

# **NSGO-CTU Investigator Meeting**

**Mansoor Raza Mirza**

# CTU Achievements in the last 12 months

## Building a great team in NSGO-CTU Office

### CTU Temadag

- September 2023
- January 2024
- September 2024

### CTU participation in DHL run

- September 2024

### CTU Team Building Trip

- October 2024 (Dublin)

## Stability and great working atmosphere

# CTU Achievements in the last 12 months

## Investigator Meetings

With multiple symposia

- December 2023
- April 2024

## NSGO-CTU Symposium in Dublin

Immunotherapy in endometrial cancer

- October 2024

## Educational Activities

**2.5 days Gynaecological Cancer Master classes** for gynae oncologists from Latin America & Middle East

- December 2023
- June 2024

**Chinese Clinical Trial leaders** one day visit with discussion on possibility of future collaboration

- October 2023

## Other academic activities

- GCIg Endometrial Cancer Consensus Conference: *Creutzberg CL, et al. Lancet Oncol 2024*
- GCIg Cervical Cancer Consensus Conference 2024

# CTU Achievements in the last 12 months

## Publications of NSGO-CTU led trials

- Auranen A, et al. Safety of dostarlimab in combination ... (RUBY). Ther Adv Med Oncol. 2024
- Valabrega G, et al. Patient-reported outcomes ...RUBY trial. Int J Gynecol Cancer. 2024
- Mirza MR, et al. A Plain Language Summary of RUBY. Future Oncol. 2024
- Mirza MR, et al. NSGO-OV-UMB1/ENGOT-OV30. Gynecol Oncol. 2024
- Powell MA, et al. Overall survival in RUBY trial. Ann Oncol. 2024
- Korsholm LM, et a. Combining HRD Testing and Functional RAD51 Analysis – AVANOVA subst. JCO Precis Oncol. 2024
- Mirza MR, et al. PD-1 and PD-L1 Blockade plus Chemotherapy in Endometrial Cancer. N Engl J Med. 2023
- Mirza MR, et al. Dostarlimab for Primary Advanced or Recurrent Endometrial Cancer. N Engl J Med. 2023

# CTU Achievements in the last 12 months

## Type C Trials: **ENGOT/Global lead**

- I. **ENGOT-EN24:** T-DXd (HER2 ADC) in first-line endometrial cancer
- II. **ENGOT-EN25:** BNT323 (HER2 ADC) in second-line endometrial cancer
- III. **ENGOT-Cx20:** MK-2870 (TROP2 ADC) in second-line cervical cancer

# CTU Achievements in the last 12 months

## Type A Trials:

### I. **Successfully secured budget for HERO trial amendment**

- I. sample size increase from 350 to 1000 (approved)
- II. follow-up extended from 3 years to 5 years (approved)
- III. funding for testing predictive biomarkers agreed (include but is not limited to FR $\alpha$ , HER2, TROP-2, PD-L1 (including interplay of 22C3 and SP263))

### II. **Successfully secured budget for PELENEO trial**

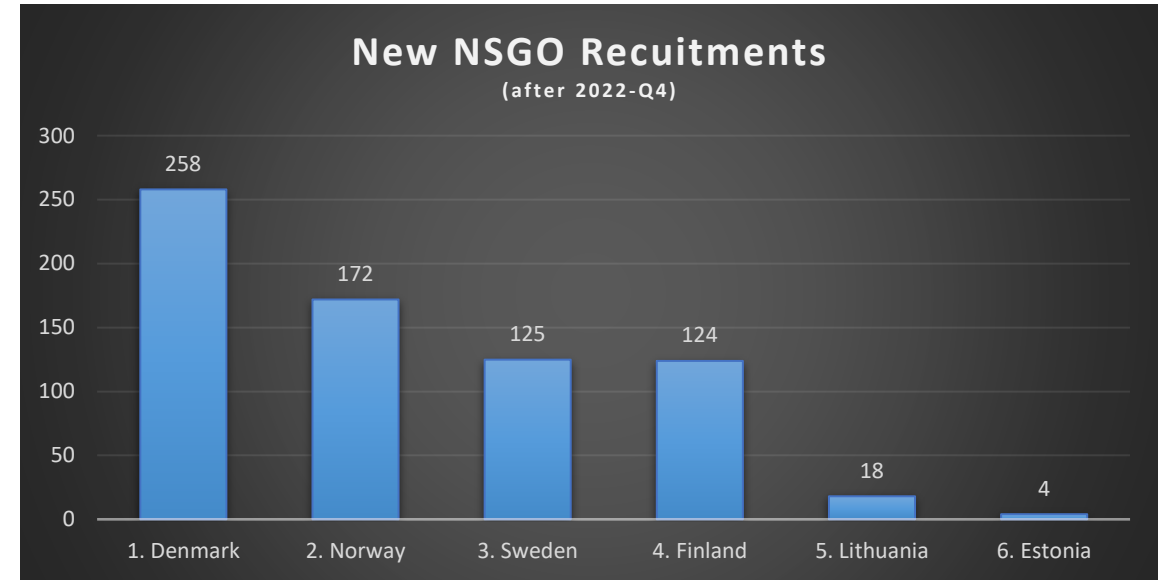
### III. **Successfully secured budget for new NSGO-CTU trial proposal on shortening the treatment duration of immunotherapy to 12 months in endometrial cancer dMMR population**

# CTU Achievements in the last 12 months

First successful CTIS Submission by NSGO-CTU on 14. October 2024:

The DOVACC study

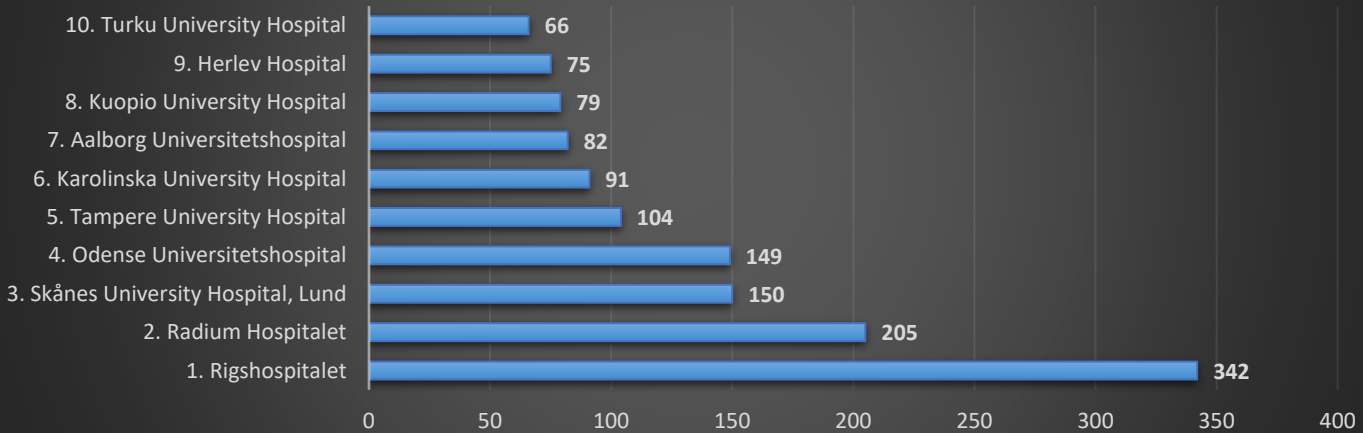
# Clinical Trial Statistics





# Clinical Trial Statistics

**NSGO Top 10 Sites**  
(Based on Total Recruitments)



New recruitments since 2022 Q4 by country

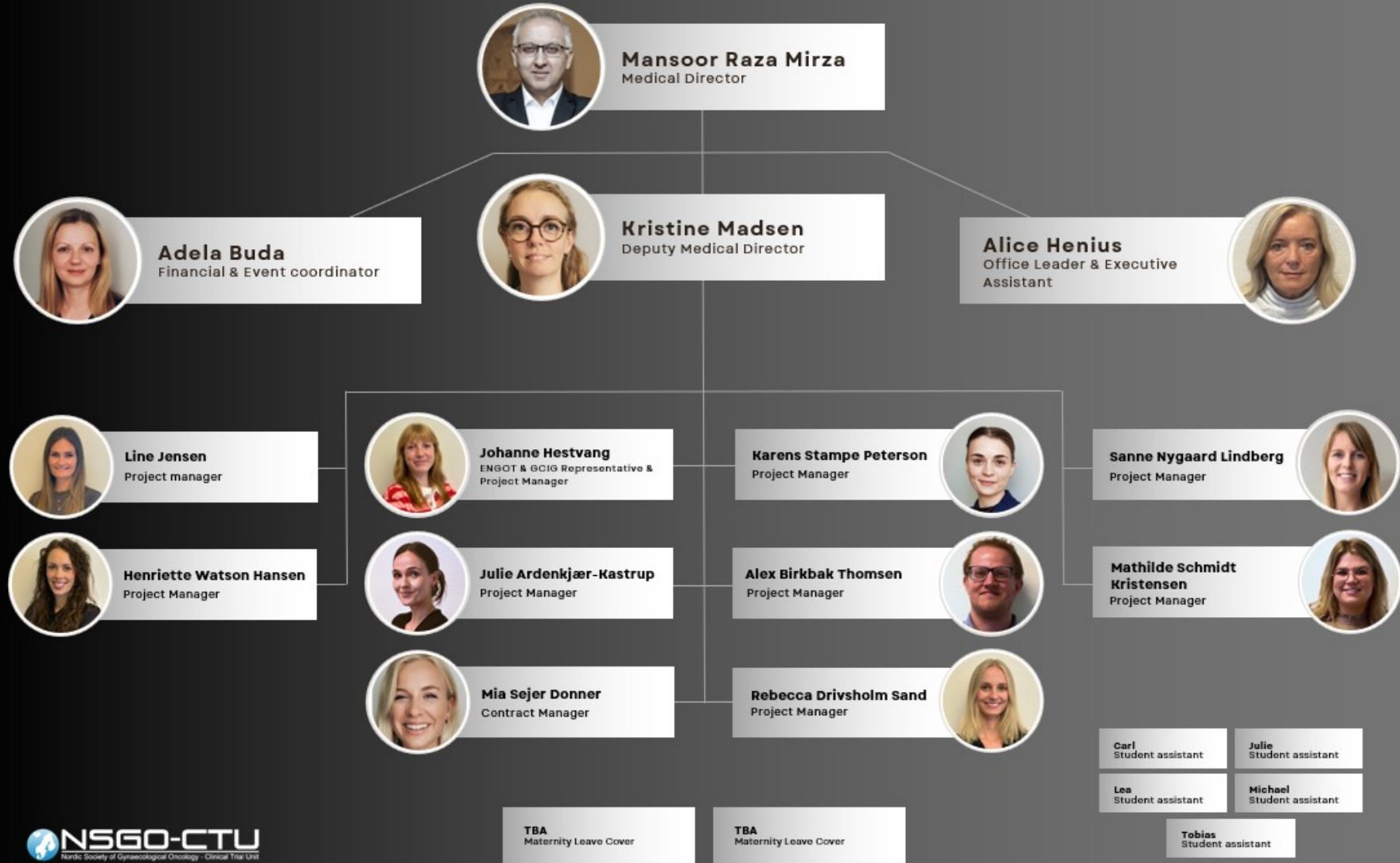
Country	New recruitments
1. Denmark	258
2. Norway	172
3. Sweden	125
4. Finland	124
5. Lithuania	18
6. Estonia	4

