# Synthetic Data for GenAI TPLC Considerations

**Yujan Shrestha, MD**

**CEO & PARTNER**

yshrestha@innolitics.com

(512) 967-6088

Innolitics

Medical Device Software
Engineering. FDA. AI/ML

# Topic

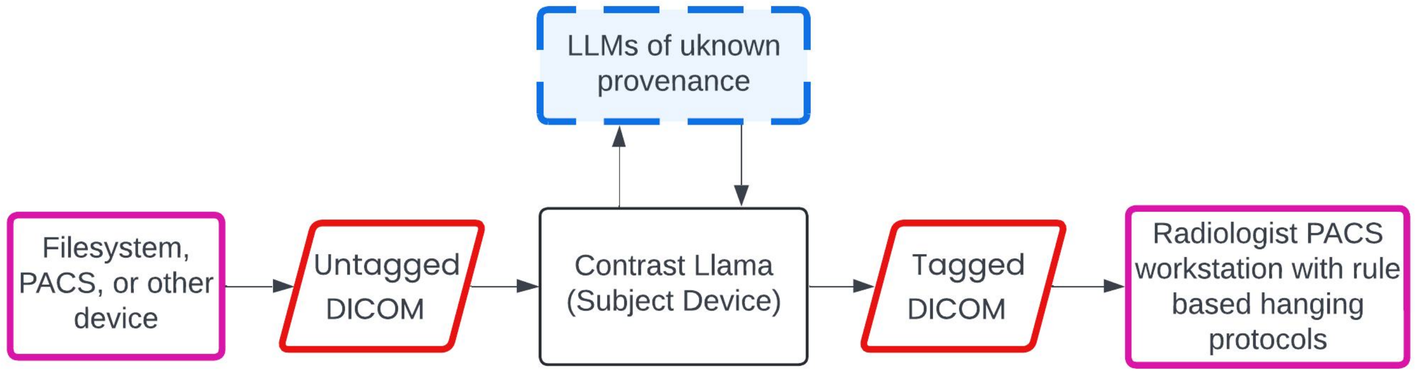
a. What specific monitoring capabilities should be considered to effectively evaluate and monitor the post market performance of generative AI-enabled devices to ensure they maintain adequate accuracy, relevance, and reliability, especially when adapting to new data?

b. What specific strategies and tools can be implemented to monitor and manage the performance and accuracy of a generative AI-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 AI-enabled devices that use a multi-layer application design, i.e., the device queries external consumer-grade AI 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**

# Verification of Synthetic Data Generation

Automated ML Verification Verification (Once per Frontier model release)

