

Data Sharing Statement

Data

Data available: Yes

Data types: Deidentified participant data, with the exception of pharmacokinetic or genetic data.

How to access data: For details on submitting a request, see the instructions provided at www.vivli.org.

When available: Data are available to request 6 months after the indication studied has been approved in the US and EU and after primary publication acceptance, whichever is later. No expiration date of data requests is currently set once data are made available.

Supporting Documents

Document types: None

Additional Information

Who can access the data: Access is provided after a proposal has been approved by an independent review committee identified for this purpose and after receipt of a signed data sharing agreement.

Types of analyses: For specified purpose.

Mechanisms of data availability: Access is provided after a proposal has been approved by an independent review committee identified for this purpose and after receipt of a signed data sharing agreement. Data and documents, including the study protocol, statistical analysis plan, clinical study report, blank or annotated case report forms, will be provided in a secure data sharing environment.