Comments CT3
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Chapter	Number	Comment Waldeyer
4.3.2.	37	Instead of „only adverse reactions“: “only suspected adverse reactions” Justification: a proof is not possible
	38	I propose to delete the whole sentence, since “on the other hand” is not fitting and it is not required to have “absolute certainty”.
4.3.3.	**44 and 45**	**The most important point to change for me:** **I urgently request to delete both passages. It is not the qualification and task for the investigator to assess expectedness. An investigator will only assess expectedness as clinical expected for the patient, this will often be contradictory to the expectedness assessment in the light of the product information.**
4.6.	50	Volume 9A instead of Volume 9. The bookmark 13 is not correct. Instead of OJ L 136, 30.4.2004, p. 1. 13 http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol3_en.htm. **It must be:** http://ec.europa.eu/health/documents/eudralex/vol-9/index_en.htm
4.7.2.2.	70	The example “e.g. the day of the birth date” is not adequate, since often the birth date is taken for duplicate check. A better example should be used, like “not relevant laboratory values”.
4.7.3.	General	At the moment, some authorities forward SUSARs to EVCTM, other require double reporting to the Authority and EVCTM, the third group gives no information what the authority does with the reports. I can only support that the cases should only be reported to EVCTM only.
4.7.3.3.	78	Is it correct “exclusively in another Member State” or should it not mean “exclusively in a third country” like in chapter 4.4. number 46?
	81	Should this not mean “….and the SUSAR is **not** reported to a Member State”, otherwise I do not understand this sentence.
	83	Bookmark 27: spelling error: EudraCT instead of EduraCT
6.3.	109	“Alerts of SUSARs……fatal reactions, pancytopenia,..” One remark: please be aware of the variety of indications. In oncology, e.g. high-dose chemotherapy, a pancytopenia, especially leukopenia, is the desired effect of the therapy and should not qualify as an alert.