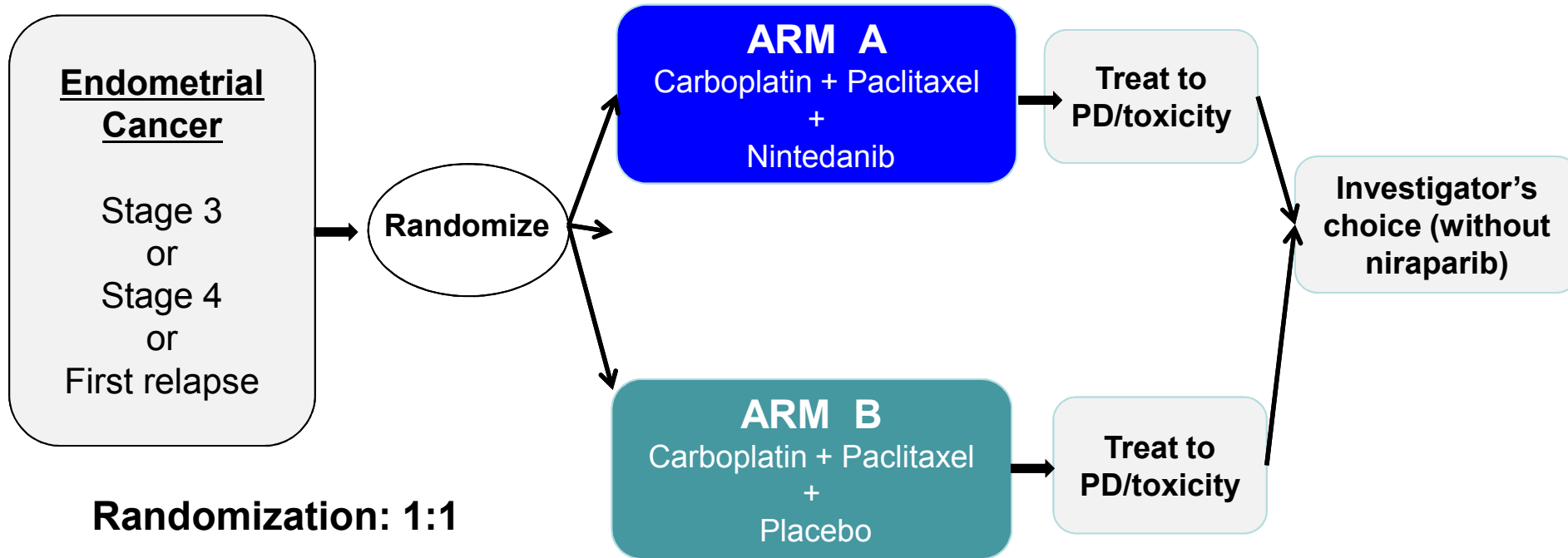


A randomized double-blind placebo-controlled phase II trial of first-line combination chemotherapy with Nintadenib for patients with advanced or recurrent endometrial cancer

ENGOT-EN1 / FANDANGO

Sponsor & ENGOT Lead Group: NSGO

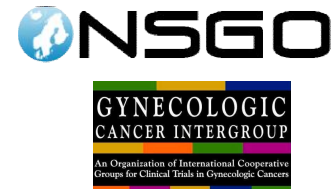


Stratifications

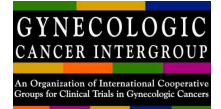
- stage of disease (stage 3 vs. stage 4 vs. recurrent disease)
- Prior adjuvant chemotherapy (yes/no)
- Disease status (no macroscopic disease vs. macroscopic disease)



Patient Population



- **Primary stage 3C high grade or 4**
- **Relapse after primary adjuvant treatment for early stage disease.**
Patients may have received adjuvant chemotherapy for stage 1 or 2. In this case the treatment-free interval shall exceed 12 months. Only post-operative adjuvant chemotherapy is allowed
- **Other prior treatment**
The following prior treatments are allowed: surgery, EBRT, brachytherapy, hormonal therapy.
- **Disease status**
Patients must have measureable disease or non measurable disease on CT scan according to RECIST 1.1 outside irradiated field. For stage 3C high-grade disease patients without measureable or non-measureable disease are accepted.



Status

- Contract with Boehringer is signed
- Submissions to authorities starts in December 2015
- Planned first patient in: March 2016