

MARSH

# What is Clinical Trial Insurance?



Presented by: Andy Wong  
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# Current News on Clinical Trials



# Current News on Clinical Trial Litigation against Pfizer in Nigeria for testing of “Trovan”

*The Washington Post*

## Pfizer Reaches Settlement In Nigerian Drug-Trial Case

*By Joe Stephens*

Washington Post Staff Writer

Saturday, April 4, 2009

Pfizer has reached a broad agreement to pay millions of dollars to Nigeria's Kano state to settle a criminal case alleging that the drug company illegally tested an experimental drug on gravely ill children during a 1996 meningitis epidemic.

The details remain private, but sources close to the negotiations said the total payments -- including those to the children, their families, the government and the government's attorneys -- would be about \$75 million under the current settlement terms. Other details, including how the money will be distributed, are to be worked out within weeks.

Nigerian authorities say Pfizer's infamous trial of the antibiotic Trovan killed 11 children and disabled scores more. The

amicable agreement, it means both parties need to give and take."

Nigerian lawyers close to the negotiations, held over the past year in Nigeria, London and Dubai, told The Washington Post that Pfizer set a number of conditions, specifics of which remain undisclosed.

In 2007, Nigeria's federal government and the state of Kano filed four civil and criminal actions against Pfizer and 10 individuals, including former Pfizer chief executive William C. Steere Jr. The actions sought \$9 billion in restitution and damages, and included 31 criminal counts, including homicide.

"We have made good progress in the negotiations," Pfizer said in a formal statement issued yesterday from its corporate headquarters in New York. "There are still several important issues that need



# Current News on Clinical Trial Litigation against Pfizer in Nigeria for testing of “Trovan”

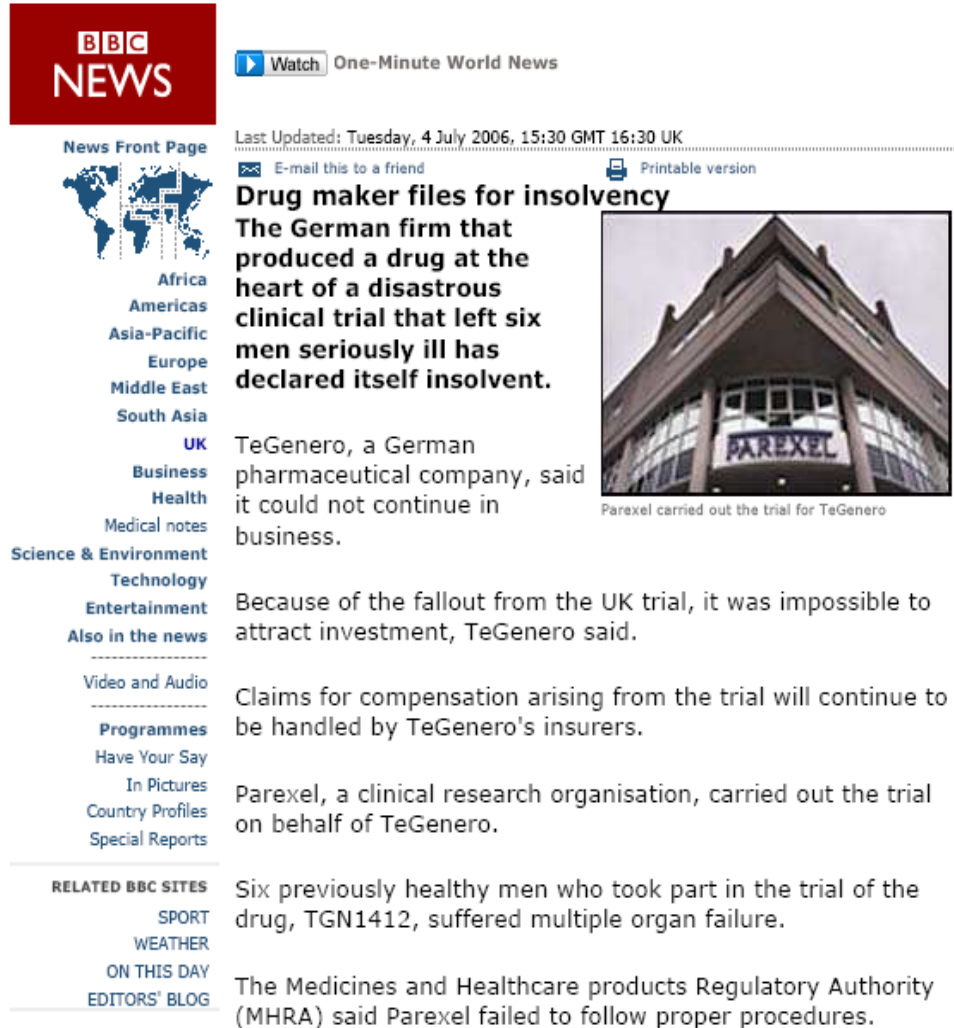
- Background
  - Drug Manufacturer: Pfizer
  - Testing of antibiotic “Trovan” for treatment of Meningitis epidemic starting from 1996.
  - 11 Children died and about 200 injured.
  - Litigation starts since 2001.
- Allegation investigated by Washington Post
  - Trial did not conform to US patient-protection standards
  - The oral form of the drug used in the trial had not been previously tested in children
  - No signed consent forms for the children
  - Reliance on falsified ethics approval letter
  - Researchers also gave children substandard dose of a comparison antibiotic
- Settlement
  - USD75mil

