DUO-O

- Newly diagnosed advanced high grade epithelial OvC stage III-IV
- Primary surgery or interval debulking surgery (IDS)
- All comers

N = 927

1:1:1

Arm 1 (SOC)
N=309
CTX 6 cycles q3wk
Bevacizumab q3wk

Arm 2 (Tx intensification)
N=309
CTX 6 cycles q3wk
Bevacizumab q3wk
Durvalumab q3wk

Arm 3 (Tx intensification with olaparib maintenance)
N=309
CTX 6 cycles q3wk
Bevacizumab q3wk
Durvalumab q3wk

Olaparib 300mg BD (24 months)

5 months | 15 months | 30 months

Maintenance for all pts without PD on CTX (CR, PR, SD)

Olaparib till PD for pts with evidence of disease at 24 mo

Primary:
- PFS by Inv (BICR sensitivity)

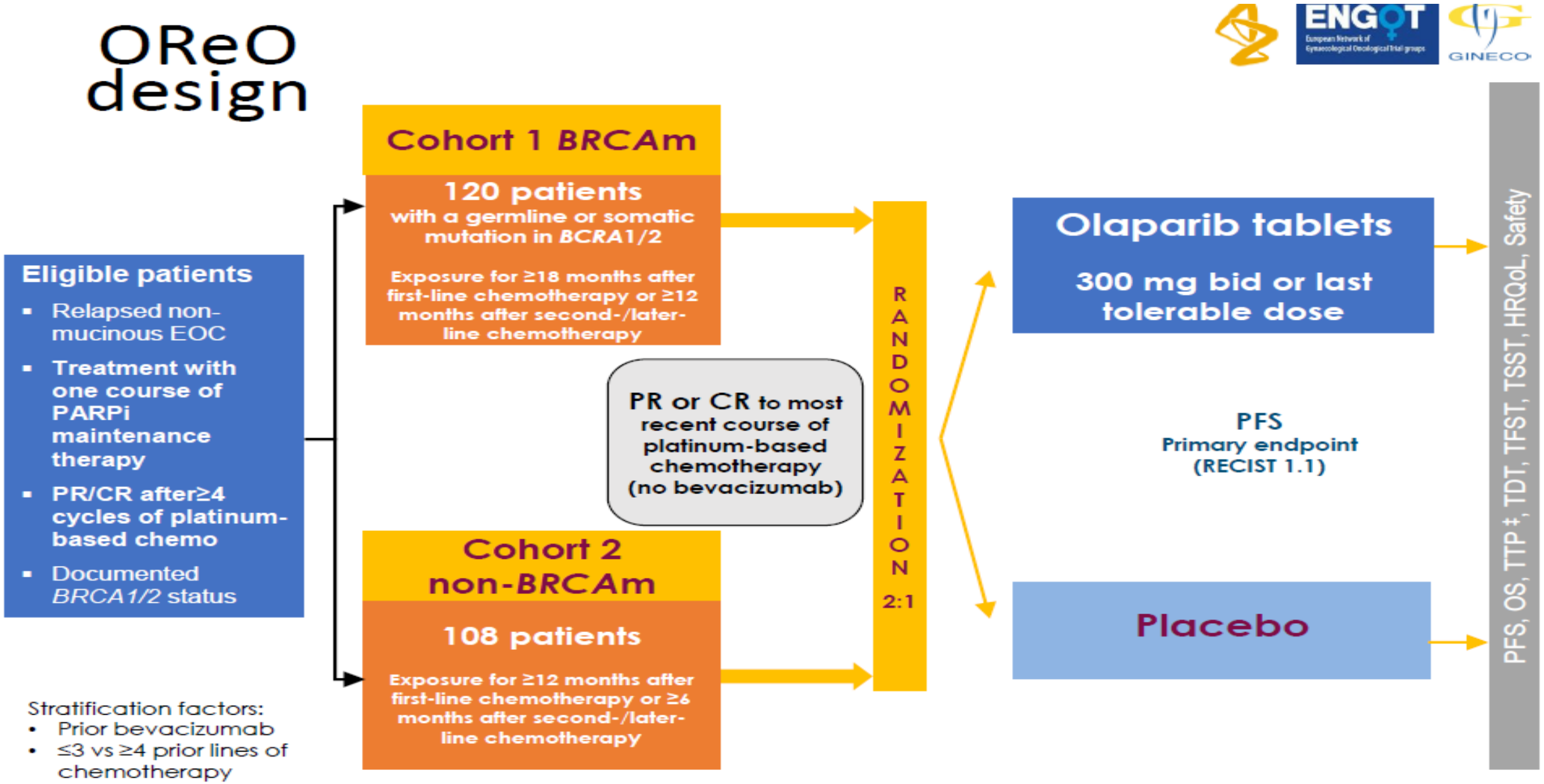
Formal Secondary (tested):
- OS

Other secondary
- PFS2
- ORR
- HRQOL
- TFST, TSST, TDT

Stratification:

