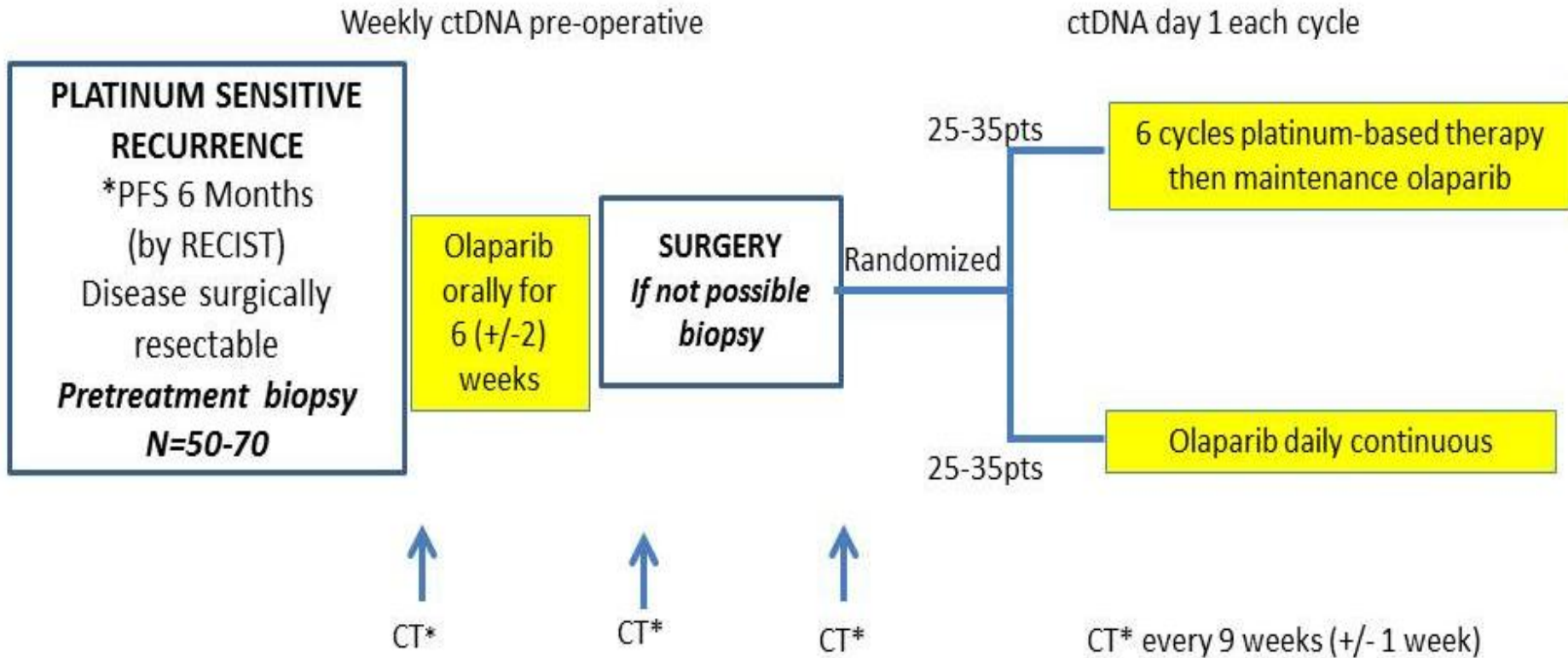


PHASE II COMMITTEE

Elise Kohn NCI-US

Mansoor Mirza NSGO

PMHC NEO Trial Schema



CT* - PET scan could be substituted as per institution guidelines

INTERESTED GROUPS: BGOG/ANZGOG/NCRI

ANTICIPATED OPENING 1/16



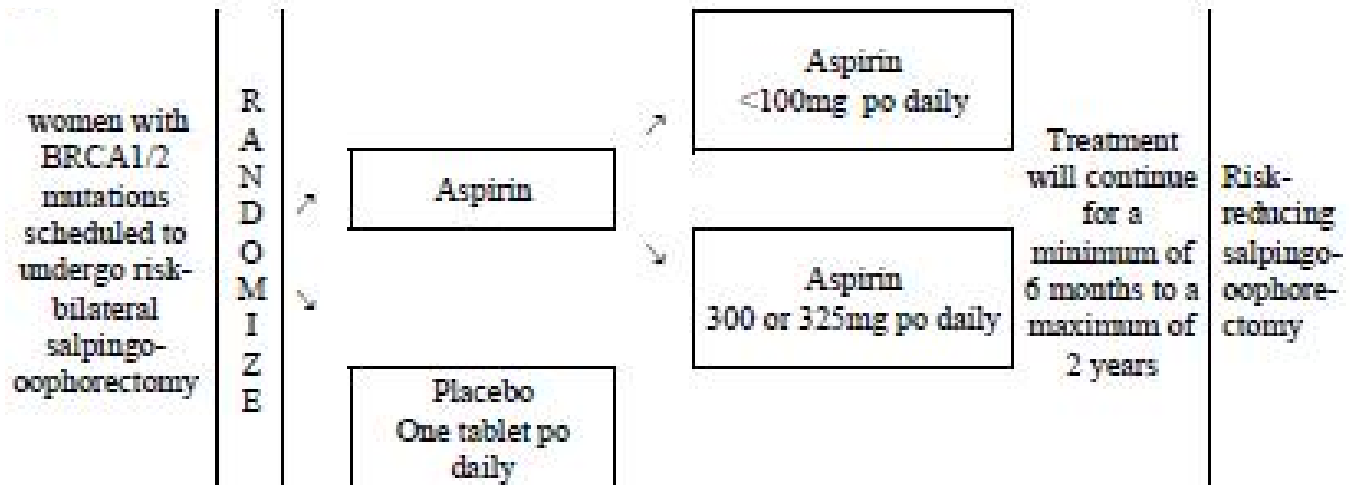
STICS AND STONES

International, multicentre, phase II, double-blind, placebo-controlled randomized trial comparing the effects of daily aspirin (<100mg or 300/325mg) versus placebo on the frequency of pre- and early-malignant lesions in resected RRSO specimens from women harboring germline *BRCA1/2* mutations

