GILEAD
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Application of AI/ML and Computer Vision in Drug Development

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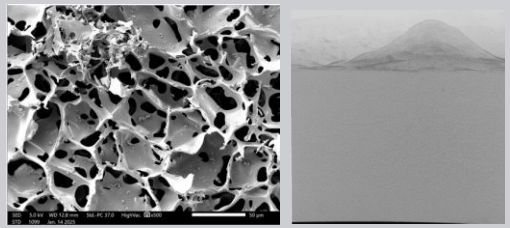
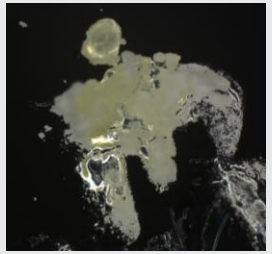
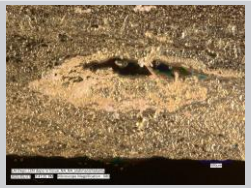
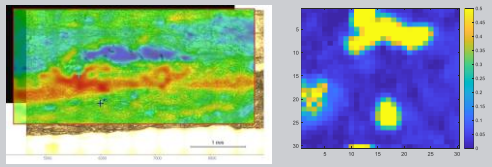
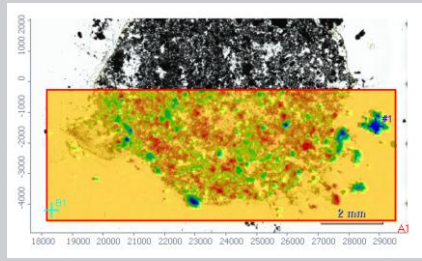
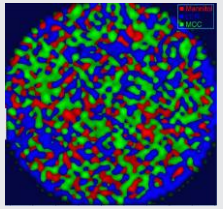
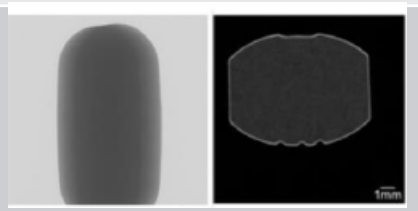
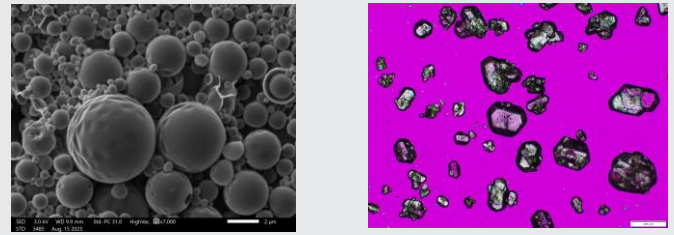
Pharmaceutical Development and Manufacturing
Gilead Science

Gilead utilizes a variety of image techniques to support drug development and characterization

Material	Technique	Example Image
Lyocake	SEM/CT	
Depot	CT/Optical Microscopy/SEM	
Tissues	Raman/FTIR/ Optical Microscopy	 

Material	Technique	Example Image
Drug Substance	IR	
Tablet	Raman	
Tablet	Micro CT	
Drug Substance	SEM/Optical	

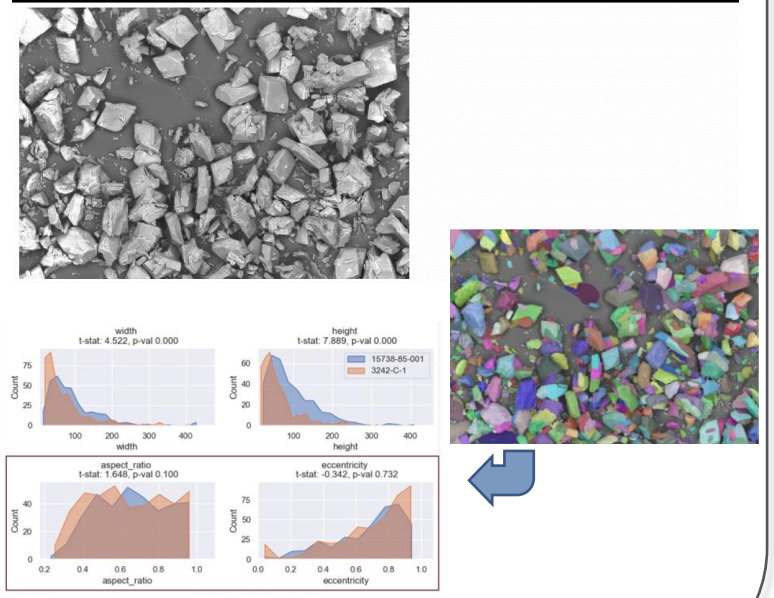
Apply AI/ML and Computer Vision to analyze image data and support quantitative decision making

