**Adequate definition** of severity required either detailed description of the severity or reference to a known scale of severity, with separate reporting of at least severe or life threatening events. At least 2 adverse effects have to be defined in this way, with numbers or rates given for each study arm.

**Partially adequate** is defined as, trial reports of severity combine moderate with severe counts, or that the numbers of severe cases are separately specified for only 1 of many reported clinical adverse events per study arm.

**Inadequate definition** of severity includes protocols reporting the total number of severe adverse events and those not reporting adverse effects at all. We also included a category for those studies that explicitly stated no adverse events were observed; in these cases no scale or description could be provided.

‘**No harms reported**’; where the trial clearly reports that no adverse events were experienced. This addition was made to allow for studies which did not encounter any harms data and would not meet the definition of ‘adequate’ reporting.