

REQUESTING ACCESS TO CLINICAL DATA

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 clinical 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 might jeopardize incentives for future investment in biomedical research.
- There are contractual or legal or consent provisions that prohibit transfer to third parties. Where this applies, summary information will be offered instead where possible.
- Where provision of the requested data 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 and patient care.
- The understanding of the existing data and the ability of the proposed research to meet the stated objectives whilst avoiding all sources of bias.
- The publication plan for the research.
- 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.
- The qualifications and experience of the research team planning to conduct the proposed research.

Assessment of the requests for clinical data sharing will require up to 3 months.

Where possible, access to the requested clinical data will usually be provided within 3 months of the Scientific Review Board approval. However, access to complex or extensive sets of clinical data may require up to 12 months.