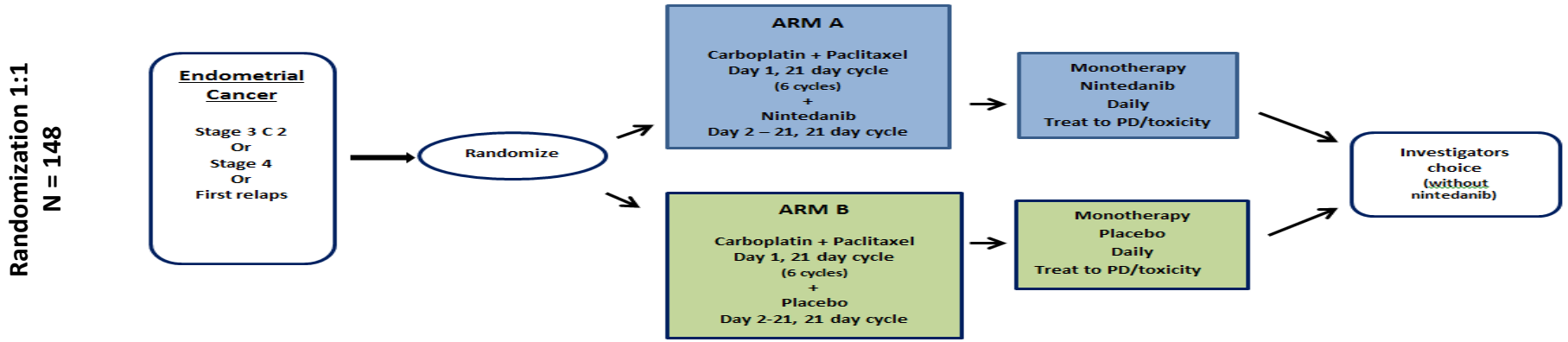
Ongoing Trials – status update

EN1/FANDANGO
Sponsor: NSGO

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

Study Design:



Stratification:

- Stage of disease (stage 3C 2 vs. stage 4 vs. recurrent disease)
- Prior adjuvant chemotherapy (yes/no)
- Disease status (Measurable vs. non-measurable disease according to RECIST 1.1)

Planned No. of patients: 148

Current accrual: 128

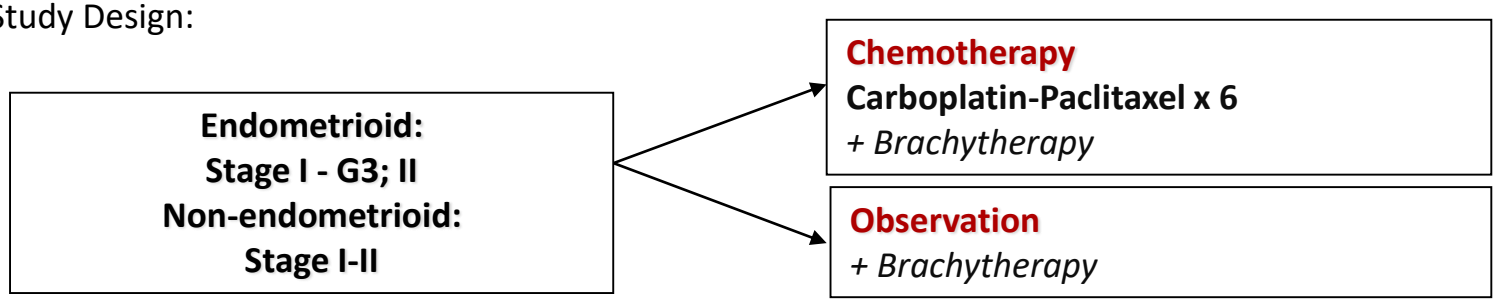
Other important information: Status - recruiting

Ongoing Trials – status update

ENGOT- N2-DGCG
Sponsor: DGCG

A phase II Trial of postoperative chemotherapy or no further treatment for patients with node-negative stage I-II intermediate or high risk endometrial cancer.

