The Medical Writer's Role Across the Drug Development Lifecycle

Communicating complex science from research to real-world care

Drug Development Stages

Preclinical Stage

Documents: Target product profiles, early study protocols, preclinical summaries

Writer's Role:

- Literature synthesis
- Drafting rationale for studies
- Formatting study protocols

Clinical Trials (Phases I–III)

Documents: Protocols, Investigator Brochures (IB), Informed Consent Forms (ICF), Clinical Study Reports (CSR)

Writer's Role:

- Data interpretation
- Authoring trial documents
- Ensuring ICH-E3 compliance
- Reviewing QC

Regulatory Submissions

Documents: CTD Modules (2.5, 2.7), Risk Management Plans (RMPs), Briefing documents

Writer's Role:

- Writing CTD summaries
- Aligning with regulatory guidance
- Reviewing submission-ready documents
- Working with safety and regulatory teams

Post-Marketing (Phase IV)

Documents: PSURs, DSURs, PBRERs, Signal Detection Reports

Writer's Role:

- Writing aggregate safety reports
- Interpreting real-world safety data
- Updating product safety sections

Medical Affairs & Scientific Communication

Documents: Slide decks, FAQs, Patient Information Leaflets, Lay Summaries

Writer's Role:

- Storytelling for healthcare providers
- Plain language communication
- MSL support & training materials

Skills That Power Every Phase

Scientific Accuracy ✔️ **Regulatory Knowledge** 📄 **Literature Review** 📚

Data Interpretation 📊 **Team Collaboration** 🤝 **Clear Communication** 💬

Medical writers are translators of complex science into actionable knowledge