Meeting the EFPIA Principles for Responsible Clinical Trial Data Sharing

Grünenthal has committed to meet the *EFPIA Principles for Responsible Clinical Trial Data Sharing*, i.e.:

- to enhance data sharing with researchers,
- to enhance public access to clinical trial information,
- to share results with subjects who participate in clinical trials,
- to publish clinical trial results.

This document describes how Grünenthal will meet these principles for clinical trials sponsored by Grünenthal and submitted in support of marketing authorizations held by Grünenthal in the United States (US) and/or the European Union (EU).

For a definition of “clinical trials”, see the EU Regulation No. 536/2014.

Enhancing data sharing with researchers

Upon request from qualified scientific and medical researchers Grünenthal will share patient-level data, trial-level data, and related documentation (e.g., protocols) as necessary for conducting legitimate research.

The process for requesting access to clinical trial data and for assessing the legitimacy of the proposed research is described on the freely accessible Grünenthal *Clinical Trial Portal*. This process requires an independent Scientific Review Board to determine the legitimacy of the research proposal and the adequacy of the researcher(s) qualifications.

All subject-level data that is shared with researchers will be protected by anonymization and (if possible) contractually.

Enhancing public access to clinical trial information

Clinical trial information will be made publically accessible by:

- Registering clinical trials and disclosing clinical trial information on freely accessible internet registries, e.g., ClinicalTrials.gov.
- Posting expert (ICH E3 synopses) and lay-language summaries of clinical trial results on either a freely accessible internet registry or on the freely accessible Grünenthal *Clinical Trial Portal*.

Sharing results with subjects who participate in clinical trials

Trial-level results will be shared with subjects who participate in clinical trials by posting lay-language summaries on the freely accessible Grünenthal *Clinical Trial Portal*.

Publication of clinical trial results

Trial results (for all primary and secondary endpoints) of completed clinical trials will be submitted for publication in peer-reviewed journals wherever possible. If not accepted for publication or if publication in peer-reviewed journals is considered not possible, public access to the results will be made publically accessible by posting an expert summary (ICH E3 synopsis) of the results on the Grünenthal *Clinical Trial Portal*.

References

- EFPIA Principles for Responsible Clinical Trial Data Sharing (July 2013).
- ICH E3: Structure and Content of Clinical Study Reports; note for guidance on structure and content of clinical study reports. CPMP/ICH/137/95 (July 1996)
- Regulation (EU) No. 536/2014 Repealing Directive 2001/20/EC (April 2014).