Gynecologic Cancer InterGroup
Cervix Cancer Research Network

GCIG CCRN Education Symposium

Good Clinical Practice GCP

and

GCIG CCRN QA

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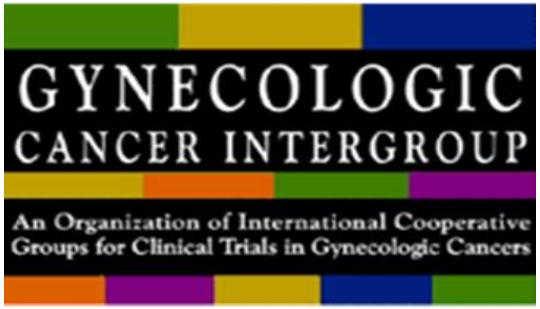
GCIG

Cervix Cancer Education Symposium, January 2017, Mexico



Background:

1949 The Nuremburg Code
1964 Declaration of Helsinki (World Medical Association)
1990 EU, USA & Japan – unified approach
1996 International Conference on Harmonization (ICH)
2000 revised Declaration of Helsinki

ICH GCP

ICH GCP

Definition: an internationally mandated ethical and scientific quality standard for the design, approval, conduct, performance, monitoring, auditing, recording, analyzing and reporting of clinical trials that involve the participation of human subjects

** adherence to ICH GCP is required for all (international) submissions to regulatory authorities **

versions of implementation differ but underlying principles do not

- eg: ICH GCP versus FDA GCP
- eg: European Directive

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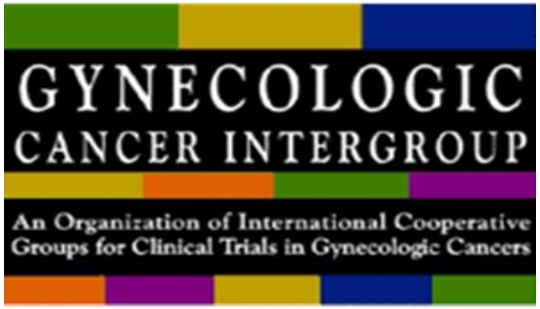

ICH GCP

- Glossary
- Principles
- Investigator
- Sponsor
- Trial Protocol and Amendments
- Investigator's Brochure
- Essential Documents

Composition of Ethics Committees

Cervix Cancer Education Symposium, January 2017, Mexico

GCP

key points:

1) The objectives, design, conduct, analysis and reporting of a clinical trial must be defined in a written protocol before study initiation and strictly followed throughout.

2) Protection of subjects is the shared responsibility of the investigator, the sponsor, and the ethics review board(s).

3) Investigator must select, train and keep a log of study team members with delegated responsibilities.

GCP

key points:

4) Accurately predict recruitment and maintain subject enrollment log.

5) Strict attention to ethical considerations; such as informed consent procedures and vulnerable populations.

6) Immediately report serious adverse events.

7) Document product accountability precisely.

GCP

key points:

8) Collect and record reliable study data diligently.

9) Maintain organized collection of source documents, files and archives.

10) Integrity: the rights, safety and well-being of the trial subjects prevails over the interests of science and society.

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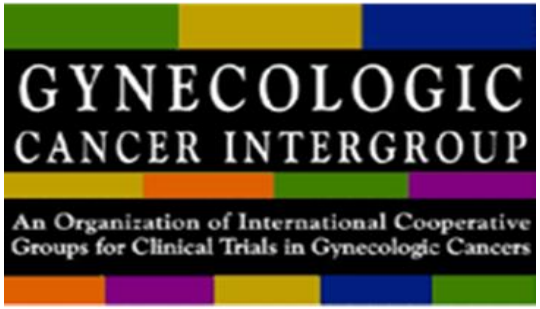

OVERSIGHT:

National Regulatory Authorities

National, Regional and Local -- Ethics Review Boards

Trial Steering Committees

Data Safety Monitoring Boards/Committees

GCP Certification

Resources and Checklist (ref.ONS CTN Manual, 3rd ed.,2015. pp.71-76) and

WHO GCP handbook www.who.int/medicines/areas/quality_safety/safety_efficacy/gcp1.pdf