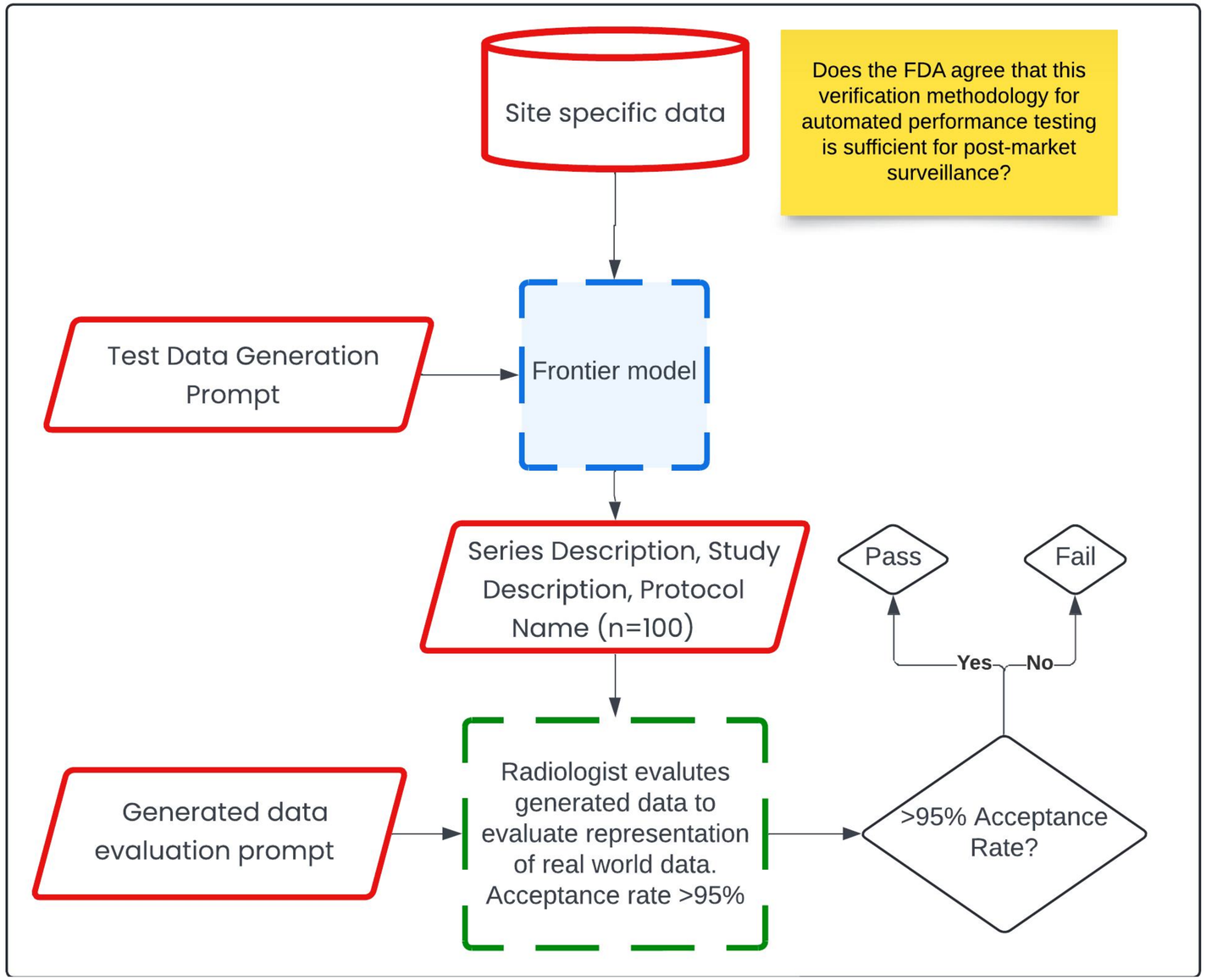



**Diagram key**

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

# Comparison to Human Truther

Manual Ground Truthing Description

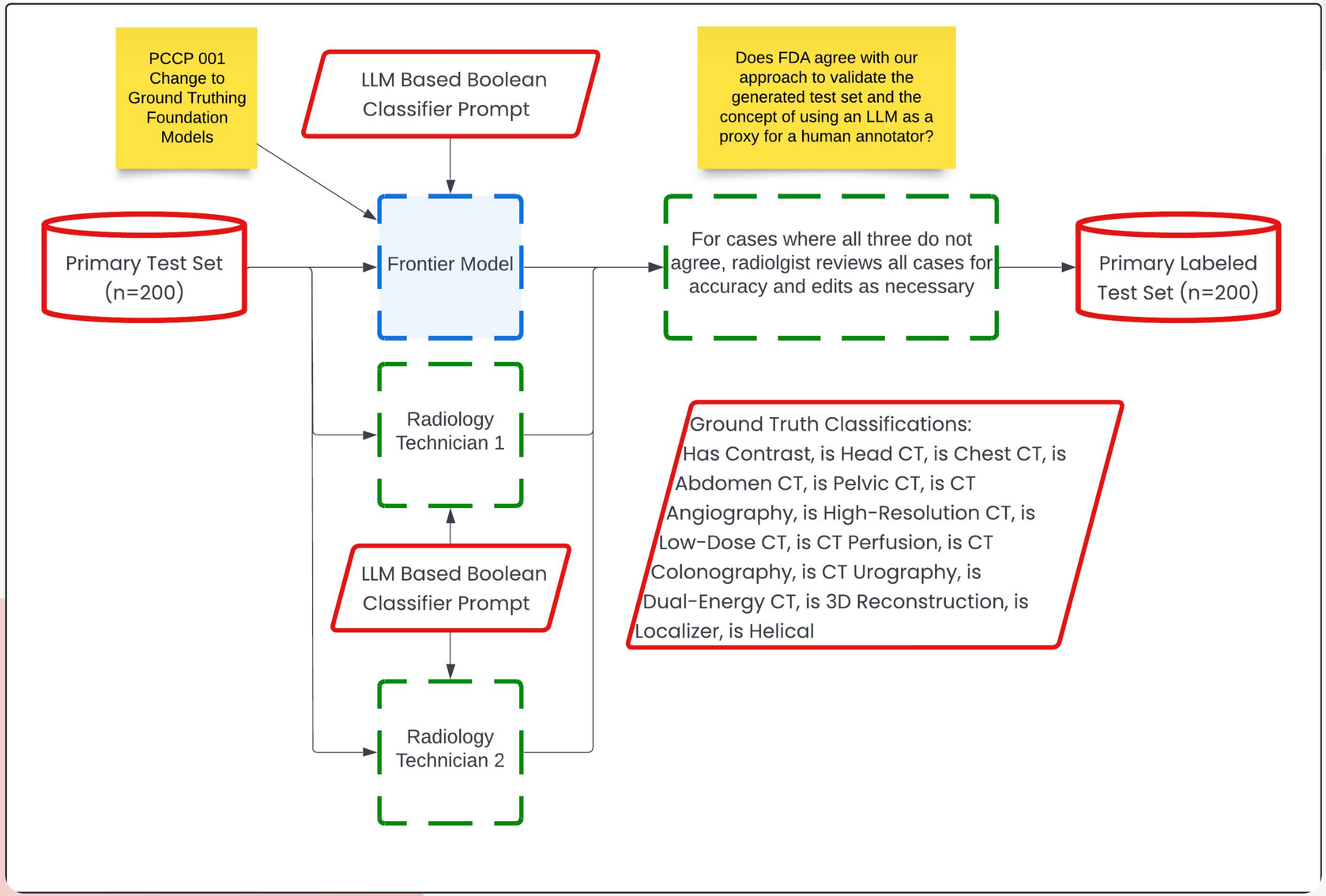
