GYNECOLOGIC CANCER INTERGROUP

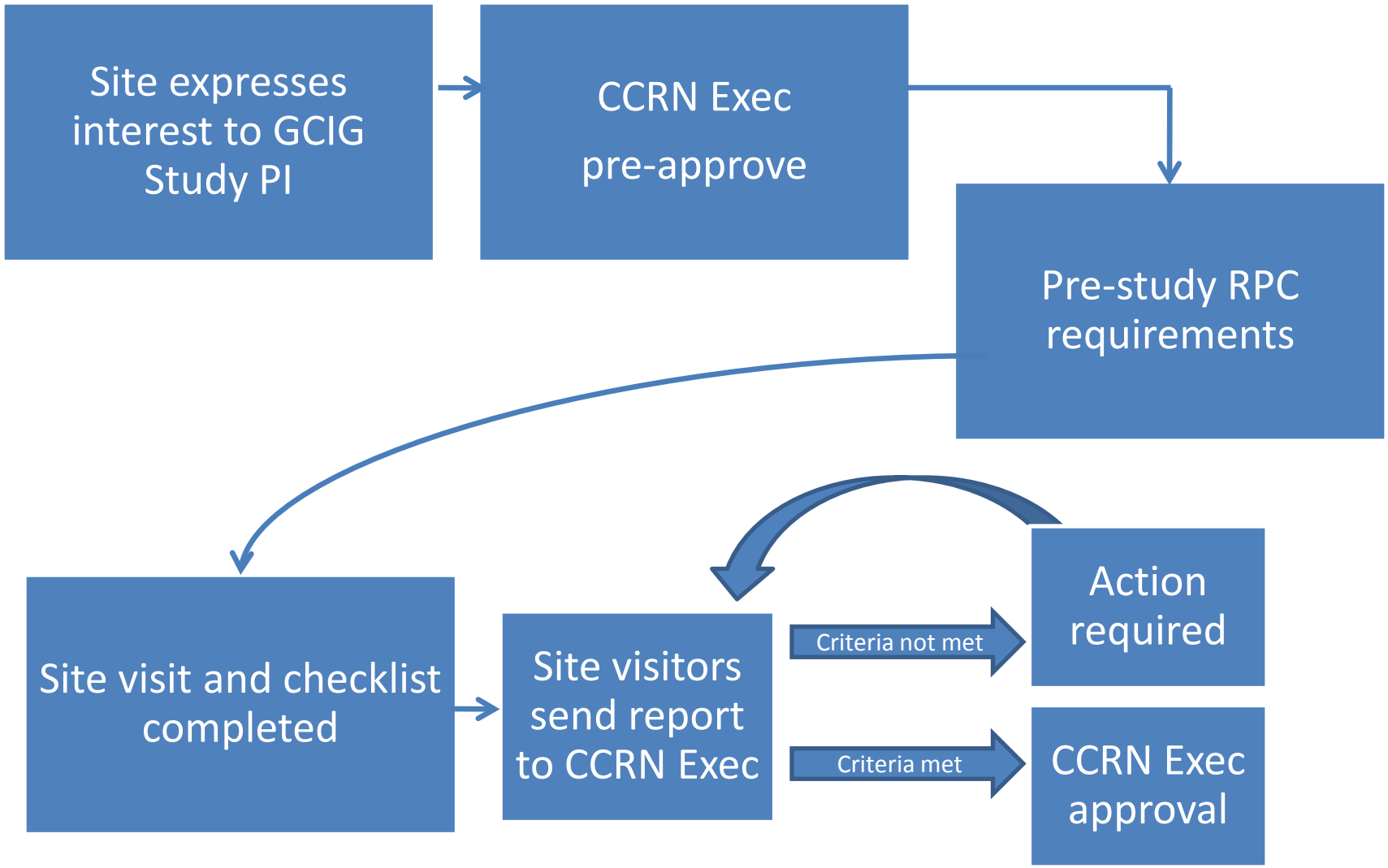
An Organization of International Cooperative Groups for Clinical Trials in Gynecologic Cancers

CCRN Operations Review

Julie Martyn

ANZGOG

CCRN site approval process



Gynecologic Cancer InterGroup (GCIG)

Cervix Cancer Research Network (CCRN)