Computer Vision in Drug Development and Characterization

Dry Powder

Morphological profiling of dry powder from SEM images

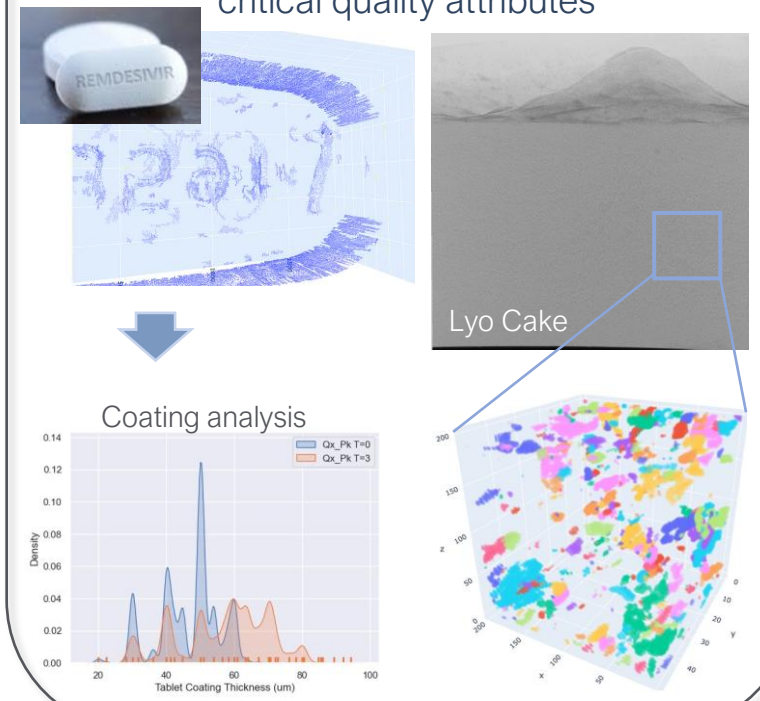
Advanced Segmentation



Morphology characterization and Statistical analysis to compare lots

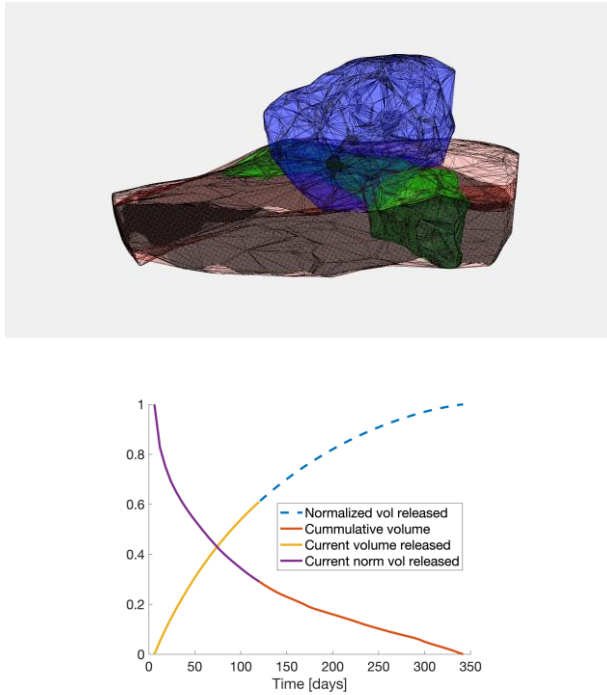
Drug Product

Correlating 3D microstructural properties (coating, porosity) with critical quality attributes



Ex vivo

Depot characterization for formulation and device screening



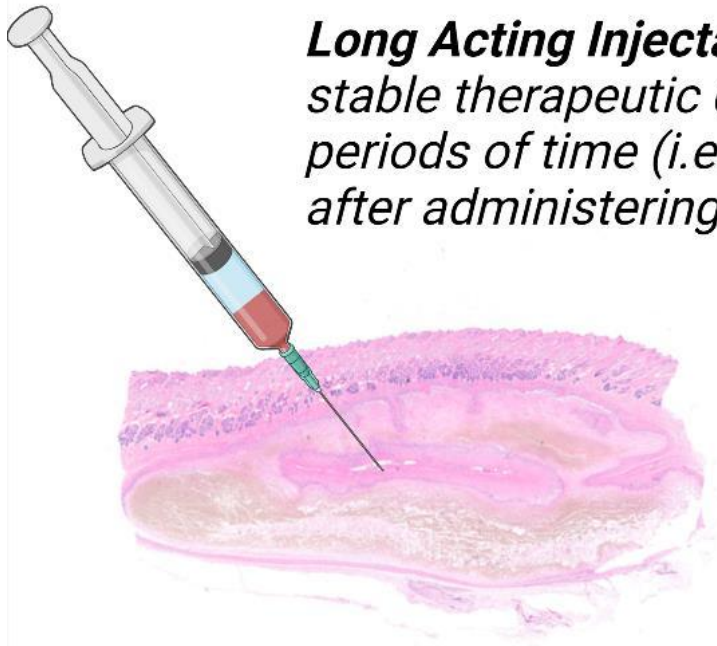
Chu et al., Simulation-based content uniformity engineering for drug development and manufacturing, International Journal of Pharmaceutics, 2025

Tin et al., A Nondestructive Image-Based Microstructural Characterization of Solid Oral Dosage Forms. IS&T International Symposium on Electronic Imaging 2025

