

RARE TUMORS WORKING GROUP

Leiden, Dec 2012

Tumor types & national group

Subject	1st coordonator	Sub coordonator
Ov & Ut Carcinosarcoma	GINECO (D Berton Rigaud) ✓	
Low Malignant Potential Tumors	AGO (P Harter) ✓	
Low grade serous carcinoma	GOG (D Gershenson) ✓	MRC/NCRI (C Gourley) ✓
Sex Cord Stromal Tumor	GINECO (I Ray-Coquard) ✓	Mango (N Colombo) ✓
Germ cell tumors	GOG (J Brown) ✓	UK (pediatrician TBD)
Squamous Ov carcinoma	SGCTG (Ros Glasspool) ✓	
Small cell carcinoma cervix	GOTIC (Keiichi Fujiwara) ✓	EORTC (N Reed)
Small cell carcinoma Ov	EORTC (N Reed)	GINECO (P Pautier) ✓
Vulvar & vagina non squamous C	US NCI (MSKCC Merio Leitel) ✓	SGOG (Xi Cheng)
Carcinoid tumor	GICOM (Eva Gomez)	EORTC (N Reed)

✓ **Confirmative mail;**

waiting for confirmative e mail

Tumor types & national group

Subject	1st coordonator	Sub coordonator
Pseudomyxoma Peritonei & Mucinous carcinoma	MRC/NCRI (M Gore)	GOG (D Gershenson) ✓
Clear cell carcinoma Ov - Cervix & Ut	JGOG (A Okamoto) ✓	SGCTG (R Glasspool) ✓
Trophoblastic diseases	MITO (K Larusso) ✓	
Low Grade Endometrial Stromal Sarcoma	EORTC (F Amant)	
HG Uterine sarcoma	GINECO (P Pautier) ✓	
Uterine papillary serous carcinoma	JGOG (S Sagae) ✓	
Adenosarcoma	ANZGOG (M Friedlander) ✓	
Ut & Ov Leiomyosarcoma	US NCI (M Hensley) ✓	
Glandular carcinoma of cervix	GOTIC (Keiichi Fujiwara) ✓	

