NCI MIDI Workshop

Advances in Medical Imaging
De-Identification and the Impact of
Regulatory Constraints

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State of the Art in Pixel De-identification of DICOM Images

- Tool to delineate PHI by region and apply pixel removal across multiple images
- · Can be problematic if series are misaligned
- May require individual region redaction by user
- Two possible next gen approaches in prototype stage
 - Define modality "formatting" and automatically remove region
 - Use ML and LLMs to find text in images and remove names
 - Have prototyped using AWS Rekognition
 - Requires uploading images containing PHI!



Harnessing AI and LLMs in De-identification of DICOM Images

- Leverage trained model for both pixels and structured reports
- How do Al solutions operate? Computer-assisted or autonomous
- Scalability and adaptability of Al solutions to handle large datasets and various medical imaging formats: Where will this run?
- If de-identifying video, will processing time be an issue?



Overcoming Regulatory Hurdles in Deidentification of DICOM Images

- Exploring regulatory changes to allow de-identification in the cloud
- Will investigator sites allow local software installation? (Is that practical?)

The technology is here to enable ML/LLM-driven de-id.

Investigator sites' IT departments are not ready



Navigating Machine Learning Integration in GxP Compliant Systems

- Addressing the dynamic nature of machine learning models in the context of GxP compliance requirements
- Establishing validation processes for AI and LLM-driven deidentification tools within GxP frameworks
- What does Change Control, Traceability and Reproducibility mean for machine learning models?

Need to collaborate with regulatory authorities to develop clear guidance for integrating machine learning systems in GxP environments

