Scheme for Promotion of Research & Innovation in Pharma MedTech Sector

Expression of Interest

Government of India
Ministry of Chemicals and Fertilizers
Department of Pharmaceuticals

Date of issue: 7th March 2025

This EoI is issued for the sole purpose of obtaining preliminary information from interested entities regarding their potential participation under Component B of the PRIP scheme. At this EoI stage, the information provided will NOT be used for evaluating the entity/ project. Formal call for applications will follow soon.

Scheme Overview

The Scheme for "Promotion of Research and Innovation in Pharma MedTech sector (PRIP)" has been launched by the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India, with the goal of transforming India into a global powerhouse for R&D in the Pharma MedTech sector. The scheme has been notified vide Gazette Notification No. 199 dated 17th August 2023. The scheme has a total financial outlay of Rs. 5,000 Crores, of which Rs 4,250 Crores is focused on accelerating investments in the R&D ecosystem within the sector.

The scheme proposes funding across 6 priority areas and 3 funding categories:

Priority Areas

There are six priority research areas which will be covered by the PRIP scheme
(please see Appendix I for more detailed descriptions/ illustrations):

1. New Chemical Entity, New Biological Entity and Phyto-pharmaceuticals
2. Complex generics and Biosimilars
3. Precision medicine (Targeted innovative therapeutics)
4. Medical devices
5. Orphan Drugs
6. Drug development for AMR

Key Funding Categories

R&D projects (focused on one or more of the priority areas above) need to be submitted within one of the following three funding categories:

1. B I: Funding up to 35% of total project cost or ₹125 Cr (whichever is less)
   - Applicants must be Pharmaceutical or MedTech companies with:
     - Annual revenue ≥ Rs. 1,000 Cr (Pharma) or ≥ Rs. 250 Cr (MedTech)
     - R&D expenditure of 3-5% (Pharma) or 1-3% (MedTech) of total revenue in the last five years
     - Collaboration with a Government Research Institution (See Appendix II for more details)
     - Projects in priority areas at any TRL 1 to 9

2. B II: Funding up to 35% of total project cost or Rs. 100 Cr (whichever is less)
   - Entities working on R&D projects in priority areas that are at TRL 5 or 6

3. B III: Funding up to Rs. 1 Cr per project
   - Startups and MSMEs working in priority areas at TRL 1 onwards to TRL 4

For more information on TRL, kindly refer to the Appendix III

For more information related to the PRIP scheme, please visit the PRIP Scheme Web Page (including the FAQ document) or write to us at support-prip@pharma-dept.gov.in with subject title: [Company Name] – [Category B I/ B II/ B III / Not currently eligible under any category] - PRIP EoI Query

Invitation for Expression of Interest

Department of Pharmaceuticals invites Expression of Interest (EoI) from interested entities – e.g., Proprietary Firm or Partnership Firm or Limited Liability Partnership (LLP), Startups or a Company /Group of companies registered in India for project funding under the PRIP scheme.

This EoI has been designed to provide you with an opportunity to co-shape India's journey towards becoming an R&D innovation hub, by soliciting your inputs on:

- Current R&D projects in the scheme's priority areas for PRIP funding consideration
- Challenges in execution of an R&D projects
- Actions to strengthen the R&D ecosystem for Pharma and MedTech innovation in India

How the EoI process will work:

1. The "Editable PDF" version of the EoI is provided to help interested entities understand the required information and begin collecting relevant data from various stakeholders within their organizations. This pdf document is for reference only and cannot be used for the EoI submission.
2. A "Digital EoI" form will be made available on the PRIP scheme webpage. All EoI responses must be submitted exclusively through the webpage form.
3. The final date for submission of EoI responses via "Digital EoI" form is **15th April 2025.** The "Digital EoI" form will be made available on the PRIP scheme webpage 2 weeks prior to the last date for submission.
4. In case you want to be notified via email for the launch of the "Digital EoI" form, please provide us with your contact details via this link: Opt-in for PRIP "Digital EoI" Launch notification
5. Fields marked with '*' in this document are mandatory and must be completed for a valid submission.
6. Please make multiple copies of this form in case of multiple projects (from the same entity). The "Digital EoI" form will allow the submission of multiple projects.
7. For any inquiries related to the EoI process, please visit the PRIP Scheme Web Page (including the FAQ document). If additional assistance is required, contact us at support-prip@pharma-dept.gov.in with the subject line: [Company Name] – [Category B I/ B II/ B III / Not eligible under any category] - PRIP EoI Query

Disclaimer

This EoI is issued by the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India for the sole purpose of obtaining preliminary information from interested entities regarding their potential participation under Component B of the PRIP scheme. This document is not an offer, invitation to bid, or commitment of any kind and shall not be construed to create any rights, entitlements, or obligations on the part of the Government of India.

