Clarity and Openness in Reporting: E3-based

Open Session
How CORE Reference Advances Global Consistency in the Next Era of CSR Writing

Hosted by The CORE Reference Team
8 May 2026

Agenda

- Zuo Yen: Clinical trial disclosure in Asia
- Alison: Learning resilience important in an AI-augmented environment
- Speaker: Rona Vasey, Trilogy Writing
- Questions from attendees

Clinical Trial Disclosure in Asia

Presenter: Zuo Yen Lee

Background (published in 2023)

- Lee ZY. **Current clinical trial disclosure landscape in Asia**. Medical Writing Journal. 2023;32(3):96-97. doi:10.56012/vxbm4667
  - Regular section: Regulatory Public Disclosure
  - Comparison of the CT disclosure in *China, Japan, S. Korea, and Taiwan*
- Lee ZY. **Current clinical trial disclosure landscape in China**. Medical Writing Journal. 2023;32(3):98-100. doi:10.56012/kvfy4747.
  - Regular section: Regulatory Matters
  - Further describes the evolution and resources of CT disclosure in China
- The CT disclosure landscape in Japan and S. Korea largely remains unchanged since 2023; a couple of updates for China and Taiwan.

Update since 2023 (Yellow highlight) 1/3

Aspect	China	Taiwan
Mandatory national clinical trial registry	Drug Clinical Trial Registration and Information Disclosure Platform http://www.chinadrugtrials. org.cn/index.html	Taiwan Clinical Trial Information Platform (effective 01 Jan 2025) https://e-sub.fda.gov.tw/ClinicalTrialInfo/home Source: https://www.fda.gov.tw/tc/siteListContent.aspx?sid=9354&id=47875
Type of trial covered	Interventional clinical trials (Phase 1–4, BE/PK); exclude observational	Interventional Phase 1–4 and observational trials
Registration timing	Before first participant enrollment	After TFDA/CDE approval and before enrollment
Results posting required	Yes (summary results required)	No mandatory registry-based results posting
Results submission timeline	Within 12 months of study completion or before marketing authorisation (for trials supporting an NDA), whichever occurs first	Not applicable (results posting not required)
Public accessibility of results	Registry results not fully public	Not applicable (results posting not required)
Format of results	Uploaded as a separate summary or overview document. Per China CDE guidance, the results summary/ overview should at least consist of the content of the CSR Synopsis as described in the ICH E3.	Not applicable (results posting not required)

Update since 2023 (Yellow highlight) 2/3

Aspect	China	Taiwan
Language of registry	Simplified Mandarin	Traditional Mandarin
Optional registries	ClinicalTrials.gov Centre for Clinical Research and Biostatistics – Clinical Trials Registry (CCRBCTR) https://www2.ccrb.cuhk.edu.hk/ Acupuncture-Moxibustion Clinical Trial Registry (AMCTR) International Traditional Medicine Clinical Trial Registry (ITMCTR)	ClinicalTrials.gov (many studies conducted in Taiwan are also registered on this registry where trial data may be provided via links to publications) Per TFDA 01 Jan 2025 announcement: Sponsors are encouraged to register TFDA-approved protocols on CT.gov. Source: https://www.fda.gov.tw/tc/siteListContent.aspx?sid=9354&id=47875
Other disclosure mechanisms (Type of document)	For approved drugs: CDE website (CDE review reports, drug instruction manual)	For approved drugs: TFDA website (Package insert)
CSR structure/ format	ICH E3 Specific requirements for the title page and appendices. Certain sponsors may follow the old NMPA requirements in the CSR appendices, albeit not required.	ICH E3 For multinational trials, Taiwan safety and efficacy data summary should be included in the appendix.

Update since 2023 (Yellow highlight) 3/3

Aspect	China	Taiwan
CSR public disclosure	Not required	Not required
Major update since 2023	According to the requirements of the International Clinical Trials Registry Platform (ICTRP), starting from 15 Jul 2024, the ChiCTR no longer accept registrations of clinical trials in the field of traditional medicine (including Chinese medicine, acupuncture, massage, herbal medicine, ayurveda, homeopathy, complementary, and supplementary medicines, etc.). Relevant researches can be registered on the International Traditional Medicine Clinical Trial Registry (ITMCTR, http://itmctr.ccebtcm.org.cn/). Source: https://www.chictr.org.cn/	New TFDA platform launched 1 Jan 2025; sponsors must update information within 1 month of protocol changes and at scheduled intervals (June and December annually). TFDA will disclose the name of the sponsor who fails to perform regular update to the trial registry. Source: https://www.fda.gov.tw/tc/siteListContent.aspx?sid=9354&id=47875

