



# ALIENOR

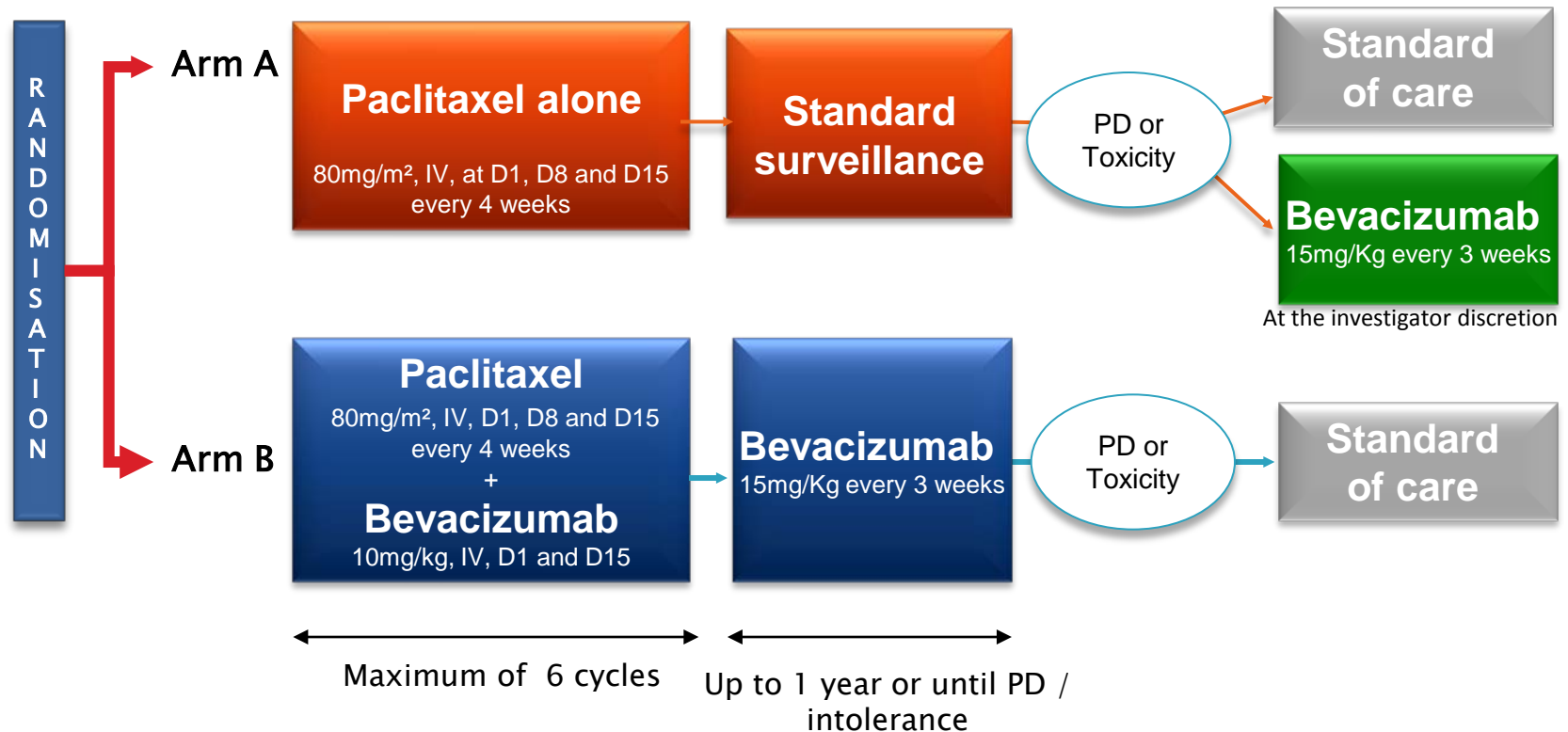
## ENGOT- OV7

### Avastin and weekly paclitaxel use in sex cord-stromal ovarian tumors

A randomized, open label, phase II trial of bevacizumab plus weekly paclitaxel followed by maintenance with bevacizumab monotherapy versus weekly paclitaxel followed by observation in patients with relapsed ovarian sex-cord stromal tumors



