

PulseMind: Industry-Ready Enhancement Roadmap

Vision Statement

Transform PulseMind from a proof-of-concept into a **production-grade, FDA-ready, cloud-native medical device platform** with enterprise-level reliability, security, compliance, and scalability.

Roadmap Overview

| Phase | Focus Area | Duration | Priority |
|---------|-------------------------------|------------|----------|
| Phase 1 | DevOps & CI/CD Infrastructure | 3-4 weeks | Critical |
| Phase 2 | Testing & Quality Assurance | 4-5 weeks | Critical |
| Phase 3 | Security & Compliance | 5-6 weeks | Critical |
| Phase 4 | Advanced ML & Analytics | 6-8 weeks | High |
| Phase 5 | Cloud & Scalability | 4-5 weeks | High |
| Phase 6 | Clinical Features & UX | 6-8 weeks | Medium |
| Phase 7 | Regulatory & Certification | 8-12 weeks | Critical |
| Phase 8 | Production Deployment | 4-6 weeks | Critical |

Total Estimated Timeline: 40-54 weeks (~10-13 months)

Phase 1: DevOps & CI/CD Infrastructure

Goal: Establish automated build, test, and deployment pipelines with industry-standard DevOps practices.

1.1 Version Control & Branching Strategy

Git Workflow

- [] Implement **GitFlow** branching model
- `main` - Production-ready code
- `develop` - Integration branch
- `feature/*` - Feature branches
- `release/*` - Release candidates
- `hotfix/*` - Emergency fixes

- ☐ Set up **branch protection rules**
- Require pull request reviews (minimum 2 reviewers)
- Require status checks to pass
- Require signed commits
- Prevent force pushes to main/develop
- ☐ Configure **commit message conventions**
- Use Conventional Commits (feat, fix, docs, test, refactor, etc.)
- Automated changelog generation

Tools

- Git + GitHub/GitLab
- Husky (pre-commit hooks)
- Commitlint

1.2 Continuous Integration (CI)

GitHub Actions / GitLab CI Pipeline

Pipeline Stages

```
stages: - lint - security-scan - unit-test - integration-test - build - docker-build -
performance-test - deploy-staging
```

Specific CI Jobs

- ☐ **Linting & Code Quality**
- Python: `black`, `flake8`, `pylint`, `mypy` (type checking)
- JavaScript: `eslint`, `prettier`
- YAML/JSON validation
- Dockerfile linting (`hadolint`)

Quality gates: SonarQube/CodeClimate

☐ **Security Scanning**

- Dependency vulnerability scanning: `safety`, `pip-audit`, `Snyk`
- SAST (Static Application Security Testing): `bandit`, `semgrep`
- Container scanning: `Trivy`, `Clair`

Secret detection: `GitGuardian`, `TruffleHog`

☐ **Automated Testing**

- Unit tests with coverage (minimum 80%)

- Integration tests
- API contract testing
- Performance benchmarks

Parallel test execution

[] **Build Artifacts**

- Multi-stage Docker builds
- Layer caching for faster builds
- Artifact versioning (semantic versioning)
- Build reproducibility

Configuration Files to Create

```
.github/ ■■■ workflows/ ■ ■■■ ci.yml ■ ■■■ security-scan.yml ■ ■■■
docker-build.yml ■ ■■■ release.yml ■■■ CODEOWNERS ■■■ pull_request_template.md
```

Tools

- GitHub Actions / GitLab CI
- SonarQube
- Snyk
- Codecov

1.3 Continuous Deployment (CD)

Deployment Environments

- [] **Development** (auto-deploy from `develop`)
- Deployed on every merge to `develop`

Ephemeral environments for feature branches

[] **Staging** (auto-deploy from `release/*`)

- Production-like environment
- Full integration testing

Performance testing

[] **Production** (manual approval from `main`)

