Nordic Society of Gynaecological Oncology

- from a Nordic interest group to a global leader in clinical trials

Line Bjørge

14. mars 2017

Profile

NSGO is a non-political, non-profit society

- ***Nordic platform*** for individual professionals dedicated to the care of women with ***gynaecological cancer***
- Works for improvements in ***the practice of prevention, diagnosis, treatment, and follow up*** of gyn cancer
- Promotes and support ***basic and clinical research***
- Promotes ***education and training*** in gynaecological oncology in all its aspects

Nordic focus – Why?

Gynecologic cancers

- Represent approximately 10% of all cancers in women

- New cases in Norway (2016)* : 1650
  - Cervix: 342
  - Womb: 774
  - Ovarian: 488
  - Vulva: 46

Nordic treatment traditions

Population: 27 000 000

- Denmark: 5 750 000
- Sweden: 10 000 000
- Finland: 5 550 000
- Norway: 5 350 000
- Iceland: 350 000

New cases in the Nordic countries (yearly)**: 8000-9000**

*
N

International cooperation

ENGOT
European Network of
Gynaecological Oncological Trial groups

GYNECOLOGIC
CANCER INTERGROUP
An Organization of International Cooperative
Groups for Clinical Trials in Gynecologic Cancers

NSGO

Cooperation with businesses

- pharmaceutical industry and non-profit organization

NSGO

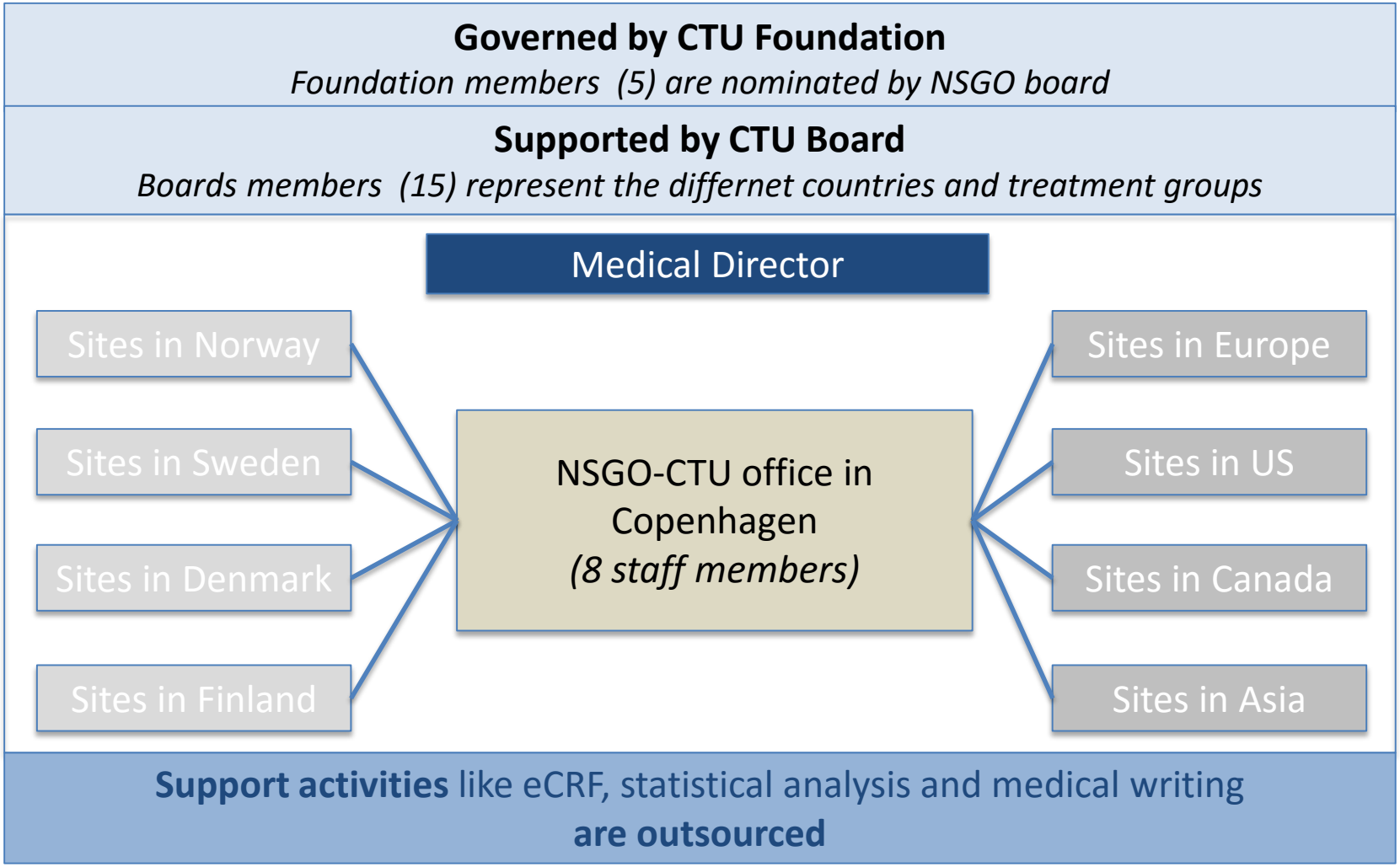
OVA CURE

From a Nordic interest group to a global leader

Expansion and growth	- From a local business to an international trendsetter - Research: Improvements and new developments
Product development	- Diversification if the portfolio - More professionalization
Corporate responsibility	- Human resources and corporate social responsibilities

1986	• ***NSGO founded*** (in Oslo): – Initial purpose: To advance the communication between the Nordic countries in the field of gynaecological cancer – Main activity: To conduct clinical trials
1986 - 2006	• Engagement in several international multicenter trials: – Intensified international cooperation – Increasing requirements to run an efficient clinical trial unit