✓ **Confirmative mail;** **waiting for confirmative e mail**

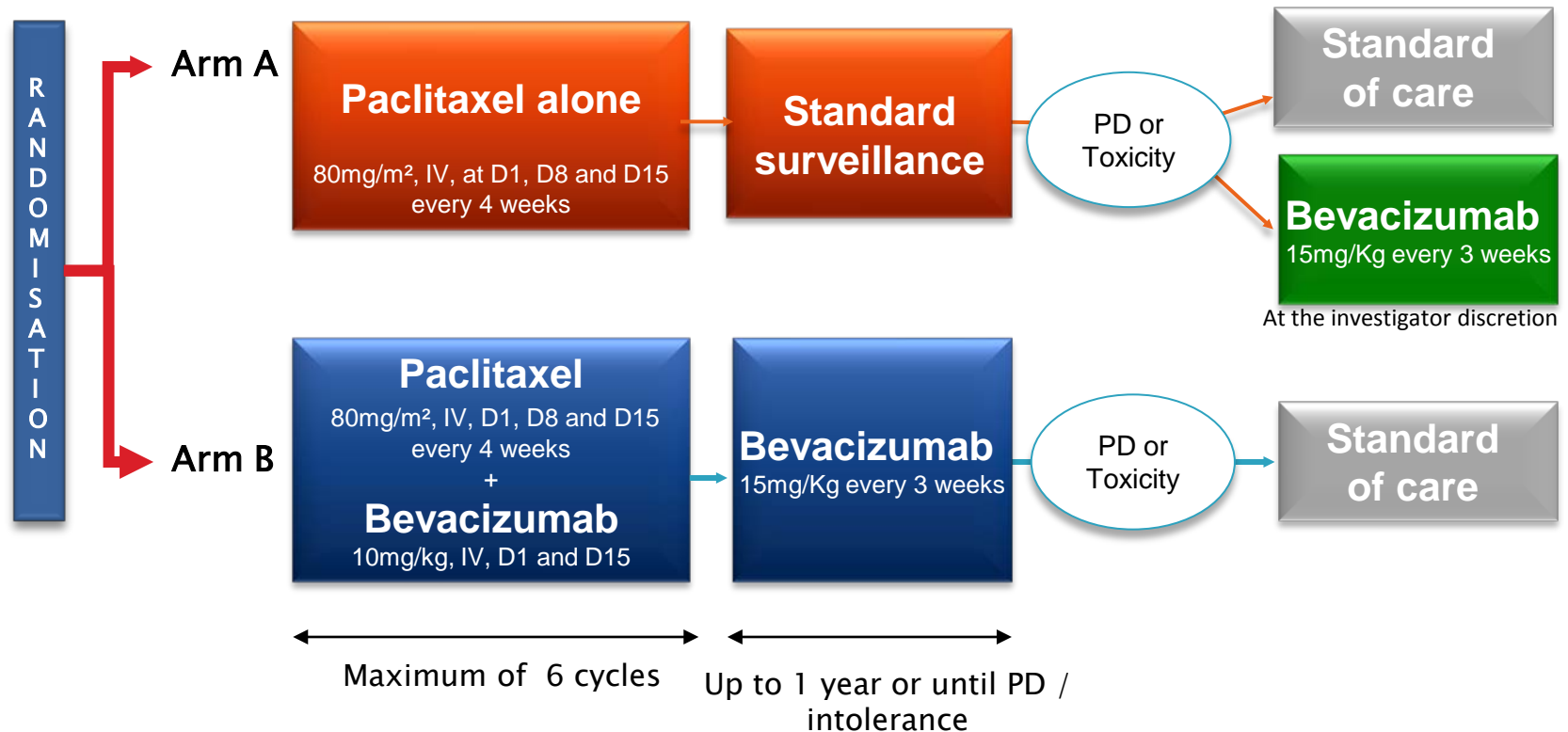
GCIIG Rare Tumors Planning Meeting – London, 16 Nov 2013

Participants: GCIIG groups (2-3 representatives for each group) & invited speakers / experts in the field

Objectives:

- To define current guidelines for rare gynecologic tumors;
- To define control arm for present and future clinical trials involving rare cancer;
- To identify national & international barriers for trials dedicated to rare gynecologic cancers
- To summarize and prioritize key issues for research and agree new set of trial concepts to address the key issues
- To prioritize and design 3 international trials in rare gynecologic cancer

ALIENOR DESIGN : 60 patients



Population :

Patients with an histologically confirmed diagnosis of ovarian sex-cord stromal tumor in relapse after a platinum-based chemotherapy.

**GYNECOLOGIC
CANCER INTERGROUP**

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



ALIENOR Status

- ▶ Final Protocol (version 1.1 28/08/2012)
- ▶ French Approval has been obtained in **September 2012**
- ▶ Amendment n°1 submitted to the French CA/EC in October 26th
(*to limit the number of scans during the chemotherapy and to restrict the biological exams to routine practice*)

Next steps :

- ▶ First Site Initiation : December 2012
- ▶ First Patient In : **January 2013**

