Technical Writing Services with a Clinical Pharmacology Focus

Allucent has extensive experience with clinical pharmacology studies and analyses needed to support drug development programs and messaging of key data to support the product label.

Our authoring tasks span the entire process from drafting, reviewing, and updating to full writing of regulatory documents, supporting clients with documents that meet industry standards in an efficient manner. Our technical writers are experienced in clinical pharmacology documents and work closely with expert input in a team approach to provide high quality deliverables ready for submission and publication.

Documents Supported

- Phase 1 study synopses
- Phase 1 protocols
- Phase 1 clinical study reports (CSRs)
- Regulatory modules (2.7.1, 2.7.2 and relevant nonclinical modules) including 505(b)(2)
- Pharmacokinetic (PK), Population PK (PopPK)/clinical pharmacology related authoring for CSRs and stand-alone reports
- Analysis plans for PK, PopPK and QT analyses
- Investigator brochure (IB) contributions
- Thorough QT (TQT) waivers
- Manuscripts
- Abstracts
- Posters

Technical Services

- Multiple collaborative integrated tools, including those to facilitate client review
- Study synopsis templates
- Literature searches
- Quality control (grammar, style, format)
- Document formatting
- Technology:
  - Consistency checks using PerfectIt software
  - Reference management using EndNote software
  - Word Macros

Allucent®
Helping bring new therapies to light

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