Data Sharing Statement

Data

Data available: Yes

Data types: Deidentified participant data

How to access 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. Data and documents, including the study protocol, statistical analysis plan, clinical study report, and blank or annotated case report forms, will be provided in a secure data sharing environment. For details on submitting a request, see the instructions provided at www.vivli.org.

When available: beginning date: 05-01-2025

Supporting Documents
Document types: None

Additional Information

Who can access the data: Anyone requesting the data with a proposal approved by an independent review committee identified for this purpose and after receipt of a signed data sharing agreement.

Types of analyses: Lilly provides access to all individual participant data collected during the trial, after anonymization, for purposes approved of in the reviewed proposal, with the exception of pharmacokinetic or genetic data.

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, and blank or annotated case report forms, will be provided in a secure data sharing environment.

Any additional restrictions: Lilly provides access to all individual participant data collected during the trial, after anonymization, with the exception of pharmacokinetic or genetic data. 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. 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, and blank or annotated case report forms, will be provided in a secure data sharing environment. For details on submitting a request, see the instructions provided at www.vivli.org.