Comparison of Clinical Trial Disclosure Platforms

Feature	ChinaDrugTrials.org.cn	ClinicalTrials.gov	EU CTIS (EU CTR)
Primary regulatory authority	NMPA / CDE (China)	U.S. NIH / FDA	European Medicines Agency
Scope	Clinical trials conducted in China	“Applicable clinical trials” (ACT) as defined in the Final Rule	Interventional trials of medicinal products in EU/EEA
Mandatory registration before trial start	✓ Yes	✓ Yes	✓ Yes
Registry publicly searchable	✓ Yes	✓ Yes	✓ Yes
Trial protocol publicly available	❌ No	✓ Upload with results (Required for CTs with a Primary Completion Date on or after 18 Jan 2017)	✓ Yes
Statistical Analysis Plan available	❌ No	✓ Yes (if not included in the protocol)	❌ Not required
Structured results reporting	❌ No	✓ Structured/granular results tables	✓ Document-based results submission
Lay summary required	❌ No	❌ No	✓ Mandatory
Clinical study report publication	❌ No	❌ No	✓ As soon as submitted (30 days from MA)
Results publicly accessible	❌ No	✓ Yes	✓ Yes

Learning Resilience in an AI-augmented environment

Presenter: Alison McIntosh

Auto Generation of Trial Documents

- Use of generative models to create and draft Plain Language Protocol Synopses (PLPS) and Informed Consent Forms (ICFs) from clinical study protocol*
- AI-Generated Protocol Summaries: generative tool produces short, non-technical summary for patients and ethics boards from clinical study protocol*
- Generative AI for Clinical Study Reports: assists in compiling clinical study reports*
- Use of AI in the development of lay summaries (LS) of clinical trial results**
- Use of AI in development of Plain Language Summaries of Clinical Trial Results in the EU***

*GenAI Proof of Concept in Pharma: Accelerating Drug Discovery and Development: https://intuitionlabs.ai/articles/genai-proof-of-concept-in-pharma

**Considerations for the use of artificial intelligence in the creation of lay summaries of clinical trial results. Medical Writing. 2025;34(2):74–81. https://doi.org/10.56012/vmag9372

***Plain language summaries of clinical trial results: What is their role, and should patients and AI be involved? Medical Writing. 2024;33(3): 34-37. https://doi.org/10.56012/yayy4394

AI-generated Outputs Need Human Oversight

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 September 2024
EMA/CHMP/CVMP/83833/2023
Committee for Medicinal Products for Human Use (CHMP)
Committee for Medicinal Products for Veterinary Use (CVMP)

Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle

2.3.5. Product information

AI/ML applications used for drafting, compiling, editing, translating, tailoring, or reviewing medicinal product information documents should be used under close human supervision. Given that generative language models are prone to include plausible but erroneous or incomplete output, quality review mechanisms need to be in place to ensure that all model-generated text is both factually and syntactically correct before submission for regulatory review.

https://www.ema.europa.eu/en/documents/scientific-guideline/reflection-paper-use-artificial-intelligence-ai-medicinal-product-lifecycle_en.pdf

Cognitive off-loading*

- "Google Effect" - people expect information to be easily accessible online, and are less likely to remember it themselves
- Over-reliance on AI tools can act as a replacement to critical thinking and effective learning
  - Thinking develops for speed rather than comprehension

*Jose B et al., (2025) Outsourcing cognition: the psychological costs of AI-era convenience. Front. Psychol. 16:1645237. doi: 10.3389/fpsyg.2025.1645237

Over reliance on AI tools

Potential to

- Reduce knowledge
- Impact engagement
- Impact critical thinking skills
- Reduce deep engagement with content
- Create the illusion of competence

Medical writers must guard against this outcome

Gerlich, M. AI Tools in Society: Impacts on Cognitive Offloading and the Future of Critical Thinking. *Societies* **2025**, *15*, 6. https://doi.org/10.3390/soc15010006

Medical Writers Must Develop Learning Resilience

AI must complement, not replace, human expertise and review of complex clinical trial data

EMA guidance for use of AI "under close human supervision"

Requires active participation by the user (MW)

