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**Data sharing**

The journal encourages authors to state the data sharing in their submission. Authors may state linking to a repository or declaring confidentiality of the data. Since 2019, all manuscripts reporting clinical trials must be submitted with a data sharing statement (Table 1). If authors describe this in their manuscripts, the description will be published alongside their manuscripts.

**Table 1.** Examples of data sharing statements that fulfill the ICMJE requirements

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Example 1 | Example 2 | Example 3 | Example 4 |
| Will individual participant data be available (including data dictionaries)? | Yes | Yes | Yes | No |
| What data in particular will be shared? | All of the individual participant data collected during the trial, after de-identification. | Individual participant data that underlie the results reported in this article, after de-identification (text, tables, figures, and appendices). | Individual participant data that underlie the results reported in this article, after de-identification (text, tables, figures, and appendices). | Not available |
| What other documents will be available? | Study protocol, statistical analysis plan, informed consent form, clinical study report, analytic code | Study protocol, statistical analysis plan, analytic code | Study protocol | Not available |
| When will data be available (start and end dates)? | Immediately following publication. No end date. | Beginning at 3 months and ending 5 years following the article publication. | Beginning at 9 months and ending 36 months following the article publication. | Not applicable |
| With whom? | Anyone who wishes to access the data. | Researchers who provide a methodologically sound proposal. | Investigators whose proposed use of the data has been approved by an independent review committee (learned intermediary) identified for this purpose. | Not applicable |
| For what types of analyses? | Any purpose | To achieve aims in the approved proposal. | For individual participant data meta-analysis. | Not applicable |
| By what mechanism will data be made available? | Data are available indefinitely at (Link to be included). | Proposals should be directed to xxx@yyy. To gain access, data requestors will need to sign a data access agreement. Data are available for 5 years at a third party website (Link to be included). | Proposals may be submitted up to 36 months following article publication. After 36 months, the data will be available in our University’s data warehouse but without investigator support other than deposited metadata. Information regarding submitting proposals and accessing data may be found at (Link to be provided). | Not applicable |

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