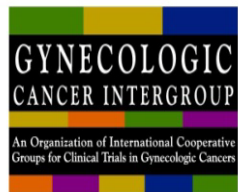


# Symptom Benefit Working group General Assembly

London, Saturday & Sunday, 16-17 November, 2013  
03:00-05:30

Chairs: F Joly, J McAlpine



# Agenda

- **Update publications brainstorming Leiden**

*F Joly*

- **Lecture**

Patient preferences (illustration Portec 3 trial)

*L Mileshkin*

- **Working group session**

Ovar16 QoL substudy

*F Hilpert for M Friedlander*

- **Ongoing studies**

SB Study

*L Mileshkin*

EWOC study

*F Joly for G Freyer*

GOG 273

*F Joly for G Fleming*

Patient satisfaction (expression III/IV)

*J Sehouli*

Others

*Alls*

- **Projects**

*J McAlpine and alls*

Endometrial cancer survey patients and physicians expectations

Perspectives : longitudinal cohort survivors? (European grant?)

# Update publications

- The 2 publications of SB Leiden brainstorming have been submitted as companion papers in August to Annals of Oncology
- We are waiting for the reviews (still on process)

# PACT in PORTEC 3: Preferences for adjuvant chemotherapy in endometrial carcinoma: what makes it worthwhile to patients and their doctors?

Linda Milesshkin



AUSTRALIA NEW ZEALAND  
GYNAECOLOGICAL ONCOLOGY GROUP

# Aims of Patient preferences sub-study in PORTEC 3

To determine

- the **minimum benefits** patients and their doctors judge sufficient to make **worthwhile the addition of chemotherapy** to pelvic radiotherapy in women with high-risk and advanced endometrial carcinoma, and
- the factors influencing these preferences

# Inclusion criteria and questionnaires

## Patients

- All patients participating in PORTEC-3 in **ANZ sites**
- Patient Questionnaire

## Doctors

- All gynaecological oncologists, radiation oncologists, and medical oncologists of patients participating in PORTEC-3
- Dr PACT-Q

## Evaluation at T0 and 9 months

# Challenges of preferences studies

- Doctor concern that asking patients about their preferences will cause distress – **rarely a problem**
- Patient Baseline:  $79/87 = 91\%$
- Patient 9 months:  $62/70 = 89\%$
- Dr PACT gyn onc:  $39/87 = 49\%$
- Dr PACT med onc:  $56/87 = 64\%$
- Dr PACT rad onc:  $73/87 = 84\%$
- **Doctors may be uncomfortable** with giving predictions about patient outcomes!

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# Quality of life in patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer (AEOC) receiving either pazopanib monotherapy or placebo after first-line chemotherapy: AGO-OVAR16 results

M. Friedlander<sup>1</sup>, S. Knoll<sup>2</sup>, W. Meier<sup>3</sup>, A. Lesoin<sup>4</sup>, J.W. Kim<sup>5</sup>,  
A. Poveda<sup>6</sup>, M. Buck<sup>7</sup>, G. Scambia<sup>8</sup>, M. Shimada<sup>9</sup>, A. du Bois<sup>10</sup>

<sup>1</sup>ANZGOG and The Prince of Wales Hospital, Randwick, NSW, Australia;

<sup>2</sup>GlaxoSmithKline Pharmaceuticals, Collegeville, USA; <sup>3</sup>AGO and Evangelisches Krankenhaus, Duesseldorf, Germany; <sup>4</sup>GINECO and Centre Oscar Lambret, Lille, France; <sup>5</sup>KGOG and Seoul National University, Seoul, Korea; <sup>6</sup>GEICO and Fundación Instituto Valenciano de Oncología, Valencia, Spain; <sup>7</sup>ANZGOG and Sir Charles Gairdner Hospital, Nedlands, Australia; <sup>8</sup>MITO and Università Cattolica del Sacro Cuore Policlinico Gemelli, Rome, Italy; <sup>9</sup>JGOG and Tottori University Hospital, Yonago City, Japan; <sup>10</sup>AGO and Kliniken Essen Mitte, Essen, Germany



# Health-Related Quality of Life

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- Secondary endpoint: evaluate health-related quality of life (HRQOL) as measured by **EORTC QLQ-C30**, **OV28** and **EQ-5D** (captures health status across five dimensions: mobility, self-care, usual activities, pain/discomfort, anxiety/depression)
  - Data were collected at baseline, week 13, months 7, 10, 13, 16, 25 (end of treatment), and 31 (post-treatment)
- Pre-specified analyses examined HRQOL differences while on treatment
- Maintenance therapy with pazopanib will result in a small but statistically significant decline in global HRQOL and more side effects during the time on treatment, but will be associated with an overall benefit to patients

## Conclusions of QoL Substudy

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- Predefined QoL endpoint
  - Maintenance therapy with pazopanib results in
    - an improvement in median PFS of 5.6 months
    - a small decrement in overall HRQOL for patients on treatment
    - a significant increase in patient-reported diarrhea
- Post-hoc analyses
  - Progression results in worse HRQOL and initiation of further chemotherapy
  - Quality-adjusted PFS supports the net value of maintenance therapy

## WG discussions

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- **Limitations of post-hoc analyses**
  - highlight the importance of including a priori HRQOL hypotheses in future studies
- Limits of the current QoL tools for maintenance therapy
- Necessity to develop some specific questions on the impact of symptoms (induced by maintenance therapy) to daily life
- Opportunities to work with the EORTC-QoL working group to try to add specific questions to the current modules to answer to the question

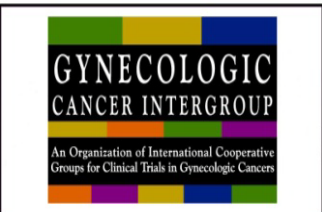
# Ongoing studies

- SB Study
- Ewoc study
- GOG 273 study
- Expression III and IV

# Symptom Benefit Study

## Update and current status

GCIG Symptom Benefit Study  
M Friedlander



# Schema – Stage 2-SBS

## Target Population

- Informed consent
- ≥18yrs
- Platinum Resistant/Refractory\*
- ECOG 0-3
- Life expectancy > 3 months
- Able to commence treatment within 2wks of registration
- Able to complete questionnaires independently

