Gynecologic Cancer InterGroup
Cervix Cancer Research Network

GCIG CCRN Education Symposium

Good Clinical Practice

GCP

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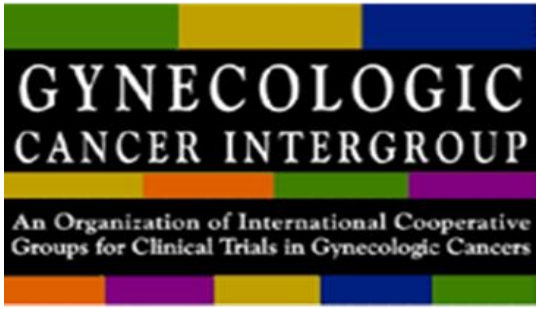
GCIG

Cervix Cancer Education Symposium, January 2016, Bangkok, Thailand



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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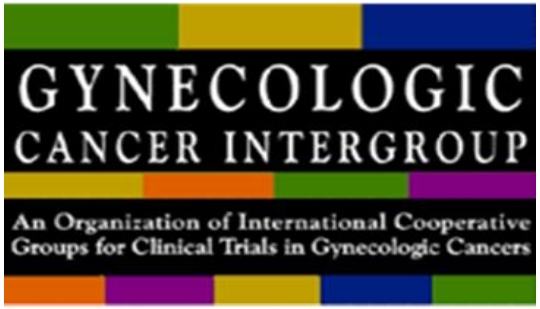

ICH GCP

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

Composition of Ethics Committees

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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.

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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.

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

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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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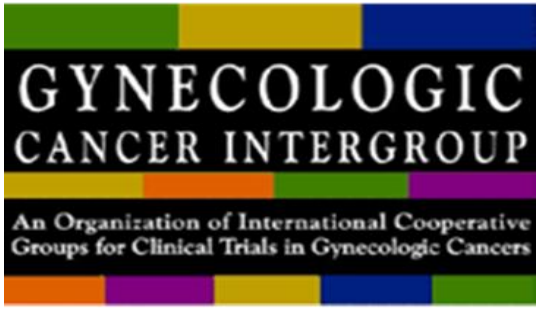

OVERSIGHT:

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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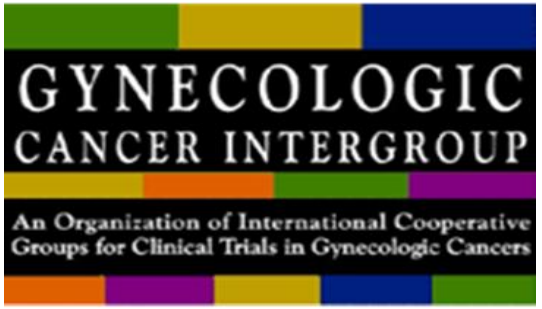

The standard for clinical research conduct has evolved and it is viewed as necessary to provide public assurance of trial participant protection and public and policymaker assurance that credible and reliable evidence exists for making informed decisions about medical practice and public health.

(Woltz & Moore, 2015)

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THANK YOU

questions???