Clarity and Openness in Reporting: E3-based

Webinar by Mirjana Miric, Worldwide Clinical Trials
“CTIS and Clinical Trial Transparency: Strategies, Challenges, and CRO Insights”

Hosted by Sam Hamilton, for The CORE Reference Team
16 January 2026

Agenda

- CORE Reference CPD resources
- CORE Reference: 10 year anniversary
- External speaker: Mirjana Miric, Worldwide Clinical Trials
- Questions from webinar attendees

What is CORE Reference

- Original open-access best practice resources published in May 2016
  - **CORE Reference**
  - **Mapping Tool**
  - Launch paper in BMC
  - **Website launch**
- emwa.org/resources/the-core-reference-project/

CPD Resources

- **Quarterly CPD through 2018**
  - 2017: Utility Survey
- **Monthly CPD Dec 18 – Apr 22**
  - Jul 19: comments on FDA pilot program
  - 2019: BMC paper critiquing T/Cel CSR template; estimand integrated to Terminology Table worked example
- **EMWA Special Project Apr 22**
  - +3 team members, expanded CPD
- **Monthly CPD since May 22**
  - Dec 22: Comparison T/Cel CPT and ICH M11 template Level 2 headings
  - Jun 23: Webinar
  - Dec 23: Utility Survey
  - Dec 24: Webinar
  - Jun 25: Webinar
  - Jan 26: Webinar

CORE Reference

10-Year Anniversary

Medical Writing (MEW):

