Introduction to Good Clinical Practice (GCP) for non-drug studies

25th January 2011
Mackenzie Building
University of Dundee

COURSE CONTENT:
Development and Principles of GCP; Ethics of Clinical Research; Roles, Responsibilities & Informed Consent; Research Governance and documentation, Data management
Website www.tasc-research.org.uk

- Principal information source for TASC
  - Web pages for all TASC functions
  - Research clinics
  - Training programmes - **GCP Online**
  - SOPs
- Evolving
  - Suggestions for content welcome
For our Researchers

From improving access to research & development information, to increasing access to specialised research advice, a key aim of TASC is to enhance the research support for both institutions therefore making it easier for all health professionals to participate in research within Tayside.
SOP42 APPLYING FOR EXTERNAL PERMISSIONS AND APPROVAL

Safety & Pharmacovigilance

SOP11 IDENTIFYING, RECORDING AND REPORTING ADVERSE EVENTS FOR CLINICAL TRIALS OF INVESTIGATIONAL MEDICINAL PRODUCTS
SOP15 PREPARING AND SUBMITTING PROGRESS AND SAFETY REPORTS
SOP37 ACCOUNTABILITY, RETURNS AND DESTRUCTION OF INVESTIGATIONAL MEDICINAL PRODUCTS IN CLINICAL TRIALS OF INVESTIGATIONAL MEDICINAL PRODUCTS
SOP38 MANUFACTURING, ASSEMBLY, PACKAGING AND LABELLING OF IMPs IN CLINICAL TRIALS OF INVESTIGATIONAL MEDICINAL PRODUCTS
SOP39 SUPPLY, TRANSPORT AND STORAGE OF IMP IN CLINICAL TRIALS OF INVESTIGATIONAL MEDICINAL PRODUCTS
SOP43 DRUG PRODUCT RECALL

Trial Management

SOP02 ESTABLISHING AND MAINTAINING A TRIAL MASTER FILE (TMF) FOR THE CONTROL OF CLINICAL TRIALS OF INVESTIGATIONAL MEDICINAL PRODUCTS
SOP06 ESTABLISHING AND MAINTAINING AN INVESTIGATOR SITE FILE (ISF) FOR CLINICAL TRIALS OF INVESTIGATIONAL MEDICINAL PRODUCTS
SOP07 OBTAINING INFORMED CONSENT FROM COMPETENT ADULTS IN CLINICAL TRIALS OF INVESTIGATIONAL MEDICINAL PRODUCTS
SOP10 FOR ESTABLISHING AND MAINTAINING A TRAINING RECORD
SOP12 IDENTIFICATION OF PARTICIPANTS IN CLINICAL TRIALS OF INVESTIGATIONAL MEDICINAL PRODUCTS
SOP13 ARCHIVING CLINICAL RESEARCH DATA FOR CLINICAL TRIALS OF INVESTIGATIONAL MEDICINAL PRODUCTS
SOP14 WRITING A PROTOCOL TO GOOD CLINICAL PRACTICE FOR CLINICAL TRIALS OF INVESTIGATIONAL MEDICINAL PRODUCTS
SOP16 CLOSURE OF CLINICAL TRIALS OF INVESTIGATIONAL MEDICINAL PRODUCTS
SOP18 STUDY START UP IN CLINICAL TRIALS OF INVESTIGATIONAL MEDICINAL PRODUCTS
SOP19 PREPARING AND MAINTAINING CASE REPORT FORMS (CRFs) FOR USE IN CLINICAL TRIALS OF INVESTIGATIONAL MEDICINAL PRODUCTS
SOP23 COMPLETION OF DELEGATION LOGS
TASC Research Training Programme

• Training events advertised on website
  - GCP training
  - GLP training
  - TASC seminars eg Caldicott, Approvals
  - Research clinics
  - SOP training
Facilitators

• Mark Ferguson
  Training Manager, TASC

• Caroline Ackland
  Scientific Officer, East of Scotland Research Ethics Service

• Steve McSwiggan
  Senior Trials Manager, Tayside Clinical Trials Unit

• Clark Crawford
  Research Governance Manager, TASC

• Shaun Treweek
  Assistant Director, Tayside Clinical Trials Unit
Introduction to Good Clinical Practice (GCP) for non Drug studies

Tuesday 25\textsuperscript{th} January 2011

CTA, Mackenzie Building

1.30pm to 4pm

\textbf{Agenda}

1.30pm to 2pm
- Development & Principles of GCP
  Mark Ferguson

2.00pm to 2.30pm
- Ethics of clinical research
  Caroline Ackland

2.30pm to 3.00pm
- Roles, Responsibilities and Informed Consent
  Steve McSwiggan

3.00pm to 3.30pm
- Research Governance & Documentation
  Clark Crawford

3.30 to 4.00pm
- Data management
  Steve Tassie
• Good Clinical Practice (GCP)
  – International ethical and scientific quality standard
  – For designing, conducting, recording and reporting trials
  – Involving the participation of human subjects.

