# Synthetic Data for GenAl TPLC Considerations





Yujan Shrestha, MD
CEO & PARTNER
yshrestha@innolitics.com

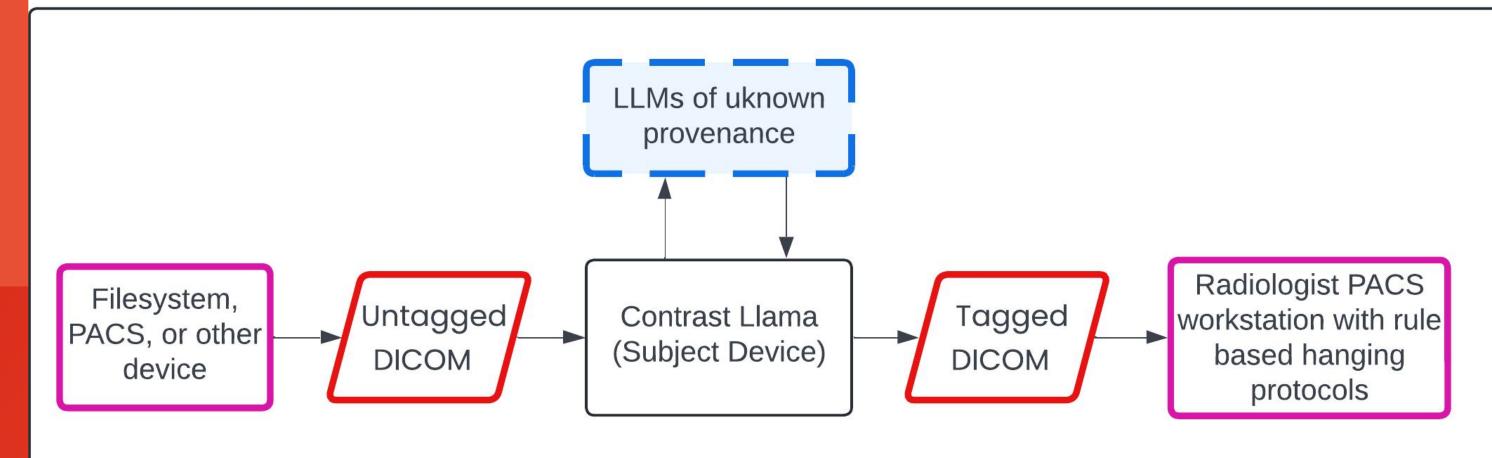
ysnrestna@innolitics.com (512) 967-6088

## Topic

- a. What specific monitoring capabilities should be considered to effectively evaluate and monitor the post market performance of generative Al-enabled devices to ensure they maintain adequate accuracy, relevance, and reliability, especially when adapting to new data?
- b. What specific strategies and tools can be implemented to monitor and manage the performance and accuracy of a generative Al-enabled device implemented across multiple sites, ensuring consistency, and addressing potential regional biases and data variations compared to the device that was authorized?
- c. What methods and metrics can be utilized to effectively monitor and evaluate the post market performance of generative Al-enabled devices that use a multi-layer application design, i.e., the device queries external consumer-grade Al services that are not themselves medical devices?

