Indemnity

for Sponsored Clinical Trials

2012 HA Practical Workshop on Clinical Research Compliance

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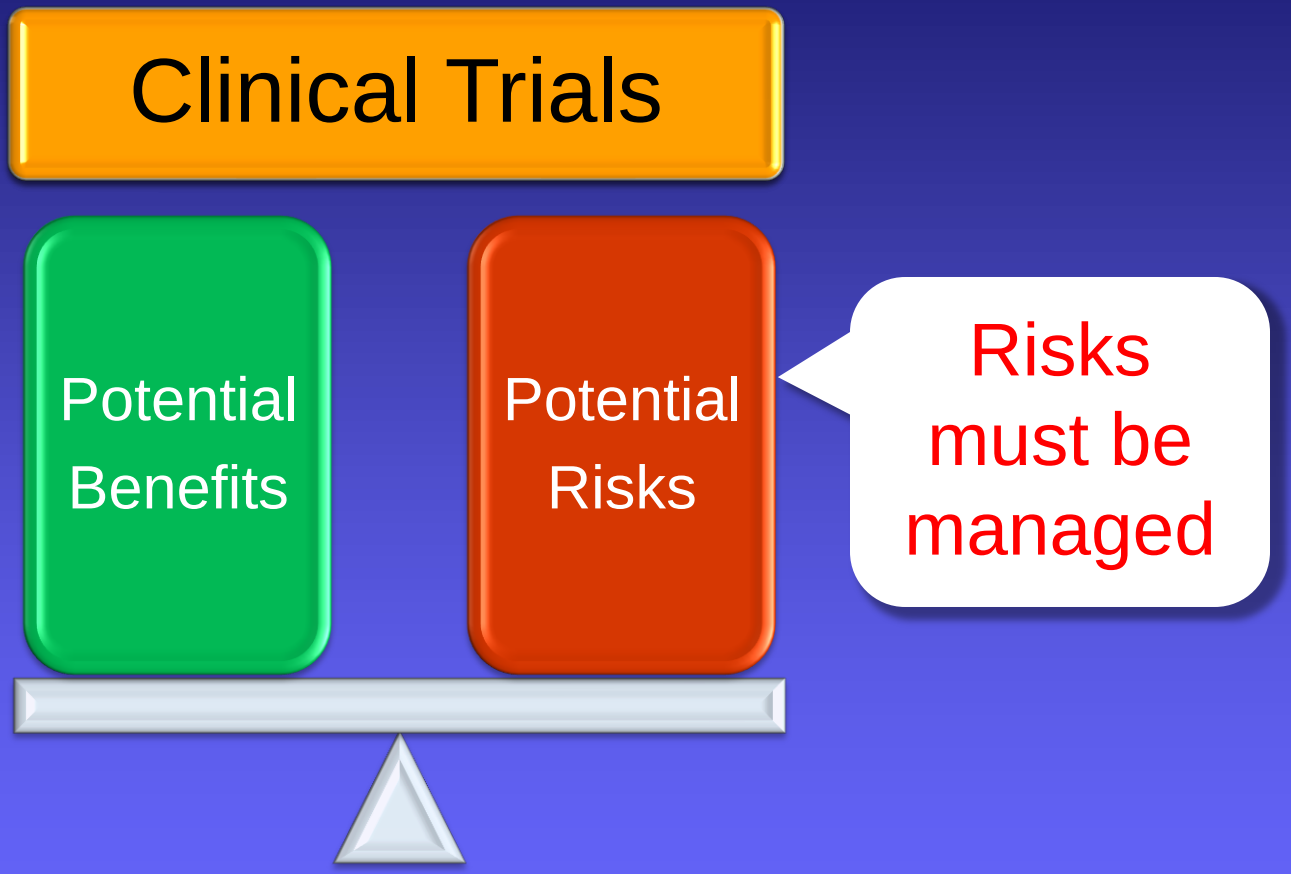
Indemnity for Sponsored Clinical Trials

