



# STANDARD TREATMENTS AND NEW DIRECTIONS IN GYNAECOLOGICAL CANCERS

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## ENDOMETRIAL CANCER TRIALS

Opening studies 1st line

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# Conflict of interests

- GSK: advisory board, speaker fees
- MSD: advisory board, speaker fees
- Astrazeneca: advisory board, speaker fees
- Eisai: advisory board
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# ENDOMETRIAL CANCER TRIALS - 1st line

## Opening and recruiting trials

- RAINBO BLUE

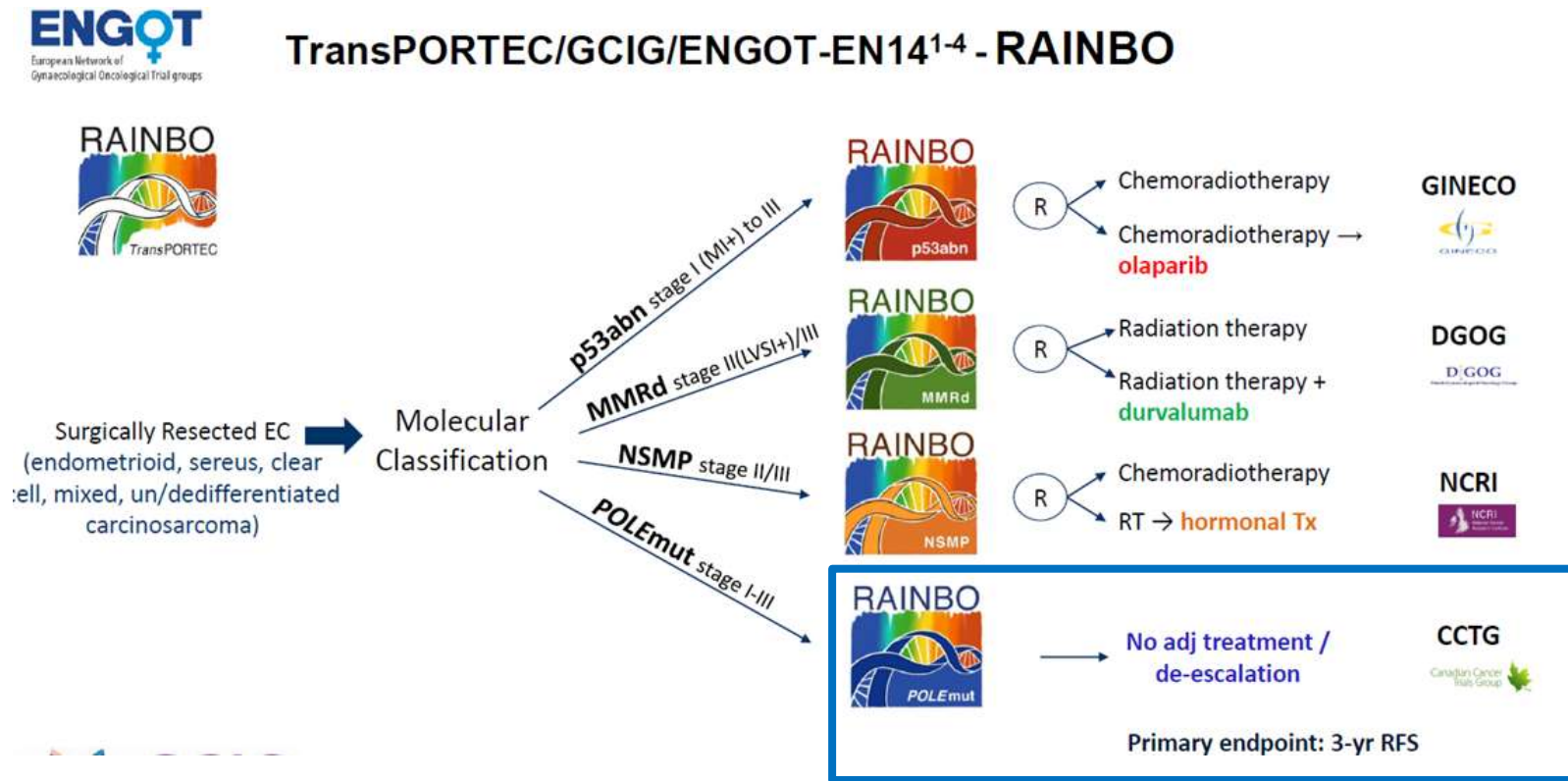
## Opening and planned trials

- ENGOT-en24 / DESTINY-EC01
- ENGOT-en29 / TroFuse-033
- ENGOT-en30 / DESTINY-EC02
- ENGOT-en27 / Expression XXI

# Endometrial cancer trials 1st line - Opening & recruiting **RAINBO BLUE**

**RAINBO BLUE & TAPER** A phase II study of tailored adjuvant therapy in Pole-mutated and p53-wildtype/NSMP early stage endometrial cancer

