



MEDICAL & SCIENTIFIC WRITING

REGULATORY MW ACTIVITIES



Study initiation/development

DEVELOPMENT

- Literature reviews
- Study synopsis, protocols and protocol amendments



SUBMISSION/REVIEW

- Investigator's Brochure
- Case Report Forms
- Informed Consent Forms
- Pediatric Assent Forms
- Educational Material for patients, healthcare professionals, and pharmaceutical company personnel



ACTIVATION



CONDUCT



OVERSIGHT



DATA VERIFICATION & ANALYSIS

Study reporting & publication

PUBLICATION

Study documents

- Clinical Study Reports, including CSR Synopses for public disclosure
- Toxicology and Permitted Daily Exposure (PDE) report
- Clinical Evaluation (CER) and Trend Report for medical devices
- Temporary Use Authorisation (ATU) reports
- Registration of results in Clinical Trials database
- EMA Policy 70 Redactions
- Clinical and non-clinical sections of the Common Technical Document (CTD) including summaries and overviews for the EU and US Regulatory Authorities



Safety documents

- Patient Safety narratives
- Development Safety Update Reports (DSUR)
- Periodic Safety Update reports (PSUR)

Communication documents

- Conference materials: abstracts, posters, slide set presentations
- Papers for submission in peer-reviewed journals, including systematic reviews
- Medical marketing reviews and reports
- Product website content for scientific and patient audiences



ARCHIVE



100+ PEER-REVIEWED PAPERS

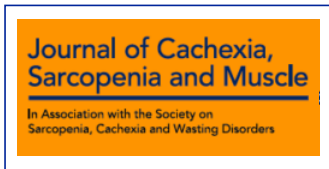
MWs in the team have participated to over 100 peer-reviewed papers in high impact journals



Treatment outcomes in patients with central nervous system metastases from breast cancer in the real-life ESME MBC cohort.
European Journal of Cancer (Impact Factor=7.275)



Modeling individual and relative accuracy of screening tools in geriatric oncology.
Annals of Oncology (Impact Factor=18.2)



Staging of nutrition disorders in non-small-cell lung cancer patients: utility of skeletal muscle mass assessment.
Journal of Cachexia, Sarcopenia and Muscle (Impact Factor=12.5)

TEAM OF EXPERTS



29 MEMBER TEAM

The MW team comprises 29 members



10+ YEARS EXPERIENCE

High level of task-related expertise, with up to 14 years of experience in medical writing



MSC, MD, PHARMD, PHD

Highly qualified MWs with university degrees at the MSc level and above (MD, PharmD or PhD in a life science)



CONTINUING EDUCATION

In addition to internal trainings, team members benefit from high-quality continuing education through training courses, seminars and congresses as those offered by the European Medical Writers Association in areas such as:

- Statistics
- Clinical study methodology
- Medical devices
- Patient reported outcomes