Clarity and Openness in Reporting: E3-based

Open Session
“Celebrating a Decade of CORE Reference: Still Powering Quality CSRs Today”

Hosted by The CORE Reference Team
6 May 2026

Agenda

- CORE Reference: original resource
- CORE Reference: current monthly offering
- Speaker: Philip Burridge, Morula Health
- Questions from webinar attendees

The CORE Team

					
Dr Sam Hamilton Original Author and Chair	Vivien Fagan Original Author and Committee	Dr Zuo Yen Lee Committee	Dr Alison McIntosh Committee	Dr Aaron B. Bernstein Original Author	Tracy Farrow Original Author
					
Dr Graham Blakey Original Author	Debbie Jordan Original Author	Dr Walter Seiler Original Contributor	Anna Shannon Original Contributor	Dr Art Gertel Strategic Regulatory Advisor	

What is CORE Reference

- Original open-access best practice resources published in May 2016
  - **CORE Reference**
  - **Mapping Tool**
  - Launch paper in BMC
  - **Website launch**

- Original website: www.core-reference.org
- EMWA EPDP Workshop '**CORE Reference. Clarity and Openness in Reporting: E3-based**'

History of CPD Resources

- **2018: Quarterly CPD**
  - 2017: Utility Survey
- **Dec 18 – Apr 22: Monthly CPD**
  - Jul 19: comments on FDA pilot program
  - 2019: BMC paper critiquing T/Cel CSR template; estimand integrated to Terminology Table worked example

CORE Reference today

- emwa.org/resources/the-core-reference-project/
- EMWA Special Project
- 10-Year Anniversary
- Follow us on

History of CPD Resources, c'ntd

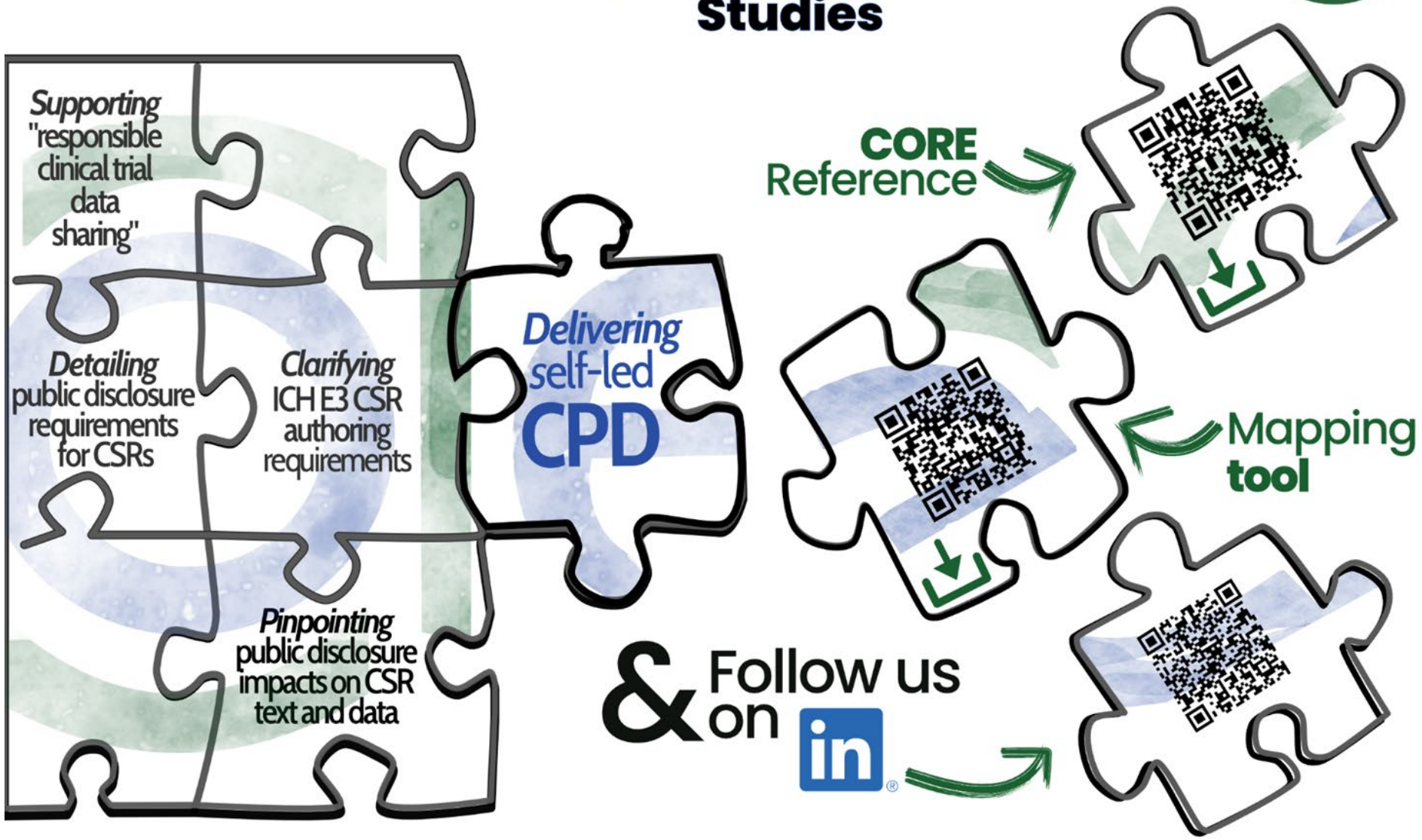
- **Apr 22: EMWA Special Project**
  - +3 team members, expanded CPD
- **May 22 onwards: Monthly CPD**
  - Dec 22: Comparison T/Cel CPT and ICH M11 template Level 2 headings
  - Jun 23: Webinar
  - Dec 23: Utility Survey
  - Dec 24/Jun 25/Jan 26: Webinar
  - Jun 26: Webinar

61st EMWA Conference Barcelona

Join us at the following additional lunchtime sessions:

- Thursday 7 May 2026
  - Panel member(s): EMWA REG SIG & ICH M11 discussion group
- Friday 8 May 2026
  - Future of CORE Reference Project
  - Presentation by Rona Vasey, Trilogy Writing

An Open Access Resource to Support Authoring of Clinical Study Reports for Interventional Studies



Speaker

Philip Burridge, Morula Health

"Practical implementation of the CORE Reference user manual for delivering high quality CSRs"

EMWA Spring 2026 61st Conference

CORE REFERENCE

Morula Health

Operational delivery of high-quality CSRs for Biotech using CORE Reference

Philip Burridge

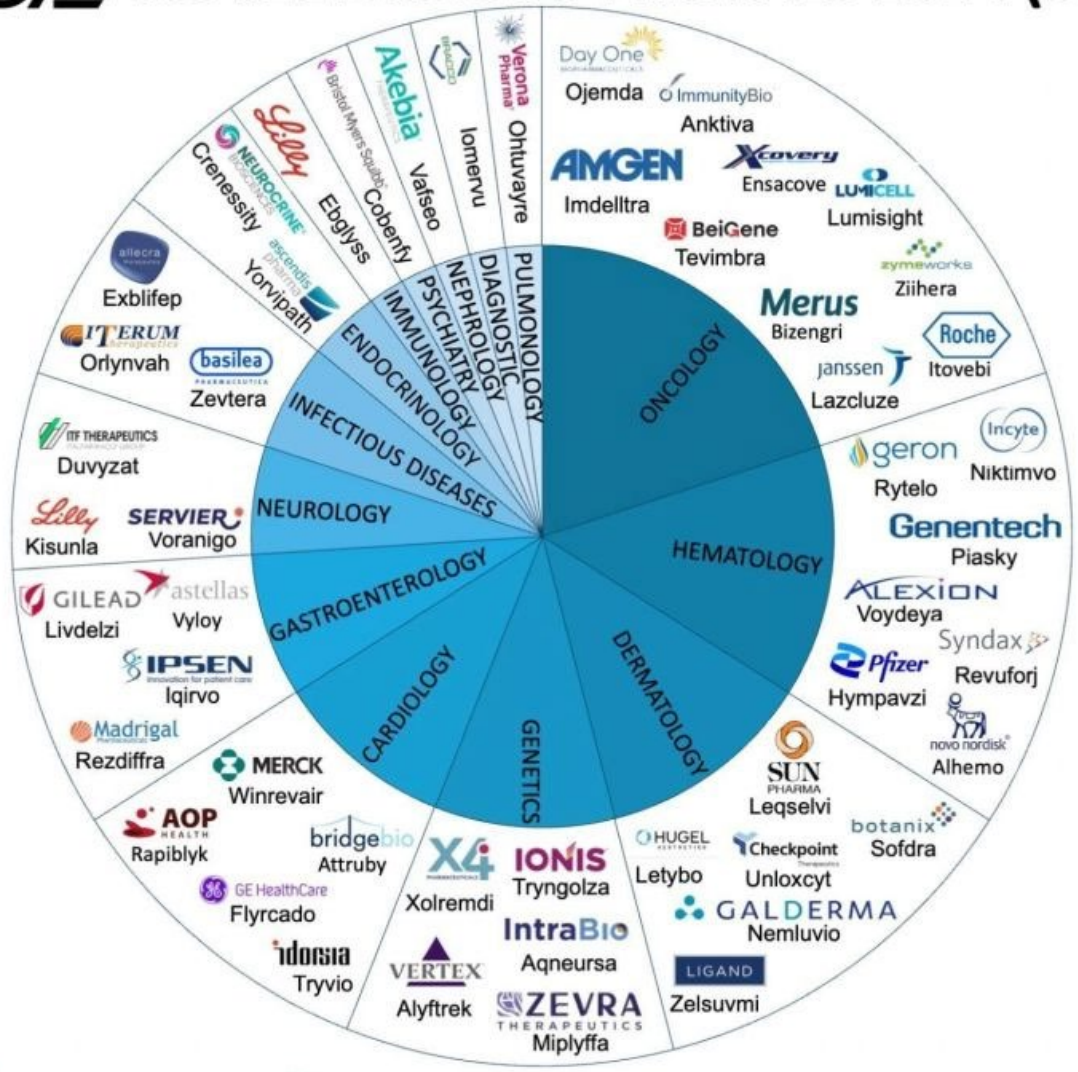
Morula Health

Wednesday 6 May 2026

A few questions…

- Keen to get a feel for the experience in the room
- Hands up if you have written CTD module 2.7 and/or 2.5 for a marketing approval?
- Hands up if you have written CTD modules 2.7 and/or 2.5 for a marketing approval, and also written one or more CSRs for that submission?

FDA NOVEL DRUG APPROVALS 2024 (50)



joanna-sadowska-phd @jmsadowska

Source: https://www.fda.gov/drugs/novel-drug-approvals-fda/novel-drug-approvals-2024

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- Only 11 out of 50 were owned by Top 20 Pharmaceutical companies
- 5 of which were developed in-house and 6 were acquired after preclinical discovery
- Of the 39 developed by small and mid-size biopharma 30 were developed in-house and 9 were acquired

