

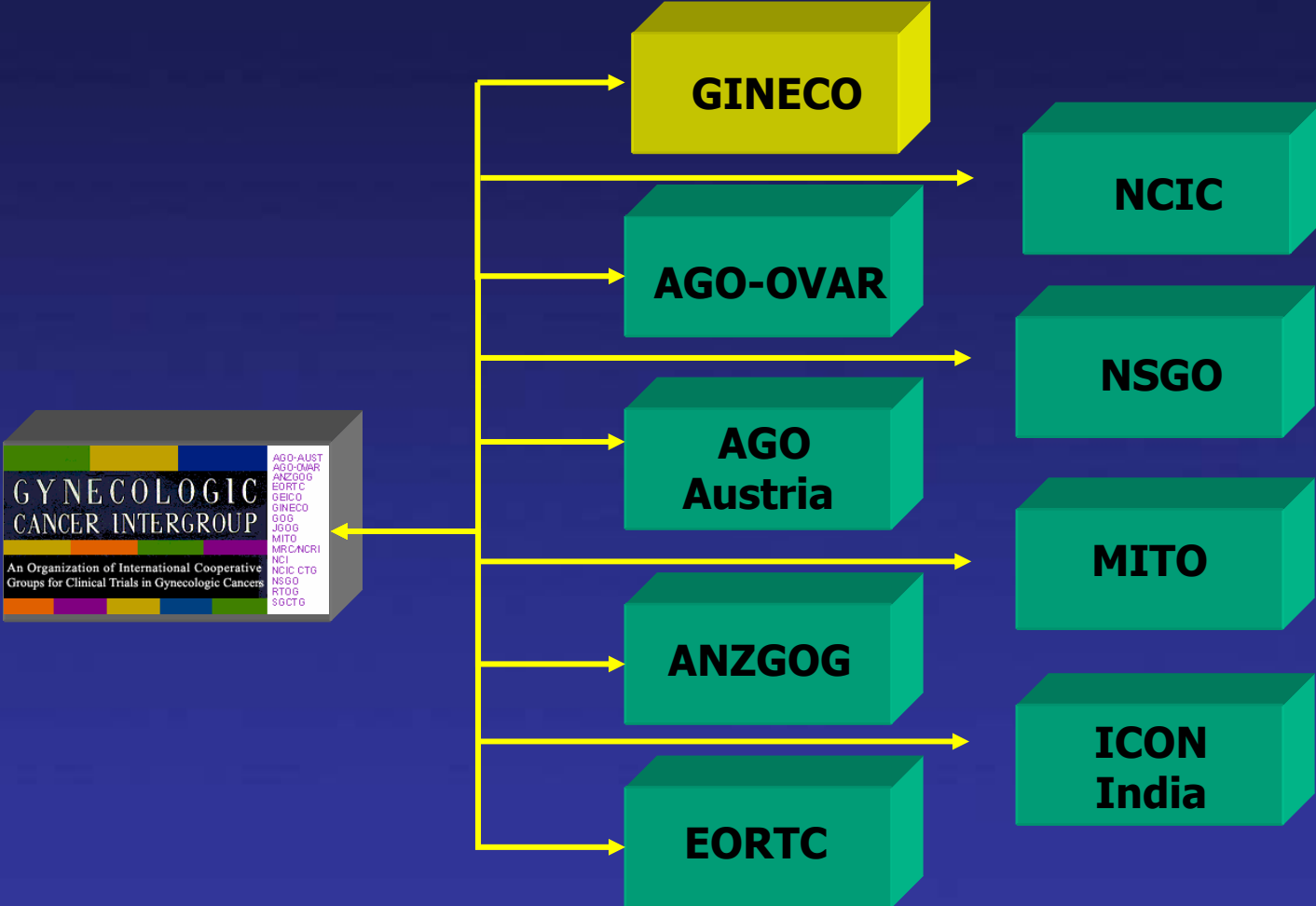
# CALYPSO/AGO-OVAR 2.9

**A multinational randomized Phase III  
GCIC Intergroup Study  
comparing  
Pegylated Liposomal Doxorubicin (CAELYX®) and  
Carboplatin (CaC)  
versus  
Paclitaxel and Carboplatin (TC)  
in patients with epithelial ovarian cancer in late  
relapse (> 6month)**

