Managing Clinical Study Report Development

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The Clinical Study Report is an “integrated” report of an individual study of any therapeutic, prophylactic, or diagnostic agent (referred to herein as drug or treatment) conducted in human participants.

The clinical and statistical description, presentations, and analyses are integrated into a single report, incorporating tables and figures into the main text of the report or at the end of the text, with appendices containing such information as the protocol, sample case report forms, investigator-related information, information related to the test drugs/investigational products including active control/comparators, technical statistical documentation, related publications, patient data listings, and technical statistical details such as derivations, computations, analyses, and computer output.

(Adapted from the ICH E3 GUIDELINE on the STRUCTURE AND CONTENT OF CSRs)
Contents of a CSR

1 TITLE PAGE
2 SYNOPSIS
3 TABLE OF CONTENTS
4 LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS
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10 STUDY PARTICIPANTS
11 EFFICACY EVALUATIONS
12 SAFETY EVALUATION
13 CONCLUSIONS
14 SUPPLEMENTAL TABLES AND/OR FIGURES
15 LIST OF REFERENCES
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Strategies for Management of CSR development

- Effective and collaborative management of the team
- Lean authoring to understand and interpret data easily
### Teams and Tasks

<table>
<thead>
<tr>
<th>Personnel/Team</th>
<th>Tasks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead MW</td>
<td>Kick-off document development, author, revise, resolve issues and</td>
</tr>
<tr>
<td></td>
<td>manage draft (Sections 1-16) from inception to finalization</td>
</tr>
<tr>
<td>MW2</td>
<td>Manage Section 14-additional tables and figures</td>
</tr>
<tr>
<td>Editors (3)</td>
<td>Appendices assembly– Section 16, QC draft, Section 14 and appendices</td>
</tr>
<tr>
<td>Clinical (2 - 4)</td>
<td>Author and review</td>
</tr>
<tr>
<td>Statistics (2)</td>
<td>Review data and draft</td>
</tr>
<tr>
<td>Regulatory (1- 3)</td>
<td>Review draft</td>
</tr>
<tr>
<td>Management (2-3)</td>
<td>Review draft and approve final report</td>
</tr>
</tbody>
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Abbreviation: MW, Medical writer
Managing Timeline and People

Lead MW

Kick-Off

Consensus

Team

Revise

Management

Review draft

Revise

Editor 2

QC draft

Approve Final Report

Author first draft

Assemble appendices

QC appendices

Editor 3

Author Sec 14

MW2

Editor 1
Lean Authoring

Aim to present data in a way that the regulatory agency would find clear, and easy to locate and understand

- Start with the most important information, at the top of the paragraph
- Present data in tables and figures only, and interpret that data in the text
- Avoid repeating information
- Use parallel structure to maintain consistency
- Use consistent language, format, and style throughout the report
- Use hyperlinked cross-references