

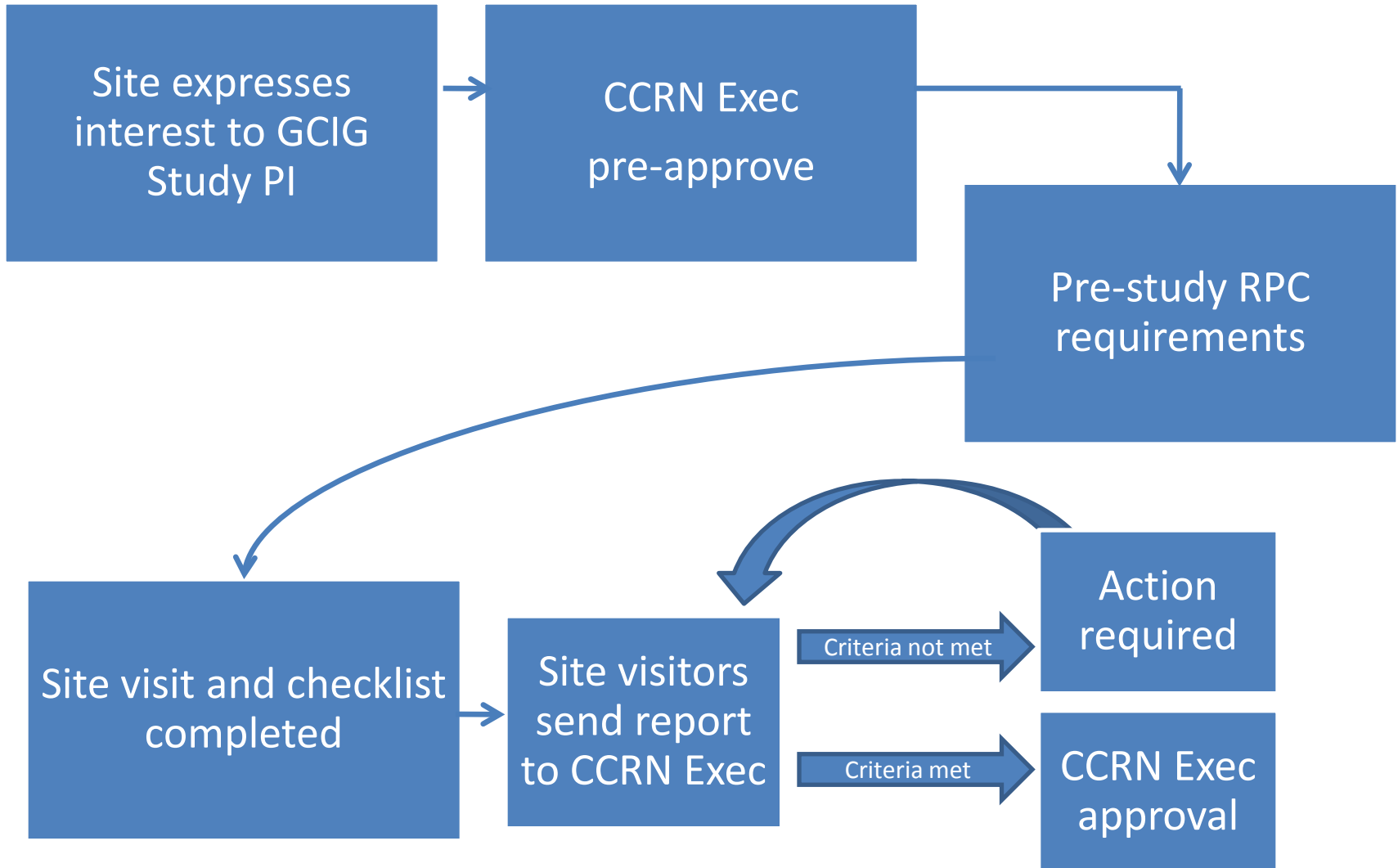


# CCRN Operations Review

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 <u>NEW</u> cancer patients seen in the hospital/site per year: ___
Average number of <u>NEW</u> GYN cancer patients seen in the hospital/site per year: ___
Average number of <u>NEW</u> 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): \_\_\_\_\_

<u>IT facility/support</u>	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)

# GCIIG Operations Nominees

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