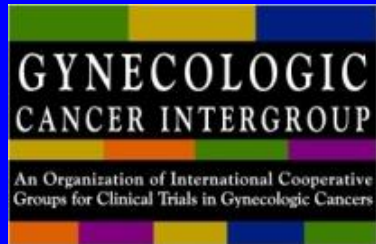


NiCCC

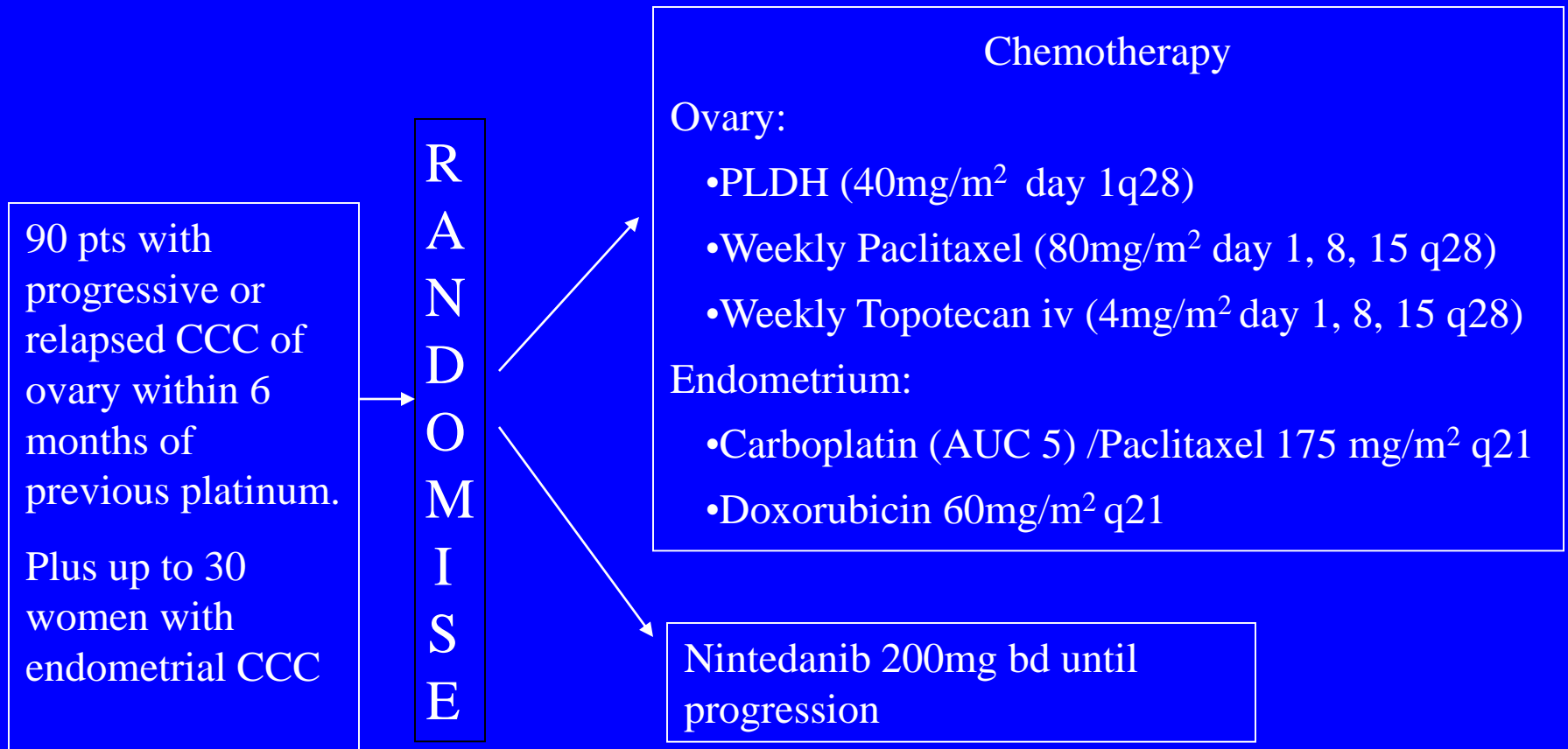
Nintedanib in Clear Cell Carcinoma