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

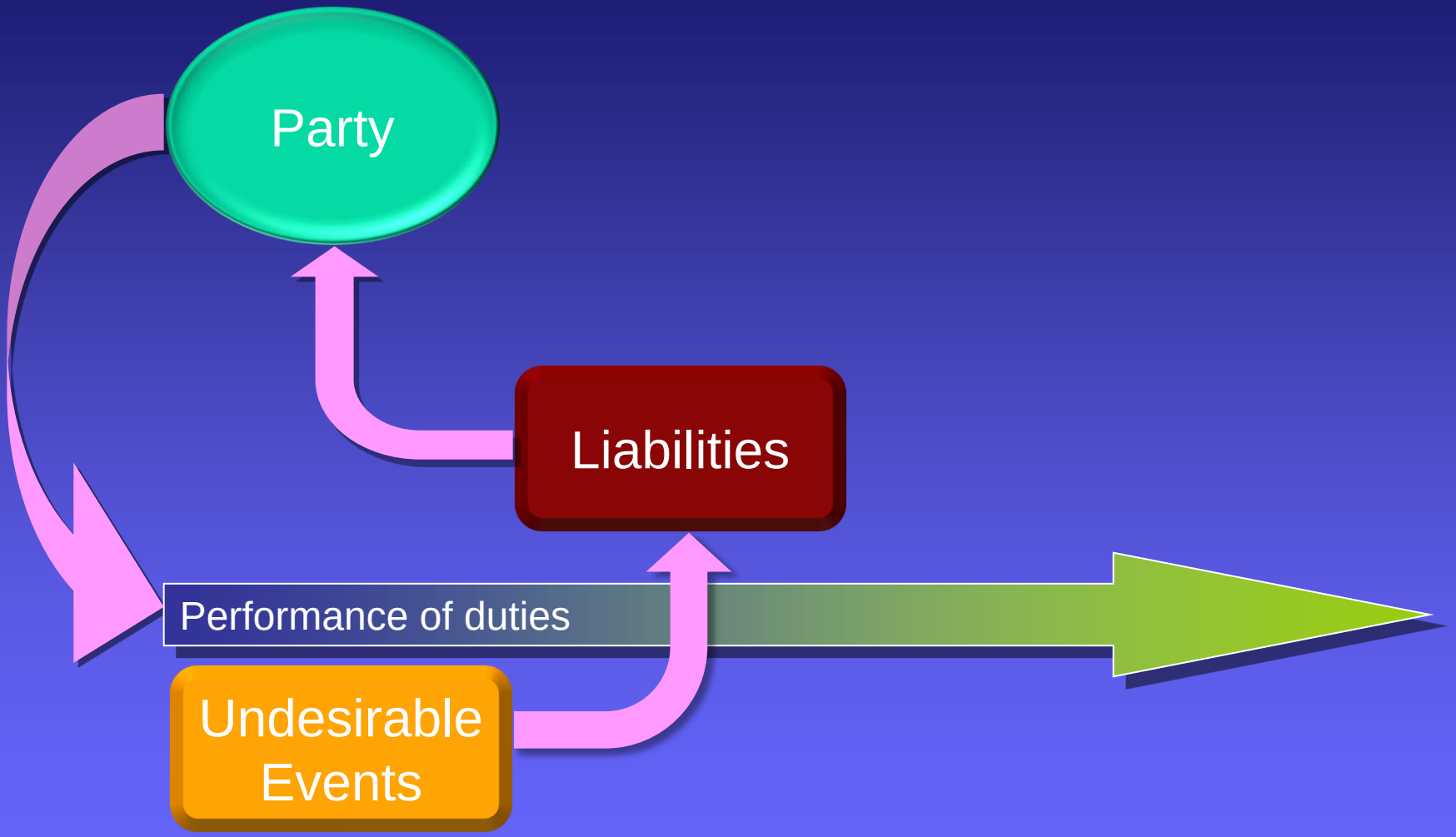
What is an indemnity ?

