

PV GATE EVALUATION ANALYSIS

Sepsis Early Warning AI System

Problem & Value Quantification (PV) Gate · Risk & Value Assessment

WORK PRODUCT ID WP-PV-2025-0142	PROCESS DOMAIN PV · Problem & Value	GATE DATE 2025-10-12	EVALUATOR AI Governance Committee
OPERATING MODEL CHAR	STANDARD ISO/IEC 42001	VERSION 1.0	CLASSIFICATION Internal · Confidential



Decision: Conditional Fail · requires risk mitigation before advancement

4/5
passed

80%
rate

1
blocker

EXECUTIVE SUMMARY

The PV (Problem & Value Quantification) gate evaluation reveals a strong clinical value proposition and technical feasibility, but identifies a critical patient-safety risk that must be mitigated before proceeding to the solution architecture phase. The project demonstrates an 80% pass rate (4 of 5 criteria) but cannot advance until patient-safety risk is reduced from HIGH to MODERATE through documented mitigation strategies addressing false-negative scenarios.

GATE ASSESSMENT SUMMARY

CRITERION	THRESHOLD	RESULT	RATIONALE	RISK
Positive Value Probability	≥ 85% confidence	PASS	Strong evidence for early sepsis intervention; clinical champions support.	Low
Patient Safety Risk	≤ Moderate	FAIL	Risk exceeds moderate threshold; mitigation plan required before proceeding.	Critical
Bias Assessment Required	Completed	PASS	Assessment completed; concerns documented for mitigation.	Medium
Regulatory Pathway Clear	Identified & resourced	PASS	Regulatory strategy developed; timeline acceptable.	Low
Technical Feasibility Confirmed	Reasonable confidence	PASS	Technical feasibility reasonable based on comparable systems.	Low

BLOCKING ISSUE

Patient-Safety Risk: HIGH (RPN 60). Target: MODERATE (RPN ≤ 20), a 67% reduction.

REQUIRED ACTION & NEXT REVIEW

Documented mitigation plan. Re-gate scheduled week of 2025-10-27.

01 Overall Gate Decision

Decision Element	Status	Detail
Overall Gate Status	Conditional Fail	Cannot proceed without patient-safety risk mitigation.
Passing Criteria	4 of 5	80% pass rate.
Blocking Issues	1 Critical	Patient-Safety Risk.
Required Actions	Mitigation Plan	Must address safety risk before advancement.
Next Review Date	2025-10-27	Re-gate evaluation scheduled.
Governance Action	Risk Mitigation	Immediate mitigation plan development required.

02 Risk Mitigation Requirements

● Critical Priority: Patient Safety Risk (HIGH to Moderate)

Objective: reduce patient-safety risk from HIGH to MODERATE through comprehensive mitigation strategies addressing false-negative scenarios.

Mitigation Strategy	Owner	Timeline	Success Criteria	Status
Implement robust alerting with escalation protocols	Clinical Lead	2 weeks	Documented escalation paths for false negatives	Not Started
Add human-in-the-loop verification for high-risk predictions	AI System Owner	3 weeks	100% human review for predictions above risk threshold	Not Started
Establish safety-monitoring dashboard with real-time tracking	MLOps Team	2 weeks	Dashboard operational with defined alert thresholds	Not Started
Conduct failure-mode and effects analysis (FMEA)	Quality / Safety Team	4 weeks	Completed FMEA with risk scores ≤ Moderate	Not Started
Define clear scope limitations and contraindications	Clinical SMEs	1 week	Documented use boundaries and exclusion criteria	Not Started

EXPECTED RISK REDUCTION PATH

HIGH · RPN 60

Severity 5 · Probability 4 · Detection 3

→

MODERATE · RPN 20

Severity 5 · Probability 2 · Detection 2

67%

reduction in Risk Priority Number

● Medium Priority: Bias Assessment Concerns

Objective: address identified bias concerns through data-diversity improvements and continuous fairness monitoring.