10-Year Anniversary Article
Spring 2026 ‘Careers’ Issue

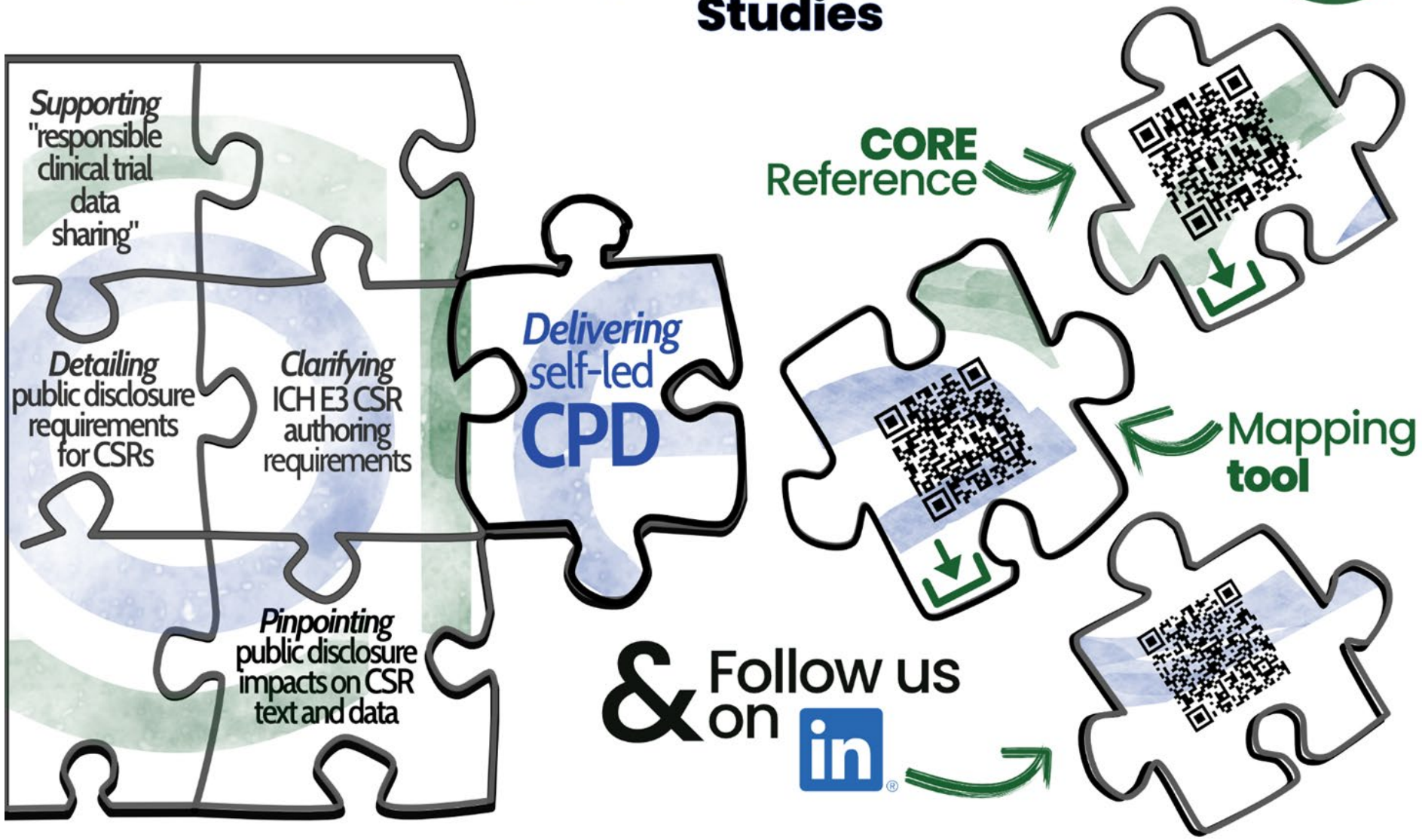
61st EMWA Conference Barcelona

Join us at the following lunchtime sessions:

- Wednesday 6 May 2026
  - Project history
  - Monthly CPD offering
  - Presentation by Celebration Supporter, Morula Health
- 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 Celebration Supporter, Trilogy Writing

info@emwa.org

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



Webinar

External speaker: **Mirjana Miric,** Worldwide Clinical Trials

“CTIS and Clinical Trial Transparency: Strategies, Challenges, and CRO Insights”

CTIS and Clinical Trial Transparency: Strategies, Challenges, and CRO Insights

Mirjana Miric, Transparency and Disclosure Manager

CTIS and Clinical Trial Transparency: Strategies, Challenges, and CRO Insights

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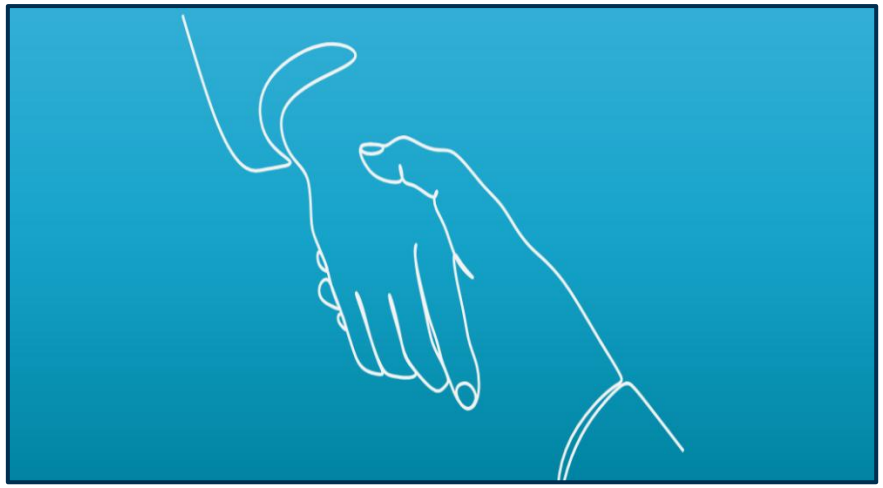
Worldwide Clinical Trials is a leading full-service global CRO, therapeutically focused on neuroscience, oncology, rare diseases, and cardiometabolic.