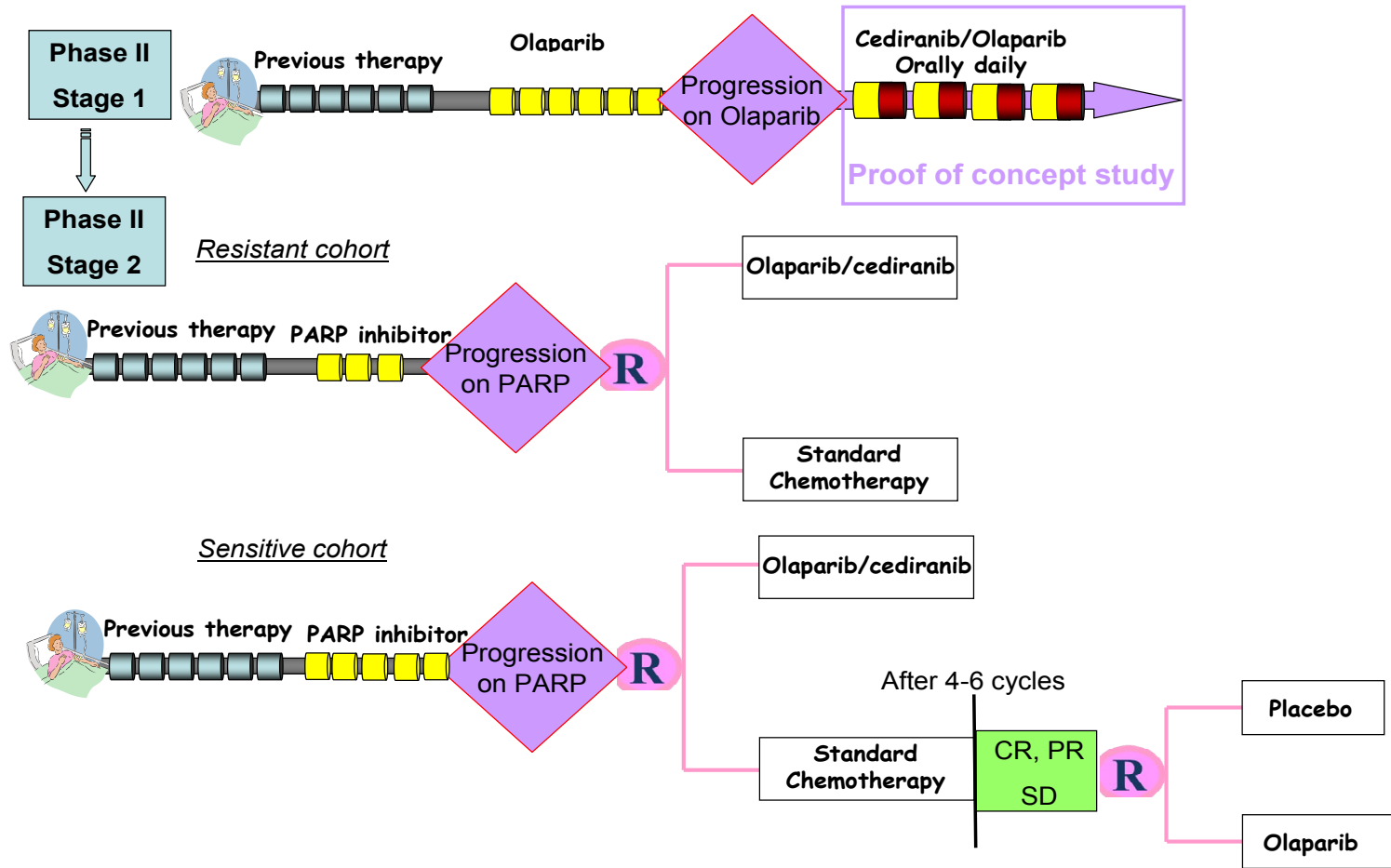
- Window of Opportunity Trial



- 2:1 Randomization



PMHC/eVolve



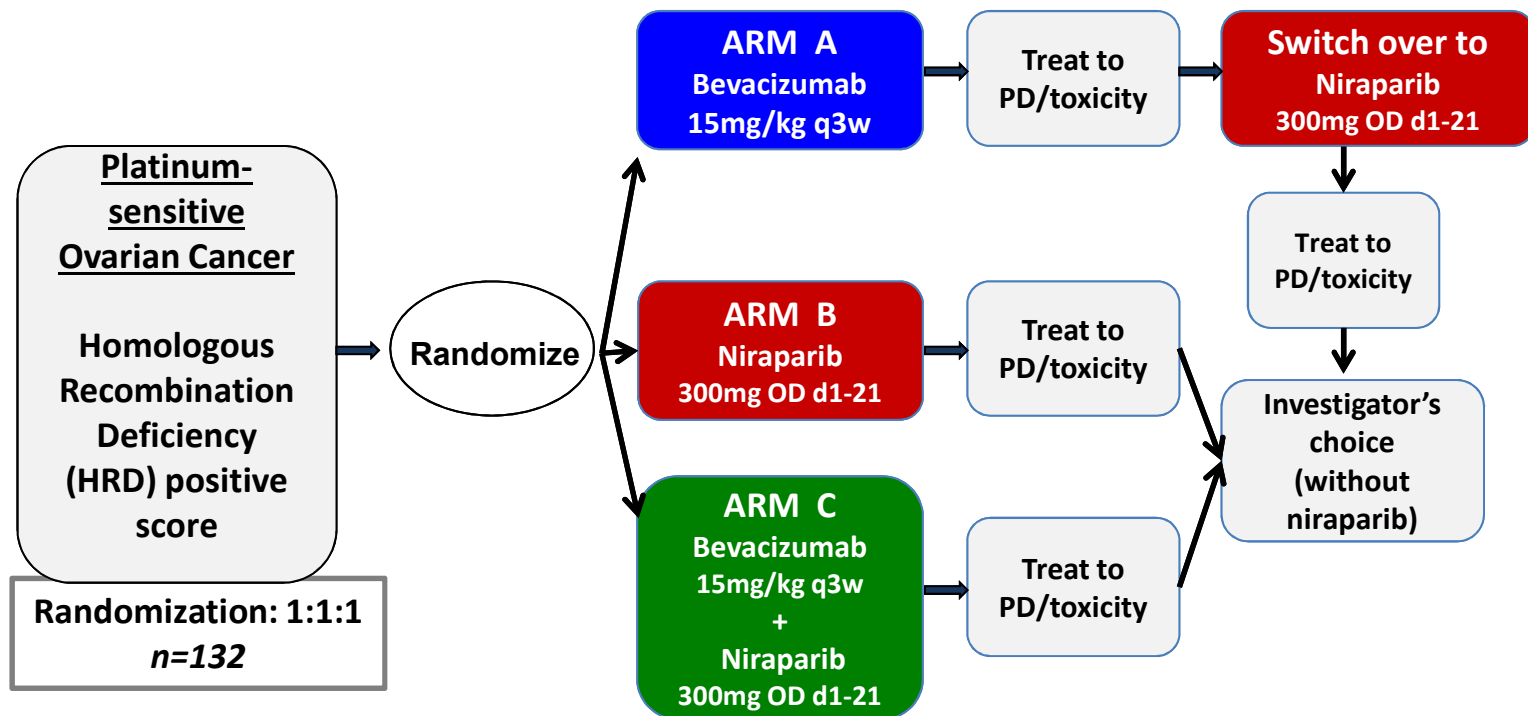