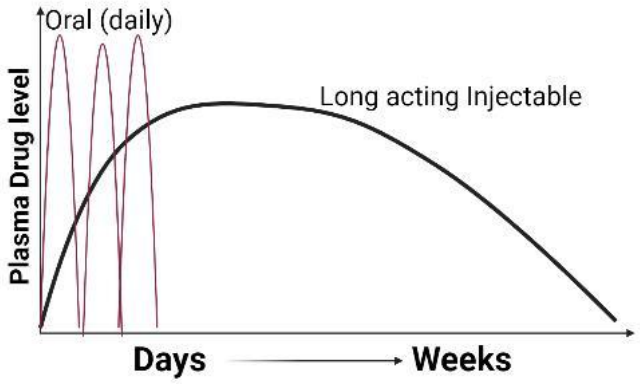
Wei-Ting Liu, Nicole Tin, Robert Gresham, Pallavi Pawar, Tyler Novak, Remus Osan. to be published

Apply AI/ML and Computer Vision for Long-Acting Injectable Depot Characterization and Tissue Interactions

Long-Acting Therapies Are Established as Providing Novel Benefits



Long Acting Injectable *(LAI) formulations provide stable therapeutic drug exposure for prolonged periods of time (i.e., weeks to several months) after administering a single dose.*



IM: Intramuscular, SC: Subcutaneous

Examples

- ***Olanzapine Pamoate-*** Once 2-4 weeks (1-2.7 mL), IM for Schizophrenia
- ***Lenacapavir-*** Once in 6 months (1.5 mL X 2), SC for HIV

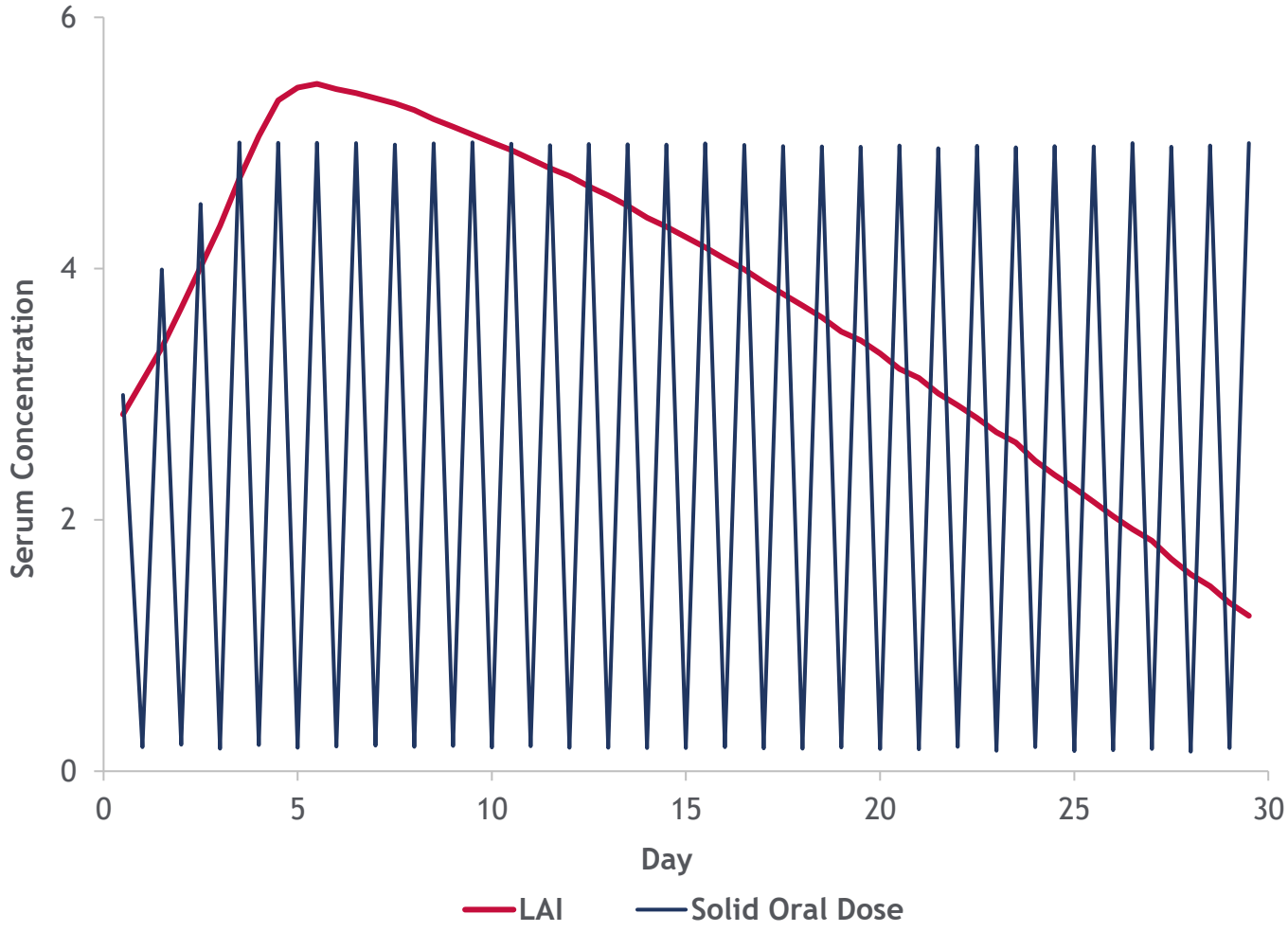
Enhance patient adherence to treatment, improve efficacy