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## Data Collection

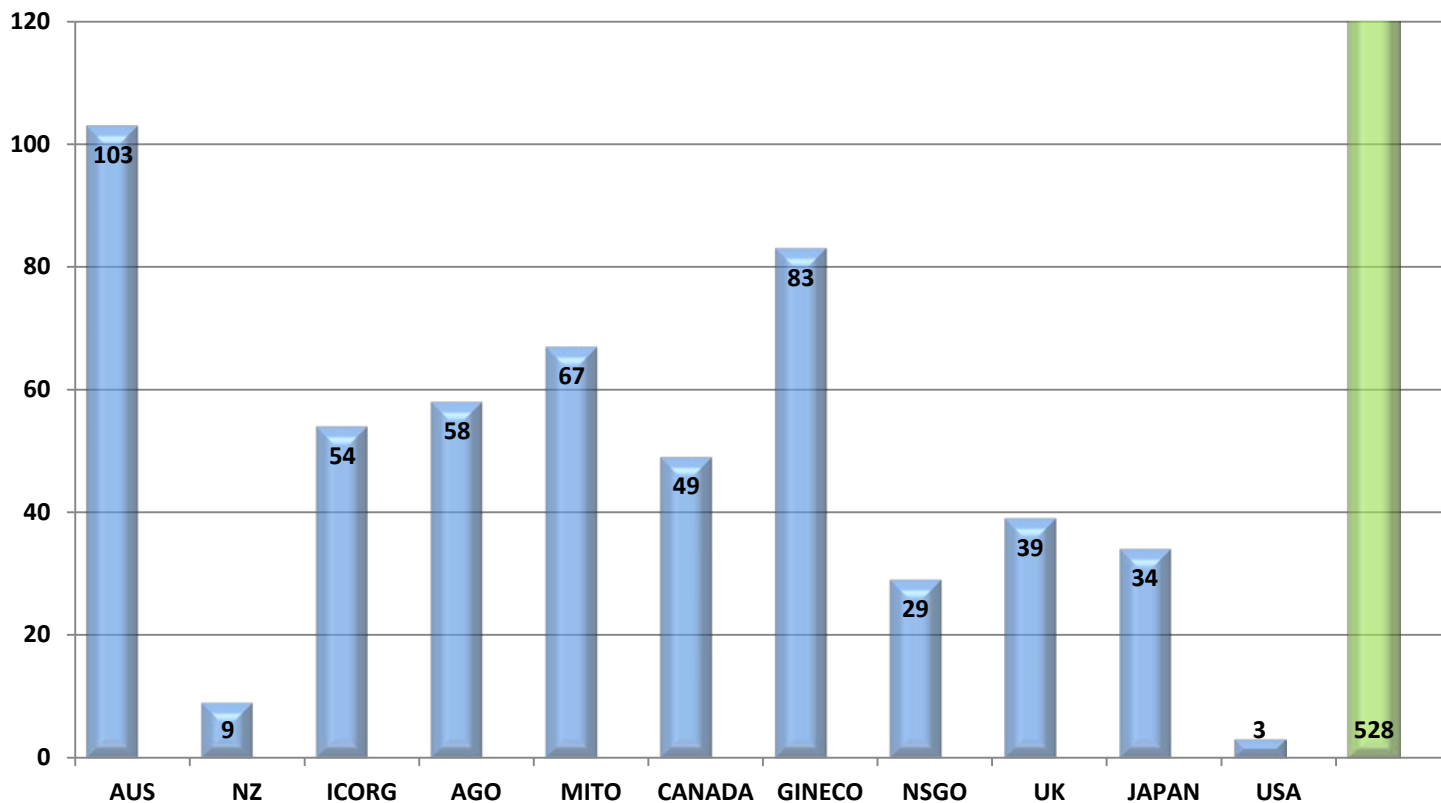
- Baseline
- Each treatment cycle
- One month post completion of treatment or until disease progression

**To validate the MOST (QoL questionnaire for pts with palliative CT)**

\* Amendment included ALL patients receiving 3<sup>rd</sup> line or greater lines of treatment - including potentially platinum sensitive

# Total Accrual

ANZGOG-0701 - Total Accrual\* (11/11/13)



•At current rate, total projected accrual would be **963** at study close (31 Dec 2014)

# Discussion Points from ANZGOG group

- Suggest that the instrument is called the GCIG-MOST providing that there is needed **agreement by GCIG**
- The instrument would be made freely available to whoever wishes to use it in clinical trials.
- The MOST instrument and User Manual will be available on GCIG website as well as ANZGOG and PoCOG websites





# EWOC-1

## Elderly Women Ovarian Cancer

Multicenter, randomized trial of carboplatin +/- paclitaxel in vulnerable elderly patients with stage IIB-IV advanced ovarian cancer

