Indemnity

for Sponsored Clinical Trials

2012 HA Practical Workshop on Clinical Research Compliance

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Indemnity for Sponsored Clinical Trials

Highlights:

- Risk management in clinical trials
- Concepts of indemnity
- Key elements of indemnity agreements
- The controversy about indemnity

Risk-benefit Ratio in Clinical Practices



Risk-benefit Ratio in Clinical Trials



Risk Management Measures for Clinical Trials

Research Ethics Committee (REC)

Regulatory Agency

Data and Safety Monitoring Committee

Monitoring, Auditing, Inspection

Standard Operating Procedures (SOPs)

Training for Investigators and Research Personnel

Indemnity and Insurance

Definition of Indemnity

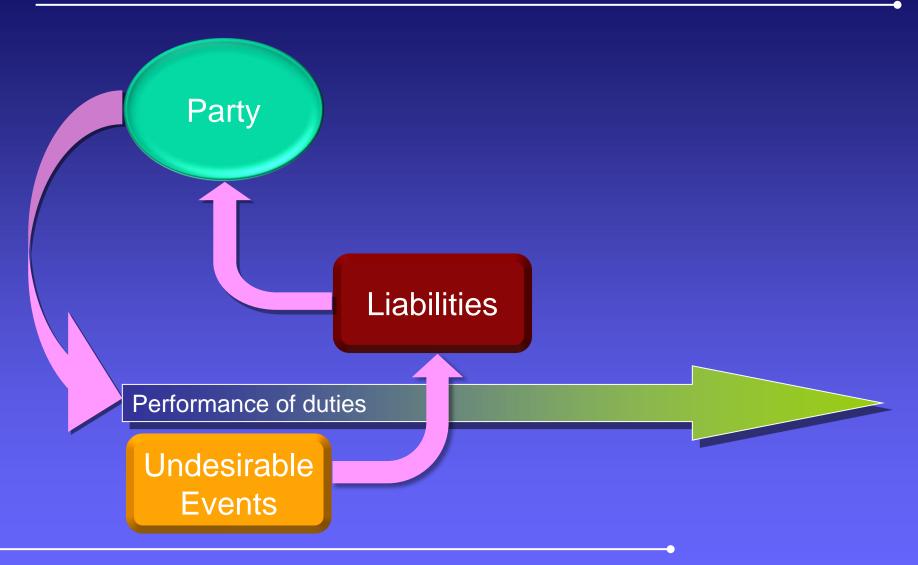
What is an indemnity?

 A promise by one party to another party to bear certain liabilities on occurrence of certain undesirable events

What is an indemnity?

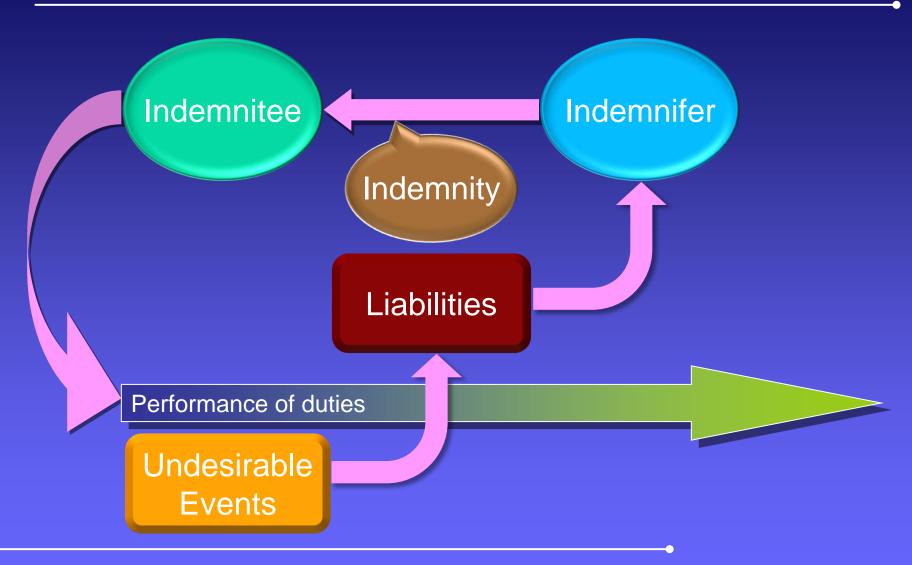
- A promise
- by one party to another party
- to bear certain liabilities
- on occurrence of certain undesirable events

Illustration of Indemnity



Concepts of Indemnity

Illustration of Indemnity



Concepts of Indemnity

Indemnity for Clinical Trials – Indemnifer and Indemnitee

Indemnitee

Indemnifer

Indemnity

- Research institution (e.g. HA, hospitals, universities)
- Investigators (e.g. principal investigator, co-investigators)
- Study coordinators (e.g. nurses, research assistants)
- Other research personnel (e.g. pharmacists, radiologists, laboratory technicians)

Sponsor (e.g. pharma companies, device companies, heathcare organizations)

ICH GCP

• **5.8.1:** "If required by the applicable regulatory requirement(s), the sponsor should provide insurance or should **indemnify** (legal and financial coverage) the investigator / the institution against claims arising from the trial, except for claims that arise from malpractice and/or negligence."

