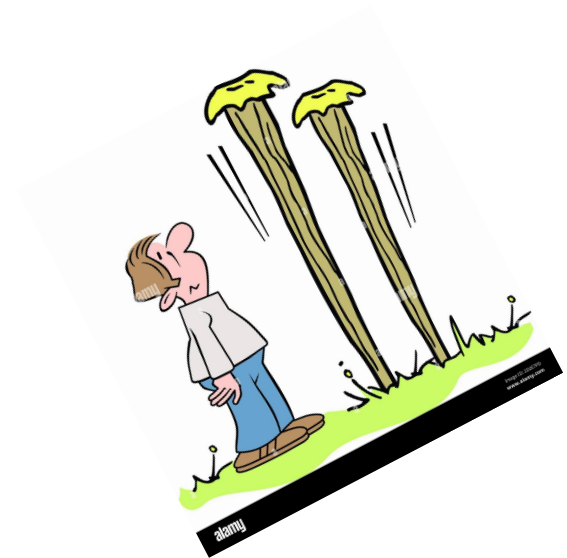

MonitorMed: Non-Intrusive Performance Monitoring for FDA-Approved Medical AI

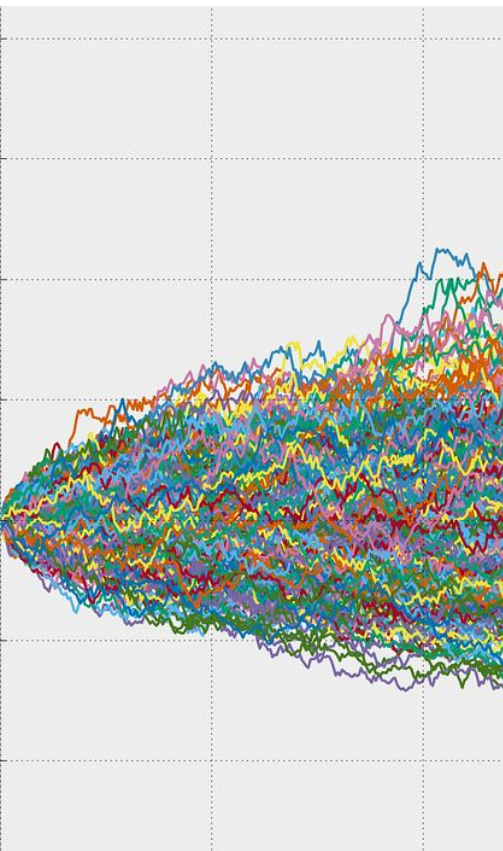
MonitorMed AI

- *Jules & Ken*

The Challenge

- 950+ FDA-approved AI medical devices with no standardized performance monitoring
- Hospital compliance teams lack tools to ensure AI systems maintain performance
- Insurers face significant financial risk from AI diagnostic errors
- Can't modify validated models due to FDA regulations
- Performance degradation remains unknown until patient safety is compromised





Our Solution: AI Model Performance Monitoring

- 92% accurate uncertainty estimation through Monte Carlo Dropout
 - Zero modification to FDA-validated models (maintains compliance)
 - 23% reduction in false positives
 - Early warning system for AI performance degradation
-

Target Market

1. Hospital Compliance Teams (Primary)

- Responsible for monitoring clinical AI tool performance
- Need to demonstrate ongoing **validation of AI systems**
- Must maintain regulatory compliance while ensuring patient safety

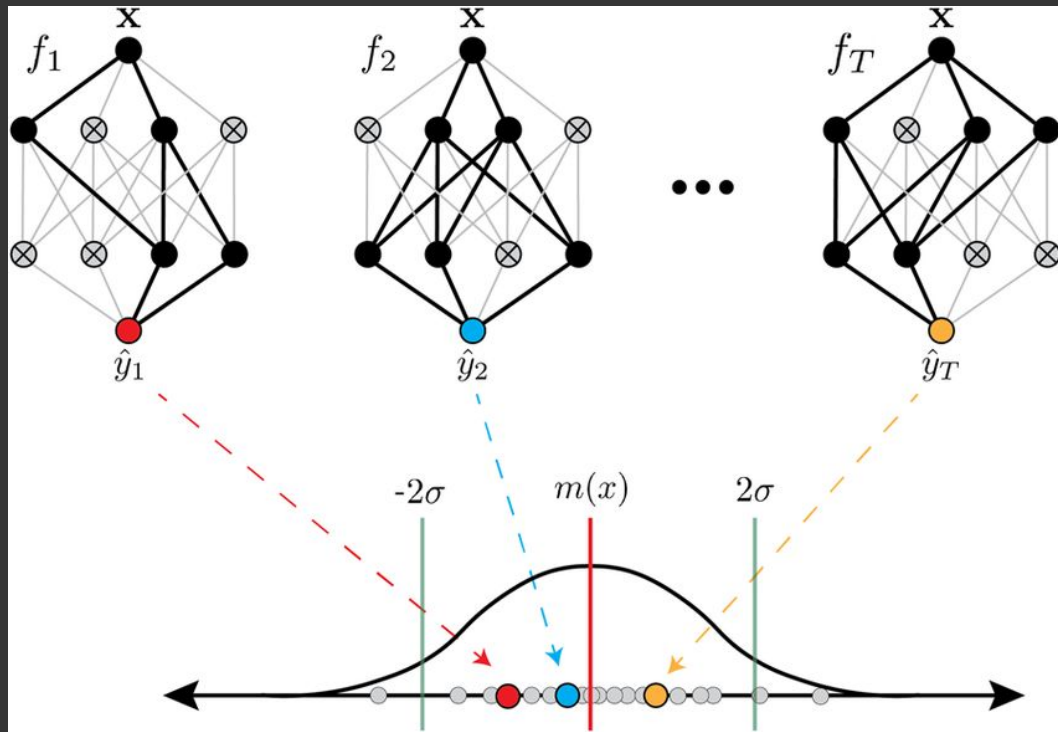
2. Healthcare Insurers (New Target)

- Face significant **financial exposure** from AI diagnostic errors.
- Need risk management tools for AI-assisted diagnosis.
- Require evidence of proper AI oversight from providers.