*(Reference: The Washing Post 4 April 2009)*



# Current News on Clinical Trial

## Serious adverse condition on research subject for trial conducted by TeGenero AG



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### Drug maker files for insolvency

The German firm that produced a drug at the heart of a disastrous clinical trial that left six men seriously ill has declared itself insolvent.



Parexel carried out the trial for TeGenero

TeGenero, a German pharmaceutical company, said it could not continue in business.

Because of the fallout from the UK trial, it was impossible to attract investment, TeGenero said.

Claims for compensation arising from the trial will continue to be handled by TeGenero's insurers.

Parexel, a clinical research organisation, carried out the trial on behalf of TeGenero.

Six previously healthy men who took part in the trial of the drug, TGN1412, suffered multiple organ failure.

The Medicines and Healthcare products Regulatory Authority (MHRA) said Parexel failed to follow proper procedures.



# Current News on Clinical Trial

## Serious adverse condition on research subject for trial conducted by TeGenero AG

- Background
  - Drug manufacturer: TeGenero AG.
  - Clinical Research Organisation, Parexel, carried out the trial on behalf of TeGenero.
  - Phase I trial for testing of drug “TGN1412”.
  - Six out of eight subjects taken part in the trial suffered multiple organ failure.
  
- Development
  - TeGenero AG goes into insolvency after the event.
  - Claims for compensation arising from trial handled by TeGenero’s insurer.

*(BBC News 3 March 2006 and 4 July 2006)*



# Clinical Trials Risks Perspective

- Increasing no. of clinical trials conducted worldwide.
- Increasing awareness on human rights.
- Increasing demand for appropriate risks management measures and clinical trials liability insurance.

