Insurance, Compensation and Indemnification of Trial Subjects

Module 8 Topic 4

Insurance & Indemnity

Indemnity is giving an undertaking that compensation will be paid

- Indemnity is the provision of a written assurance or contract confirming that liabilities will be provided
- Purpose is to ensure that in the event of injury there is a facility that compensation (financial) can be paid to reinstate the claimant to the same financial position that they were in prior to the incident

Insurance & Indemnity (contd)

Whereas

Insurance is paying a premium for an insurance policy, so that the insurer will pay compensation in the event of a claim for injury or bodily harm being made

- Insurance is a contract or policy which requires premium to be paid into a fund from which compensation payments can be made in the event of a claim

Indemnify	Insure
Compensation for damage, loss, or injury suffered	To make sure, certain, or secure
Insure someone against legal responsibility for their actions	Pay money in order to receive financial compensation if something is lost or damaged or someone is hurt or killed

Liability

The state of being legally obliged & responsible to pay money to another – as insurer

Clinical Research – Main Risks

- Injury (physical and psychological) to participants from poorly designed or executed research
- Breach of privacy and confidentiality in relation to inappropriate research methodologies and publication practices
- Breach of rights and dignity of participants in relation to consent
- Lack of compliance with legislation and regulations
- Damage to good-name and reputation

Clinical Research – Main Risks (contd)

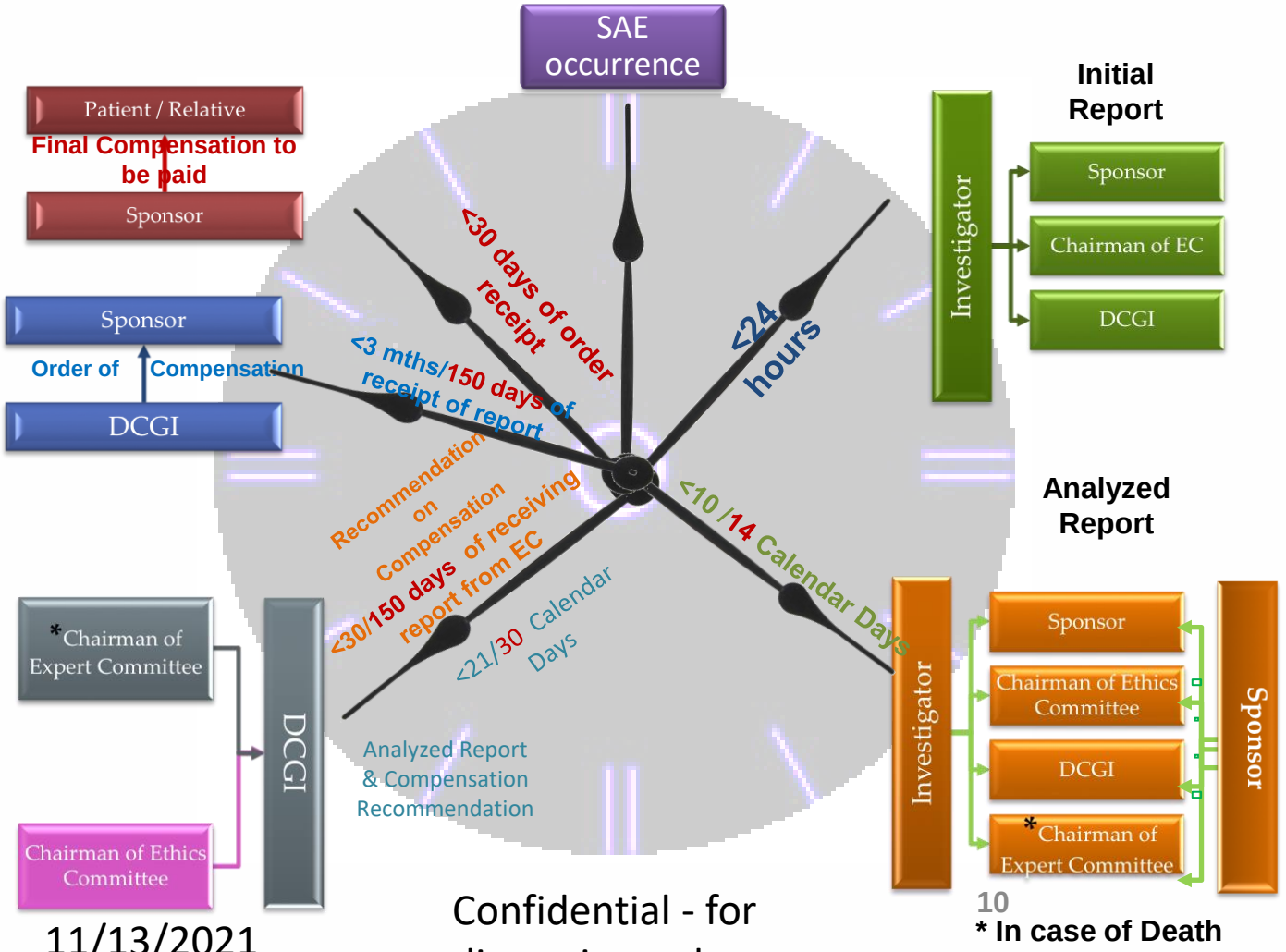
- Inappropriate usage or wastage of resources
- Financial impropriety and inequity in support and funding
- Variance in the standards of the conduct of research
- Breach of indemnity or insurance requirements
- Absence of a learning and research culture

