

PLEASE READ THIS FIRST: BioMarin Data Sharing Request Policy

BioMarin DATA SHARING REQUEST POLICY

BioMarin gives qualified scientific researchers access to patient-level data collected in clinical trials to provide additional opportunities for conducting research that can improve patient care and help advance medical science. Upon request and subject to the circumstances identified below, BioMarin will provide access to patient-level data to qualified researchers with a scientifically valid research proposal (which includes their statistical analysis plan) for clinical trial data that has been published in manuscript form on or after January 1, 2019. Data will be made available beginning 6 months and ending 2 years after publication in a peer reviewed journal. Since respect for patient privacy is a paramount concern, all necessary measures are taken to ensure that privacy is safeguarded.

Certain circumstances may prevent BioMarin from fulfilling data requests. These circumstances may involve:

- Clinical data for which anonymization is unreasonably difficult, there is a reasonable likelihood of re-identification (e.g., small studies, single-center studies, studies terminated early for lack of enrollment, clinical studies of rare diseases, or studies for which data does not exist in a format that can be readily anonymized), or there is a reasonable likelihood of otherwise violating the privacy rights of individuals;
- Clinical data that have been collected subject to legal, regulatory, contractual, or consent provisions or considerations that prevent transfer to third parties;
- Locally administered studies in which data and results are only available in languages other than English;
- Case narratives, documentation for adjudication, imaging data (e.g., x-rays, MRI scans, etc.), genetic data, and exploratory biomarker data; or
- Substantial practical constraints to providing technical data access (e.g., older, pre-electronic data for which files cannot be located).
- Any request for data associated with any ongoing development program unless made six (6) months or later following approval of the relevant product;
- Or Any request other than for non-commercial, academic purposes.

Where BioMarin has a co-research, co-development, or co-marketing/co-promotion agreement or where the product has been out-licensed, it is recognized that the responsibility for disclosure may be dependent on the agreement between BioMarin and another party or parties. Under these circumstances, BioMarin will make reasonable efforts to gain agreement to share data in response to requests.

Researchers seeking access to patient-level data or other information such as clinical study reports are required to enter into a Data Access Agreement committing the applicant to use the data only for the stated research purposes and not to disclose the data to third parties.