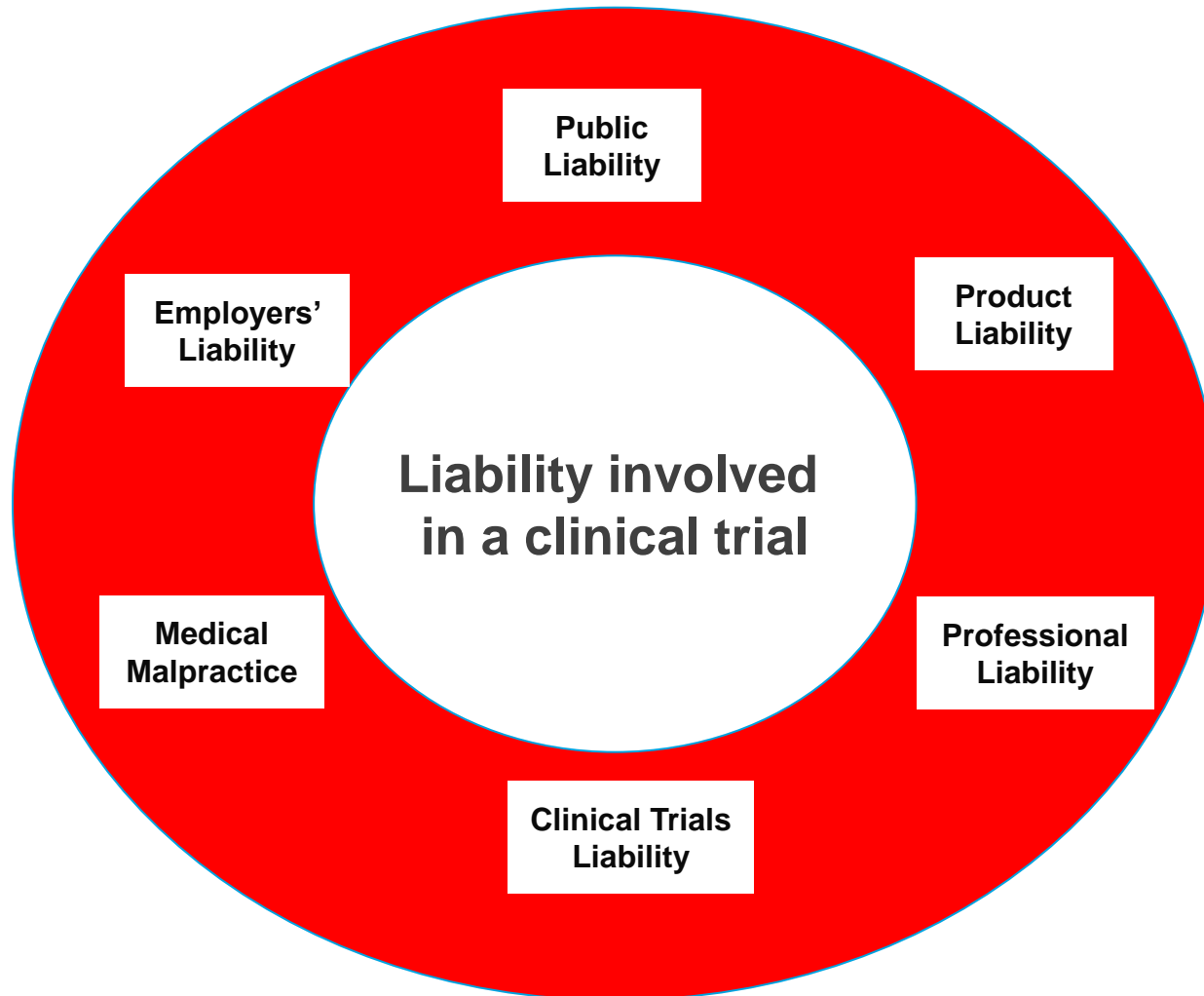


# Liability and Risks involved in a Clinical Trials





# Liability involved in a clinical trial



# Risks Exposure on Clinical Trials relating to Bodily Injury

Risks	Source of Claim	Possible remedy
Bodily Injury to Test Subjects	Slip and fall	Test site's general liability insurance
	Directly related to protocol	Sponsor's clinical trials liability insurance
	From medical care not directly related to protocol	Investigator or test site's medical malpractice liability insurance
	Not related to protocol	CRO's errors and omissions liability insurance  Investigator's or test site's medical malpractice liability insurance
	From contaminated or noncompliant product	Manufacturer's product liability insurance  Sponsor's clinical trial liability insurance



# What is Clinical Trial Insurance?



# What is Clinical Trial Insurance?

- In principle, it covers the design risks of the protocol.
- Cover liability/ compensation to the research subject for bodily injury or death resulting from their participation in the trial.
- It is a no fault compensation.