- ENGOT model: A
- Sponsor: CCTG
- ENGOT Lead Group: DGOG
- MaNGO coordinating group for Italy
- De-escalation trial
- Primary outcome: time to recurrence at 3 years
- Expected pts: 393; randomization according to molecular features
- Accrual: 36 months
- Follow-up: 36 months



# Endometrial cancer trials 1st line - Opening & recruiting **RAINBO BLUE**

Endometrial carcinoma treated by hysterectomy, bilateral salpingo-oophorectomy, lymph node assessment (pelvic lymph node surgical assessment required for grade 3 and/or stage II) [sub-study A1 and sub-study B]:

- Stage IA (not confined to polyp), grade 3, pN0, with or without LVI
- Stage IB, grade 1 or 2, pNx/N0, with or without LVI
- Stage IB, grade 3, pN0, without substantial/extensive LVI
- Stage II (microscopic), grade 1 or 2, pN0, without substantial/extensive LVI

Sub-study A2 cohort:

- Stage IA (not confined to polyp) grade 3 – Stage III not included in above,
- Multiple molecular classifiers Stage IA (not confined to polyp), grade 3 - Stage III

Molecular classification  
(MMR, p53, *POLE*)

Study Enrollment

Sub-study B (TAPER)

p53 wildtype/NSMP ER+ EC  
Observation or de-escalated  
adjuvant treatment

Sub-study A (RAINBO BLUE)

Cohort A1  
*POLE*-mutated EC  
Observation

Cohort A2  
*POLE*-mutated EC  
Observation or de-escalated adjuvant  
treatment

N=120 *POLE*-mutated (Sub-study A, Cohort A1)

180 p53 wildtype/NSMP (Sub-study B)

As per Amendment #2, the cohort A2 will be re-opened  
*POLE*-mutated cohort (Sub-study A, Cohort A2):

Up to 68 multiple classifiers (*POLE*-mutated+p53 abn and/or MMRd) and 25 non multiple classifiers

## Global Enrollment update:

- Sub-study A (RAINBO BLUE) accrual: 62/145 (28 to A2 Cohort)
- Sub-study B (TAPER) accrual: 80/180
- Number of sites active: 64 (13 Canadian, 51 International)



# Endometrial cancer trials 1st line - Opening & recruiting **RAINBO BLUE**

## Update MaNGO sites - June 2025

	Hospital	First Name	Last Name	Notes
1	Istituto Europeo di Oncologia, Milano	Ilaria	Betella*	*MaNGO PI Active site ( <b>3 patients enrolled</b> )
2	Spedali Civili, Brescia	Germana	Tognon	Contract finalization
3	Ospedale Manzoni, Lecco	Romerai	D'Amico	Contract finalization
4	Arcispedale S. Maria Nuova, Reggio Emilia	Alessandra	Bologna	Contract finalization
5	Policlinico Careggi, Firenze	Cristina	Petrella	EC Submission ongoing
6	Ospedale Umberto I, Roma	Federica	Tomao	Contract finalization
7	Ospedale Del Ponte, Varese	Francesca	Zefiro	EC Submission ongoing
8	Ospedale S. Anna, Torino	Elisa	Piovano	EC Submission ongoing

*The protocol amendment will be submitted in July 2025*

# Endometrial cancer trials 1st line – Opening & planned **ENGOT-en24**

CONFIDENTIAL

# Endometrial cancer trials 1st line – Opening & planned **ENGOT-en29**

CONFIDENTIAL



# Endometrial cancer trials 1st line – Opening & planned **ENGOT-en30**

CONFIDENTIAL

# Endometrial cancer trials 1st line – Opening & planned **ENGOT-en27**

**ENGOT-en27 / Expression XXI** European survey for endometrial cancer patients: Acute and long-term toxicity

- Sponsor: NOGGO e.V.
- MaNGO coordinating group for Italy
- Study Design: International, online patient survey
- Planned No. of patients: 500
- Current status: In preparation for ethics submission by the sponsor

**Trial setting:** Women with primary and relapsed endometrial cancer independent of their state of disease and treatment

Planned start of survey Q2 2025 Germany / Q3 2025  
International

Duration: around 18 months

## Background/Objectives:

- The survey examines comorbidities, health status, polypharmacy, quality of life, treatment experiences, the impact of the disease on daily life, including work, social relationships, and emotional well-being.
- The survey compares:
  - Group A: women with primary
  - Group B: relapsed
  - Group C): follow-up care
- The primary objective is to determine the frequency of side effects, particularly polyneuropathy and hair loss, and their impact on quality of life within these three groups.
- Secondary objectives include evaluating treatment preferences, adherence to therapy, financial and time burdens, and patient education on treatment options and medical guidelines.

*The survey will be circulated within MaNGO sites to evaluate the interest in the participation*

***Grazie per l'attenzione***