Annexure-II

Technology Readiness Levels (TRLs) for 'Investigational Medical Devices' and 'New In-vitro Diagnostic Medical Device' (which do not have a predicate*)

Stage	TRL	TRL achieved once milestones complete
Ideation	TRL 1	Problem statement/unmet need defined and documented. Selection of the idea for a device for the intended application
Proof of Principle	TRL 2	Preliminary device design selected and technical product specifications defined. Applicable technical standards identified. Freedom to operate (FTO) search completed & market analysis done. Suppliers and design partners identified. Establish preliminary "Intended Use Statement".
Early-stage Proof of Concept	TRL 3	In-house-prototype designed, In-house analytical performance tested.
Advanced Proof of Concept (Design freeze)	TRL 4	In-house-prototype safety and efficacy analysed, Design finalised after iterations, device class identified, test-quantity and protocol defined, framed Instructions for use (IFU), submission of application for the Test license (MD-12)
Test-batch Evaluation	TRL 5	MD-13 (Test License) obtained. Test-batches manufactured in compliance with schedule V, and evaluated by applying bench testing, simulated testing, analytical performance, stability, in compliance with device-specific standards. Submission of data for undertaking -clinical investigation (CI) of medical device (MD-22)/-clinical performance evaluation (CPE) of In-vitro Diagnostic medical device (MD-24)
Pilot CI/CPE studies	TRL 6	MD-23 (Permission for clinical investigation (CI) of Medical device), / MD-25 (Permission for clinical performance evaluation (CPE) of IVD), obtained. Submission of Safety and efficacy data of Pilot clinical study along with fee to pursue pivotal study.
Pivotal CI/CPE studies	TRL 7	Safety and efficacy data from Pivotal clinical study; Submission of data for permission to manufacture of medical device (MD-26)/IVD (MD-28)
Pre-commercialization	TRL 8	MD-27 (Mfg Licence for medical device) /MD-29 (Mfg Licence for IVD), MD-29. ISO 13485-compliant manufacturing line established. Packaging and labelling completed.
Commercialization and Post Market Studies	TRL 9	Product launched with Post-Market Surveillance (PMS) system in place. User feedback system operational.

***(For more details, please refer to MDR 2017, CDSCO and some relevant definitions derived from MDR 2017, CDSCO provided below)**

Technology Readiness Levels (TRLs) for 'Medical Devices' and 'In-vitro Diagnostic Medical Devices' (having a predicate*)

Stage	TRL	TRL achieved once milestones complete
Ideation	TRL 1	Problem statement/unmet need defined and documented. Selection of the idea for a device for the intended application
Proof of Principle	TRL 2	Preliminary device design selected and technical product specifications defined. Applicable technical standards identified. Freedom to operate (FTO) search completed & market analysis done. Suppliers and design partners identified. Establish preliminary "Intended Use Statement".
Early-stage Proof of Concept	TRL 3	In-house-prototype designed, In-house analytical performance tested.
Advanced Proof of Concept (Design freeze)	TRL 4	In-house-prototype safety and efficacy analysed, Design finalised after iterations, device class identified, test-quantity and protocol defined, framed Instructions for use (IFU), submission of application for the Test license (MD-12)
Test-batch Evaluation	TRL 5	MD-13 (Test License) obtained. Test-batches manufactured in compliance with schedule V, and evaluated by applying bench testing, simulated testing, analytical performance, stability, in compliance with device-specific standards.
Clinical evidence including Substantial - equivalence to the predicate device	TRL 6-7	Clinical evaluation for Medical Device and Performance evaluation for IVD. Established substantial equivalence to the predicate. Application submitted for Manufacturing license (MD-3 for Medical Devices Class A/B, MD-7 for Medical Devices Class C/D).
Pre-commercialization	TRL 8	Manufacturing license obtained (MD-3 for Medical Devices of Class A/B, MD-7 for Medical Devices of Class C/D). ISO 13485-compliant manufacturing line established. Packaging and labelling completed.
Commercialization and Post Market Studies	TRL 9	Product launched with Post-Market Surveillance (PMS) system in place. User feedback system operational.

***(For more details, please refer to MDR 2017, CDSCO and some relevant definitions derived from MDR 2017, CDSCO provided below)**

Some relevant definitions derived from MDR 2017:

(For more clarity, please refer to MDR 2017)

1. "Investigational medical device" means a medical device

(i) which does not have its predicate device; or

(ii) which claims for new intended use or new population or new material or major design change; and is being assessed for safety or performance or effectiveness in a clinical investigation.

2. "New in-vitro diagnostic medical device" means any medical device used for in vitro diagnosis that has not been approved for manufacture for sale or for import by the Central Licensing Authority and is being tested to establish its performance for relevant analyte or other parameter related thereto including details of technology and procedure required;

3. A device shall be deemed to substantially equivalent in comparison to a predicate device, if it has

(i) the same intended use and technological characteristics; or

(ii) same intended use and different technological characteristics, and demonstrate that the device is as safe and effective as the predicate device.

A claim of substantial equivalence does not mean that the proposed medical device and predicate device are identical. Substantial equivalence shall be established with respect to intended use, design, energy used or delivered, materials, chemical composition, manufacturing process, performance, safety, effectiveness, labeling, biocompatibility, standards, and other characteristics, as applicable.

Checklist for comparing your device with a predicate

Product Details

Intended Use

Indications

Materials

Design Characteristics

Mode of Action

Contraindications

Biocompatibility

Product Specification

Storage

Packaging and Labeling

Advantages

Disadvantages

4. An application for grant of permission to conduct,- a pilot clinical investigation on an investigational medical device as referred to in sub-rule (1) shall be accompanied with a fee as specified in the Second Schedule along with information as specified in the Seventh Schedule. Explanation.— For the purposes of these rules, the pilot clinical investigation means clinical investigation to be carried out for the first time in human participants;

5. A pivotal clinical investigation on an investigational medical device shall be made on the basis of data emerging from pilot clinical investigation, accompanied with a fee as specified in the Second Schedule: Provided that no fee shall be payable by any institute, organisation, hospital run or funded by the Central Government or the State Government, as the case may be, for conduct of clinical investigation.

Annexure-III

List of National Health Priorities

A. Communicable Diseases

1. Tuberculosis

2. Vector Borne Disease

3. AMR

4. Neglected Tropical Diseases

5. Epidemic and Pandemic Readiness

B. Non-communicable Diseases

6. Cancer

7. Mental Health

8. Ambulatory care

C. Woman & Child Health and Nutrition

9. Anemia

10. Childhood malnutrition

11. Neonatal Care (including neonatal respiratory distress, neonatal support technologies and broader neonatal care continuum)

12. Maternal Health (including antenatal, intrapartum and postpartum care)

13. Women's Health and Reproductive Health

D. Acute Ambulatory Care

E. Oral Health

F. Primary Health Care

G. AI in healthcare

H. Cell and Gene Therapy (Rare genetic diseases)