ICON9:
An international phase III randomised double-blind study to evaluate the safety, tolerability and efficacy of 2 regimens of cediranib in combination with platinum-based chemotherapy and placebo controlled olaparib and cediranib maintenance therapy
(in patients with relapsed platinum sensitive ovarian cancer)

NCRI National Cancer Research Institute

CANCER RESEARCH UK

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

Trial Schema

Relapsed platinum sensitive ovarian, fallopian tube, primary peritoneal cancer

Arm 1
Chemotherapy + cediranib daily x6 cycles
followed by maintenance cediranib (daily) plus olaparib

Arm 2:
Chemotherapy + cediranib (5:2) x6 cycles
followed by maintenance cediranib (5:2) plus placebo

Stratified by 6-12 vs >12 month progression free interval; BRCA status; surgery vs no surgery at relapse prior to chemotherapy; prior bevacizumab

Cediranib: 20 mg OD
(daily vs 5 days on/ 2 days off-5:2)
Olaparib: 300 mg BD

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Study Objectives

- **ICON 9 will assess the efficacy, safety and tolerability of 2 dosing regimens of maintenance cediranib in combination with olaparib compared to maintenance of cediranib and placebo following platinum-based chemotherapy with cediranib**

- Changes in design due to amalgamation of trial protocols for original ICON9 and CATALYST trial
- Main change is use of blinded placebo controlled blister packs to assess toxicity/efficacy of dosing regimen for cediranib with chemotherapy and in maintenance setting with/without olaparib

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Study Endpoints

	End points
Primary Objective	• PFS (RECIST v1.1) • OS
Secondary objectives	• Toxicity • Adherence • PFS2 • TFST • Quality of Life (FACT-O/TOI) and Patient Reported Outcomes and EQ-5D-5L (health economic analysis) • Progression free survival by CA125 – GCIG criteria • Response rates by RECIST/CA125 at 12 weeks of maintenance therapy in patients with measureable disease or elevated CA125 at randomisation to maintenance therapy

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Details

- AZ remain supportive of trial
- 30-40 sites UK
- 20 international sites from 2-4 countries
- September 2015: Full CRUK application approved in UK
- Funding approved in Australia and Canada
- Q1 2017 (open trial)

- **GCIG Satellite meeting Friday at 10 am**