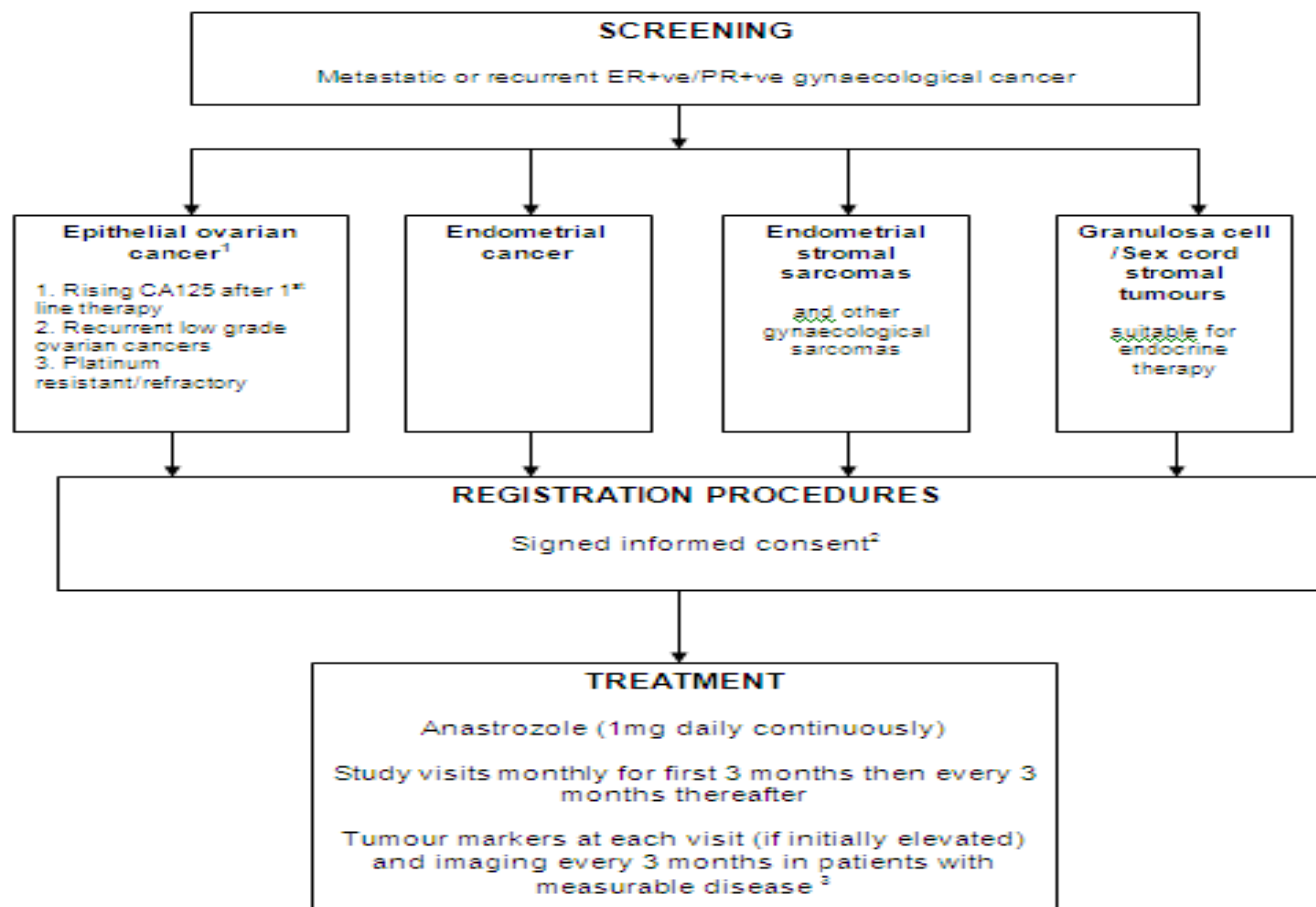
ALIENOR Groups Update

GROUPS	Countries	Commitment	Starting date
GINECO	France	20	January 2013
AGO	Germany	25	2013
ANZGOG	Australia	5	2013
GOTIC/JGOG	Japan	9	July 2013
MITO	Italy	tbd	
SCOTROG	Scotland	?	
MRC	UK	?	
BGOG	Belgium	5	2013