# Clinical Trial Activity

07.10.2024/JH										
<b>HENRIETTE WATSON HANSEN</b>	<b>LINE JENSEN</b>	<b>MATHILDE SCHMIDT KRISTENSEN</b>	<b>REBECCA DRIVSHOLM SAND</b>	<b>JOHANNE HESTVANG</b>	<b>JULIE ARDENKJÆR-KASTRUP</b>	<b>SANNE NYGAARD LINDBERG</b>	<b>KAREN STAMPE PETERSSON</b>	<b>ALEX BIRKBAK THOMSEN</b>	<b>MIA SEJER DONNER</b>	<b>LEGACY trials i Fælles Postkasse</b>
DOVACC (A)	DOVACC (A)	GLORIOSA (c-par)		DOVACC	BEATcc (B)	EN2 (A)	OVHIPEC-2 (A-rep)	AGO-OVAR 2.29 (A-par)	UP-NEXT	ATHENA
HERO (A)	RUBY (c-lead)	EVOPAR (c-par)		EN25 (c-lead)	OV79 (c-par)		FANDANGO (A)	OV65 (c-par)		CX-6
CX20 (c-lead)	DUO-O (c-par)	RAMP301 (c-par)		EN24 (c-lead)	EN24 (c-lead)	PEACE (A)	UMBRELLA (A)	CX11 (c-par)		CX-8
eVOLVE (c-par)	FIRST (c-par)	CX20 (c-lead)			ARTISTRY-7 (c-par)		AVANOVA (A)	EN15 (c-par)		PAOLA-1
OV84 (c-par)	HERO (A)				OV89 (c-par)	KANDOVA (c)	PALEO (CSR) (A)	EN11 (c-par)		TRUST
	UPLIFT (c-par)					EN25 (c-lead)	DUO-E (c-par)	OV77 (c-par)		OREO
		PELENEO (A)					EN23 (c-par)	OV86 (c-par)		NOVA
EN21 (c-par)							OV85 (c-par)			BOOST
SOLERO										INOVATYON
				(BEATcc)						PRIMA
				CX12*						
IMagyn050*				EPIK-O*						
				(UP-NEXT)			(UP-NEXT)			
		Mentor: LJ	Mentor: JH		Mentor: JH			Mentor: KSP		
				ENGOT/GCIG						
	Data mangement/eCRF	New studies		New studies					Contract Management	
Kontor: 3372 - Henriette, Line, Mathilde			Kontor: 3378 - Rebecca, Johanne, Julie			Kontor: 3398 - Sanne, Karen, Alex				
							Trials til snarlig fordeling	Upcoming trials	Quality/Security Management	
Kontor: 3389 - Adela							OV84 (c-par)	OV77 (DS6000) (c-par)	DPO: MM	
							OV85 (c-par)	OV88 (c-par)		
Studierende:	Tobias	Lea	Michael	Julie			OV86 (c-par)			
	Admin + allround	EN2, PEACE	DOVACC	DOVACC			OV89 (c-par)			* Flyttes til legacy

