Understanding Data Sharing Statements (IPD Tool)

As a condition of publication of clinical trial results, ICMJE journals require that a Data (IPD) Sharing Statement be included in the ClinicalTrials.gov registration.

- Applies to clinical trials that begin enrolling participants on or after January 1, 2019.2,3
- The statement must be in the original ClinicalTrials.gov registration.
- The answer to “will data be available?” must be No or Yes. (per official ICMJE correspondence – even though ClinicalTrials.gov provides an “Undecided” option)
- The answer can change; explain in the Plan Description when updating the record.
- Should match the data sharing statement required to be submitted (as of July 1, 2018) with the results manuscript for publication in ICMJE journals.2,3

IPD Sharing Statement Examples

The statement consists of answers to seven questions; see the ICMJE press release for complete details, including the following table2 with examples of statements that fulfill their requirements:

<table>
<thead>
<tr>
<th>ICMJE Questions</th>
<th>Example 1</th>
<th>Example 2</th>
<th>Example 3</th>
<th>Example 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Will individual participant data be available (including data dictionaries)?</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>What data in particular will be shared?</td>
<td>All of the individual participant data collected during the trial, after deidentification.</td>
<td>Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices).</td>
<td>Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices).</td>
<td>Not available</td>
</tr>
<tr>
<td>When will data be available (start and end dates)?</td>
<td>Immediately following publication. No end date.</td>
<td>Beginning 3 months and ending 5 years following article publication.</td>
<td>Beginning 9 months and ending 24 months following article publication.</td>
<td>Not applicable</td>
</tr>
<tr>
<td>With whom?</td>
<td>Anyone who wishes to access the data.</td>
<td>Researchers who provide a methodologically sound proposal.</td>
<td>Investigators whose proposed use of the data has been approved by an independent review committee (“learned intermediary”) identified for this purpose.</td>
<td>Not applicable</td>
</tr>
<tr>
<td>For what types of analyses?</td>
<td>Any purpose.</td>
<td>To achieve aims in the approved proposal.</td>
<td>For individual participant data meta-analysis.</td>
<td>Not applicable</td>
</tr>
<tr>
<td>By what mechanism will data be made available?</td>
<td>Data are available indefinitely at [Link to be included].</td>
<td>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]).</td>
<td>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]).</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

* These examples are meant to illustrate a range of, but not all, data sharing options.

1 IPD = Individual Participant Data; “data sharing statement” and “IPD sharing statement” are synonymous

This template is based on content and design developed by Stanford University.
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Mapping the Data Sharing Statement in ClinicalTrials.gov

ClinicalTrials.gov provided the **IPD Sharing Statement Module** to accommodate data sharing statements.

1. Log into the Protocol Registration and Results System (PRS)
2. Open the ClinicalTrials.gov study record
3. Open the Protocol Section, then Edit the IPD Sharing Statement Module
4. Answer the ICMJE questions using the corresponding PRS data elements:

   - **ICMJE Questions**
     - Will individual participant data be available (including data dictionaries)?
     - What data in particular will be shared?
     - What other documents will be available?
     - When will data be available (start and end dates)?
     - With whom?
     - For what types of analyses?
     - By what mechanism will data be made available?

   - **ClinicalTrials.gov PRS**

   - **Plan Description:**
     - Describe the IPD sharing plan, including what IPD are to be shared with other researchers.

   - **Supporting Information:**
     - Check all types of supporting information that will be shared.
       - Study Protocol
       - Statistical Analysis Plan (SAP)
       - Informed Consent Form (ICF)
       - Clinical Study Report (CSR)
       - Analytic Code

   - **Time Frame:**
     - Describe when the data will become available and for how long.

   - **Access Criteria:**
     - Can explain planned mechanism for sharing in Access Criteria at the time of registration; URL can be added later (if any).

   - **URL:**
     - Web address (if any) with additional information about the plan to share IPD.

   - **Questions?**
     - [INSERT INSTITUTIONAL CONTACT INFORMATION (Name(s)/Title(s)/Phone Number(s)/Email Address(es))]

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4 Mapping is based on ClinicalTrials.gov Protocol Data Element Definitions ([https://register.clinicaltrials.gov/prs/html/definitions.html](https://register.clinicaltrials.gov/prs/html/definitions.html))

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