

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. Our trial started recruiting in 2013 after having received the IRB approval. The approval did not include sharing of deidentified data and can therefore unfortunately not be shared.	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.)	Not available	55
What other documents will be available?	Not available	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.)	Not applicable	58
For what types of analyses?	Not applicable	59
By what mechanism will data be made available?	Not applicable	60