MWs need "learning resilience" in an AI-augmented environment

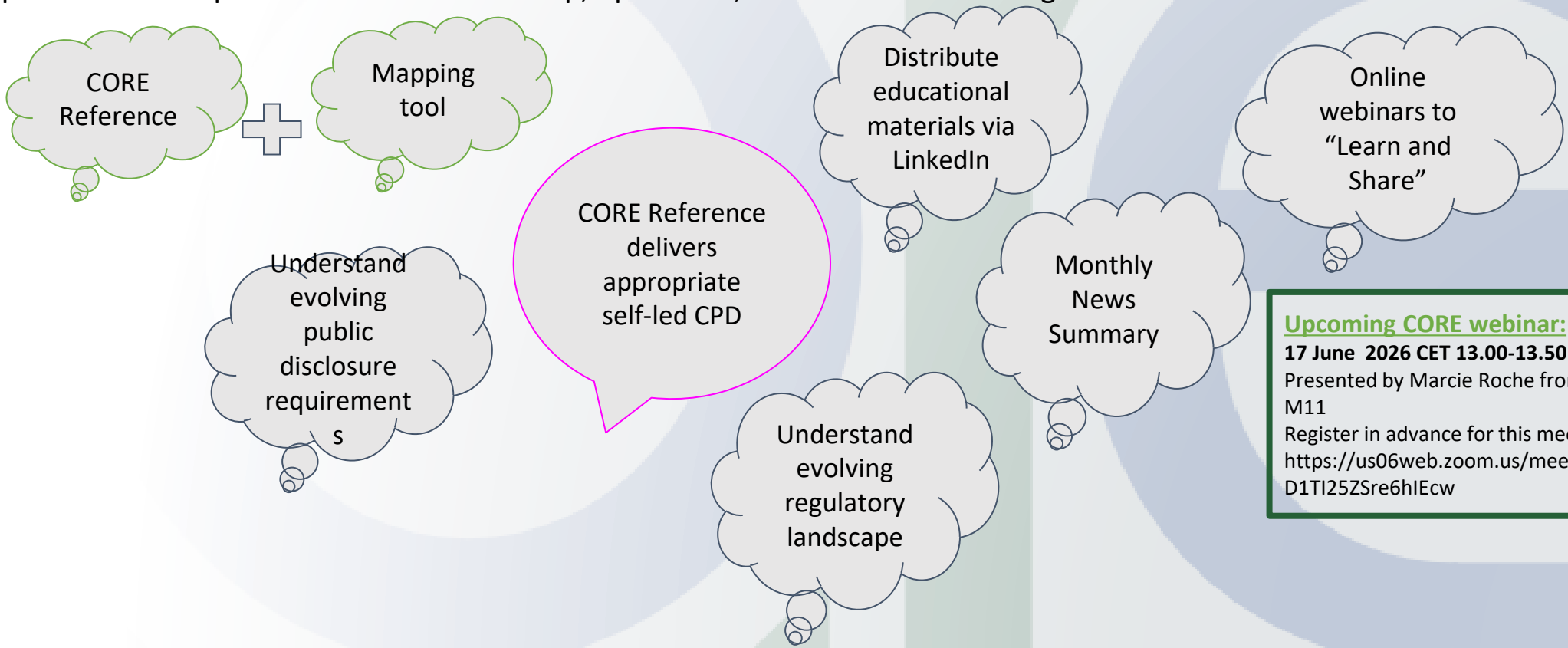
Access appropriate continuous professional development and training

Foster learning resilience, critical thinking, and in depth knowledge acquisition

MWs evolve deep understanding of CSR content

AI tools do not represent a stand-alone path to compliant CSR preparation

AI depends on the expertise of MWs with a deep, up to date, foundational knowledge



Upcoming CORE webinar:

17 June 2026 CET 13.00-13.50

Presented by Marcie Roche from Argenx on ICH M11

Register in advance for this meeting: https://us06web.zoom.us/meeting/register/4DsqsiD1TI25ZSre6hIEcw

Speaker

Rona Vasey, Trilogy Writing

“AI in CSR Writing: Why CORE Reference Still Matters”

AI in CSR Writing:
Why CORE Reference Still Matters

May 2026

indegene™

TRILOGY Writing & Consulting
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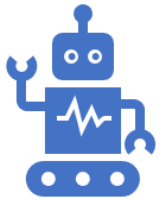
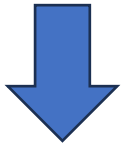
The AI Revolution



Artificial intelligence is revolutionising the generation of CSRs

Promises increased speed and efficiency

Routine tasks are perfect candidates for automation



Frees up time for medical writers to focus on critical analysis and problem-solving!

The Advantages of AI

Acceleration

- Shorten timelines without compromising quality

Quality

- Robust structure
- Consistency of language and tone

Automation of routine tasks

- Summarisation of large amounts of dense text, eg, protocol introduction
- Identification of signals or anomalies, even from very large data tables
- Compilation of summary tables