Typical example of a “treatment and compensation for health damage” provision

- However, please be aware that you may not receive compensation if it is found that you did not follow your primary doctor’s instructions or that the health damage was due to your own carelessness.”

Compensation Laws in India

New SAE Reporting Process in India



As per New Clinical Trial Rules 2019
Compensation Chapter VI

39. Compensation in case of injury or death in clinical trial or bioavailability or bioequivalence study of new drug or investigational new drug.

40. Medical Management in clinical trial or bioavailability and bioequivalence study of new drug or investigational new drug

41. Consideration of injury or death or permanent disability to be related to clinical trial or bioavailability and bioequivalence study.

42. Procedure for compensation in case of injury or death during clinical trial, bioavailability and bioequivalence study

Compensation to?

(1) Where any death of a trial subject occurs during a clinical trial or bioavailability or bioequivalence study, **the legal heir** of the trial subject shall be provided financial compensation by the sponsor or its representative, who has obtained permission to conduct the clinical trial or bioavailability or bioequivalence study, in accordance with the procedure specified in rule 42.

(2) Third Schedule Table 3

Name and address of the **nominees** and his relation to the subject (for the purpose of compensation in case of trial related death).

Heir or Nominee?

Nominee

Legal Heir

What is CT related injury or Death?

G.S.R. 53(E)

- Adverse effect of investigational product(s);
- Violation of the approved protocol, scientific misconduct or negligence by the Sponsor or his representative or the investigator;
- Failure of investigational product to provide intended therapeutic effect;
- Adverse effects due to concomitant medication excluding standard care, necessitated as part of approved protocol;
- For injury to a child in–utero because of the participation of parent in clinical trial;
- Any clinical trial procedures involved in the study

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Amendment in Informed Consent Form

G.S.R. 53(E)

- Essential elements of ICF have been amended to include statements that -
  - in the event of injury, free medical management as long as required
  - in case of CT related injury or death, compensation
- The Format of ICF have been amended to include -
  - Address
  - Qualification and Occupation
  - Annual income of the subject and Name & address of his nominee
- Mandatory for Investigator to hand over a copy of duly filled ICD to the subject or his/her attendant

