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Letter to the Editor

Current perspective of severe adverse events and compensation requirements in India

Sir,

As per Drug Controller General of India (DCGI), there are clear cut compensation guidelines for clinical trial participants in case of death and injury after amendment in schedule Y (Rule 122DAB - Compensation in case of injury or death during clinical trial). The purpose of these guidelines is to provide Severe Adverse Event (SAE) compensation calculation as well as determination of the ratio of amount in clinical trial injury.

These guidelines give clarity on the actual amount of compensation calculation procedure to ethics committees and sponsor. It is very clearly stated in regulation that the responsibility of medical management and compensation in case of clinical trial related injury lies with the sponsors. It is very important to have proper clinical trial insurance policy to safeguard the sponsors in case of SAE. It would be better for the sponsors as well as the participants for conducting and participating in the clinical trial after proper insurance coverage. Insurance company should pay full compensation payment within the time limit as per DCGI expert committee. However, any party's or stakeholder's negligence is not covered by the insurance agency.

Three factors viz. age, risk and base amount are required to decide the quantum of compensation in case of SAE (Death) related to clinical trials. In order to exclude the complexity, committee felt to adopt the simple yet best formula covering all important points. A constant base amount of 8 lacs is given to the nominee after applying all variables. The following formula is recommended:[1]

Compensation = (B x F x R)/99.37

Where,

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

F = Factor depending on the age of the subject based on Workmen Compensation Act.

R = Risk Factor depending on the seriousness and severity of the disease, presence of co-morbidity and duration of disease of the subject at the time of enrolment in the clinical trial between a scale of 0.5 to 4.

1. 0.50 terminally ill patient (expected survival not more than 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.

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. Thus, the compensation amount will vary from a minimum of Rs. 4 lacs to a maximum of Rs.73.60 lacs depending on the age of the deceased and the risk factor. The committee will examine cases of SAEs of deaths and decide the final quantum of compensation after due diligence and application of mind on the risk factor and recommend the same to DCG (I) on case to case basis. The committee also considered the above formula as provisionally final.[2]

Within 30 days after receiving reports from concerned ethics committee, Independent expert committee gives its proposal to licensing authority. The DCGI shall, then decide and pass order within three months of receiving SAE (death) report.

The advent of such clear formula has simplified the complex and dreaded issues of compensation and is expected to pave the path for meticulous clinical trials in India.

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