Author's response to reviews

Title: Population-based analysis of non-steroidal anti-inflammatory drug use among children in four European countries. What size of data platforms do we need to assess safety issues? The SOS project

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1. About ethics statements: We added the following sentence to the first paragraph of the methods section in the manuscript: "This analysis was exclusively based on routinely collected anonymized data and adhered to the European Commission’s Directive 95/46/EC for data protection". All member states have implemented the European Commission’s Directive 95/46/EC for data protection into their own national data protection legislation. All of the databases used in this study are currently already used for pharmacoepidemiological research and have a well-developed mechanism to ensure that European and local regulations dealing with ethical use of the data and adequate privacy control are adhered to. Informed consent was not required. For descriptions on the procedures to guarantee the de-identifiability of the data and the security of the centralized data warehouse, please see the paragraph on data sharing and data extraction in the methods section. Only the following three databases needed to obtain approval for data use and sharing from their governance boards: GePaRD, IPCI, and THIN. We added the names of respective committees under the description for each of those three databases in the methods section.

2. Authors’ information: We added a detailed Authors’ Contributions
section.

3. and 4. Acknowledgement: We added an Acknowledgements section with a description of the source of funding and a reference to the SOS project members, including a link to the extensive project website.