





## 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
- **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

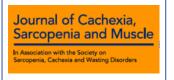


Treatment outcomes in patients with central nervous system metastases from breast cancer in the real-life ESME MBC cohort. *European Journal of Cancer (Impact Factor=7.275)* 



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