The Advantages of AI

Benefit to Pharma

- Reduced costs
- Competitive advantage and quicker ROI

Benefit to patients

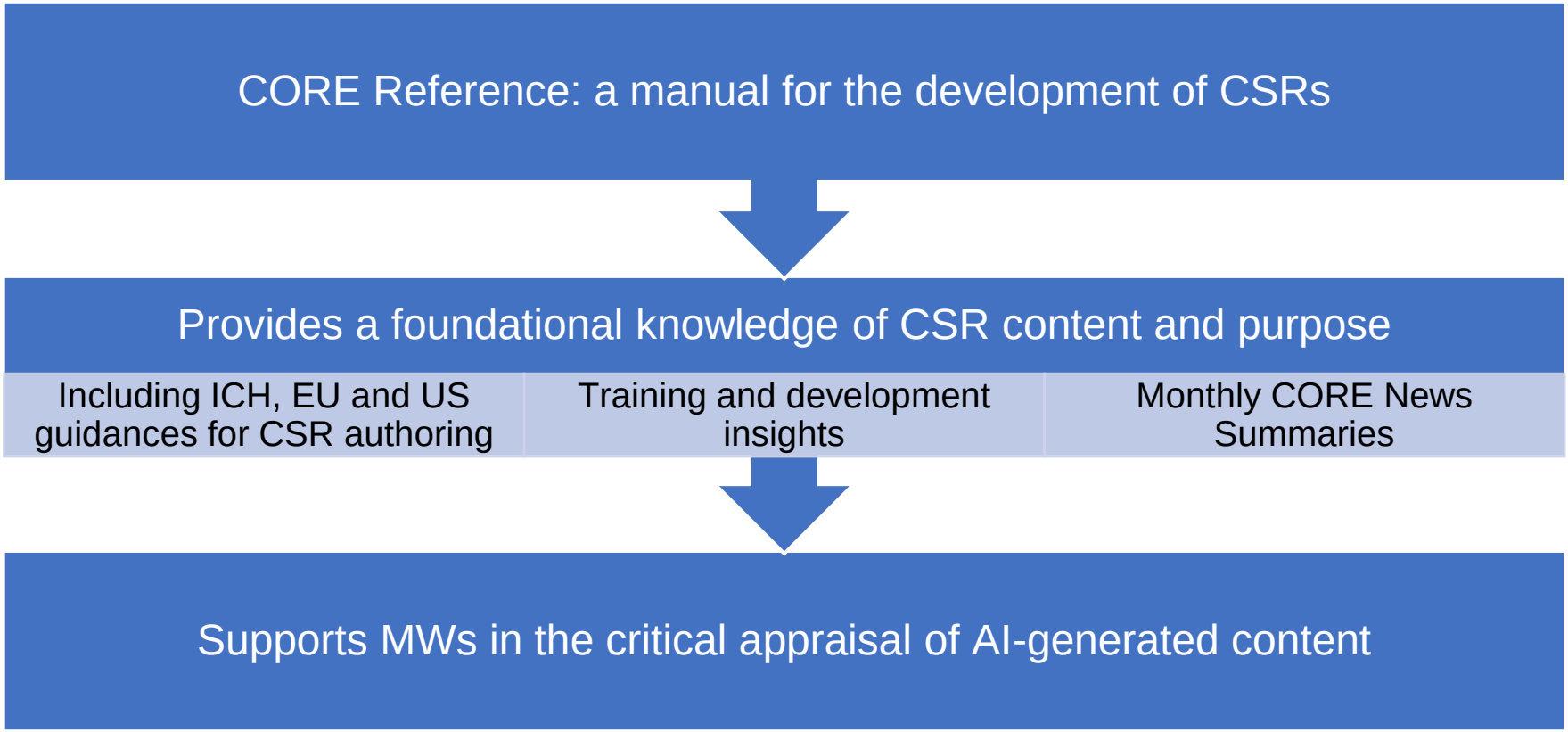
- Faster access to treatment, especially for rare diseases

Why do we still need MWs?

- Critical thinking!
  - Critically appraise the information
  - Confirm the sources
  - Ensure key messages/conclusions are supported by the data and are unbiased (no hallucinations!)
  - Consistency across documents
- Expertise and advice
  - Strategic thinking and messaging
  - Ensure all contributors are aware of the regulatory requirements
  - Process compliance