Our team of 3,500+ professionals spans 60+ countries and partners with biotechnology and pharmaceutical companies to create customized solutions that advance new medications – from discovery to reality.



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CTIS and Clinical Trial Transparency: Strategies, Challenges, and CRO Insights

Responsible disclosure of clinical information throughout the lifecycle of a clinical trial, ensuring that sensitive information is protected while maximizing the retained scientific value of every document.

Agenda:

- ❑ Building the Transparency Team
- ❑ Workflow Optimization from a CRO perspective
- ❑ Documents - what will be published & when
- ❑ What will be redacted?
- ❑ Identifying CCI and providing justification
- ❑ Best Practices for Redaction and Data Utility
- ❑ Common Issues and Proven Solutions – PPD
- ❑ Common Issues and Proven Solutions – CCI
- ❑ Overall Summary of Important Considerations
- ❑ Q&A

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Building the Transparency Team

People

- ✓ Include individuals with expertise in regulatory affairs, medical writing, and data protection for a well-rounded team.
- ✓ Invest in training and continuous learning to keep skills current.
- ✓ Define roles, responsibilities, and escalation paths for complex decisions.

Strategy

- ✓ Establish robust governance and processes with up-to-date SOPs for disclosure workflows.
- ✓ Ensure content consistency within the clinical trial to maintain compliance and clarity.

Communication

- ✓ Maintain open communication channels with the Sponsor's team for alignment.
- ✓ Centralize the submission dossier (MW–RA–TD) to enable effective collaboration and reduce time gaps.

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Workflow Optimization from a CRO perspective

The Transparency and Disclosure Lead – responsible for managing the study redaction campaign.

ONBOARDING

- Identify in-scope documents

PROTECTED PERSONAL DATA – PPD

- Inform the Sponsor of the standard redaction rules for PPD.

COMMERCIALLY CONFIDENTIAL INFORMATION - CCI

- Collaborate with the Sponsor to identify and assess CCI.
- Conduct a literature search.
- Capture decisions and findings in the CCI Redaction Control Table.

REDACTION PROPOSAL

- Document redaction decisions in the “Marked for Redaction” PDF version.
- The TD QC Reviewer performs a quality check.
- Sponsor approves redaction

FINAL REDACTED DOCUMENT

- Apply redactions.

Documents - what will be published & when

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Annex 1 – Revised Transparency Rules and Guidance Document

Documents type	Category 1		Category 2 and 3 *including integrated ph1&2*
	Paediatrics and/or PIP	**Adults**	
Protocol, synopsis, patients facing documents	Upon results' submission	30 months after EU/EEA End of Trial	First MSC decision
SmPC, if available	Never		
Subject information and informed consent form			That MSC decision
Recruitment arrangements, *including procedures for inclusion and copy of advertising material*			
Final summary of results, Lay person summary of results	As soon as submitted	30 months after EU/EEA End of Trial	As soon as submitted
Clinical study report, *if available*	As soon as submitted *(requirement: 30 days from MA)*		
All other documents, including any MS document	Never		

What will be redacted?

PROTECTED PERSONAL DATA – PPD

- Direct identifiers: name, signature, personal ID, phone number, e-mail address
- Quasi (indirect) identifiers: age, gender, race, ethnic origin, title, IP address, insurance policy numbers, specific financial agreements, etc.
- Redacted per GDPR and EU CTR requirements
- Labeled per EMA Policy 0070 guidance

PPD

COMMERCIALLY CONFIDENTIAL INFORMATION – CCI

- Any information contained within a document that, if disclosed, could undermine the legitimate economic interest of the company
- Information known to the research organization but not the public
- Redacted per Sponsor's instructions
- Labeled per EMA Policy 0070 guidance

CCI

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Identifying CCI and providing justification

	A	B	C	D	E	F
1	Project Name: Document name:	Page Number (s)	Text Proposed for Redaction by Applicant/MAH	Applicant/MAH to reference the section(s) of Annex 3 of Policy 0070 on which the redaction is based.	Detailed Justification of Proposed Redaction	WCT Comments

Examples of potential CCI

Potentially Patentable Subject Matter	Trade Secrets
Novel compound, device, indication, or pathway. Novel dose size or dosing regimen. Novel diagnostic methods and manufacturing processes.	Dose rationale, statistical methodologies, formulations, development strategy, future development plans, innovative analytical methods/assays

The specific section(s) of Annex 3 of Policy 0070 that justify the request for redaction.

