Data Sharing Statement

Hollander. Balovaptan vs Placebo for Social Communication in Childhood Autism Spectrum Disorder. *JAMA Psychiatry*. Published July 06, 2022. doi:10.1001/jamapsychiatry.2022.1717

Data
Data available: Yes
Data types: Deidentified participant data
How to access data: For eligible studies qualified researchers may request access to individual patient level clinical data through a data request platform. At the time of writing this request platform is Vivli. https://vivli.org/ourmember/roche/. For up to date details on Roche's Global Policy on the Sharing of Clinical Information and how to request access to related clinical study documents, see here: https://go.roche.com/data_sharing. Requests for data underlying the demographic, baseline and safety data in this publication requires a detailed, hypothesis-driven statistical analysis plan that is collaboratively developed by the requestor and company subject matter experts. Direct such requests to autismdatarequests@roche.com for consideration. Anonymized records for individual patients across more than one data source external to Roche can not, and should not, be linked due to a potential increase in risk of patient re-identification.
When available: With publication

Supporting Documents
Document types: None

Additional Information
Who can access the data: For eligible studies qualified researchers may request access to individual patient level clinical data by providing a data request with a commitment to publish their findings through a data request platform. Requests for data underlying the demographic, baseline and safety data in this publication requires a detailed, hypothesis-driven statistical analysis plan that is collaboratively developed by the requestor and company subject matter experts.
Types of analyses: For eligible studies qualified researchers may request access to individual patient level clinical data through a data request platform. Requests for data underlying the demographic, baseline and safety data in this publication requires a detailed, hypothesis-driven statistical analysis plan that is collaboratively developed by the requestor and company subject matter experts.
Mechanisms of data availability: Available studies are listed and searchable on the Vivli Platform. Data requestors should use the Vivli Data request form to request company's data package(s). If approved, requesters will need to sign a Data Use Agreement and the anonymized data will be shared in the Vivli secure research environment. Requests for data underlying the demographic, baseline and safety data should direct such requests to autismdatarequests@roche.com for consideration.
Any additional restrictions: A condition of providing the data is that the external requester seeks publication of their research results.