

Question Text	Author Response	Custom Submission Question ID
Please complete the following questions in accordance with the International Committee of Medical Journal Editors' recommendations on data sharing in clinical trials (guidelines and examples are available here Will individual participant data be available (including data dictionaries)?	No	54
What data in particular will be shared? (Examples include all individual participant data after deidentification, only participant data that underlies the results, or not available.)	No data sharing is permitted from our institution, without a fully executed data sharing agreement.	55
What other documents will be available?	Study protocol can be made available upon request. De-identified cumulative data will be provided in the form of tables within the manuscript.	56
When will data be available (start and end dates)?	Data collection begun in 2012 and we completed all follow-up data in 2019.	57
With whom? (Examples include anyone who wishes to access the data, researchers who provide a proposal, or not applicable.)	As per our agreement, the researchers as well as the funder (Johnson & Johnson) have access to the data.	58
For what types of analyses?	Analyses are completed internally by the researchers for the purposes of manuscript preparation as well as safety reports for the institution.	59
By what mechanism will data be made available?	A final report will be prepared by the researchers for the funder. Data will also be disseminated via journal publication and conference presentations.	60