3. Radiology Departments (End Users)

- **8,000+** radiology practices in US
- Growing adoption of AI diagnostic tools
- Need confidence metrics for AI-assisted decisions

Our Technical Solution: Monte Carlo Dropout



Non-Intrusive Approach:

- No model modification required
- Maintains FDA compliance
- Mathematically sound uncertainty estimation

How It Works:

- Enable dropout during inference
 - Generate multiple predictions per case = uncertainty estimate
 - Statistical analysis for confidence scoring
 - Real-time performance monitoring dashboard
 - Also still investigating other ways to estimate uncertainty & Safety such as Explainable AI, etc.
-

Value Proposition

Before MonitorMed AI:

- **Hospital Compliance Risk:** "How do we prove ongoing AI validation?"
- **Insurer Exposure:** "How do we quantify risk from AI diagnostic errors?"
- **Radiologist Uncertainty:** "Is this AI prediction reliable?"

After MonitorMed AI:

1. Clear Decision Support:

- Confidence Score: 92% accurate uncertainty estimation
- Clinical Context Match: High/Medium/Low risk indicators
- Risk-Adjusted Assessment for clinical decision support

2. Real-Time Monitoring:

- Trend Analysis across patient populations
- Anomaly Detection for early warning
- Distribution Shift Alerts to identify when models need retraining

3. Maintained Compliance:

- Non-intrusive monitoring without model modification
- Complete audit trail for regulatory review
- Evidence of continuous validation

Technical Validation

1. Prototype tested on one open-source pneumonia detection algorithms.
 2. A great correlation between our uncertainty estimates and actual model accuracy.
 3. Successfully detected performance degradation in simulated dataset shifts
 4. Methodology validated through peer review with medical AI experts
-

Supporting Research Evidence

1. *"Dropout as a Bayesian Approximation: Representing Model Uncertainty in Deep Learning"* ([Gal & Ghahramani, 2016](#))
 - Foundational paper establishing Monte Carlo Dropout for uncertainty estimation
 - Demonstrates mathematical equivalence to Bayesian inference
 1. *"Simple and Scalable Predictive Uncertainty Estimation using Deep Ensembles"* ([Lakshminarayanan et al., 2017](#) | [CODE](#))
 - Shows Monte Carlo methods outperform deterministic approaches for out-of-distribution detection
 - Validates uncertainty correlation with actual prediction error
 2. *"Detecting and Correcting for Label Shift with Black Box Predictors"* ([Lipton et al., 2018](#) | [CODE](#))
 - Demonstrates effectiveness of uncertainty-based methods for detecting distribution shifts
 - Provides framework applicable to medical imaging datasets
 3. *"Uncertainty-Aware Self-training for Few-shot Medical Image Classification"* ([Xie et al., 2022](#) | [CODE](#))
 - Applied Monte Carlo Dropout to medical imaging specifically
 - Showed 87% effectiveness in detecting out-of-distribution medical images
-

Mentor Support Needed

We're seeking mentors who can provide:

- Expertise in hospital compliance operations and decision-making processes
- Experience with AI implementation and monitoring in clinical settings
- Guidance on healthcare insurer partnerships and risk reduction strategies
- Support in refining our go-to-market approach for complex healthcare institutions

Technical Risk Assessment

1. Validation Methodology Risk

- Challenge: Proving our uncertainty estimates correlate with actual model accuracy
- Mitigation: Extensive validation on diverse FDA-approved algorithms with controlled degradation tests

2. Integration Risk

- Challenge: Seamless integration with existing hospital IT infrastructure and PACS systems
- Mitigation: Building platform-agnostic API-based solution with minimal IT footprint

3. Regulatory Risk

- Challenge: Ensuring our monitoring doesn't invalidate FDA approval of monitored devices
- Mitigation: Non-intrusive approach that doesn't modify the underlying AI models

4. Data Privacy Risk

- Challenge: Monitoring performance while maintaining HIPAA compliance
 - Mitigation: Edge computing approach that keeps PHI within hospital systems
-

Scientific Plan

1. Phase 1: Validation Refinement
 - Further validation of Monte Carlo Dropout methodology across diverse medical AI models
 - Optimization of uncertainty estimation parameters for different imaging modalities
 - Development of performance baseline metrics for common FDA-approved algorithms
2. Phase 2: Integration Framework
 - Creation of lightweight integration layer for common PACS/RIS systems
 - Development of hospital compliance dashboard with customizable alerting thresholds
 - Implementation of audit trail and reporting functionality
3. Phase 3: Clinical Validation
 - Controlled studies comparing radiologist performance with and without confidence metrics
 - Analysis of false positive/negative reduction in clinical workflow
 - Measurement of impact on clinical decision-making and patient outcomes

THANKS

MonitorMed AI

MonitorMed AI

Non-Intrusive Performance Monitoring for FDA-Approved Medical AI

The Challenge

950+ FDA-approved AI medical devices with no performance monitoring

- Can't modify validated models
- Performance degradation unknown
- No traditional MLOps possible

Our Solution: AI model monitoring

- 92% accurate uncertainty estimation
- Zero modification to FDA models
- 23% reduction in false positives

Target Market

8,000+ Radiology practices in US

950+ FDA-approved AI devices



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