# ALIENOR DESIGN : 60 patients



## Population :

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

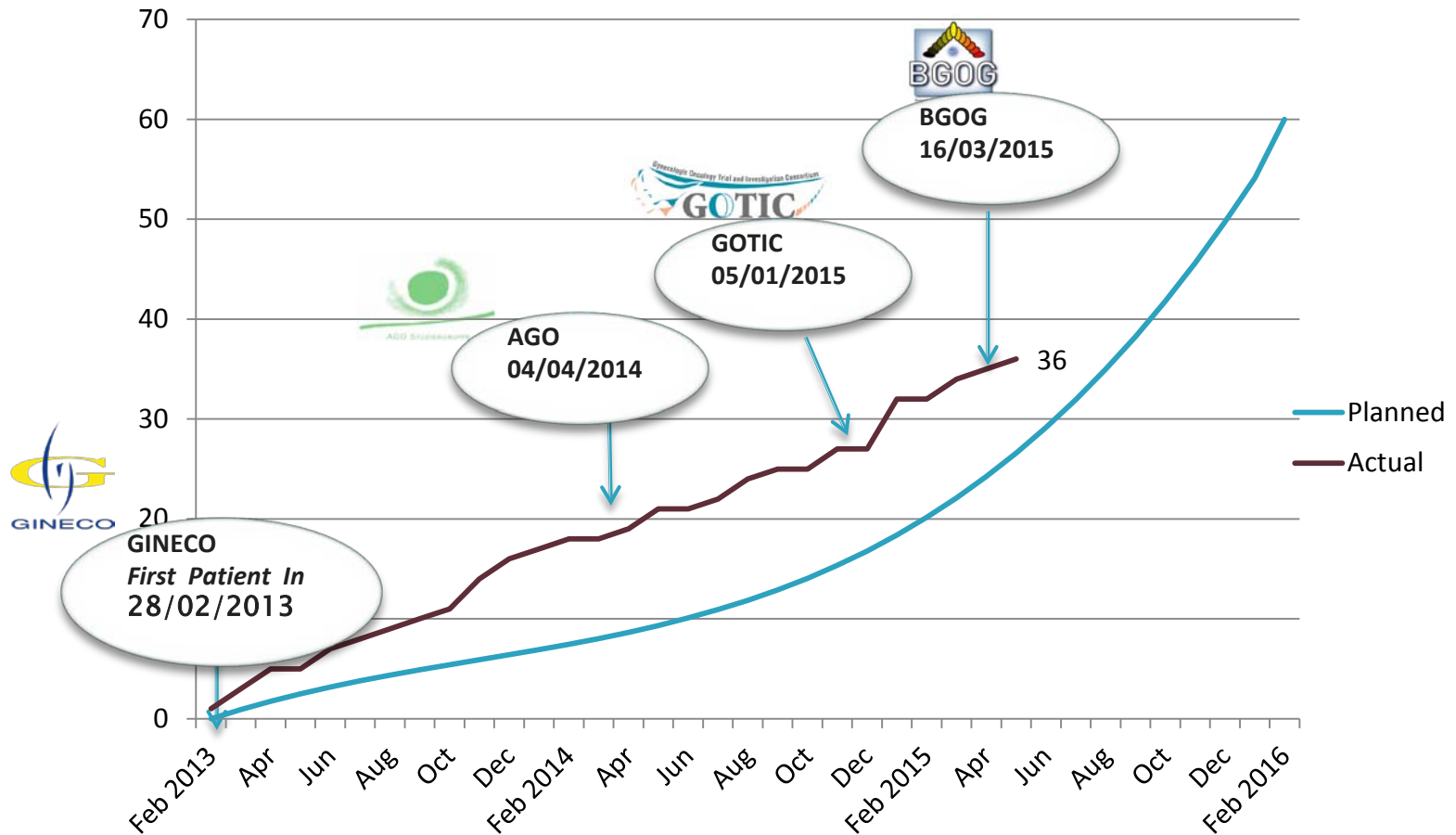
## Primary objective :

Clinical benefit rate  
(non-progression rate after 6 months of treatment)

## Stratification

Anterior chemotherapy lines :  
1 or 2 vs 3 and more  
Platinum Free Interval (PFI)  
<12 months vs ≥12 months

# ALIENOR Status



Submission in June

- Enrollment period : 36 months
- Treatment + maintenance : 18 months
- Follow-up : 36 months

First Patient In : February 2013  
 Last Patient Out of Maintenance : August 2017  
 Last Patient Out : August 2020

## First interim analysis

### Assesement of clinical benefit at 6 months of the first 20 patients

- ▶ IDMC met on 09/02/2015 and the ALIENOR Independent Data Monitoring Committee (IDMC) met on 09/02/2015 and reviewed unblinded safety and efficacy data of the 20 first patients.
- ▶ **The committee voted unanimously that ALIENOR should continue unchanged.**