# NSGO-CTU Team

## NSGO-CTU ORGANIZATION CHART



# Short Status on NSGO-CTU Sponsored Trials

**Mansoor Raza Mirza**

## NSGO-CTU Trial Overview

**NSGO-CTU Lead/Sponsor:** to be started/recruiting

**NSGO-CTU collaborating:** to be started/recruiting

**NSGO-CTU :** Trials completed recruitment

# Endometrial Cancer

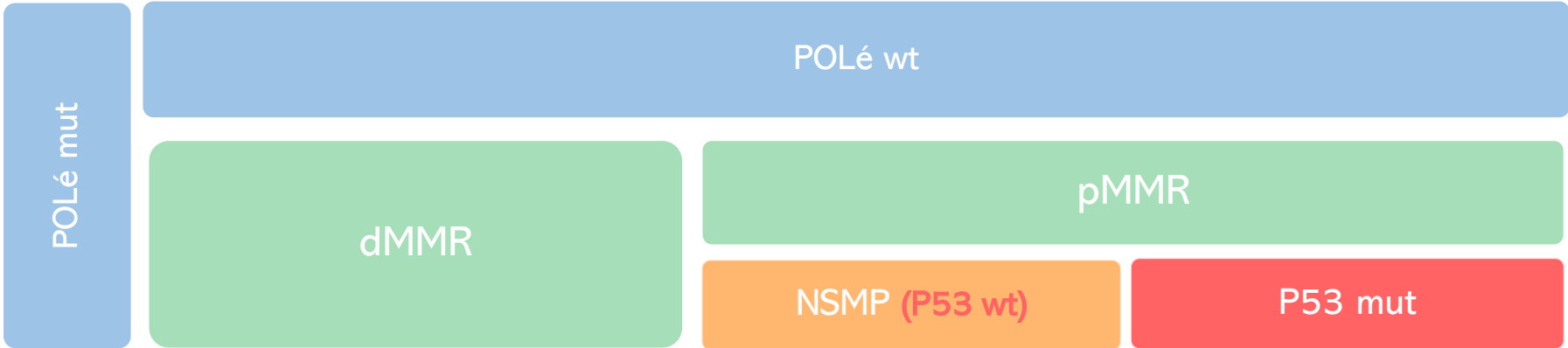
**MOLECULAR CLASSIFICATION**

**Endometrial Cancer – Neoadjuvant/Adjuvant**

POLé status

MMR status

P53 status



Trials with  
NSGO-CTU

**PELÉNEO** *Pembrolizumab*

**PELÉNEO** *Pembrolizumab*

**ENGOT-EN11/KEYNOTE-B21** *Pembrolizumab*

# Endometrial Cancer – Primary Advanced and Recurrent

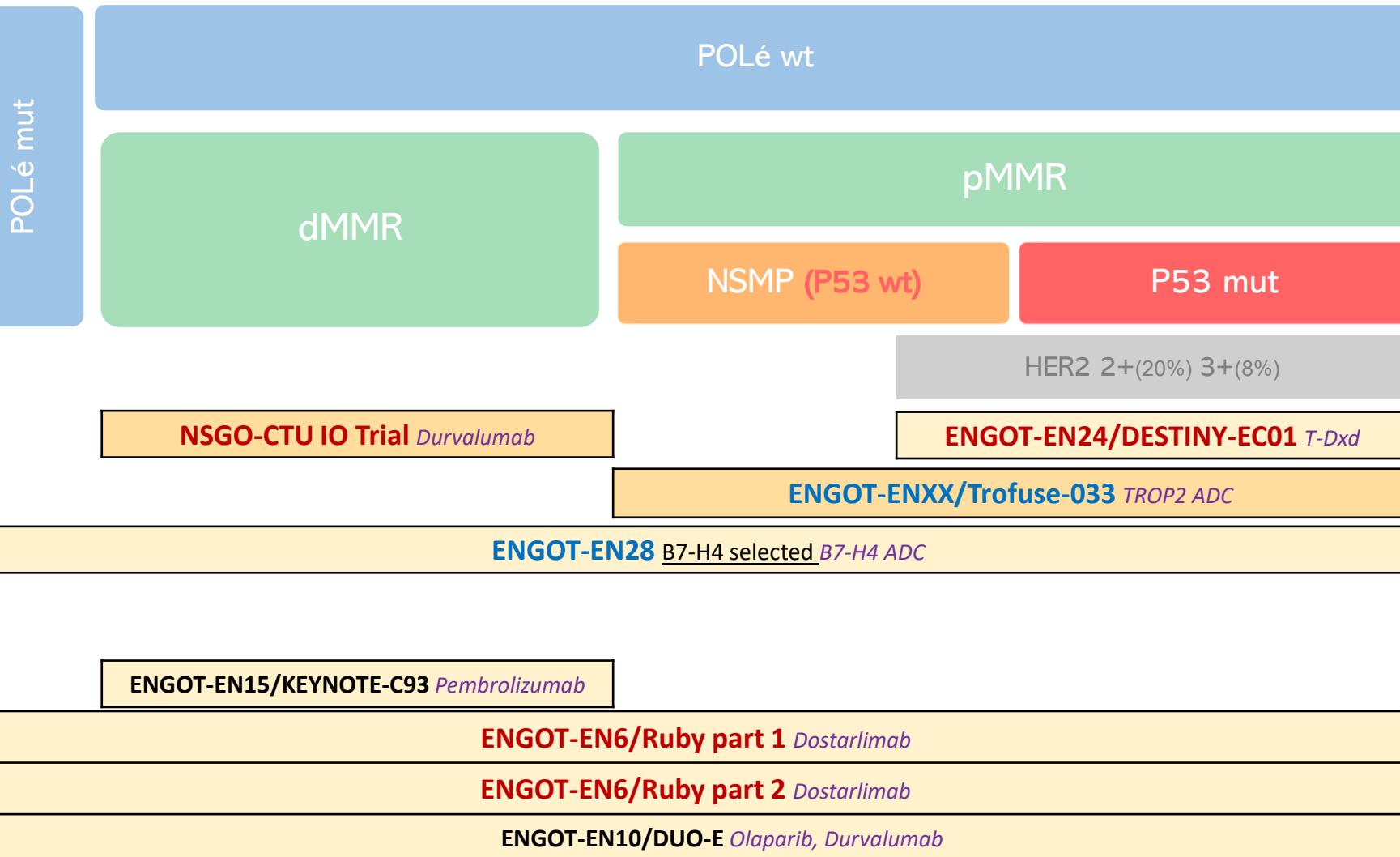
**MOLECULAR CLASSIFICATION**

POLé status

MMR status

P53 status

HER2 status



Trials with NSGO-CTU



# Endometrial Cancer – Second Line

**MOLECULAR CLASSIFICATION**

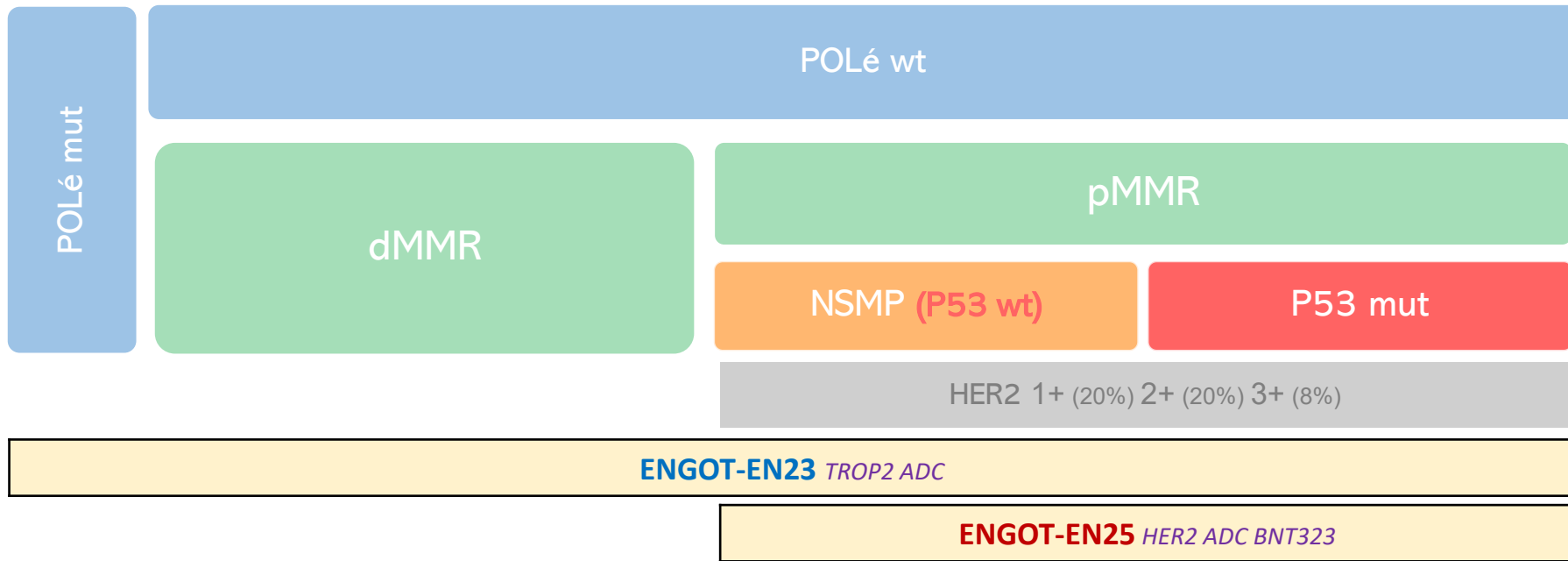
POLé status

MMR status

P53 status

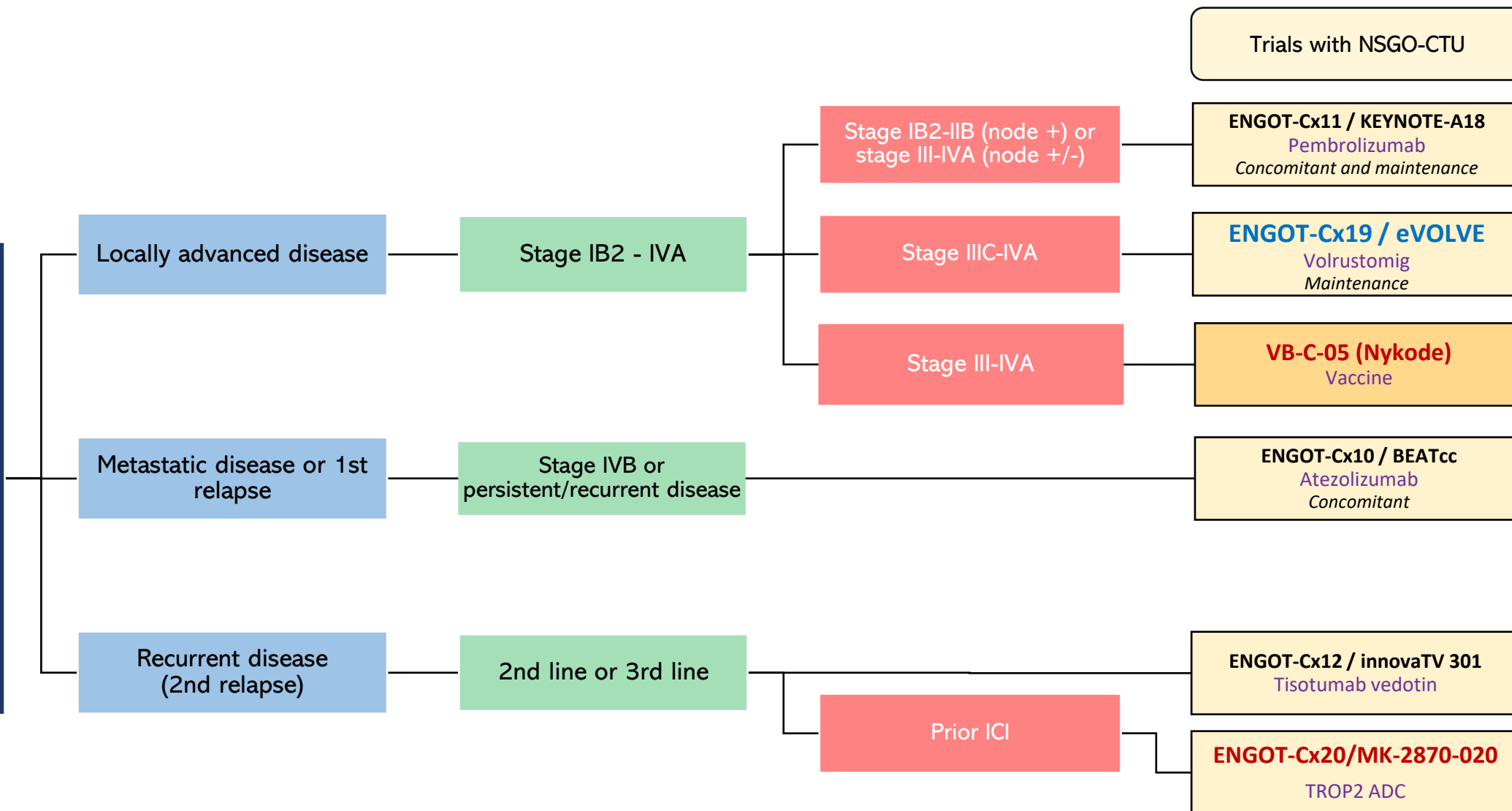
HER2 status

**Trials with  
NSGO-CTU**



# Cervical Cancer

Cervical Cancer



# Ovarian Cancer

# Ovarian cancer

## Primary disease

Stage Ic + II

Stage III+IV

HRD

HRP

BRCA mut

BRCA wt

Stage III

**ENGOT-OV85/MK2870-021** TROP-2 ADC Maintenance

**ENGOT-OV89/DESTINY OVARIAN-01** HER2 pos  
T-Dxd Maintenance