**EUDRACT # 2004-004456-39  
Original Protocol: 01nov2004  
Amendment No 1: 03mar2005  
Amendment No 2: 04jul 2005**



# Internationale Kooperationen



# AGO-OVAR 2.9 = CALYPSO

## CAeLYx in Platinum-Sensitive Ovarian Cancer

### Patientinnen

- N = 800
- pt-sensibles OC ( $\geq 6$  Monate)

### Stratifikation

- therapiefreies Intervall
  - 6 – 12
  - > 12 Monate
- Tumorvolumen
- Zentrum

Rekrutierungsphase: 30 Monate  
Nachbeobachtung: 60 Monate

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Paclitaxel 175 mg/m<sup>2</sup>, 3 h  
Carboplatin AUC 5, 0.5-1 h

alle 21 Tage x 6 Zyklen \*

PLD 30 mg/m<sup>2</sup>, 1 h  
Carboplatin AUC 5, 0.5-1 h

alle 28 Tage x 6 Zyklen \*

\* oder bis zur Progression bei Patientinnen mit SD oder PR

# CALYPSO/AGO-OVAR 2.9

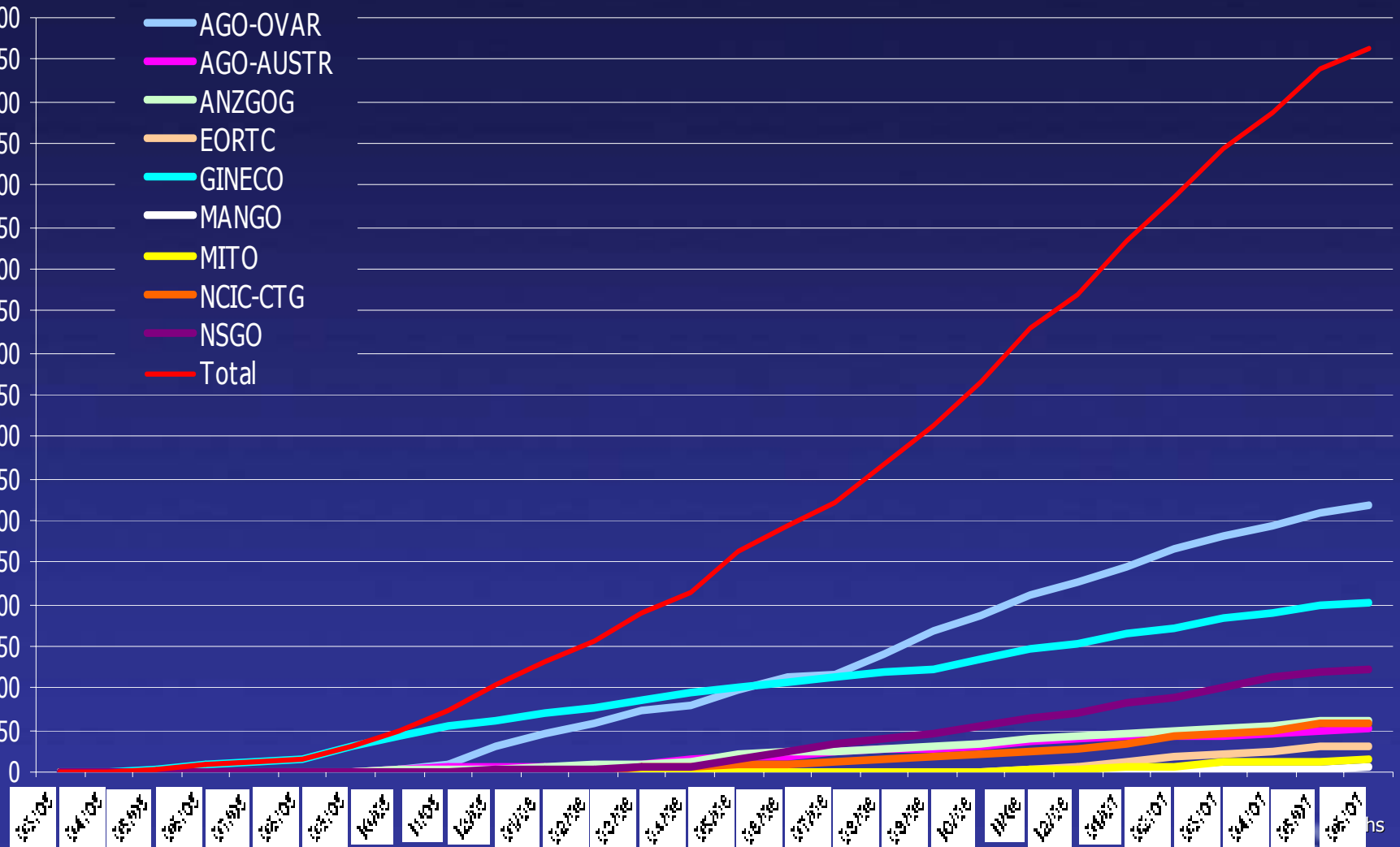
- Rekrutierungsende Deutschland: 18.06.2007, da Deutschland sich nicht dem Amendment Nr. 3 angeschlossen hat
- International wurden bis dahin 864 Patientinnen eingebracht
- In Deutschland: 317 Patientinnen
- Rekrutierungsende international am 25.09.2007 - 974 Patientinnen



