

5. Medical Devices and Diagnosis

Stage	Technology Readiness Level	Definition (Medical Devices including diagnostic devices)	Definition (In vitro Diagnostic Kits & reagents)	Definition (Biomedical implants)
Ideation	TRL-1	Need identified, Basic principles observed and reported (Scientific research begins which can be translated into applied research and development)	Need identified, Basic principles observed and reported (Scientific research begins which can be translated into applied research and development)	Need identified, Basic principles observed and reported (Scientific research begins which can be translated into applied research and development)
Proof of Principle	TRL-2	Market surveillance data and competitor analysis available to support the idea. Basic device design ready and product specifications defined based on the competitor analysis and patent landscaping. FTO ensured. Development of individual components initiated.	Hypothesis formulated and protocols developed. Market surveillance data and competitor analysis available to support idea. Individual core components of kit/reagents(Antibodies/Antigens/Aptamers/Nano particles) finalized, developed/procured for testing	Market surveillance data and competitor analysis available to support the idea. Basic implant design ready, candidate materials shortlisted and product specifications defined based on the competitor analysis and patent landscaping. FTO ensured
Proof of Concept demonstrated	TRL-3	Individual modules/Components/PCBs/Softwares/Systems developed and tested separately for its functionality on a breadboard/laboratory level. Material safety, electrical safety & biocompatibility of the systems demonstrated	Individual core components optimized at lab scale. Demonstrated the limit of detection/Sensitivity with metabolite serial dilution or ELISA or spiked biological sample studies.	Material research completed and material properties of the finalized material/composites compared against benchmarks. Relevant ASTM standard tests (strength, ductility, corrosion, surface properties, antimicrobial activity, usability, shelf life etc.) on the material performed successfully. Material sterilization method finalized. Biocompatibility (ISO 10993) proven in <i>in vitro</i> cytotoxicity assays.
Proof of concept established	TRL-4	Functional Prototype developed by integration of different modules and safety, efficacy and performance of candidate device or system demonstrated in a defined laboratory, Simulated Environment or animal model (with Institutional Animal Ethics Committee approvals)	Optimized core components integrated into the kit or platform (Microfluidics/ filter paper/ LFA etc) along with the reagents to come up with a functional prototype of the kit. Integrated system tested in house with metabolite	Material safety and or imaging compatibility proven in <i>in vivo</i> small animal model study (with Institutional Animal Ethics Committee approvals). Functional Prototype implant device developed as per the design in a near GMP condition. Sterilization and packaging established.

			serial dilution or ELISA or spiked biological sample studies.	
Early stage validation	TRL-5	Relevant IEC & ISO tests (Electromagnetic interference, Electromagnetic compatibility, Electrical safety, Biocompatibility, software test, radiation safety test drop test, packaging test, transportation test, physico –chemical and mechanical testing etc.) of the device performed and safety proven. Quality management certification (ISO13485) in place. Design iterated prototype ready to go for clinical validation. Clinical study plan approved by Institutional Ethical Committee and/or CDSCO	Integrated system tested in-house extensively with clinical samples (Blood, Urine, Sputum etc.) before taking it for clinical validation. Analytical validation of the kit completed. Shelf life, stability data of the kit reagents available. Quality management certification (ISO13485) in place Clinical study plan approved by Institutional Ethical Committee and/or CDSCO	<i>In vivo</i> pre-clinical studies performed (with Institutional Animal Ethics Committee approvals) using functional prototype implant device on the relevant small or big animal (disease) models to establish its safety (tissue reactivity/ allergy/degradability, Histopathology) and efficacy (. Quality management certification (ISO13485) in place. Design iterated prototype ready to go for clinical validation. Clinical study plan approved by Institutional Ethical Committee and/or CDSCO
	TRL-6	Fully functional clinical grade device ready with regulatory dossier for use on human subjects/patients. Quality assurance certification (like CE) applied. Pilot clinical study/trials on limited number of subjects/patients to prove safety and substantial equivalence/efficacy. Data submitted to CDSCO for Pivotal study approval	Clinical study performed on statistically significant number of samples at one or two centres to define the specificity and sensitivity of the Assay/kit. Quality assurance certification for the product applied/obtained	Clinical level implant device fabricated using clinical grade material in GMP facility with safety dossier for use on human subjects/patients. . Quality assurance certification (like CE) applied. Pilot clinical trials performed on statistically significant number of patients against the predicate implant device to prove safety, substantial equivalence/efficacy. Data submitted to CDSCO for Pivotal study approval.
Late stage Validation	TRL-7	Manufacturing lines established. Design for manufacture (DFM) finalised and devices manufactured. Documentation on design history file (DHF) ready. Pivotal clinical study/trials completed and clinical performance data submitted to CDSCO for manufacturing license	Multi-Centric Trials completed at NABL accredited centres and performance evaluation report submitted to CDSCO for Commercial license. Performance evaluation report of notified products (IVD for HIV, HCV, HBV and Blood grouping sera) obtained from NIB, Noida.	Manufacturing lines established. Design for manufacture (DFM) finalised and devices manufactured. Documentation on design history file (DHF) ready. Pivotal clinical study/trials completed and clinical performance data submitted to CDSCO for manufacturing license
Pre-commercialization	TRL-8	Manufacturing license obtained from CDSCO and commercial batch manufacturing initiated	Manufacturing license obtained and commercial scale manufacturing set up/Packing/labelling etc. Commercial batch manufacturing initiated	Manufacturing license obtained from CDSCO and commercial batch manufacturing initiated

Commercial ization and post market studies	TRL-9	Commercial launch of the new device, Post marketing studies and surveillance	Commercial launch of in vitro diagnostic kit or reagents and Post marketing studies and surveillance	Commercial launch of the implant, Post marketing studies and surveillance
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