**ENGOT-OV25/ PAOLA-1** Olaparib + Bevacizumab

**ENGOT-OV46/ DUO-O** Olaparib, Durvalumab, Bevacizumab

**ENGOT-OV26/ PRIMA** Niraparib

**ENGOT-OV44/ FIRST** Dostarlimab + Niraparib

**ENGOT-OV45/ ATHENA** Rucaparib Maintenance

**HERO**

**ENGOT-OV52/  
OVHIPEC-2**  
Surgical

Trials with  
NSGO-CTU

# Platinum Sensitive Recurrent Ovarian Cancer (PSROC), high grade

HRD	HRP
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BRCA mut	BRCA wt
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Trials with  
NSGO-CTU

<b>ENGOT-OV56/ DOVACC</b> Olaparib, Durvalumab, UV1 Maintenance	
<b>KANDOVA</b> KAND567	
<b>ENGOT-OV76/ GLORIOSA</b> <i>High FRα expression</i> MIRV Maintenance	
<b>ENGOT-OV82/ EvoPAR</b> <i>Prior PARPi</i> Saruparib Maintenance	
<b>ENGOT-OV84/ MK2870-022</b> TROP-2 ADC Maintenance	

# Platinum Resistant Recurrent Ovarian Cancer (PROC)

HRD

HRP

BRCA mut

BRCA wt

gBRCA mut

tBRCA mut

 Trials with  
 NSGO-CTU

 ENGOT-OV68/ ARTISTRY-7 *Nemvaleukin Alfa + Pembrolizumab*

 ENGOT-OV65/ KEYNOTE-B96 *Pembrolizumab*

 ENGOT-OV61/ EPIK-O *PI-3K inhibitor prohibited Alpelisib*

 ENGOT-OV79/ REFRAme *FOLRα expression Luveltamab Tazevibulin (STRO-002)*

 ENGOT-OV86/RAINFOL *Prior PARPi*

 ENGOT-OV86/ RAINFOL *Rinatabart Sesuteacan*

 ENGOT-OV77/ Rejoice *Prior PARPi*

 ENGOT-OV77/ Rejoice *DS6000*

## Ovarian cancer

Recurrent Low Grade Serous Ovarian Cancer  
(LGSOC)