Antiretroviral therapies have progressed to a one pill regimen, but treatment persistence remains an issue

40%-50% of chronic therapy patients stopped taking their medication (persistence)

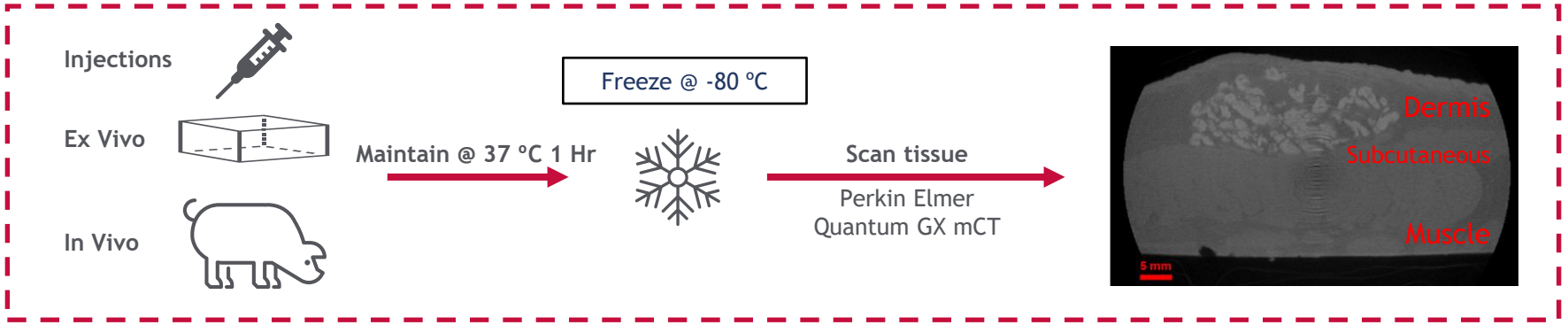
35% drop in patients who correctly dosed each day (adherence)

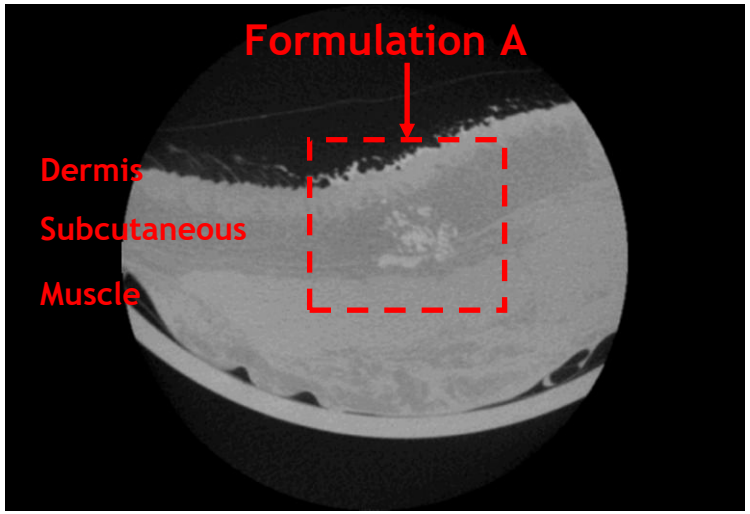
Coy, K *JIAS* (2019)

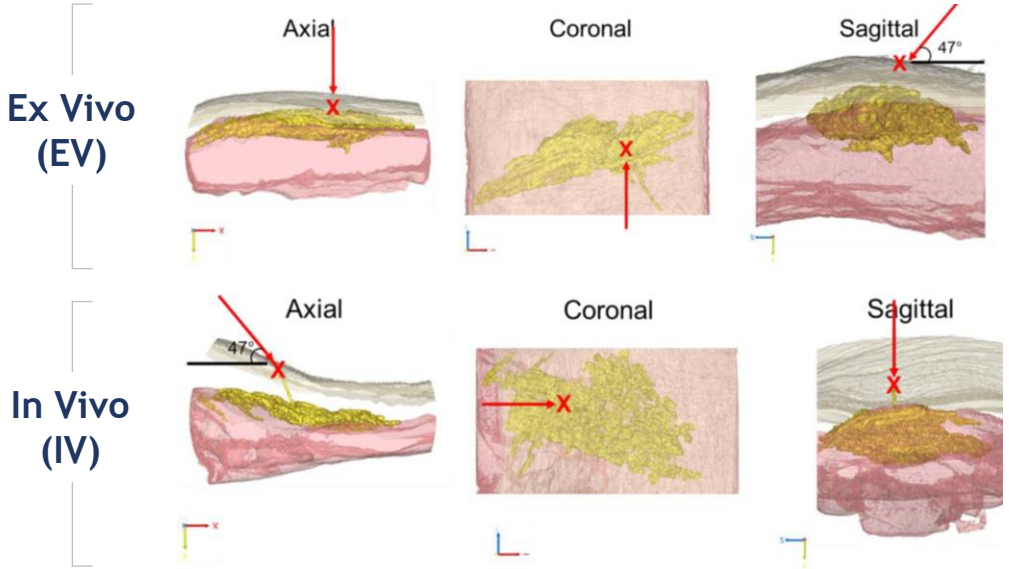


Ex vivo porcine tissue models are physiologically similar to human and µCT can visualize deposition of viscous LAI