Study Design:



1:1 randomization

Sponsor(s): DGCG

Planned No. of patients: 240

Current accrual: 220

Other important information: Status - recruiting

Supported by

Danish Cancer Society

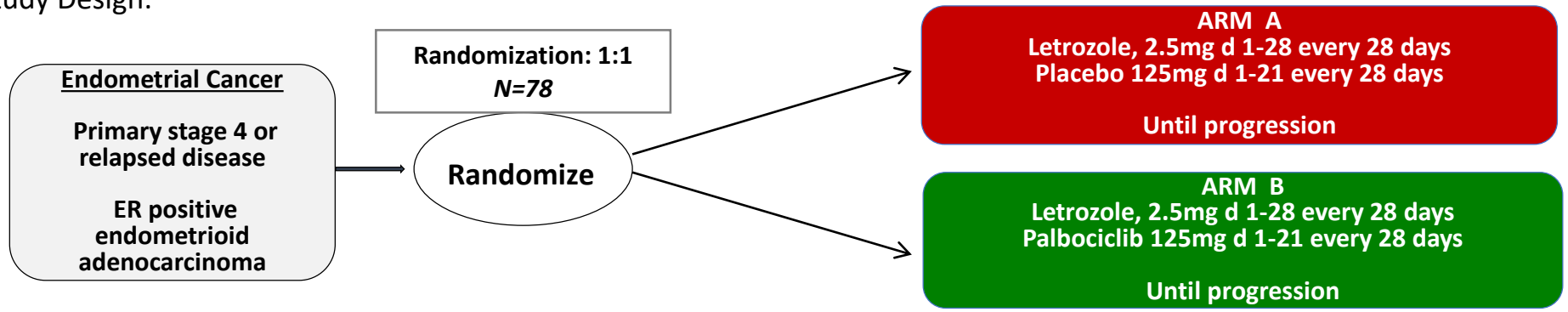
EORTC

Ongoing Trials – status update

EN3-NSGO/PALEO
Sponsor: NSGO

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.

Study Design:



Stratification:
- Number of prior lines (primary adv disease vs. 1st relapse vs. ≥2 relapses)
- Measurable vs. evaluable disease
- Prior use of MPA/Megace

