BFI NAMAH Project Proposal

Instructions for Applicant: *This document focuses on your execution strategy, technical methodology, and resource planning. Please do not simply repeat your questionnaire answers; use this space to provide the technical depth, regulatory roadmap, and financial justification the selection committee needs to evaluate your project's viability.*

---

1. Detailed Technical Methodology

(Provide a deep dive into how you plan to develop or refine your technology during your time at the acceleration hub.)

- **Engineering & Design Approach:** Detail the design architecture, materials to be used, and manufacturing processes (e.g., 3D printing, PCB fabrication).
- **Testing & Benchmarking:** Describe the specific *in-vitro* (dry/wet lab) or bench-testing protocols you will use to validate the functional prototype.
- **Data & Software (If applicable):** For SaMD or AI-driven diagnostics, detail the data architecture, algorithm training methodology, and data privacy measures.

2. Regulatory & Quality Strategy

(Outline your pathway to compliance, as per CDSCO-MDR 2017.)

- **Regulatory Pathway:** Detail your strategy for securing CDSCO approval for your specific device class.
- **Quality Management System (QMS):** How will you integrate ISO 13485 standards or Good Manufacturing Practices (GMP) into your development lifecycle during the program?

3. Clinical Validation & Translational Plan

(Explain how the technology will transition from the bench to the bedside.)

- **Pre-Clinical/Clinical Protocol:** If your milestones include early feasibility studies or clinical validation, outline the proposed study design, target patient population, and primary endpoints.
- **Clinical Partnerships:** List any existing or targeted partnerships with hospitals (listed under BFI-MedTech Incubation Centres).

4. Intellectual Property (IP) Strategy

(Describe the current status and future plans for protecting your innovation.)

- **Current IP Status:** List any filed patents, copyrights, or trademarks.

5. Project Timeline & Milestones (Gantt Chart/Roadmap)

(Provide a month-by-month breakdown of activities. Clearly define what constitutes a "successful milestone" for your project within the NAMAH framework.)

- **Phase 1 (Months X-Y):** [Objective, Key Activities, Deliverable]

- **Phase 2 (Months X-Y):** [Objective, Key Activities, Deliverable]
- **Phase 3 (Months X-Y):** [Objective, Key Activities, Deliverable]

6. Risk Assessment & Mitigation

(Identify the top risks your project faces and how you plan to overcome them.)

- **Technical Risks:** (e.g., Material failure, algorithm bias) and mitigation strategy.
- **Regulatory Risks:** (e.g., Delays in ethics committee approval, reclassification) and mitigation strategy.
- **Commercial/Market Risks:** (e.g., High cost of goods sold, adoption barriers) and mitigation strategy.