- 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



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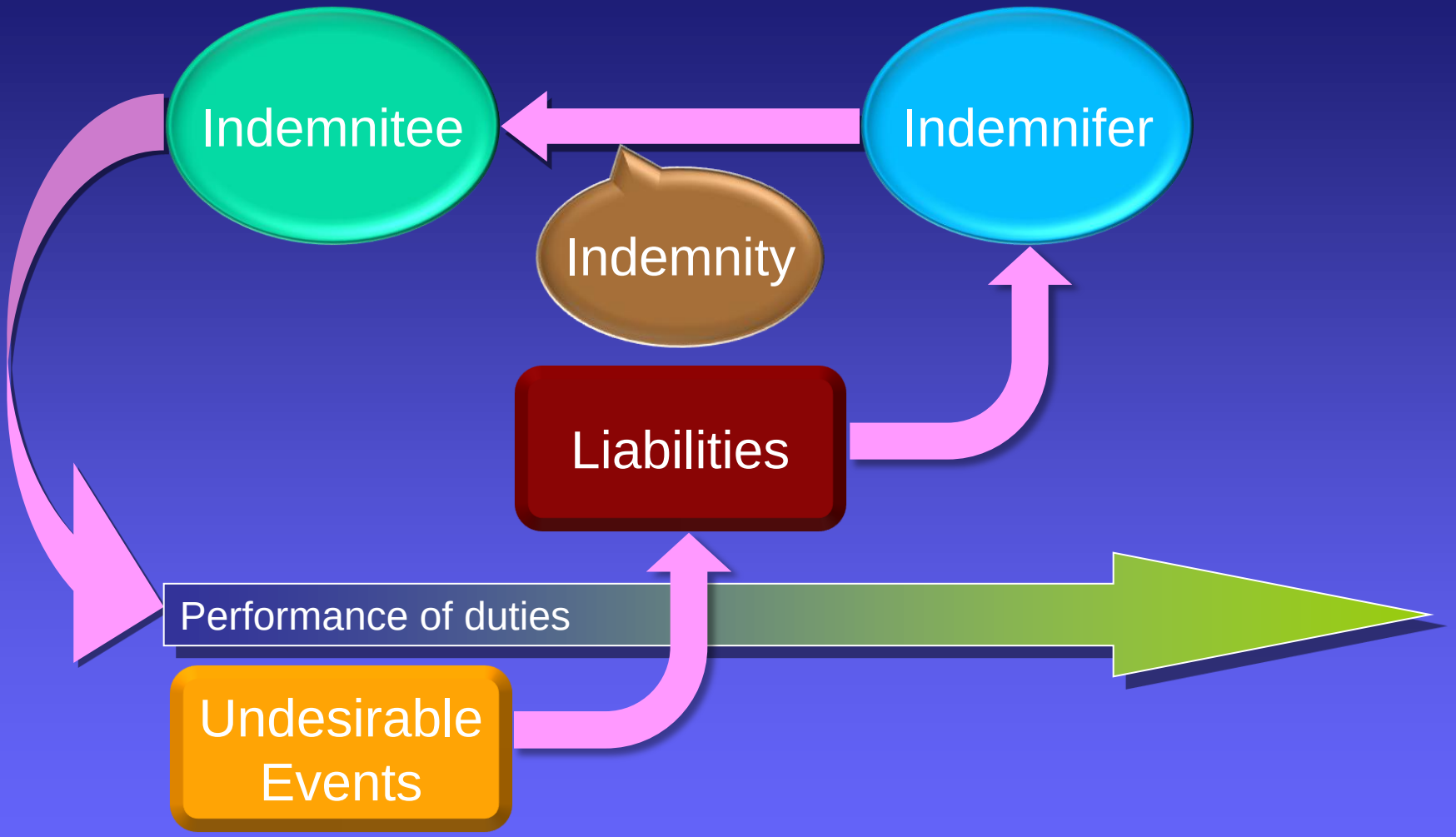
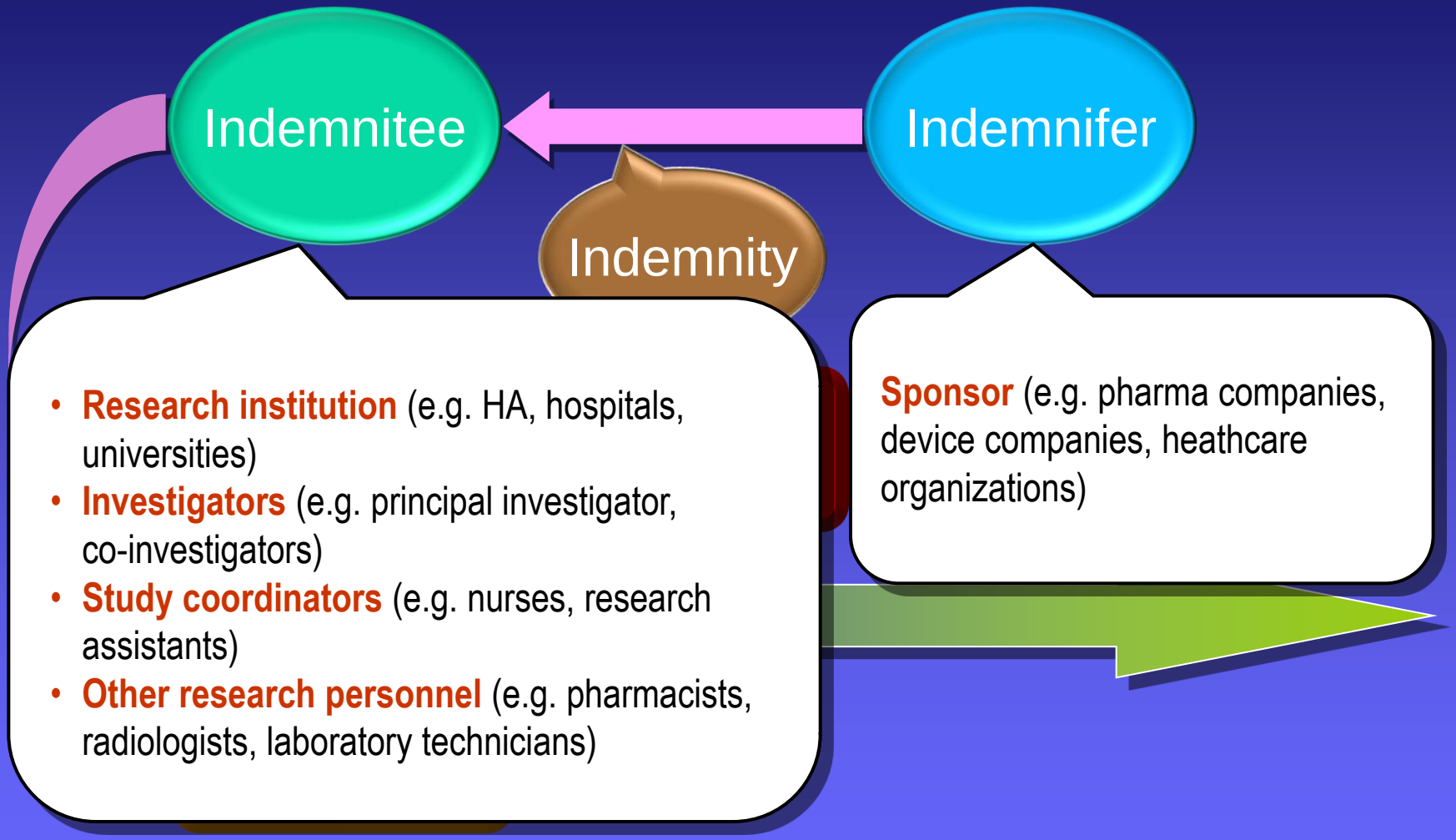


