



## ENGOT ONGOING TRIALS – STATUS October 2015

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### ENGOT-ov-1/MITO-8 – Leading Group: MITO

*Randomized trial of PLD followed by paclitaxel/carboplatin versus paclitaxel/carboplatin followed by PLD in intermediate platin sensitive recurrent ovarian cancer (S. Pignata)*

Number of patient accrued: 215

Number of patients needed: 253

Participating member groups: [MITO](#) - [MaNGO](#) - [BGOG](#) - [AGO Germany](#) (no longer recruiting)

### ENGOT- ov5 - Leading group: MaNGO

*Phase III multicenter, randomized study of Trabectedin plus Pegylated Liposomal Doxorubicin (PLD) versus Carboplatin plus PLD in patients with ovarian cancer progressing within 6-12 months of last platinum (N. Colombo) / study reactivated*

Number of patient accrued: 229 randomised / recruitment continues

Number of patients needed: 588

Participating members: [AGO](#), [MaNGO](#), [EORTC](#), [NOGGO](#), [BGOG](#), [NSGO](#), [GEICO](#), [NCRI](#), [ECOG](#)

### ENGOT-ov6 - Leading group: A-AGA

*A phase 3, Randomized, Double-Blind trial of Pegylated Liposomal Doxorubicin (PLD) Plus AMG 386 or Placebo in Women with Recurrent, Partially Platinum Sensitive or Resistant Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Cancer (Ch. Marth)*

Number of patients accrued: 223

Number of patients needed: 380

Participating member groups: [AGO](#), [A-AGO](#), [BGOG](#), [DGCG](#), [MITO](#), [MaNGO](#), [NCRI](#), [Gineco](#)

### ENGOT-ov7 - GINECO / Alienor

*Randomized open label Phase II trial of Bevacizumab plus weekly Paclitaxel followed by Bevacizumab monotherapy maintenance versus weekly paclitaxel followed by observation in patients with relapsed sex-cord-stromal tumors.*

Number of patient accrued: 42 / recruitment continues

Number of patients needed: 60

Participating members: [Gineco](#) (leading group), [AGO](#)

### ENGOT-ov8 - Leading group: NOGGO

*Single arm multicenter phase-II trial for Catumaxomab and chemotherapy in patients with recurrent ovarian cancer to investigate the feasibility and clinical activity of initial IP Catumaxomab followed by chemotherapy regimens. (J. Sehouli) / was stopped*

Date of activation: 2012

Number of patient Number of patient accrued: 235

Number of patients needed: 51

Participating members: [NOGGO](#), [AGO](#), [A-AGO](#), [BGOG](#), [MaNGO](#), [NSGO](#)

**ENGOT-ov11 - Leading group: BGOG**

*A multinational, Randomised, Open-label, Phase 3 Study of MEK162 vs. Physician's Choice Chemotherapy in Patients with Recurrent of Persistent low-grade Serous Carcinomas of the Ovary, Fallopian Tube or Primary Peritoneum. (I. Vergote). / Activated*

Number of patient accrued: 235 / recruitment ongoing

Number of patients needed: 360

Leading group: BGOG

Groups interested: [MITO](#), [MaNGO](#), [Gineco](#), [NOGGO](#), [AGO](#), [A-AGO](#), [NSGO](#), [NOGGO](#), [ISGO](#)

**ENGOT-ov 13/ICON8 - Leading group: NCRI**

*An international multi-stage randomised trial of dose-fractionated chemotherapy compared to standard three-weekly chemotherapy, following immediate primary surgery or as part of delayed primary surgery, for women with newly diagnosed epithelial ovarian cancer (J. Ledermann). / Recruitment is well running*

Number of patient accrued: 1566

Number of patients needed: 1485

Participating members: [NCRI](#), [GEICO](#), [ICORG](#), [SCOTROC](#), KGOG and Mexico

**ENGOT-ov 13/ICON8b - Leading group: NCRI**

*A study of bevacizumab and weekly dose-dense paclitaxel in ovarian cancer*

Number of patient accrued: 1

Number of patients needed: 1170

**ENGOT-ov14/ AGO-OVAR 2.20 - Leading group: AGO**

*A randomised phase II study comparing Caelyx or Topotecan or Gemcitabine with or without Pertuzumab in patients low HER3 mRNA platin-resistant ovarian cancer. (Christian Kurzeder). /*