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



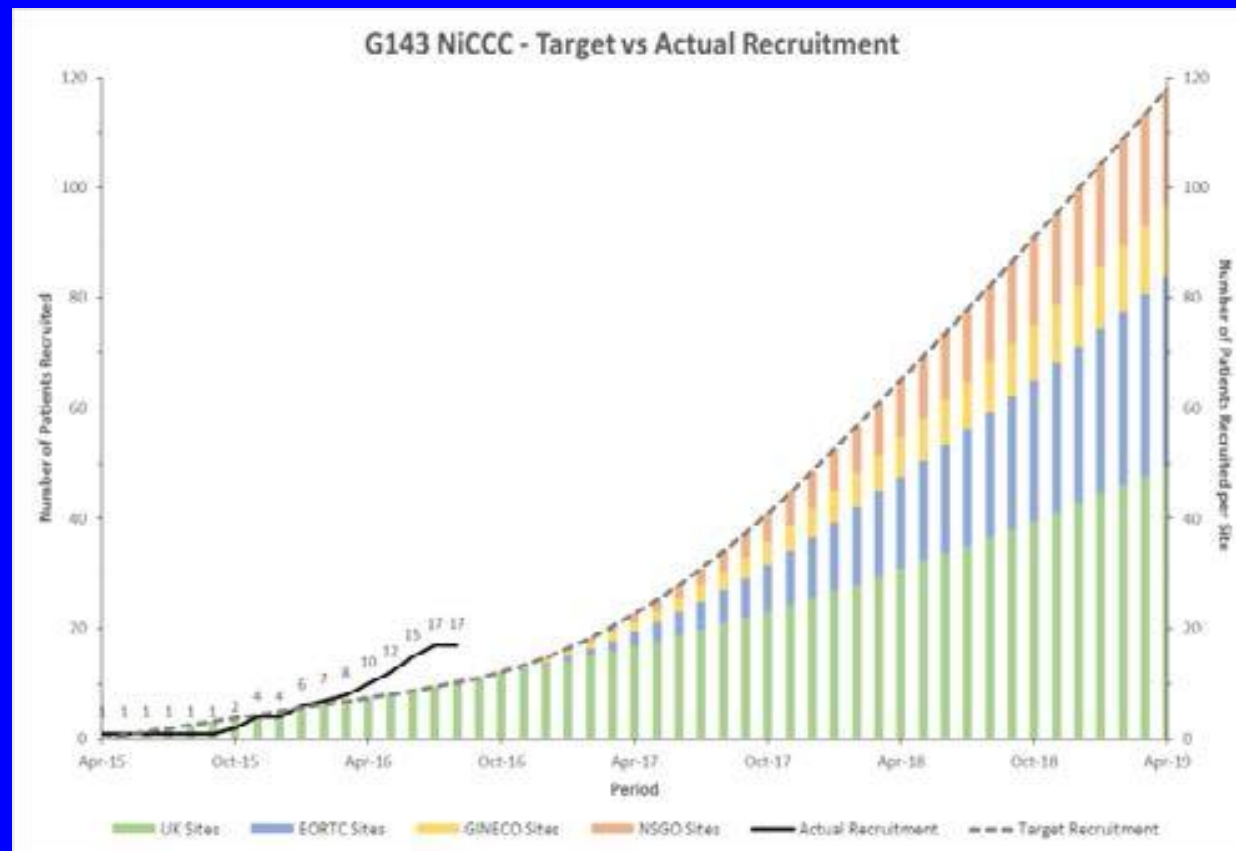
Primary Endpoint: PFS

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	