

# GCP: Discussion

Ricardo Palacios, MD, PhD  
September 2008

**GCP:  
Discussion**

**Disclaimer**

Nonclinical/  
clinical studies

GCP

Non-pharma  
studies

# Declaration of conflict of interests

The speaker have received funds from:

- WHO/TDR (monitoring & auditing)
- WHO/IVR (monitoring)
- NIH/NIAID (research staff)
- Colciencias – Colombia (reviewer)
- Pharma industry (research staff, advisor)
- FormaliS (auditor for pharma studies)

# Investigator – Sponsoring agency relationship in nonclinical studies

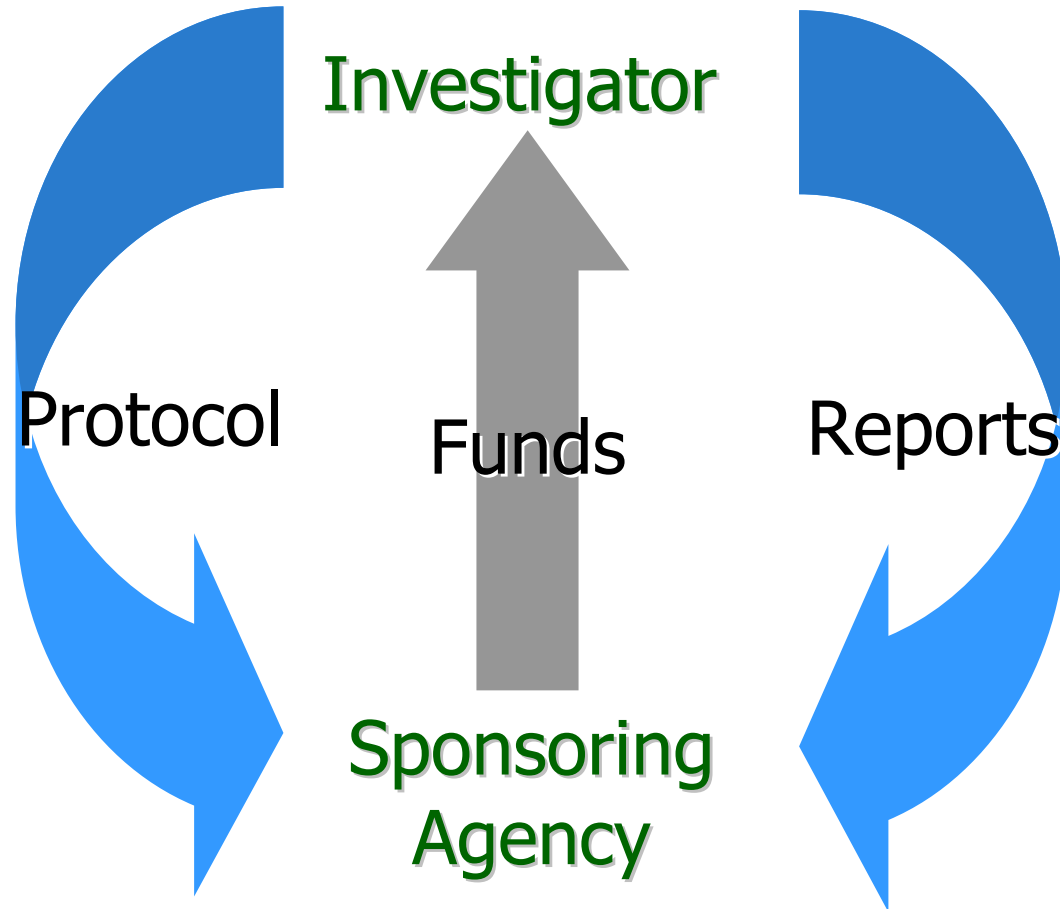
**GCP:  
Discussion**

Disclaimer

**Nonclinical/  
clinical studies**

GCP

Non-pharma  