- Product Development Rationale
- Biopharmaceutics - Detailed information on bioassays and analytical methods
- Clinical Pharmacology - PK/PD determination
- Benefits and Risks Conclusions
- Information on protocol development
- Study Objectives (including Exploratory Endpoints and Efficacy and Safety Variables)
- Determination of Sample Size

Information not considered CCI

Public Information - available in the public domain.

Public knowledge - information reflecting common knowledge shared within the scientific community.

CCI Redaction Control Table - EMA Justification Table template

Best Practices for Redaction and Data Utility

PPD

- Utilize **worst-case adversarial model** to prevent linkage attack – re-identification through quasi-identifiers combined with external datasets.
- Do not redact the names of the Principal Investigator and the Sponsor's legal representative.
- Sanitize metadata that could reveal identities.
- Redact all handwritten or digital signatures.
- Redact unique organizational titles if they enable identification.

CCI

- Anonymize CTIS structured data fields (which cannot be redacted).
- Redact only what is necessary to protect innovation and competitive advantage.
- Near-term vs. long-term CCI
- Perform a literature check for all sections flagged as CCI:
  - EUCTR, ClinicalTrials.gov, WHO ICTRP
  - Sponsor's press releases and webpage
  - Scientific literature

CTR-mandated short timelines increase the risk of human error. Do not skip QC Review.

Common Issues and Proven Solutions – PPD (1 of 2)

- Names and contact details available in the public domain: **public availability does not exempt PPD from protection requirements in CTIS** (GDPR & EU CTR).
- **Insurance number** - linkage attack risk – mosaic effect
- **Reimbursement fees** – combined redaction:
  - **PPD**
    - specific amount (eg, 50$ - in local currency €43.09, Kč1,080, Ft19,500) - linkage attack risk
    - payment per km – location identification risk
  - **CCI** - if it includes details of cost structures or agreements that could impact negotiations or market behavior, or reveal the sponsor's financial strategy.

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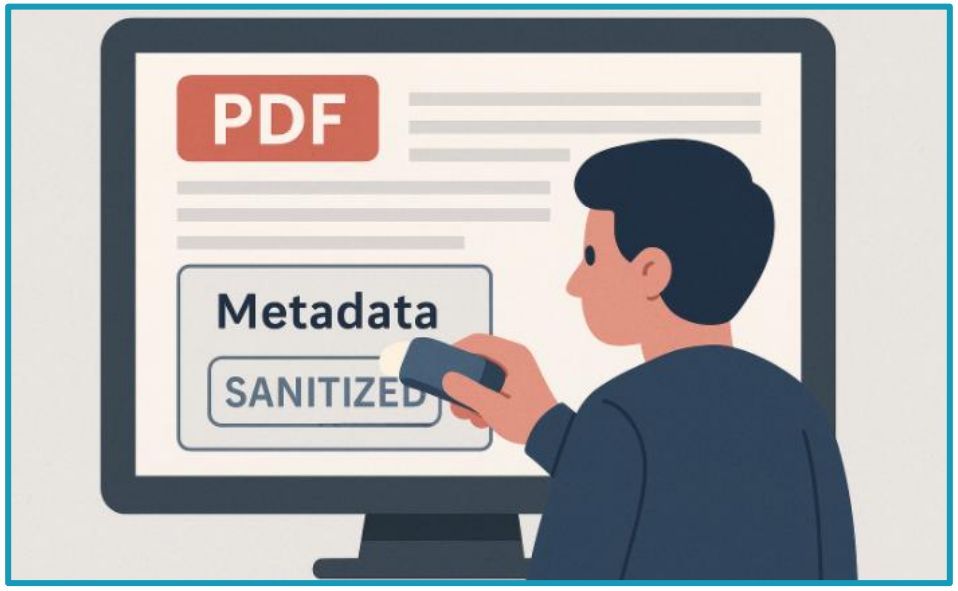
Common Issues and Proven Solutions – PPD (2 of 2)

