CEEGOG

Central and Eastern European Gynecologic Oncology Group

Hungary

Slovakia

Hungary

Czech Republic

Ukraine

Georgia

Slovenia

Serbia

Croatia

Macedonia

Romania

Belarus

CEEGOG INTRODUCTION

CEEGOG Central and Eastern European Gynecology Oncology Group

- ✓ International collaborative group founded in June 2014
- ✓ 49 centers from 12 countries

  Czech Republic, Slovakia, Poland, Hungary, Slovenia, Ukraine, Belarus, Georgia

  Croatia, Macedonia, Serbia and Romania
- ✓ Seat of the group is in Prague
- ✓ CEEGOG a member of ENGOT since September 2014

CEEGOG | Central and Eastern European Gynecologic Oncology Group

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Czech Republic, Slovakia, Hungary, Slovenia

CZECH REPUBLIC – 13 centers
Fakultní nemocnice Brno
Fakultní nemocnice Hradec Králové
Fakultní nemocnice Královské Vinohrady, Praha
Fakultní nemocnice Olomouc
Fakultní nemocnice Ostrava
Fakultní nemocnice Plzeň
Fakultní nemocnice Motol, Praha
Krajská nemocnice T. Bati, a.s., Zlín
Masarykova nemocnice v Ústí nad Labem
Nemocnice České Budějovice
Nemocnice Jihlava
Nemocnice Na Bulovce, Praha
Všeobecná fakultní nemocnice v Praze

SLOVAKIA – 6 centers
Fakultní nemocnice Nitra
Fakultní nemocnice Trenčín
Národní onkologický ústav, Bratislava
Onkologický ústav sv. Alžběty, s.r.o., Bratislava
Východoslovenský onkologický ústav, a.s., Košice
Fakultní nemocnice Bratislava

HUNGARY – 3 centers
Hungarian National Oncological Institute, Budapest
Semmelweis University Budapest
University of Debrecen

SLOVENIA–2 centers
University Medical Centre Maribor
University Medical Centre Ljubljana

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Poland, Ukraine, Belarus, Georgia

POLAND – 12 centers
Gdynia Oncology Centre
Holycross Cancer centre, Kielce
Institute of Mother and Child, Warsaw
Jagiellonian University Medical College, Krakow
Lower Silesian Cancer Centre, Wroclaw
MU Gdansk
Medical Uniwersity of Lublin
Medical Uniwersity of Bialystok
M.Sklodowska-Curie Memorial Institute, Krakow
MU Poznan
MU Warsaw
MU Szccenin

UKRAINE– 4 centers
Grigoriev Institute for Medical Radiology, Kharkov
LISOD – Israeli Oncological Hospital, Plyuty
Chernihiv Regional Oncological Center, Chernihiv
Lviv State Regional Oncological Center, Lviv

BELARUS –4 centers
N.N. Alexandrov National Cancer Center of Belarus, Minsk
Grodno Regional Clinical Hospital, Grodno
Brest Regional Oncology Center, Brest
Gomel Regional Clinical Oncological Center, Gomel

GEORGIA – 1 center
Tbilisi Cancer Center

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Macedonia, Serbia, Romania, Croatia

MACEDONIA –1 center

University clinic of Gynecology & Obstetrics, Skopje

SERBIA– 1 center

Hospital for Gynecology and Obstetrics Clinical Center Zemun - Beograd

ROMANIA – 1 center

First Obstetrics and Gynecology Clinic, University of Medicine and Pharmacy Targu Mures

CROATIA – 1 center

Clinical Hospital Center, Medical University Zagreb

PURPOSE OF CEEGOG

Aim → to facilitate collaboration on sponsored and academic trials in the management of patients with gynecological cancer

✓ improve the quality of care in gynecologic oncology in the Czech Republic and in the region of Central and Eastern Europe

✓ support research and collaboration in the region

✓ stimulate own projects, facilitate education in and improve quality of clinical trials

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ROLE OF THE CEEGOG OFFICE

- ✓ Development of trial documents
  - ICF and Information for patients
  - Designation of responsibility log
  - Patient indentification log
  - Clinical monitoring plan
  - Appointment letters, etc.

