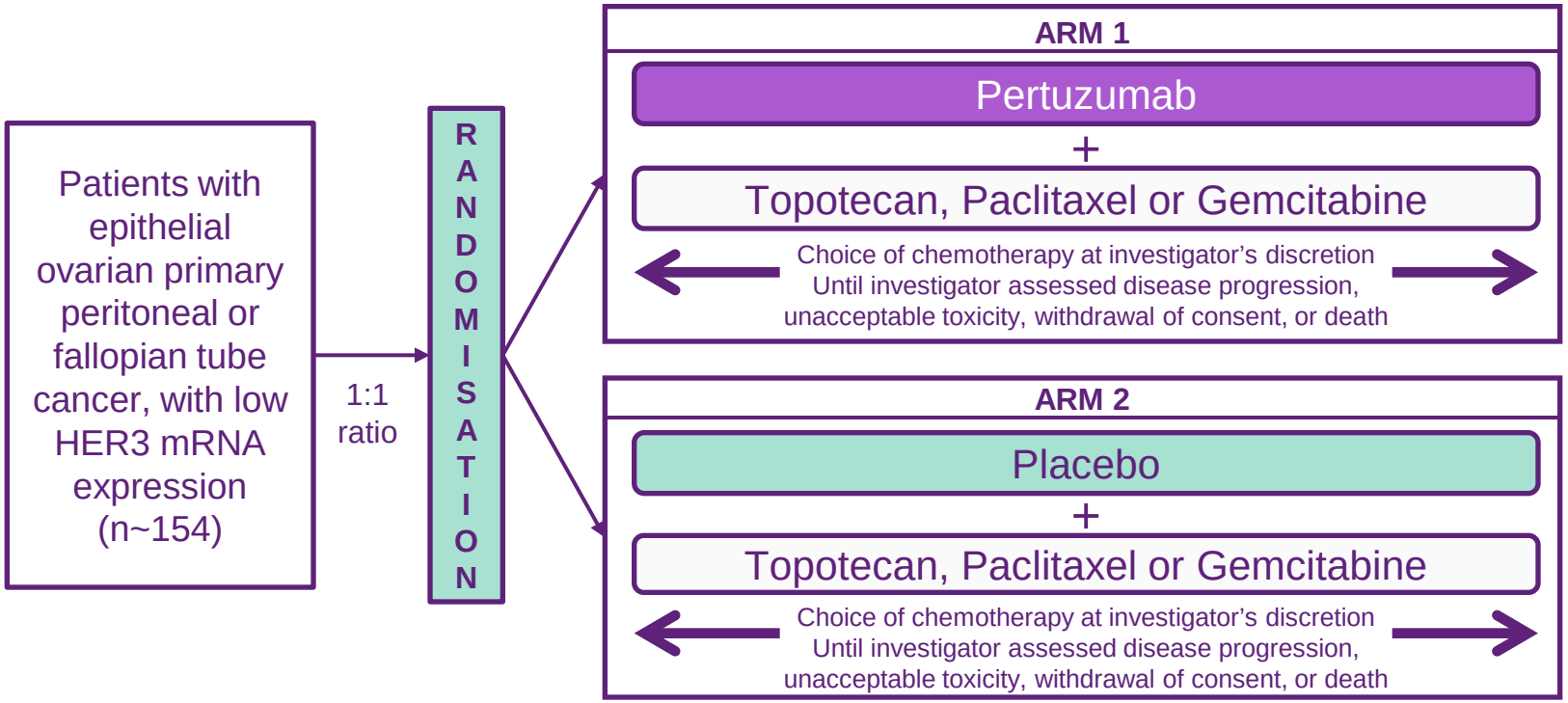
ENGOT Ov-14 Trial
AGO-OVAR 2.20
Study Design Part 2



Stratification factors:

- Selected chemo cohort (topotecan vs. paclitaxel vs. gemcitabine)
- Previous anti-angiogenic therapy (yes vs. no)
- Treatment-free interval from last cycle of platinum to disease progression after platinum therapy (strictly less than 3 months vs. 3 to 6 months inclusive)

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Country status Part 2

Group	Country	Approval Authority	Approval Ethics Committee	Comments
AGO	Germany	02-Aug-2013	29-Jul-2013	In principal ready to start PEI requests feedback IDMC
AGO-A	Austria	*Expected Mid September*	*Exp. End September*	
BGOG	Belgium	*Exp. Mid October*	*Exp. Mid October*	
DGOG	The Netherlands	*Exp. Mid September*	15-Aug-2013	EC requests feedback IDMC
GEICO	Spain	23-Jul-2013	nk-Jul-2013	Ready to start
GINECO	France	01-Aug-2013	*Exp. Mid October*	
MaNGO / MITO	Italy	10-Jul-2013	10-Jul-2013	
NSGO	Denmark	*Exp. End November*	*Exp. End November*	
NSGO	Norway	*Exp. Mid September*	08-Aug-2013	
NSGO	Sweden	*Exp. End September*	*Exp. End September*	
TRSGO	Turkey	*Exp. End September*	*Exp. End September*	

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Status 9th September 2013

- 13-Mar-2013 - Closure screening for Topotecan in Part 1
- 21-May-2013 - Closure screening for Paclitaxel in Part 1
- 02-Jul-2013 - Last Patient enrolled into Part 1

In total, 52 patients have been enrolled into Part 1.

GEICO	18 patients
GINECO	13 patients
AGO	11 patients
MaNGO	6 patients
DGOG	4 patients

- 09-Aug-2013 - F2F meeting IDMC – Review Safety Data Part 1
  → The IDMC requested to see all the safety data once all enrolled patients have completed 3 cycles, before giving the final go ahead for part 2.
- 30-Aug-2013 – requested data have been provided
- **Final go for part 2 on 23-Sep-2013**

Issue Site's compensation for TR Part and Independent Review

- May 2013: Budget including site's compensation was approved by Roche.
  → Roche affiliates and participating groups were informed accordingly

- August 2013: Roche affiliates have not been informed about agreed compensation. In fact, the Roche affiliates have been asked to contact the sites and ask for an estimation of an adequate compensation. Roche Global informed AGO that they could not negotiate a global budget for all affiliates due to the fact that they are bound by the fair market value which is different in each country. This fact was not mentioned during the negotiations. Instead Roche provide the written approval for the budget.
  → Under these circumstances AGO is not able to negotiate any international budget.

- AGO is not sure if it will be possible that German sites will take part in the PK Substudy and collect whole blood samples. This will be discussed with the German sites.