Palliation

Trials with  
NSGO-CTU

**ENGOT-OV81/RAMP-301** *KRAS mut*

Avutometinib + Defactinib

**PEACE**

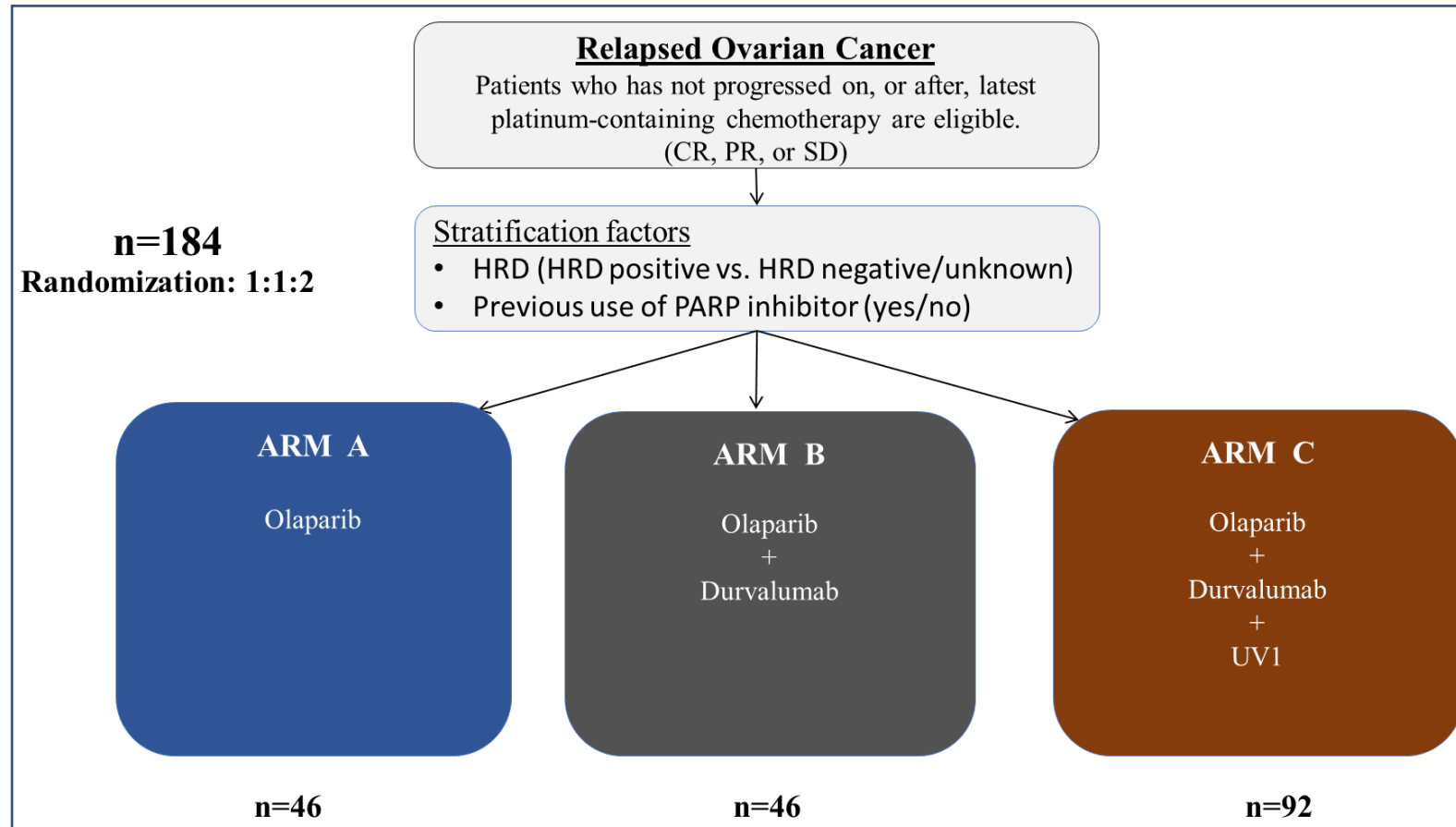
EOL care



# ENGOT-OV56/DOVACC

A Randomized Clinical Trial Investigating Olaparib, Durvalumab (MEDI4736) and UV1 as Maintenance Therapy in BRCAwt Patients with Recurrent Ovarian Cancer

