

| Question Text                                                                                                                                                                                                                                                                                                                       | Author Response                                    | Custom Submission Question ID |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------|-------------------------------|
| Please complete the following questions in accordance with the <a href="#">International Committee of Medical Journal Editors'</a> recommendations on data sharing in clinical trials (guidelines and examples are available <a href="#">here</a> )<br>Will individual participant data be available (including data dictionaries)? | yes                                                | 54                            |
| What data in particular will be shared?<br>(Examples include all individual participant data after deidentification, only participant data that underlies the results, or not available.)                                                                                                                                           | individual participant data after deidentification | 55                            |
| What other documents will be available?                                                                                                                                                                                                                                                                                             | approval documents                                 | 56                            |
| When will data be available (start and end dates)?                                                                                                                                                                                                                                                                                  | after publication during 5 years                   | 57                            |
| With whom? (Examples include anyone who wishes to access the data, researchers who provide a proposal, or not applicable.)                                                                                                                                                                                                          | researchers who provide a proposal                 | 58                            |
| For what types of analyses?                                                                                                                                                                                                                                                                                                         | for similar cost analysis, reproduction            | 59                            |
| By what mechanism will data be made available?                                                                                                                                                                                                                                                                                      | shared-file                                        | 60                            |