

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).	Yes	54
Will individual participant data be available (including data dictionaries)?		
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.)	Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices)	55
What other documents will be available?	Study Protocol	56
When will data be available (start and end dates)?	Not Applicable	57
With whom? (Examples include anyone who wishes to access the data, researchers who provide a proposal, or not applicable.)	Investigators whose proposed use of the data has been approved by an independent review committee ("learned intermediary") identified for this purpose	58
For what types of analyses?	Any purpose	59
By what mechanism will data be made available?	Not applicable	60