Project Charter:

1. General Information

Project Title:

Fetosense AI-Based Fetal Monitoring with Remote Fetal Monitoring

Project Sponsor(s):

UNICEF Venture Fund
CareNX Innovations Pvt. Ltd.

Project Manager:

CareNX Innovations Pvt. Ltd.

Date of Approval:

7th Nov 2024

2. Vision Statement

To create an accessible, AI-driven fetal monitoring solution that ensures every pregnancy is monitored effectively, regardless of geographic or resource constraints, leading to better maternal and fetal health outcomes globally.

3. Mission Statement

To develop and deploy an AI-based fetal classification model that enables general physicians (GPs) in remote and underserved areas to accurately assess fetal health, reducing complications and improving pregnancy care through scalable and open-source technology.

4. Community Statement

Fetosense aims to foster a global community of healthcare providers, researchers, policymakers, and technologists dedicated to improving maternal-fetal health through AI-driven solutions. By open-sourcing the AI model, we invite collaboration from public health organizations, universities, and developers to enhance and adapt the technology for diverse healthcare ecosystems worldwide.

5. Licensing Strategy

- The AI-based fetal classification model will be released under an open-source license to ensure accessibility and adaptability for global healthcare use.
- Software components will follow an **Apache 2.0 or MIT license**, allowing broad modification and distribution while maintaining transparency and security.
- Hardware designs and technical documentation will be shared under **Creative Commons (CC BY 4.0)** to enable replication and integration into other maternal health programs.
- Compliance with national and international data privacy laws (GDPR, HIPAA, NDHM) will be strictly maintained.

6. Identification of Key Trademarks

- **Fetosense®** – Registered trademark of CareNX Innovations Pvt. Ltd.
- **CareMother®** – Trademarked platform associated with maternal healthcare solutions.
- Any third-party technology integrated will be used under appropriate licensing agreements.

7. Project Overview

Background & Purpose:

The shortage of gynecologists in rural and remote areas significantly affects access to proper fetal monitoring, leading to preventable complications during pregnancy. The Fetosense solution, currently used by gynecologists, employs a decision tree algorithm for basic clinical assessments. This project aims to enhance the Fetosense system with an AI-based fetal classification model to empower general physicians (GPs) in remote settings. By leveraging supervised machine learning on a large dataset of fetal heart rate (FHR) and clinical parameters, the project will improve decision-making, reduce unnecessary NICU admissions, and enhance maternal-fetal outcomes.

Alignment with Digital Public Goods (DPG) Principles:

- **Open Source & Open Standards:** AI model will be open-sourced for global accessibility.
- **Privacy & Security:** Adheres to data protection regulations, ensuring patient confidentiality.
- **Scalability:** Designed for deployment in low-resource settings with minimal technical dependency.
- **Interoperability:** Compatible with existing maternal health platforms.

8. Objectives & Scope

Objectives:

- Deploy 30 Fetosense devices with 30 general physicians in remote areas.
- Collect fetal monitoring data from 3,000 pregnancies over 11 months.
- Develop and validate an AI-based fetal classification model for accurate interpretation of fetal health conditions.
- Open-source the AI model to promote broader adoption in low-resource settings.
- Improve early detection of fetal distress, reducing NICU admissions and maternal-fetal complications.

Scope:

In Scope:

- Hardware and software deployment in pilot locations.
- Data collection, model training, and validation.
- AI model integration into Fetosense platform.
- Open-sourcing the AI model for public use.

Out of Scope:

- Commercial deployment of AI-enabled Fetosense beyond the pilot phase.
- Regulatory approvals for widespread implementation.

9. Key Deliverables

- Deployment of 30 Fetosense devices in pilot locations.
- Data collection and analysis framework for 30,000 pregnancy screenings.
- AI-based fetal classification model with validation results.
- Open-source repository for the AI model and implementation guidelines.
- Final impact report highlighting key outcomes and recommendations.

10. Stakeholders

- UNICEF Venture Fund
- CareNX Innovations Team
- General Physicians (Pilot Participants)
- Pregnant Women in Pilot Locations
- Public Health Organizations
- AI Researchers & Developers

11. Project Timeline & Milestones

- **Month 1-2:** Device deployment and physician training.
- **Month 3-9:** Data collection and AI model development.
- **Month 10-11:** Model validation and pilot evaluation.
- **Month 12:** Open-source release and final reporting.

12. Budget & Funding

- UNICEF funding support for hardware, software, and AI development.
- Operational costs for device deployment and data collection.
- Research and development expenses for AI training and validation.

13. Risks & Mitigation Strategies

- **Risk:** Limited data quality from remote locations.
  Mitigation: Standardized data collection protocols and training for physicians.
- **Risk:** AI model biases and inaccuracies.
  Mitigation: Diverse data collection, rigorous testing, and expert validation.
- **Risk:** Resistance to adoption by GPs.
  Mitigation: Training and support for physicians, demonstrating clinical benefits.

14. Success Criteria

- Successful deployment and use of Fetosense devices by 30 general physicians.
- Collection and analysis of 3,000 pregnancy screenings.
- AI model achieving high accuracy in fetal classification.
- Reduction in unnecessary NICU admissions in pilot locations.
- Open-source adoption by health organizations and researchers.

15. Governance & Compliance

- Adherence to Digital Public Goods Alliance (DPGA) standards.
- Compliance with ethical AI and data protection regulations.
- Periodic review by independent evaluators.

11. Approval & Signatures

- **CareNX Innovations Pvt. Ltd.** – Project Executioner

- **UNICEF Venture Fund Representative** – Project Sponsor
- **Other Key Stakeholders** – As required

This document serves as the formal charter for the Fetosense AI-based fetal classification project, aligning with Digital Public Goods (DPG) principles to ensure accessibility, scalability, and ethical deployment.