# CALYPSO/AGO-OVAR 2.9 Recruitment (18.06.2007)

Patients

- AGO-OVAR
- AGO-AUSTR
- ANZGOG
- EORTC
- GINECO
- MANGO
- MITO
- NCIC-CTG
- NSGO
- Total



**GYNECOLOGIC  
CANCER INTERGROUP**

An Organization of International Cooperative  
Groups for Clinical Trials in Gynecologic Cancers

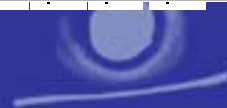
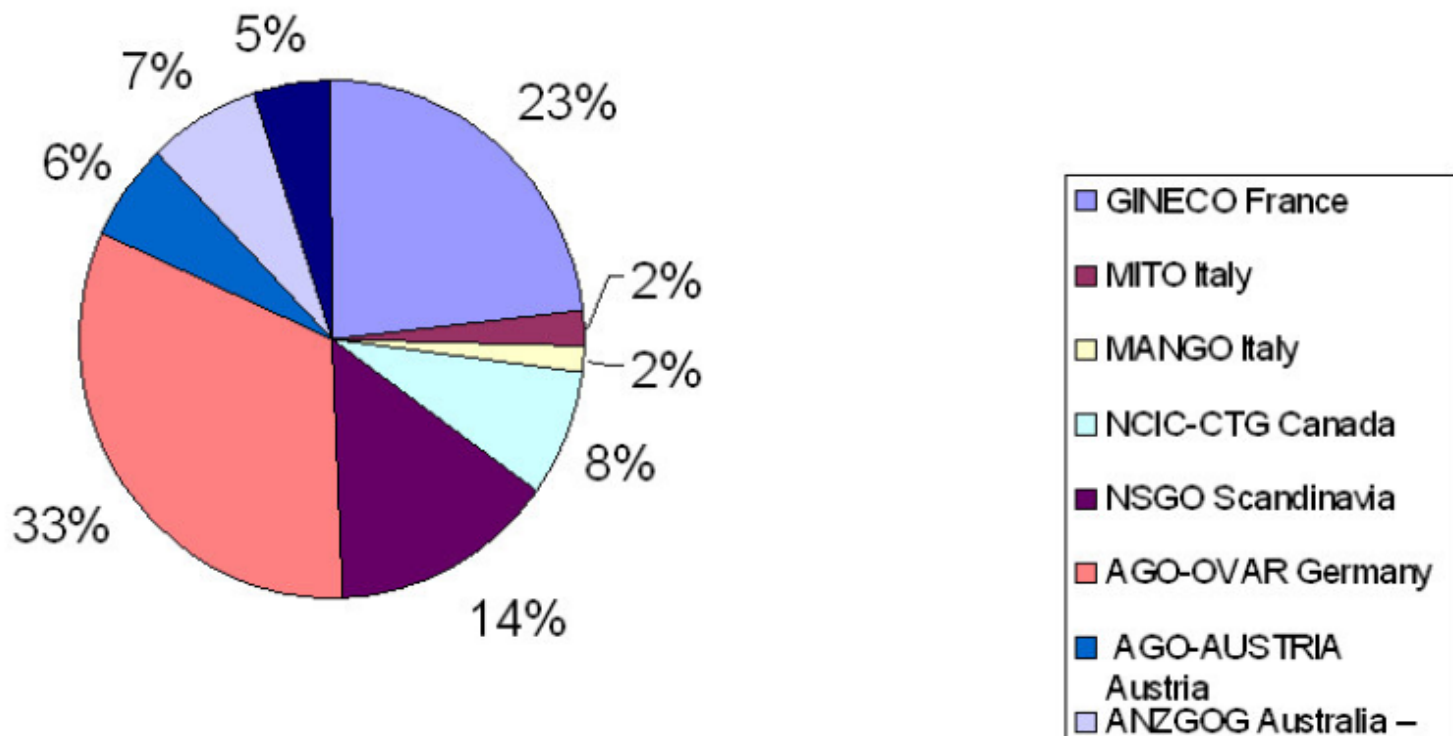
AGO-AUST  
AGO-OVAR  
ANZGOG  
EORTC  
GINECO  
GOG  
JGOG  
MANGO  
MITO  
MINDORI  
NCI  
NCIC-CTG  
NSGO  
RTCG  
SGOG



# CALYPSO/AGO-OVAR 2.9 Recruitment (25.09.2007)

Patients

## PERCENTAGE OF TOTAL INCLUSIONS PER GROUP



# 2nd Interim Analysis on the first 200 patients

## Objectives

- To review safety data
  - Hematology, AEs, SAEs
  - Reasons for treatment discontinuations
  - Dose reductions, treatment delays, supportive treatments



# Major Non-hematological Toxicities (1/2)

| Toxicities      | Caelyx™<br>(n=102) | Taxol™<br>(n=98) |
|-----------------|--------------------|------------------|
| gr2 Alopecia    | 9                  | 81               |
| gr1-2 Nausea    | 67                 | 54               |
| gr3-4           | 3                  | 10               |
| gr1-2 Fatigue   | 64                 | 74               |
| gr3-4           | 7                  | 8                |
| gr1-2 Mucositis | 35                 | 24               |
| gr3-4           | 6                  | 1                |
| gr1-2 Infection | 2                  | 5                |
| gr3-4           | 3                  | 2                |

# Major Non-hematological Toxicities (2/2)

| Toxicities           | Caelyx™<br>(n=102) | Taxol™<br>(n=98) |
|----------------------|--------------------|------------------|
| gr1 Neuropathy       | 20                 | 37               |
| gr2-3                | 4                  | 30               |
| gr1-2 Cardiovascular | 3                  | 5                |
| gr3-4                | 0                  | 1                |
| gr1-2 Allergy        | 12                 | 25               |
| gr3-4                | 3                  | 9                |
| gr1-2 Hand and Foot  | 33                 | 7                |
| gr3-4                | 2                  | 1                |
| gr1-2 Arthr-Myalgia  | 12                 | 36               |
| gr3-4                | 0                  | 2                |

ALL THE GINECO TEAM  
WISH TO THANK YOU  
FOR YOUR GREAT PARTICIPATION !!!

Terrific recruitment  
Good data flow  
Quality monitoring  
=  
Fantastic job !