studies



# Investigator – Sponsor (pharma) relationship in GCP Clinical Studies

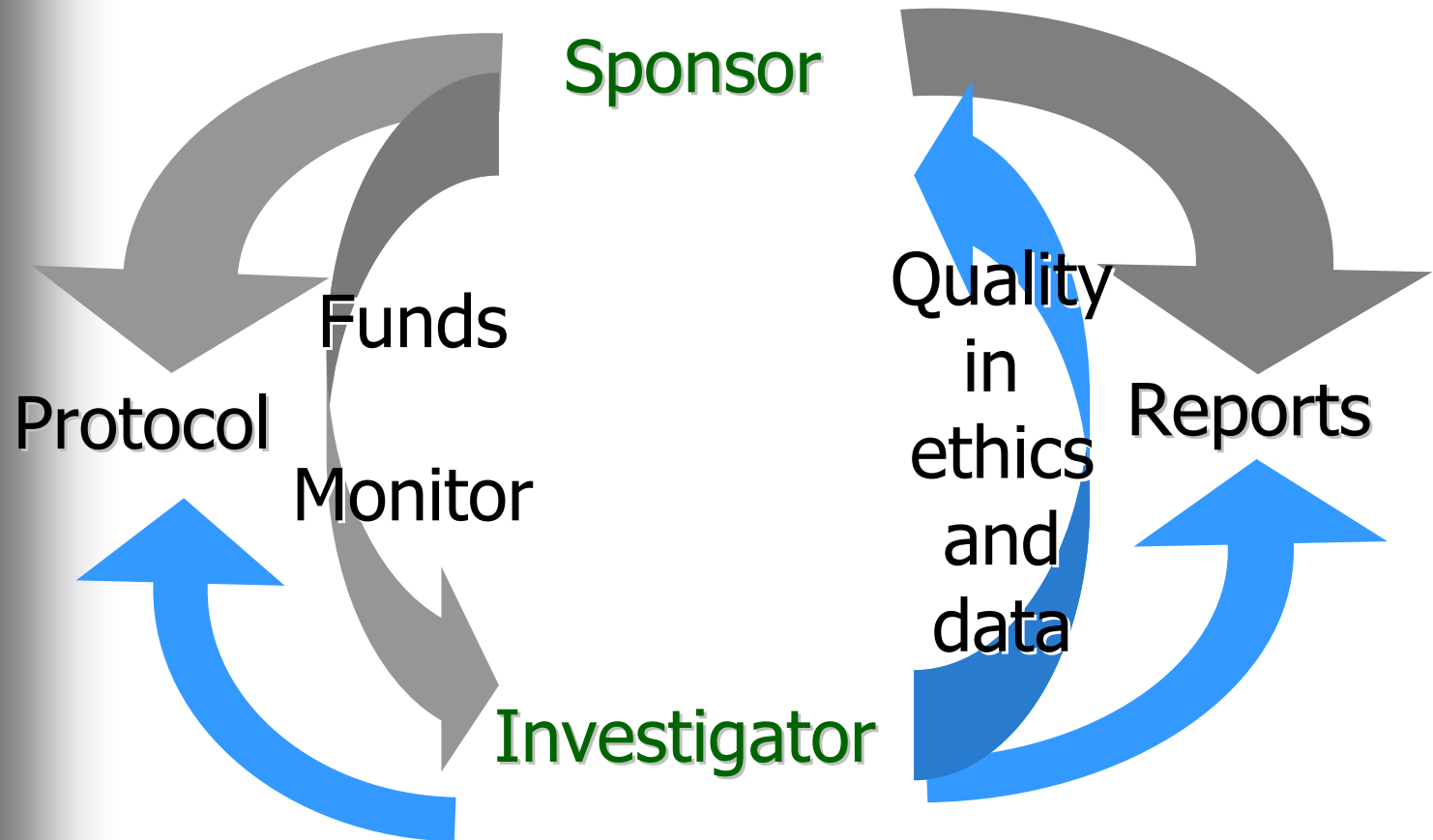
**GCP:  
Discussion**

Disclaimer

**Nonclinical/  
clinical studies**

GCP

Non-pharma  
studies



## GCP: Discussion

Disclaimer

Nonclinical/  
clinical studies

**GCP**

Non-pharma  
studies

# ICH E6 GCP - Introduction

- This guideline should be followed when generating clinical trial data that are intended to be submitted to regulatory authorities.
- The principles established in this guideline may also be applied to other clinical investigations that may have an impact on the safety and well-being of human subjects.

