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MonitorMed AI: Regulatory Strategy

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Jules & Ken

MonitorMed AI

Non-Intrusive Performance Monitoring for FDA-Approved Medical AI

The Challenge

950+ FDA-approved AI medical model/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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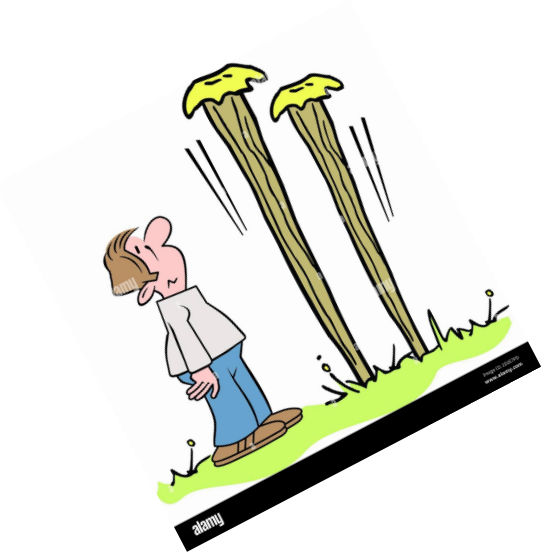
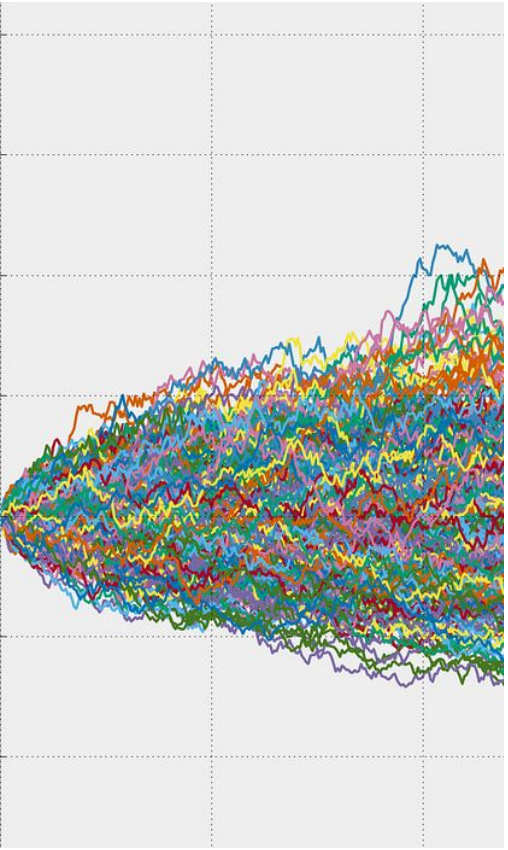
The Challenge

- 950+ FDA-approved AI medical model 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.
- Centralized platform for tracking all AI models per hospital or location.

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

Value Proposition

Before MonitorMed AI:

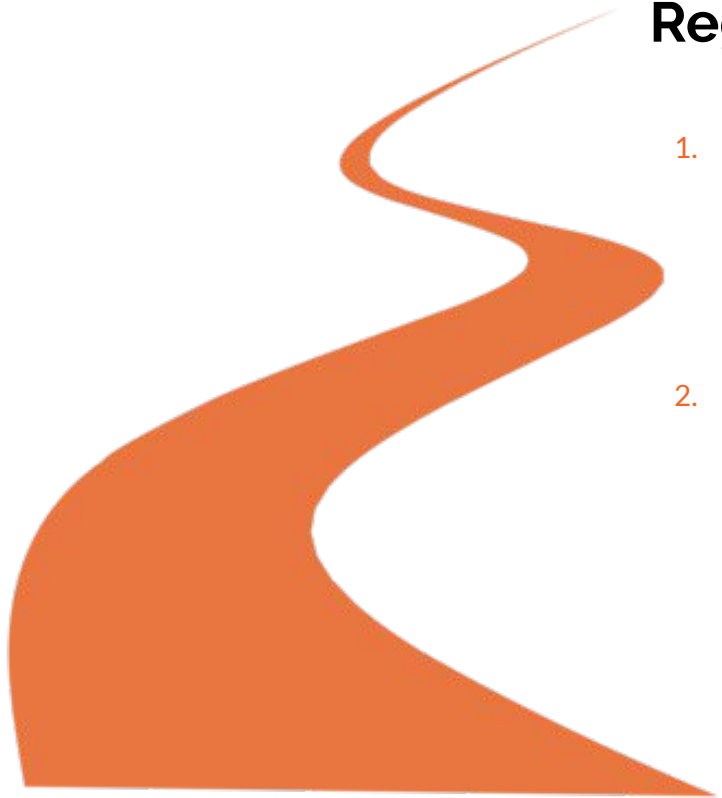
- Hospital Compliance Risk: "How do we prove ongoing AI validation?"
- Insurer Exposure: "How do we quantify risk from AI diagnostic errors?"
- Radiologist Uncertainty: "Is this AI prediction reliable?"

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

Our Regulatory Path & Timeline

Regulatory Pathway Summary



1. FDA Classification: Software as a Medical Device (SaMD)
    - Class II Medical Device - moderate risk, general controls with special controls
    - Clinical Decision Support (CDS) software pathway
    - Key Exemption Advantage: Non-intrusive monitoring approach
2. Regulatory Strategy Components:
    - Submit through 510(k) Premarket Notification pathway
    - Leverage Digital Health Software Precertification Program eligibility
    - Implement Quality Management System compliant with 21 CFR Part 820
    - Establish Medical Device Reporting (MDR) system for post-market surveillance

Regulatory Timeline & Milestones

1. Phase 1: Preparation & Pilot (Months 0-12)

- Submit **Pre-Submission (Q-Sub) to FDA** (Month 3)
- Develop **Quality Management System** (Months 1-6)
- Conduct **Pilot Studies** at 3-5 academic medical centers (Months 6-12)
- Submit **IRB applications** for clinical validation (Month 4)
- Prepare **510(k) documentation** (Months 9-12)

2. Phase 2: Initial Approval & Validation (Months 12-24)

- Submit **510(k) Premarket Notification** (Month 13)
- Anticipate **FDA clearance** (Month 19)
- Begin **controlled market release** to initial hospital partners (Month 20)
- Establish **post-market surveillance system** (Months 20-24)
- Initiate **HIPAA compliance verification** process (Months 13-16)

3. Phase 3: Expansion & Iteration (Months 24-36)

- Submit **510(k) updates** for expanded feature set (Month 26)
- File for **international regulatory approvals** (CE Mark, Health Canada) (Month 28)
- Develop **insurers integration framework** with compliance documentation (Months 24-30)
- Implement **AI vendor certification program** with regulatory documentation (Months 30-36)

Key Regulatory Challenges & Mitigation Strategies

Challenge 1: Demonstrating Effectiveness Without Interference

- **Risk**: FDA concerns about monitoring impact on validated AI models
- **Mitigation**: Produce validation studies showing zero modification to underlying AI systems
- **Consultation**: Partner with FDA Digital Health team through Pre-Submission program

Challenge 2: Data Privacy & Integration Standards

- **Risk**: HIPAA compliance issues when integrating with hospital systems
- **Mitigation**: Develop healthcare-specific data governance framework
- **Consultation**: Engage healthcare compliance officers and legal experts

Challenge 3: Proving Clinical Benefit

- **Risk**: Insufficient evidence of performance improvement
- **Mitigation**: Develop case studies demonstrating 23% reduction in false positives
- **Consultation**: Collaborate with academic medical centers for peer-reviewed validation

Challenge 4: Establishing Performance Standards

- **Risk**: Lack of established benchmarks for AI monitoring solutions
- **Mitigation**: Propose industry standards through FDA collaboration
- **Consultation**: Work with industry associations and standards organizations

THANKS

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