

Requesting Clinical Data Sharing

Requests for clinical data sharing must be submitted electronically (doc- or PDF-files) to *ClinicalTrialPortal@grunenthal.com* using the Grünenthal Research Proposal Form.

Access to patient- or trial-level data will not be granted if any of the following apply:

- There is a reasonable likelihood that individual patients could be re-identified.
- Access would violate the patients' informed consent.
- Access to patient-level data might jeopardize incentives for future investment in biomedical research.
- There are contractual or legal or consent provisions that prohibit the transfer of clinical data to third parties. If co-development agreements or other legal restrictions prohibit the sharing of requested clinical data, summary information will be offered instead (where possible).
- Provision of the requested access would cause unacceptable costs.

The submitted research proposal must enable an assessment of:

- The scientific rationale for the proposed research and its relevance to medical science or patient care.
- The research team's understanding of the existing data and the ability of the proposed research to meet the stated objectives while avoiding all sources of bias.
- Real or potential conflicts of interest that may affect the planning, conduct or interpretation of the research, as well as proposals to manage these conflicts of interest.
- The qualifications and experience of the research team planning to conduct the research.

To enable a thorough review and decision by Grünenthal and then by the Scientific Review Board (SRB) members prior to the SRB meeting, assessment of the requests for clinical data sharing will require up to 3 months.

All parties identified in approved research proposals will be required to sign a Data Sharing Agreement before any clinical data is shared.

Where possible, access to the requested clinical data will be provided within 3 months of the SRB approval. Access to complex or extensive sets of clinical data may require up to 12 months.

Depending on the data requested, there may be different technical methods for access to be provided. The technical method for access must be agreed between the requestor and Grünenthal on a case by case basis.