- Blue-green deployment
- Canary releases
- Automated rollback on failure

Deployment Strategies

- [] **Blue-Green Deployment**

- Zero-downtime deployments

Instant rollback capability

- [] **Canary Releases**

- Gradual traffic shifting (10% → 50% → 100%)
- Automated health checks

Rollback on error rate increase

- [] **Infrastructure as Code (IaC)**

- Terraform for cloud infrastructure
- Ansible for configuration management
- Helm charts for Kubernetes deployments

Tools

- ArgoCD / Flux (GitOps)
- Terraform
- Helm
- Kubernetes

1.4 Monitoring & Observability

Metrics & Monitoring

- [] **Application Metrics**

- Prometheus for metrics collection
- Grafana for visualization
- Custom dashboards per service

SLA/SLO tracking

- [] **Logging**

- Centralized logging: ELK Stack (Elasticsearch, Logstash, Kibana)
- Structured JSON logs (already implemented)
- Log aggregation and search

Log retention policies

- [] **Distributed Tracing**

- Jaeger / OpenTelemetry

- End-to-end request tracing

Performance bottleneck identification

[] Alerting

- PagerDuty / Opsgenie integration
- Alert rules for:
 - Service downtime
 - High error rates
 - Latency spikes
 - Resource exhaustion
- On-call rotation management

Key Metrics to Track

- Request rate, error rate, duration (RED metrics)
- CPU, memory, disk, network (USE metrics)
- Business metrics: pacing decisions/min, safety violations, etc.

Tools

- Prometheus + Grafana
- ELK Stack
- Jaeger
- PagerDuty

1.5 Container Orchestration

Kubernetes Migration

- [] **Kubernetes Manifests**
- Deployments for each service
- Services (ClusterIP, LoadBalancer)
- ConfigMaps for configuration
- Secrets for sensitive data

Persistent Volumes for data storage

[] Helm Charts

- Parameterized deployments
- Environment-specific values

Chart versioning

☐ Resource Management

- Resource requests and limits
- Horizontal Pod Autoscaling (HPA)
- Vertical Pod Autoscaling (VPA)

Pod Disruption Budgets

☐ Service Mesh (Optional - Advanced)

- Istio / Linkerd
- Traffic management
- mTLS between services
- Circuit breakers

Tools

- Kubernetes (EKS, GKE, or AKS)
- Helm
- Istio (optional)

Phase 2: Testing & Quality Assurance

Goal: Achieve comprehensive test coverage with automated testing at all levels.

2.1 Unit Testing

Coverage Requirements

- ☐ Minimum **80% code coverage** across all services
- ☐ 100% coverage for safety-critical modules (Control Engine)

Testing Framework

- ☐ **Python:** `pytest` with plugins
- `pytest-cov` for coverage
- `pytest-asyncio` for async tests
- `pytest-mock` for mocking
- `pytest-xdist` for parallel execution

What to Test

- ☐ Signal processing algorithms (bandpass filter, peak detection)
- ☐ HSI computation formulas

- [] AI model inference (with mock models)
- [] Control engine state transitions
- [] Safety constraint validation
- [] Edge cases and error handling

Test Organization

```
tests/
├── unit/
│   ├── test_signal_processor.py
│   ├── test_hsi_computer.py
│   ├── test_rhythm_classifier.py
│   └── test_pacing_controller.py
├── integration/
└── e2e/
    └── performance/
```

2.2 Integration Testing

Service Integration Tests

- [] **API Contract Testing**

- Pact for consumer-driven contracts

Ensure service compatibility

- [] **Database Integration**

- Test with real database instances

Transaction rollback after tests

- [] **MQTT Integration**

- Test message publishing/subscribing

Message format validation

- [] **Service-to-Service Communication**

- Test full data flow: Signal → HSI → AI → Control
- Test error propagation
- Test timeout handling

Tools

- Pact
- Testcontainers (for database/MQTT)
- pytest

2.3 End-to-End (E2E) Testing

Scenario-Based Testing

- [] **Happy Path Scenarios**

- Normal sinus rhythm → Monitor only
- Bradycardia → Moderate pacing

Tachycardia → Stabilization

- [] **Edge Cases**

- Signal artifacts → Safe mode
- Service failures → Graceful degradation

Network latency → Timeout handling

- [] **Safety Scenarios**

- Extreme heart rates → Emergency mode
- Low confidence → Conservative pacing
- Conflicting inputs → Safe defaults