CORE Reference is a critical resource to support Medical Writers

CORE Reference and AI



AI in CSRs: What AI can do and what to look out for

AI as a Tool

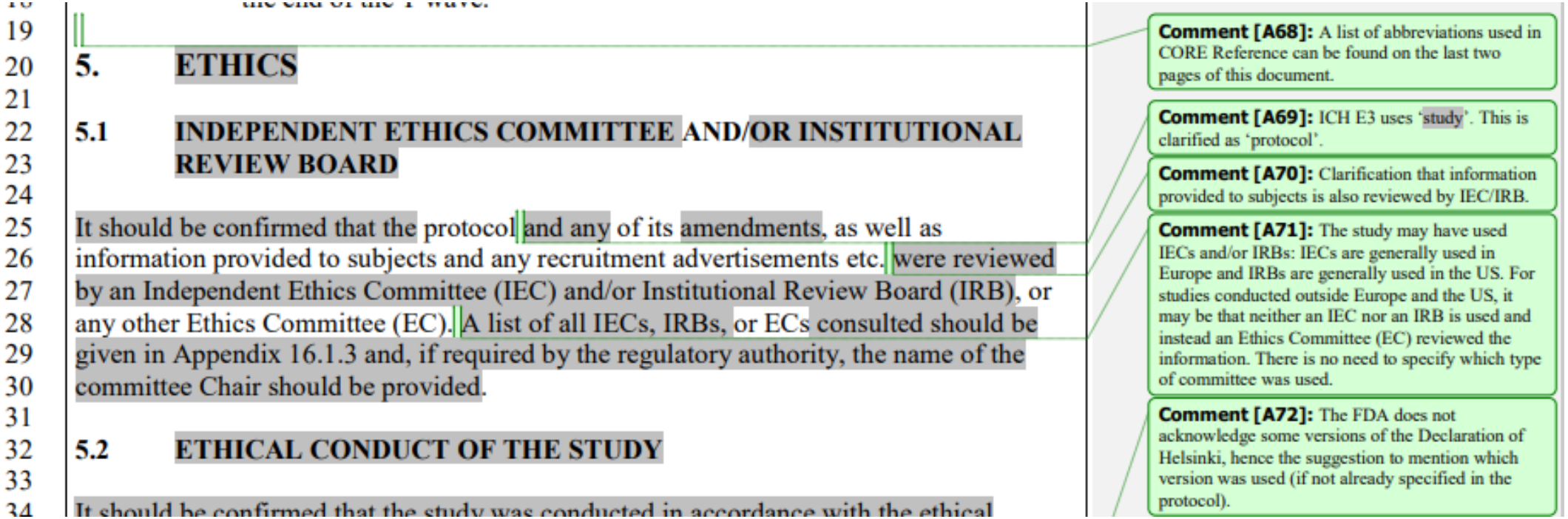
Want a fresh rewrite of a lengthy paragraph?	Rewrite the highlighted text for clarity and apply lean authoring principles. Use abbreviations and flag for inclusion in a separate List of Abbreviations.
Want to summarize a large data table?	Summarise the highlighted table. Apply lean writing principles.
Want to check for inconsistencies?	Reviewing this document are there any inconsistencies that should be clarified?
Are my hyperlinks accurate?	In the highlighted text, check and confirm that all in-text cross-references refer to the correct section in the document. Ignore the table of contents.

But beware…

Want a fresh rewrite of a lengthy paragraph?	Check accuracy of key messages and ensure the tone is consistent with the rest of the document
Want to summarize a large data table?	Review for data accuracy
Want to check for inconsistencies?	Ensure the context of any updates are accurate
Are my hyperlinks accurate?	Check the destination of the links exist

Ethics

- Ethics section commonly uses template text.
- Difficult to get AI tool to recognize required template text – it can try to "improve" it.
- **Check that the recommended text has not been amended**



5. ETHICS

5.1 INDEPENDENT ETHICS COMMITTEE AND/OR INSTITUTIONAL REVIEW BOARD

It should be confirmed that the protocol and any of its amendments, as well as information provided to subjects and any recruitment advertisements etc. were reviewed by an Independent Ethics Committee (IEC) and/or Institutional Review Board (IRB), or any other Ethics Committee (EC). A list of all IECs, IRBs, or ECs consulted should be given in Appendix 16.1.3 and, if required by the regulatory authority, the name of the committee Chair should be provided.

5.2 ETHICAL CONDUCT OF THE STUDY

It should be confirmed that the study was conducted in accordance with the ethical

Comment [A68]: A list of abbreviations used in CORE Reference can be found on the last two pages of this document.

Comment [A69]: ICH E3 uses 'study'. This is clarified as 'protocol'.

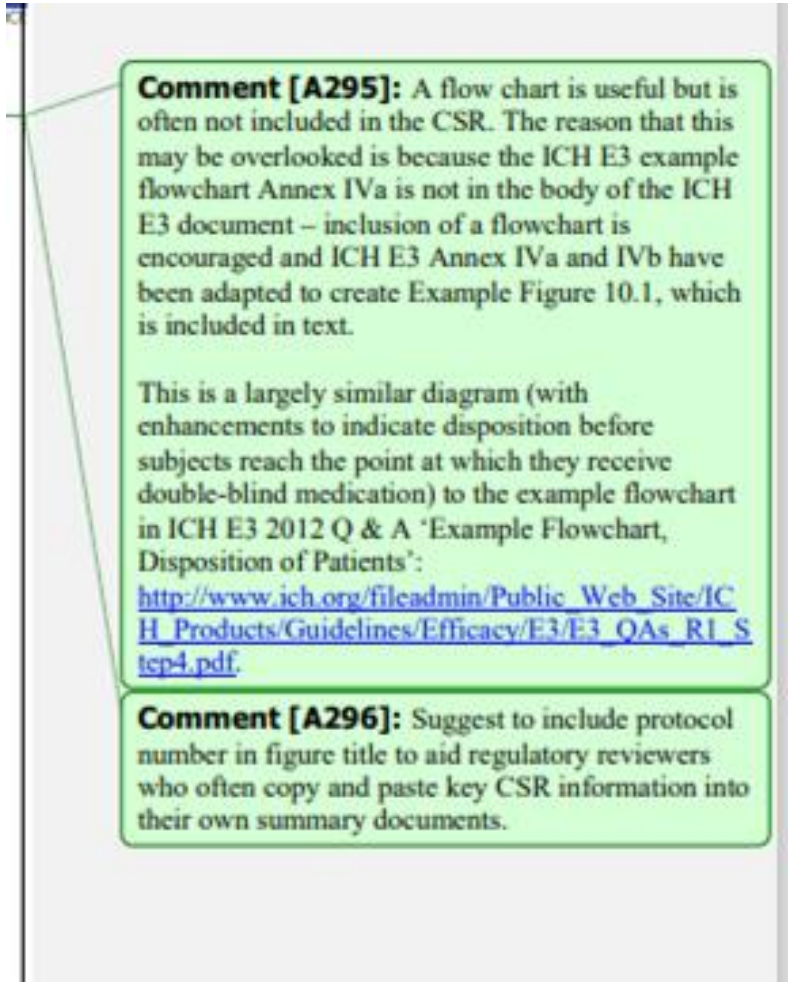
Comment [A70]: Clarification that information provided to subjects is also reviewed by IEC/IRB.

Comment [A71]: The study may have used IECs and/or IRBs: IECs are generally used in Europe and IRBs are generally used in the US. For studies conducted outside Europe and the US, it may be that neither an IEC nor an IRB is used and instead an Ethics Committee (EC) reviewed the information. There is no need to specify which type of committee was used.

Comment [A72]: The FDA does not acknowledge some versions of the Declaration of Helsinki, hence the suggestion to mention which version was used (if not already specified in the protocol).

Disposition

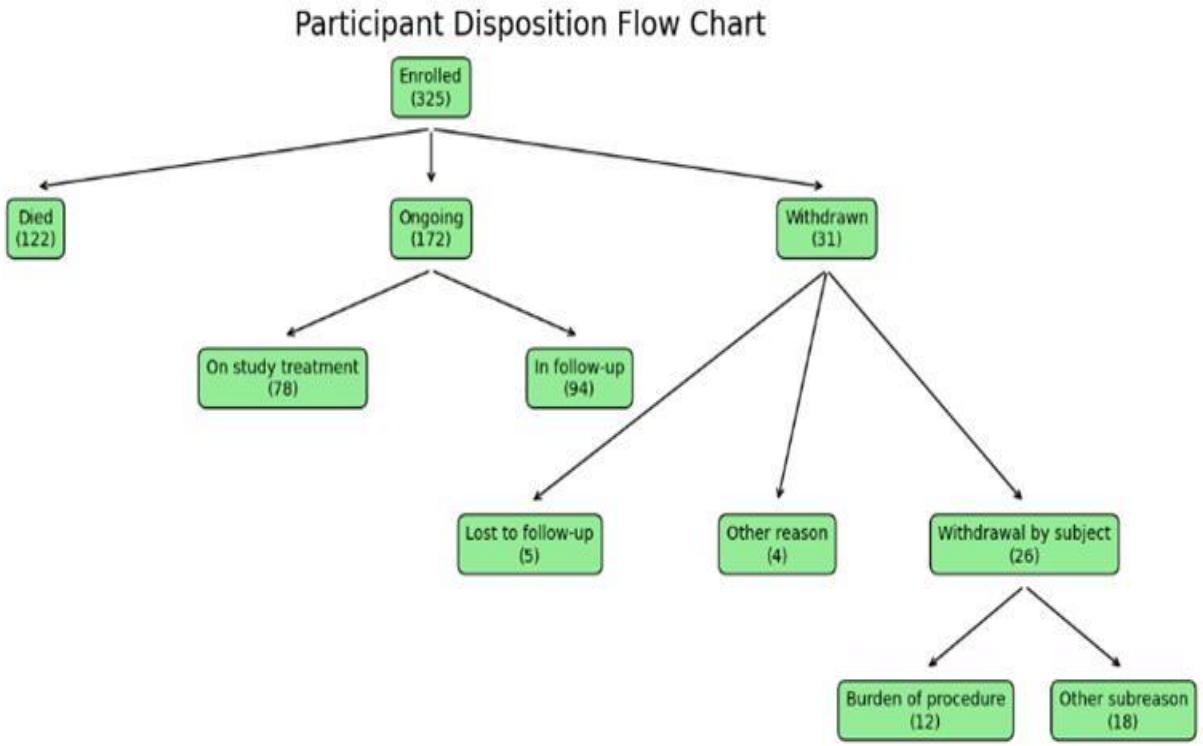
- A flow chart is recommended in CORE Reference but often overlooked
- Can be tricky and time consuming to prepare



