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## Safeguarding CCI in the Age of AI

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THE OPINIONS IN THIS PRESENTATION ARE OF OUR OWN  
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# WHY THIS CONVERSATION MATTERS NOW

- AI is increasingly embedded in clinical authoring and review workflows
- Transparency obligations continue to expand globally
- CCI protection remains a core sponsor responsibility
- AI changes how we must think about exposure and control

# WHAT IS COMMERCIALLY CONFIDENTIAL INFORMATION (CCI)?

**CCI is information that, if disclosed publicly, could:**

- Undermine competitive advantage
- Reveal proprietary scientific or strategic decisions
- Expose trade secrets or process innovation
- Signal future development direction
- Alter market positioning

**CCI is strategic — not just technical.**

# WHY CCI IS DIFFICULT TO DETECT?

- Rarely labeled as “confidential”
- Embedded in interpretation, not raw data
- Context-dependent
- Often harmless in isolation
- Sensitive when combined with other signals
- Distributed across sections of a document

# WOULD YOUR WORKFLOW FLAG THIS?

*“An exploratory cohort evaluated a modified lipid nanoparticle ratio to improve hepatic targeting. Internal modeling suggested improved durability compared to the legacy platform.”*

- Not a primary endpoint
- Scientifically appropriate
- Strategically revealing

**Would your system flag it?**

# HOW CCI IS TYPICALLY REVIEWED TODAY

- Manual document review
- Keyword-based searches
- Reviewer judgment and experience
- Static redaction workflows
- Post-hoc justification documentation

## AI CAN AMPLIFY

- Generate narrative at scale
- Connect insights across sections
- Surface relationships humans may not immediately see

## AI CAN DETECT

- Identify contextual patterns
- Recognize exploratory or forward-looking language
- Surface cross-section thematic signals

## AI CAN EXPOSE

Exposure Risk can be introduced by:

- External tool usage
- Insufficient boundary controls
- Lack of structured audit trace

# MOVING BEYOND KEYWORDS: CONTEXTUAL DETECTION

**AI can be designed to:**

- Analyze meaning, not just terms
- Detect exploratory or forward-looking language patterns
- Identify references to internal modeling or optimization
- Recognize thematic signals across sections
- Flag content based on contextual sensitivity

# CALIBRATING SENSITIVITY: HUMAN-IN-THE-LOOP CONTROL

**AI flagging can operate at different levels:**

- Word-level precision
- Sentence-level interpretation
- Paragraph-level strategic context

**Allows reviewers to:**

- Adjust thresholds by submission type
- Calibrate based on regulator expectations
- Balance transparency with protection

# FROM DETECTION TO DEFENSIBILITY

## **Structured Workflow:**

1. AI flags contextually sensitive content
2. Reviewer validates, adjusts, or overrides
3. Redaction is applied consistently
4. System generates a structured justification shell

## **Output Includes:**

- Redacted document
- Linked decision log
- Pre-formatted justification table

# AI ENVIRONMENT MATTERS

## Public / External AI Tools

- External data boundaries
- Limited control over model retraining
- Minimal audit trace of decision logic
- Not designed for regulated documentation workflows

## Secure Enterprise AI Environments

- Controlled data isolation
- Defined governance and access controls
- Traceable decision logs
- Alignment with validation and quality systems

# DESIGNING FOR DEFENSIBILITY

**Mature CCI safeguarding in AI-enabled workflows requires:**

- Contextual semantic detection
- Reviewer-controlled sensitivity thresholds
- Structured redaction-to-justification pairing
- Human-in-the-loop validation
- Secure enterprise AI boundary
- Integrated governance and audit traceability

# LOOKING AHEAD

## **As AI becomes embedded in clinical workflows:**

- Transparency and protection must coexist
- CCI decisions must remain defensible
- Governance must evolve with capability
- Architecture determines outcome

The background is a dark blue field with a subtle, glowing network of white lines and dots, resembling a digital or neural network. The letters 'AI' are large, white, and bold, positioned on the left side of the image.

**AI**

**CAN EITHER  
AMPLIFY  
EXPOSURE OR  
STRENGTHEN  
DEFENSIBILITY**

**THE DIFFERENCE IS  
ARCHITECTURE**