## **Device Overview**

#### Big Picture View



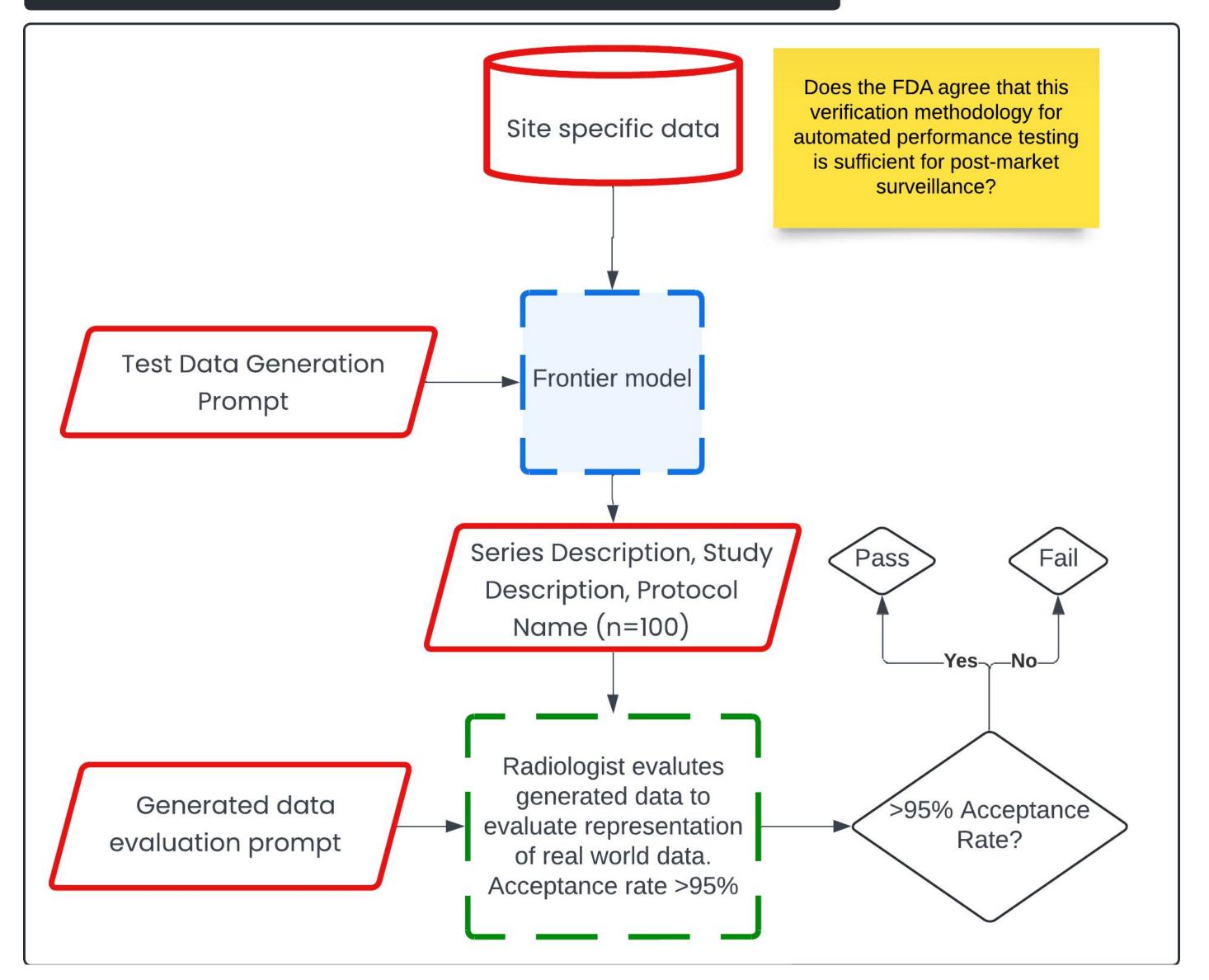
#### Goals

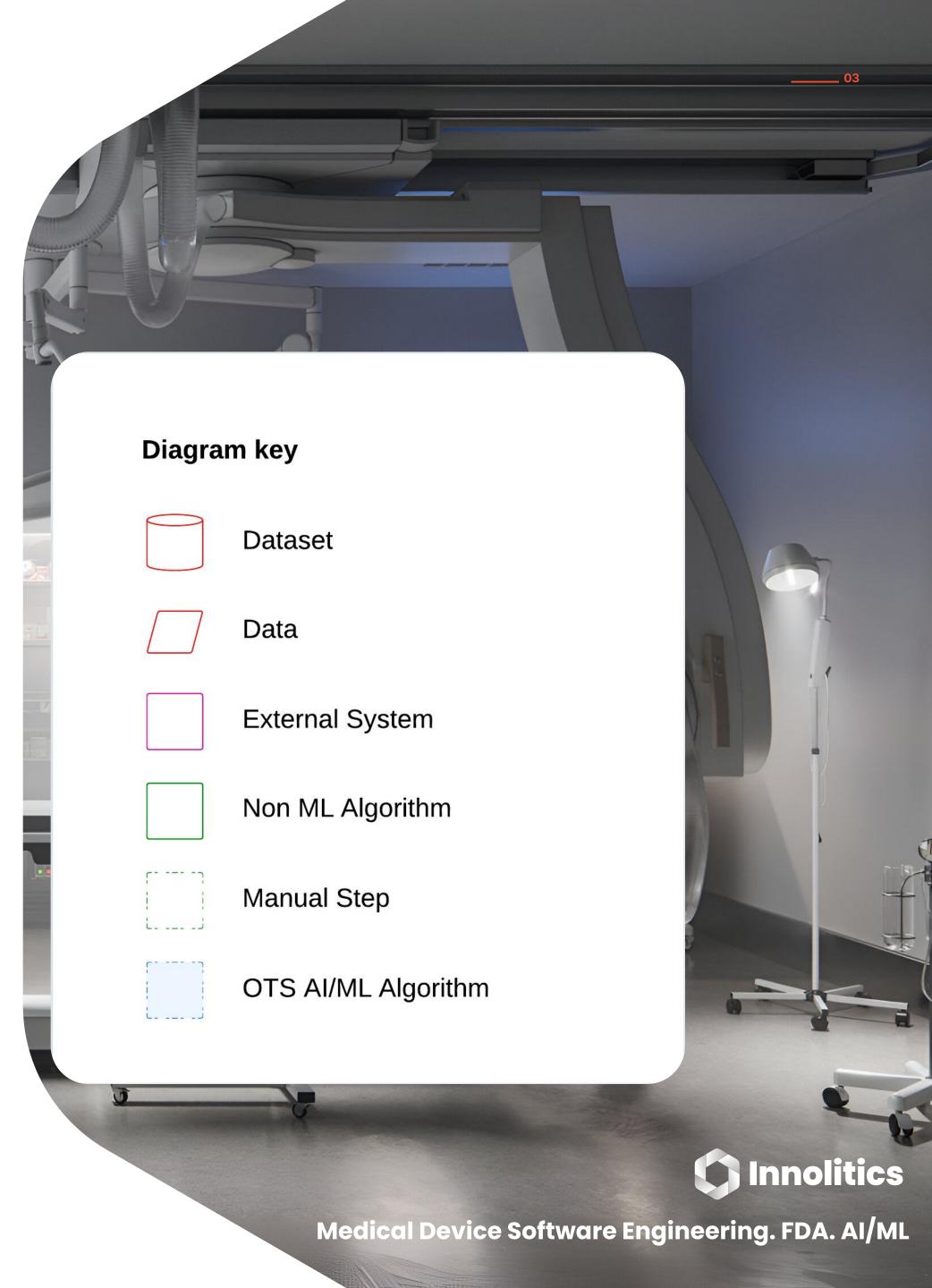
- To better understand FDA's thoughts on using foundation models like LLMs for low risk devices
- To better understand FDA's thoughts on PCCPs ustilizing LLMs
- To better understand FDAs thoughts on verification of LLMs of unknown provenance
- To better understand FDA's thoughts on ongoing surveillance and data drift mitigation
- To better understand FDA's thoughts on risk control measures for devices utilizing LLMs
- Such that Contrast Lllama and future LLM-based SaMD can have a clearer pathway to FDA clearance.

Diagram key	
	Dataset
	Data
	External System
	Non ML Algorithm
	Manual Step
	OTS AI/ML Algorithm

# Verification of Synthetic Data Generation

Automated ML Verification Verification (Once per Frontier model release)





