AVANIA
ADVANCING YOUR MEDICAL TECHNOLOGY

When You Need to Advance Your Technical and Medical Writing, It Takes Avania

Avania Has the Writing Skills and Expertise You Need

Successful clinical documentation takes a team with deep and diversified medical writing expertise. **It Takes Avania.**

Our medical writers work closely with our statisticians, data analysts, and clinical operations team to ensure that clinical trial documentation aligns with all perspectives.

Medical Writing at Avania

Avania offers precision writing supported by proven processes and backed by years of experience. Whether you are looking for services directly related to the clinical trials that you are considering or documentation related to your product's technical file, our team of dedicated medical writers are available to immediately support your needs.

Our medical writers are trained on ISO 14155 and ICH-GCP, and are qualified according to the MEDDEV 2.7/1 Revision 4 and the European Medical Device Regulation (MDR) 2017/745 requirements. Our team possesses a rare combined knowledge of research methodology, information management, regulatory requirements, and medical writing. We offer a high level of flexibility and can provide you medical writing services in accordance with your standard operating procedures or ours, as you prefer.

Output Documentation

Avania's medical writers can help you with a variety of documents. Prior to the start of your clinical trials, you may be looking for support in getting a study designed, a clinical evaluation plan developed, a trial protocol outlined, or an investigator's brochure written. Then, following your clinical trials, you may be interested in support in the analysis and write-up of the data in the form of a study report or a scientific manuscript. And, especially for those products intended to be marketed in Europe or Australia, you may need some expertise around getting your clinical evidence lined up, whether by means of a clinical evaluation report, a summary of safety and clinical performance, and/or a patient information letter. The writing and editing of these documents (and several others) is part of our day-to-day business, and we would be delighted to support your efforts.

Clinical data collection may be required in the premarket or the post-market phase of your product, or both. Avania has experience in the design and conduct of clinical trials in each marketing phase and is able to guide you through the associated requirements.

Avania's Medical Writing team has worked on 150+ clinical evaluations in several therapeutic areas, including:

- Cardiology
- Dermatology
- Gastroenterology
- General surgery (e.g., medical equipment)
- Neurology
- Orthopedics
- Ophthalmology
- Pulmonology
- Radiology
- Reconstructive surgery

Clinical Trial Design

Our years of experience, comprehensive knowledge, and state-of-the-art processes can help you plan an optimal study design to reach your regulatory milestones in the United States, Europe, Australia, and New Zealand. In addition to our internal expertise, we can assist you in getting direct feedback on your study design through meetings with panels of clinical experts.

However, having a general outline of your study design is one thing; having a study protocol ready for regulatory submissions is another. Avania's team of medical writers is well equipped to develop the study protocol that you need according to ISO 14155 and/or ICH-GCP standards, as applicable for the country of conduct.

Clinical Evaluation

The European MDR 2017/745 emphasizes the need to conduct a clinical evaluation on safety and performance, including post-market clinical follow-up, throughout the life cycle of a medical device and regardless of the device's classification. During the clinical evaluation process, all data that could provide information on the clinical safety and performance of the device is analyzed and assessed. The clinical evaluation becomes an integral part of the device's technical file.

Several steps can be identified in the clinical evaluation process, including:

- Development of a clinical evaluation plan
- Conduct of a systematic literature review on the "state of the art"
- Conduct of a systematic literature review to identify clinical performance and clinical safety data not held by the manufacturer
- Analysis of all clinical data to reach conclusions on:
  - Compliance with the General Safety and Performance Requirements
  - Correctness of the contents of information materials supplied to customers
  - Residual risks and uncertainties or unanswered questions, whether these are acceptable for (continued) CE marking, and whether they are required to be addressed during post-market clinical follow up

Avania is an integrated global, full-service CRO with specialized expertise in medical device, novel technology, and combination products. They advance products from feasibility all the way through post-approval in analytics, clinical trials, consulting, regulatory, reimbursement, and more.