Tools

- Playwright / Selenium (for dashboard)
- Custom Python scripts for API testing

2.4 Performance Testing

Load Testing

- [] **Throughput Testing**

- Test with 100, 1000, 10000 requests/sec
- Identify bottlenecks

Measure latency at different loads

- [] **Stress Testing**

- Push system beyond normal capacity
- Identify breaking points

Test recovery mechanisms

- [] **Endurance Testing**

- Run for 24+ hours
- Check for memory leaks
- Monitor resource usage over time

Tools

- Locust / K6 / JMeter
 - Apache Bench (ab)
-

2.5 Chaos Engineering

Resilience Testing

- [] **Service Failures**

- Kill random services
- Test graceful degradation

Verify fallback mechanisms

- [] **Network Issues**

- Introduce latency
- Simulate packet loss

Test timeout handling

- [] **Resource Exhaustion**

- CPU throttling
- Memory pressure
- Disk space limits

Tools

- Chaos Mesh
 - Gremlin
 - Pumba
-

2.6 Regression Testing

- [] **Automated Regression Suite**

- Run on every commit
- Test all critical paths

Visual regression testing for dashboard

- [] **Test Data Management**

- Synthetic test datasets
- Anonymized clinical data (if available)
- Data versioning

Tools

- Percy (visual regression)
- Custom pytest suite

Phase 3: Security & Compliance

Goal: Implement enterprise-grade security and prepare for medical device compliance.

3.1 Authentication & Authorization

User Management

- ☐ **Identity Provider Integration**

- OAuth 2.0 / OpenID Connect
- Support for SSO (Single Sign-On)

Multi-factor authentication (MFA)

- ☐ **Role-Based Access Control (RBAC)**

- Roles: Admin, Clinician, Technician, Viewer
- Granular permissions per service

Audit logs for access

- ☐ **API Authentication**

- JWT tokens for API access
- API keys for service-to-service
- Token rotation and expiration

Tools

- Keycloak / Auth0
- JWT libraries

3.2 Data Security

Encryption

- ☐ **Data at Rest**

- Database encryption (AES-256)
- Encrypted backups

Secure key management (AWS KMS, HashiCorp Vault)

- ☐ **Data in Transit**

- TLS 1.3 for all HTTP traffic
- mTLS for service-to-service communication

MQTT over TLS

[] **Secrets Management**

- HashiCorp Vault for secrets
- No secrets in code/config
- Automatic secret rotation

Tools

- HashiCorp Vault
- AWS KMS / Azure Key Vault
- cert-manager (for TLS certificates)

3.3 Network Security

Infrastructure Security

- [] **Network Segmentation**
- Separate VPCs/VNets for environments
- Private subnets for databases

Bastion hosts for SSH access

[] **Firewall Rules**

- Strict ingress/egress rules
- IP whitelisting

DDoS protection

[] **Web Application Firewall (WAF)**

- OWASP Top 10 protection
- Rate limiting
- Bot detection

Tools

- AWS WAF / Cloudflare
- Network policies (Kubernetes)

3.4 Compliance & Auditing

HIPAA Compliance (if handling patient data)

- ☐ **Data Privacy**

- PHI (Protected Health Information) encryption
- Data anonymization/pseudonymization

Patient consent management

- ☐ **Audit Trails**

- Log all data access
- Immutable audit logs

Retention for 7 years

- ☐ **Business Associate Agreements (BAA)**

- With all third-party vendors
- Cloud provider BAAs

GDPR Compliance (if serving EU)

- ☐ **Data Subject Rights**

- Right to access
- Right to erasure

Data portability

- ☐ **Privacy by Design**

- Data minimization
- Purpose limitation
- Consent management

Medical Device Standards

- ☐ **IEC 62304** (Medical Device Software Lifecycle)

