



SCHOOL OF INTERNATIONAL BIODESIGN -SYNERGIZING HEALTHCARE INNOVATION & ENTREPRENEURSHIP (SIB-SHInE)

Need Identification Record-

(This record is to be maintained for all the selected problem statements from the visit to clinical departments)

1. Date of visit:
2. Clinical Area/ Department of observation:
3. Location of observation:
4. Clinical mentor or in-charge for the visit:
5. Problem Observation:
6. Current practice if any-
7. Frequency of problem:

Need Evaluation Matrix

Sno.	Criteria	Score (1–5)
1	Clinical Impact	
2	Number of patients affected	
3	Severity of problem	
4	Existing solution gap	
5	Feasibility (Technical)	
6	Market potential	
7	Regulatory complexity	
8	Total score:	

Decision:

☐ Selected ☐ Dropped ☐ Needs more study

Reason for decision:

Solution Concept Sheet

1. Selected need:
2. Proposed solution:
3. Working model/Method:
4. Key features:
5. Design approach:
6. Alternative Concepts Considered:
7. Type of technical or medical experts required for mentorship:
8. Why this concept was selected:

Technical Evaluation

1. Core Technology Required:
2. Availability of Technology: ☐ Easily available ☐ Needs development
3. Key Technical Challenges:
4. Prototype feasibility: ☐ Easy ☐ Moderate ☐ Difficult
5. R&D Needs:
6. Device type:
7. Risk class:
8. Regulatory authority for the particular product other than CDSCO-
9. Predicate Device Available? ☐ Yes ☐ No
10. Intellectual Property (IP) Protection
11. Regulatory Pathway:

Remarks:

Market Evaluation

Target Users:	
Customer vs User:	
Existing Products in Market:	
Gap Identified:	
Estimated Market Size:	
Price Sensitivity: Break down all costs: – Development / R&D – Raw materials & manufacturing – Marketing & sales – Operations & overheads – Regulatory & certification costs	
Business Model Idea:	
Scalability	
Distribution & Go-to-Market Channels	
Break-even Analysis	
Revenue Projections	
Funding Requirements	

Risk Analysis : (High/Medium/Low)

Market risk	
Technology risk	
Financial risk	
Regulatory risk	
Operational risk	

SWOT + PESTLE Analysis

Go / No-Go Decision

Need:

Solution:

Summary of Evaluation:

Technical:

Market:

Regulatory:

Final Decision:

☐ Proceed ☐ Pivot ☐ Drop

Reason: