

GRÜNENTHAL PUBLIC DISCLOSURE DECLARATION

The sharing of health information is fundamental for the good functioning of healthcare services, for patients' safety, and to advance research and improve public health.

Grünenthal is committed to disclose health information, in line with all applicable laws and regulations, including data privacy laws. This includes the results from clinical trials for which Grünenthal is responsible for the data.

Grünenthal commits to the below items for interventional clinical trials (Phase I and beyond) investigating authorized treatments, non-authorized used of authorized treatments, and investigational medicinal products for which Grünenthal is responsible for the data:

- 1) To register all clinical trials with first protocol approval from 2003 onwards in a primary internet registry endorsed by the World Health Organization (WHO) before enrollment of the first subject.
- 2) To publicly post expert summaries of the outcomes for all primary and secondary outcome measures, irrespective of outcome, in the publicly-accessible *Grünenthal Clinical Trial Portal* within 30 months (Phase I trials) or 12 months (Phase II-III trials) of trial completion.
- 3) To publicly post lay readable summaries of key results, in the languages used in the trial, in the publicly-accessible *Grünenthal Clinical Trial Portal* within 30 months (Phase I trials) or 12 months (Phase II-III trials) of trial completion.
- 4) To give trial subjects, via the principal investigator, access to their health data collected during the clinical trial.
- 5) To share upon request clinical study reports issued from 2003 onwards of clinical trials submitted in support of authorized treatments in the EU and US (unless no plans to submit in the second region):
 - This sharing will be subject to contractual, security, and privacy controls to protect personal data and to prevent commercial use of the shared information.
 - Personal data in shared clinical study reports will be redacted.

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- This sharing will be no earlier than 30 months (Phase I trials) or 12 months (Phase II-III trials) after trial completion.
- 6) For clinical trials conducted in support of authorized treatments in the EU and US (unless no plans to submit in the second region) only, to share upon request data including individual patient-level data:
- This sharing will be subject to contractual, security, and privacy controls to protect personal data and to prevent commercial use of the shared information.
 - Personal data in individual patient-level data will be anonymized.
 - Access will be subject to approval by a 2-step process including review by an independent review board to assess the scientific question and the value the data will create for patients and the clinical decision making process. Membership of the board, will be made public.
 - The outcomes of all requests for access will be made public.
- 7) To submit results for primary and secondary outcome measures, irrespective of outcome, for publication to academic journals wherever possible, ideally to journals providing free public full text access.
- 8) To publicly post annual reports of compliance with this declaration (these reports will summarize the outcomes of any audits and monitoring performed on compliance with this declaration).

Compliance with this declaration

The requirements of this declaration are anchored in written standard operating procedural documents. As part of the Grünenthal quality management system, compliance with these requirements will be subject to regular audits.