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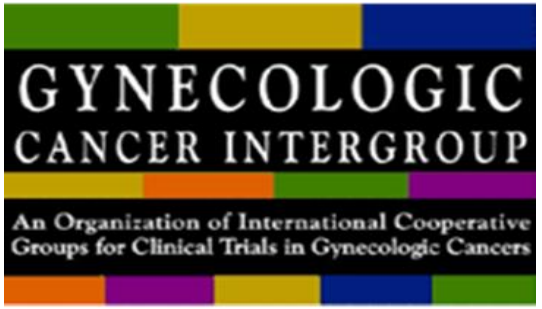


The standard for clinical research conduct has evolved and it is viewed as necessary to provide public assurance of trial participant protection and public and policymaker assurance that credible and reliable evidence exists for making informed decisions about medical practice and public health.

(Woltz & Moore, 2015)

GCIG CCRN

- Criteria:
  - Referred by a GCIG member group leading a CCRN trial
  - CCRN Chair approves initiation of SOPs
  - Capability Questions
  - RPC Questionnaire
  - Site Review Visit
  - Activated

GYNECOLOGIC CANCER INTERGROUP

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

CCRN CAPABILITY QUESTIONS

A. Are your clinical trial subjects entitled to medical management without cost as long as required; and entitled to financial compensation for clinical trial related injury or death? In case of death of the subject, is the compensation payable to the nominee(s) of the subject?

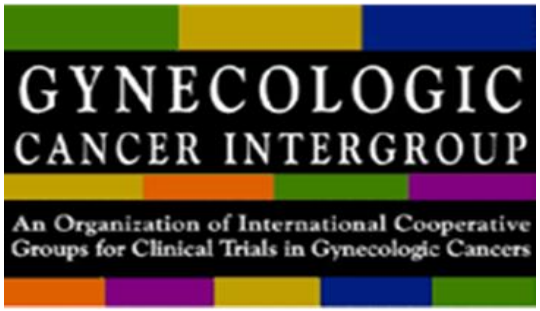
B. Do you have (national) definitions of what constitutes 'clinical trial related injury or death'?

C. Is the Sponsor or representative ("Sponsor Representative") [whosoever has obtained regulatory permission to conduct the clinical trial in country] obligated to bear the expenses of the Subject's medical management and provide financial compensation?

D. Is 'Serious Adverse Event' defined in country, as per the definitions of 'Adverse Event' and 'Serious Adverse Event' set out in ICH Good Clinical Practice [GCP] Guidelines)?

E. As well as protocol-mandated reporting through the data reporting mechanism, is there a national regulatory procedure for reporting serious adverse events and processing of incidental claims of financial compensation for country? As country's sponsor of the study, does the site's Principal Investigator and Ethics Committee have to submit a report of these events to a national Regulatory Committee within a stipulated time?

Responses reviewed/queried/commented/approved by CCRN QA



RPC QUESTIONNAIRE

- The IROC Houston QA Center in conjunction with the Advanced Technology Consortium (ATC) developed an electronic facility questionnaire to gather site information for participation in the Gynecologic Cancer InterGroup (GCIG) Cervix Cancer Research Network (CCRN) clinical trials.
- Current information regarding the status of staff, contact information, equipment, and QA procedures.

Responses reviewed/queried/commented/approved by CCRN QA

Site Review Visit

- Site visitors (at least 1 independent of the referring trial group) will perform QA checks as per CCRN QA Checklist.
  - Includes:
    - Infrastructure – clinical trials operations, ethics, regulatory, staffing, record-keeping
    - Radiation Therapy SOPs, equipment and facility
    - Physics
    - Pharmacy

Activation

- Site visitor(s) will provide written report to CCRN Chair of findings and recommendations.
- CCRN Chair will notify site of approval (or not); contingencies.
- Referring lead group study chair will be notified of CCRN QA approval (or not).

- Lead group will initiate study specific local activation requirements.
- Additional trial-specific QA requirements are the responsibility of the lead group.

- **OVERSIGHT**: independent CCRN QA committee should receive reports from trial-specific IDMC.

THANK YOU

questions???