For long acting injectables, the evaluation of formulation impact takes much longer than conventional injectables. Physiologically representative *in silico* models are essential to understand how formulations affect depot formation and the subsequent pharmacokinetics.

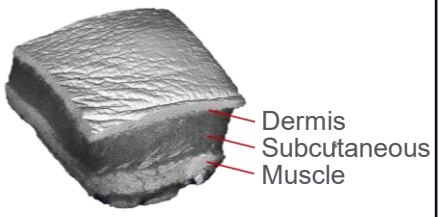




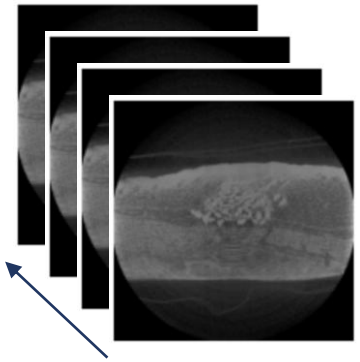


Apply AI/ML in 3D Analysis on Depot Geometry and Tissue Interactions

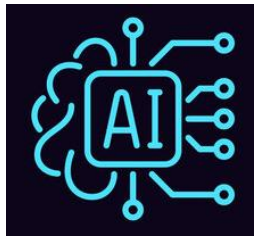
- Perform 3D analysis of depot geometry and dissolution simulation to support decision-making for screening and testing new formulations



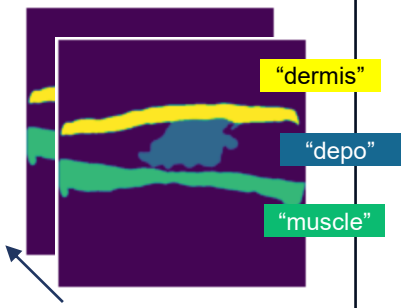
MicroCT images of LEN formulation injected in a representative porcine SC tissue



300-400 slices per sample

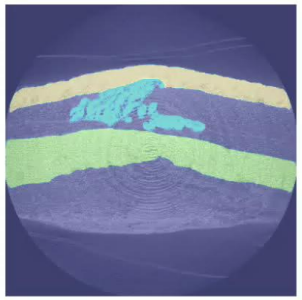


Create labels using AI assisted annotations for model building

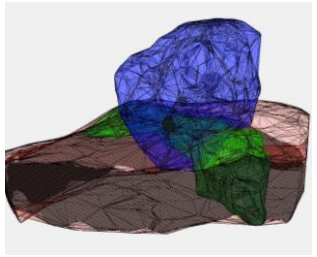


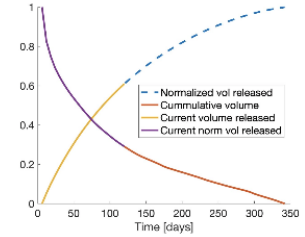
10-20 slices

Use Neural Network models to annotate full dataset

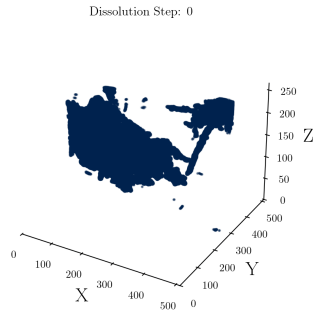


Construct in 3D and extract key features (i.e. surface area, volume, porosity).





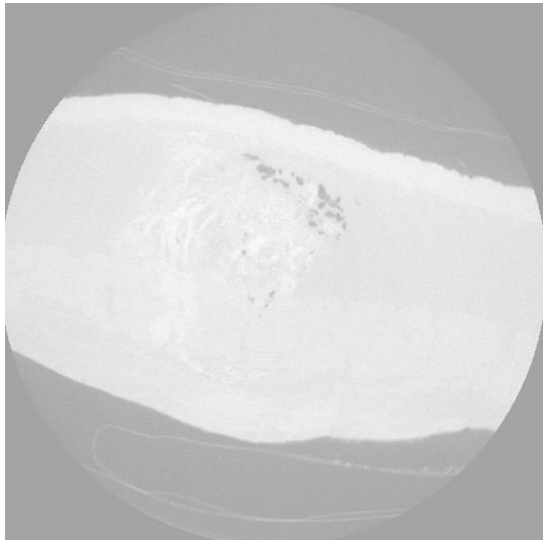
Develop computational models to estimate drug release