INTERESTED GROUPS: NSGO/ANZGOG/SGOG/GEICO

ANTICIPATED OPENING 1/16

ENGOT-OV24-NSGO / AVANOVA

Phase 2 design

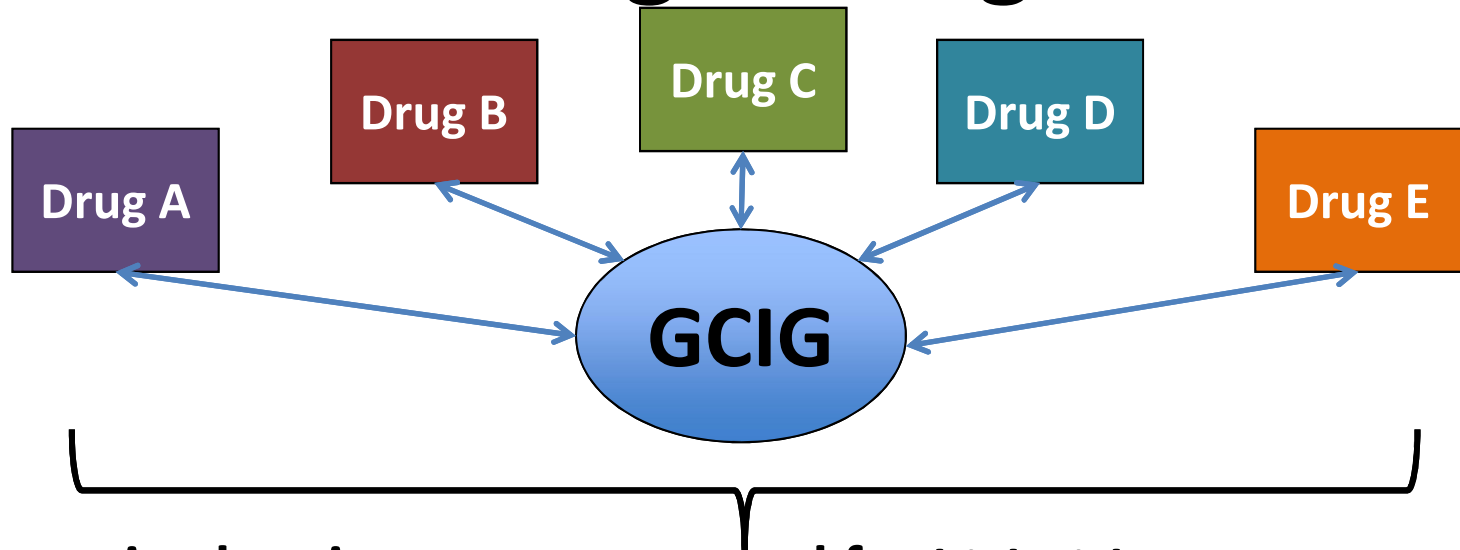
Niraparib and niraparib-bevacizumab combination against bevacizumab alone in women with Homologous Recombination deficient (HRD) platinum-sensitive epithelial ovarian, fallopian tube, or peritoneal cancer