2007	• Establishment of *"Nordisk Selskab for Gynækologisk Onkologi 's Kliniske Forskningsfond" and the operating unit* ***NSGO-Clinical Trial Unit*** *(CTU)*
2007 - 2018	• Participating in more and more trials • More differentiated trial portfolio: international multicenter trials vs. own initiated trials • More professionalization of the CTU • Economic sustainable organization

NSGO-CTU – Office
Organization and workflow



Tradition: High recruitment numbers

Supplementary appendix

List of participating sites

Institute (country) Investigator [Number of patients]

Oslo University Hospital, Dept Gynecologic Oncology and Institute for Cancer Genetics and Informatics, and Oslo University (NOR) Pr. Gunnar B. Kristensen [29]
Maria Skłodowska – Curie Institute of Oncology (POL) Dr. Mariusz Bidzinski [27]
National Institute of Oncology (SVK) Dr. Tomas Minarik [25]
St. Elisabeth Institute of Oncology (SVK) Dr. Lydia Helpianska [25]
St. John's Cancer Center (POL) Dr. Elzbieta Kutarska [25]
Haukeland University Hospital (NOR) Dr. Line Bjørge [24]
Minnesota Oncology Hematology, PA (USA) Dr. Patrick Flynn [21]
HELIOS, Dr. Horst Schmidt Kliniken Wiesbaden (DEU) Dr. Rita Hils [19]
Lund University Hospital (SWE) Dr. Susanne Malander [18]
Policlinico Universitario A. Gemelli (ITA) Pr. Giovanni Scambia [17]
Centre Léon Bérard (FRA) Dr. Olivier Tredan [16]
General Hospital of Athens "Alexandra" (GRC) Pr. Aristotelis Bamias [16]
Universitätsklinikum Essen (DEU) Pr. Pauline Wimberger [16]
Centre François Baclesse (FRA) Pr. Florence Joly [15]
University of Milan Bicocca and European Institute of Oncology (ITA) Pr. Nicoletta Colombo [15]
Rigshospitalet - Copenhagen University Hospital (DNK) Dr. Mansoor Raza Mirza [15]
Yale University School of Medicine (USA) Dr. Maysa Abu-Khalaf [15]
Clinical Oncology Dispensary (RUS) Dr. Alla Lisyanskaya [14]
UZ Leuven - Campus Gasthuisberg (BEL) Pr. Ignace Vergote [14]
Piedmont Hematology Oncology Associates (USA) Dr. Charles H Pippitt [13]
Stavanger University Hospital (NOR) Dr. Bent Fiane [13]

