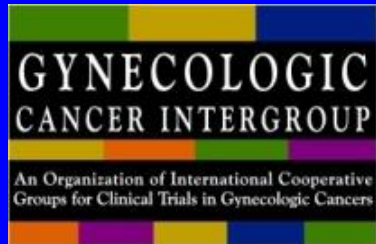


NiCCC

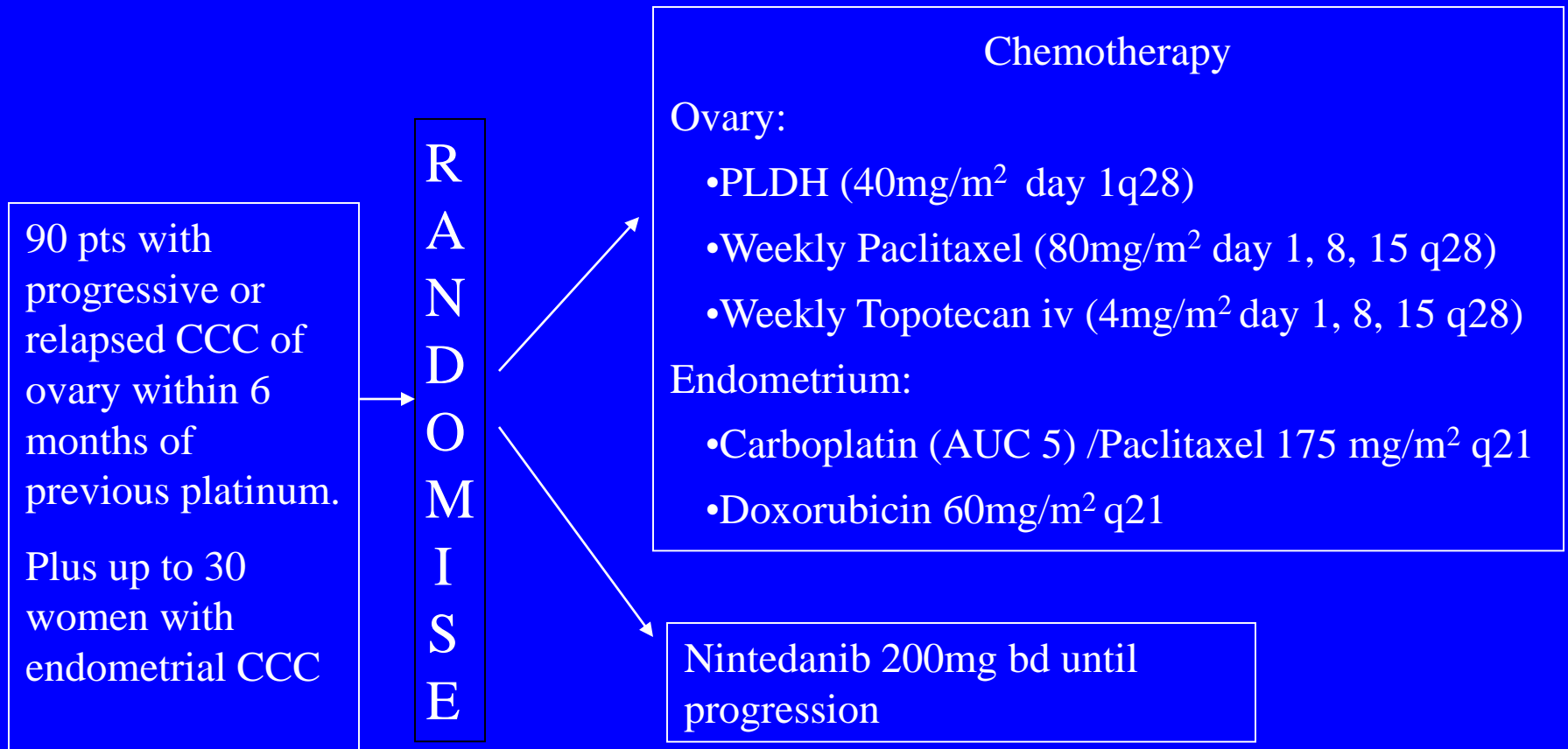
Nintedanib in Clear Cell Carcinoma

A Randomised Phase II Study of BIBF 1120 versus
Chemotherapy in Recurrent Clear Cell Carcinoma of the
Ovary or Endometrium