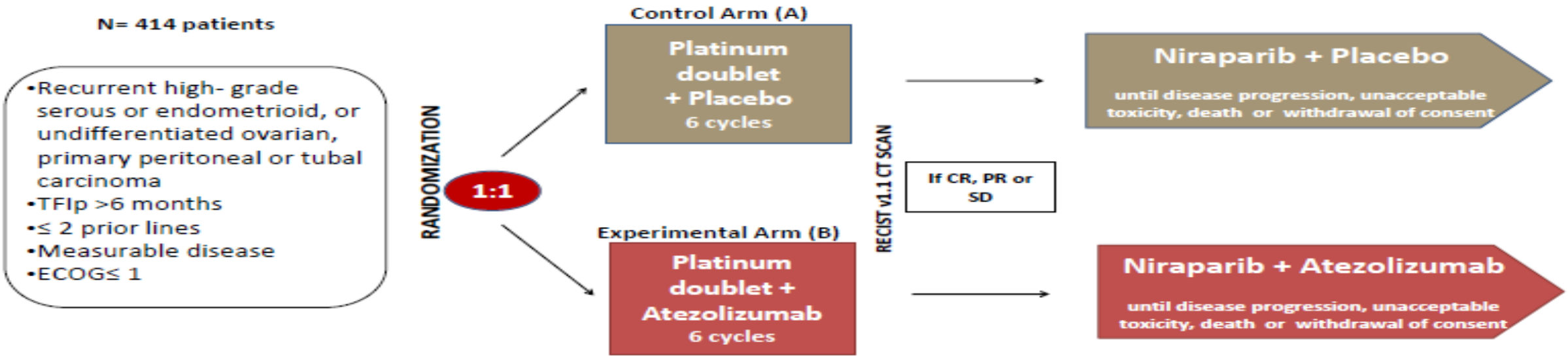
1) No residual vs. residual or IDS
2) tBRCAwt vs. tBRCAmut
3) Region: US; EU, RoW

OReO design



Stratification factors:
- Prior bevacizumab
- ≤3 vs ≥4 prior lines of chemotherapy

Study design ANITA

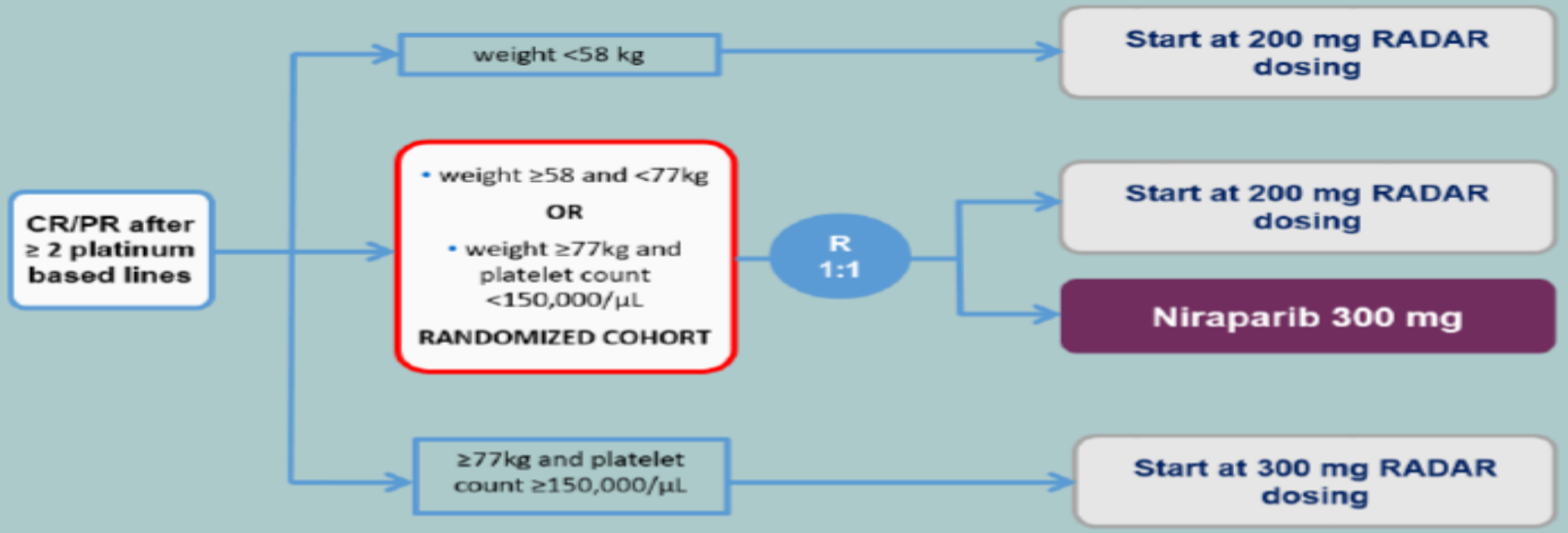


Stratification factors:

- Platinum based regimen selected
- PFI (6-12 months vs. > 12 months)
- BRCA mutation status (mutated vs. non-mutated)
- PD-L1 expression status (positive vs. negative vs. non informative)

Disegno dello studio

NEWTON



Fattori di minimizzazione per la parte randomizzata:

- sensibilità al platino (da 6 a <12 mesi vs ≥12 mesi);
- l'utilizzo di bevacizumab concomitante alla penultima linea di terapia a base di platino;
- la migliore risposta (parziale o completa) durante l'ultima linea di trattamento con platino.

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N.B. non arrotondare il valore del peso

Es. peso di 57.9 kg → gruppo non randomizzato