Indemnity for Clinical Trials – Indemnifer and Indemnitee



Indemnity Requirements for Clinical Trials

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]**

Indemnity Requirements for Clinical Trials

Hong Kong Hospital Authority (HA)

Version A

For clinical trials involving only HA hospitals/clinics

Sponsor/HA (11/10/01)

Effective from 11 Oct, 2001

INDEMNITY FOR CLINICAL TRIAL

THIS INDEMNITY is provided on _____

By the Sponsor:

Name of Company: _____

Address: _____ (the "Sponsor")

Fax No.: _____

To the following Indemnitees:

Indemnity Requirements for Clinical Trials

Hong Kong Hospital Authority (HA)

Version B

For clinical trials involving HA hospitals/clinics and a university

Sponsor/University/HA (11/10/01)

INDEMNITY FOR CLINICAL TRIAL

THIS INDEMNITY is provided on _____

By the Sponsor:

Name of Company: _____

Address: _____ (the "Sponsor")

Fax No.: _____

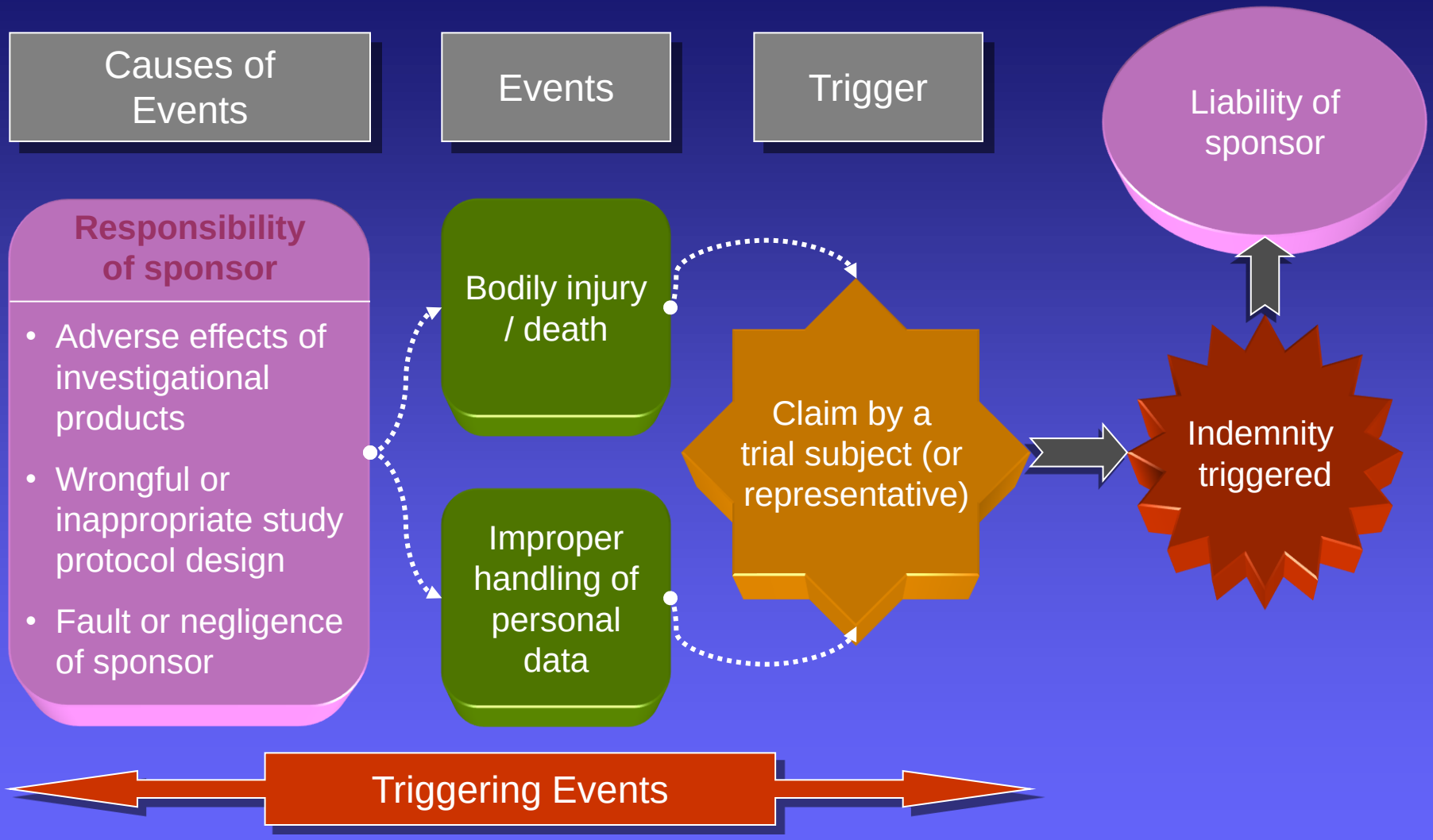
To the following Indemnitees:

Elements of Indemnity Agreement

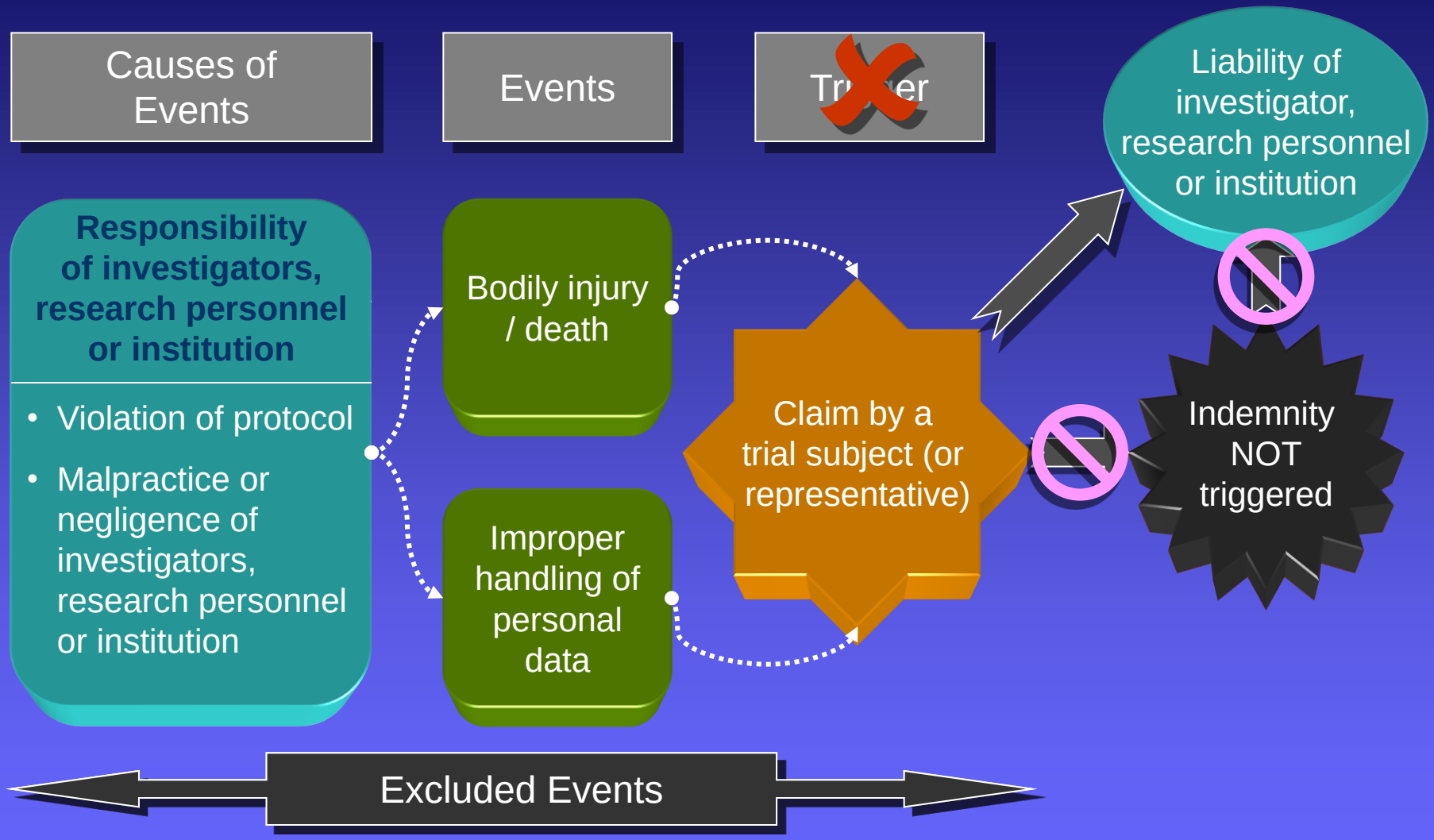
3 Major Elements:

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

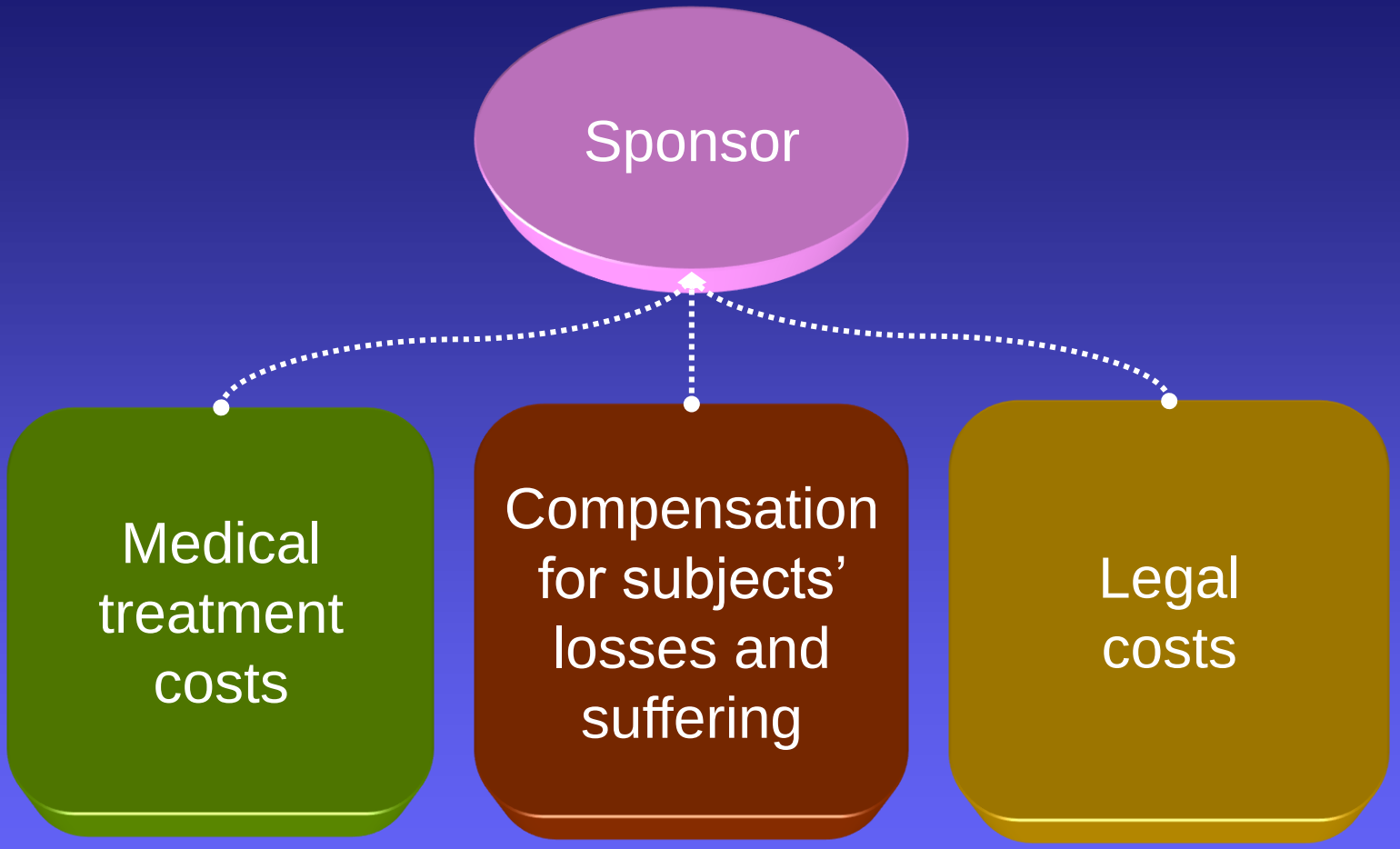
Triggering Events and Excluded Events



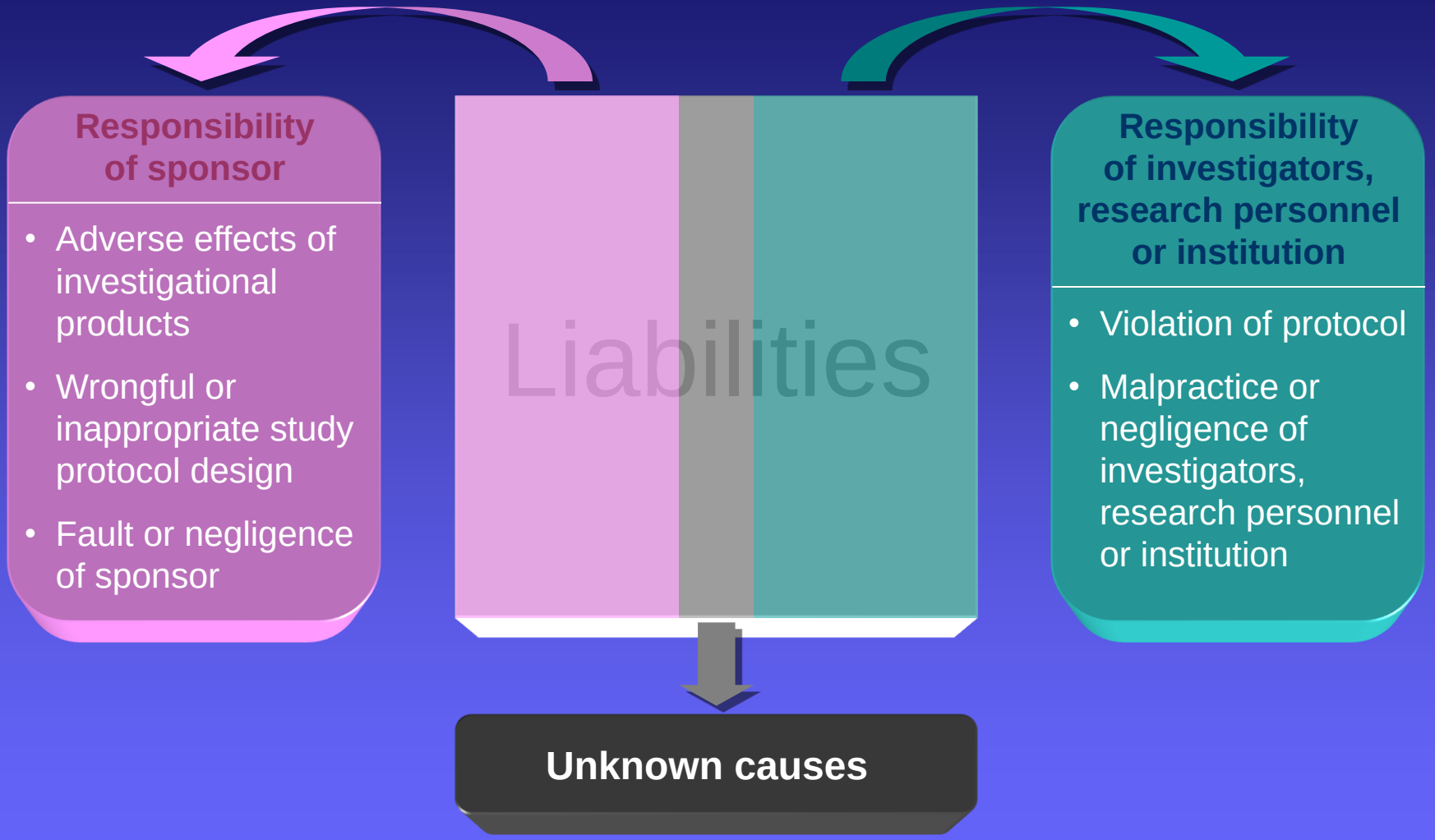
