To whom it may concern…

I am a member of the ECRIN working party 8 on pharmacovigilance. I would like to comment on an individual basis to the Public Consultation Document on the draft detailed guidance on the collection, verification and presentation of adverse reactions arising from clinical trials on medicinal products for human use (CT-3).

I work as a project manager/clinical trial manager at an academic research center at Uppsala University/Uppsala University Hospital and represent the academic researchers who run clinical trials without support from the pharmaceutical industry. I work mainly with phase I oncology studies and have experienced the frustration with SUSAR reporting at a close distance for years.

The draft guideline suggests that direct or indirect SUSAR reporting may apply, which I find to be a great improvement of the present guideline. However, it also says that it is for the member stat to decide whether they will allow indirect reporting or not. I suggest that this phrasing (section 75) is further accentuated, so that it will be mandatory for each national competent authority to provide the service of indirect reporting for academic researchers.

Justification:
Reporting of SUSARs into the EVCTM is a huge problem for the academic researchers and it is not an option for them to do the electronic reporting themselves, since it requires an expensive 3 day course in London. The researchers often have very limited research budgets and cannot always afford to pay someone to do the reporting for them. In my opinion the requirement of direct reporting is a safety risk that may lead to that unexpected serious adverse events are assessed as “not related” to avoid the reporting procedure.
It is my firm conviction that SUSAR reporting should be simple and free of charge for academic researchers and that the responsibility of reporting to EVCTM should stay with the competent authorities.

Yours sincerely,

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