Mitigation Strategy	Owner	Timeline	Success Criteria	Status

Expand training-data diversity across demographics	Data Science Team	6 weeks	Representative samples: Race ≥90%, Age ≥85%, Sex ≥95% of target population	In Progress
Implement fairness-metrics monitoring (equalized odds, demographic parity)	ML Engineering	3 weeks	Automated bias detection in production with alerts	Not Started
Establish bias-audit schedule and reporting	Ethics / Fairness Lead	2 weeks	Quarterly review protocol defined and approved	Not Started
Engage community advisory board for fairness validation	Stakeholder Engagement	4 weeks	Initial meeting completed, feedback incorporated	Not Started

FAIRNESS TARGETS

< 0.10
 Equalized-odds difference across protected attributes

< 0.15
 Demographic-parity difference across protected attributes

< 0.05
 Within-group calibration error

03 Re-Gate Evaluation Criteria

Re-gate scheduled: week of 2025-10-27.

Requirement	Status	Target	Verification Method	Approval Authority
Patient-Safety Risk reduced to Moderate	Not Started	2025-10-27	Updated FMEA + Risk Committee approval	AI Governance Committee
All mitigation plans documented in Risk Registry	Not Started	2025-10-27	Registry updated with all mitigations + tracking	Risk Manager
Safety-monitoring infrastructure operational	Not Started	2025-10-27	Dashboard demo + test alerts + SOP	MLOps Lead
Bias-mitigation roadmap approved	In Progress	2025-10-27	Fairness Committee sign-off	Ethics / Fairness Lead
Human-oversight protocols defined	Not Started	2025-10-27	SOP documented + training plan	Clinical Operations

All CRITICAL mitigations completed and verified

Patient-Safety Risk ≤ MODERATE with documented evidence

Governance approvals obtained

Operational readiness demonstrated

04 Governance Actions Required

Action	Responsible	Due	Status	Notes
Present mitigation plan to AI Governance Committee	Project Lead	2025-10-20	Scheduled	60-minute session, mitigation plan + timeline
Update project risk register with new entries	Risk Manager	2025-10-18	Pending	Add patient-safety risk + all mitigations

Notify stakeholders of conditional gate status	Communications Lead	2025-10-15	Pending	Email + dashboard update
Schedule re-gate review meeting	Governance Coordinator	2025-10-27	Pending	90-minute session with all reviewers
Document gate decision and rationale in project records	Governance Coordinator	2025-10-15	Pending	Full documentation in project repository
Initiate Human Oversight Policy instantiation	Policy Lead	2025-10-16	Pending	Now mandatory due to safety risk
Escalate resource needs for mitigation work	Project Sponsor	2025-10-17	Pending	Additional FTE for safety monitoring

05 Process Domain Implications

PROCESS DOMAIN	IMPACT	REQUIRED ACTIONS	TIMELINE
RM · Risk Management	● High	Immediate risk-mitigation planning; update risk registry with all identified risks and mitigations	Week 1
PV · Problem & Value	● Medium	Document value-proposition adjustments based on safety constraints; update business case	Week 2
SA · Solution Architecture	● High	Redesign architecture to incorporate safety mechanisms (alerts, human-in-loop, monitoring)	Weeks 2 to 4
HO · Human Oversight	● High	Define and implement human-oversight protocols; create training materials	Weeks 1 to 3
MON · Monitoring	● High	Establish safety-monitoring infrastructure before deployment; define KPIs and alert thresholds	Weeks 1 to 2
EF · Ethics & Fairness	● Medium	Address bias concerns through data strategy and continuous monitoring	Weeks 2 to 6

06 Policy Artifact Implications

Mandatory Policy Instantiation

POLICY ARTIFACT	STATUS	PRIORITY	RATIONALE	TARGET
Human Oversight Policy	Required	● Critical	HIGH patient-safety risk mandates human-in-the-loop controls	Week 2
Model Monitoring Policy	Required	● Critical	Safety-monitoring infrastructure required before deployment	Week 2
Risk Management Policy	Required	● Critical	Multiple risk-mitigation strategies must be governed	Week 1
AI Ethics & Fairness Policy	Required	● High	Bias concerns identified in assessment	Week 3
Data Governance Policy	Recommended	● Medium	Data-diversity improvements needed for bias mitigation	Week 4