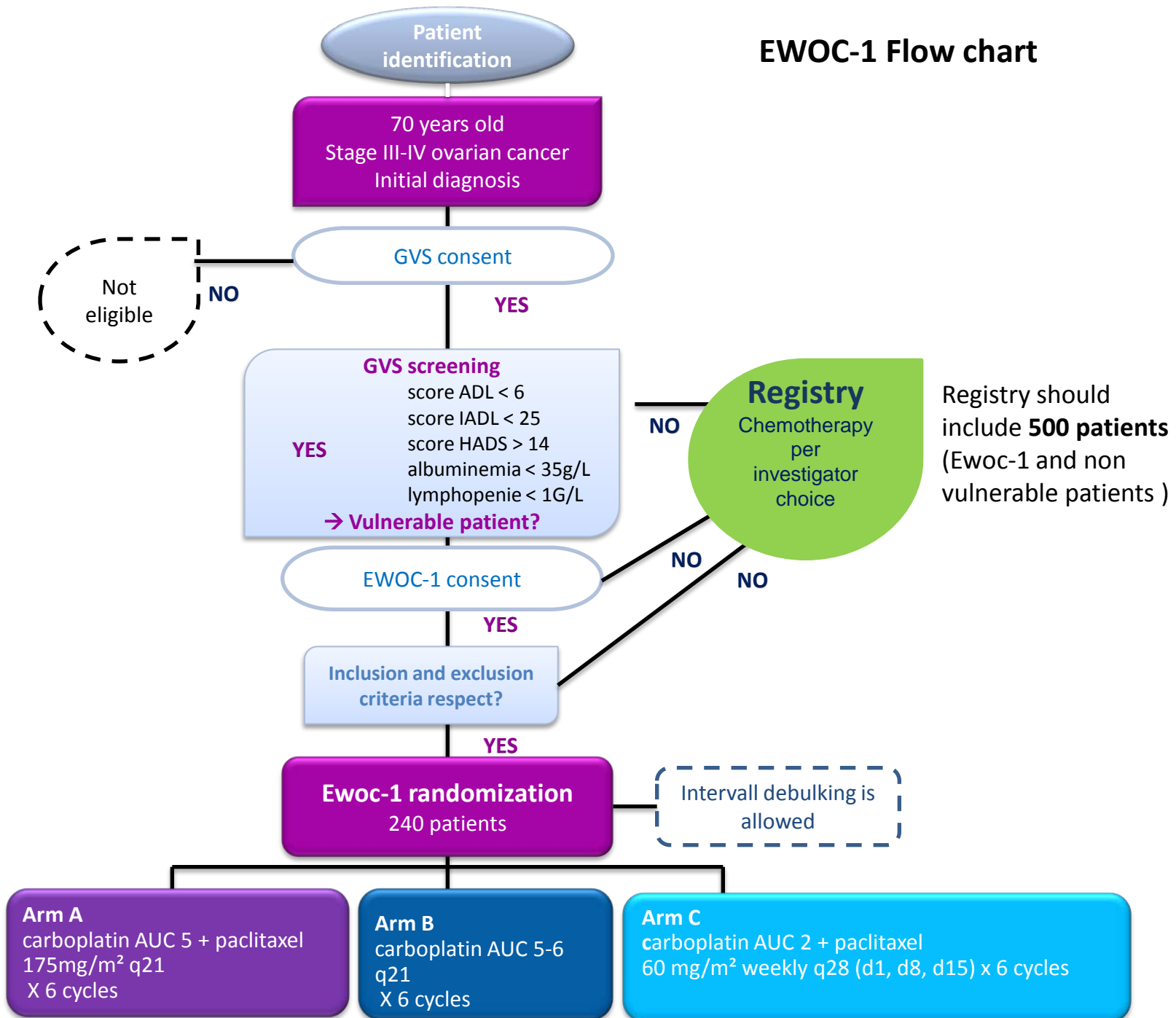
## First ENGOT-GCIG international study of elderly patients in Ovarian Cancer