## Comparison to Human Truther

#### Manual Ground Truthing Description

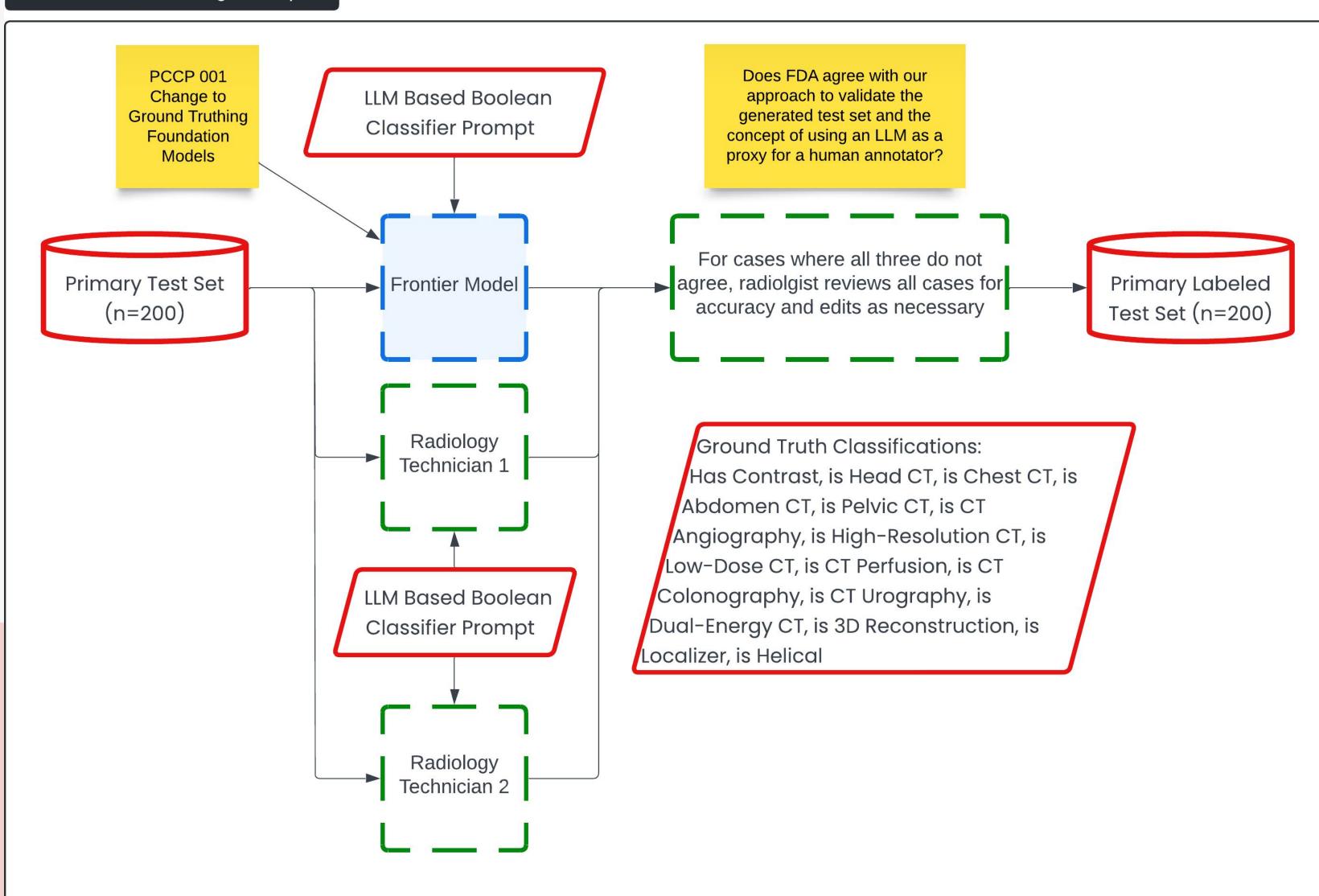


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# Nightly Automatic Validation

#### Automated ML Verification (Nightly) Does FDA agree that this method Diagram key is sufficient for proactive Site specific data post-market surveillance for data drift and other quality control Dataset initiatives? Data **Test Data Generation** Manual Step Frontier model Prompt OTS AI/ML Algorithm User Image Site specific simulated data (n=2000) LLM Based Boolean Frontier model Device model Classifier Prompt Overall Sensitivity and Specificty >0.9 and **Predicted** LLM Based Classifications: **Actual** LLM Based Classifications: Has Contrast, is Head CT, is Chest CT, is Has Contrast, is Head CT, is Chest CT, is Abdomen CT, is Pelvic CT, is CT Angiography, Abdomen CT, is Pelvic CT, is CT is High-Resolution CT ... Angiography, is High-Resolution CT... Pass

### 01. Data Drift Mitigation

Using site-specific data to generate new examples could mitigate data drift and detect generalization issues during software installation and well into the post-market.

#### 02. Continuous Verification

Frontier models will improve over time and so will the ability to approximate a human ground truther and creation of simulated data.

## 03. Multi-Layer Application Drift Mitigation

Third party APIs can be invoked nightly to detect changes to consumer-grade AI services that are not themselves medical devices.



# Thank You

info@innolitics.com

+1 (512) 967-6088

Innolitics LLC 1101 West 34th St. #550 Austin, TX 78705