Exemplar Control Activation

CONTROL	CONTROL NAME	ACTIVATION TRIGGER	OWNER
EXC-A5-04	Risk Mitigation Planning	Critical patient-safety risk identified	Risk Manager
EXC-A5-03	Bias & Fairness Risk Assessment	Bias concerns documented	Ethics / Fairness Lead
EXC-A9-01	Human Oversight Mechanisms	HIGH safety risk requires human verification	Clinical Operations
EXC-A9-02	Monitoring and Measurement	Safety monitoring mandatory	MLOps Lead
EXC-A5-05	Residual Risk Review	Post-mitigation risk assessment required	Risk Committee

07 Detailed Risk Analysis

Patient-Safety Risk: False-Negative Scenarios

Risk description: the AI system fails to detect early sepsis indicators, resulting in delayed intervention and potential patient harm.

CURRENT RISK ASSESSMENT

5

Severity

4

Probability

3

Detection

Risk Priority Number

60 · HIGH

CONTRIBUTING FACTORS

●

Model-performance limitations in edge cases

●

Data-quality variations in production vs. training

●

Population drift from training distribution

●

Complex sepsis presentation patterns

●

Time-critical nature of the intervention window

Failure-Mode Scenarios

SCENARIO	DESCRIPTION	IMPACT	LIKELIHOOD	CURRENT CONTROLS
False Negative: Early Stage	Model misses subtle early indicators	Severe	Medium	Clinical judgment backup
False Negative: Atypical Presentation	Unusual symptom patterns not in training data	Critical	Medium to High	None
System Latency	Delayed predictions miss intervention window	Severe	Low	SLA monitoring
Integration Failure	Data-feed issues prevent model execution	Critical	Low	System monitoring

08 Bias Assessment Details

Identified Bias Concerns

BIAS TYPE	DESCRIPTION	EVIDENCE	SEVERITY	PRIORITY
Selection Bias	Training data over-represents certain patient populations	68% White, 12% Black vs. 58% / 18% in target population	● Medium	High

Label Bias	Sepsis diagnosis criteria may vary by provider / setting	Literature review indicates diagnostic variation	● Medium	Medium
Measurement Bias	Vital-sign measurement quality varies by unit / equipment	Historical data shows 15% missing / erroneous vitals	● Low	Medium
Temporal Bias	Training data from 2018 to 2022 may not reflect current practice	Treatment protocols updated 2023	● Medium	High

Performance Equity Analysis (preliminary)

DEMOGRAPHIC GROUP	TRAINING N	SENSITIVITY	SPECIFICITY	CONCERN
Age 18 to 40	1,234	0.82	0.91	● Acceptable
Age 41 to 65	3,456	0.85	0.89	● Acceptable
Age 65+	2,109	0.78	0.88	● Below target
White	4,621	0.83	0.90	● Acceptable
Black	815	0.79	0.87	● Below target
Hispanic	542	0.76	0.86	● Below target
Asian	286	0.81	0.89	● Small sample
Male	3,598	0.82	0.89	● Acceptable
Female	3,201	0.83	0.90	● Acceptable

Target performance: Sensitivity ≥ 0.80, Specificity ≥ 0.85 across all groups. Equity target: within-group performance variance < 5 percentage points.

09 Technical Feasibility Assessment

Prior-Art Review Summary

SIMILAR SYSTEM	PERFORMANCE	POPULATION	SETTING	RELEVANCE
System A (Institution X)	AUROC 0.84 · Sensitivity 0.81	Adult ICU	Academic medical center	High
System B (Published 2023)	AUROC 0.82 · Sensitivity 0.78	Adult ED + ICU	Multi-site community	High
System C (Vendor Solution)	AUROC 0.86 · Sensitivity 0.83	Adult ICU	Mixed academic / community	Medium

FEASIBILITY CONCLUSION
Moderate-to-high confidence in achieving target performance (AUROC > 0.80, Sensitivity > 0.80) based on comparable use cases in the literature.