Triggering Events and Excluded Events



Liabilities Covered



The Controversy



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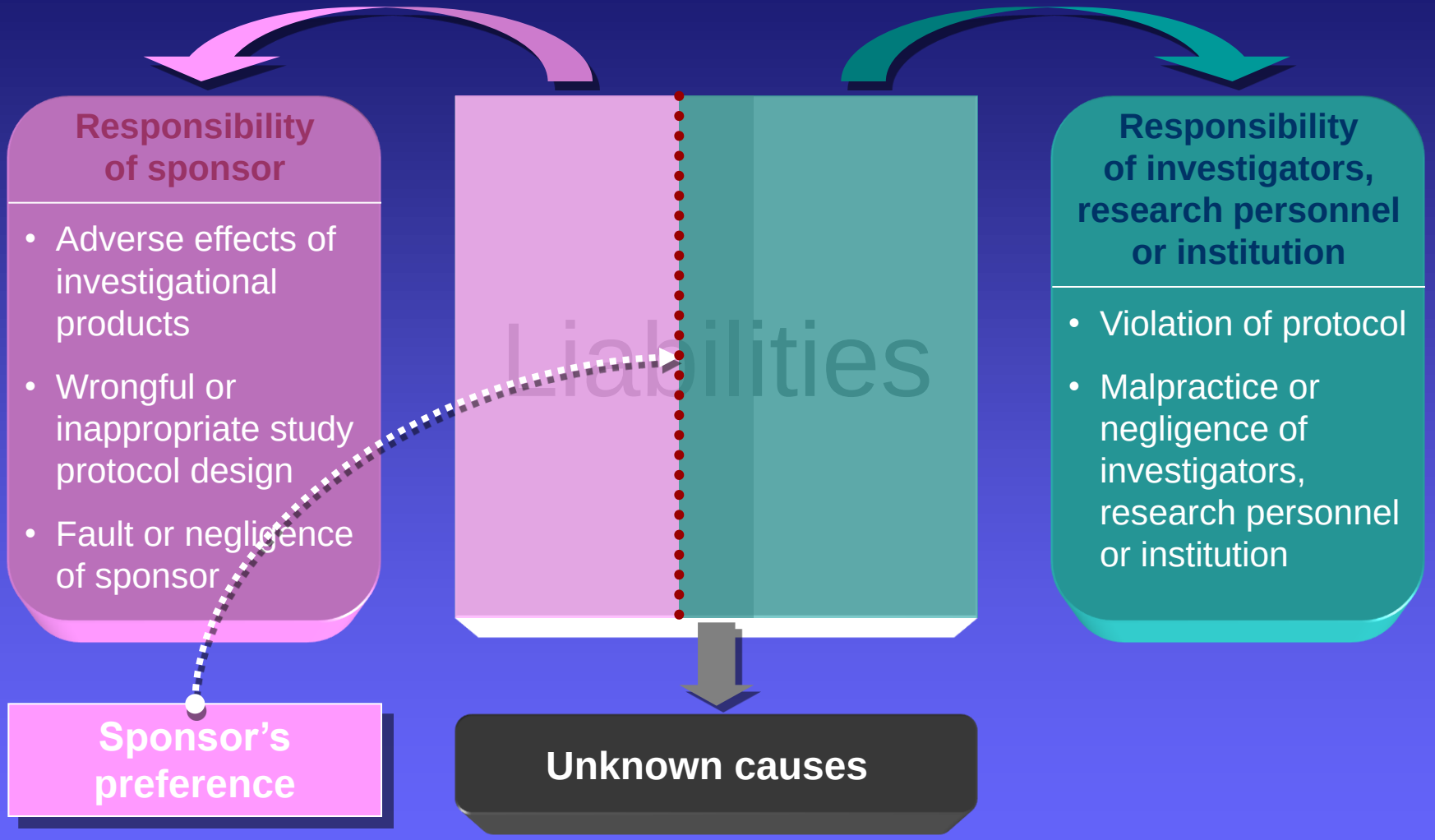