- Software safety classification
- Risk management

Configuration management

- ☐ **ISO 13485** (Quality Management)

- Quality management system
- Design controls

Document management

- ☐ **IEC 60601** (Medical Electrical Equipment)

- Safety requirements
- EMC (Electromagnetic Compatibility)
- Usability engineering

Tools

- Compliance management platforms
- Audit logging systems

3.5 Vulnerability Management

Security Practices

- [] **Regular Security Audits**
- Quarterly penetration testing
- Annual third-party security audit

Bug bounty program

- [] **Dependency Management**

- Automated dependency updates (Dependabot)
- Vulnerability scanning in CI

Security patch SLA (critical: 24h, high: 7 days)

- [] **Incident Response Plan**

- Security incident playbook
- Breach notification procedures
- Post-incident reviews

Tools

- Snyk / WhiteSource
- Dependabot
- HackerOne (bug bounty)

Phase 4: Advanced ML & Analytics

Goal: Enhance AI capabilities with state-of-the-art models and real-time analytics.

4.1 Advanced ML Models

Deep Learning Models

- [] **LSTM/GRU for Sequence Modeling**
- Better capture temporal dependencies
- Predict rhythm changes before they occur

Multi-step ahead forecasting

[] **1D CNN for Signal Processing**

- Automated feature extraction
- End-to-end learning from raw signals

Real-time inference optimization

[] **Transformer Models**

- Attention mechanisms for rhythm analysis
- Transfer learning from large ECG datasets
- Multi-modal fusion (PPG + ECG + other vitals)

Model Improvements

- [] **Ensemble Methods**
- Combine Random Forest + Deep Learning
- Voting classifiers

Stacking models

[] **Online Learning**

- Patient-specific model adaptation
- Incremental learning from new data

Concept drift detection

[] **Explainable AI (XAI)**

- SHAP values for feature importance
- LIME for local explanations
- Attention visualization

Tools

- TensorFlow / PyTorch
- ONNX for model interoperability
- TensorFlow Lite for edge deployment

4.2 Model Lifecycle Management (MLOps)

ML Pipeline

- [] **Experiment Tracking**
- MLflow / Weights & Biases
- Track hyperparameters, metrics, artifacts

Model versioning

[] **Feature Store**

- Centralized feature repository
- Feature versioning

Online/offline feature serving

[] **Model Registry**

- Model versioning and lineage
- A/B testing framework

Champion/challenger models

[] **Automated Retraining**

- Scheduled retraining pipelines
- Performance monitoring
- Automatic model deployment on improvement

Model Monitoring

- [] **Data Drift Detection**
- Monitor input distribution changes
- Alert on significant drift

Trigger retraining

[] **Model Performance Monitoring**

- Track accuracy, precision, recall over time
- Segment performance by patient demographics
- Detect model degradation

Tools

- MLflow / Kubeflow
- Feast (feature store)
- Evidently AI (drift detection)

4.3 Real-Time Analytics

Analytics Dashboard

- ☐ **Clinical Analytics**

- Patient cohort analysis
- Treatment efficacy metrics

Adverse event tracking

- ☐ **Operational Analytics**

- System uptime and reliability
- Service performance metrics

Resource utilization

- ☐ **Predictive Analytics**

- Risk stratification
- Readmission prediction
- Complication forecasting

Data Warehouse

- ☐ **ETL Pipeline**

- Extract from operational databases
- Transform for analytics

Load into data warehouse

- ☐ **Data Lake**

- Store raw signal data
- Historical data for research
- Compliance with data retention policies

Tools

- Apache Kafka (streaming)
- Apache Spark (processing)
- Snowflake / BigQuery (warehouse)
- Tableau / Looker (visualization)

4.4 Federated Learning (Advanced)

Privacy-Preserving ML

- ☐ **Federated Model Training**
- Train on distributed patient data
- No data leaves local devices

Aggregate model updates

[] **Differential Privacy**

- Add noise to protect individual privacy
- Privacy budget management

Tools

- TensorFlow Federated
- PySyft

Phase 5: Cloud & Scalability

Goal: Build cloud-native, globally scalable infrastructure.