### Participating Groups

GINECO, AGO, MITO, ANZGOG, Canada, JGOG, GOTIC, NSGO

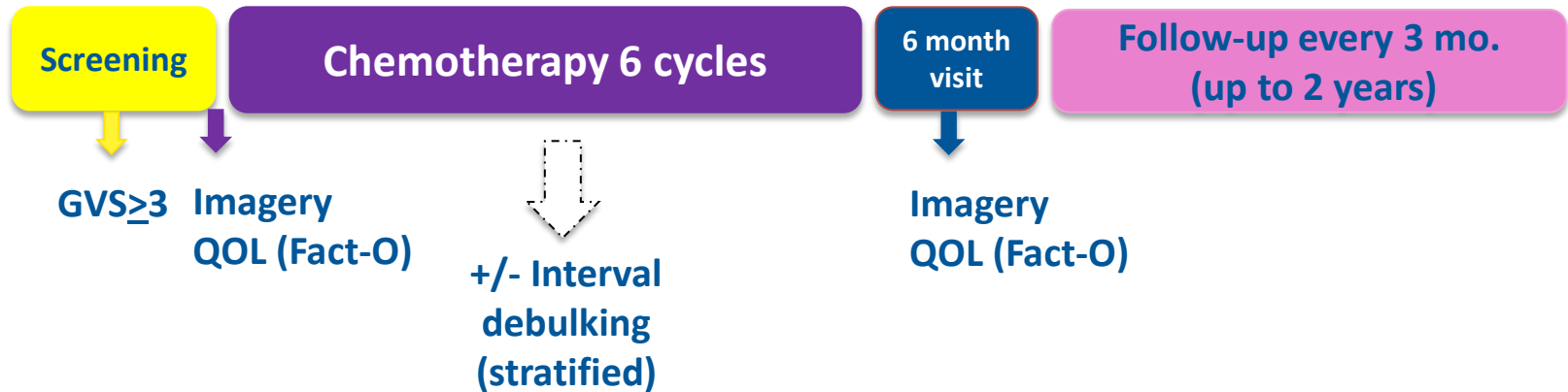


# EWOC-1 Flow chart



# PRIMARY ENDPOINT

To compare the rate of success to deliver 6 courses of chemotherapy without progression at 6 months or unacceptable toxicity\* of 3 different regimens in vulnerable elderly patients



\* Unacceptable Toxicity = is defined as a major adverse event related to chemotherapy or treatment procedures leading either to early treatment stopping, to an unplanned hospital admission or to death.



