The Role of the Writer in Regulatory Affairs

Julie Bowdler

18 May 2015

How I became a regulatory writer

- Degree in Biochemistry
- DPhil in Neuropharmacology
- Medical publishing and conference organization (sales and account/project management)
- 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 4.5 years
- Back to freelance status in 2007

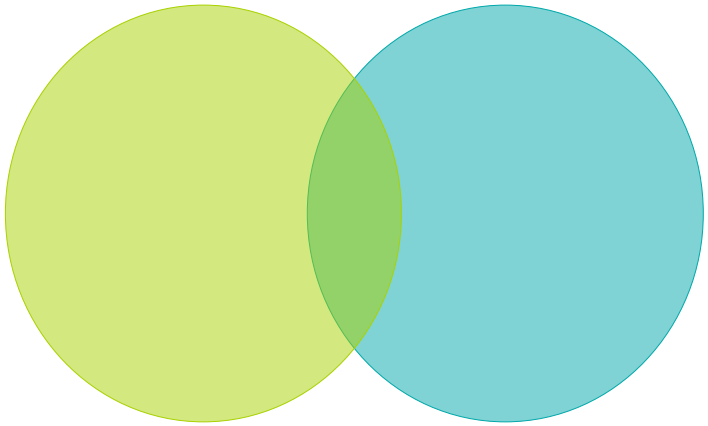
Aims

- Show there is an alternative to Med Comms!
- Indicate where a writer can fit into Reg Affairs
- Give an idea of some of the types of projects