5.1 Cloud Architecture

Multi-Cloud Strategy

- [] **Primary Cloud Provider**
- AWS / Azure / GCP
- Managed Kubernetes (EKS, AKS, GKE)

Managed databases (RDS, Aurora, Cloud SQL)

[] **Cloud-Agnostic Design**

- Avoid vendor lock-in
- Use Kubernetes for portability
- Terraform for multi-cloud IaC

Microservices Enhancements

- [] **Service Mesh**
- Istio / Linkerd
- Traffic management (retries, timeouts, circuit breakers)

Observability (distributed tracing)

[] **API Gateway**

- Kong / AWS API Gateway
 - Rate limiting
 - Request/response transformation
 - API versioning
-

5.2 Database Strategy

Database Selection

- ☐ **Operational Database**

- PostgreSQL (relational data)
- TimescaleDB (time-series data for signals)

Redis (caching, session management)

- ☐ **NoSQL for Unstructured Data**

- MongoDB (patient records, documents)
- Cassandra (high-write throughput)

Database Optimization

- ☐ **Sharding & Partitioning**

- Horizontal scaling

Partition by patient ID or time

- ☐ **Read Replicas**

- Offload read traffic

Geographic distribution

- ☐ **Backup & Disaster Recovery**

- Automated daily backups
- Point-in-time recovery
- Cross-region replication

5.3 Caching Strategy

Multi-Layer Caching

- ☐ **Application-Level Cache**

- Redis for frequently accessed data

Cache invalidation strategies

- ☐ **CDN for Static Assets**

- CloudFront / Cloudflare

Edge caching for dashboard assets

- ☐ **Query Result Caching**

- Cache expensive computations
 - TTL-based expiration
-

5.4 Message Queue & Event Streaming

Asynchronous Processing

- [] **Message Queue**
- RabbitMQ / AWS SQS
- Decouple services

Retry mechanisms

[] **Event Streaming**

- Apache Kafka
- Real-time event processing
- Event sourcing pattern

Use Cases

- Asynchronous AI inference
 - Batch processing of historical data
 - Event-driven architecture
-

5.5 Global Distribution

Multi-Region Deployment

- [] **Geographic Load Balancing**
- Route users to nearest region

Failover to backup regions

[] **Data Residency Compliance**

- Store data in specific regions (GDPR, HIPAA)
- Cross-region replication for DR

Tools

- AWS Route 53 / Cloudflare
 - Multi-region Kubernetes clusters
-

Phase 6: Clinical Features & UX

Goal: Build production-ready clinical workflows and user experience.

6.1 Enhanced Dashboard

Clinical Dashboard Features

- [] **Real-Time Monitoring**

- Live PPG waveform display
- Real-time HSI trends

Pacing status indicators

- [] **Patient Management**

- Patient profiles
- Treatment history

Medication tracking

- [] **Alert System**

- Critical alerts (emergency mode, safety violations)
- Configurable alert thresholds

Alert acknowledgment workflow

- [] **Reporting**

- Daily/weekly/monthly reports
- Export to PDF/CSV
- Compliance reports

UX Improvements

- [] **Responsive Design**

- Mobile-friendly interface
- Tablet optimization

Progressive Web App (PWA)

- [] **Accessibility**

- WCAG 2.1 AA compliance
- Screen reader support

Keyboard navigation

- [] **Internationalization (i18n)**

- Multi-language support
- Localization for different regions

Tools

- React / Vue.js (modern frontend)
- Chart.js / D3.js (visualizations)
- Material-UI / Ant Design