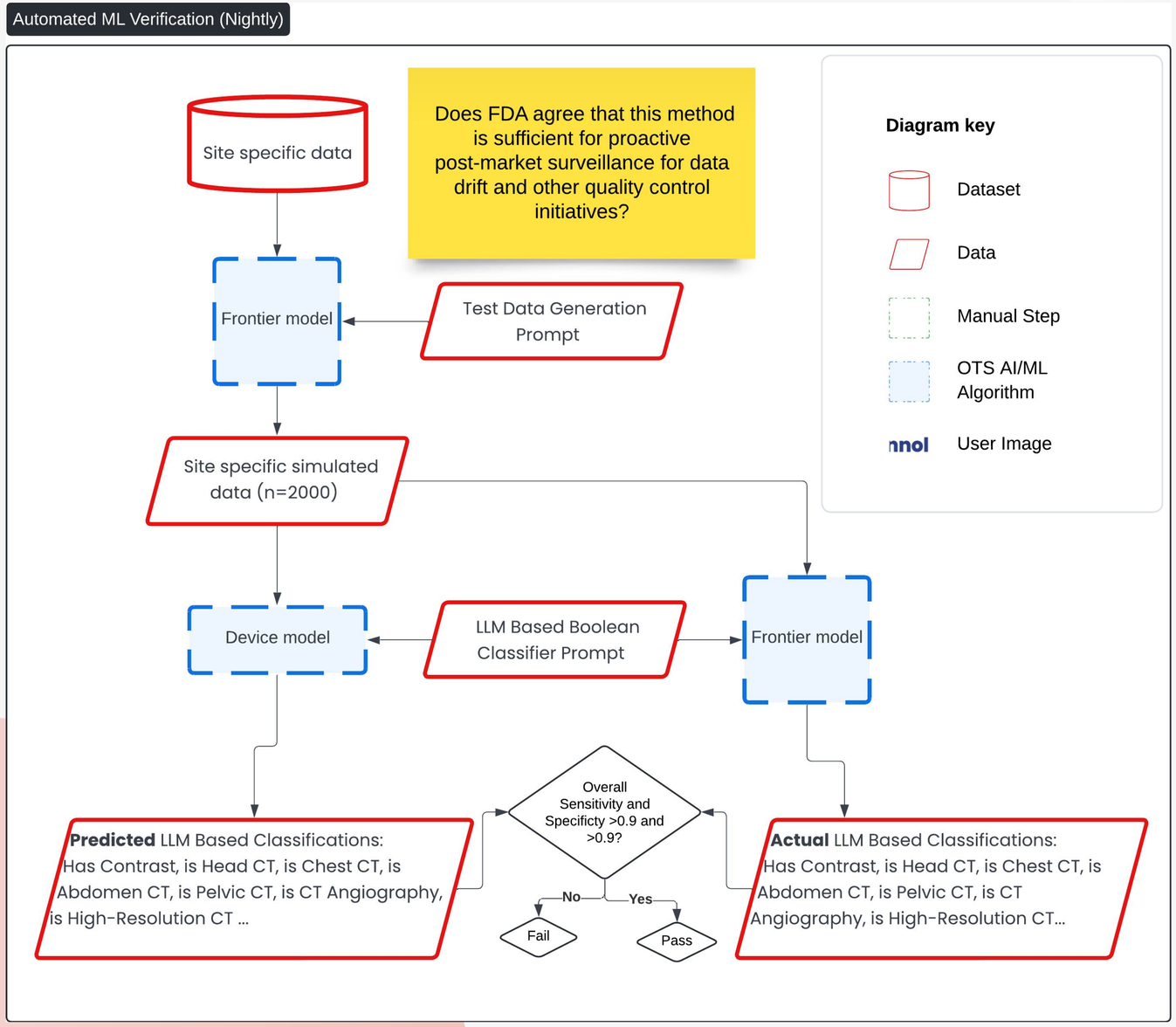



**Diagram key**

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

# Nightly Automatic Validation

Automated ML Verification (Nightly)




## 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

Innolitics