The Association of the British Pharmaceutical Industry (ABPI)



FORM OF INDEMNITY FOR CLINICAL STUDIES

England & Wales

To: [Name and address of sponsoring company] ("the Sponsor")

From: [Name and address of health authority/health board/NHS Trust] ("the

Authority")

Re: Clinical study No () with [name of product]

Version A	For clinical trials involving		
	only HA hospitals/clinics	only HA hospitals/clinics	
	Spon	nscr/HA((11/10/01)	
	INDEMNITY FOR CLINICAL TRIAL		
	A SECTION OF THE SECT	Effective from	
THIS INDEMNITY	Y is provided on_	11 Oct, 2001	
THIS INDEMINIT	is provided on		
By the Sponsor:			
Name of Company:			
Address:		(the "Sponsor")	
Fax No :			

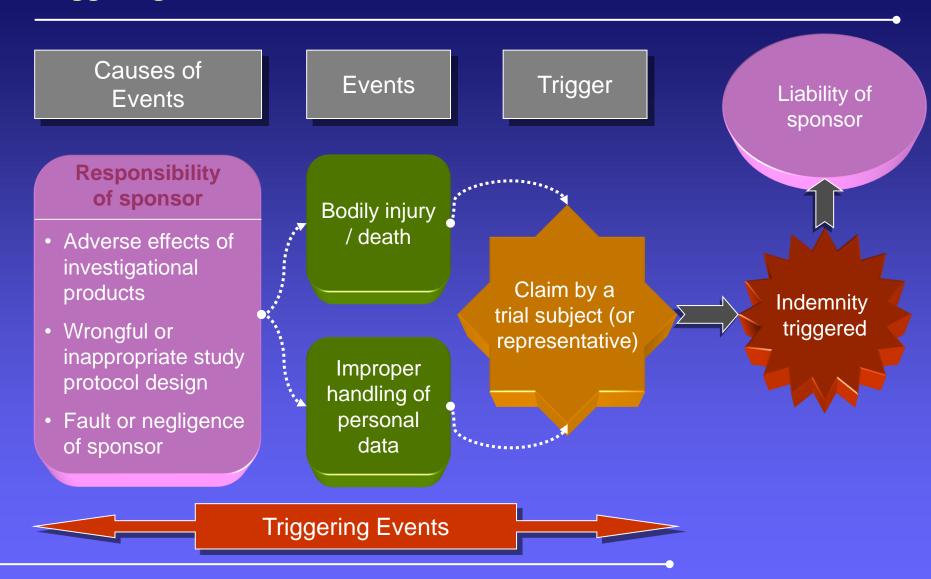
Version B For clinical trials involving HA hospitals/clinics and a university Sponsor/University/HA ()1/10/01) INDEMNITY FOR CLINICAL TRIAL THIS INDEMNITY is provided on By the Sponsor: Name of Company: Address: To the following Indemnitees:

Elements of Indemnity Agreement

3 Major Elements:

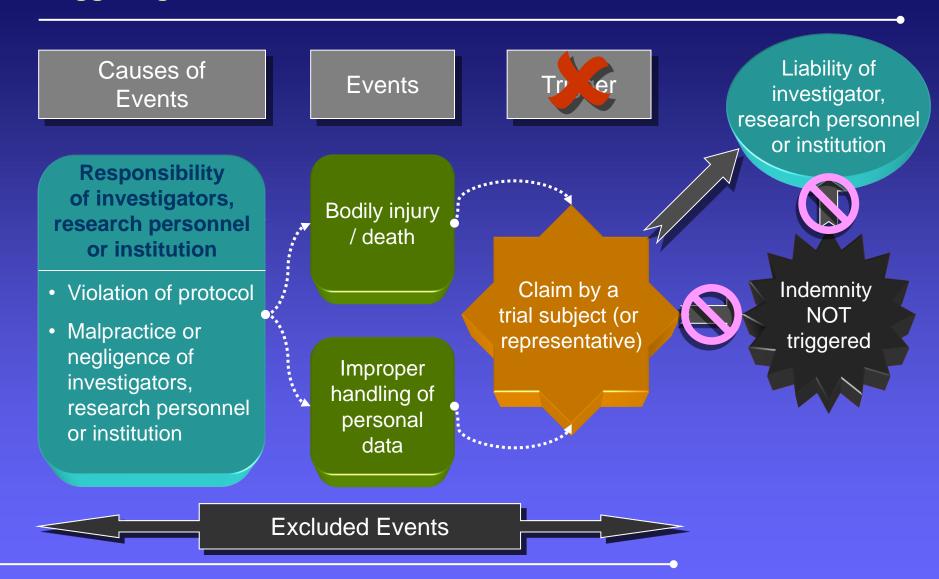
- Triggering events:
 In what circumstances will an indemnity become effective
- Excluded events:
 In what circumstances will an indemnity become <u>NOT</u> effective
- Liabilities covered:
 What kinds of liabilities will be covered

