

At the public GCP-unit in Copenhagen we have following contribution to the CT-3 draft :

4.3.3: Expectedness

43: What does the expression "in the light of the applicable product information" mean? Until now we have understood it in that way, that the event should never had been described before in IB/SmPC to be considered as a possible SUSAR

45: In public studies we could fear that this would lead to over-reporting, since the investigator often would consider a SAR as "unexpected" if he had not seen/heard of it before in the clinic. As the sponsor must not downgrade the investigators opinion, this SAR would be reported as a SUSAR, even if one can find it in the IB/SmPC.

Kind Regards

Jeanette Blom  
Copenhagen University GCP-Unit  
University Hospital Bispebjerg  
Bispebjerg Bakke 23, Building 51, 3. floor  
DK-2400 Copenhagen NV  
Denmark