Comments from a contributor who wishes to remain anonymous

All comments are described below:

- My main comment concerns the length of the document and the complexity. There is not much difference with a document which would be transmitted to a professional, except the terms easier to understand. I think that it is necessary to reduce the number of section; for example compile the section 7 and 8 and to have more summary and fewer details. For section 6, I suggest being more concise and just have a description of tolerance of the trial and no list of adverse events.
- Line 265: In all local languages or only one of them ?
- Line 266: Please precise: “countries where the study was authorized” or “countries where at least one patient included”?
- Line 274: The Sponsor have no information concerning the identity of patients. All information must be transmitted by the investigator (or by study team of center)
- Line 275: Must be done by investigators (or study team of hospital) and not the sponsor.
- Page 14: section 3 (same comment as line 266)
- Page 16; section 5: Confusing for patients, it is better to identify the drug by the same name indicated in the protocol.
- Page 16; section 5 : In some pathologies it's difficult to use the term “chance”, we propose to replace by "possibility".
- Page 16; section 6: The document concerns lay persons, it will be difficult for these people to understand this section. It would be better to propose a brief description of tolerance (by arm if applicable).
- Page 19; section 7: For lay person, the results must be concise, and only one section for the description of results is preferable, the section 8 of this document is suitable.