# Clinical DriftOps Platform Charter

(PMI-CPMAI Phase I — Business Understanding)

Project Title: Clinical DriftOps Platform  
Version: 1.0  
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## 1. Purpose & Objective

To define a repeatable, auditable, and ethical framework for detecting and mitigating model and data drift in clinical AI systems—enhancing reliability, compliance, and clinician trust. Objective: Reduce false alerts and performance decay in sepsis, readmission, and medication-adherence models while ensuring regulatory alignment and measurable trustworthiness across deployments.

## 2. Scope of the Project

Primary AI Function: Drift detection & bias monitoring for predictive clinical models  
Operational Environment: Hybrid cloud (Azure ML + FHIR-compliant data lake)  
Model Types: Classification & forecasting models (sepsis risk, readmission, adherence)  
Boundaries: No direct patient action without human validation; outputs for clinical decision support only.

## 3. Expected Business Outcomes / KPIs

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| --- | --- | --- | --- |
| **KPI** | **Target** | **Measurement Method** | **Owner** |
| False-alert reduction | ≥ 20 % vs baseline | Comparative alert log analysis | Clinical Lead |
| Drift detection latency | ≤ 3 days | PSI / KS test pipeline reports | Data Science Lead |
| Clinician trust score | ≥ 8 / 10 | Quarterly surveys + focus groups | Compliance Officer |
| Model AUC stability | ≤ 5 % degradation QoQ | Validation dashboard metrics | Data Ops Engineer |

## 4. Stakeholders & Roles

|  |  |  |
| --- | --- | --- |
| **Role** | **Name** | **Responsibility** |
| Project Sponsor | Dr. Elaine Wu, Chief Clinical Officer | Approves scope & funding alignment with clinical safety goals |
| Clinical Lead | Dr. Samuel Lin (MD) | Validates clinical output interpretability & usability |
| Data Science Lead | Rand Sobczak Jr., PMI-CPMAI™ | Oversees drift model design, bias audits, & MLOps integration |
| Compliance Officer | Maria Torres, JD | Ensures HIPAA/FDA GMLP/EU AI Act compliance and audit readiness |
| DevOps Engineer | Victor Nguyen | Implements CI/CD, Docker containers, and MLflow lineage tracking |

## 5. Regulatory & Ethical Framework

Applies the principles of HIPAA, FDA Good Machine Learning Practice (GMLP), and EU AI Act across data governance and model operations.  
- All models include human-in-the-loop review for critical decisions.  
- Full audit logs maintained via MLflow & Policy-as-Code monitor.  
- Data de-identified & stored per FHIR and NIST SP 800-53 standards.  
- Bias and fairness tests executed at each model iteration.

## 6. Risks & Mitigation Plan

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| --- | --- | --- | --- |
| **Risk** | **Likelihood** | **Impact** | **Mitigation** |
| Model drift undetected due to data pipeline delay | Medium | High | Real-time drift dashboards + alerting system (Evidently AI) |
| Data bias in training corpus | Medium | High | SHAP feature importance analysis + demographic fairness audits |
| Regulatory updates impact compliance | High | Medium | Policy-as-Code sentinel scans FDA & HIPAA feeds daily |
| Clinician adoption hesitancy | Medium | Medium | Stakeholder training + transparent explainability modules |

## 7. Approval & Next Steps

Go/No-Go Decision: ☑ Go  
Next CPMAI Phase: II — Data Understanding  
Immediate Actions:  
- Collect baseline MIMIC-IV v2.2 tables and profile drift metrics.  
- Configure Evidently AI for PSI/KS monitoring.  
- Establish data lineage map & metadata dictionary.  
  
Signatures  
Dr. Samuel Lin (MD) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Maria Torres, JD \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Data Science Lead: Rand Sobczak Jr., PMI-CPMAI™ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_