- ✓ Site initiations

CRO activities

ROLE OF THE CEEGOG OFFICE

- ✓ Facilitation of the trial conducting
  - Recruitment support
  - Newsletters, study updates

- ✓ Remote and on-site monitoring
- ✓ Personal on-site visits
- ✓ Others
  - Samples transportation logistics
  - Information system up-dates

CRO activities

CEEGOG ACADEMIC TRIALS

SALVAGE	A retrospective trial on patients who have undergone salvage surgery for a recurrent uterine or cervical cancer Closed
SENTIX	Sentinel node in cervix cancer A prospective observational trial on sentinel lymph node biopsy in patients with early stage cervical cancer
HE4-FU-OVCA	The Role of HE4 in the Follow-up of Advanced Ovarian, Fallopian Tube and Primary Peritoneal Cancer
ABRAX	ABandoning of RAd hyst in cerviX cancer, Oncological outcome after completing or ab andoning (radical) hysterectomy in patients with cervical cancer and intraoperative LN positivity
RSS – EAC -PAT	The Risk Stratification System for endocervical adenocarcinoma based on tumor pattern
FERTISS	FERTIlity Sparing Surgery in cervical cancer patients outside controlled trials

SENTIX

CEEGOG conference, Prague, Dec 2017

CEEGOG Central and Eastern European Gynecologic Oncology Group

ENGOT European Network of Gynaecological Oncological Trial groups

A prospective observational trial on sentinel lymph node biopsy

in patients with early stage cervical cancer

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ENGOT European Network of Gynaecological Oncological Trial groups

SENTIX

A prospective observational trial on sentinel lymph node biopsy in patients with early stage cervical cancer

ClinicalTrials.gov: **NCT02494063**
ENGOT CX2

SENTIX

Primary objective

To evaluate whether a **less radical surgical approach** with **sentinel lymph node biopsy** is non-inferior to treatment with systematic pelvic lymphadenectomy.

The null hypothesis is that the recurrence rate after **SLN biopsy** is non-inferior to the **reference recurrence rate of 7 % (at the 24th month of follow-up)** in patients after systematic pelvic lymphadenectomy, but that the less radical surgery is associated with **significantly lower postoperative morbidity**.

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ENGOT European Network of Gynaecological Oncological Trial groups

BGOG Belgian Gynaecological Oncology Group

ENGOT-Cx 2

SENTIX

A prospective observational trial on sentinel lymph node biopsy in patients with early stage cervical cancer

- ENGOT model: **A**
- Sponsor(s): **CEEGOG**
- Planned No. of patients: **350-400**
- No. of already **recruited** patients: **245**
- Status: recruiting
- Timeline: **30/May/2016** (first patient recruited)

  2018 (planned trial closing)

Countries participating: **17**

Sites activated: **39**

Sites expected to be authorized: **6**

Sentix video available

a) SENTIX video

Please watch the new film which was prepared to help new centers but also harmonize procedures, especially SLN detection. It is available on the link bellow. It should guide you step by step through the protocol.

https://drive.google.com/open?id=0B4KK01zs0LnZa3phXzJnczl0U0U

SENTIX

- Web-based Sentix Information System (SIS)
- Continuous remote data monitoring
- Central pathology reading – SLN pathology assessment quality control

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ENGOT-Cx3/CEEGOG/ABRAX

Oncological outcome after completing or abandoning (radical) hysterectomy in patients with cervical cancer and intraoperative LN positivity

ABRAX (ABandoning RAd hyst in cerviX cancer)

Retrospective cohort study

ENGOT-Cx3/CEEGOG/ABRAX

Objectives	**1) To determine if the performance of radical hysterectomy improves oncological outcome in patients with intraoperative detection of LN involvement (comparing to radio(chemo)therapy alone)** **2) Compare the prevalence of ≥ G2 treatment-related morbidity between the group with or without radical hysterectomy** **3) Evaluate if the survival benefit of radical hysterectomy is modified by prognostic parameters (tumour size, histological type, type of metastases, presence of LVSI, number of involved LN)**