- PPD in **QR Codes**: Decode the QR Code, extract, and review the full content. Potential PPD – names and contact details of service providers' employees (agents, DPOs).

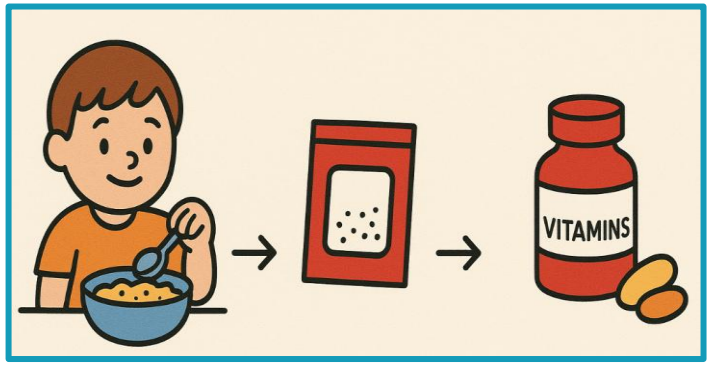
- **PPD in Document Metadata** - sanitize document to remove background information such as:
  - author information
  - timestamps of contributors' comments in revision history containing their names or initials.



Common Issues and Proven Solutions – CCI (1 of 2)

- Third-party **intellectual property** – CTIS placeholder or redaction per service provider's instructions.
- Unit values can be considered CCI, and **measurement units** must be disclosed. Exception example: first weight-based vs. unique dose or vice versa.
- CCI in **advertising material**. Disqualify CCI or request that the content be changed.

- Failure to recognize **CCI redacted in protocol** in children's **assent visuals**. Examples:



- Novel IMP-specific delivery systems or formulations (e.g. granules)
- Use of IMP-specific concomitant medication

- Protocol-driven clinical assessments (e.g., related to IP's risk profile)
- Specific diagnostic procedures that are not routine clinical assessments

Common Issues and Proven Solutions – CCI (2 of 2)

Revision of the CCI redaction strategy: an assessment of **short-term** versus **long-term CCI** should be conducted for every CTIS modification. For example, information previously considered CCI may have been published in other regulatory registries, presented in scientific articles, or disclosed at conferences.

Exception: Adding new CCI is acceptable only if it results from changes to the deferral mechanism introduced by the Revised Transparency Rules, which removed the option for Sponsors to delay the publication of core clinical trial documents on the CTIS public portal for a defined period.

Logical inference that can reveal CCI:

- Pattern Recognition
- Contextual Clues
- Structural Consistency

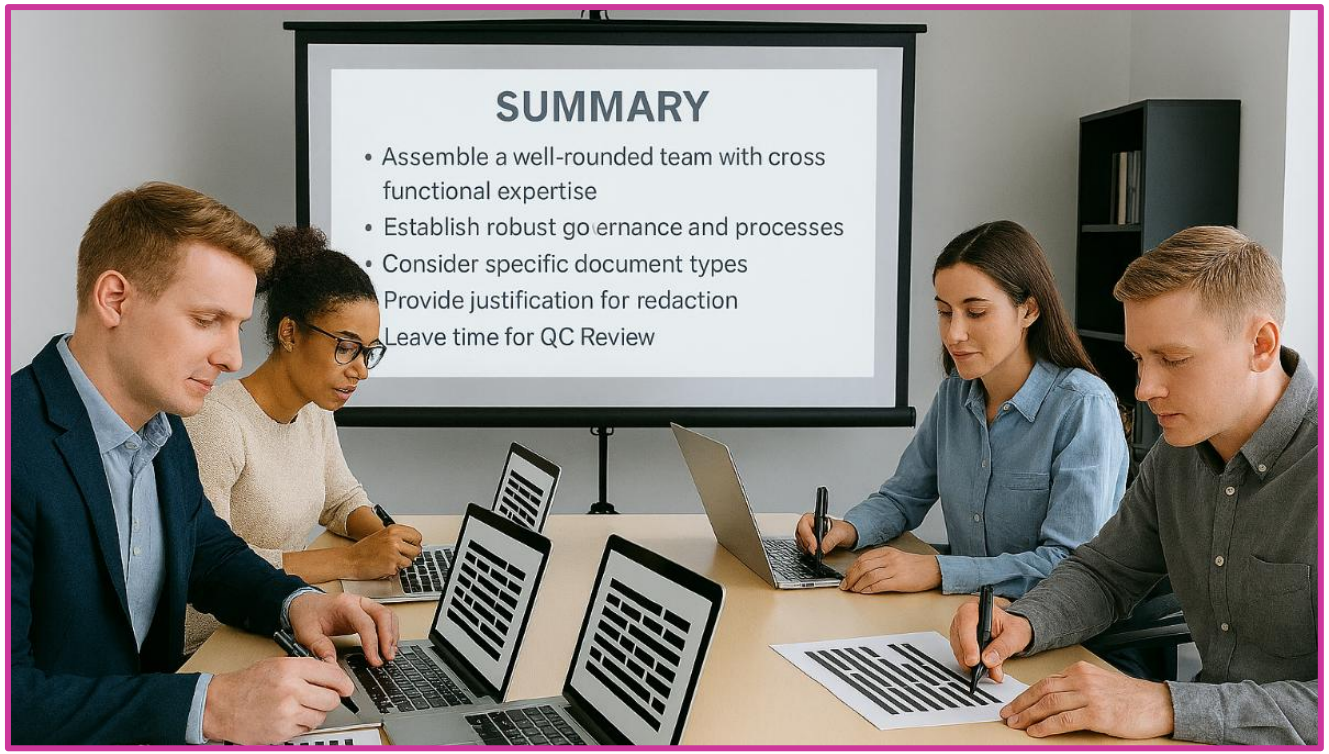
Redaction focused on removing the sensitive term itself, not the surrounding context. Logical deduction fills the gaps by comparing patterns.

For the dose-finding phase, which involves four mandatory cohorts, each participant is randomized to one of four doses of ABC-007: 1.5 mg/kg, 3 mg/kg, 4.5 mg/kg, and 6 mg/kg. Based on previous studies with ABC-007, randomized dosing does not raise any safety concerns.

For the dose-finding phase, which involves four mandatory cohorts, each participant is randomized to one of four doses of ABC-007: CCI [redacted] Based on previous studies with ABC-007, randomized dosing does not raise any safety concerns.

Overall Summary of Important Considerations

- Assemble a well-rounded team with cross-functional expertise
- Establish robust governance and processes
- Consider specific document types
- Provide justification for redaction
- Leave time for QC Review



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Please feel free to ask any questions or share your thoughts

USEFUL RESOURCES:

- EU CTR
- Guidance document on how to approach the protection of personal data and commercially confidential information while using the Clinical Trials Information System (CTIS)
- Revised CTIS Transparency Rules
- Sponsor handbook CTIS user guidance on the sponsor's workspace
- External guidance on the implementation of the European Medicines Agency Policy 0070 on the publication of clinical data for medicinal products for human use

Thank you!

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