Disposition

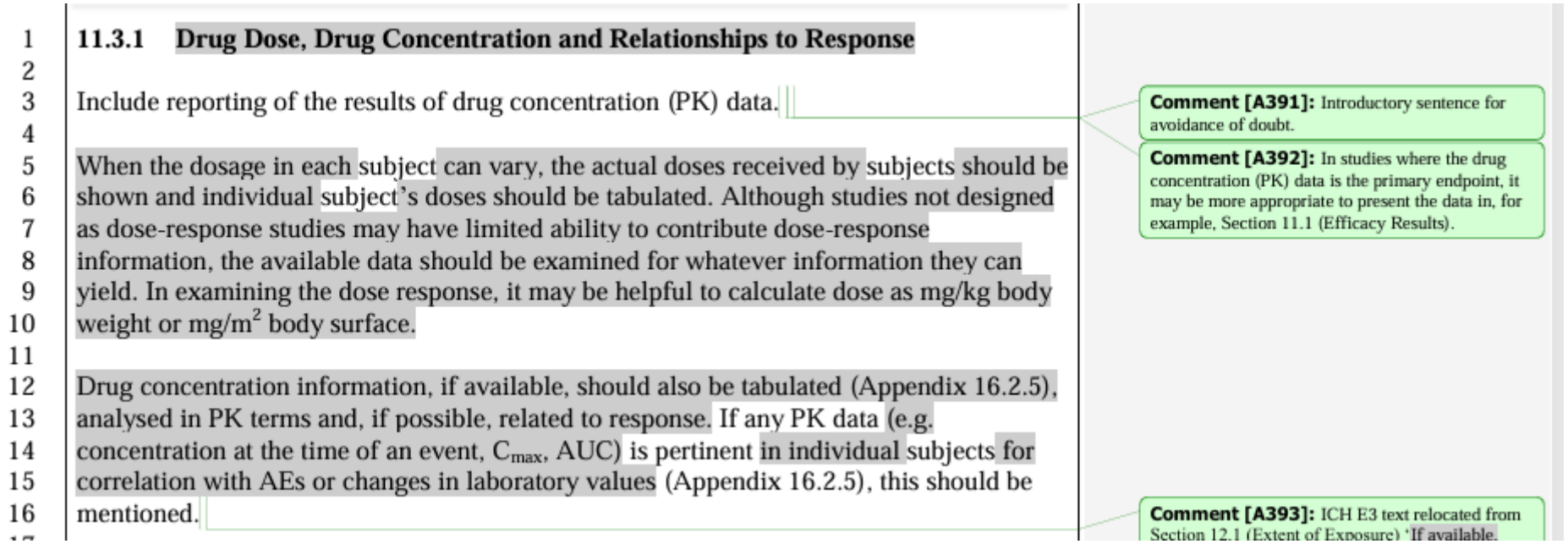
- **Prompt (with table uploaded as source):**

Generate a flow chart that starts with the # of participants enrolled and their disposition. The full text of each category should be visible and not overlap other categories. The arrow should not be presented between the categories



In-text Tables

- Much of the foundational knowledge regarding data presentation is available in CORE Reference



11.3.1 Drug Dose, Drug Concentration and Relationships to Response

Include reporting of the results of drug concentration (PK) data.

When the dosage in each subject can vary, the actual doses received by subjects should be shown and individual subject's doses should be tabulated. Although studies not designed as dose-response studies may have limited ability to contribute dose-response information, the available data should be examined for whatever information they can yield. In examining the dose response, it may be helpful to calculate dose as mg/kg body weight or mg/m^2 body surface.

Drug concentration information, if available, should also be tabulated (Appendix 16.2.5), analysed in PK terms and, if possible, related to response. If any PK data (e.g. concentration at the time of an event, C_{max}, AUC) is pertinent in individual subjects for correlation with AEs or changes in laboratory values (Appendix 16.2.5), this should be mentioned.

Comment [A391]: Introductory sentence for avoidance of doubt.

Comment [A392]: In studies where the drug concentration (PK) data is the primary endpoint, it may be more appropriate to present the data in, for example, Section 11.1 (Efficacy Results).

Comment [A393]: ICH E3 text relocated from Section 12.1 (Extent of Exposure) 'If available,

Preparing In-text Tables with AI… The MW needs to know:

Which data points do I need to present to support my message?

How do I want the data displayed?

What is the purpose of this section?