Submission of an EoI is not a mandatory step and does not form part of the formal application process under the PRIP scheme. The information provided in response to this EoI will be treated as confidential and will not be used for evaluation, selection, or funding decisions. Entities are not required to disclose any proprietary or confidential information as part of this process.

The Government of India reserves the absolute right to amend, modify, or withdraw this document at any time without prior notice or liability. Participation in this EoI does not confer any right or guarantee of future engagement, funding, or approval under the scheme. Any decision regarding funding will be subject to the applicable evaluation and approval processes outlined in the PRIP scheme's operational guidelines.

By submitting a response, interested entities acknowledge that the Government of India shall bear no responsibility for any costs, losses, or liabilities incurred in connection with their participation in this EoI. No claims arising from this process shall be entertained under any circumstances.

1. Details of the entity submitting an EoI for the PRIP Scheme

1.1. Entity name*

1.2. Applicable entity identifier*

1.3. Name of the entity identifier

1.4. Entity identification number selected above*

2. Details of the contact person

2.1. Name*

2.2. Designation*

2.3. Official email address*

3. Project details

Project summary

3.1. Project category*

3.2. State reasons for your ineligibility under any category and the rationale to consider your project for PRIP funding (Answer if you selected "Currently not eligible under any category" in 3.1) (Word limit: 50)

3.3. Project area (Select all that apply) *

- ☐ **New chemical entities**
- ☐ **New biological entities**
  - ☐ Antibodies (Large molecules)
  - ☐ Vaccine
  - ☐ Peptide therapeutics
  - ☐ Antibody drug conjugates
  - ☐ Plasma derived therapy
  - ☐ DNA & RNA therapeutics
  - ☐ Cell and gene therapy
  - Others
- ☐ **Phyto-pharmaceuticals**
- ☐ **Complex generics**
  - ☐ A complex active ingredient(s) (e.g., peptides, polymeric compounds, complex mixtures of APIs, naturally sourced ingredients)
  - ☐ A complex formulation (e.g., liposomes, colloids)
  - ☐ A complex formulation technology and manufacturing processes permeation enhancers, continuous flow manufacturing
  - ☐ A novel route of delivery (e.g., locally acting drugs such as dermatological products and complex ophthalmological products and optic dosage forms that are formulated as suspensions, emulsions or gels)
  - ☐ A complex/novel dosage form (e.g., modified release formulations, transdermal, metered dose inhalers, extended release injectable)
  - ☐ Innovative drug-device combination products (e.g., medicated catheters, auto injectors, metered dose inhalers
  - Others
- ☐ **Biosimilars**
- ☐ **Precision medicine**
  - ☐ Stem cell therapy, gene therapy
  - ☐ Biomarkers
  - ? Others
- ☐ **Medical devices**
  - ☐ AI/ML based medical devices with software development, Software as Medical Device (SaMD) and software in Medical Device (SiMD)
  - ☐ Medical devices with telemedicine facilities
  - ☐ Medical diagnostics and screening devices with genetic technology
  - ☐ Robotic medical devices for surgical procedures
  - ? Others — Drop down
- ☐ **Orphan drugs** ?
- ☐ **Drug development for AMR**

Others

3.4. Which stage is the project currently at?*

3.5. Current progress in the selected project stage (Word limit: 50)

3.6. Verifiable documents to demonstrate project progress (Word limit: 50)

Project details

3.7. Project overview (Word limit: 100) *

Provide a summary of project overview

- Concise and self-explanatory title
- A description of the specific problem or gap in the market that the R&D project aims to address
- Explain how the project will address the problem, highlighting key innovations or advancements

3.8. Technical details (Word limit: 100) *

Provide summary of technical details

- For projects developing products/technology similar to existing (Global/ India) products/ technologies, explain how your project is more efficacious or cost effective
- For projects targeting new innovations explain the novelty of your product/technology

3.9. Target market/ patient base

Total number of patients/ consumers that can benefit from the product/technology in your target market (e.g., India v/s multiple countries v/s global)