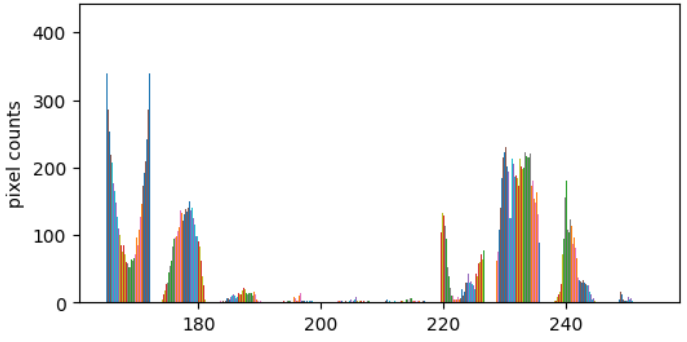


Data Preprocessing and AI-assisted Labeling to Prepare Training dataset

Histogram equalization: improves the contrast in an image, stretch out the intensity range via mapping to a more uniform distribution

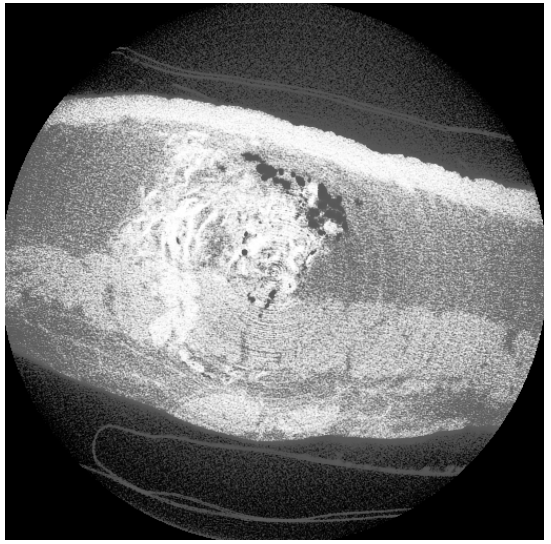
Raw image

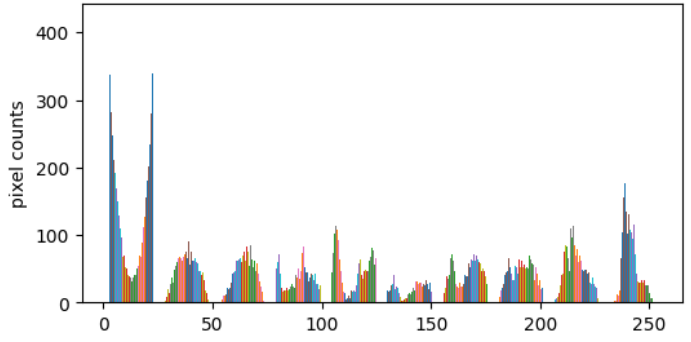




Histogram equalization

Enhanced image

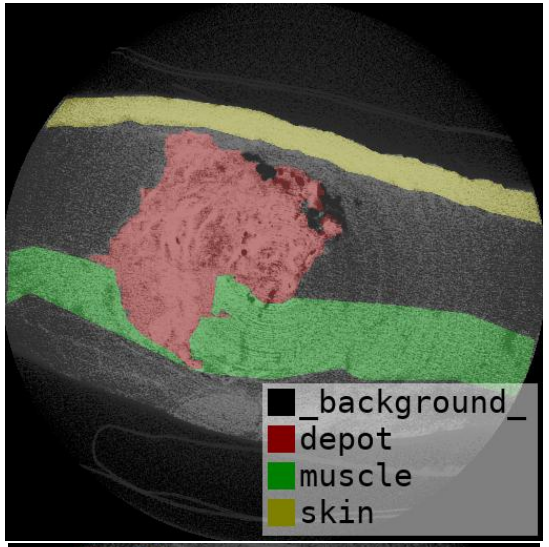


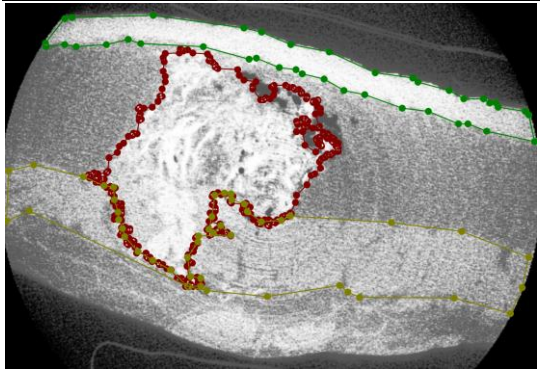


Prepare training data

AI assisted + manual adjustments

Labeled training image





AI/ML model building and digital twins allows investigating depot morphology and extract key attributes

Establish training library on a subset of images
(20 image slices per sample)

