

# ENGOT-enXX

## AGO-OP.6



**Pelvic and Para-aortic Lymphadenectomy in Patients with Stage I or II Endometrial Cancer with High Risk of Recurrence**

**Endometrial Cancer Lymphadenectomy Trial  
(ECLAT)**

**A Multicenter, Prospective Randomized Controlled Trial**

**Coordinating Investigator**

Prof. Dr. med. Günter Emons

University Hospital Göttingen

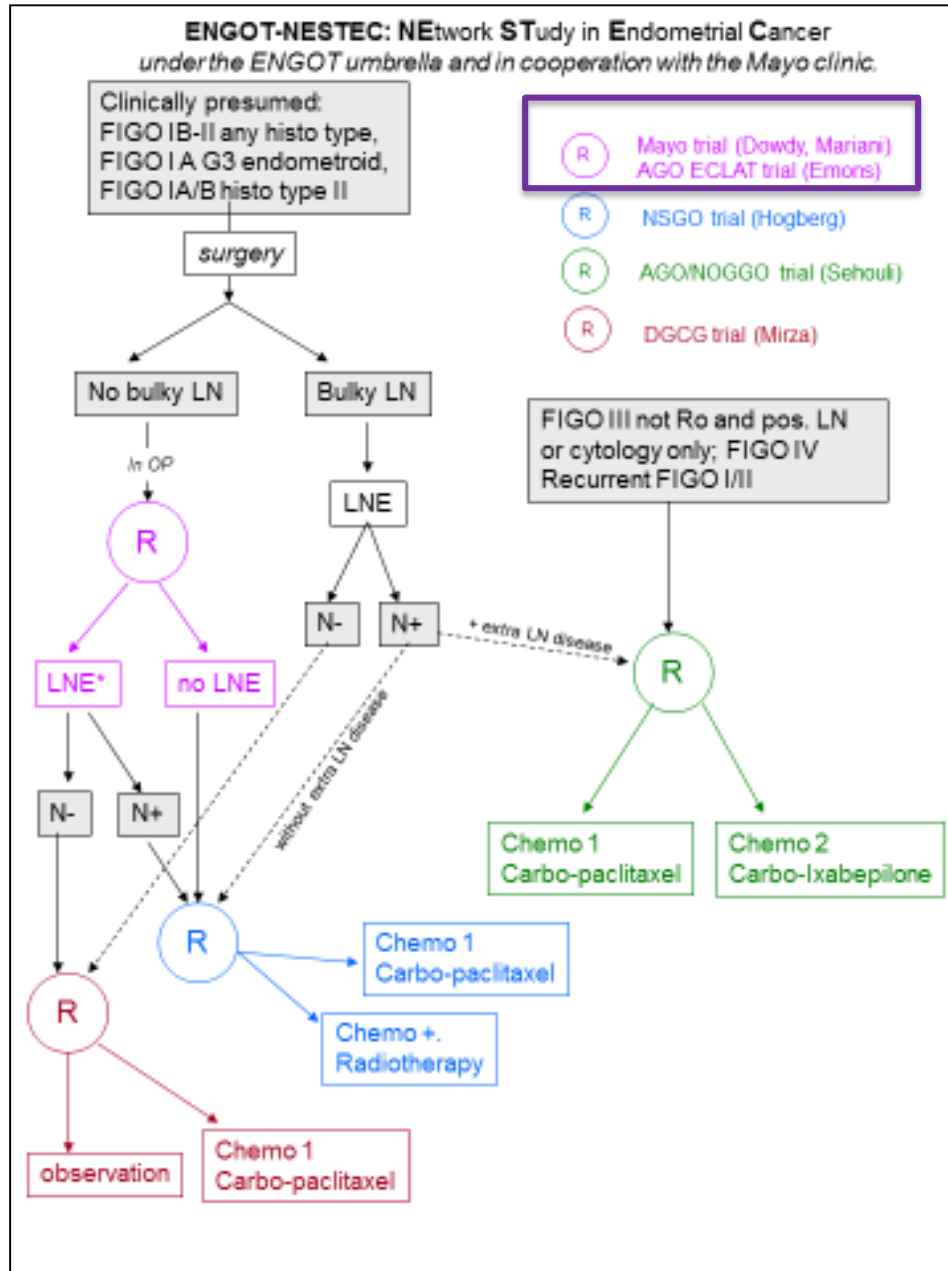
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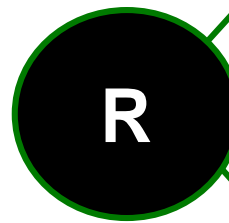
# The history: presented and discussed already in 2008....



# ECLAT-Endometrial Cancer Lymphadenectomy Trial

AGO-OP.6

- histology diagnosis of EC
- FIGO IB, II (all subtypes)
- FIGO IA, G3 (type I)
- FIGO IA (Type II)
- Absence of bulky nodes
- Age 18-80y



n=640

## System. lymphadenectomy

- pelvic
- para-aortic

## no lymphadenectomy

**Primary endpoint: Overall Survival**

Type I: endometrioid, endometrioid + squamous differentiation, mucinous  
Type II: serous, clear cell, carcinosarcoma

*SLN in LNE arm as additional procedure allowed*

# ...a long and hard way!



- Submitted to „Deutsche Forschungsgemeinschaft“ for funding in 2009
  - REJECTED after international review
    - “Developments in systemic therapy are likely to make the outcome of limited interest in 10 years...”
- Multiple discussions (NCI and many other groups) if somebody is able to achieve an adequate international funding
  - FAILED
- Submitted to „Deutsche Krebshilfe“ in 2015
  - TRIAL APPROVED
  - BUDGET UNDER NEGOTIATION

# *ECLAT-Endometrial Cancer Lymphadenectomy Trial*

*AGO-OP.6*



- randomized Phase III trial, prospective, multicentre
- primary endpoint: overall survival (5 year OS 75->83%)
- secondary endpoints:  
QoL, side effects of LNE, progression-free and disease free survival
- Recruitment: 5 years / 640 pts.
- Coordinating investigator: Günter Emons
- Sponsor: Philipps-University Marburg/AGO Study Group
- ENGOT Model A



— Applying for an ENGOT Number

# Interested Groups

GINECO

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Participating centers have to qualify!

- Comparable to LION: 12 reports from surgery and pathology of systematic LNE at a high quality level within 12 months
- Active Centers in LION (without major changes in the surgical team): modified qualification process