AGO-OVAR 12,

Lancet Oncol 2016;17:78-89

- 165 of 1366 participants

NSGO-CTU : Nordic Collaboration
Selection of trials

Aim: Establish and maintain a balanced portfolio

Formal process

- Screening
- Evaluation
- Final decision

Medical Director and Deputy Medical Director

Core group with national representatives

NSGO-CTU-Board

Feasibility questioner (national coordinators)

Similar processes both for international multicenter trials and own initiated trials, but the use of internal resources is higher for the latter

Status: Collaborations

Lead Groups	No. of Trials as Lead Group	No. of Trials as Collaborative Group
AGO Aust	**2**	15
AGO Germ	**7**	19
BGOG	**6**	25
CEEGOG	**2**	6
DGOG	**1**	7
GEICO	**3**	19
GINECO	**8**	17
MaNGO	**2**	22
MITO	**6**	23
NCRI	**4**	5
NOGGO	**6**	10
NSGO	**8**	**19**
SGCTG	**1**	3

Collaborating Groups	No. of Trials as Collaborative Group
Cancer Trials Ireland	4
EORTC	2
HECOG	4
ISGO	4
PGOG	1
SAKK	2
TRSGO	3

NSGO sponsored trials

Endometrial Cancer

- EN1 / FANDANGO
- EN2
- EN3 / PALEO

Ovarian Cancer

- NOVA
- AVANOVA
- AVANOVA-IMMUNE
- OV-UMB1

Cervical Cancer

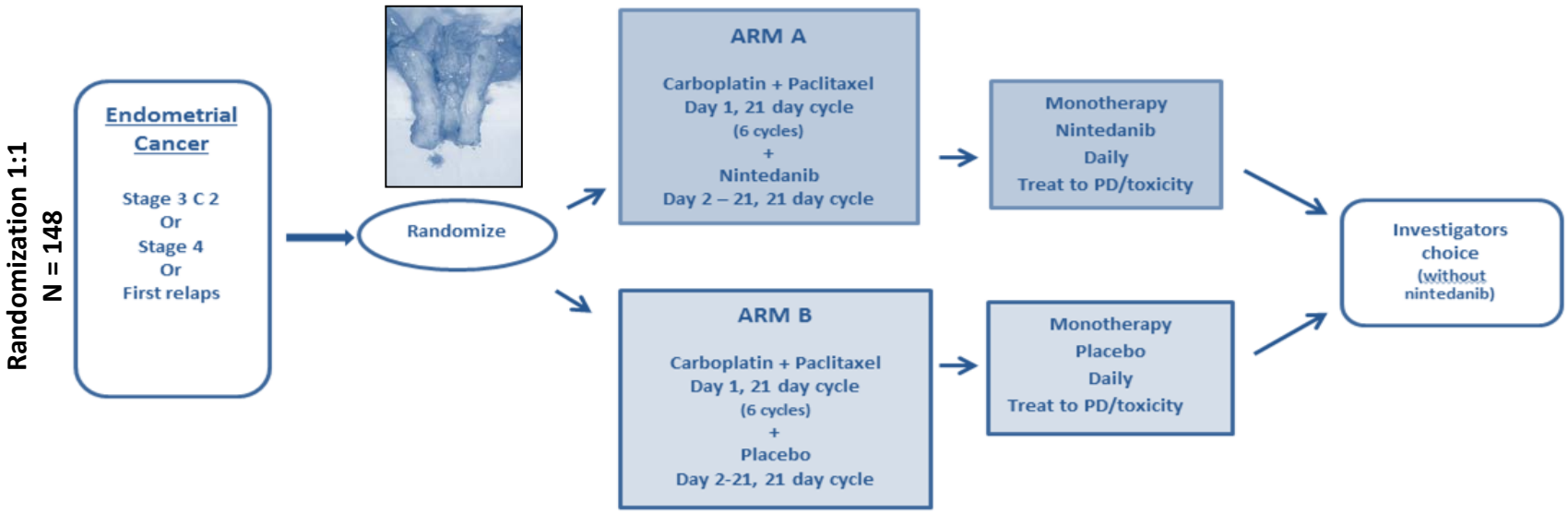
- MaRuC

Ovarian Cancer

- OvaTIL for Cure

EN1/ FANDANGO

A randomised double-blind placebo-controlled phase II trial of first line combination chemo-therapy with nintedanib/placebo for patients with advanced or recurrent endometrial cancer

