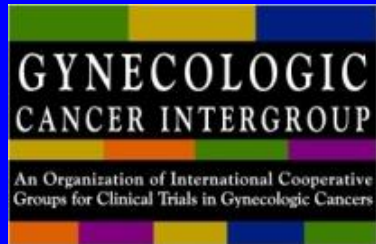


# NiCCC

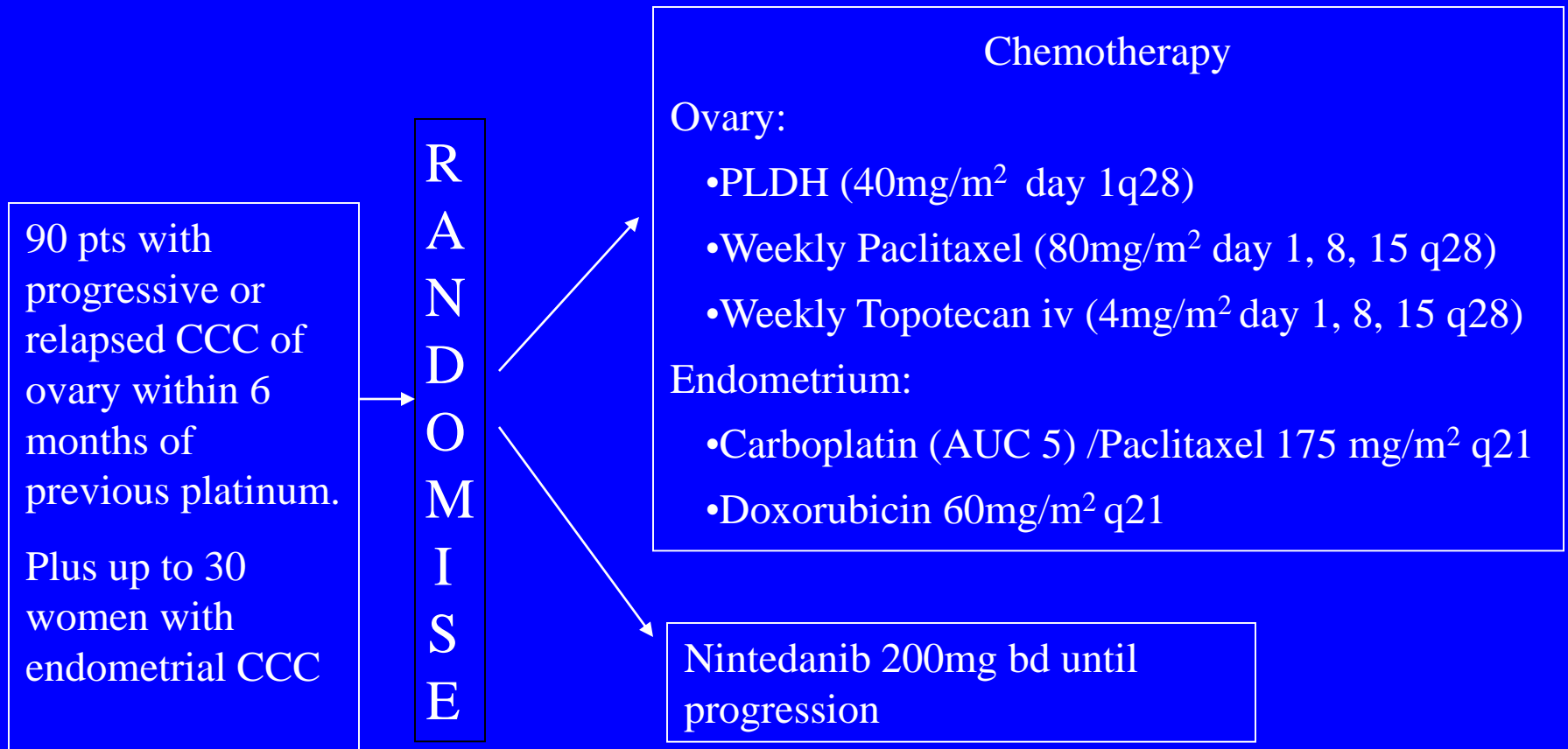
## Nintedanib in Clear Cell Carcinoma

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



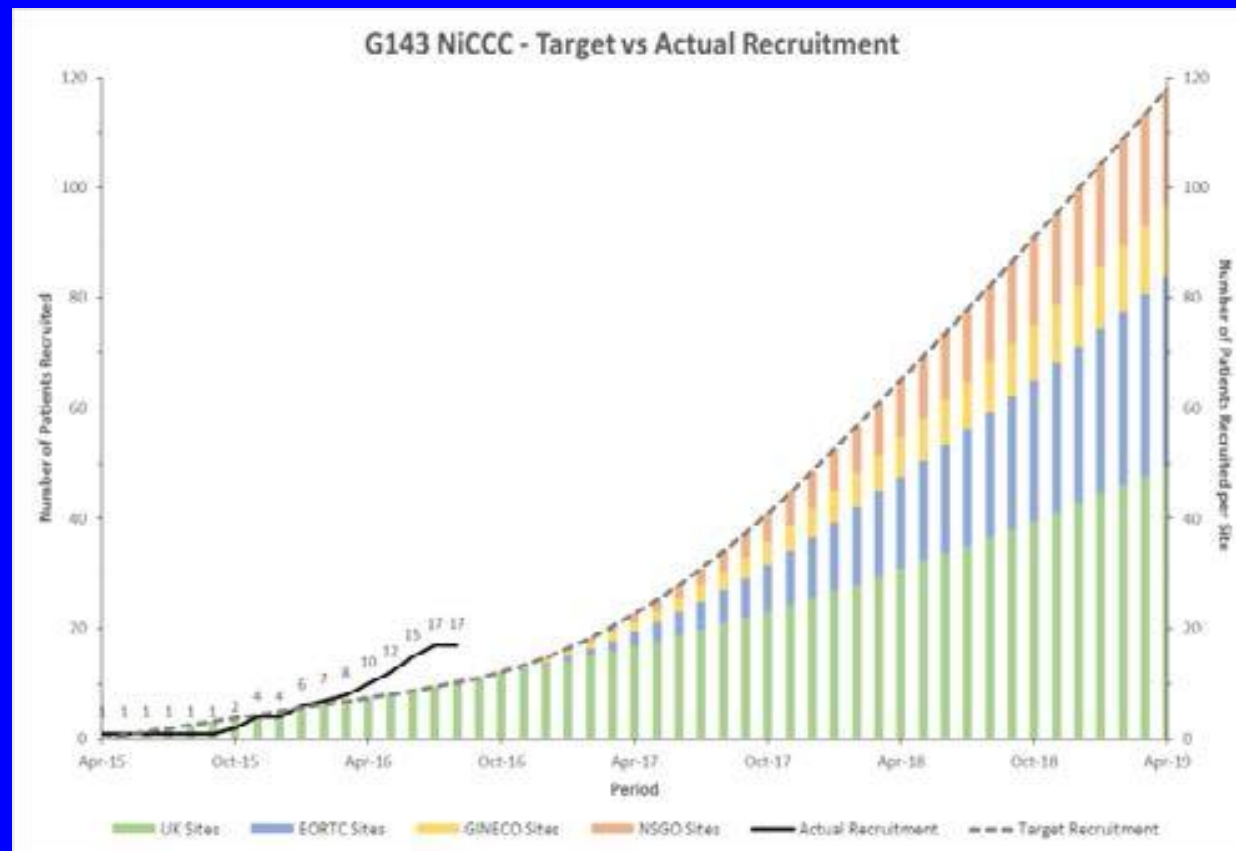
Primary Endpoint: PFS

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
<b>Beatson West of Scotland Cancer Centre</b>	02 Apr 2015	6 & 1 pt transfer	2 per year / 8 in total	
<b>Belfast City Hospital</b>	04 Mar 2016	0	1 per year	
<b>Bristol Haematology and Cancer Centre</b>	08 Dec 2015	3	2 per year	
<b>Clatterbridge Cancer Centre</b>	05 May 2016	0	5 in total	1 patient in screening
<b>The Christie, Manchester</b>	29 Jun 2016	1	4 per year	
<b>Great Western Hospital, Swindon</b>	04 Sep 2015	1 - Pt transferred to BWoSCC	3 per year	
<b>Guy's Hospital, London</b>	17 Feb 2016	1	2 per year	
<b>East Kent Hospitals NHS Trust (3 sites in 1 Trust)</b>	09 Dec 2015	1	1.5 per year from all sites	
<b>Musgrove Park Hospital</b>	12 May 2015	1	4 in total	
<b>Ninewells Hospital, Dundee</b>	17 Mar 2016	0	1 per year	
<b>Royal Marsden Hospital (2 sites in one Trust)</b>	23 Jul 2015	3	5 total	
<b>St James' Hospital, Leeds</b>	23 Jul 2015	1	12 in total	1 patient in screening
<b>St Bartholomew's Hospital, London</b>	22 Sep 2016	0	3 in total	
<b>University College London Hospital</b>	5 <sup>th</sup> October 2016	0	5 per year	
<b>Velindre Hospital</b>	27 Nov 2015	0	1 per year	