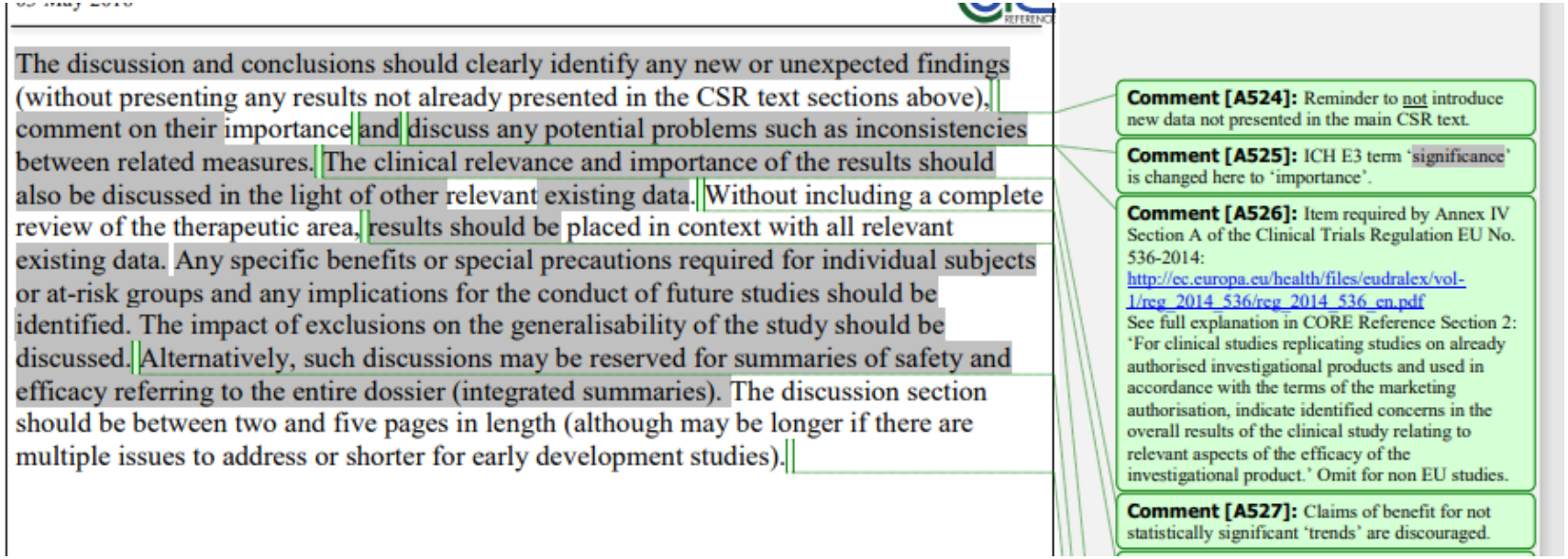
How do I 'explain' this in prompts?

Prompt:

- For the uploaded study report, provide the following:
  - Extract verbatim all pharmacokinetic parameter tables for Drug X and metabolites X1, X2, and X3 from the list of tables
  - Capture all columns and rows exactly as shown in the CSR, including n, Mean (SD), CV%, Median, Min–Max, and any footnotes.
  - Do not round numbers but use the exact precision presented in the CSR tables.
  - If any table is split across pages, combine it into one continuous table.
  - Output in a structured format suitable for Word tables
- Present the Table with the following columns:
  - N - Study Dose (mg) - Tmax (h) - Cmax (ng/mL) - AUC0-last (h·ng/mL) - AUC0-∞ (h·ng/mL) - t1/2 (h·)
  - Present a separate set of rows for each dose or part.
  - For Tmax -present Median (minimum, maximum).
  - For Cmax - present mean, SD (standard deviation), and CV%
  - For T1/2 - mean, SD, and CV%
  - For AUC0-last - mean, SD, and CV%
  - For AUC0-∞ (h·ng/mL) - mean, SD, and CV%
- **##Important** Do not invent data; if unavailable, say NR for Not Reported.
- For each parameter, place mean, SD, and CV% in the same cell
- State as a table footnote whether geometric mean or arithmetic mean is used.
- Add CSR references as footnotes under each table.
- **##Important** Prepare a formatted Word document containing all the PK tables and include them in the same document.
- Name the Word document as Study-Code-PK-Tables-Date (YYYY-MMM-DD format)

Conclusion/Discussion

- AI tools are surprisingly accurate with key messages
  - Could detect something that the MW has overlooked
  - Could verify something already identified by the MW
- It is important to tell the tool what are your parameters for considering something "clinically meaningful"
- Great start point for the MW to apply their critical thinking



Take Home Messages

- AI accelerates repetitive, data-intensive tasks
- Medical writers offer what computer algorithms cannot!
  - Critical thinking, contextualisation, and a nuanced understanding of reviewer expectations
- CORE Reference underpins high quality CSR development and informed AI use
  - Provides foundational knowledge of CSR development
  - Supports MWs in the critical appraisal of AI output

References

- CORE Reference
  EMWA/AMWA Budapest Working Group (03 May 2016). The CORE Reference Manual. Available at DOI: https://doi.org/10.56012/copjhc4062
- **AI in medical writing – tools, tantrums, and testimonies**
  Author: Lisa Chamberlain James
  Medical Writing. 2025;34(2):98–99. https://doi.org/10.56012/zdsk2809


thank
you