LIST OF TRIALS ACCESSIBLE FOR DATA SHARING

Requests for access to clinical data will be accepted for clinical trials which meet all of the following criteria:

• Were interventional clinical trials conducted in patients.
• Were sponsored by Grünenthal.
• Had first protocol approval after 15 July 2014.
• Were submitted by Grünenthal in support of licensed treatments in the European Union or the United States.

Current trials eligible for data sharing are:

- KF5503-73
  EudraCT number 2014-002259-24
  Open-label evaluation of the population pharmacokinetic profile, safety, tolerability, and efficacy of intravenous tapentadol solution for injection for the treatment of post-surgical pain in children aged from birth to less than 2 years, including preterm neonates

- KF5503-75
  EudraCT number 2019-000205-77
  Open-label investigation of the pharmacokinetic profile, safety, tolerability, and efficacy of multiple administrations of tapentadol oral solution used for treatment of acute pain in children aged 2 years to less than 7 years

Notes:

Data from clinical trials is also accessible in clinical study reports for clinical trials with first protocol approval from 2003 onwards. For further details, see, “Requests for Access to Clinical Data”. 