SDN-PUBDISCL-DECLARATION-01

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, this includes the results from Grünenthal-sponsored clinical trials.

Grünenthal commits to the below items for Grünenthal-sponsored interventional clinical trials (Phase I and beyond, worldwide) investigating licensed treatments, unlicensed used of licensed treatments, and unlicensed treatments:

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; ongoing or completed clinical trials not already meeting this commitment will be registered retrospectively by the end of 2018.
2) To publicly post expert summaries of the outcomes for all predefined 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, upon request via the principal investigator, access to their health data collected during the clinical trial.
5) To share upon request clinical study reports for clinical trials that had first protocol approval from 2003 onwards:
    - This sharing will be subject to contractual controls to protect personal data and to prevent commercial use of the shared information.
    - Personal data in shared clinical study reports will be masked.
    - This sharing will be no earlier than 30 months (Phase I trials) or 12 months (Phase II-III trials) after trial completion.

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6) To share upon request clinical data (including individual patient data) for clinical trials with first protocol approval after 15 July 2014 that were submitted in support of licensed treatments:
    - This sharing will be subject to contractual controls to protect personal data and to prevent commercial use of the shared information.
    - Personal data in individual patient data will be de-identified (anonymized).
    - Access will be subject to approval by a 2-step process including review by an independent Scientific 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, including any existing board member relationships with Grünenthal, will be publicly posted.
7) To consider on a case-by-case basis requests for access to documents/data for clinical trials not explicitly covered by this declaration, e.g., requests for access to individual patient data from clinical trials investigating unlicensed uses of licensed treatments and unlicensed treatments.
8) To submit results for all predefined outcome measures, irrespective of outcome, for publication to academic journals wherever possible, ideally to journals providing free public full text access.
9) To publicly post the outcomes of all requests for access to clinical study reports and/or clinical data and 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 internal audits.

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