Our contribution *"Can be directly published provided that I/my organisation remain(s) anonymous (I consent to publication of any information in my contribution in whole or in part (which may include quotes or opinions I express) provided that this is done anonymously. I declare that nothing within my response is unlawful or would infringe the rights of any third party in a manner that would prevent publication)".*

All comments are described below:

- Line 504: Only changes must be documented? The confirmation of the consent throughout the progress of the study: how to organize it? Does it mean a "repetition" of the consent? and if so, with which frequency. We propose an oral consent with traceability in the document of the trial (and or medical record)l. We have the same observation for the consideration of the evolution of the maturity of the child in the course of trial.
- Line 615: About the test, we propose to specify "when it's possible".
- Line 669: What do you mean by "preferably in written", signature for this age group?
- Section 7.2.4: Concerning the age group for the minors and the level of maturity: the last group envisaged (10-18 years) seems extremely wide and the maturity of the child evolves very quickly between 10 and 18 years. It would have been convenient to plan an intermediate category 10/13 or 10/14 and another one until 18 years.
- Line 699: It's important to specify who is the first to receive the information about the clinical trial. If the parents/legally designated representative, are the first and if they refuse it will be not necessary to solicit the child. In the case we avoid the difference of opinion.
- Line 961: Sponsor instead of investigators?
- Section 19.1: we agree for the summary understandable by laypersons but in case of a pediatric study conducted in children whose age is 3 to 5 years , we assume that this is not applicable?