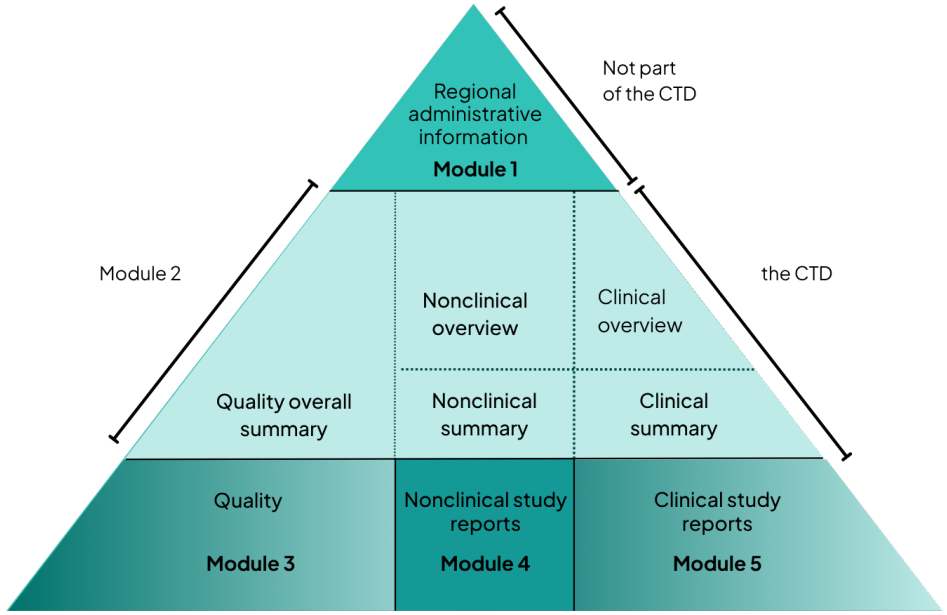
What is a small biopharma?

Morula Health

Realities of small and mid size biopharma and why high-quality CSRs matter to them

- Innovative, agile, flexible, fast decisions, little bureaucracy
- Small teams
- High turnover
- Multiple CROs
- Minimal tech, systems / messy
- Little to no data analytics and data room sophistication

CTD Module 2.7 and 2.5



