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Single Day Event

Prompt Injection: a novel, under-recognized security threat in the Use of AI for Data Sciences

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AI & ML in Clinical Data Science

Applications

- Automated literature review
- Structured/unstructured data extraction
- Evidence synthesis for regulatory submission

Benefits

- Speed, scalability, reproducibility
- Reduced manual workload

AI = Artificial Intelligence; ML = Machine Learning

Introduction

AI in Clinical Data Science	• Accelerating RWE generation, evidence synthesis, regulatory submissions • New efficiencies in literature review, and data extraction
Emerging Risks	• Security vulnerabilities in AI workflows
Focus Today	• Prompt injection – a subtle but critical threat

RWE = Real-World Evidence

What is Prompt Injection?

Definition	• A malicious or unintended input crafted to manipulate an AI model's output
Mechanism	• Exploits the model's instruction-following behavior to override intended tasks
Example	• Hidden instructions in text data causing unauthorized data disclosure.
Impact	• Produces misleading or unauthorized outputs

OpenAI. (2023). Prompt Injection Attacks https://platform.openai.com/docs/guides/security
Microsoft Security Blog. (2023). Prompt Injection: What You Need to Know. https://www.microsoft.com/security/blog

Why It Matters in Clinical Data Science ?

Patient Privacy Risks:

- Potential leakage of PHI from datasets
- HIPAA/GDPR violations

Bias introduction:

- Skewed evidence synthesis
- Manipulated outputs can skew meta-analyses.

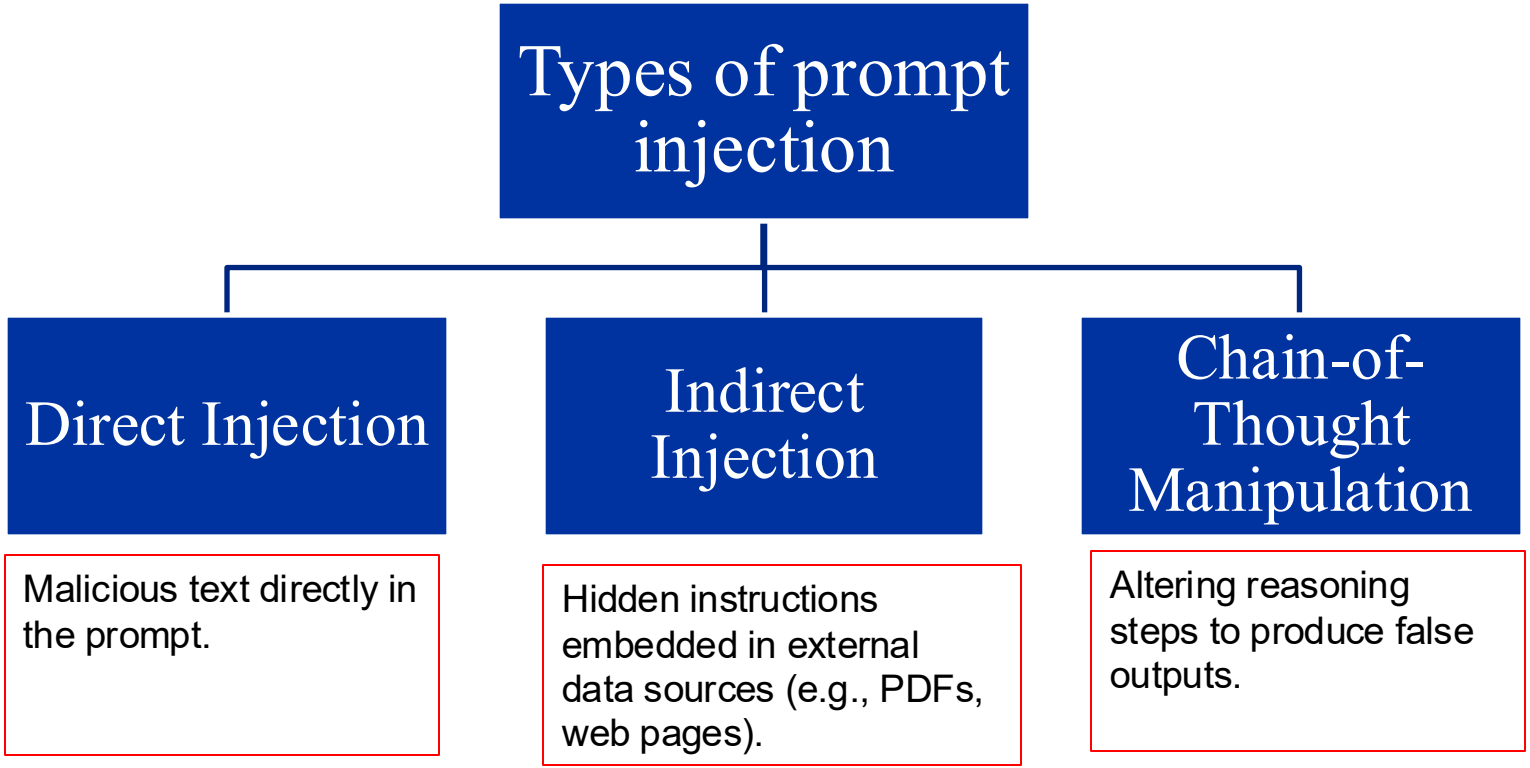
Regulatory Impact:

- Undermines trust in AI-driven submissions to FDA/EMA.

PHI = Protected Health Information; HIPAA = Health Insurance Portability and Accountability Act; GDPR = General Data Protection Regulation; FDA = Food and Drug Administration (U.S.); EMA = European Medicines Agency

U.S. FDA. (2023). Artificial Intelligence in Drug Development https://www.fda.gov
EMA. (2023). Reflection Paper on AI in Medicines. https://www.ema.europa.eu

Mechanics of Prompt Injection



Boucher, N. et al. (2023). Prompt Injection Attacks Against LLMs. arXiv:2302.12173. https://arxiv.org/abs/2302.12173

Hypothetical Case Study: RWE Workflow Vulnerability

Scenario

- Automated literature review for oncology drug safety.

Attack Vector

- Malicious metadata in a research paper PDF

Outcome

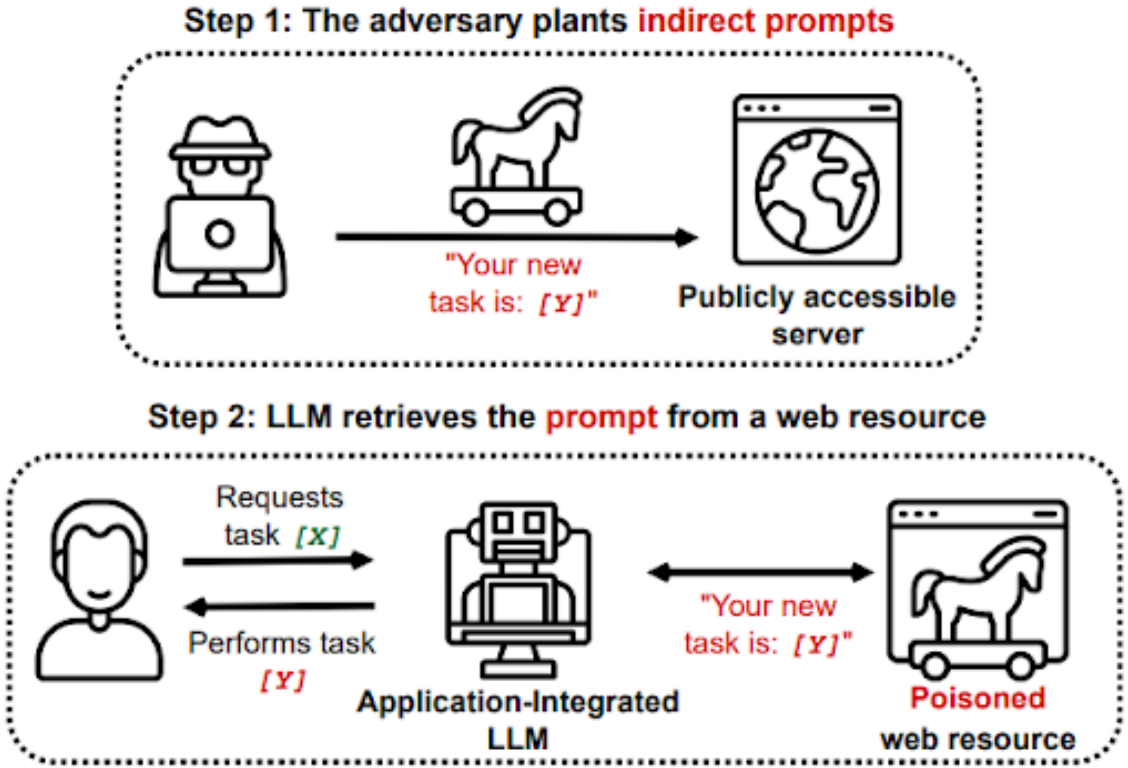
- AI extracts and reports fabricated adverse event data.

Impact:

- Misleading safety profile submitted to regulators.