➤ Groups have to seek their own funding



PARAGON Trial Schema



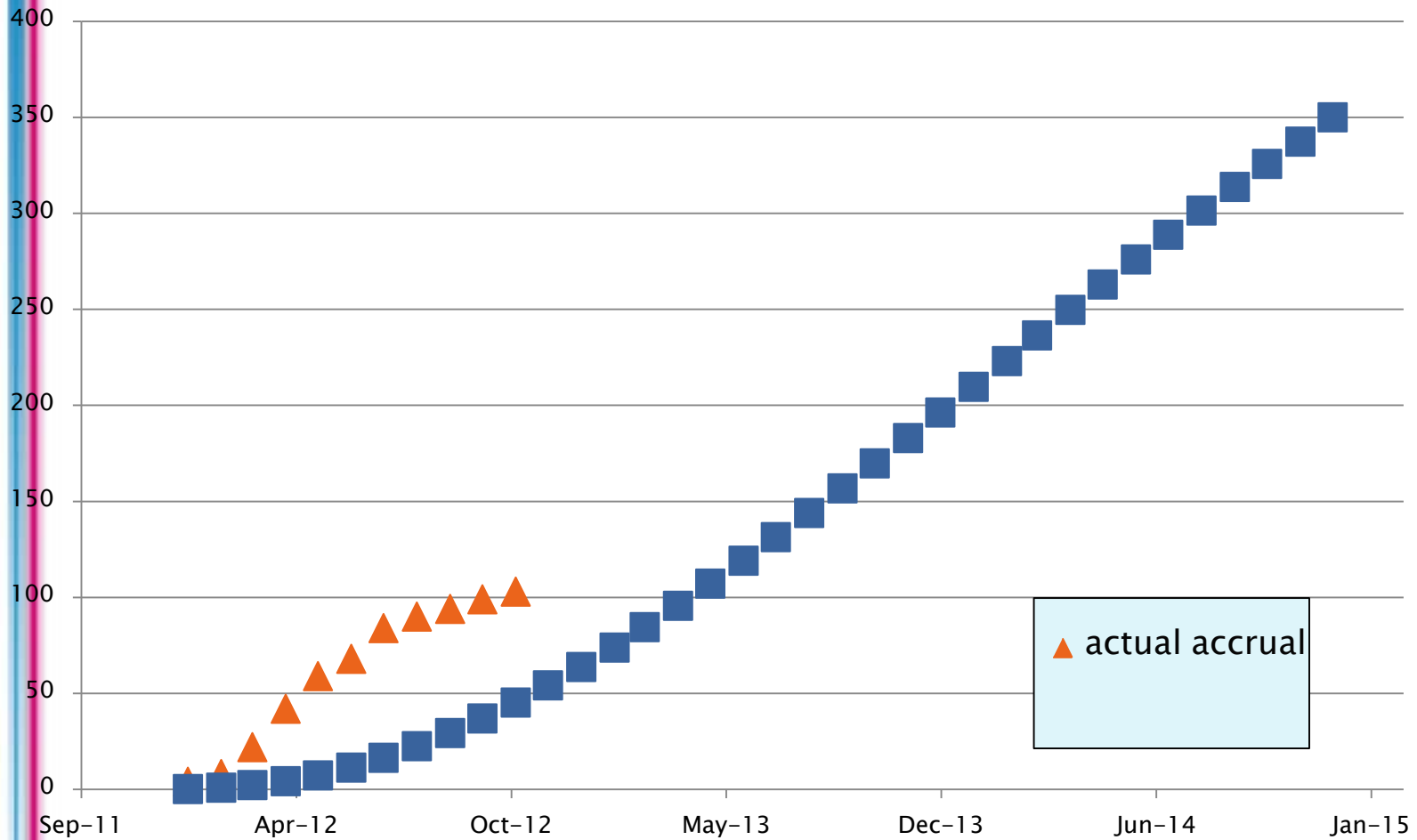
¹ This also includes cancers of the fallopian tube as well as primary peritoneal cancers

² All patients will have a tumour block or slides submitted for central review at a later date and repeat quantitative immunostaining for ER and PR receptors