- **Module 2**: common technical document summaries

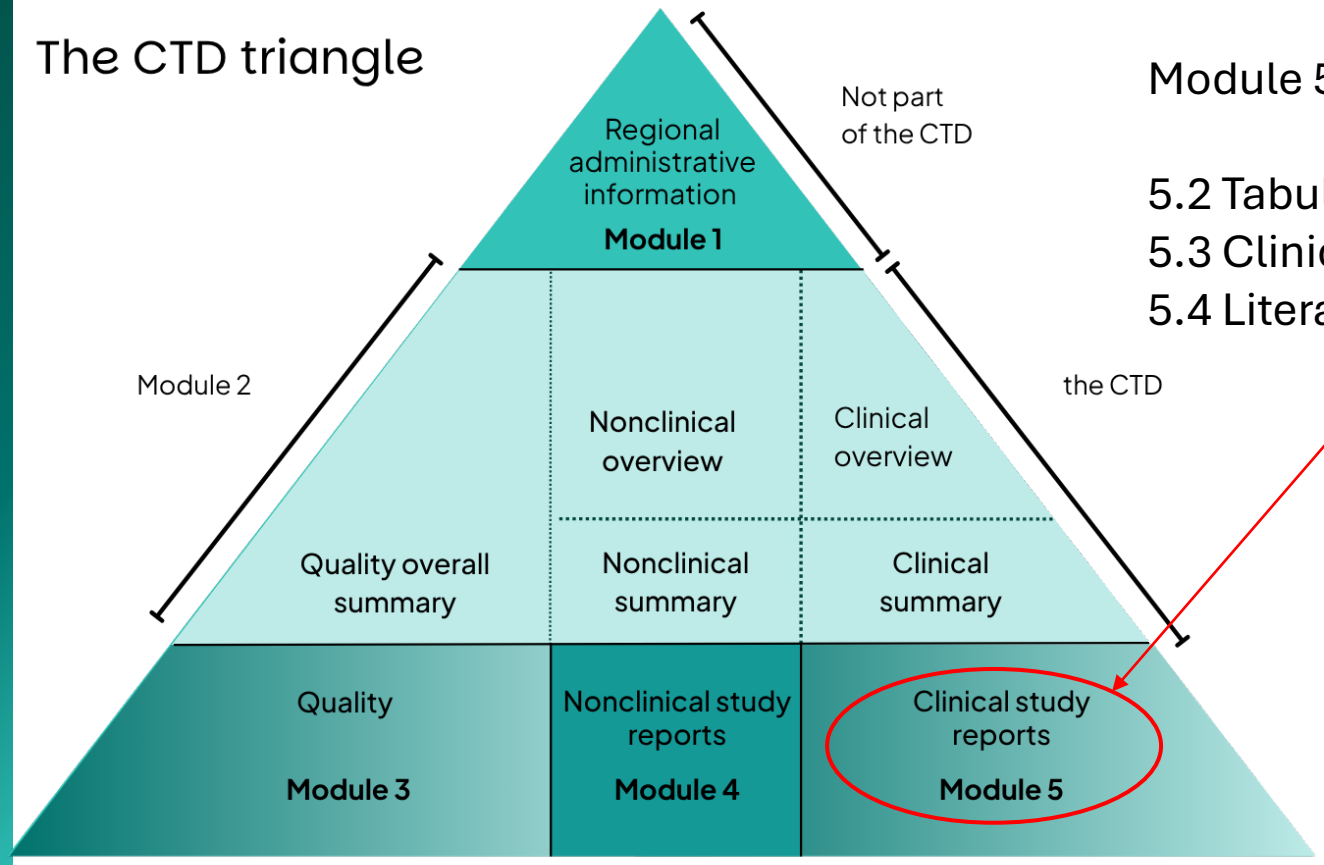
Clinical Summary should provide a detailed factual summarisation of the clinical information in the CTD, and the Clinical Overview should provide a succinct discussion and interpretation of these findings together with any other relevant information (e.g., pertinent animal data or product quality issues that may have clinical implications).

- **2.7.4** – Summary of Clinical Safety:

This section should be a summary of data relevant to safety in the intended patient population, integrating the results of individual clinical study reports as well as other relevant reports

https://www.fda.gov/media/93569/download

CSR writing: start with the end in mind…



The Common Technical Documents triangle is organised into five models. Module 1 is region specific and modules 2,3,4 and 5 are intended to be commons for all regions

CSRs underpin the whole of your submission

Module 5 – Your evidence

5.2 Tabular Listing of all clinical studies
5.3 Clinical study reports and related information
5.4 Literature references

Value of medical writing: A regulator's Perspective

Julia Cooper,[1] Lisa Chamberlain James,[2] Joan Affleck,[3] Brian Bass,[4] Julia Forjanic Klapproth,[5] Dylan Harris[6], on behalf of the AMWA Value of Medical Writing Working Group / [1]Parexel International, Dublin, Ireland; [2]Trilogy Writing and Consulting, Cambridge, UK; [3]Merck & Co, Inc, Rahway, NJ, USA; [4]Bass Global Inc, Fort Myers, FL, USA; [5]Trilogy Writing and Consulting, Frankfurt, Germany; [6]Takeda Pharmaceutical Company Limited, Lexington, MA, USA

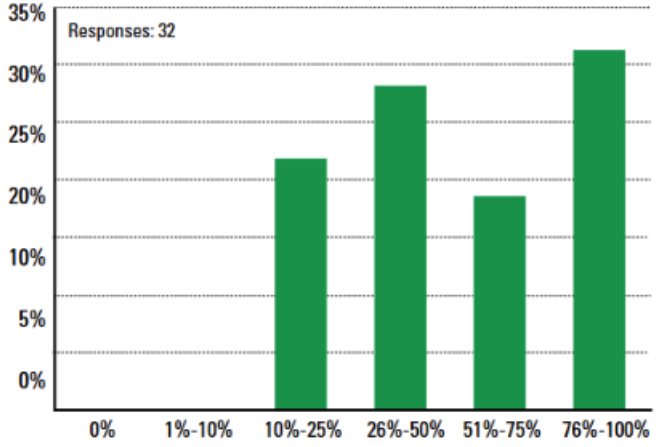


Figure 2. In your current position/role, what percentage of your time do you spend reviewing documents?

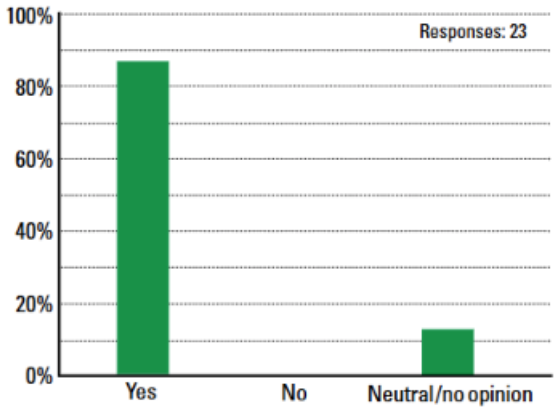


Figure 3. Does poor document quality impede your ability to provide regulatory assessment?

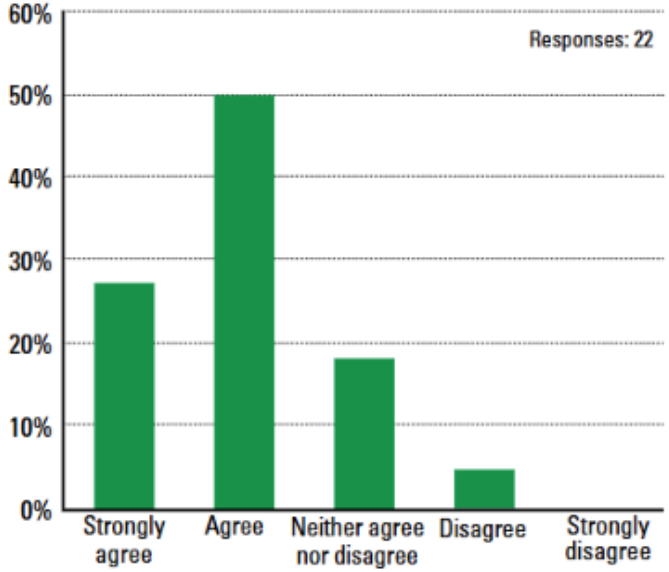


Figure 6. For applications that are ultimately approved, a poorly written document delays the approval process.

