Clinical AI Readiness Index™ - Detailed Scoring Rubric

This document provides a detailed scoring rubric for The Clinical AI Readiness Index™. It is intended to help clinicians, researchers, and developers understand the nuances behind each question and to interpret their AI model's readiness for clinical application more thoroughly.

Scoring: Each "Yes" answer to a question on the Index scores 1 point. A "No" answer scores 0 points. The total score is out of 15.

Overall Score Interpretation:

- 13-15 Points (High Readiness): Your AI model demonstrates strong characteristics of clinical readiness. It appears to have been developed with a robust methodology, considering key aspects of safety, efficacy, fairness, and transparency. Continue with rigorous post-deployment monitoring and validation.
- 8-12 Points (Moderate Readiness): Your AI model shows good progress but has identifiable areas that require further attention and development before it can be confidently considered for widespread clinical deployment. Focus on addressing the questions answered with "No."
- 0-7 Points (Low Readiness): Significant gaps exist in your AI model's development, validation, or documentation. Substantial work is required to address these critical areas to ensure the model is safe, effective, and ethically sound for clinical use. It is not recommended to proceed with clinical deployment without addressing these shortcomings.

Detailed Rubric for Each Question:

Below is a breakdown of each question, what a "Yes" implies, and considerations for a "No."

1. Data Provenance & Quality: Is the data used to train and validate the AI model clearly documented, ethically sourced, representative of the target patient population, and of sufficient quality and quantity for the intended clinical application? (Relevant frameworks: CLAIM, FUTURE-AI - Universality, WHO/ITU) * "Yes" Implies: Comprehensive

documentation exists detailing data sources, collection methods, inclusion/exclusion criteria, and preprocessing steps. Ethical approvals (e.g., IRB/ethics committee) are in place. The dataset reflects the diversity (age, sex, ethnicity, comorbidities, etc.) of the intended patient population. Data quality checks (e.g., for missing values, errors, biases) have been performed, and the dataset size is statistically appropriate for the complexity of the model and the clinical task. * Considerations for “No": Lack of clear data documentation raises concerns about reproducibility and transparency. Non-representative or poor-quality data can lead to biased, unreliable, or poorly generalizing models. Ethical sourcing is non-negotiable.

2. Model Transparency & Explainability: Can the AI model’s decision-making process be sufficiently understood by clinicians? Are there mechanisms to explain why the AI reached a specific conclusion for an individual patient, or to highlight the key input features driving its output? (Relevant frameworks: FUTURE-AI - Explainability, CLAIM) * "Yes” Implies: The model is not a complete “black box.” Explainability methods (e.g., SHAP, LIME, attention maps, feature importance) are used and their outputs are presented in a clinically interpretable way. Clinicians can gain insight into the model’s reasoning, which is crucial for trust and for identifying potential model errors or limitations. * Considerations for “No": Opaque models make it difficult for clinicians to trust predictions, override incorrect suggestions, or understand failure modes. This can hinder adoption and safe use.

3. Robustness & Reliability: Has the AI model been rigorously tested for performance across diverse datasets, different clinical settings, and various patient subgroups, including edge cases and potential adversarial attacks? How does the model handle uncertainty or ambiguous inputs? (Relevant frameworks: FUTURE-AI - Robustness, SUDO, FURM - Reliable, Health Care AI Toolkit) * "Yes” Implies: Performance has been validated on external datasets beyond the initial training/test sets. Stability across different demographics, equipment, or sites has been assessed. The model’s response to noisy, incomplete, or out-of-distribution data is understood and managed. Sensitivity analyses and stress tests have been conducted. * Considerations for “No": A model performing well on one dataset may fail in another. Lack of robustness testing can lead to unexpected failures in real-world deployment, potentially harming patients.

4. Clinical Validation & Efficacy: Is there robust evidence from well-designed clinical studies (e.g., randomized controlled trials or prospective real-world studies) demonstrating the AI model’s safety, accuracy, and actual clinical benefit (e.g., improved patient outcomes, enhanced diagnostic capabilities, or workflow efficiency) in its intended use case? (Relevant frameworks: CLAIM, TEHAI, Health Care AI Toolkit) * "Yes” Implies: Beyond technical performance metrics (like AUC), there is evidence that the AI tool positively impacts clinical practice. This could be through improved diagnostic accuracy leading to better treatment decisions, faster workflows, reduced costs, or directly improved patient outcomes, demonstrated in studies that reflect real clinical conditions. *

Considerations for “No": High technical accuracy does not automatically translate to clinical utility or safety. Without clinical validation, the real-world impact of the AI is unknown and could even be detrimental.

