The Role of the Writer in Regulatory Affairs

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Aim

To provide broad information on:

- the role of writers in regulatory affairs
- some of the types of work that writers perform
Regulatory Affairs versus Writing

**RA Managers**
- Liaison between pharmaceutical company and regulatory bodies
- Review
- Summarize
- Manage project eg, MAA
- Guidelines and regulations
- Development plans

**Writers**
- Write Clinical Study Reports
- Write protocols
- Write manuscripts

**Overlap**
- Write Summaries and Overviews
- Write Investigator Brochures
- Paediatric Investigation Plans
The Common Technical Document

Module 1: Administrative information and prescribing information
Module 2: Summaries and overviews
Module 3: Non-clinical study reports
Module 4: Clinical study reports
Module 5: Clinical study reports

Quality
Clinical Study Reports

- CSRs describe the background, rationale, methodology and full results for a clinical study
- Called integrated reports as they cover clinical and statistical aspects
- Guideline ICH E3 on structure and content of CSRs: 53 pages of ‘guidance’
- Main text often around 80-200 pages; complete reports with tables and figures plus appendices (including listing of all recorded data) are usually 1000s of pages
- Move over time from all paper to completely electronic reports – which involve ‘publishing’
- Elapsed time: 2-6 months; writing time 3-8 weeks
Contents of a CSR

- Title page
- Synopsis
- Table of contents
- List of abbreviations and definitions of terms
- Ethics
- Investigators and study administrative structure
- Introduction
- Study objectives
- Investigational Plan
- Study Subjects
- Efficacy Evaluation
- Safety Evaluation
- Discussion and Overall Conclusions
- Tables and Figures
- References
- APPENDICES Including listings
Clinical Study Reports

- Biometrics
- Pharmacovigilance
- Clinical
- Quality Assurance
The Common Technical Document

- Module 1: Administrative information and prescribing information
- Module 2: Summaries and overviews
- Module 3: Quality
- Module 4: Non-clinical study reports
- Module 5: Clinical study reports
<table>
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How Big? How Long?

Module 2.5
Overview
About 30 pages

4-8 weeks

Module 2.7
Summary
50 to 400 pages
(excluding appended tables)

8-20 weeks
## Module 2.7

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<th>Summary of Biopharmaceutic Studies and Associated Bioanalytical Methods</th>
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Module 2.7.3
Summary of Clinical Efficacy

2.7.3.1 Background and Overview of Clinical Efficacy
2.7.3.2 Summary of Results of Individual Studies
2.7.3.3 Comparison and Analyses of Results Across Studies
  2.7.3.3.1 Study Populations
  2.7.3.3.2 Comparison of Efficacy Results of All Studies
  2.7.3.3.3 Comparison of Results in Sub-populations
2.7.3.4 Analysis of Clinical Information Relevant to Dosing Recommendations
2.7.3.5 Persistence of Efficacy and/or Tolerance Effects
2.7.3.6 Appendix
Critical analysis of non-clinical and clinical data in CTD
Discussion and interpretation of data

Strengths and limitations of development programme and results
Benefits and risks
How results support prescribing recommendations
## Module 2.5

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Qualifications and Skills

- Ability to write and enjoy writing!
- Life sciences degree
- Ability to assimilate information quickly
- Attention to detail
- Work under pressure and meet deadlines
- An understanding of statistics
- Proficiency in Microsoft Word
My Route

• Degree in Biochemistry
• DPhil in Neuropharmacology
• Medical publishing and conference organisation (sales!)
• Medical writer and project coordinator in industry
• 16 years as a freelance writer (but long-term relationships with a number of companies)
• Head of Medical Writing at a CRO for 4+ years
• Back to freelance
How to Get Started

• Contract Research Organisations/Companies willing to take on those with aptitude
  – Written a thesis
  – Published papers
  – Be prepared to take a test

• EMWA

• Training Positions for Regulatory Staff
A Final Word

Jobs in regulatory/medical writing are not for those who want to lock themselves away and work in isolation.

Working from home is common, but communication is crucial.