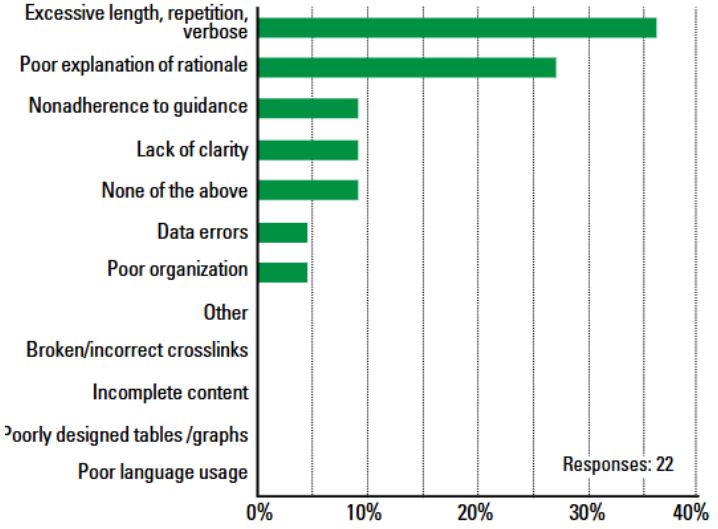
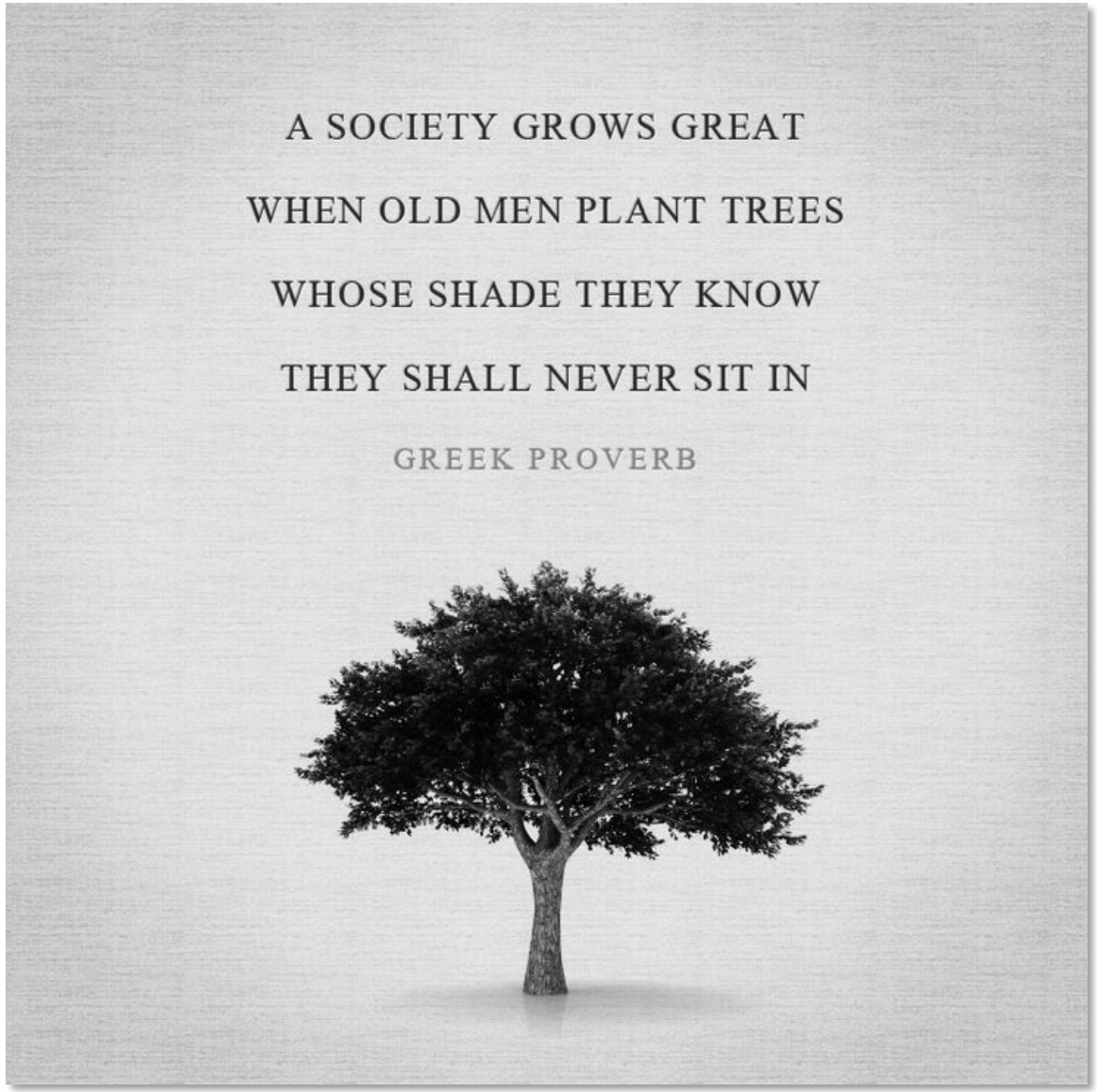


Figure 9. Which one of these issues related to document quality do you encounter most frequently?