Triggering Events and Excluded Events



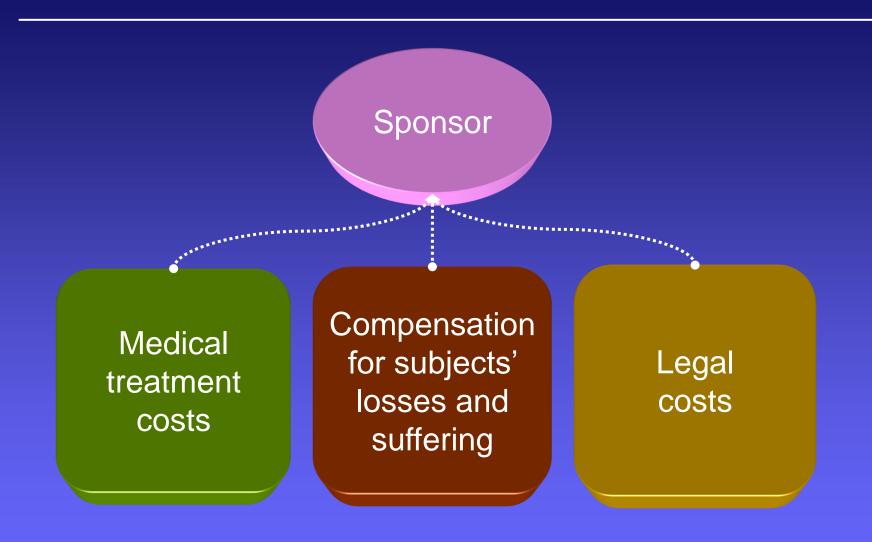
Indemnity for Clinical Trials

Triggering Events and Excluded Events



Indemnity for Clinical Trials

Liabilities Covered



The Controversy

Responsibility of sponsor

- Adverse effects of investigational products
- Wrongful or inappropriate study protocol design
- Fault or negligence of sponsor

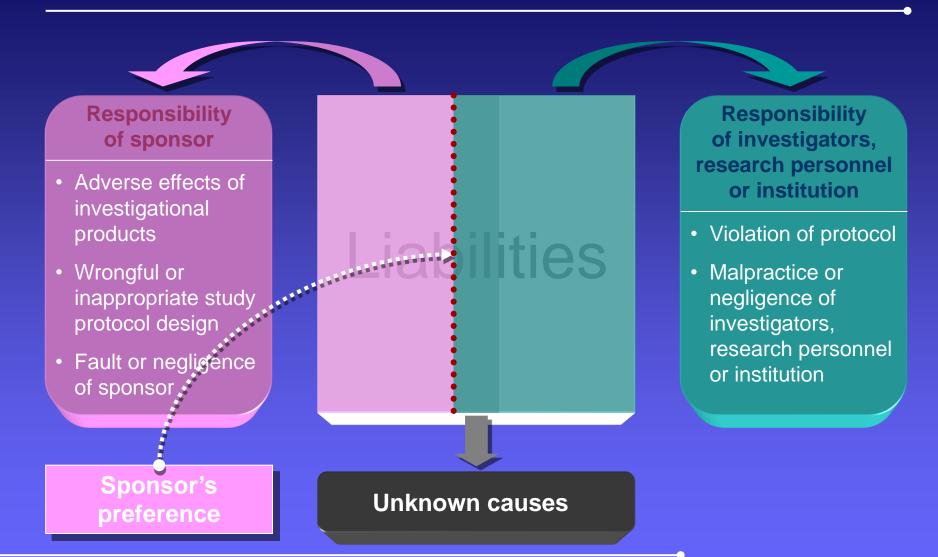
Liabilities

Responsibility of investigators, research personnel or institution

- Violation of protocol
- Malpractice or negligence of investigators, research personnel or institution

Unknown causes

The Controversy



Indemnity for Clinical Trials

The Controversy

Responsibility of sponsor

- Adverse effects of investigational products
- Wrongful or inappropriate study protocol design
- Fault or negligence of sponsor

Responsibility of investigators, research personnel or institution Violation of protocol Malpractice or negliger.

•••investigators, research personnel or institution Study site's **Unknown causes** preference

Indemnity for Clinical Trials

Indemnity for Sponsored Clinical Trials

Highlights:

- Indemnity is one of the risk management measures for clinical trials
- Indemnity applies only to sponsored clinical trials
- Protocol violation, malpractice and negligence by investigators and study site personnel are not covered
- The HA standard indemnity agreement must be followed