**Draft revision of the data sharing section in the ANZCTR**

In this section, we will add a brief description of individual participant data, data sharing and how it is possible through the HDA for certain Australian trials (e.g. link to ARDC or ARDC-endorsed videos).

If the study sponsor answers ‘yes’ to the first question, all 6 follow-on questions are mandatory – as per WHO and ICMJE requirements.

**Will individual participant data be available?**

Yes  
No

If study sponsor replies ‘no’, they are asked to provide a reason in a free-text box.

If the study sponsor replies ‘yes’, they need to provide a response to all questions below.

**What individual participant data will be shared?** (select any that apply)

Contingent on the specific data request being assessed and approved by the trial custodian or data sharing committee   
Individual participant data, after deidentification, that underlie the:  
       Published results  
       Primary outcome(s)  
       Safety data  
       Other data (to provide free-text field for these details)  
All individual participant data collected, after deidentification  
Other (to provide free-text field)  
  
**What types of analyses would be possible with the shared individual participant data?** (select any that apply)

Unrestricted use (any purpose)  
To achieve aims in the approved protocol or data request  
IPD meta-analysis or systematic review   
  
Audit or verification of results  
Other (to provide free-text field)

**When would individual participant data be made available?**

|  |  |  |  |
| --- | --- | --- | --- |
| **From:** Dropdown options | At the end of the study | **To:**  Dropdown options | Indefinitely |
| After completion of first data analysis | Specific date (give option for days/months, years or calendar) |
| After publication of main results | Not yet decided |
| Specific date (calendar option) |  |
| Other (free text) | Other (free text) |
|  |  |

**To whom will the individual participant data be made available?** (choose any that apply)

Anyone who wishes to access the data  
Investigators with a scientifically sound proposal  
Investigators whose proposed use of data has been approved by the trial custodian or data sharing committee  
Other (free text field)

**Where or how can individual participant data be requested or obtained?** (select any that apply)

|  |  |  |  |
| --- | --- | --- | --- |
| **Data request** | **Contact** | **Role or other details** |  |
| Data repository | URL | Additional details | - |
| Email | Email address | Role | *Options to choose from:* |
| Principal investigator |
| Senior author |
| Study sponsor |
| Other (free-text) |
| Post | Name and address | Role | *Options to choose from:* |
| Principal investigator |
| Senior author |
| Study sponsor |
| Other (free-text) |
| Other | … | … | … |