6.2 Mobile Application

Native Mobile Apps

- **[] iOS & Android Apps**

- React Native / Flutter
- Real-time monitoring on mobile

Push notifications for alerts

- **[] Offline Mode**

- Local data caching

Sync when online

- **[] Wearable Integration**

- Apple Watch / Wear OS
- Quick glance at patient status

6.3 Clinical Decision Support

AI-Assisted Recommendations

- **[] Treatment Recommendations**

- Suggest optimal pacing parameters
- Evidence-based guidelines

Contraindication warnings

- **[] Risk Scoring**

- Calculate patient risk scores
- Predict adverse events

Stratify patients by risk

- **[] Drug Interaction Checker**

- Check for drug-device interactions
- Alert on contraindications

6.4 Telemedicine Integration

Remote Monitoring

- [] **Remote Patient Monitoring (RPM)**

- Home-based monitoring
- Automatic data upload

Clinician alerts

- [] **Video Consultation**

- Integrated telehealth
- Screen sharing for data review

Tools

- Twilio Video
- WebRTC

Phase 7: Regulatory & Certification

Goal: Achieve FDA clearance and international certifications.

7.1 FDA Submission (USA)

510(k) Premarket Notification

- [] **Device Classification**

- Determine device class (likely Class II)

Identify predicate devices

- [] **Design Controls**

- Design inputs and outputs
- Design verification and validation

Design transfer documentation

- [] **Risk Management**

- ISO 14971 risk analysis

- Hazard analysis

Risk mitigation strategies

☐ **Clinical Evaluation**

- Clinical data collection
- Clinical study (if required)

Literature review

☐ **Software Documentation**

- Software requirements specification
- Software design specification

Software verification and validation

☐ **Labeling**

- Instructions for use
- Warnings and precautions
- Contraindications

Timeline

- 6-12 months for submission preparation
- 3-6 months for FDA review

7.2 CE Marking (Europe)

Medical Device Regulation (MDR)

☐ **Conformity Assessment**

- Notified Body selection
- Technical documentation

Clinical evaluation report

☐ **Quality Management System**

- ISO 13485 certification

Design and development procedures

☐ **Post-Market Surveillance**

- Vigilance system
- Periodic safety update reports

Timeline

- 8-12 months for preparation
- 6-12 months for Notified Body review

7.3 Other Certifications

- ☐ **Health Canada** (Canada)
- ☐ **TGA** (Australia)
- ☐ **PMDA** (Japan)
- ☐ **NMPA** (China)

7.4 Clinical Trials

Study Design

- ☐ **Pilot Study**
- 20-50 patients
- Safety and feasibility

IRB approval

☐ **Pivotal Trial**

- 200-500 patients
- Randomized controlled trial
- Primary and secondary endpoints

Data Management

- ☐ **Electronic Data Capture (EDC)**
- REDCap / Medidata Rave
- eCRF design

Data validation rules

☐ **Statistical Analysis**

- Statistical analysis plan
- Interim analysis
- Final analysis and reporting

Phase 8: Production Deployment

Goal: Launch production system with enterprise support.

8.1 Production Infrastructure

High Availability

- [] **Multi-AZ Deployment**

- Redundancy across availability zones

Automatic failover

- [] **Load Balancing**

- Application Load Balancer
- Health checks

Auto-scaling

- [] **Disaster Recovery**

- RTO (Recovery Time Objective): <1 hour
 - RPO (Recovery Point Objective): <15 minutes
 - Regular DR drills
-

8.2 Operational Readiness

Runbooks & Documentation

- [] **Operational Runbooks**

- Deployment procedures
- Rollback procedures

Incident response playbooks

- [] **System Documentation**

- Architecture diagrams
- API documentation

Configuration guides

- [] **Training Materials**

- User manuals
- Training videos
- FAQ

Support Structure

- [] **24/7 On-Call Support**

- Rotating on-call schedule

- Escalation procedures

SLA commitments

☐ **Customer Support**

- Helpdesk ticketing system
- Knowledge base
- Live chat support

8.3 Go-Live Checklist

Pre-Launch

- ☐ **Security Audit**

- Penetration testing
- Vulnerability assessment

Compliance verification

- ☐ **Performance Testing**

- Load testing at expected scale
- Stress testing

Chaos engineering

- ☐ **Backup & Recovery Testing**

- Test backup procedures
- Test restore procedures

Validate DR plan

- ☐ **User Acceptance Testing (UAT)**

- Beta testing with select clinicians
- Feedback incorporation
- Sign-off from stakeholders