# Who is the Insured of Clinical Trial Insurance?

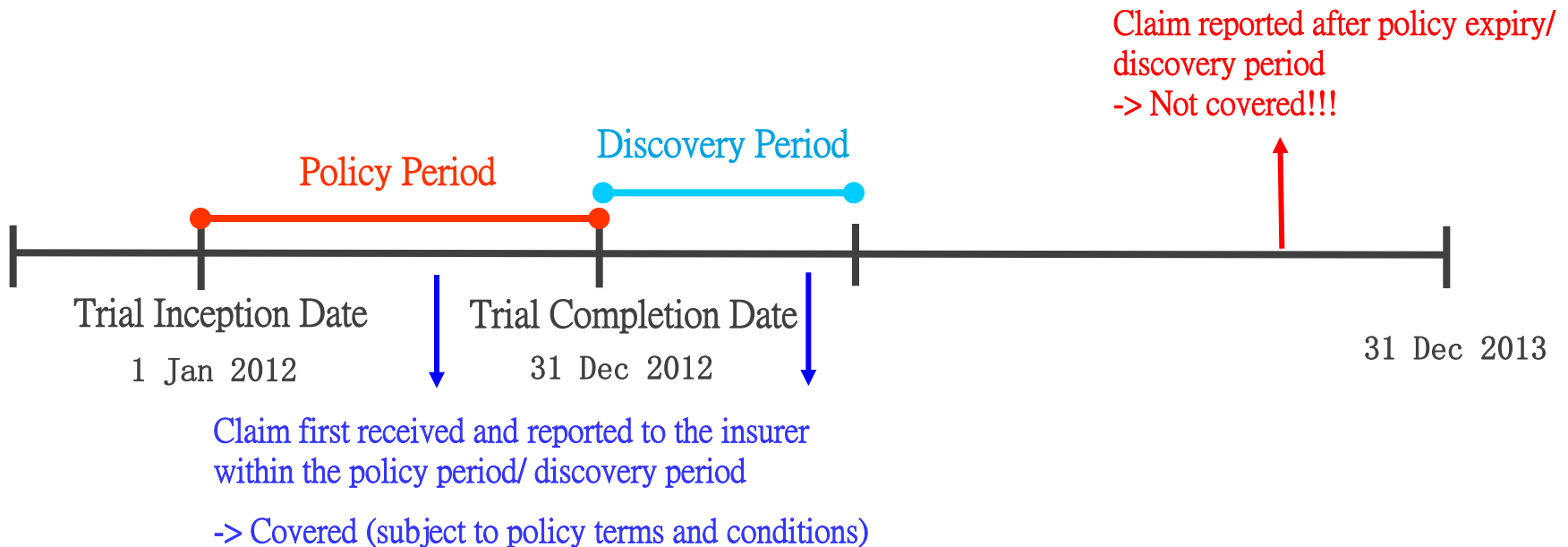
- Investigators
- Sponsor
- Clinical Research Organisation (CRO)
- Education institutions
- Institutional Review Boards (IRBs)/ Ethics Committees

**\*But only in respect of the design risks of the protocol.**



# What is “Claims-Made” Policy?

- Clinical Trial Insurance is usually arranged on a claims-made basis.
- Claims first received and notified to insurer within the policy period/ discovery period is covered subject to policy terms and conditions.



# Major Coverage

- Compensation to research subjects.
- Legal liability attached to the insured.
- Legal costs and expenses incurred during the settlement/ claim litigation.
- Discovery period/ run-off cover shall be considered after the trial is completed.



# Major Exclusions

- Failure to follow protocol exclusion
- Failure to obtain consent from research subjects exclusion
- Pre-existing health problems exclusion
- Medical malpractice liability exclusion
- Known harmful substance exclusion (on named basis)
- Unapproved trial exclusion
- War/ Radiation/ Nuclear Exclusion





# Arrangement of Clinical Trial Insurance

- To be arranged by Sponsor/ Education Institution/ Investigators
- Can be arranged on a specific clinical trial basis (multi-year policy); or
- Can be arranged on a company basis (annual policy) covering all clinical trials conducted in a year



# Information required for obtaining a quotation on Clinical Trial Insurance

To arrange clinical trial insurance on a specific trial basis

- Protocol of the trial – *Description on details of the trial. Any subsequent changes on protocol shall be reported to insurer.*
- Informed consent form – *Being able to prove that consent was informed is key to defending a litigation.*

To arrange clinical trial insurance on a company basis

- Past claim history
- Portfolio of clinical trials for recent and past years



# Contact Details

- Should you have any questions, please do not hesitate to call us:

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# Questions & Answers



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