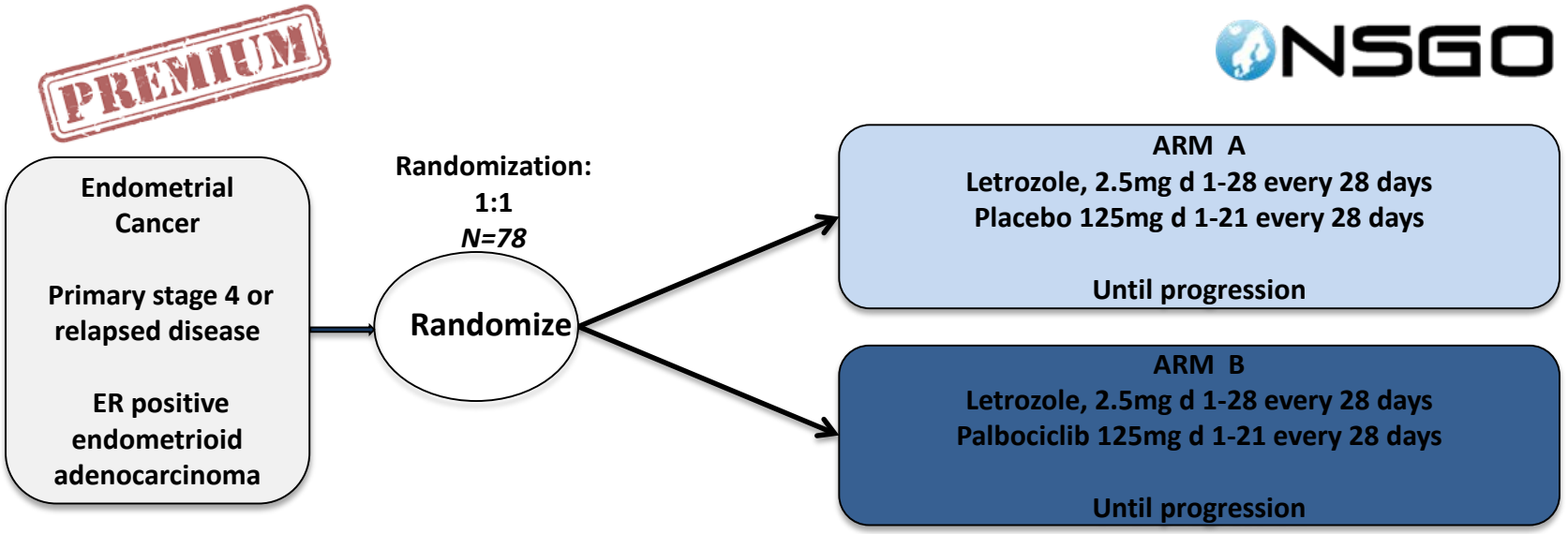


Key words: - Experience with the drug and study design from AGO-OVA 12
- Reputation as excellent recruiter

No. of already recruited patients: 42 – Planned no. of patients: 148 -Status: Recruiting

EN3-NSGO/ PALEO

A randomized, double-blind, placebo-controlled, phase II trial of Palbociclib in combination with Letrozole versus Placebo in combination with Letrozole for patients with Estrogen Receptor Positive advanced or recurrent Endometrial cancer



Key words: - Use concepts from other diseases
- New treatment principle for endometrial cancer
- Might result in change in treatment practice

