

Regulatory and Clinical Medical Writing

The clear and accurate description and interpretation of your key data are critical during clinical development and for supporting new drug registration. Based upon our **track record of successful drug submissions**, we can offer expertise in drafting a variety of supportive documents required during your drug's clinical development.

Examples include:

- CTD format drug submissions according to ICH guidance and the required national and international guidelines

- Clinical study reports
- Clinical study protocols
- Informed consent documents
- Investigator's brochures
- Clinical development plans.

We focus not only on the details of producing the **content**, but also on the **process management** to ensure timely review and integration of comments from the study team and upper management. In the end, you receive integrated, guideline compliant documents that **maximise your drug's potential**. By foreseeing what drug regulatory authorities will require from your documentation during the various stages of clinical development, we can ensure the best chances of a successful registration the first time around. In this way, you ultimately save time and money, and free yourself up for other tasks requiring your attention.