https://amwajournal.org/index.php/amwa/article/view/83/70

Empathy goes a long way…

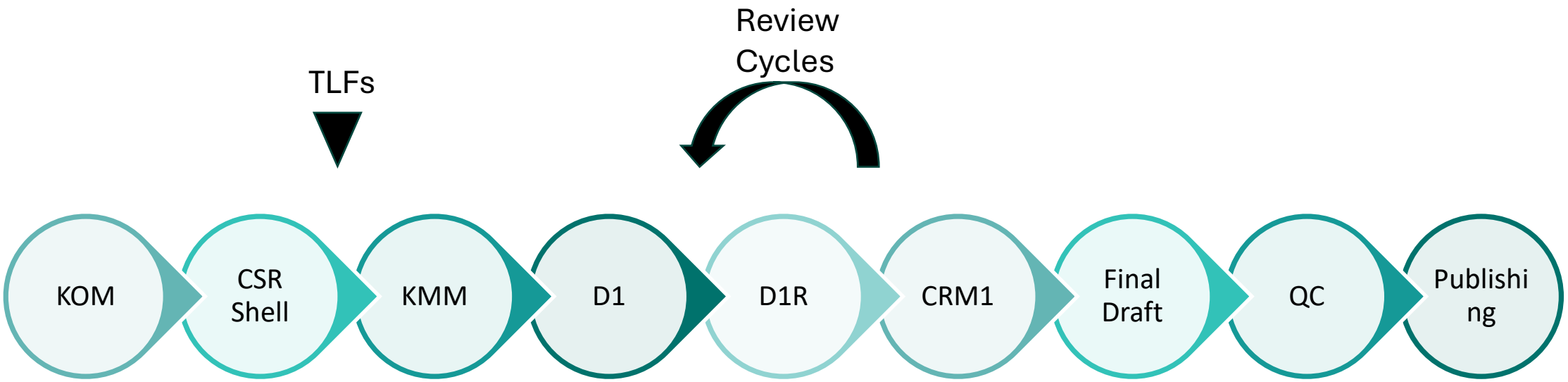


And women

Why we value CORE Reference and how it supports us to deliver high quality CSRs

- Regulatory submission-ready CSRs that can outlive the people and the companies that own them
- Clearly define your study - objectives, endpoints, changes, analysis, results and data – clear, concise explanation of rationale
- Comprehensive without using links doesn’t mean verbose
- Clearly defined reasoning for sections and headings – removal of repetition
- What you include in a CSR matters much more than the CSR template you use

CSR writing flow process



Kick-Off Meeting & Preparation

Source Documents

- CSR Template
- Protocol and Amendments
- SAP
- Style Guide
- Mock Shells
- SOPs

- Key Personnel - Chief Medical Officer, Head of Clinical Development – Senior Management
- CSR Writing process – CSR Shell, Final TLFs, Data Interpretation, CSR (D1, D2)
- Study Rationale and Changes to the study design
- CSR Template
- Inconsistencies between SAP and Protocol

Next Step – CSR Shell
CORE Reference can support with what questions to ask about the source documents for putting together the CSR Shell

Key Messages Meeting

- Chief Medical Officer / Head of Clinical Development
- Don’t attempt data interpretation until all data is available
- Data to include in CSR body versus cross reference
- Discuss the data – explanations, limitations and interpretations
- What to include in safety results summary and efficacy results summary
- What data should go where? Structuring of efficacy – by objective?
- 10.3 Data Sets Analysed – Better in Section 10 versus in 11.1?
- What to include in discussion and conclusion – CMO to do D1?

Next Step – CSR Draft 1
CORE Reference can support with what questions to ask about the final TLFs for putting together Draft 1

Document Review / Comment Resolution Meeting

- Opportunity to influence – what makes sense of the clinical study, the data and the story you are trying to tell
- Following input on conclusions by Sponsor, can engage on what best to include in accordance with CORE Reference

- Tip - Have the CORE Manual there at hand to support (Use MS Edge with Copilot and pdf in browser to ask prompts in real time)

Next Step – Next CSR Draft
CORE Reference can support with influencing the team about what should go in the CSR, possible structure changes and questions to ask to support you with delivering a comprehensive next Draft

Quality Control

- QC performed by an independent medical writer, at the end on a final draft. QC & QC Implementation with a structured audit trail
- Inconsistencies, repetition
- Compliance with international guidelines
- Completeness of all sections of the CSR
- Correctness and completeness of CSR content

Next Step – Finalization
CORE Reference can support with ensuring you have a Regulatory submission-ready CSRs that can outlive the people and the companies that own them

Process

- SOPs
- Work Instructions
- Templates
- Checklists (and questions to ask) – LOVE a Checklist

MW training around CORE Reference is essential

- CORE Reference Manual
- Monthly CPD via News Summaries

Morula Health

THANK YOU

Philip Burridge

Director, Operations & Strategy

Morula Health