

Data Sharing Statement

Montalban X, Arnold DL, Weber MS, et al. Placebo-Controlled Trial of an Oral BTK Inhibitor in Multiple Sclerosis. N Engl J Med. DOI: 10.1056/NEJMoa1901981.

Question	Authors' Response
Will the data collected for your study be made available to others?	No
Would you like to offer context for your decision?	Evobrutinib is under clinical investigation and has not yet been approved in any sought-after indication by any health authority worldwide. Therefore, there is no plan for data-sharing at this point in time. Please note that for all new products or new indications approved in both the European Union and the United States after January 1, 2014, Merck KGaA will share patient level, study level data after de-identification, as well as redacted study protocols and clinical study reports from clinical trials in patients. These data will be shared with qualified scientific and medical researchers, upon researcher's request, as necessary for conducting legitimate research. Such requests must be submitted in writing to the company's data sharing portal (https://www.merckgroup.com/en/research/our-approach-to-research-and-development/healthcare/clinical-trials/commitment-responsible-data-sharing.html) and will be internally reviewed regarding criteria for researcher qualifications and legitimacy of the research purpose.
Which data?	—
Additional information about data	—
How or where can the data be obtained?	Evobrutinib is under clinical investigation and has not yet been approved in any sought-after indication by any health authority worldwide. Therefore, there is no plan for data sharing at this point in time. Please note that for all new products or new indications approved in both the European Union and the United States after January 1, 2014, Merck KGaA will share patient level, study level data after de-identification, as well as redacted study

	protocols and clinical study reports from clinical trials in patients. These data will be shared with qualified scientific and medical researchers, upon researcher's request, as necessary for conducting legitimate research. Such requests must be submitted in writing to the company's data sharing portal (https://www.merckgroup.com/en/research/our-approach-to-research-and-development/healthcare/clinical-trials/commitment-responsible-data-sharing.html) and will be internally reviewed regarding criteria for researcher qualifications and legitimacy of the research purpose
When will data availability begin?	N/A
When will data availability end?	—
Will any supporting documents be available?	—
Which supporting documents?	—
Additional information about supporting documents	—
How or where can supporting documents be obtained?	—
When will supporting documents availability begin?	—
When will supporting documents availability end?	—
To whom will data be available?	—
For what type of analysis or purpose?	—
By what mechanism?	—
Any other restrictions?	—
Additional information	—

This statement was posted on May 10, 2019, at NEJM.org.