Regulatory Affairs versus Writing

RA Managers

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



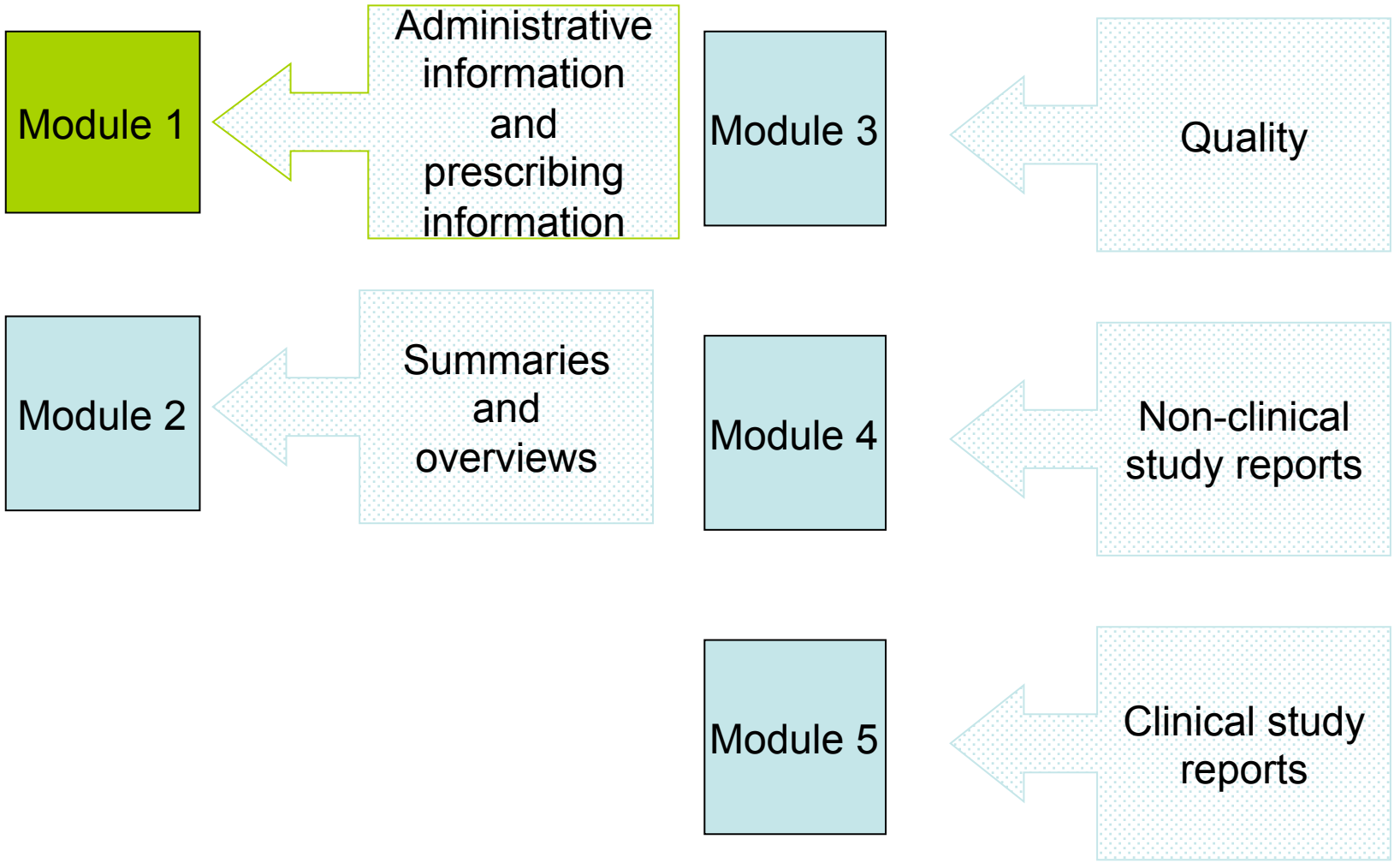
Writers

Write Clinical Study Reports
Write protocols
Write manuscripts
Write literature reviews

Overlap

Write Summaries and Overviews
Write Investigator Brochures
Write Paediatric Investigation Plans
Write Briefing Books
Write responses

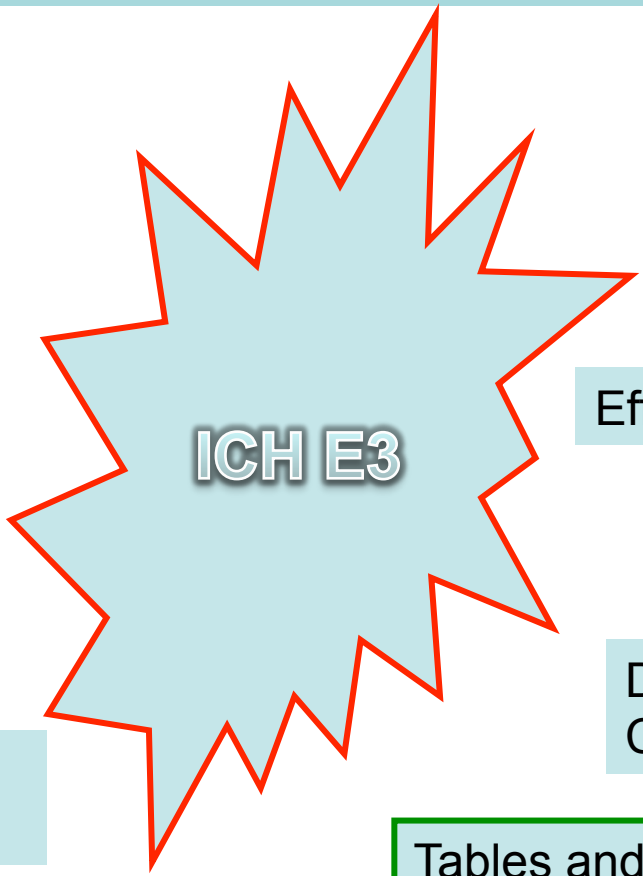
The Common Technical Document



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: 2-12 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