ENGOT-Cx3/CEEGOG/ABRAX

Inclusion criteria	✓ Histologically confirmed squamous cell carcinoma, adenocarcinoma, adenosquamous carcinoma ✓ Stage pT1a – pT2b ✓ Patient referred for primary surgical treatment (neoadjuvant chemotherapy is not an exclusion criteria) intended to perform LN staging followed by radical / simple hysterectomy or fertility-sparing procedure (FST) ✓ Intraoperative detection of LN involvement (any type of metastasis): ○ Macroscopic involvement = grossly involved lymph nodes (if confirmed by final pathology) OR ○ Microscopic involvement = SLN / LN intraoperative pathologic evaluation (frozen section) ✓ Follow-up data available for ≥ 2 years ✓ Surgery performed between January 2005 and December 2015

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CEEGOG ACADEMIC TRIALS

CEEGOG ACADEMIC TRIALS - PROTOCOLS UNDER DEVELOPMENT

Methylation of selected tumor suppressor genes in glandular lesions of the uterine cervix (Pilsen, CR)

Adjuvant radiotherapy vs. chemoradiotherapy in vulvar cancer patients with nodal metastases (Holycross cancer centre, Kielce, Poland)

A randomized trial of adjuvant chemoradiotherapy versus no further treatment in intermediate risk (N0; combination of risk factors) stage IB cervical cancer after radical hysterectomy and pelvic LN staging

CEEGOG RESPOSIBILITIES

CEEGOG resposibilities

- ✓ Site selection and Feasibility process (evaluation of CEEGOG center interest, center quality, adequate experience, adequate infrastructure resources and staff resources, number of patients…)
- ✓ Submission to Regulatory agency and EC according to national guidelines (in the Czech Republic, other countries on their own)
- ✓ Control of suggested medicine label (in the Czech Republic, other countries on their own)
- ✓ Translation of required documents (ICF, Information for patients...)
- ✓ Insurance
- ✓ Further specific documents as per national guidelines

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ENGOT STUDIES

ENGOT-EN2-DGCG

Sponzor 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

ATALANTE Atezolizumab and Avastin in late recurrent disease

Sponzor ARCAGY-GINECO

A randomized, double blinded, phase III study of Atezolizumab versus placebo in patients with late relapse of epithelial ovarian, fallopian tube, or peritoneal cancer treated by platinum-based chemotherapy and Bevacizumab

IMagyn050 OVARIAN

Sponzor F.Hoffmann-La Roche Ltd

A phase III, multicenter, randomized study of Atezolizumab versus placebo administered in combination with Paclitaxel, Carboplatin, and Bevacizumab for patients with newly-diagnosed stage III or stage IV ovarian, fallopian tube, or primary peritoneal cancer

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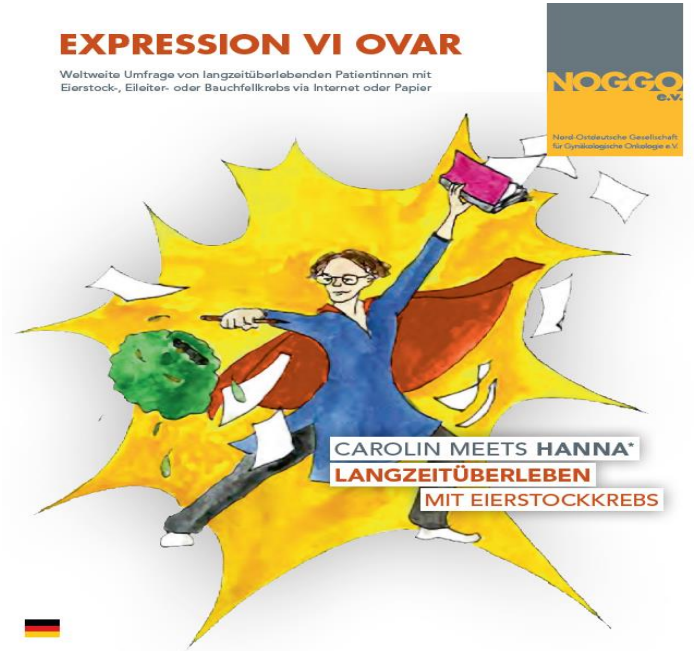
ENGOT STUDIES