Date of activation: 2012 / recruitment closed in September 2014

Number of patient accrued: 156

Number of patients needed: 220

Participating members: [AGO](#), [A-AGO](#), [NSGO](#), [Gineco](#), [GEICO](#), [BGOG](#), [MaNGO](#), TRSGO

**ENGOT-ov15/AGO-OVAR 17 - Leading group: AGO**

*A prospective randomised Phase III trial to evaluate optimal treatment duration of first-line bevacizumab in combination with carboplatin and paclitaxel in patients with primary epithelial ovarian, fallopian tube or peritoneal cancer. The BOOST (Bevacizumab Ovarian Optimum Standard Treatment) Trial. (J. Pfisterer)*

Number of patient accrued: 927 / Recruitment Completed. Results expected in 2017

Number of patients needed: 900

Participating members: [AGO](#), [Gineco](#), [NSGO](#)

**ENGOT-ov16/NOVA - Leading group: NSGO**

*Maintenance with Niraparib Versus Placebo in Patients with Platinum Sensitive ovarian Cancer (Manour R. Mirza). / Recruitment is well running*

Number of patient accrued: 553 / Recruitment ongoing

Number of patients needed: 360

Participating members: [AGO](#), [A-AGO](#), [ISGO](#), [Gineco](#), [GEICO](#), [MaNGO](#), [MITO](#), [NCRI](#).

**ENGOT-ov17/MITO 16**

*Phase III trial with second line chemotherapy +/- Bevacizumab in patients with platinum sensitive ovarian cancer recurrence after Bevacizumab and chemotherapy in the first line. (S. Pignata)*

Date of activation: 2013 April

Number of patient accrued: 117 / Recruitment ongoing

Number of patients needed: 400

Participating members: [MITO](#) (leading), [MaNGO](#), [Gineco](#), HECOG, SAKK

#### ENGOT-ov18/AGO-OVAR 2.21

*In this trial patients with platinum sensitive recurrent ovarian cancer (more than 6 months platinum-free interval) will be randomised between Carbo/Gem with Bevacizumab versus Carbo/Caelyx with Bevacizumab. (J. Pfisterer) / Recruitment is well running*

Date of activation: 2013

Number of patient accrued: 682

Number of patients needed: 654

Participating members: [AGO](#), [Gineco](#)

#### ENGOT-ov19 - GEICO

*Phase III multicenter randomised study of BIBF 1120 versus placebo combined standard chemotherapy (PLD/Carboplatinum) in platinum resistant and platinum -sensitive disease (Jose Maria del Campo). / Trail is on Hold*

Date of activation: 2013

Number of patient accrued: 600

Number of patients needed: 900

Participating members: [GEICO](#), [NSGO](#), [GOG](#), [Gineco](#), [BGOG](#), [MaNGO](#), [MITO](#), [NCRI](#), DGOG

#### ENGOT-ov20 Desktop 3 - Leading group: AGO

*Randomised trial investigating secondary debulking versus no-secondary debulking in platin sensitive disease. (A. du Bois)*

Number of patient accrued: 408 / Last patient recruited in March 2015 / OS analysis planned for 2019

Number of patients needed: 408

Participating members: [AGO](#), [A-AGO](#), [BGOG](#), [MITO](#), [Gineco](#), [NSGO](#), [GEICO](#), [NCRI](#), SGCTG (KGOG)

#### ENGOT-ov21 / Solo2-3 - Leading group: GINECO

*Study of Olaparib on Ovarian Cancer (Eric Pujade-Lauraine).*

Number of patient accrued: 295 randomised out of 603 / Recruitment finished October 2014

Number of patients needed: 440

Participating members: [AGO](#), [DGOG](#), [MITO](#), [ISGO](#), [NCRI](#), [MANGO](#).