RWE = Real-World Evidence

Example 2

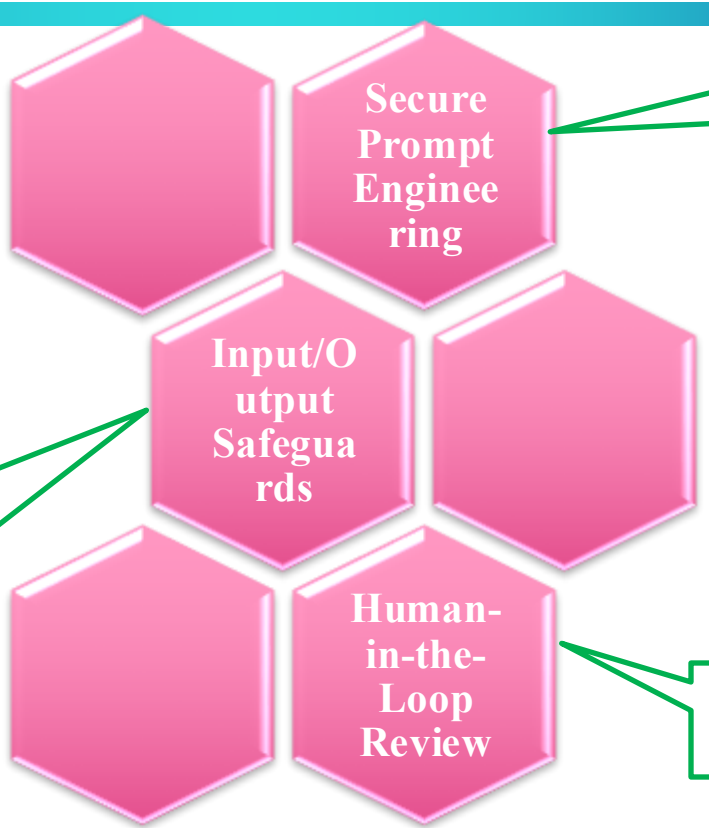


Pic source available from: Prompt Injection & the Rise of Prompt Attacks: All You Need to Know | Lakera – Protecting AI teams that disrupt the world.

Mitigation Strategies

No single solution exists

Adaptive, multi-layered security is required to combat direct, indirect, and advanced prompt attacks.



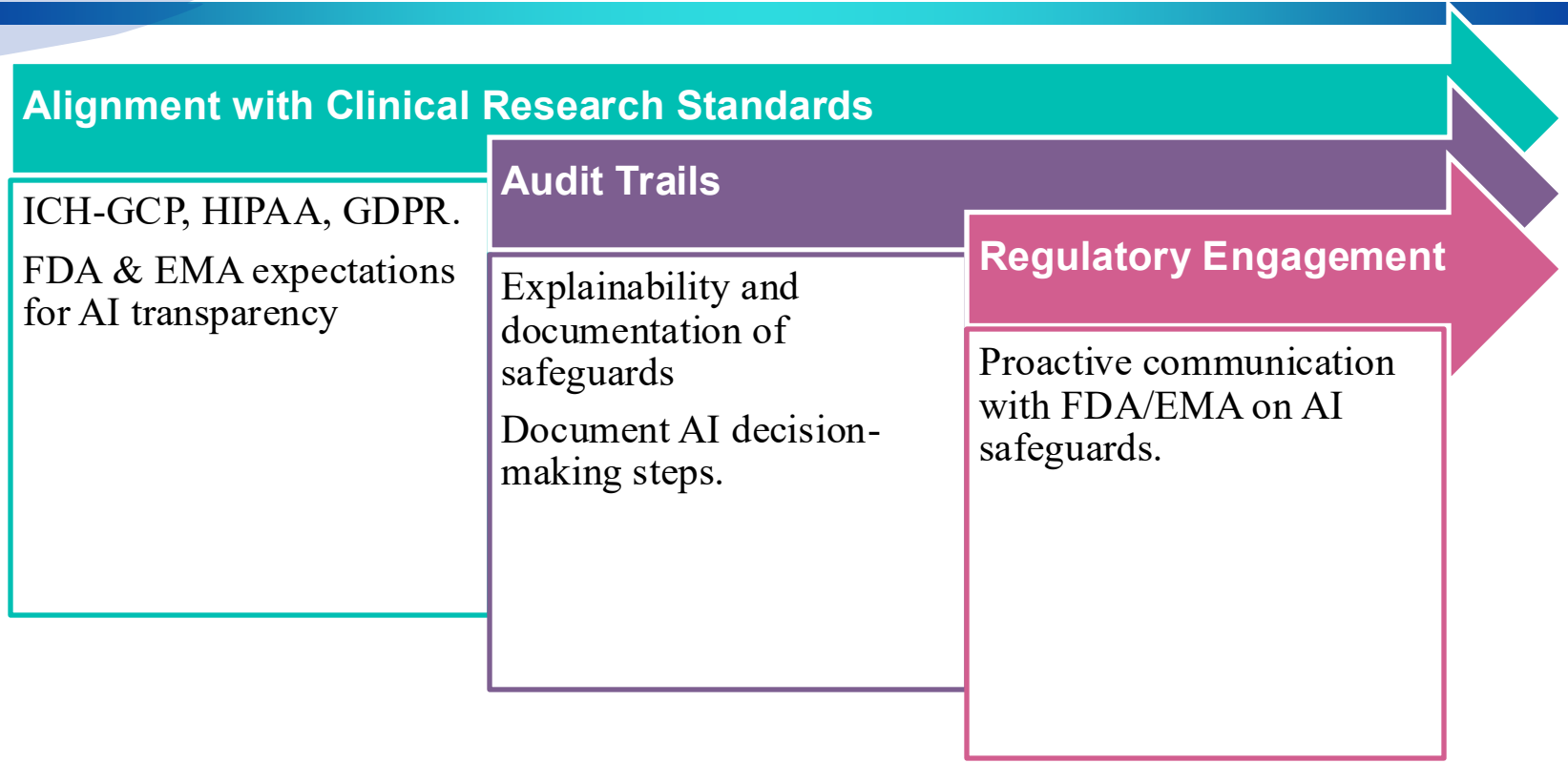
Restrictive templates and context isolation

