



STANDARD TREATMENTS AND NEW DIRECTIONS IN GYNAECOLOGICAL CANCERS

MILANO June 26th-29th, 2025

Responsabili Scientifici:
NICOLETTA COLOMBO, FRANCESCO RASPAGLIESI



CERVICAL CANCER TRIALS

Short summary on ongoing studies

Mara Mantiero, Istituto Nazionale dei Tumori IRCCS, Milano

CERVICAL CANCER TRIALS SUMMARY

Trials ongoing with accrual closed

- ENGOT-cx4 / SENTICOL III
- ENGOT-cx10 / BEATcc

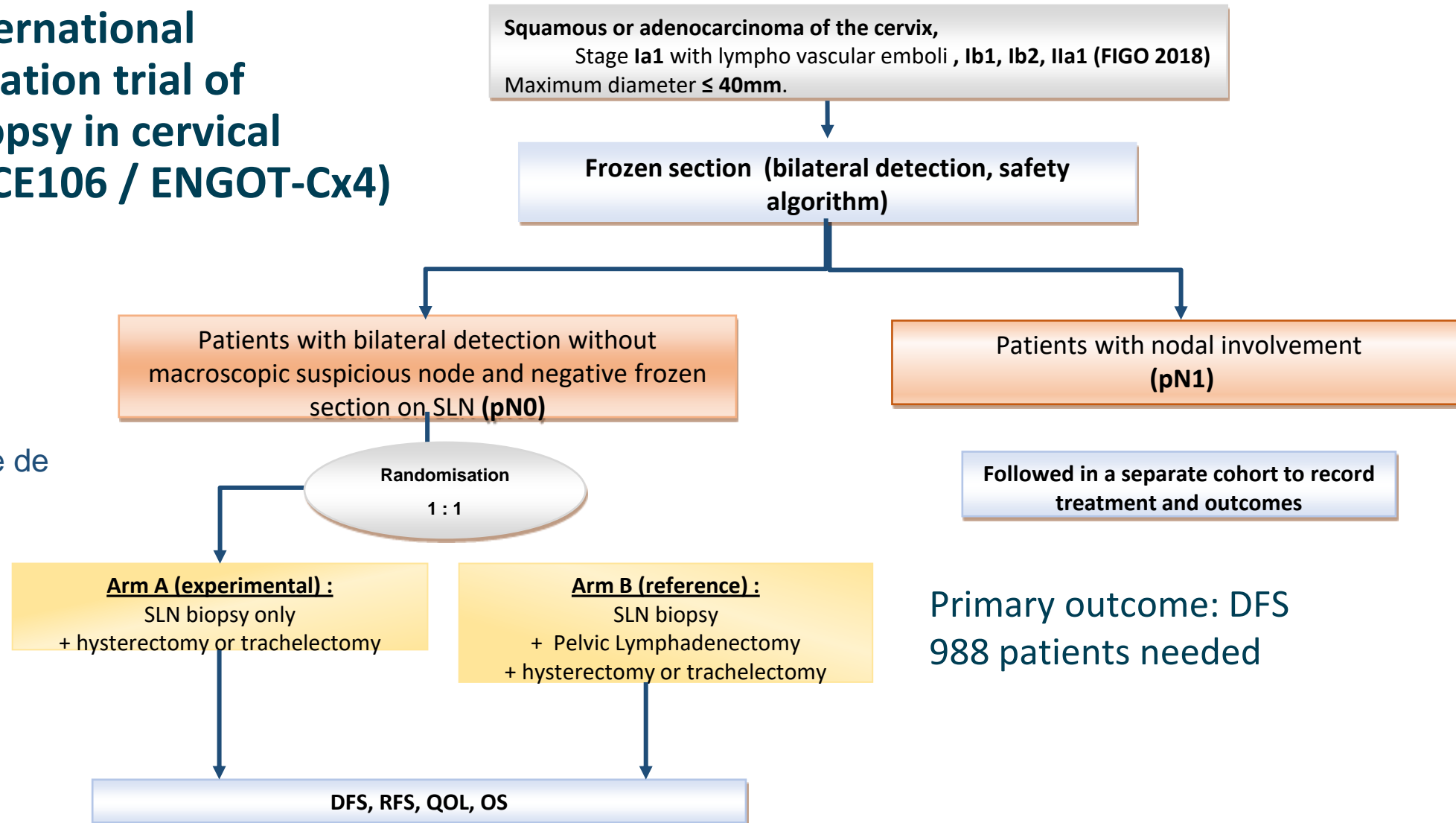
Cervical cancer trials summary - Accrual closed SENTICOL III