# EWOC-1 Status

May 2013

French HA and EC approval

Nov 2013

**First inclusions in France**



❖ **International coordination to be started now**

**GCIIG Participation** : AGO, MITO, NSGO, Canada , JGOG, DGOG

❖ **Interested** : KGOG and Shangai GOG

# GOG/NRG Elderly WG

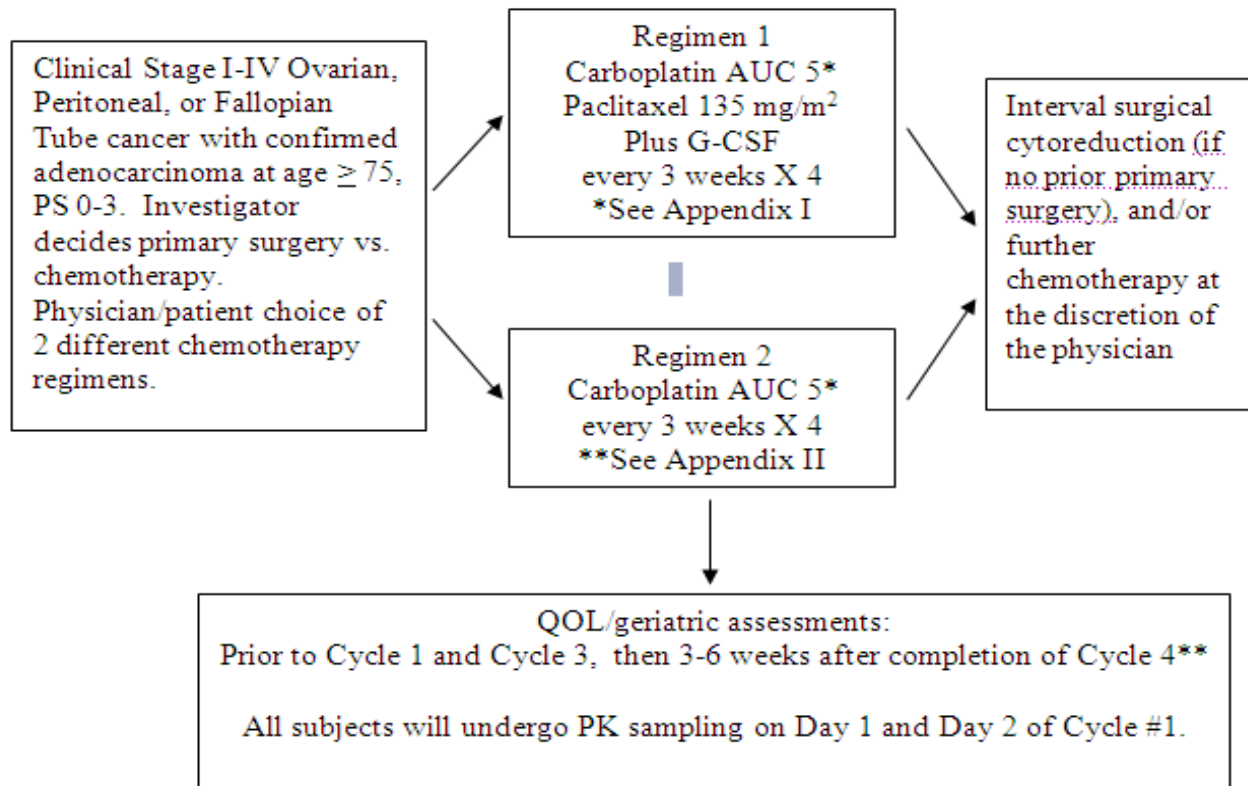
Update Fall 2013

J Fleming

# GOG 273-Original

## SCHEMA

This is a prospective observational study, not a comparison of treatment regimens.



\*Patients for whom the physician deems a carboplatin dose of AUC dose of 5 to be unsafe, may be given an AUC of 4.

# GOG 273

- Accrual to the first two arms complete (slight overaccrual, n=212)
- If possible, first results will be presented at SGO meeting March 22-25, 2014
- **Third arm : Carboplatin AUC 5\* every 3 weeks Plus Weekly Paclitaxel 60 mg/m<sup>2</sup> over 1 hour every 3 weeks X 4 cycles (Day 15 Paclitaxel is optional)**
  - the Geriatric Assessment Score (GAS) and tolerance to chemotherapy

# ELD1106

- Approved by DCP, protocol under development
- Will explore predictive value of GAS for **surgical toxicity**
- Goal to have one geriatric assessment that can be used throughout GOG/NRG protocols, surgical and chemotherapy





# GCIG London 2013

## Expression III

**What do primary and recurrent ovarian cancer (OC )  
patients expect from their doctors and therapy  
management?  
(NOGGO/ENGOT-ov4 study).**

