

Using Vivli to meet ICMJE Data Sharing Requirements

In June of 2017, the International Committee of Medical Journal Editors, or ICMJE, released [new requirements for data sharing statements](#), for submissions to their publications. The ICMJE represents the most well-respected and influential publications in the biosciences, including [the New England Journal of Medicine](#); [the Lancet](#); [Annals of Internal Medicine](#); [the BMJ](#); and [PLOS Medicine](#):



These publications, and the many others which follow their lead, now require the inclusion of a data sharing statement in all submissions for publication. ICMJE publication editors may take these statements into consideration, when making editorial decisions. Researchers should also know that as of **1 January 2019**, ICMJE requires inclusion of your data sharing statement at the time of trial registration.

In their guidance to researchers, the ICMJE notes that when it comes to data sharing, “undecided is not an acceptable answer.” Rather than remaining “undecided,” see the chart below to learn how to use Vivli in completing your ICMJE data sharing statement:

ICMJE Question	How to respond, if using Vivli to share your data:
Will IPD (and data dictionaries) be made available?	Yes
What data in particular will be shared?	Final cleaned individual participant-level data, *anonymized
What other documents will be made available?	Final protocol, statistical analysis plan, and the data dictionary. (Note: additional documents such as CRFs and analytic code may also be included.)
When will data be made available?	X months /years after study completion
With whom?	Anyone with the relevant skillsets to conduct the analysis, who submitted an approved proposal on Vivli. Proposals are submitted on vivli.org.
For what types of analysis?	To achieve the aims and objectives in the scientific proposal as approved via Vivli.

<p>By what mechanism will data be made available?</p>	<p>Data are made available via a secure research environment or downloaded (data contributor to choose appropriate option).</p> <p>Once a request is approved, a Data Use Agreement must be executed.</p>
<p>What is the availability of the data?</p>	<p>The dataset(s) from the *DC name* trial(s) are made available through a controlled access method that follows best practices of sharing human-subjects clinical research data. This method protects participants' privacy and the request has been approved by an independent review panel or accelerated review (data contributor to choose appropriate option). To request the data, researchers should apply using this same controlled access method via https://vivli.org/</p>

For more information or assistance in using Vivli to meet data sharing requirements, email support@vivli.org.

* Vivli [partners](#) with [Real Life Sciences](#), [Privacy Analytics](#) and [Instem](#), to provide anonymization of complete clinical research data at a discounted rate for researchers who store and share their data on Vivli. Contact support@vivli.org for more information.