Launch

- ☐ **Phased Rollout**

- Pilot with 1-2 hospitals
- Gradual expansion

Monitor metrics closely

- ☐ **Marketing & Communication**

- Launch announcement
 - Press release
 - Customer onboarding
-

8.4 Post-Launch

Continuous Improvement

- [] **User Feedback Loop**

- In-app feedback collection
- Regular user surveys

Feature request tracking

- [] **Performance Monitoring**

- Real-time dashboards
- Weekly performance reviews

Monthly business reviews

- [] **Regular Updates**

- Monthly feature releases
 - Quarterly major updates
 - Security patches as needed
-

■ Technology Stack Summary

Development

- **Languages:** Python 3.11+, JavaScript/TypeScript
- **Frameworks:** FastAPI, React/Vue.js, React Native/Flutter
- **ML:** TensorFlow, PyTorch, scikit-learn

Infrastructure

- **Cloud:** AWS / Azure / GCP
- **Orchestration:** Kubernetes, Helm
- **IaC:** Terraform, Ansible
- **CI/CD:** GitHub Actions, ArgoCD

Data

- **Databases:** PostgreSQL, TimescaleDB, MongoDB, Redis
- **Streaming:** Apache Kafka
- **Analytics:** Apache Spark, Snowflake

Monitoring

- **Metrics:** Prometheus, Grafana
- **Logging:** ELK Stack
- **Tracing:** Jaeger, OpenTelemetry
- **Alerting:** PagerDuty

Security

- **Auth:** Keycloak, Auth0
- **Secrets:** HashiCorp Vault
- **Scanning:** Snyk, Trivy

Testing

- **Unit:** pytest, Jest
- **E2E:** Playwright, Selenium
- **Load:** Locust, K6
- **Chaos:** Chaos Mesh

■ Estimated Resource Requirements

Team Composition

| Role | Count | Phase Focus |
|--------------------|-------|---------------|
| DevOps Engineer | 2 | Phase 1, 5, 8 |
| QA Engineer | 2 | Phase 2 |
| Security Engineer | 1 | Phase 3 |
| ML Engineer | 2 | Phase 4 |
| Backend Developer | 3 | All phases |
| Frontend Developer | 2 | Phase 6 |
| Regulatory Affairs | 1 | Phase 7 |

| | | |
|---------------------|---|------------|
| Clinical Specialist | 1 | Phase 6, 7 |
| Project Manager | 1 | All phases |

Total Team Size: 15-17 people

Infrastructure Costs (Monthly Estimates)

- **Cloud Infrastructure:** \$5,000 - \$15,000
- **Third-Party Services:** \$2,000 - \$5,000
- **Monitoring & Security Tools:** \$1,000 - \$3,000
- **Total Monthly:** \$8,000 - \$23,000

■ Success Metrics

Technical KPIs

- **Uptime:** 99.95% (4.38 hours downtime/year)
- **Latency:** p95 < 200ms, p99 < 500ms
- **Error Rate:** < 0.1%
- **Test Coverage:** > 80%
- **Security Vulnerabilities:** 0 critical, < 5 high

Business KPIs

- **Time to Market:** 10-13 months
- **Regulatory Approval:** FDA 510(k) clearance
- **Customer Satisfaction:** NPS > 50
- **Adoption Rate:** 100+ hospitals in first year

■ Next Steps

1. **Review & Prioritize:** Stakeholder review of roadmap
2. **Resource Allocation:** Secure budget and team
3. **Detailed Planning:** Break down each phase into sprints
4. **Kickoff Phase 1:** Begin DevOps infrastructure setup
5. **Quarterly Reviews:** Assess progress and adjust roadmap

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