Medical writing

A-pharmaconsult provides its expertise for medical writing both for your development projects and your already registered drugs.

- **Non-clinical Modules** (2.4, 2.6 and 4)
- **Clinical Modules** (2.5, 2.7 and 5)
- **Variation applications (safety, clinical, CMC)** & responses to Authorities questions
- MA renewal including **Addendum to the Clinical Overview (ACO)**
- Company Core Data Sheet (**CCDS**) / Core Safety Data Sheet (**CSDS**)
- Periodic Safety Update Report (**PSUR**)

- Product information: **Summary of Product Characteristics** (SmPC), leaflet & labeling
- **Risk management plan/report**
- Environmental Risk Assessments (**ERA**)
- Regulatory compliance for promotional materials

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