGOG, MaNGO). Recruitment status: 230 patients.

ENGOT-OV13/ICON8

■ An international, multistage, randomized trial of dose-fractionated chemotherapy compared with standard three-weekly chemotherapy, following immediate primary surgery or as part of delayed primary surgery, for women with newly diagnosed epithelial ovarian cancer (NCRI, GEICO, ICORG). Recruitment goal: 1485 patients.

ENGOT-EN2/DGCG

■ A Phase III trial of postoperative chemotherapy or no further treatment for patients with node-negative stage I/II intermediate or high-risk endometrial cancer (DGCG, AGO, A-AGO, BGOG, EORTC, MaNGO, NSGO). Recruitment goal: 678 patients.

ENGOT-V1/DGOG- GROINSS-VII

■ Observational study to define the efficacy of radiotherapy in patients with vulvar carcinoma with a metastatic sentinel node (DGOG, BGOG, NCRI, NSGO). Recruitment goal: 135 patients with involved sentinel nodes.

Data taken from [101].

Financial & competing interests disclosure

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■ **Website**

- 101 ENGOT trials.
www.esgo.org/engot/Pages/ENGOTTrials.aspx