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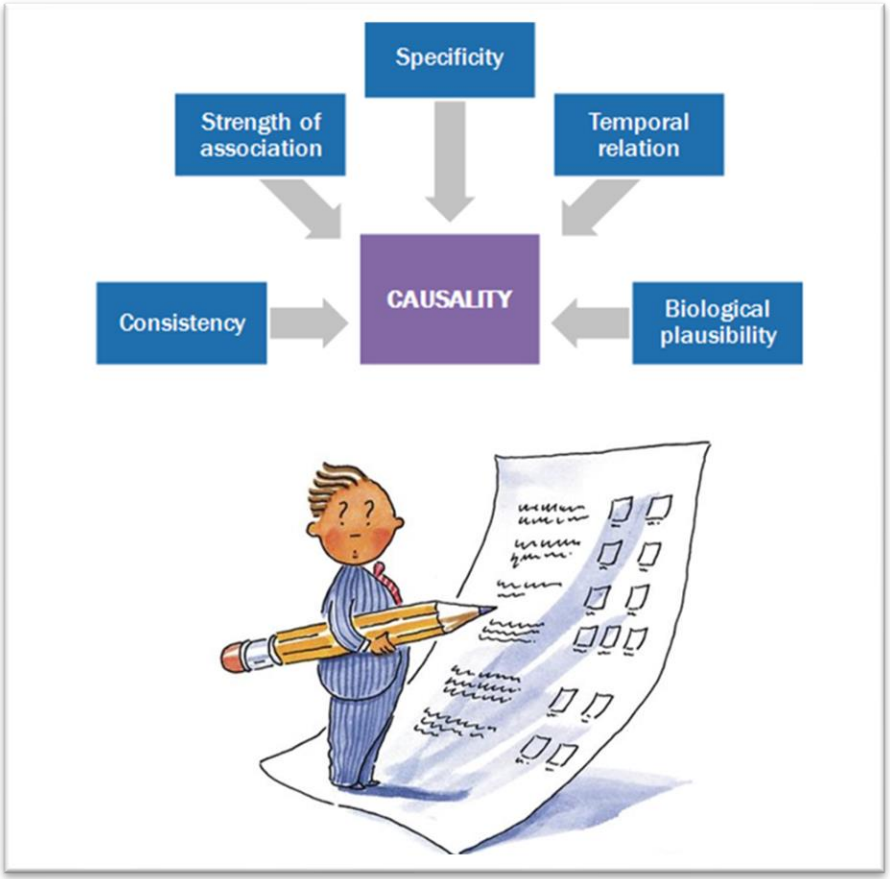
Causality Assessment

The evaluation of the likelihood that a medicine was the causative agent of an observed adverse event



Execution Steps for Compensation in India

- Licensing authority primarily responsible for the causal assessment of injury/death and compensation amount to be paid for it to trial participant
- In case of occurrence of serious adverse event (SAE), the Expert Committee communicates its recommendation about causality and quantum of compensation to the licensing authority, and then, the licensing authority shall pass the final order

Execution Steps for Compensation in India (contd)

- The sponsor needed to compensate the participant as per order of licensing authority. In case of failure to comply with the order, licensing authority may take necessary action as per rule, including suspension or cancellation of the clinical trial and/or restricting sponsor including his representative(s) to conduct any further clinical trials in India

Execution Steps for Compensation in India (contd)

- In case of SAE other than death, the cause of injury and amount to be given to participant is finalized by the DCGI as per the report submitted by Investigator, Sponsor, and Ethics Committee

Formula In Case Of Death

Compensation = (B x F x R)/ 99.37

Where,

B = Base amount (i.e. 8 lacs)

F = Age Factor (based on Workmen Compensation Act)

R = Risk Factor of the subject at the time of enrolment in the clinical trial between a scale of 0.5 to 4 as under:

- 1 .0.50 terminally ill patient (expected survival NMT 6 months)
- 2.1.0 Patient with high risk (expected survival between 6 to 24 months)
- 3.2.0 Patient with moderate risk
- 4.3.0 Patient with mild risk
- 5.4.0 Healthy Volunteers or subject of no risk

Formula In Case Of Death (contd)

However, in case of patients whose expected mortality is 90% or more within 30 days, a fixed amount of Rs 2 lacs should be given

To simplify

Age	Risk factor	Compensation
> 65 yrs	4	32 Lacs
< 16 yrs	4	73.59 Lacs
>65 yrs	0.5	4 Lacs
< 16 yrs	0.5	9 Lacs

Responsibilities-Investigator

- Responsible for the conduct of the trial according to the protocol, GCP Guidelines, Regulations and Standard Operating Procedures
- Ensure that adequate medical care is provided to the participant for any adverse events.
- Report all serious and unexpected adverse events to the Sponsor within 24 hours and to the Ethics Committee that accorded approval to the study protocol within 10 working days of their occurrence

Responsibilities-Ethics Committee

- Safeguard the rights, safety and well being of all trial subjects, particular care to protect the rights, safety and well being of all vulnerable subjects
- Conduct ongoing review of trials to ensure adherence to protocol and protection of subjects
- Stop the trial if in their opinion the subjects are at risk of injury or death
- If an ethics committee refuses approval, it must record the reasons in writing. If it revokes an approval, the same must be communicated to DSCO

Powers-Ethics Committee

- Decide on every proposal giving:
  - Approve the proposed study
  - Suggest changes prior to approval
  - Reject the proposal
- Review the study periodically to ascertain that the study adheres to the conditions of approval and that subjects' rights are protected.
- Take appropriate action in case of default
- Take cognisance of any complaints from any stake holder, investigate and take appropriate action