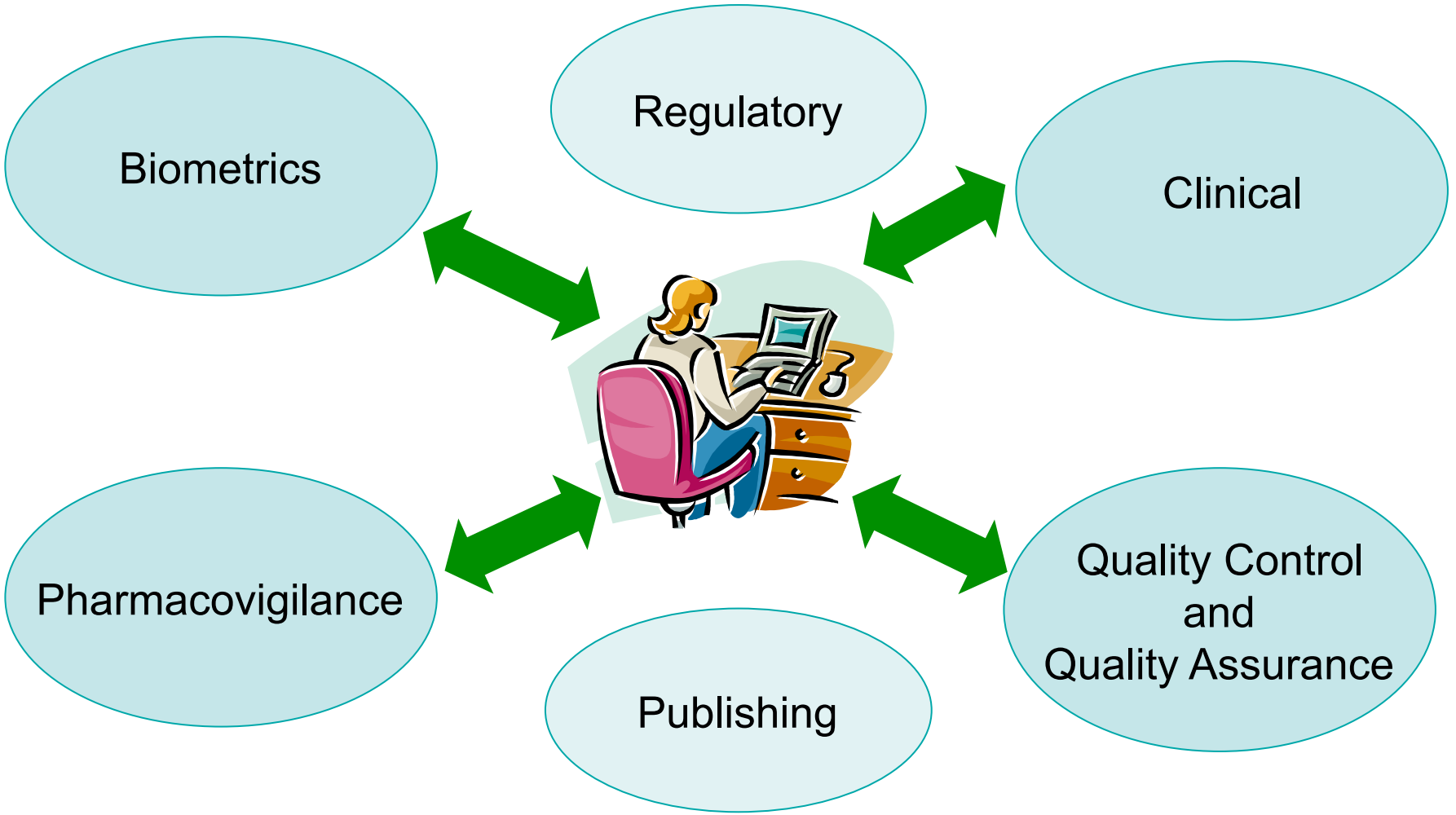
Discussion and Overall Conclusions

Tables and Figures

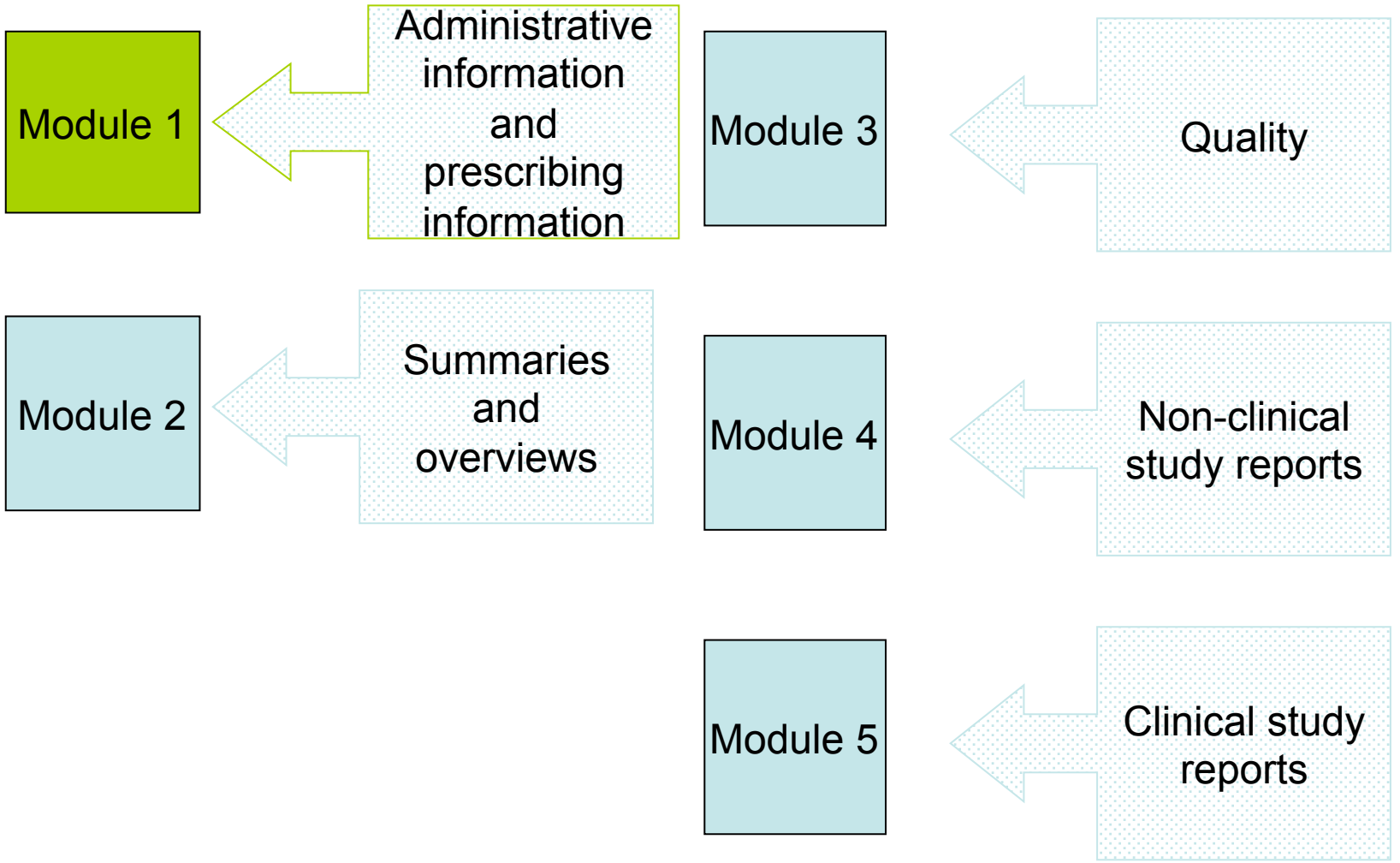
References

APPENDICES Including listings

Clinical Study Reports



The Common Technical Document



Module 2
Summaries and Overviews

- CTD Table of Contents (Module 2.1)
- CTD Introduction (Module 2.2)
- Quality Overall Summary (Module 2.3)
- Non-clinical Overview (Module 2.4)
- Clinical Overview (Module 2.5)
- Non-clinical Summary (Module 2.6)
- Clinical Summary (Module 2.7)

How Big? How Long?

Module 2.5
Overview
About 30-80 pages

4-8 weeks

8-20 weeks

Module 2.7
Summary
50 to 500 pages
(excluding appended tables)

Trend to much longer documents, especially in US

Module 2.7

2.7.1 Summary of Biopharmaceutic Studies and Associated Bioanalytical Methods

2.7.2 Summary of Clinical Pharmacology Studies

2.7.3 Summary of Clinical Efficacy

2.7.4 Summary of Clinical Safety

2.7.5 Literature References

2.7.6 Synopses of Individual Studies

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

Non-clinical and Clinical Overviews

Critical analysis of non-clinical and clinical data in CTD
Discussion and interpretation of data
Relevance to current practice
Discuss relevant literature

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

EU versus US

Expert input

Module 2.5

2.5.1 Product Development Rationale

2.5.2 Overview of Biopharmaceutics

2.5.3 Overview of Clinical Pharmacology

2.5.4 Overview of Efficacy

2.5.5 Overview of Safety

2.5.6 Benefits and Risks Conclusions

2.5.7 Literature References

Qualifications and Skills

- Ability to write and enjoy writing!
- Life sciences degree
- Ability to assimilate information quickly
- Enjoy working with huge amounts of data
- Attention to detail
- Work under pressure and meet deadlines
- An understanding of statistics
- Proficiency in Microsoft Word

How to Get Started

- CROs/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

Final Few Words

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