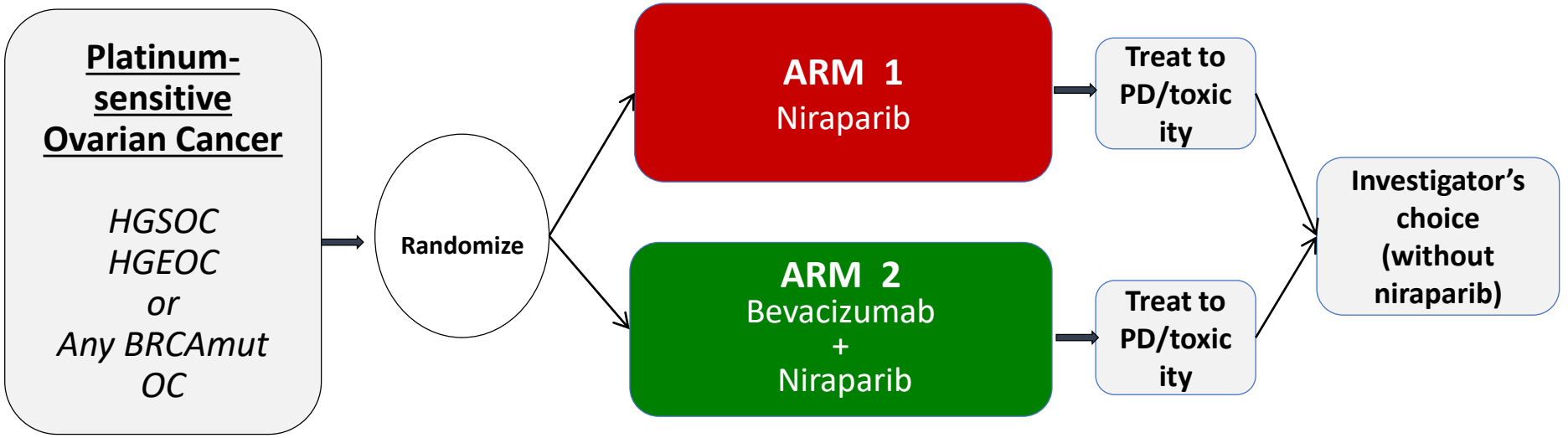
Planned No. of patients: 78

Current accrual: 67

Other important information: *Slow recruitment in the PALEO study.* ***MITO still pending regarding approvals from CA and EC***

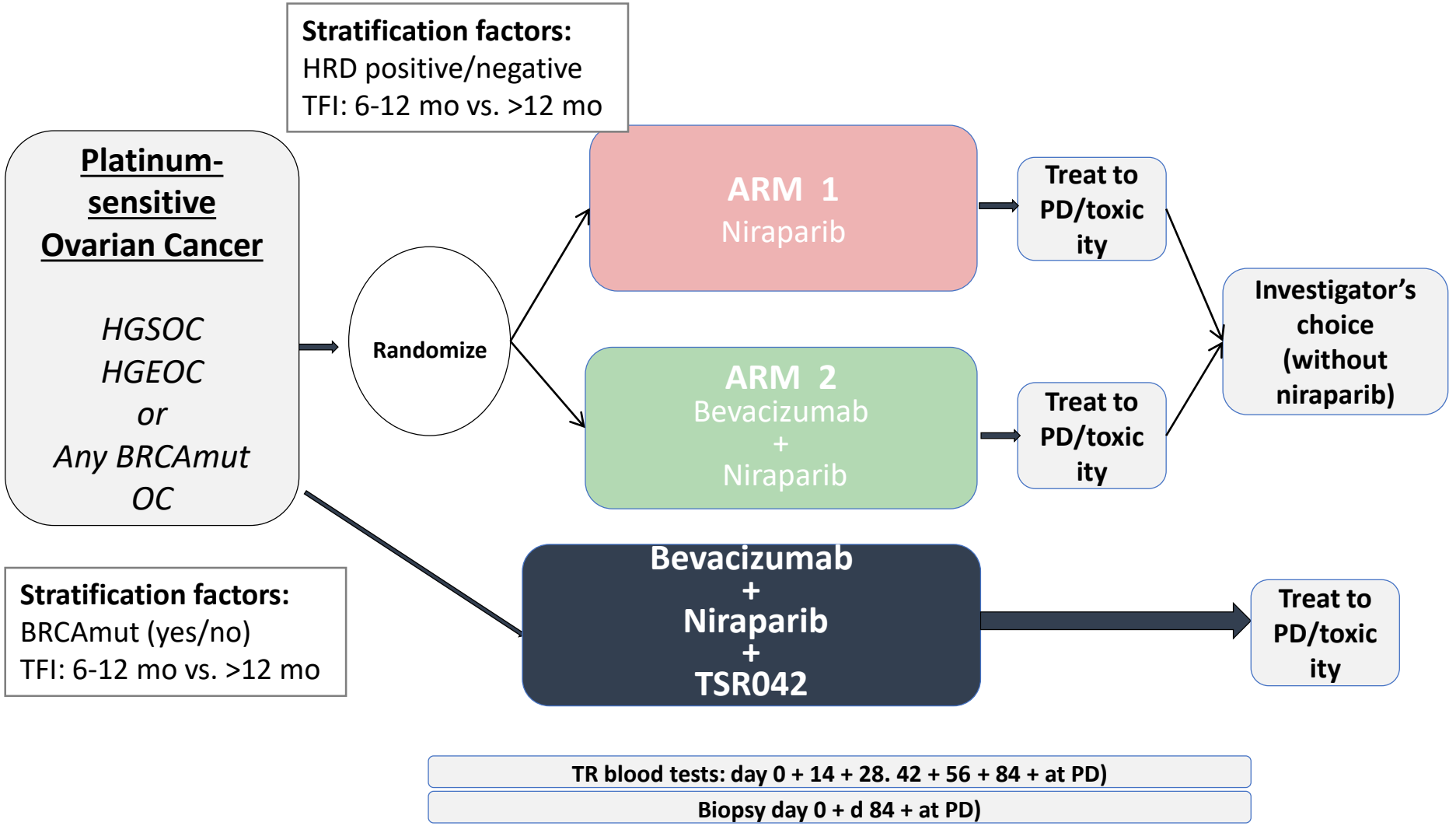
ENGOT-OV24-NSGO / AVANOVA part 3
Sponsor: NSGO