SGCTG/NCRI/NSGO



NiCCC Trial Design



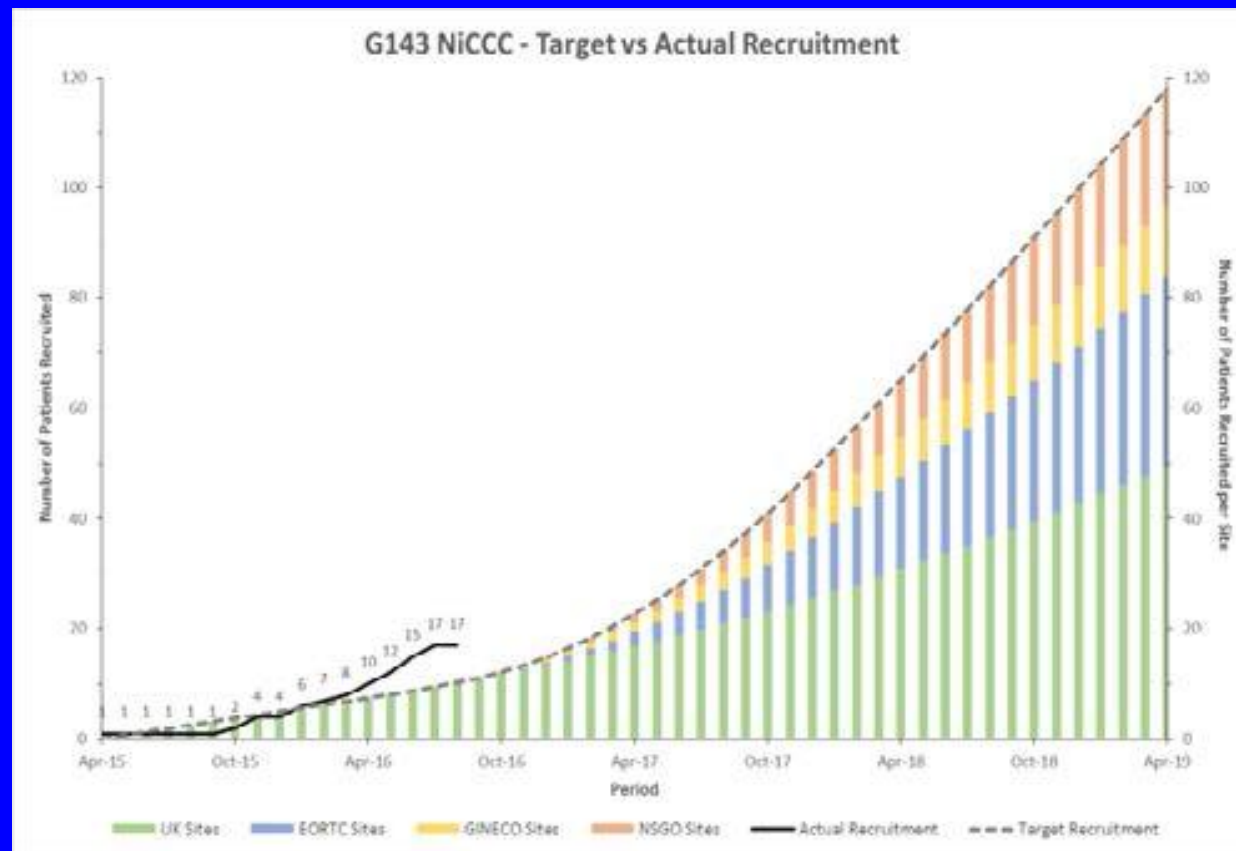
Primary Endpoint: PFS

Secondary Endpoints: OS, Toxicity, RR, QoL, Q-Twist

Trial Status

- Study opened in the UK April 2015
 - 18 centres are open
 - 18 patients randomised
 - 2 patients registered for central pathology review
- GINECO due to open Nov 2016
- EORTC estimate Competent Authority submission Oct/Nov 2016
- NSGO estimate site activation in Denmark March 2017

Recruitment Graph



Recruitment by Site

| Site | Date Activated | Total no. patients | Recruitment target (patients/month) | Comment |
|---|------------------------------|------------------------------|-------------------------------------|------------------------|
| Beatson West of Scotland Cancer Centre | 02 Apr 2015 | 6 & 1 pt transfer | 2 per year / 8 in total | |
| Belfast City Hospital | 04 Mar 2016 | 0 | 1 per year | |
| Bristol Haematology and Cancer Centre | 08 Dec 2015 | 3 | 2 per year | |
| Clatterbridge Cancer Centre | 05 May 2016 | 0 | 5 in total | 1 patient in screening |
| The Christie, Manchester | 29 Jun 2016 | 1 | 4 per year | |
| Great Western Hospital, Swindon | 04 Sep 2015 | 1 - Pt transferred to BWoSCC | 3 per year | |
| Guy's Hospital, London | 17 Feb 2016 | 1 | 2 per year | |
| East Kent Hospitals NHS Trust (3 sites in 1 Trust) | 09 Dec 2015 | 1 | 1.5 per year from all sites | |
| Musgrove Park Hospital | 12 May 2015 | 1 | 4 in total | |
| Ninewells Hospital, Dundee | 17 Mar 2016 | 0 | 1 per year | |
| Royal Marsden Hospital (2 sites in one Trust) | 23 Jul 2015 | 3 | 5 total | |
| St James' Hospital, Leeds | 23 Jul 2015 | 1 | 12 in total | 1 patient in screening |
| St Bartholomew's Hospital, London | 22 Sep 2016 | 0 | 3 in total | |
| University College London Hospital | 5 th October 2016 | 0 | 5 per year | |
| Velindre Hospital | 27 Nov 2015 | 0 | 1 per year | |