KEY DIFFERENTIATORS

- Enhanced feature engineering incorporating recent vital trends
- Integration of nursing assessments and clinical notes
- Real-time data-quality validation

TECHNICAL RISKS

- Data-pipeline complexity and latency requirements
- Feature-engineering reproducibility in production
- Model drift in an evolving clinical environment
- Integration with existing EHR workflows

10 Regulatory Strategy Summary

FDA Software as a Medical Device (SaMD) · Class II · Moderate Risk

● Informs clinical management of a life-threatening condition

● Supports (not replaces) clinical judgment

● Significant risk if a false negative occurs

Regulatory Milestones

MILESTONE	TARGET	STATUS	DEPENDENCIES
Pre-submission meeting request	2025-11	Planned	Gate approval, safety mitigation complete
Clinical validation protocol finalized	2025-12	Planned	Human oversight policy, monitoring policy
510(k) submission	2026-Q2	Planned	Clinical validation complete
FDA clearance	2026-Q4	Projected	Based on typical review timeline

✓ Regulatory affairs consultant engaged

✓ \$150K budget allocated for submission preparation

🕒 Clinical validation study protocol under development

🕒 Quality management system alignment underway

11 Stakeholder Communication Plan

Internal Stakeholders

GROUP	KEY MESSAGE	METHOD	FREQUENCY	OWNER
Executive Leadership	Gate status, resource needs, timeline impact	Executive briefing	Weekly during mitigation	Project Sponsor
Clinical Champions	Safety-mitigation approach, input needed	Working sessions	Bi-weekly	Clinical Lead
IT / MLOps Teams	Technical requirements for safety infrastructure	Sprint planning	Weekly	Technical Lead
Quality / Safety	FMEA process, risk-mitigation validation	Quality committee	Monthly	Quality Manager
Legal / Compliance	Regulatory implications, liability considerations	1:1 meetings	As needed	Regulatory Lead

External Stakeholders

GROUP	KEY MESSAGE	METHOD	TIMING	OWNER
FDA (Pre-Sub)	Development approach, safety strategy	Written communication	Post-mitigation	Regulatory Affairs
Clinical Partners	Validation study planning	Email + meetings	Q4 2025	Clinical Lead
Vendor Partners	Integration requirements	Technical calls	Ongoing	Technical Lead

12 Success Metrics for Re-Gate

Quantitative

METRIC	CURRENT	TARGET
Patient-Safety Risk RPN	60 (HIGH)	≤ 30 (MOD)
Mitigation Completion Rate	0%	100%
Safety Monitoring Uptime	N/A	≥ 99.5%
FMEA Risk Scores	Multiple HIGH	All ≤ MOD
Bias Mitigation Progress	20%	≥ 80%

Qualitative

METRIC	CURRENT	TARGET
Clinical Champion Confidence	Moderate	High
Governance Committee Satisfaction	Conditional	Full approval
Safety Protocol Clarity	Undefined	Documented
Stakeholder Alignment	Partial	Full

13 Lessons Learned (Preliminary)

KEY INSIGHTS

- Early safety assessment is critical: identifying HIGH patient-safety risk at the PV gate prevents costly rework later in development.
- Bias-assessment value: pre-assessment revealed concerns that can be addressed through data strategy before model development.
- Regulatory-planning importance: a clear pathway identified early enables appropriate resource allocation.
- Stakeholder engagement: clinical-champion involvement in gate evaluation improved the quality of risk assessment.

PROCESS IMPROVEMENTS

- Enhance the PV gate checklist to include a preliminary FMEA.
- Require bias pre-assessment for all clinical AI projects.
- Integrate regulatory consultation into gate preparation.
- Improve documentation templates for risk-mitigation planning.

14 Document Control & Signatures

Document Control

DOCUMENT VERSION	1.0
CREATION DATE	2025-10-12
LAST UPDATED	2025-10-12
NEXT REVIEW	2025-10-27 (Re-Gate)
DOCUMENT OWNER	AI Governance Committee

Signatures

AI Governance Committee Chair	2025-10-12
Project Sponsor	2025-10-12
Clinical Lead	2025-10-12

APPROVAL AUTHORITY	AI Governance Committee Chair
DISTRIBUTION	Project team, governance committee, executive sponsors
CLASSIFICATION	Internal · Confidential

Risk Manager

[Name]

2025-10-12

This gate evaluation follows the CHAR operating model PV (Problem & Value Quantification) gate process on the FORGE™ platform and aligns with ISO/IEC 42001 risk-management requirements.