Potential market value (in Rupees Crores) for the product/technology, based on the markets where the product/ technology will be launched (Word limit: 25)

If the product/ technology is focused on certain diseases/ disease categories, please provide a brief description of this information: (Word limit: 25)

Budget

Past expenditure of the project*

3.10. Total expenditure incurred on the project to date (₹ Cr)

Future expenditure projections of the project*

3.11. Estimate the total cost required to advance the project from its current stage to:

- Obtaining manufacturing license - if the project is proposed for BI or B II category
- Reaching "Proof of concept established" – if the project is proposed for BIII category

Received or approved funding and sources

3.12. Of the total cost required (as mentioned in 3.11), amount of funding (₹ Cr) that has already been received or formally approved

3.13. Sources of received or formally approved funding (as mentioned on 3.12)

- ☐ Internal budget allocation
- ☐ Government Grants
- ☐ PE/VC investments
- ☐ Personal network financing
- ☐ Strategic corporate investments
- ☐ Others

3.14. Details of Government Grant (Answer if you selected "Government Grants" was selected in 3.13) (Word limit: 25)

Funding requirements from PRIP

3.15. Funding required from PRIP scheme (₹ Cr) *

3.16. Please provide a summary description of the top 3 expenditure items (e.g., updating infrastructure/ equipment, personnel, approvals, trials) where the potential PRIP funding will be used (and the associated approximate break-down): (Word limit: 100)

Benefit sharing with PRIP

3.17. Which option for the benefit sharing is preferrable under the PRIP Scheme*

3.18. State reasons for not preferring any of the benefit sharing option under the PRIP scheme. (Answer only if "none" is selected in 3.17) (Word limit: 50)

Milestones and timeline

3.19. Project start year (YYYY)*

3.20. Which major milestones are planned to be achieved utilizing the PRIP funding – please specify the timeframe to achieve the milestones and the verifiable documents that can ascertain milestone achievement*

	Verifiable documents	Completion Date
Milestone 1		
Milestone 2		
Milestone 3		
Milestone 4		
Milestone 5		

3.21. Expected year to obtain manufacturing license for BI and BII category projects and reaching "Proof of concept established" stage for B III category (YYYY)*

Academic partnership(s)

3.22. Existing/ proposed academic partnership - Status

3.23. Name of the academic partner(s) (Answer if you have MoU signed or a partner identified in 3.22) (word limit: 30)

3.24. Specify role of academic & industry partner in R&D project as per the MoU or basis discussions with the partner (Answer if you have MoU signed or a partner identified in 3.22) (word limit: 50)

4. Feedback

4.1. Provide any ideas to make the PRIP scheme more effective (Word limit :100)

4.2. Anticipated challenges in success of your R&D projects (Word Limit: 100)

4.3. Measures that can help mitigate challenges (as stated in 4.2) for your R&D projects (Word limit 100)

4.4. Any other queries related to PRIP Scheme (Word Limit: 100)

Appendix I

PRIORITY AREAS

1. Area/Product 1

1.1 New Chemical Entities

1.2 New Biological Entities

1.3 Phyto-Pharmaceuticals

2. Area/Product 2

2.1 Complex Generics: Products with

- 2.1.1 A complex active ingredient(s) (e.g., peptides, polymeric compounds, complex mixtures of APIs, naturally sourced ingredients)
- 2.1.2 A complex formulation (e.g., liposomes, colloids)
- 2.1.3 A complex formulation technology and manufacturing processes permeation enhancers, continuous flow manufacturing
- 2.1.4 A novel route of delivery (e.g., locally acting drugs such as dermatological products and complex ophthalmological products and optic dosage forms that are formulated as suspensions, emulsions or gels)
- 2.1.5 Innovative drug-device combination products (e.g., medicated catheters, auto injectors, metered dose inhalers)

2.2 Biosimilars

3. Area/Product 3 – Precision medicine (Targeted innovation therapeutics)

3.1 Any approach that uses information about a person's own genes or proteins to prevent, diagnose, or treat a disease

3.2 Stem cell therapy, gene therapy

3.3 Biomarkers

4. Area/ Product 4 – Medical devices

4.1 AI/ML based medical devices with software development Software as Medical Device (SaMD) and software in Medica Device (SiMD)

4.2 Medical diagnostics and screening devices with genetic technology

4.3 Robotic medical devices for surgical procedures

4.4 Medical devices with telemedicine facilities

5. Area/Product 5- Orphan Drugs

5.1 Medicinal products intended for diagnosis, prevention or treatment of life threatening or very serious diseases or disorders that are rare- about 450 rare diseases recorded in India (in tertiary care hospitals)

