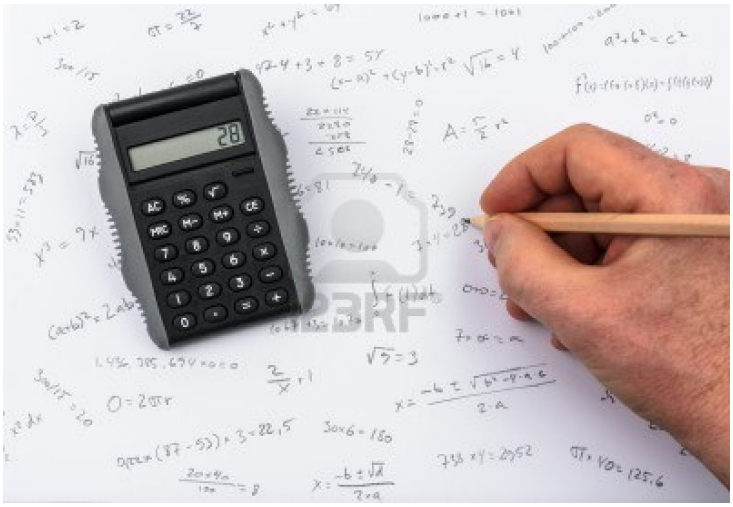
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CDSCO's compensation formula for clinical trial deaths

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CDSCO's compensation formula for clinical trial deaths



The compensation formula for the patient deaths in clinical trials, recently released by the CDSCO is as under:

Compensation = B * F * R/99.37

Here, B = Base amount (Rounded) which is fixed as Rs 8.0 lakh. This base amount has been fixed with consideration of minimum wages act.

F = Factor depending on the age of the subject as per the Annexure given, which is 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 4.0 as under:
0.50 - Terminally ill patient (Expected survival not more than 6 months)
1.0 - Patient with high risk (Expected survival between 6 to 24 months)
2.0 - Patient with moderate risk (Moderate risk if not defined)
3.0 - Patient with mild risk (Mild risk is not defined)
4.0 - Healthy volunteers or subject of no risk

Here, 99.37 is the factor for age 65 in the table of worksmen compensation act. The concept used is that the base amount 8.0 lakhs should refer to the age of 65 years which corresponds to factor 99.37.Thus, considering an example:
If the age of the subject is 30 years, the factor F as per the factor given in the table comes to 207.98
If the subject is with mild risk, R = 3.0
Thus,
Compensation = 8,00,000 * 207.98 * 3.0 / 99.37 = 50,23,165/-

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However, in case of patients whose expected mortality is 90% or more within 30 days, a fixed amount of Rs. 2.0 lacs should be given.

If calculations are done, the compensation amounts range from Rs. 4.0 lacs to a maximum of Rs. 73.60 lacs depending on the following factors:
a) Age
b) Risk factor

The CDSCO has still not released any clarity on the calculation of compensation amount in case of clinical trial related injury (Which does not progress to death).

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