CCRN site visit documentation
Date of visit:

General Site Information

Name of Site:	
Contact Person for CCRN:	E-mail Address:
Address:	Phone Number:
	Fax Number:

Average number of NEW cancer patients seen in the hospital/site per year: ___
Average number of NEW GYN cancer patients seen in the hospital/site per year: ___
Average number of NEW Cervix cancer patients seen in the hospital/site per year: ___

Name of the GCIG study:	
Contact Person for study :	E-mail Address:
Address:	Phone Number:
	Fax Number:

Site Resources [if any of these resources are off-site, please explain]

Routine Hematology	Yes	No
Routine Biochemistry	Yes	No
Routine Anatomical Pathology	Yes	No
Specimen storage facility (long term)	Yes	No
Designated gyne. Pathologist	Yes	No
Any specialized pathological services : (Please describe) _____		
Transfusions facility	Yes	No
Critical Care facility	Yes	No
Radiology Facilities:	Yes	No
Plane X-Ray	Yes	No
Ultra-sound	Yes	No
CT	Yes	No
MRI	Yes	No
PET	Yes	No
PET/CT	Yes	No
Dedicated gyne. Radiology specialist	Yes	No

Other (notes): _____

IT facility/support	Yes	No
eMail available during working hrs?	Yes	No
Access to PC for Doctors, Technologists, Data Managers and Nurses?		
	Yes	No
Is your facility capable of digital data exchange?	Yes	No

Clinical Trial Operations

Does your site have a Clinical Trials Unit? Yes No

Do you have a team that can manage a GCIG study at your site? Yes No

Primary Principal Investigator: _____

Research Nurse: _____

Data Manager: _____

Designated research Pharmacist: _____

On-Site Monitor: _____

If you join a GCIG study, do you have a trained data manager? Yes No

If you do not have a qualified data manager, how do you plan to perform data management at your institution? :

Do you have prior experience with electronic data entry (web-based CRFs): _____

Do you have a secure on-site storage area for clinical trial data: _____

Do you have a secure on-site pharmacy area for clinical trial agents: _____

Does your site have regular Tumour Board review/meetings for Gyne cancers? _____

In how many oncology clinical trials has your site participated over the past 5 years: _____

In how many cervical cancer clinical trials has your site participated over the past 5 years: ____

Has your site participated in multi-center clinical trials (national or international) : _____

Has your site agreed to be the National Sponsor (ethics and regulatory) for your country? ____

If so, have you signed a clinical trial agreement with the lead group? _____

If not, have you signed a clinical trial agreement with the national sponsor? _____

Is your site able to abide by standard ethical, regulatory, and safety reporting requirements?

Please **attach** a short summary of the Ethics and Regulatory approval processes at national, regional and site levels, including reference to initial approval, protocol amendments, annual reporting and safety reporting requirements. Please also provide documentation of ICH GCP education and practice on site.

Site visits to date

- Tata Memorial, Mumbai, India (for OUTBACK trial)
  - Sept 2011, Kailash Narayan (radiation oncologist) and Sylvia Van Dyk (brachytherapist)
- Bangalore Institute of Oncology (for OUTBACK trial)
  - Nov 2011, Kailash Narayan (radiation oncologist), Sylvia Van Dyk (brachytherapist) and Julie Martyn (operations)
- Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow (for OUTBACK trial)
  - Nov 2011, Kailash Narayan (radiation oncologist), Sylvia Van Dyk (brachytherapist) and Julie Martyn (operations)
- Ramathibodi Hospital, Bangkok, Thailand (for TAKO trial)
  - January 2012, David Gaffney (radiation oncologist), Julie Martyn (operations)

Outcomes to date

- Tata Memorial Hospital approved, OUTBACK site activation proceeding
- Bangalore: RPC requirements outstanding
- SGPMI, Lucknow: RPC requirements outstanding. Data management support needed
- Ramathibodi Hospital approved. TAKO team to follow up.

Pending visits

- Cluj, Romania (Interlace and OUTBACK)
- South Africa (Interlace)
- Trivandrum, India (OUTBACK)

GCIG Operations Nominees

- Benedicte Votan, Gabriel Elser, Karen Carty, Anastassia Negrouk, Eriko Aotani, Bette Stonebraker, Monica Bacon, Julie Martyn