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Clinical Trials Insurance: Are we enriching or making insurance companies richer?

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Outline

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- Understanding SAEs
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Introduction

Clinical trials involve human participants (in different phases of the drug development cycle ;Phase 1-4) – potential risks exist.

Participant protection is a cornerstone of ethical research. Regulatory frameworks in clinical trials are built around participant safety (*reference: CT regulations and guidelines)*

Clinical trials Insurance provides a safety net should harm occur.

The focus of the discussion will be importance of CT insurance, participant benefits, regulator & PI roles.

Why Clinical Trial Insurance?

New drugs,new dosage, new formulation

Sometimes preclinical data maynot sufficiently cover safety, continued safety monitoring is necessary during clinical trials

Regulatory requirement (section 21, CT regulations,2024), National guidelines for research , 2014 (UNCST)

Patient’s right incase of harm

Understanding Serious Adverse Events (SAEs)

Any event causing death, hospitalization/Prolonged hospitalization, life-threatening condition, or disability.

Reporting timelines are explicit to the sponsor and regulators between 7-14 days following an occurrence of an SAE.

Insurance provides medical/financial support if there is causal connection between the clinical trial and body harm/injury or death to the study participant.

Challenges with Compensation

- Not clear procedure for determining causation requiring compensation by study team
- Lack of awareness about this provision by study participants
- Defining the types of harm /injury in the insurance policy that are eligible for compensation
- Defining the role of the different players in supporting this process following approval of the clinical trial

Challenges in Practice

Delays in reporting SAEs/quality of reports

Disputes around causality assessments.

Lack of a dedicated person to review SAEs and ensure claims are made.

What's changing?

Review available guidance to define procedures for compensation and who shall be in charge at institution level

Define types of compensation harm

Define types of compensation to ensure fair treatment

Define a compensation process at institutional, regulatory and insurance levels of oversight.

Role of the Principal Investigator (PI)

- Ensures valid insurance coverage before trial starts.
- First point of contact for SAE reporting.
- Reports SAEs accurately and within timelines.
- Ensure study participants are aware about compensation procedures at consenting
- File a claim if harm is related to the clinical trial
- Identify an independent medical monitor to review and identify SAEs that would qualify for compensation.
- Communicate transparently with participants/families.

Role of the Regulator

Require proof of insurance policy and certificate before approving trials from a local insurance provider .it should be sufficient for the clinical trial

Approved insurance providers are available on the IRA website; Goldstar, Britam, ICEA, Jubilee, UAP old mutual, MUA insurance (Uganda) limited

Provide insurance guidelines and oversight.

Monitors all adverse events related to the clinical trial

Liaise with the RECs following safety evaluation to ensure monitoring and compensation for the affected study participants

Ensure study participants are aware of the compensation procedures at consenting.

Role of the Insurance Provider

Review and assess the claim within reasonable timeframes

Support in training of study teams on the compensation processes

Participant Benefits

- Guaranteed medical treatment if harmed.
- Financial compensation for disability or death.
- Fairness and transparency in protection.
- Greater confidence in volunteering for trials.

Moving Forward

Strengthen	Strengthen regulatory frameworks on insurance.
Improve	Improve participant awareness on rights.
Ensure	Ensure transparent and timely compensation/ utilize the complaints bureau at IRA
Harmonize	Harmonize guidelines on clinical trial insurance.

Conclusion & Discussion

Clinical trial insurance is essential for ethical research.

Protects participants, builds trust, ensures compliance.

Requires collaboration between regulator, PI, sponsor, and insurer.

Final message: Protecting participants = Protecting science.


THANK YOU