**J Sehouli**

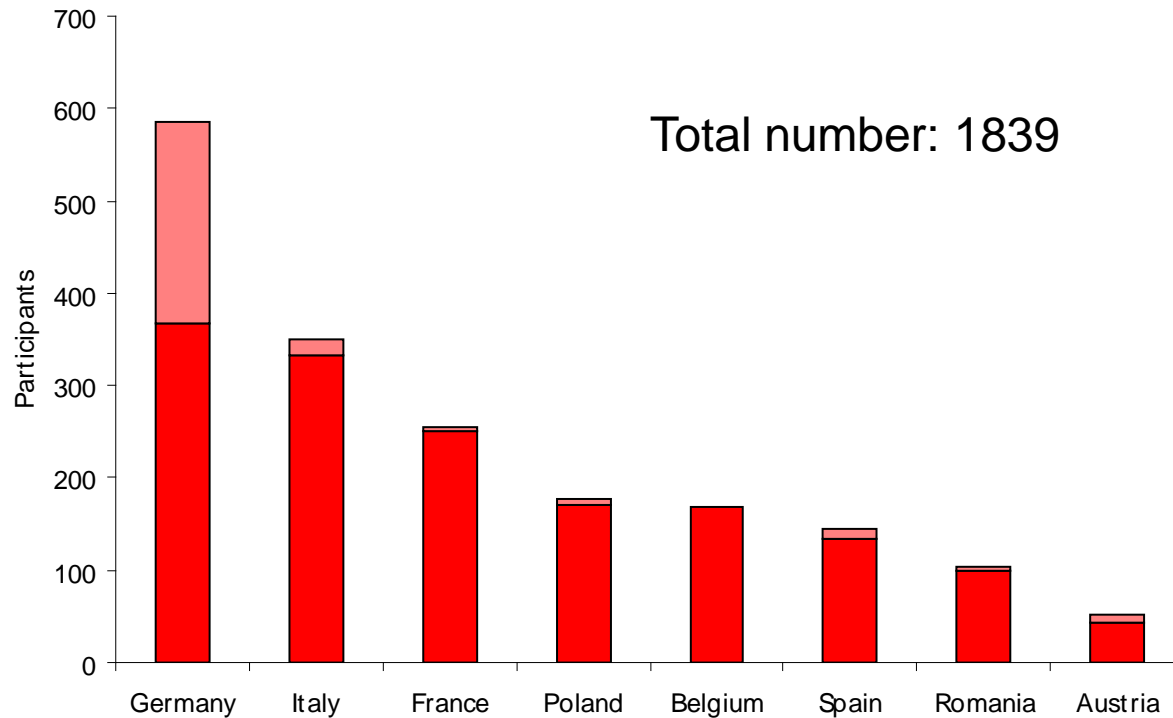
**NOGGO**  
e.v.

Nord-Ostdeutsche Gesellschaft  
für Gynäkologische Onkologie e.V.

**ESGO**  
European Society of  
Gynaecological Oncology



# Results



Numbers of participants in each country, light red columns represents online survey, dark red print survey

# Conclusions

- This study underlines the high need of ovarian cancer patients to discuss all details concerning treatment options and clinical management with only minor difference between the countries.
- Patients also need more information about side effects of cancer therapies and second opinion opportunities.
- Besides effectiveness of therapy, alopecia and fatigue are the most important side effects bothering the patients.

Final analysis regarding intercultural aspects until the end of the year

**EXPRESSION IV-Ovar**  
**What do primary and recurrent  
ovarian cancer (OC) patients  
expect from maintenance therapy?**  
**ENGOT-ov22**

# Aim and design

## Aim:

current available drugs for maintenance therapy have:

- different side effects
- administration forms
- schedules

identification of information needs and preferences regarding maintenance therapy among patients with ovarian cancer

## Design:

European survey (10-12 countries)

- 200-300 patients / country (all groups of ENGOT intent their participation)
- Internet version and hard copy version

# Project

- Survivorship of endometrial cancer
  - Endometrial cancer survey patients
  - Physicians expectations?

# Survivorship in Endometrial Cancer:

QoL in long term survivors, needs,  
and influencing factors



J McAlpine on behalf of the SB Group

# Why is it important to do a survivorship study in EM cancer?

- No clear idea of “best” follow-up/surveillance strategies for EM ca patients
- No clear idea of long term survivorship needs of all patients so we could address and support
- Beginning to understand interaction of cancer, comorbidities and BMI...needs further work
- Design interventions?



# We need a tool-do we start again?

- Many questionnaires exist-what are the essential components we want to capture?  
There are some survivorship aspects that may be unique to EM cancer patients...
- Encompassing questionnaire for ovarian cancer survivors being employed by ANZGOG → can we adapt for EM

# Components ANZGOG OvQuest survey

Series of initial questions re demographics, weight and height, prior treatment including how many lines, what drugs, participation in a clinical trial?, IP vs. IV, physicians seen, etc ...

- FACT-O
- FACT-GOG-NTX
- Insomnia severity index
- SPHERE 12
- IPAQ short form
- Supportive care needs survey-SF-34

# SB Working group

- Discussion on needs of translational research on survivorships
- Discussion on interventional studies to cope with the sequelae of the treatments (i.e. lymphoedema)
- ➡ In conclusion, the group will start with a survey and the results will be presented to the next GCIIG meeting