SENTICOL III : International prospective validation trial of sentinel node biopsy in cervical cancer (GINECO-CE106 / ENGOT-Cx4)

ENGOT Model: **B**
(academic)

Sponsor: Centre
Hospitalier Universitaire de
Besancon

Lead Group: GINECO



SENTICOL III : International prospective validation trial of sentinel node biopsy in cervical cancer (GINECO-CE106 / ENGOT-Cx4)

SENTICOL III Primary objective: to evaluate Disease-Free Survival (DFS) by determining whether Sentinel Lymph Node (SLN) biopsy alone is non-inferior (HR: 1.54) to the combination of SLN and Pelvic Lymph Node (PLN) dissection in patients classified as pN0.

Sample size: 988

Events: 135

Interim at 45 events

- Recruitment is closed
- **990 patients randomized** (MaNGO: 55)
- **Disease-Free Survival (DFS) final analysis expected around 2027**

- Countries: France, Brazil, Germany, Canada, Italy, China, Czech Republic, Norway, Slovakia, Japan, Spain, India
- MaNGO sites: **IEO** (V. Zanagnolo) 28 pts randomized, 5 screen failures. **Monza** (T. Grassi) 27 pts randomized (including 2 end of study), 4 screen failures

Cervical cancer trials summary - Accrual closed SENTICOL III

Interim analysis results at 43 events (cut-off April 2024)

Data Safety Monitoring committee: *we cannot definitively determine whether SLN biopsy alone is non-inferior to the combination of SLN and PLN dissection (H0) or if it is, in fact, inferior(H1). However, the results so far are promising, and we will need to validate these findings in the final analysis.*

No concerning signals have been observed regarding the experimental arm.

Chinese study PHENIX, recently presented at SGO >> highly similar to SENTICOL III.

The PHENIX-I trial (Sentinel Lymph Node Biopsy versus Pelvic Lymphadenectomy in Cervical Cancer) **showed promising results that are very encouraging for the ongoing SENTICOL III study.**

However, the PHENIX study highlights some methodological issues, such as the use of an outdated tracer and a high number of lymph nodes removed, which exceeds standard practice.

Though, the existence of two similar studies strengthens the validity and relevance of the final conclusions.

Cervical cancer trials summary - Accrual closed BEATcc

ENGOT-cx10 / BEATcc: A Randomized Phase III Trial of Platinum Chemotherapy plus Paclitaxel with Bevacizumab and Atezolizumab versus Platinum Chemotherapy plus Paclitaxel and Bevacizumab in Metastatic (stage IVB), Persistent, or Recurrent Carcinoma of the Cervix

- ENGOT Model: B
- Sponsor: GEICO
- Lead Group: GEICO
- Groups: AGO, GINECO, GOG-F, JGOG, MaNGO, MITO, NSGO
- Nr. of patients randomized by MaNGO sites: 17
- MaNGO sites: IEO, IOV, AOU Pisa, AOU S.Anna, Monza

Update May 2025:

Randomized: **410** patients / On treatment: **17** patients

Completed: **393** patients

Events: 273 OS events

Last Patient Last Visit planned for: **31 August 2025**

MaNGO sites: QUERIES and CHECKS urgent solving

Publications : TiP ASCO 2019 , ESMO 2023, ESGO 2024, SGO 2024, Manuscript in Lancet, PROs data poster ESMO 2024

- Planned publications : PRO manuscript , Final OS data TBC