6. Area/ Product 6 - Drug development for AMR

6.1 Prioritization will be done within and among the categories based on future

Appendix II

INSTITUTE OF NATIONAL REPUTE AFFILIATED TO PHARMACEUTICALS AND MEDICAL DEVICES

Note: this list is indicative only and non-exhaustive*

	Department of Pharmaceuticals Institute
1	National Institute of Pharmaceutical Education and Research, Mohali (http://www.niper.gov.in)
2	National Institute of Pharmaceutical Education and Research, Hajipur (https://www.niperhajipur.ac.in)
3	National Institute of Pharmaceutical Education and Research, Kolkata (http://www.niperkolkata.edu.in)
4	National Institute of Pharmaceutical Education and Research, Hyderabad (http://www.niperhyd.ac.in)
5	National Institute of Pharmaceutical Education and Research, Guwahati (https://niperguwahati.ac.in)
6	National Institute of Pharmaceutical Education and Research, Ahmedabad (https://www.niperahm.ac.in)
7	National Institute of Pharmaceutical Education and Research, Raebareli (http://niperraebareli.edu.in)
	CSIR INSTITUTES
1	Centre for Cellular and Molecular Biology (www.ccmb.res.in)
2	Central Drug Research Institute (www.cdriindia.org)
3	Institute of Genomics and Integrative Biology (www.igib.res.in)
4	CSIR-Institute of Himalayan Bioresource Technology (https://www.ihbt.res.in/en/)
5	CSIR-Indian Institute of Chemical Biology (http://www.iicb.res.in)
6	Indian Institute of Chemical Technology (www.iictindia.org)
7	Indian Institute of Integrative Medicine (www.iiim.res.in)
8	Indian Institute of Toxicology Research (www.iitrindia.org)
9	CSIR-Institute of Microbial Technology (https://www.imtech.res.in/)
10	National Chemical Laboratory (www.ncl.india.org)

DBT INSTITUTES

1	National Institute of Immunology (http://www.nii.res.in/)
2	National Centre for Cell Science (https://www.nccs.res.in/)
3	National Brain Research Centre (http://www.nbrc.ac.in/newweb/)
4	Institute of Life Sciences (https://www.ils.res.in/)
5	Rajiv Gandhi Centre for Biotechnology (https://www.rgcb.res.in/)
6	Institute for Stem Cell Science and Regenerative Medicine (https://www.instem.res.in/)
7	Translational Health Science and Technology Institute (https://thsti.res.in/newthsti/)
8	National Institute of Biomedical Genomics (https://www.nibmg.ac.in/)
9	Regional Center for Biotechnology (https://www.rcb.res.in/)
10	Center for DNA Fingerprinting and Diagnostics [CDFD]
11	National Institute of Plant Genome Research
12	National Institute of Animal Biotechnology (NIAB)
13	International Center for Genetic Engineering and Biotechnology (ICGEB)
14	National Centre for Cell Science (NCCS), Pune
15	National Institute of Biomedical Genomics (NIBMG), Kalyani

Department of Higher Education

1	Indian Institute of Technology (IIT), Hyderabad (https://www.iith.ac.in)
2	Indian Institute of Technology (IIT), Mumbai (https://www.iitb.ac.in)
3	Indian Institute of Technology (IIT), Patna (https://www.iitp.ac.in)
4	Indian Institute of Technology (IIT), Delhi (https://www.iitd.ac.in)
5	Indian Institute of Technology (IIT), Ropar (https://www.iitrpr.ac.in)
6	Indian Institute of Technology (IIT), Mandi (https://www.iitmandi.ac.in)
7	Indian Institute of Technology (IIT), Roorkee (https://www.iitr.ac.in)
8	Indian Institute of Technology (Banaras Hindu University), Varanasi (http://www.iitbhu.ac.in)
9	Indian Institute of Technology (IIT), Jammu (https://www.iitjammu.ac.in)