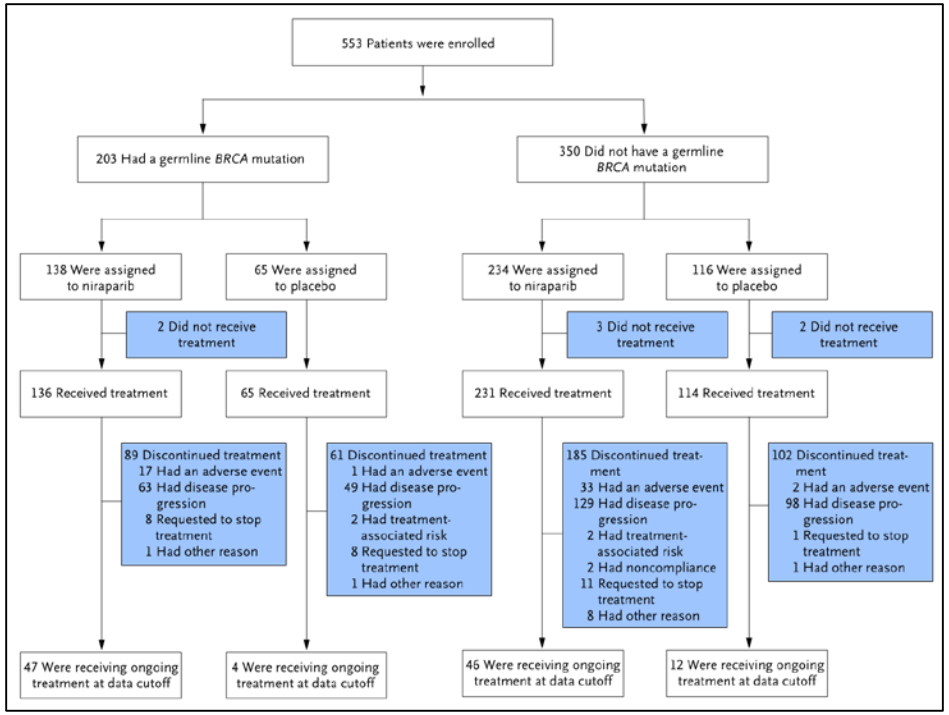
No. of already recruited patients: 10; Planned no. of patients: 78; Status: Recruiting

ENGOT-OV16 / NOVA

Niraparib Maintenance Therapy in Platinum-Sensitive, Recurrent Ovarian Cancer

NSGO

PREMIUM



Key words:

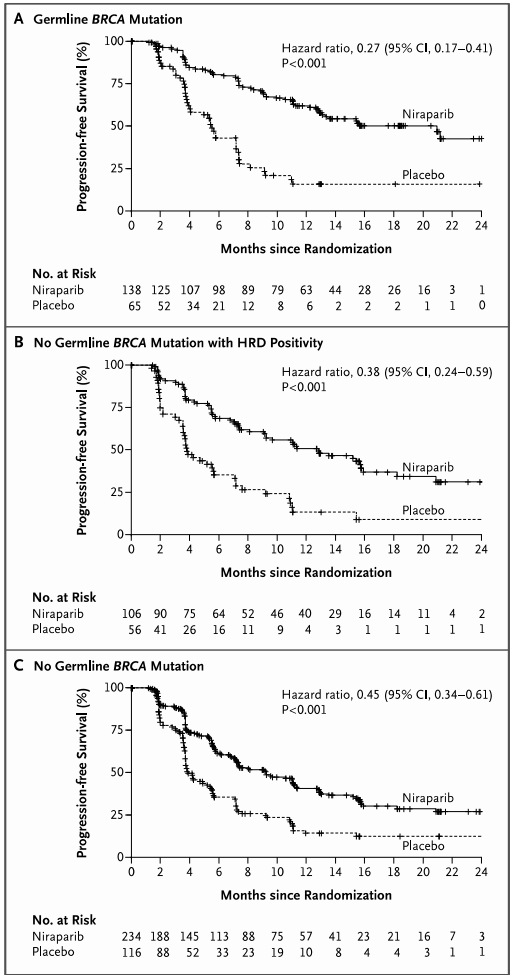
- Second international PARP-inhibitor trail for ovarian cancer
- New treatment principle
- Change of practice

