



Gynecologic Cancer InterGroup (GCIG)
P.O.Box 24032 (Kingslake)
1201 Division Street
Kingston, Ontario
K7K 7A6 Canada.
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GCIG/CCRN SOPs (site review visits)

- 1) Sites which are not members of a GCIG member research group may be facilitated to join launched GCIG cervix cancer studies by joining the CCRN initiative.
- 2) Certain steps/requirements must be met to join the CCRN initiative:
 - a. Lead group study chair to inform GCIG/CCRN of potential site(s) and provide contact information;
 - b. CCRN Chair and GCIG Chair must approve potential site(s) and authorize visits;
 - c. Potential site will receive pre-qualifying questionnaire (p-q q);
 - d. Pre-qualifying questionnaire to be completed and returned; reviewed by CCRN QA;
 - e. Following approval of p-q-q, site visit will be scheduled;
 - f. Site visitor(s) will perform QA checks as per CCRN QA Checklist;
 - g. Site visitor(s) will notify CCRN Chair of findings and recommendations;
 - h. CCRN Chair will notify site of approval (or not);
 - i. Lead group study chair will be notified of CCRN QA approval;
 - j. Lead group will then initiate study specific local activation requirements.
- 3) By nature of GCIG membership, sites within GCIG member groups do not require CCRN QA.
- 4) Additional trial-specific QA requirements are the responsibility of the lead group.
- 5) Each GCIG study requiring CCRN QA visits will be allotted \$\$ for this purpose only.
- 6) Each authorized CCRN QA visitor will be reimbursed upon receipt of GCIG Expense Claim Form with attached receipts, boarding passes, etc.
- 7) There should always be at least one CCRN site reviewer who is independent of the referring trial
- 8) GCIG CCRN RT QA subcommittee will create a roster of available site reviewers.
- 9) GCIG Harmonization Committee will create a roster of available site reviewers (familiar with GCIG Harmonization guidelines and policies as well as experienced in performing site reviews) .

OVERSIGHT: independent CCRN QA committee receives reports from trial-specific IDMC.

ROSTERS:

GCIG CCRN RT QA Site Reviewers:

David Gaffney, Bill Small, Mary McCormack, Kailash Narayan, Manjeet Chadha, Anuja Jhingran, Charles Kunos, Mansoor Mirza, Loren Mell.

GCIG CCRN Harmonization – Ops Site Reviewers:

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

(for future consideration: Sandra Polleis, Karen Adema, Federico Nepote, Anna Shevlin, Jane Bryce, Laura Farrelly/Lindsay James, and Andrea Hiltz)