## GCP: Discussion

Disclaimer

Nonclinical/  
clinical studies

**GCP**

Non-pharma  
studies

# ICH E6 GCP - Introduction

- This guideline should be followed when generating clinical trial data that are intended to be submitted to regulatory authorities.
- The principles established in this guideline may also be applied to other clinical investigations that may have an impact on the safety and well-being of human subjects.

# Studies in human subjects (non-exhaustive list)

*Pharma industry*

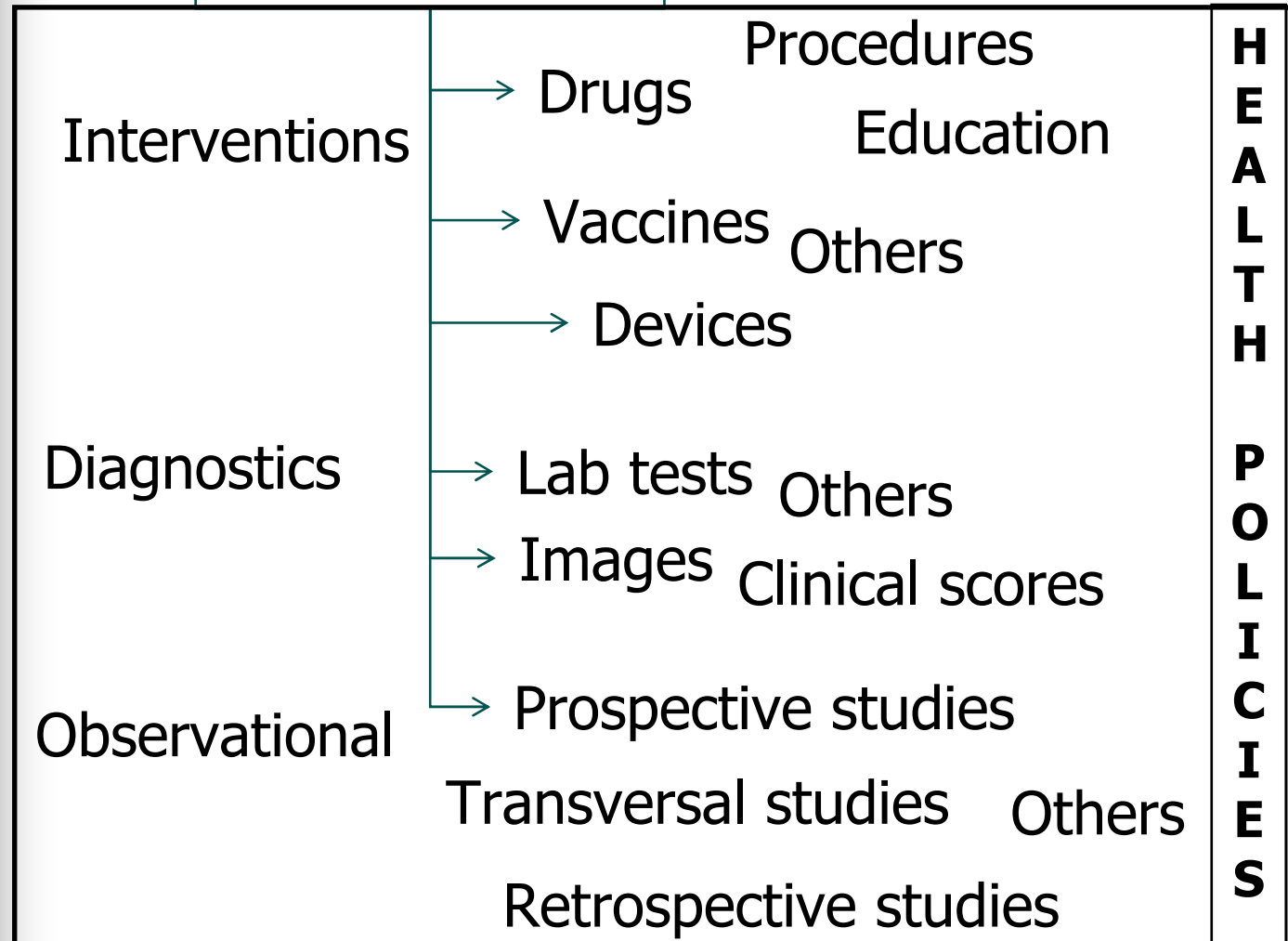
**GCP:  
Discussion**

Disclaimer

Nonclinical/  
clinical studies

GCP

**Non-pharma  
studies**



## **GCP: Discussion**

Disclaimer

Nonclinical/  
clinical studies

GCP

**Non-pharma  
studies**

# Contents of the Guideline for Good Clinical Practice

- Glossary & Principles
- Set of responsibilities
  - Ethics Committee / IRB
  - Investigator
  - Sponsor
- Guidance to write Protocol and Investigator's Brochure, and to file.

## **GCP: Discussion**

Disclaimer

Nonclinical/  
clinical studies

GCP

**Non-pharma  
studies**

# Contents of the Guideline for Good Clinical Practice

- Glossary & Principles
- Set of responsibilities
  - Ethics Committee / IRB
  - Investigator
  - Sponsor
- Guidance to write Protocol and Investigator's Brochure, and to file.

## **GCP: Discussion**

Disclaimer

Nonclinical/  
clinical studies

GCP

**Non-pharma  
studies**

# Who should take the sponsor responsibilities in non-pharma clinical studies?

- The sponsoring agency and should create a structure to deal with this
- The sponsoring agency, but can hire a CRO to deal with this