Mirza MR et al. N Engl J Med 2016;375:2154-64

ENGOT-OV16 / NOVA

PI/chair: Mansoor Raza Mirza

Niraparib Maintenance Therapy in Platinum-Sensitive, Recurrent Ovarian Cancer



g*BRCA*mut

Treatment	PFS Median (95% CI) (Months)	Hazard Ratio (95% CI) p-value	% of Patients without Progression or Death	
			12 mo	18 mo
Niraparib (N=138)	21.0 (12.9, NR)	0.27 (0.173, 0.410) p<0.0001	62%	50%
Placebo (N=65)	5.5 (3.8, 7.2)		16%	16%

non-g*BRCA*mut

Treatment	PFS Median (95% CI) (Months)	Hazard Ratio (95% CI) p-value	% of Patients without Progression or Death	
			12 mo	18 mo
Niraparib (N=234)	9.3 (7.2, 11.2)	0.45 (0.338, 0.607) p<0.0001	41%	30%
Placebo (N=116)	3.9 (3.7, 5.5)		14%	12%

Status of FDA & EMA approvals for Niraparib

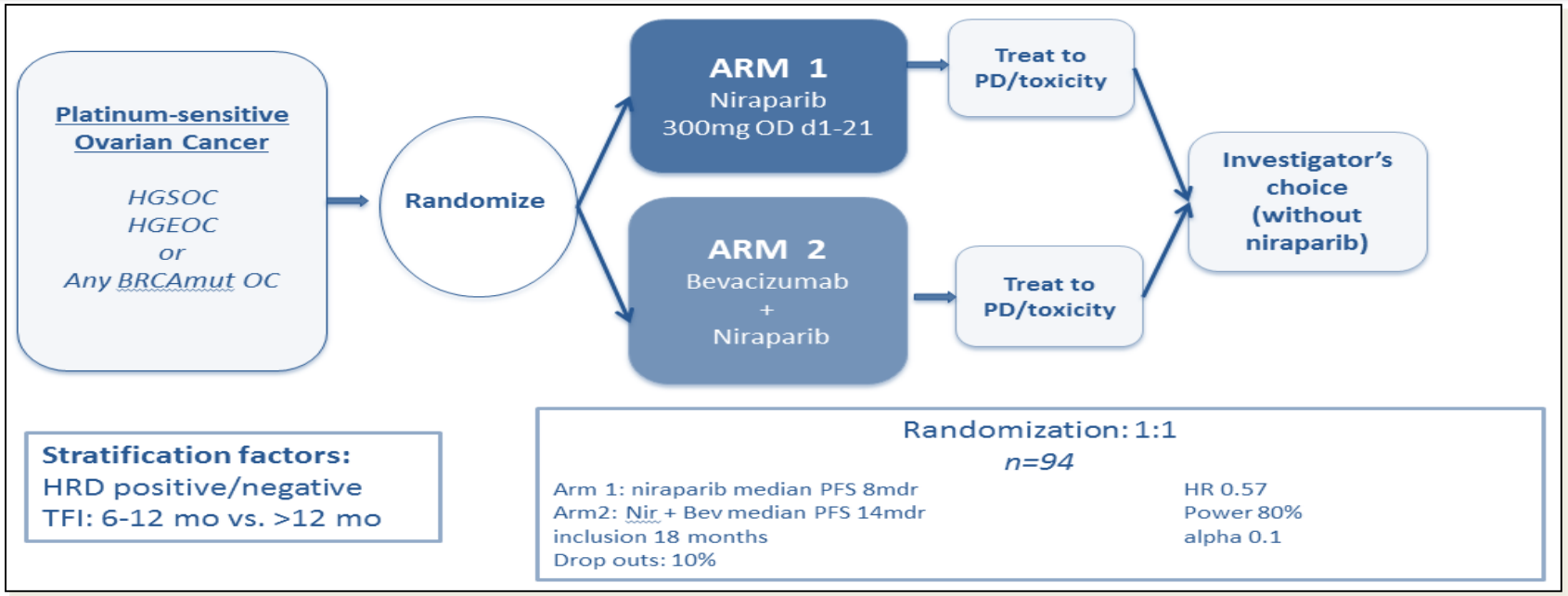
- Maintenance Therapy-

FDA	EMA
All patients regardless of histology, BRCA & HRD status	All patients regardless of BRCA & HRD status Positive CHMP opinion

What will be the priority setting decision?