5. Fairness & Bias Mitigation: Has the AI model been systematically audited for potential biases related to demographic factors (age, sex, ethnicity), socioeconomic status, geographic origin, or other relevant characteristics? Are there effective strategies in place to mitigate identified biases and ensure equitable performance and outcomes across all patient groups? (Relevant frameworks: FUTURE-AI - Fairness, SUDO, FURM - Fair, WHO/ITU) * "Yes” Implies: A proactive approach has been taken to identify and measure performance disparities across subgroups. Where biases are found, mitigation strategies (e.g., data re-sampling, algorithmic adjustments, post-processing corrections) are implemented and their effectiveness evaluated. The goal is equitable benefit for all patients. * Considerations for “No": Biased AI can perpetuate or even exacerbate existing health disparities, leading to poorer outcomes for underserved populations. This is a critical ethical and safety concern.

6. Usability & Clinical Workflow Integration: Is the AI tool designed for seamless and intuitive integration into existing clinical workflows? Has its usability been tested with representative clinical users to ensure it can be used effectively and efficiently with minimal disruption to patient care? (Relevant frameworks: FUTURE-AI - Usability, TEHAI, Health Care AI Toolkit) * "Yes” Implies: The AI tool is not a standalone gadget but fits naturally into how clinicians work. User interface is intuitive, information is presented clearly, and the tool does not add undue burden or time to clinical tasks. Human factors engineering and user-centered design principles have been applied and tested. * Considerations for “No": Poor usability or workflow integration can lead to workarounds, errors, user frustration, and ultimately, abandonment of the tool, regardless of its technical accuracy.

7. Traceability & Auditability: Can the AI model’s predictions, the input data it used, and its version be logged and audited? Is there a clear and maintained record of model development, updates, and ongoing performance monitoring? (Relevant frameworks: FUTURE-AI - Traceability, CLAIM) * "Yes” Implies: Systems are in place to log every instance of the AI’s use, its inputs, outputs, and the specific model version used. This is crucial for error analysis, accountability, quality improvement, and regulatory compliance. Version control for models and datasets is maintained. * Considerations for “No": Lack of traceability makes it impossible to investigate adverse events, understand model performance over time, or ensure accountability when things go wrong.

8. Regulatory & Ethical Compliance: Does the AI model, its development process, and its planned deployment comply with all relevant local and international regulatory requirements (e.g., FDA, CE marking, GDPR, HIPAA) and established ethical guidelines for

AI in healthcare? (Relevant frameworks: FUTURE-AI, FURM - Ethical, WHO/ITU) * "Yes" Implies: A thorough review of applicable regulations (medical device regulations, data privacy laws) has been conducted, and the AI system meets these standards. Ethical considerations (autonomy, beneficence, non-maleficence, justice) have been addressed throughout the AI lifecycle. * Considerations for "No": Non-compliance can lead to legal penalties, reputational damage, and most importantly, can put patients at risk. Ethical breaches erode trust in AI in healthcare.

9. Real-World Performance Monitoring & Governance: Is there a comprehensive plan for continuous monitoring, evaluation, and governance of the AI model's performance in the real-world clinical setting after deployment? Does this include mechanisms for collecting user feedback, detecting performance degradation, and implementing timely updates or recalibrations? (Relevant frameworks: TEHAI, Health Care AI Toolkit) * "Yes" Implies: Deployment is not the end point. A plan exists for ongoing surveillance of the AI's performance, including metrics to track, triggers for re-evaluation (e.g., concept drift, changes in patient population), and processes for updating or retiring the model. User feedback channels are active. * Considerations for "No": AI models can degrade over time as clinical practices or patient populations change. Without monitoring, this degradation may go unnoticed, leading to declining performance and potential harm.

