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

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

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
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Maria Torres, JD _____

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