



CLINPHARM SUPPORT GmbH
Leimenstrasse 57
CH-4051 Basel

What do we offer?

We have specialized in conducting clinical pharmacology studies and offer complete package service or support with individual steps:

- Protocol design
- Protocol writing as well as design and production of clinical report forms
- Clinical study execution according to Good Clinical Practice (GCP)
- Chemical drug analysis according to Good Laboratory Practice (GLP)
- Statistical analysis according to regulatory requirements
- Report writing according to ICH guidelines
- Compilation of expert reports in support of the registration process

Our Services include clinical pharmacology studies of all development phases (I-III) and their conduct according to the ICH Tripartite Guideline on GCP (e.g. bioequivalence, drug-drug interactions, drug-food interaction, “bridging” studies [Asians vs. Caucasians], etc.). Moreover, we perform exploratory ‘proof of concept’ studies for tolerability and efficacy. We deliver the scientific base for the design, evaluation and interpretation of our studies and assist during or with interactions with the regulators.

CLINPHARM SUPPORT GmbH (CS) is a small internationally based company established in 1996 with its headquarter in Basel and a branch in Budapest (CLINPHARM SUPPORT Gyógyszeripari Kereskedelmi Képviselet, H-1082 Budapest). The team of CS consists of internationally recognized clinical pharmacology and clinical experts as well as managers with many years of working experience in the pharmaceutical industry. We are specialized in all clinical pharmacology aspects of study design, evaluation and study interpretation. Our expert team also supports interactions with the regulators.

CS executes its clinical studies according to ICH-GCP and FDA standards in well recognized clinical units in Hungary. The clinical units, which passed successfully local and international audits, allow short-term and long-term hospitalisation for up -to 4 weeks. The execution and local control of our studies lays in the hands of our branch in Budapest. The branch is headed by a former director of clinical operations of QUINTILES Ltd. The chemical laboratories used by CS in Switzerland and Germany are, for their adherence to Good Laboratory Practice (GLP), under the control of ANALYTIK-SERVICE, Berlin.

We have presently the capacity of up -to 10 studies per year. Our aim is to built strong relationships with our sponsors resulting in long-term partnerships.

CS team: Dr. Klaus Stoeckel, CH-4051 Basel; Prof. Dr. David Jardine Edwards, Wayne State University Detroit, MI 48202; Prof. Dr. William L. Hayton, The Ohio State University, Columbus Ohio; Prof. Dr. Patrick John McNamara, University of Kentucky, Lexington, KY 40536; Prof. Dr. David Lalka, West Virginia University, Morgantown, WV 26506; Prof. Dr. Nicholas H. G. Holford, University of Auckland, Auckland New Zealand.