PREMIUM OV24/ AVANOVA

A two-arm, open-label, phase II randomized study to evaluate the efficacy of niraparib versus niraparib-bevacizumab combination in women with platinum-sensitive epithelial ovarian, fallopian tube, or peritoneal cancer



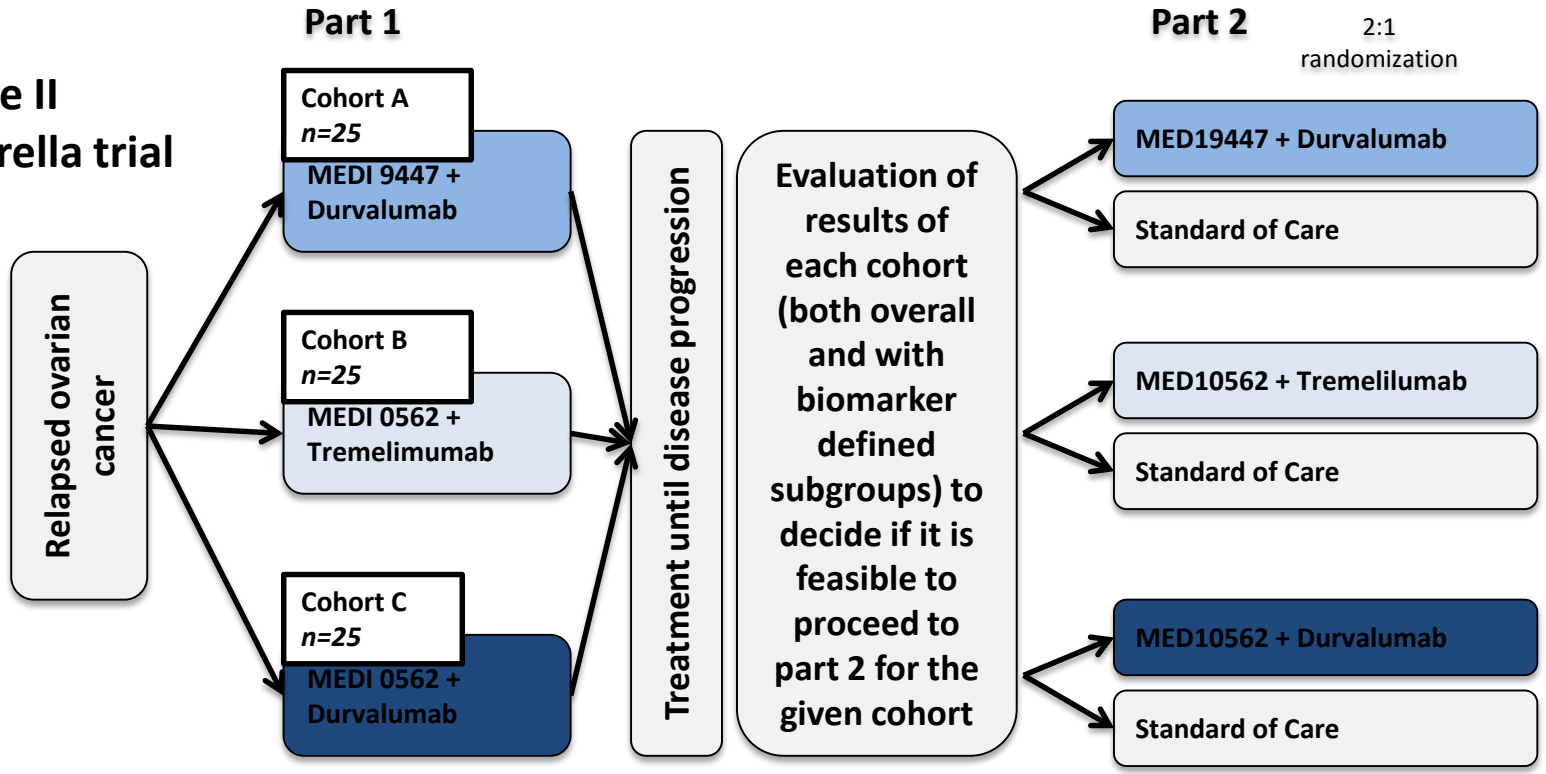
Key words:

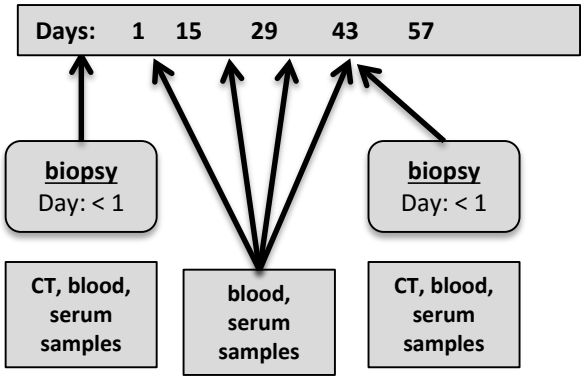
- A chemo-free alternative / New treatment principle
- Change of practice

No. of already recruited patients: 98; Planned No. of patients: 94;Status: Closed for recruitment

ENGOT-OV30 / NSGO-OV-UMB1

Design:
- **phase II**
- **umbrella trial**

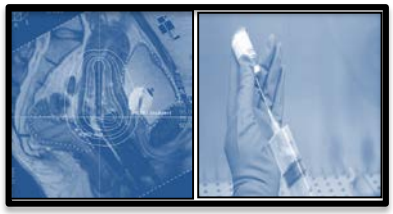




Key words:
- New study design
- New way to collaborate
- Increasing complexity
- Advance translational research protocols

ENGOT-CX7-NSGO/MaRuC

A randomized double-blind placebo-controlled phase II trial of Rucaparib maintenance therapy for patients with locally advanced cervical



n = 162
Randomization: 2:1

Cervical cancer

Squamous, adenosquamous, adenocarcinoma

Stage 2B, 3 & 4

Patients have successfully completed definitive treatment

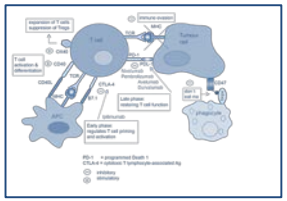
→ **No residual disease** → **Randomize**

Arm A
Rucaparib 600mg BID for 24 months

Arm B
Placebo BID for 24 months

Key words: - Use concepts from other diseases
- New treatment principle for cervical cancer
- Might result in change in treatment practice

OVATIL for Cure



Relapsed ovarian cancer

Each Cohort *n=12*

- **Cohort 1: Carboplatin-Pegylated Lyposomal Doxorubicin (PLD) x2 followed by High-Dose CT & TIL**
- **Cohort 2: Carboplatin-PLD x2 followed by High-Dose CT & TIL followed by acetylsalicylic acid**
- **Cohort 3: Carboplatin-PLD x2 followed by High-Dose CT & TIL followed by acetylsalicylic acid in combination with Durvalumab**
- **Cohort 4: Carboplatin-PLD x2 followed by High-Dose CT & TIL followed by acetylsalicylic acid in combination with Durvalumab + IDOi**
- **Cohort 5: Carboplatin-PLD x2 followed by High-Dose CT & TIL followed by acetylsalicylic acid in combination with Durvalumab + A2aRi**
- **Cohort 6: Carboplatin-PLD x2 followed by High-Dose CT & TIL followed by acetylsalicylic acid in combination with Durvalumab +MEDI9447**

Treatment until disease progression

Evaluation of results of each cohort to decide if it is feasible to proceed to part 2 for the given cohort

Days: 1 day -7of TIL day -1 of TILL day 21 of TIL

biopsy Day: < 1		Biopsy
CT, blood, serum samples	blood, serum samples	CT, blood, serum samples

Key words:

- Early phase studies
- Advanced and complex

From a Nordic interest group to a global leader

Expansion and growth

- From a local business to an international trendsetter
- Economic sustainable organization

Product development

- Research: Improvements and new developments
- Diversification if the portfolio

Corporate responsibility

- More professionalization
- Human resources and corporate social responsibilities

2007 - 2018

- Participating in more and more trials
- More differentiated trial portfolio: international multicenter trials vs. own initiated trials
- More professionalization of the CTU
- Economic sustainable organization

Success factors

Network and networking

Strategic thinking

Dedication

Economy

Professionalization

Education and training

Contact information

@	Email Line Bjørge line.bjorge@uib.no
twitter	@DrLB and @reachoutinova
f	Like 'Line Bjørge' and 'Reachout Inova'
in	Follow 'Line Bjørge'
www.	https://inova.w.uib.no