



our mission is to support you,
in a rapidly changing environment,
shaping your successful achievements
in the **right way**
for the **right customer**
at the **right time**

Consulting & Medical writing

■ ■ ■ Our services

■ **Medical and Scientific Writing (Journals and Conferences)**

Manuscripts, abstracts and posters
White papers, guidelines, consensus statement...
Meeting transcripts, minutes, executive summaries

■ **Regulatory and pharmacovigilance documents**

Investigational medicinal product dossier
Investigator's brochures
Integrated summaries of safety and efficacy
IND Briefing documents (FDA)
EMA scientific advice documents
Pediatric investigational plan (EMA)
Pediatric Study Plan and Amendments (FDA)
Orphan drug designation (FDA and EMA)
Response to regulatory bodies questions
Periodic benefit-risk evaluation reports (PBRERs)
Development safety update reports (DSURs)
Addendum to clinical overviews (ACO)

■ **In depth data analysis, gap assessment and search for product value**

Due diligence and results analysis
Systematic reviews & meta-analysis
Epidemiology data review
Core Value Dossier
R&D strategic planning

■ **Literature search and review of published data**

■ **Expert Advisory Board set-up, management and support**

... transversality is our strength... your business prosperity and sustainability our goal...

our values

Trust

Passion

Integrity

Creativity

Excellence



partner **4** health

diagnostics/therapeutics development & market access

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Get things done

Get the benefit 