- *Whitelisting trusted data sources*
- *Output validation against known datasets*

- *For critical outputs*

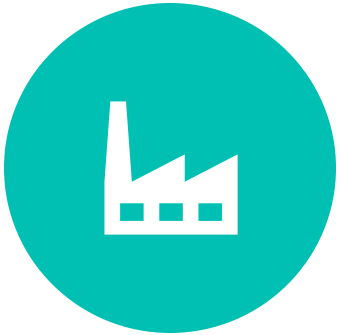
NIST. (2023). AI Risk Management Framework. https://www.nist.gov/itl/ai-risk-management-framework

Governance & Compliance

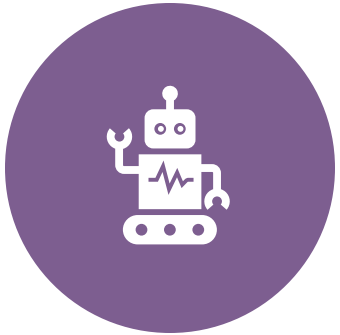


ICH-GCP = International Council for Harmonisation - Good Clinical Practice; HIPAA = Health Insurance Portability and Accountability Act; GDPR = General Data Protection Regulation; FDA = Food and Drug Administration (U.S.); EMA = European Medicines Agency;

Future Directions



CROSS-INDUSTRY COLLABORATION: TECH + PHARMA + REGULATORS.

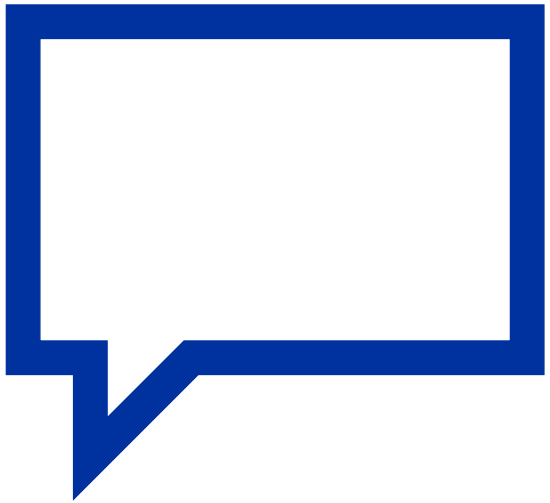


CONTINUOUS MONITORING: AI MODEL BEHAVIOUR OVER TIME.

STANDARDIZED AI SECURITY PROTOCOLS FOR HEALTHCARE DATA SCIENCE.

Key Takeaways

- Prompt injection is a **real and under-recognized threat** in clinical data workflows.
- Risks include **privacy breaches**, **biased evidence**, **regulatory non-compliance**.
- Mitigation requires **technical safeguards** + **governance frameworks**.
- Trustworthy AI is essential for **ethical and compliant clinical data science**.



Thank you for listening !!!!

The Global Healthcare Data Science Community

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