



From Chaos to Clarity: Can AI/ML Truly Decode Unstructured Clinical Data?

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Meet the Speaker



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Speaker: Uma Adiseshan

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Uma is a Clinical Consultant at Zifo Technologies, Inc., with over 13 years of experience spanning drug discovery, clinical data management, and scientific business process improvements. She is specialized in translating complex R&D needs into innovative, compliant, and efficient solutions. With expertise in CDISC standards, RBM, QbD, and regulatory frameworks, she is passionate about leveraging technology and process improvements to accelerate drug development and improve patient outcomes.

Why Unstructured Clinical Data Matters

- *Unstructured data includes physician notes, patient-reported outcomes, and clinical images*
- *Clinical images contain high-value information for downstream analysis, biomarker discovery, and long-term reuse*
- *Secondary use depends on privacy-safe sharing and standardization*

Compliance Barrier: HIPAA / GDPR

- *Regulations restrict sharing unless Protected Health Information (PHI) is removed*
- *PHI may exist in pixel overlays and metadata (e.g., DICOM headers)*
- *HIPAA Safe Harbor: 18 categories of identifiers must be removed for de-identification*

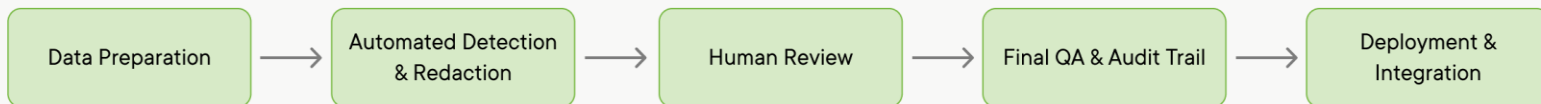
PHI Redaction in Images: Why It's Hard

- *Modality/device variability across sites (fundus, OCT, external)*
- *Noisy borders, partial occlusion, handwriting, low-quality text*
- *PHI exists in both pixels and metadata*
- *Must preserve diagnostic regions to maintain data utility*
- *Auditability and traceability requirements*

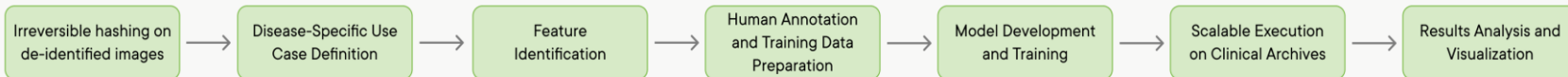
Redaction Approaches (and Why Hybrid GenAI)

- *Manual redaction: accurate but slow and hard to scale*
- *Traditional image processing / rule-based automation: brittle under variability*
- *Hybrid GenAI + human-in-the-loop: balances scalability, accuracy, and adaptability*

Method Overview: High-Level Workflow

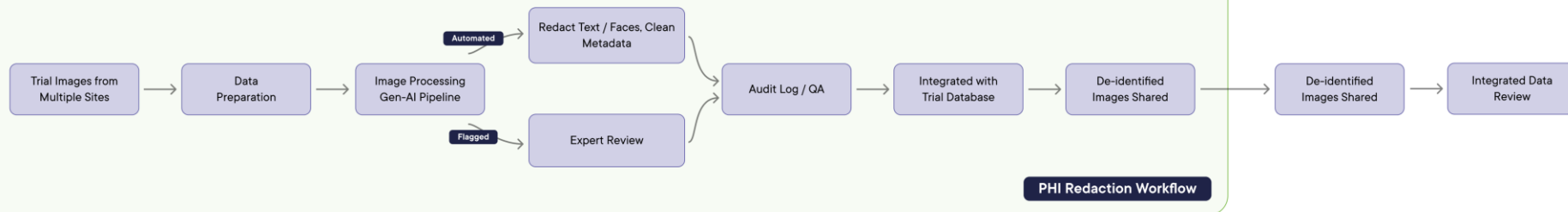


PHI Redaction with hybrid Generative AI solution



Enhancing Image Utilization in Clinical Trials with Machine Learning

Use Case: Ophthalmology Trial



Benefits

- *50% Faster PHI Redaction after image reception from clinical sites*
- *Empowered Clinical Analysis with image data and extracted features*
- *Enabled re-examination of archived images to identify new biomarkers, validate hypotheses, and maximize the value of clinical image data.*

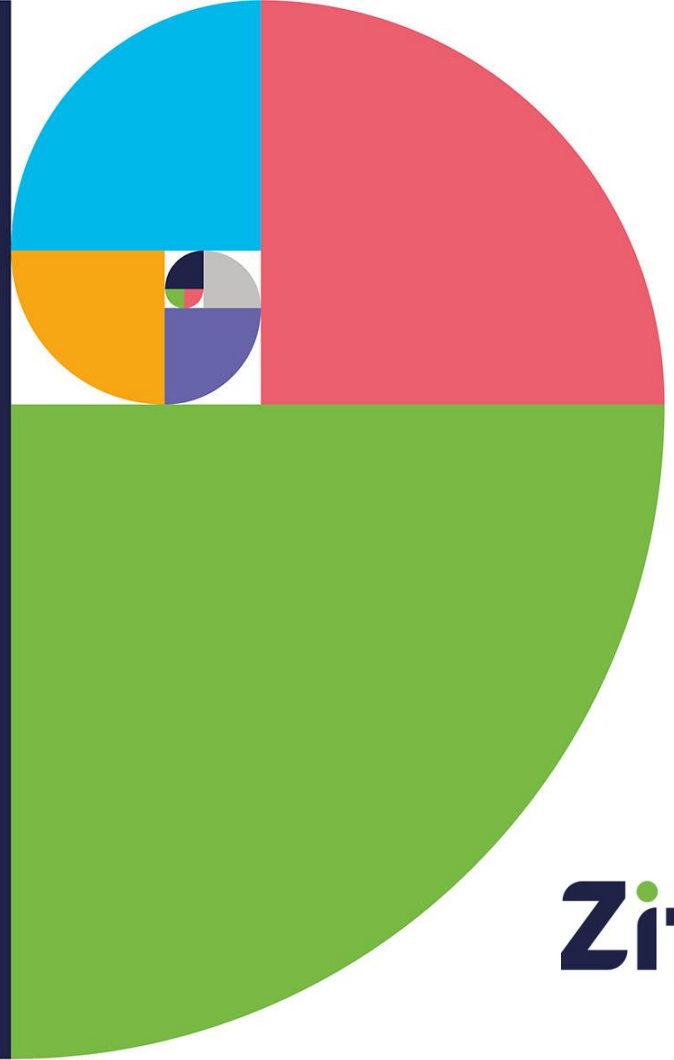
Regulatory & Lifecycle Readiness

- *Align with FDA PCCP concepts and Good Machine Learning Practices (GMLP)*
- *Data quality management, versioning, validation; completeness strategies*
- *Traceability through audit trails and lineage; structured risk assessment + explainability sites*

Conclusion

- *Hybrid GenAI + human-in-the-loop scales PHI redaction while preserving data utility*
- *Enables de-identified, standardized image archives for secondary analysis and feature extraction*
- *Requires monitoring, audits, and regulatory-aligned controls as expectations evolve*

Thank you



Zifo.