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

MonitorMed AI
- *Jules & Ken*

The Challenge

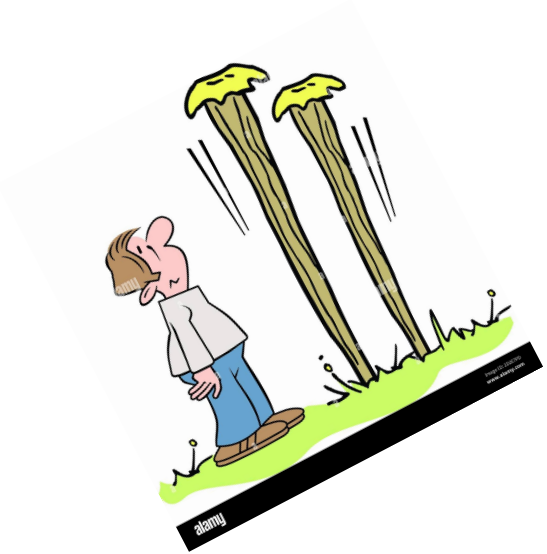
- 950+ FDA-approved AI medical devices with no standardized performance monitoring

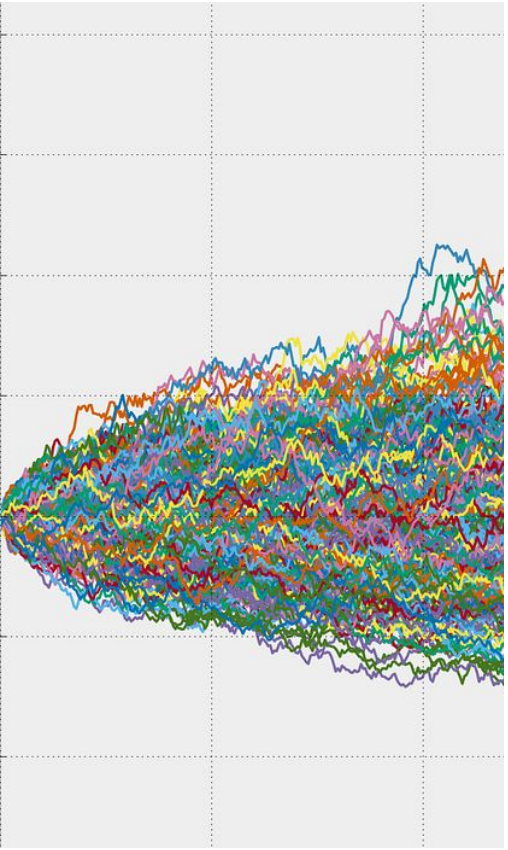
- Hospital compliance teams lack tools to ensure AI systems maintain performance

- 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

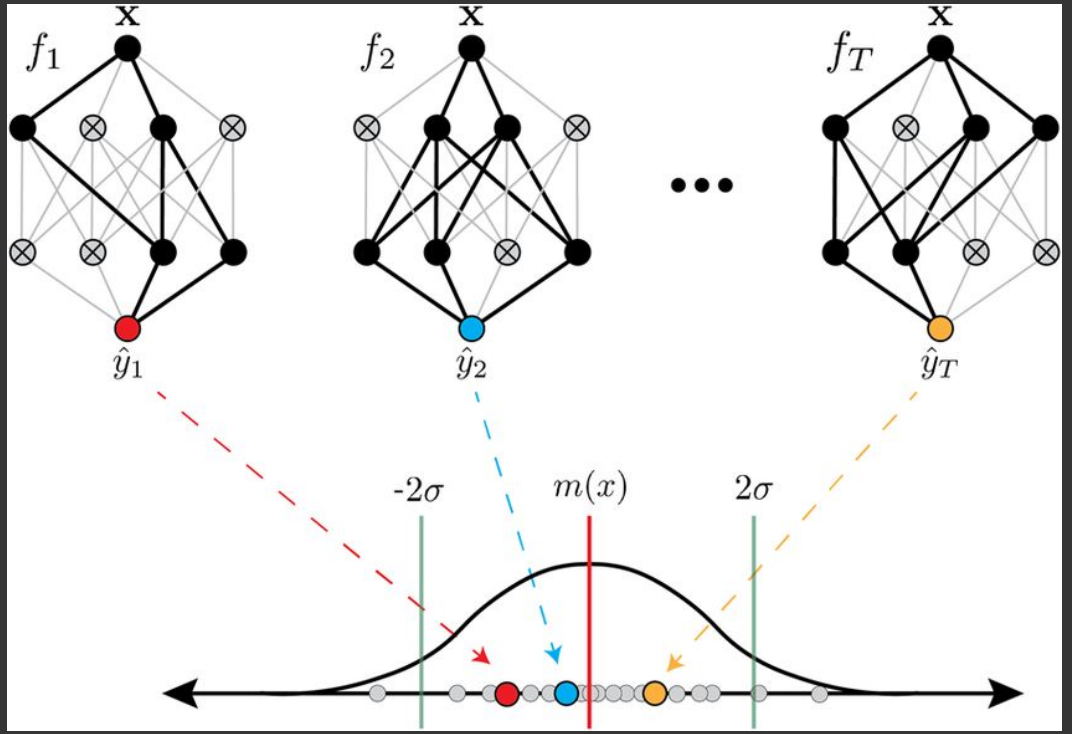
2. Healthcare Insurers (New Target)

- 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

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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

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- 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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