#### ENGOT-ov22 - Leading group: NOGGO

*Expression IV- What do primary and recurrent ovarian cancer (OC) patients expect from maintenance therapy?*

Number of patient accrued: 1248 / Still open till March 2016 for interested groups

Number of patients needed: 200-300

Participating members: NOGGO

#### ENGOT-ov23: GINECO EWOC- 1 Leading group: NOGGO

*Multicenter, randomized trail of carboplatin +/-paclitaxel in vulnerable elderly patients with stage IIB- IV advanced ovarian cancer / Recruitment is running*

Number of patient accrued: 68

Number of patients needed: 240

#### ENGOT-ov24 - AVANOVA: NSGO

*Niraparib and/or Niraparib-bevacizumab combination against bevacizumab alone in Women with platinum-sensitive epithelial ovarian, fallopian tube, or primary peritoneal cancer*

Number of patient accrued: 132

Number of patients needed: 612

Participating members: ISGO, MITO, GEICO

### ENGOT-ov25 - PAOLA: GINECO

*Randomized, Double-blind, Phase III Trial of olaparib vs. placebo in combination with bevacizumab in women following first-line chemotherapy plus bevacizumab for advanced high grade epithelial ovarian, fallopian tube, or primary peritoneal cancer.*

Number of patient accrued: 18

Number of patients needed: 612

Participating members: AGO-Austria, AGO-Germany, BGOG, GEICO, NSGO, MANGO, MITO,

### ENGOT-ov26 - Leading group: GEICO

*Phase 3 Maintenance Study to Evaluate the Efficacy and Safety of Niraparib Versus Placebo in Women Who Have Not Progressed after First Line Chemotherapy for Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer.*

Number of patient accrued: 84

Number of patients needed: 530

Participating members: ISGO, MITO, HeCOG, ICORG, NSGO, BGOG, GINECO, SAKK, AGO-Germany, TRGOG.

### ENGOT-ov27 - Leading group: BGOG

*A Randomized, Double-Blind, Placebo-Controlled, Phase 2 Study to Assess the Efficacy and Safety of Farletuzumab (MORAb-003) in Combination with Carboplatin plus Paclitaxel or Carboplatin plus Pegylated Liposomal Doxorubicin (PLD) in Subjects with Low CA125 Platinum-Sensitive Ovarian Cancer*

Number of patient accrued: 17

Number of patients needed: 210

Participating members: MITO, GEICO, NOGGO

### ENGOT-EN1-I - Leading group: NSGO

*Randomized phase II trial of first-line combination chemotherapy with BIBFI 120 or placebo for patients with advanced or recurrent cancer. (Mansoor Raza Mirza) /Study not started yet*

Number of patient accrued: First patient planned for March 2016

Number of patients needed: 150

Leading Group: NSGO

Groups interested: [MITO](#), [Gineco](#), [NOGGO](#), [AGO](#), [EORTC](#), [BGO](#)

### ENGOT-EN2 - Leading group: DGCG

*Adjuvant chemotherapy in node negative endometrial carcinoma. (Mansoor Raza Mirza)*

Number of patient accrued: 100

Number of patients needed: 678

Participating members: [DGCG](#), [NSGO](#), [EORTC](#), [MITO](#), [AGO](#), [A-AGO](#), [NOGGO](#), [BGOG](#), [MaNGO](#), DGOG Mayo Clinic and Gothic (Japan) will be cooperating.

### ENGOT-EN3 - PALEO- Leading group: NSGO

*A randomized phase II trial of Palbociclib in combination with letrozole versus letrozole for patients with oestrogen receptor positive recurrent endometrial cancer.*

Number of patient accrued: First patient planned for April 2016

Number of patients needed: 80

Leading Group: NSGO

Groups interested:

### ENGOT-GYN1 / SGCTG - NSGO

*A phase II trial of a triple angiokinase inhibitor (BIBF1120) in the treatment of patients with recurrent clear cell ovarian cancer. (Mansoor Raza Mirza)*

Date of activation: 2013

Number of patient accrued: 1 / Open in UK

Number of patients needed: 90

Participating members: SGCTG (lead group, in cooperation with [NSGO](#)), [NCRI](#), [EORTC](#), [GINECO](#)

### ENGOT-VI/DGOG - GROINSV-2 - Leading group: DGOG

*Radiotherapy in vulvar carcinoma with small metastatic sentinel nodes.* (A. van der Zee)