• EVERYONE involved has a duty to GCP
  – Regulatory authorities, sponsor, ethics, investigator, trial managers, research nurse, pharmacist, project monitors, patients....
Tuskegee Syphilis Study (1932-1972)

"The men’s status did not warrant ethical debate. They were subjects, not patients; clinical material, not sick people" (John Heller director of the Venereal Diseases unit of the PHS from 1943 to 1948)

Lessons learned
ICH-GCP

- International Conference on Harmonisation (ICH) / WHO Good Clinical Practice standards.
  - Produced in May 1996
  - Accepted by EU, Japan, USA since 1997
    - EU, Japan, United States, Australia, Canada, Nordic countries and World Health Organisation (WHO)
    - Detailed guidelines

- The principles of good clinical practice are referred to in European Law
  - GCP Directive 2005
  - Clinical Trials Directive 2001
Legislation & Regulation

1947  Nuremberg Code
1964  Declaration of Helsinki (last updated 2008)
1965  First Research Ethics Committee convened
1997  International Conference on Harmonisation/Good Clinical Practice Guideline
1998  Data Protection Act
2000  Adults with Incapacity (Scotland) Act
2004  Medicines for Human Use (Clinical Trials) Regulations 2004
2006  Human Tissue (Scotland) Act
2006  The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006
2006  The Medicines for Human Use (Clinical Trials) Amendment (No.2) Reg’s 2006

- Required by the Scottish Government
- Governed by Legislation and Regulation
- Encompasses established international standards of Good Clinical Practice ICH/GCP

The RGF covers.

- Research
- Research involving humans etc
- Clinical research
- CTIMP's
Research Governance Framework (RGF)

(UK NHS Standard - not law but must be adhered to for all studies conducted within the NHS)

‘There are powerful incentives to adhere to the principles, requirements and standards of good practice set out in the framework. These include the law, the duty of care in the NHS and social care, and the high professional and ethical standards that most care professionals and researchers uphold.’
GCP Principle 1

Studies should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with GCP and the applicable regulatory requirement(s)
• Study of new surgical intervention for haemorrhoids
• 60 patients to be recruited
• General rather than local anaesthetic
• Extra 2 days in hospital
• One year follow-up

Before a study is started, foreseeable risks and inconveniences should be weighed against the anticipated benefit for the individual study subject and society. A study should be initiated and continued only if the anticipated benefits justify the risks
GCP Principle 3

The rights, safety, and well-being of the study subjects are the most important considerations and should prevail over interests of science and society.
GCP Principle 4

Non-clinical/clinical data for Investigational medicinal Product (IMP) is adequate to support the clinical trial
GCP Principle 5

Studies should be scientifically sound, and described in a clear, detailed protocol.

Peanuts comic strip:

I think I've discovered something.

When you wake up at night, and your head hurts and your stomach feels funny...

The first thing you do is put on your bathrobe.

Then you drink a glass of water and take some pills. And you sit by yourself in the dark for awhile until you're ready to go back to bed...

But it's not the pills that made you feel better...

It's the bathrobe!
A study is conducted in compliance with the protocol that has been approved by a research ethics committee.
**GCP Principle 7**

The medical care given to, and medical decisions made on behalf of, subjects should always be the responsibility of a qualified physician or, when appropriate, of a qualified dentist.

However in non-drug studies this can equally be a physiotherapist, specialist nurse etc.
Each individual involved in trial (study) conduct is qualified by training, education and experience to perform their tasks.
GCP Principle 9

Freely given informed consent obtained from every subject prior to study participation
GCP Principle 10

Study information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.
GCP Principle 11

The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).
GCP Principle 12

IMP’s – manufactured, handled, stored, in accordance with GMP and used in accordance with approved protocol
GCP Principle 13

Systems with procedures that assure the quality of every aspect of the study should be implemented.
Regulation and Review

• Sponsor Approval
• UK-wide review
  – Medicines and Healthcare Regulatory Agency (for drug and device studies)
• Ethics
  – Research Ethics Committee
• Local Responsibility
  – NHS approval
Summary

- Ethical Principles
  - Declaration of Helsinki
- Detailed Guidance

- Studies must have all necessary approvals in place before it begins and must be conducted in accordance with
  - GCP
  - RGF
  - Protocol

- Above all else, patient safety is paramount!