

## **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

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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.