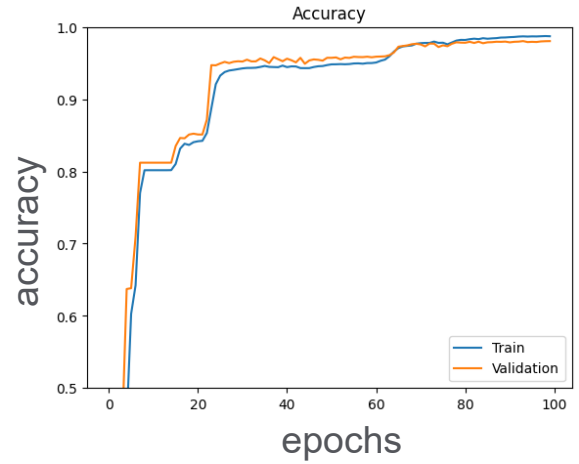
Train-Validation split

Train
(80%, 16 images)

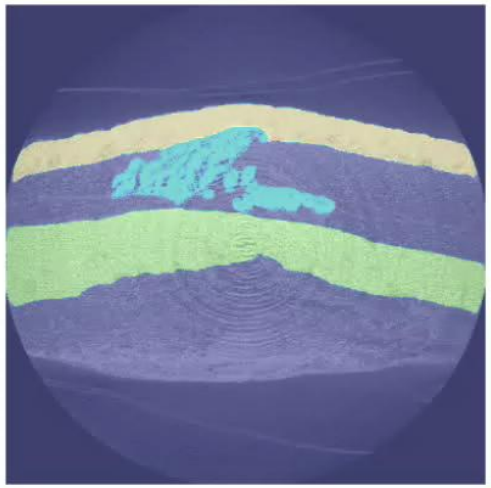
Validation
(20%, 4 images)

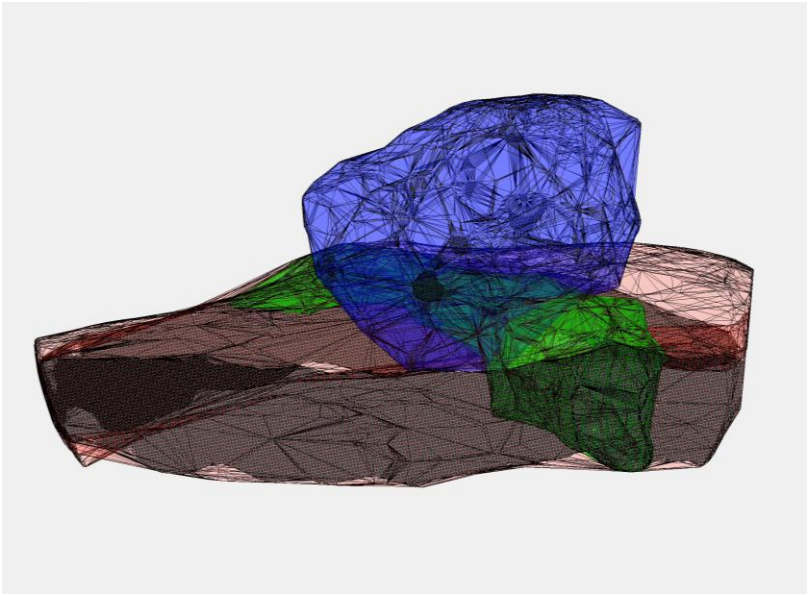
Models were trained using 80% of labeled data, and evaluated with the rest 20% of training data

With training 100 epochs, the model reached > 95% accuracy on validation data



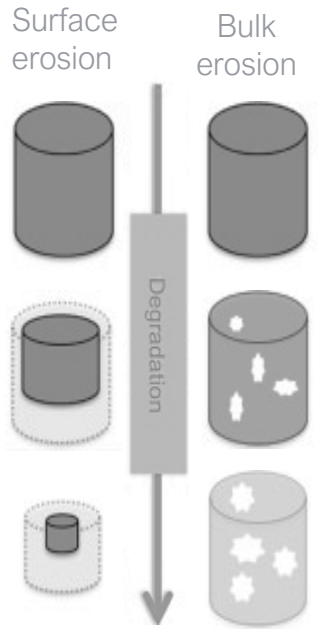
Use Model to annotate full data (400 slices)