³ Treatment will continue until disease progression, unacceptable toxicity or physician / patient preference



Accrual rate





Current Status

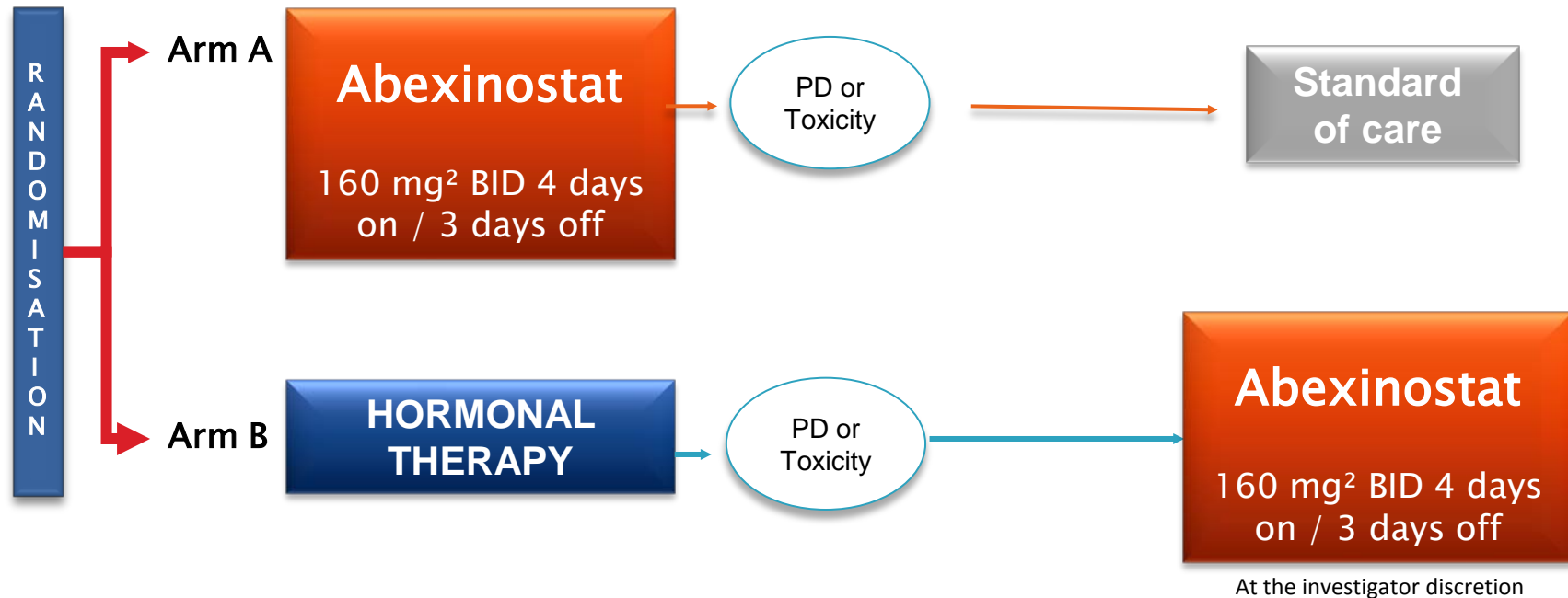
Sites Activated: 20 from Australia and New Zealand. 14 from UK

Patients Recruited – 103/350 (92 from ANZGOG, 11 from UK)

International Collaboration: Leuven group in Belgium in final contract signing stage.

Interim review by IDMC recommended continued accrual to platinum resistant refractory subtype and asymptomatic, rising CA125 sub-type

Study DESIGN SCT/ LGS OvCa



Population :

Patients with an histologically confirmed diagnosis of ovarian sex-cord stromal tumor in relapse after a platinum-based chemotherapy.

Primary Objective : an increase of the 6-month progression free rate from 16% in arm B to 40% in arm A (ESTIM results)

Secondary Objectives : PFS, OS, RR, QoL, Safety profile