ENGOT-ov40/NOGGO/Expression VI

Sponsor NOGGO



„Caroline meets HANNA – Holistic Analysis of LoNgterm-survival with OvariaN CAncer"

The German project of patient survey for long-term survivors named Expression VI is aimed at the rare and scientifically inadequately studied group of ovarian carcinoma patients, who have survived despite relapse over eight years, wants to identify factors that can be applied to other ovarian carcinoma patients.

BGOG-EN5/ENGOT-EN5/SIENDO

Sponsor BGOG

A randomised double-blind, placebo-controlled phase III trial of maintenance Selinexor/placebo after combination chemotherapy for patients with advanced or recurrent endometrial cancer.

Study coordinators training

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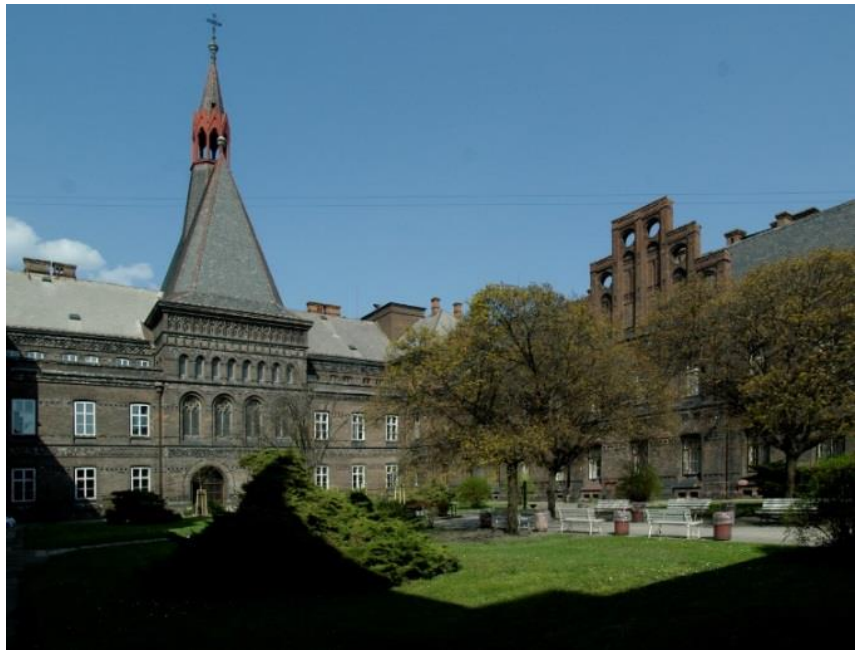
- ✓ a two-day training at the CEEGOG office in Prague
- ✓ for one or two study coordinators from the respective center
- ✓ SC from 4 countries attended so far

(i.e. Czech Republic, Poland, Hungary and Slovakia)

Purpose:

- ✓ to facilitate trial running under the CEEGOG umbrella
- ✓ to share trial experience



Study coordinators training

Main **objective**

➡ to show how study coordinators could facilitate the conducting of the trials

- ✓ Introduction of CEEGOG
- ✓ CEEGOG non-commercial trials
- ✓ Introduction of ENGOT
- ✓ CEEGOG cooperation with ENGOT
- ✓ Specifics of ENGOT trials
- ✓ Commercial trials
- ✓ CEEGOG cooperation within commercial trials