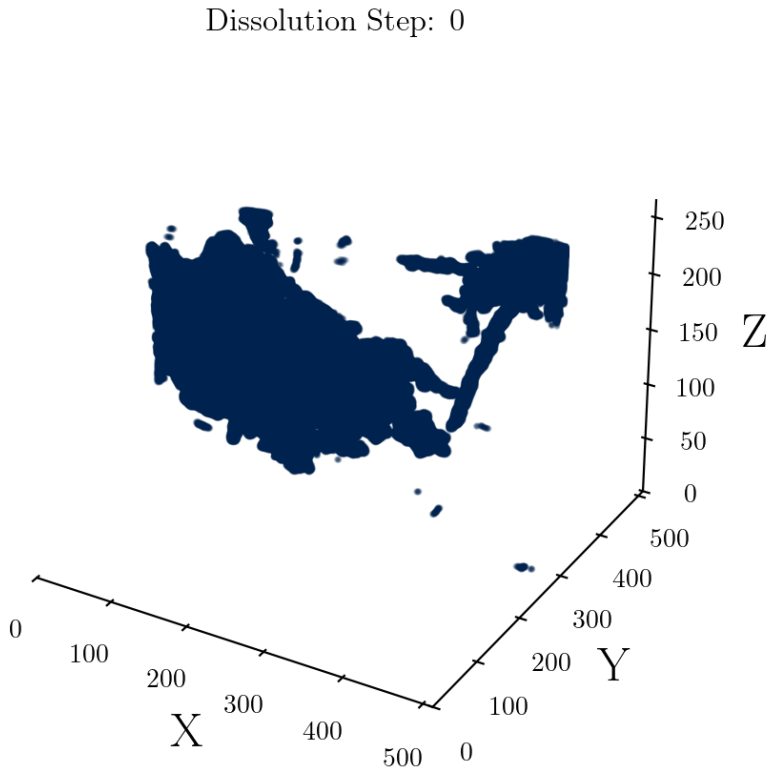


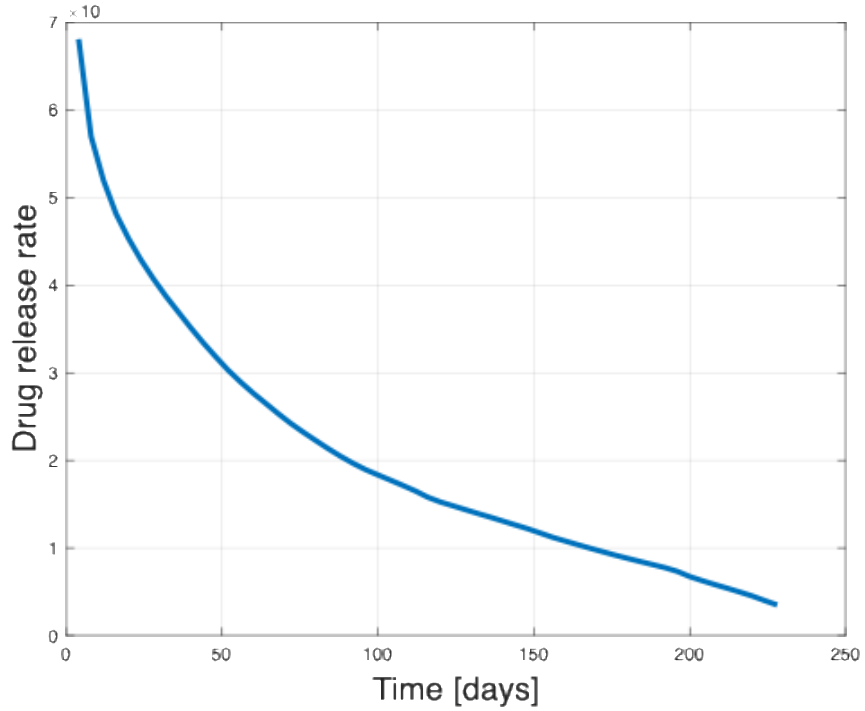


From 3D depot geometry to drug release rates

- Develop computational models to estimate drug release based on the 3D geometry







In silico modeling to predict drug dissolution and release rate

Conclusion

AI and deep learning algorithms efficiently segment µCT scanned LAI depots and dissolution models are developed to predict drug release profile

This model is broadly applicable to high viscosity LAI compounds, and we believe that this predictive model can abbreviate clinical trial requirements and accelerate transformative drug products to patients.

Acknowledgment

Analytical Development and Operations

- Remus Osan
- Chris Foti
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- Analytical Science Team

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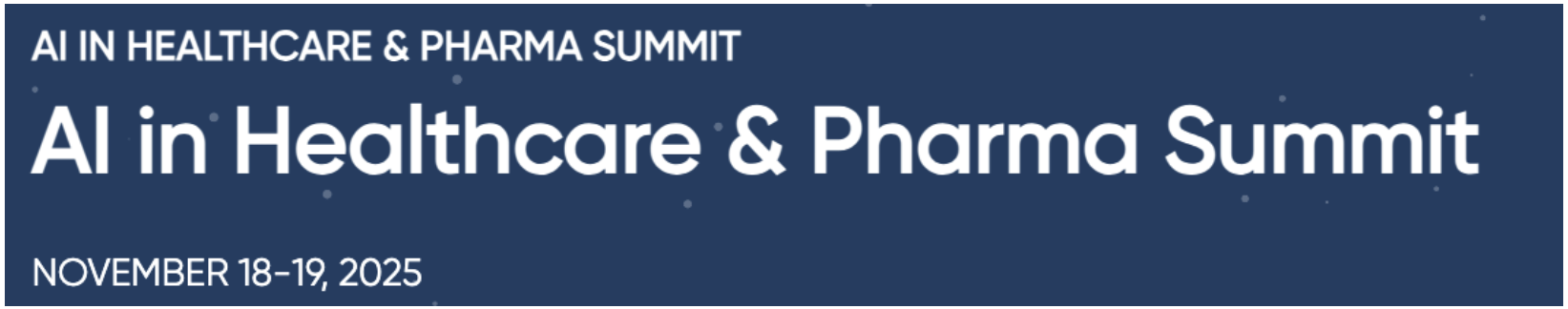
- Robert Gresham
- Tyler Novak
- Monica Swinney



Thank You