Number of patient accrued: 1500

Number of patients needed: 500

Participating members: DGOG, [BGOG](#), [NCRI](#), [NSGO](#), GOG

### ENGOT-Cx/BGOG-cxI

*A randomized phase II trial of paclitaxel-carboplatin 3-weekly with or without Nintedanib (BIBFI 120) in advanced or recurrent cervical cancer.* (I. Vergote)

Date of activation: Q1 / 2013

Number of patient accrued: 23 randomised out of 120

Number of patients needed: 120

Participating members: [BGOG](#), [MITO](#), [Gineco](#), [GEICO](#), [NCRI](#), [MaNGO](#)

## PAST TRIALS

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### ENGOT-ov2/BGOG-ov7 - Leading group: BGOG

*AMG386/paclitaxel/carboplatin versus paclitaxel/ carboplatin as first-line therapy in advanced ovarian, peritoneal and fallopian tube cancer.* (I. Vergote)

Number of patient accrued: 832

Number of patients needed: 2000 (reduced to 1000)

Participating members: [BGOG](#) (leading), [AGO](#), [A-AGO](#), [GEICO](#), [Gineco](#), [HECOG](#), [MITO](#), [MaNGO](#) (and GOG), DGOG

Closure: 2013

### ENGOT-ov-3/ Aurelia – Leading group: GINECO

*Randomized trial comparing chemotherapy with or without bevacizumab in recurrent platin-resistant ovarian cancer.*

Number of patient accrued: 360

Number of patients needed: 360

Participating members: [Gineco](#), [AGO](#), [BGOG](#), [DGCG](#), [GEICO](#), [MITO](#), [NSGO](#), [HECOG](#)

Closure: 4/2012 /

Publications:

#### 1. [The AURELIA Open-Label Randomized Phase III Trial](#)

Eric Pujade-Lauraine, et al.

Published 17 March 2014, 10.1200/JCO.2013.51.4489

#### 2. [Patient-Reported Outcome Results From the Open-Label Phase III](#)

Martin R. Stockler, et al.

Published 31 March 2014, 10.1200/JCO.2013.51.4240

### ENGOT-ov-4 – Leading group: NOGGO

*Perceptions and expectations on clinical management of ovarian cancer European survey: Expression III.* (J. Sehouli).

Number of patients accrued: 1776 (closed)

Participating groups: [NOGGO](#), [AGO](#), [BGOG](#), [MITO](#), [MaNGO](#), [NCRI](#), [Gineco](#), [GEICO](#)

Publication expected

### ENGOT-ov6 - Leading group: A-AGA

*A phase 3, Randomized, Double-Blind trial of Pegylated Liposomal Doxorubicin (PLD) Plus AMG 386 or Placebo in Women with Recurrent, Partially Platinum Sensitive or Resistant Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Cancer.*(Ch. Marth). / Study is closed

Number of patients accrued: 223

Number of patients needed: 380

Participating member groups: [AGO](#), [A-AGO](#), [BGOG](#), [DGCG](#), [MITO](#), [MaNGO](#), [NCRI](#), [Gineco](#)

**ENGOT-ov9 - Leading group: 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 carcinoma. (J. Sehouli)*

Number of patient accrued: 174

Number of patients needed: 174

Participating members: [AGO](#), [NOGGO](#)

Closure: 2013 / Data immature yet.

**ENGOT-ov-10/MITO-7 - Leading group: MITO**

*First line weekly carboplatin and paclitaxel vs every 3 weeks carboplatin/paclitaxel in patients with ovarian cancer: Phase III multicenter trial. (S. Pignata).*

Number of patient accrued: 824 (closed)

Number of patients needed: 800

Participating members: [MITO](#) - [MaNGO](#) - [Gineco](#) - [HECOG](#)

Publications: [ENGOT ov10 paper \(MITO-7\)](#)

[ENGOT ov10 appendix](#)

**ENGOT-ov12 - Leading group: MITO**

*Pathway to diagnosis of ovarian cancer : an observational retrospective multicentre trial. (J. Bryce).*

Number of patient accrued: 695 (closed) / Publication in progress

Number of patients needed: xxx

Participating members: [MITO](#), [MaNGO](#), [BGOG](#), [Gineco](#), [NOGGO](#)