# Investigator – Sponsor (non-pharma) relationship in GCP Clinical Studies

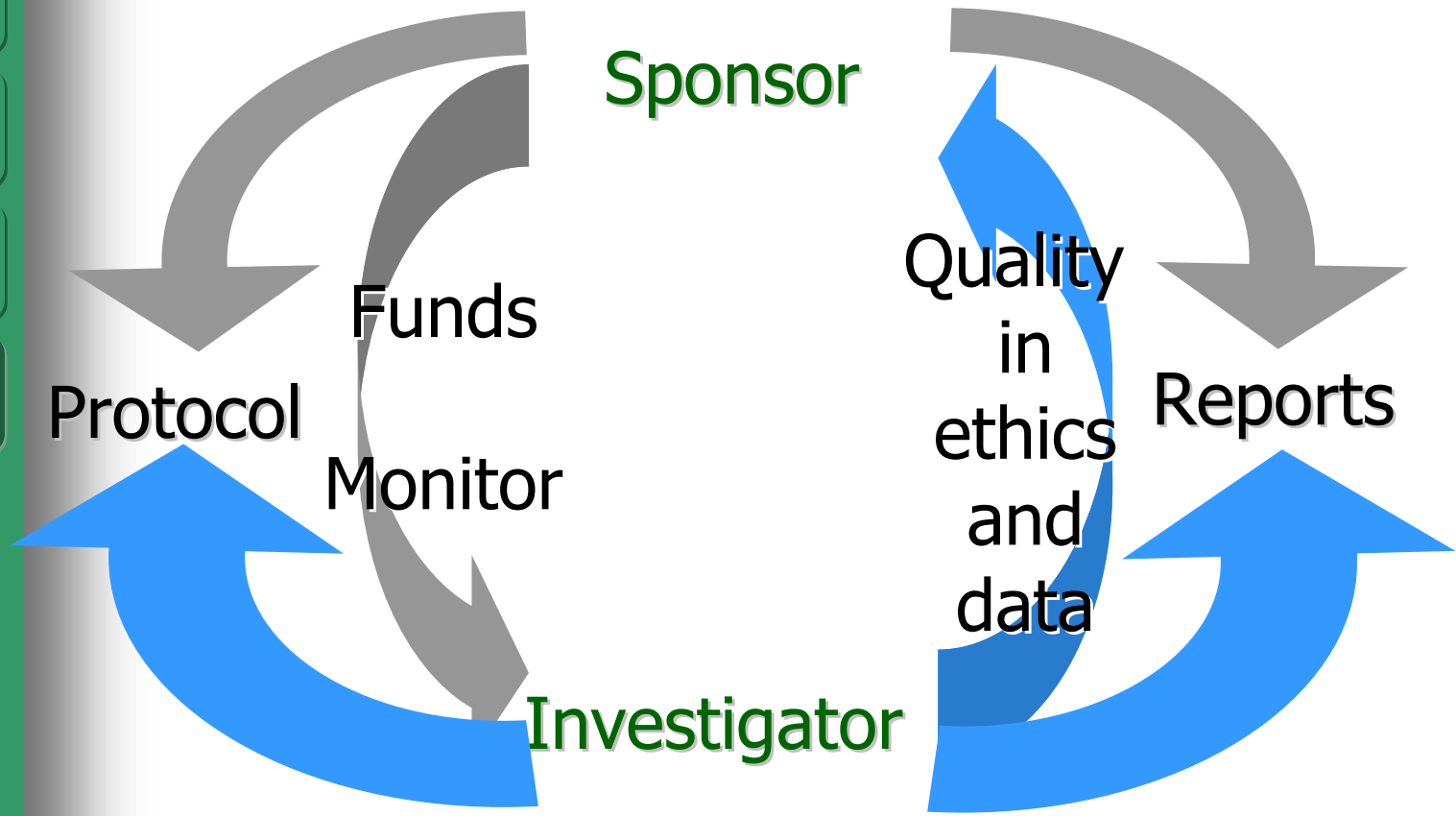
**GCP:  
Discussion**

Disclaimer

Nonclinical/  
clinical studies

GCP

**Non-pharma  
studies**



## GCP: Discussion

Disclaimer

Nonclinical/  
clinical studies

GCP

**Non-pharma  
studies**

# Who should take the sponsor responsibilities in non-pharma clinical studies?

- The sponsoring agency and should create a structure to deal with this
- The sponsoring agency, but can hire a CRO to deal with this
- The investigator should deal with this as described in the proposal
- This issue is only relevant if the peer reviewers of the proposal raise it
- Nobody knows...

**GCP:  
Discussion**

Disclaimer

Nonclinical/  
clinical studies

GCP

**Non-pharma  
studies**

# GCP: a bronze standard for clinical research

Lancet 2005; 366: 172–74

- Development process: name, consensus and updating
- Contributors: anonymous, researchers and consumers excluded
- Allocation concealment: no procedures to reduce bias
- Documentation: 50 “essentials” documents, complexity
- Accessibility: Not in PubMed
- Audience: Guidance for industry

## GCP: Discussion

Disclaimer

Nonclinical/  
clinical studies

GCP

**Non-pharma  
studies**

# ... But what is GCP about?

## ICH E6 GCP - Introduction

- Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.

## GCP: Discussion

Disclaimer

Nonclinical/  
clinical studies

GCP

**Non-pharma  
studies**

# ... But what is GCP about?

## ICH E6 GCP - Introduction

- Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.

# Does GCP principles fit into any study in human subjects?

**GCP:  
Discussion**

Disclaimer

Nonclinical/  
clinical studies

GCP

**Non-pharma  
studies**

Interventions

Drugs      Procedures  
                 Education  
Vaccines    Others  
                 Devices

Diagnostics

Lab tests    Others  
Images      Clinical scores

Observational

Prospective studies  
Transversal studies    Others  
Retrospective studies