# ENGOT-OV56/NSGO-CTU-DOVACC

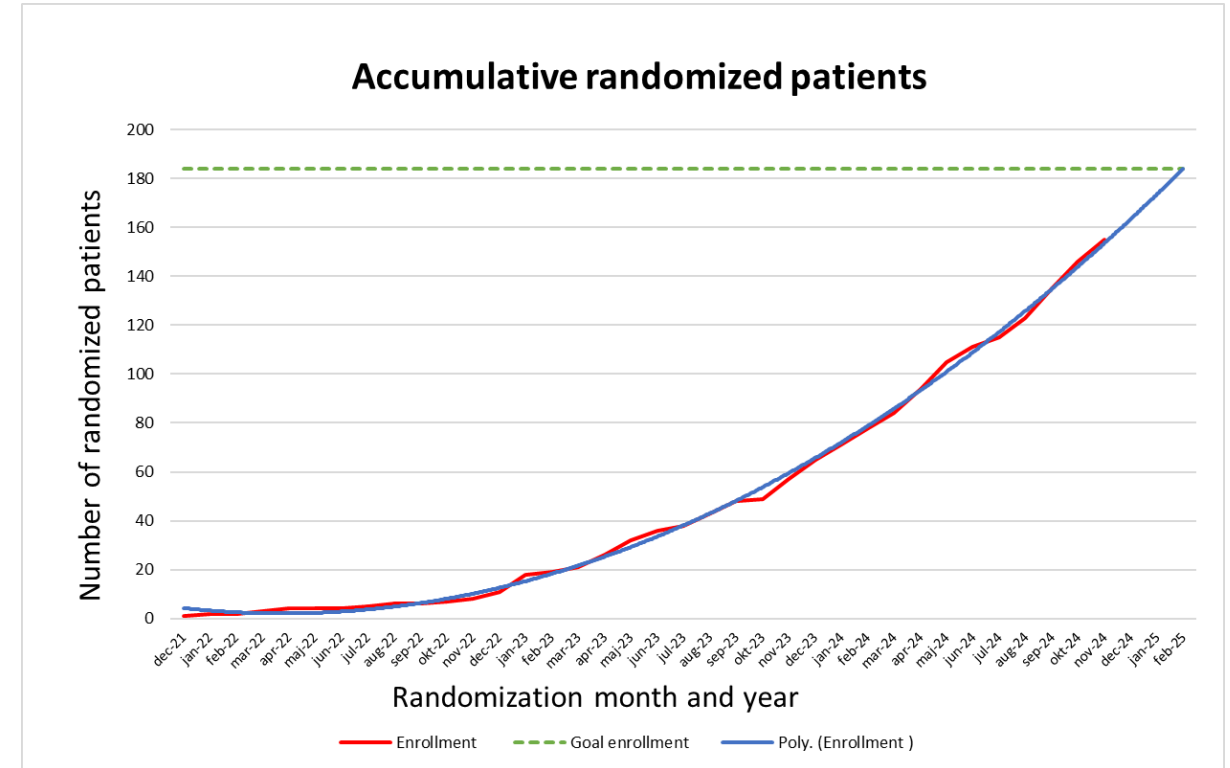


# ENGOT-OV56/NSGO-CTU-DOVACC

## STUDY STATUS AND EXPECTED ENROLLMENT

Approved in CTIS 13.11.24

GROUP	PATIENTS IN SCREENING	PATIENTS RANDOMIZED	SCREEN FAILURES
<b>NSGO-CTU and ENGOT GROUPS</b>			
NSGO-CTU	5	98	35
AGO Austria	3	10	3
BGOG	4	13	8
DGOG	0	4	1
NOGGO	16	30	4
<b>TOTAL</b>	<b>28</b>	<b>155</b>	<b>51</b>



Date: 26-11-2024

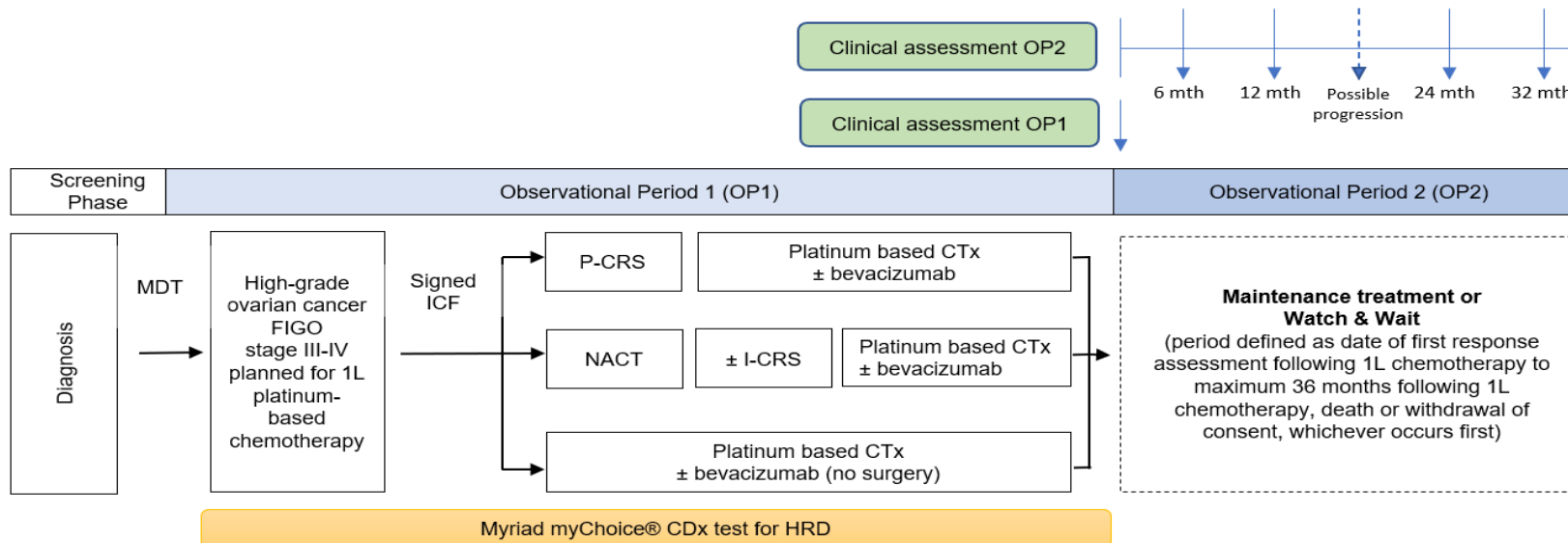
# Ovarian Cancer:

## **NSGO-CTU-HERO (RWE study)**

Characterization of High-Grade Ovarian Cancer Patients in Terms of Homologous Recombination Phenotype – A Prospective Observational Study

# NSGO-CTU-HERO

## Characterization of High-grade Serous Ovarian Cancer Patients in Terms of Homologous Recombination Phenotype – A Prospective Observational Study



ENGOT model: A

Status: Recruiting

Planned number of patients: 1000

Sponsor: NSGO-CTU

NSGO-CTU Lead PI: Mansoor Raza Mirza

NSGO-CTU Contacts: Henriette Watson Hansen, Line Jensen, Kristine Madsen and Mansoor Raza Mirza

Primary Endpoint: OP1: Number of HR deficient patients

OP2: Progression at 6 months in subgroups

# NSGO-CTU-HERO

## Key Inclusion criteria

- Histologically confirmed epithelial ovarian cancer
  - FIGO stage I-II with a known *BRCA1/2* mutation (gBRCA or tBRCA)
  - FIGO stage III-IV of any histology
- Intended for platinum-based doublet chemotherapy
- Patients consent to provide archival tumor tissue sample