HRD by Myriad, 2 week turnaround

ANTICIPATED OPENING 12/15

G-TAC: GCIIG - Targeted Agents in CxCa

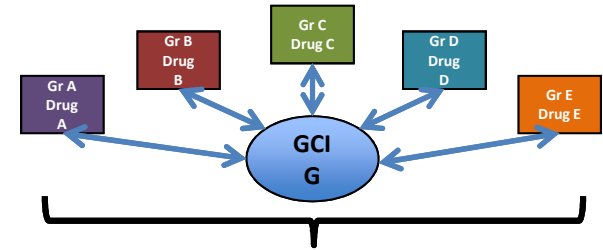


- **Harmonized maintenance protocol for high risk post CCRT pts**
 - randomization v. worldwide SoC of observation
 - PFS at 2 yrs
- **Mandatory collection of pretreatment tissue for uniform translational analyses**
 - WES across all arms will build large resource for mining
- **Opportunity for per arm translational/imaging add-ons relative to their arm or across arms**

DESIGN ELEMENTS

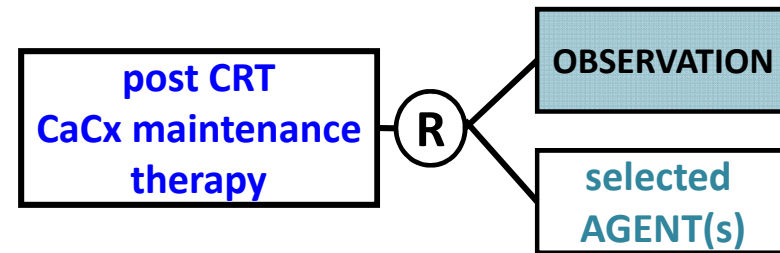
OBJECTIVES

- 1⁰: 2 yr EFS
- 2⁰: translational endpoints; meta analysis of control patients; OS?; PRO; compliance/feasibility
- Per group(s) added translational science/imaging, etc
- need to think about patient outreach and education

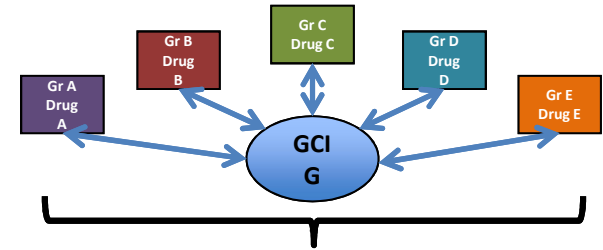


DESIGN

- RP2 with common observation control arm across all components
- window 10-12 weeks for entry
- unbalanced randomization (2:1 or 3:1)
- eligibility (*in development*): IB2 – IVA
 - all LN+
 - ? all IIIB/IVA



DESIGN ELEMENTS



AGENTS:

- pending partnerships (Thanks to Tesaro for first commitment!)
- participation may be dependent upon company regulatory plans
- open for recommendations

PARTICIPATION:

- may have multiple groups per drug randomization

HARMONIZATION –CRITICAL

- minimum data required
- common data elements
- eCRFs
- minimum translational targets harmonized