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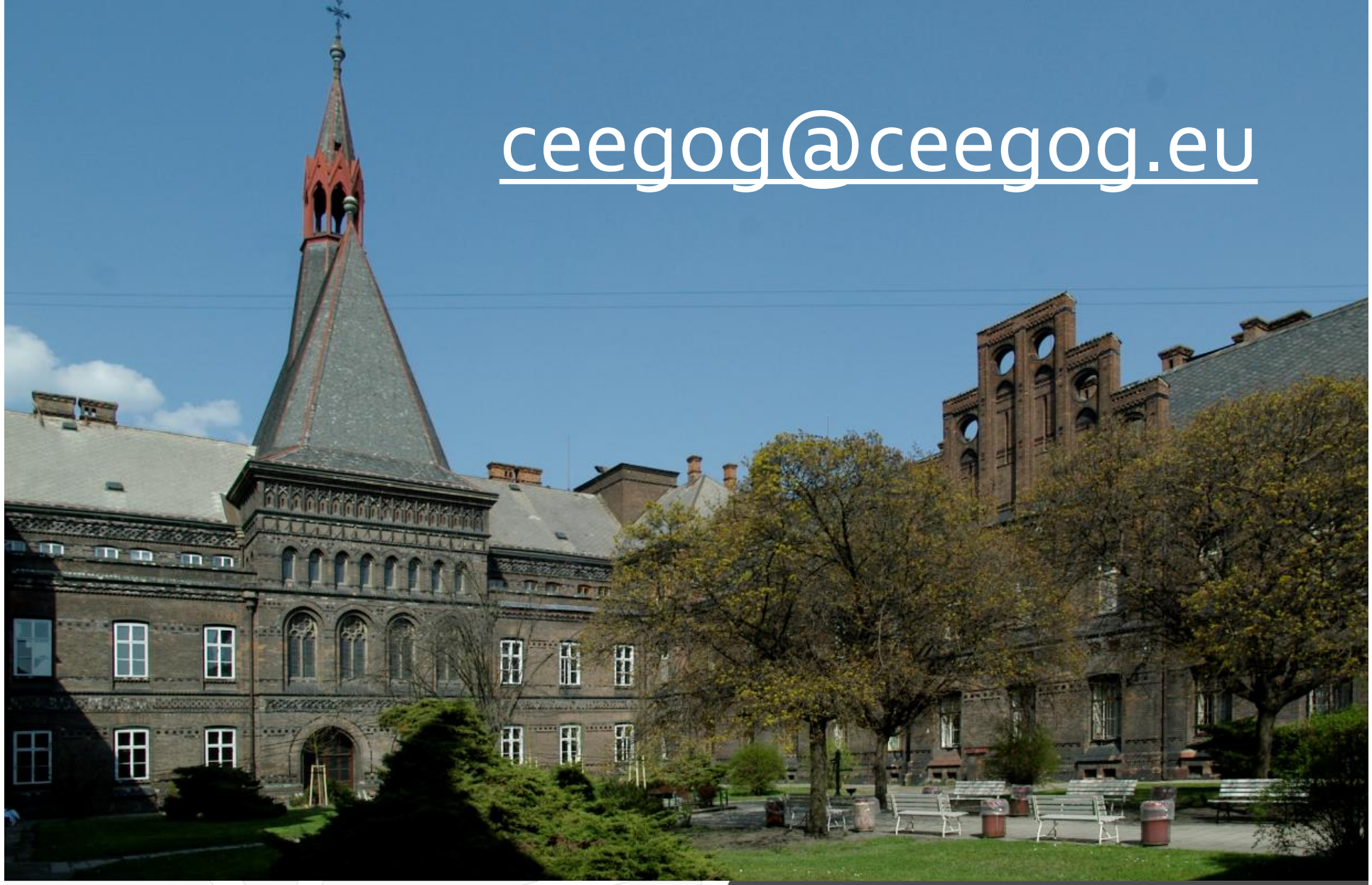
CEEGOG - opportunities

- High incidence of cervical cancer
- Tradition in surgical treatment
- Low competition in Clinical trials

CEEGOG - challenges

- Regulatory barriers
- Lack of infrastructure (admin, SC, language, institutions)
- Inadequate funding



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