10. Benefit vs. Risk Assessment: Has a thorough and documented assessment been conducted to weigh the potential clinical benefits of the AI model against its potential risks, including but not limited to misdiagnosis, over-reliance by clinicians, deskilling, or introduction of new types of errors? (Relevant frameworks: FURM - Usefulness, Health Care AI Toolkit) * "Yes" Implies: A formal risk management process has been followed (e.g., ISO 14971 for medical devices). Potential harms and their likelihoods have been identified, and measures to mitigate these risks are in place. The expected benefits clearly outweigh the residual risks. * Considerations for "No": Deploying AI without a clear understanding of its risk-benefit profile is irresponsible. Unforeseen risks can emerge, and the claimed benefits may not materialize in practice.

11. Clear Intended Use & Limitations: Is the specific intended clinical use of the AI model unequivocally defined, including the target patient population and clinical conditions? Are its known limitations, contraindications, and appropriate scope of use clearly communicated to users? (Relevant frameworks: CLAIM, Health Care AI Toolkit) * "Yes" Implies: There is no ambiguity about what the AI is designed to do, for whom, and under what circumstances. Users are made aware of situations where the AI should not be used or where its outputs should be interpreted with extra caution. * Considerations for "No": Vague intended use can lead to off-label or inappropriate application of the AI, increasing the risk of errors. Users must understand the boundaries of the AI's competence.

12. Uncertainty Quantification & Communication: Does the AI model provide a reliable indication of its confidence or uncertainty for each prediction or output? Is this uncertainty communicated to clinicians in an understandable and actionable manner? (Relevant frameworks: SUDO, FUTURE-AI - Robustness) * "Yes" Implies: The model doesn't just give an answer, but also an assessment of how sure it is about that answer. This uncertainty information is presented to clinicians in a way that helps them decide how much weight to give to the AI's suggestion (e.g., flagging low-confidence predictions for human review). * Considerations for "No": Without uncertainty information, clinicians may over-trust AI outputs, even when the model is not confident. This can be particularly dangerous in ambiguous or borderline cases.

13. Data Security & Patient Privacy: Are robust technical and organizational measures in place to ensure the security, integrity, and privacy of patient data used by and generated by the AI model, in full compliance with data protection regulations and best practices? (Relevant frameworks: FUTURE-AI, WHO/ITU) * "Yes" Implies: Strong data governance, encryption, access controls, de-identification/anonymization techniques (where appropriate), and audit trails are implemented to protect sensitive patient information throughout the AI lifecycle, adhering to laws like GDPR or HIPAA. * Considerations for "No": Data breaches or privacy violations can have severe consequences for patients and institutions, eroding trust and leading to legal repercussions.

14. Stakeholder Engagement & Training: Have all relevant stakeholders (including clinicians, nurses, IT staff, and patients where appropriate) been involved in the selection, development, or validation process of the AI tool? Is there adequate and ongoing training provided for all users to ensure competent and safe use? (Relevant frameworks: TEHAI, Health Care AI Toolkit) * "Yes" Implies: The AI tool was not developed in a vacuum. End-users and other affected parties have had input, increasing the likelihood of acceptance and appropriate use. Comprehensive training programs are in place to ensure users understand how to use the tool correctly, interpret its outputs, and understand its limitations. * Considerations for "No": Lack of stakeholder involvement can lead to tools that don't meet user needs or fit workflows. Insufficient training is a major safety risk, as users may misuse the AI.

15. Contingency & Downtime Planning: What are the established protocols and contingency plans if the AI system fails, provides clearly erroneous information, or becomes unavailable due to technical issues? How will patient care be managed safely and effectively in such scenarios without relying on the AI tool? (Relevant frameworks: Health Care AI Toolkit) * "Yes" Implies: There's a plan for when the AI isn't working or is unreliable. This includes procedures for reverting to manual methods or alternative tools, ensuring patient care is not compromised. System monitoring and alerts for failures are in place. * Considerations for "No": Over-reliance on AI without backup plans can lead to significant disruptions or patient safety issues during system outages or malfunctions.

This detailed rubric is intended to accompany The Clinical AI Readiness Index™. It should be used as a guide for deeper self-assessment and to identify areas for improvement in AI model development and deployment in healthcare.