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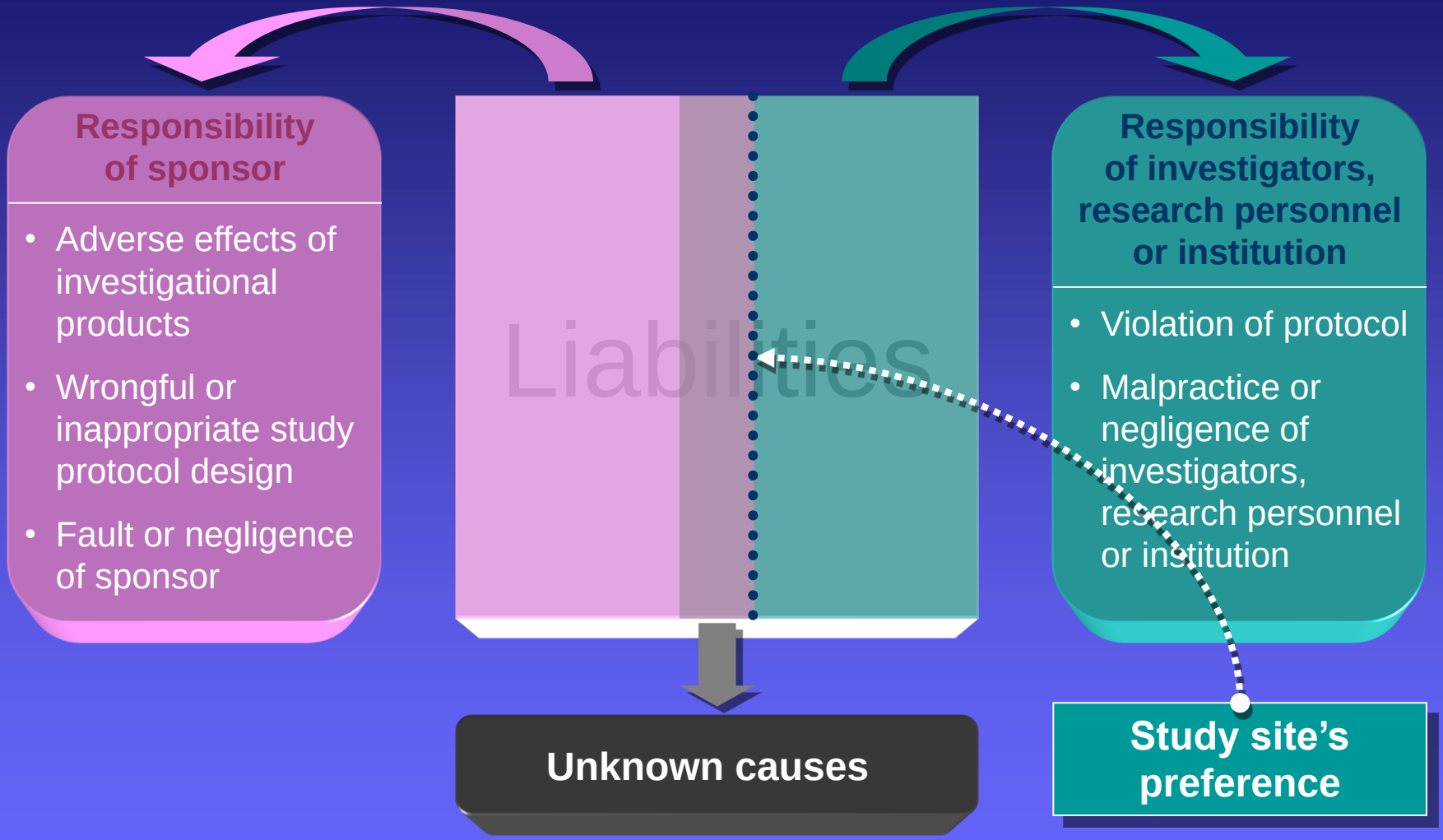

Indemnity for Sponsored Clinical Trials

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