## Key Exclusion criteria

- Non-epithelial ovarian cancer, borderline tumors, low-grade tumors, or mucinous histology
- Patients with FIGO stage I-II, *BRCA*wt ovarian cancer

# NSGO-CTU-HERO (Observational study)

Characterization of High-Grade Ovarian Cancer Patients in Terms of Homologous Recombination Phenotype  
– A Prospective Observational Study

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## AMENDMENT

**A: Increase follow-up from 36 months to 60 months**

**B: Increase sample size to 1000 patients**

**C: Publish Annual report** (*possibility to share data with the grant provider*)

**D: Initiate translational research**

**1: HRD tested in all patients**

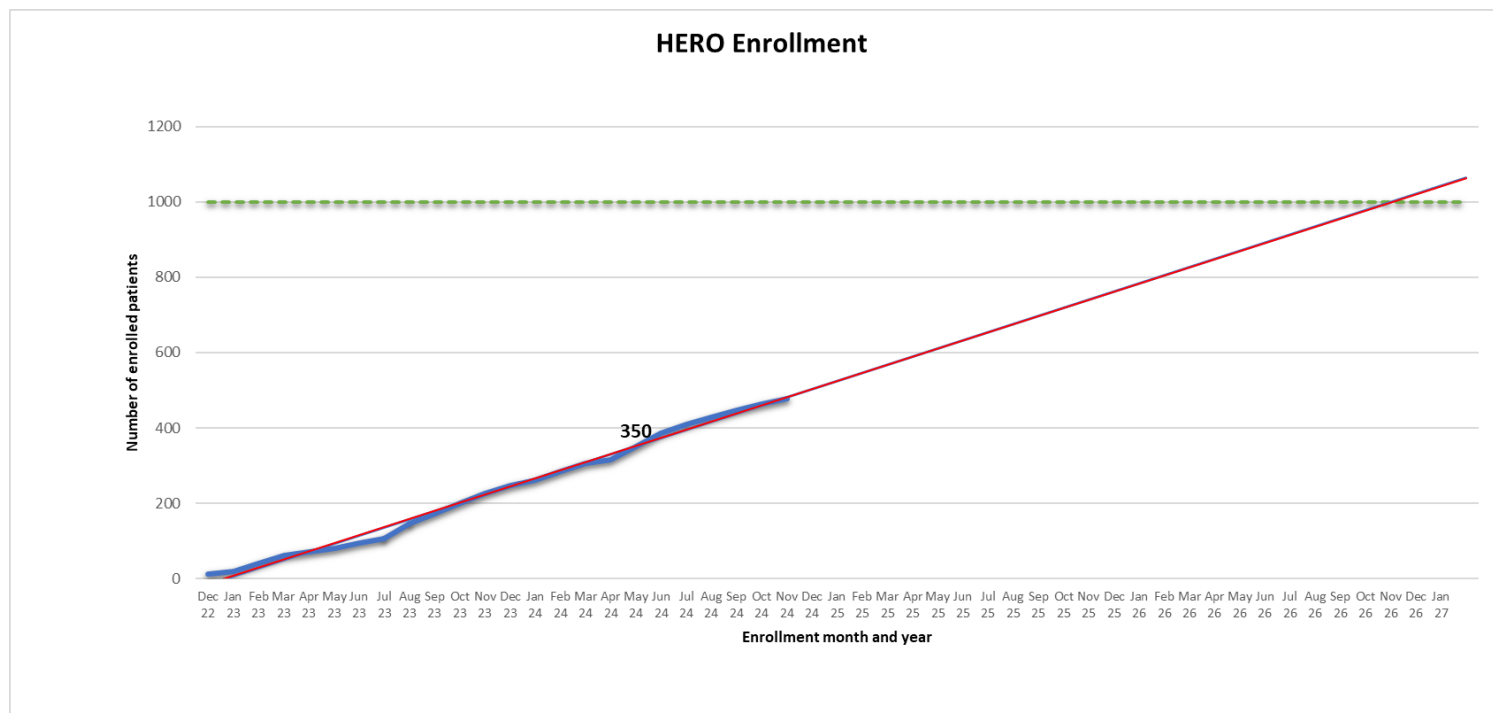
**2: Tumour tissue blocks/slides are stored, and patients are consented:** Exploratory translational analyses will be performed on the collected archival tumour tissue. This will include but is not limited to FR $\alpha$ , HER2, TROP-2, PD-L1 (including interplay of 22C3 and SP263) -these are potential drug targets for the future - but also ~~genomic~~ <sup>bio-molecular</sup> profiling (panel), histology.

# NSGO-CTU-HERO (Observational study)

Characterization of High-Grade Ovarian Cancer Patients in Terms of Homologous Recombination Phenotype  
 – A Prospective Observational Study

## STUDY STATUS AND EXPECTED ENROLLMENT

Last patient in expected in Q4 2026



Date: 26-11-2024

Country/Site	HERO	
	PI and NC	Inclusion
<b>NORWAY</b>		
Oslo	Elstrand	55
Kristiansand	Vistad	10
Tromsø	Ingebrigtsen	22
Trondheim	Aune	32
Stavanger	Nilsen	17
Bergen	Björke	0
<b>TOTAL</b>		<b>136</b>
<b>SWEDEN</b>		
Lund	Malandar (NC)	88
Uppsala	Dimoula	7
Linköping	Lindahl	8
<b>TOTAL</b>		<b>103</b>
<b>DENMARK</b>		
Rigshospitalet	Mirza (NC)	73
Vejle	Adimi	39
Odense	Knudsen	18
Gødstrup	Hæe	6
<b>TOTAL</b>		<b>136</b>
<b>FINLAND</b>		
Kuopio	Sopo	19
Helsinki	Lassus (NC)	57
Oulu	Simojoki	7
Tampere	Staff	19
<b>TOTAL</b>		<b>102</b>
<b>NSGO-CTU TOTAL</b>		<b>477</b>



# Future Directions

- Clinical Trials Masterclass for the young Nordic-Baltic colleagues
- Conclusion of DOVACC study
- Yearly clinical & translational reports from HERO study
- Initiation of PELENEO
- Initiation of IO treatment duration trial in dMMR EC
- Initiation of “Endometrial-HERO” study
- Financial stability