Stratification factors:
HRD positive/negative
TFI: 6-12 mo vs. >12 mo



Randomization: 1:1
n=94
Hypothesis: Arm 1: niraparib median PFS 8mdr
Arm2: Nir + Bev median PFS 14mdr
HR 0.57
Power 80%
alpha 0.1
inclusion 18 months

ENGOT-OV24-NSGO/AVANOVA – Part 3



ENGOT-OV24-NSGO / AVANOVA part 3
Sponsor: NSGO

Same Inclusion / exclusion criteria
Same sites
Number of BRCAmut patients capped to the same ratio as in part 2

Trial status:

PART 1 *(phase 1; niraparib-bevacizumab; 12 patients)*
Manuscript being prepared

PART 2 *(phase 2 randomized; niraparib-bevacizumab versus niraparib; 103 patients)*
Events maturity awaited

PART 3 *(phase 2 triplet; niraparib-bevacizumab-TSR042; 72 patients)*
To be started in Q1

ENGOT-OV30 / NSGO / UMBRELLA
Sponsor: NSGO

A phase II umbrella trial in patients with relapsed ovarian cancer
ENGOT-OV30 / NSGO

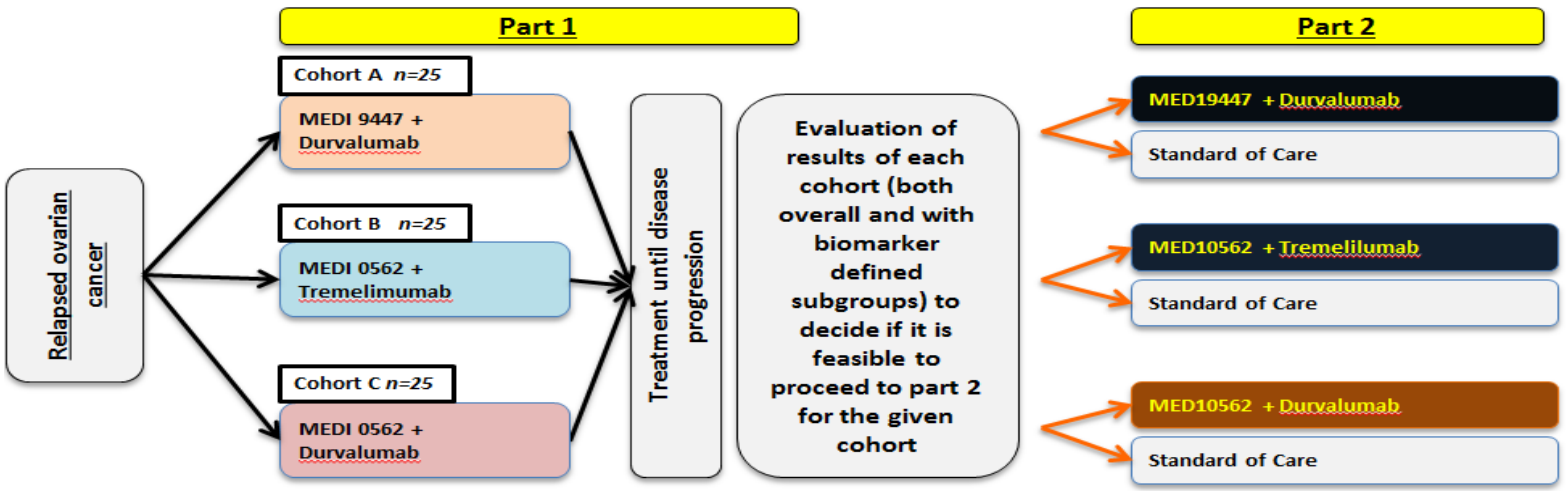
Participating groups & Lead PIs:

NSGO:	MR Mirza
SGCTG UK:	C Gourley
PMHC Canada:	A Oza
BGOG Belgium:	I Vergote
ANZGOG Australia:	M Friedlander
COGI US:	J Barek
GOTIC Japan:	K Fujiwara
KGOG S Korea	SY Ryu
NOGGO Germany:	Jalid Sehouli

Study Status

- **Cohort A: Enrolling.**
- **Cohort B & C: To be submitted in Q4**

ENGOT-OV30 / NSGO UMBRELLA



NSGO-OV-UMB1
ENGOT-OV30

A randomized trial of atezolizumab, niraparib and bevacizumab combination for patients with recurrent ovarian cancer.

ENGOT-OV42 / NSGO / BAN-ROC

Sponsor: NSGO

Study Chair: Mansoor Raza Mirza

FPI (expected): Q3 2019

ENGOT-OV42 / NSGO / BAN-ROC

Sponsor: NSGO

- CFI of 1-6 months of last receipt of chemotherapy
  OR
- CFI of <1 month of last receipt of chemotherapy
- Patients must have received platinum-containing therapy
- Max of 5 series of prior therapies for the relapsed disease though max 2 series of prior therapies for plat-resistant relapse.
- Patients may have received bevacizumab.
- Patients may have received PARP inhibitor
- No prior immunotherapy.

Standard of Care
Mono-chemotherapy with/without bevacizumab

1:2 randomization
N 168

Non-chemo experimental arm
Bevacizumab-Atezolizumab-Niraparib

Stratification
- Prior use of PARPi (yes/no)
- Prior use of bevacizumab (yes/no)
- treatment free interval to prior therapy (upto 4 wks versus >4 wks)
- No. of lines of therapy as platinum resistant disease. (one versus more)

Treat until progression of disease

ENGOT-OV42 / NSGO / BAN-ROC

Objectives

Primary objectives:

- Compare Overall Response Rate (ORR) according to RECIST (ORR) of niraparib-bevacizumab-atezolizumab against Standard of care (SoC) therapy.
- In hierarchal pattern if ORR is positive, progression-free survival (PFS) will be evaluated

Main secondary objective:

- Overall survival (OS)
- Duration of response

Secondary objectives:

- Safety and tolerability of atezolizumab when given in combination with niraparib-bevacizumab.
- PFS according to trial stratification factors.
- Objective response rate according to irRECIST (irORR)
- Disease control rate (DCR) (CR+PR+SD)
- Patient Reported Outcomes (PROs)
- TFST, PFS2, TSST

ENGOT-OV42 / NSGO / BAN-ROC

Treatment arms

- **Arm A:**

chemotherapy alone (weekly paclitaxel or PLD or gemcitabin)
or
chemotherapy + bevacizumab (only bevacizumab naïve patients can receive bevacizumab).

- **Arm B:**

Niraparib 200mg PO once daily until disease progression.
Bevacizumab 15mg/kg IV q 21 days until disease progression
Atezolizumab until progression (dose to be added)