



## Medical Writing.

Premier Research's global medical writing team produces expert clinical documentation that is clear, concise, and scientifically accurate with format and content in strict accordance with current regulations and guidance.

### Services

- Clinical Study Reports
- Protocols
- Investigator Brochures
- Manuscripts (peer-reviewed journals)
- NDAs in CTD format and aNDAs
- Risk Evaluation and Mitigation Strategy (REMS)

### Expertise: The People

- All medical writers are experienced in major therapeutic areas
- Senior writers are scientists and/or medical personnel who have strong analytical and communication skills

### Benefits

- High quality writing services support the conduct of clinical trials, report on their outcomes, and summarize their results
- Proactive participation in and contribution to the project team throughout the study
- Medical writing deliverables are thoroughly reviewed by team members and undergo a thorough quality control review to assure accuracy
- Parallel Processing Approach™ enables reports to be completed within weeks of database lock
- Experience with multiple templates provides documents customized to the specifications of each client

### Case Study: Rapid Clinical Study Report Writing

A pharmaceutical company contracted Premier Research to write a clinical study report in patients with Alzheimer's Disease. Using the Parallel Processing Approach, Premier Research wrote the majority of the report prior to database lock using information from the existing protocol, SAP, and CRF. As the statistical team worked to finalize the tables and listings after database lock, the medical writing department worked in teams to format the tables and listings and write, QC, and revise the first draft of the final report.

We delivered the first draft of the final report to the sponsor within two weeks of receiving the final statistical tables. The dedication of the entire Premier Research team helped streamline the process.

### Premier Research

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