10	Indian Institute of Technology (IIT), Palakkad (https://www.iitpkd.ac.in)
11	Indian Institute of Technology (IIT), Tirupati (https://www.iitp.ac.in)
12	Indian Institute of Technology (IIT), Goa (https://www.iitgoa.ac.in)
13	Indian Institute of Technology (IIT), Bhilai (https://www.iitbhilai.ac.in)
14	Indian Institute of Technology (IIT)Dharwad (https://www.iitdh.ac.in)
15	Indian Institute of Technology Gandhinagar (https://iitgn.ac.in)
16	Indian Institute of Technology Kharagpur, West Bengal (https://www.iitkgp.ac.in/)
17	Indian Institute of Technology Madras, Chennai, Tamil Nadu (https://www.iitm.ac.in/)
18	Indian Institute of Technology Guwahati, Assam(https://www.iitg.ac.in/)
19	Indian Institute of Technology Jodhpur, Rajasthan (https://www.iitj.ac.in/)
20	Indian Institute of Technology Kanpur, Uttar Pradesh (https://www.iitk.ac.in/)
21	Indian Institute of Technology Indore, Madhya Pradesh (https://www.iiti.ac.in/)
22	Indian Institute of Science Education and Research (IISER), Pune (https://www.iiserpune.ac.in)
23	Indian Institute of Science Education and Research (IISER), Kolkata (https://www.iiserkol.ac.in)
24	Indian Institute of Science Education and Research (IISER), Mohali (https://vvww.iisermohali.ac.in)
25	Indian Institute of Science Education and Research (IISER), Bhopal (https://www.iiserb.ac.in)
26	Indian Institute of Science Education and Research (IISER), Thiruvanathapuram (https://www.iisertvm.ac.in)
27	Indian Institute of Science Education and Research (IISER), Tirupati (http://www.iisertirupati.ac.in/)
28	Indian Institute of Science Education and Research (1ISER), Berhampur (https://www.iiserbpr.ac.in)
29	All India Institute of Medical Sciences, Rishikesh
30	All India Institute of Medical Sciences, Bhopal, Madhya Pradesh
31	All India Institute of Medical Sciences, Bathinda, Punjab
32	All India Institute of Medical Sciences, Bhubaneswar, Odisha
33	All India Institute of Medical Sciences, Bibinagar, Telangana
34	All India Institute of Medical Sciences, Deoghar, Jharkhand
35	All India Institute of Medical Sciences, Gorakhpur, Uttar Pradesh

36	All India Institute of Medical Sciences, Jodhpur, Rajasthan
37	All India Institute of Medical Sciences, Mangalagiri, Andhra Pradesh
38	All India Institute of Medical Sciences, Nagpur, Maharashtra
39	All India Institute of Medical Sciences, Kalyani, West Bengal
40	All India Institute of Medical Sciences, New Delhi, Delhi
41	All India Institute of Medical Sciences, Patna, Bihar
42	All India Institute of Medical Sciences, Raebareli, Uttar Pradesh
43	All India Institute of Medical Sciences, Raipur, Chhattisgarh
44	Postgraduate Institute of Medical Education and Research, Chandigarh
45	Dr. B. R. Ambedkar National Institute of Technology, Jalandhar, Punjab
46	Maulana Azad National Institute of Technology, Bhopal Madhya Pradesh
47	National Institute of Technology, Calicut Kozhikode Kerala
48	Motilal Nehru National Institute of Technology, Allahabad
49	National Institute of Technology, Durgapur, West Bengal
50	National Institute of Technology, Hamirpur, Himachal Pradesh
51	Malaviya National Institute of Technology, Jaipur, Rajasthan
52	National Institute of Technology, Yupia, Arunachal Pradesh
53	National Institute of Technology, Andhra Pradesh
54	National Institute of Technology, Sikkim Ravangla
55	National Institute of Technology, Nagaland, Dimapur
56	National Institute of Technology, Mizoram
57	National Institute of Technology, Manipur, Imphal
58	National Institute of Technology, Delhi
59	National Institute of Technology, Meghalaya, Shillong
60	National Institute of Technology, Goa
61	National Institute of Technology, Puducherry, Puducherry

62	National Institute of Technology, Warangal Warangal Telangana
63	National Institute of Technology, Agartala, Tripura
64	National Institute of Technology, Raipur, Chhattisgarh
65	Sardar Vallabhbhai National Institute of Technology, Surat, Gujarat
66	National Institute of Technology, Karnataka Surathkal Karnataka
67	National Institute of Technology, Tiruchirappalli Tamil Nadu
68	National Institute of Technology, Rourkela, Odisha
69	National Institute of Technology, Silchar, Assam
70	National Institute of Technology, Srinagar, Jammu and Kashmir
71	National Institute of Technology, Uttarakhand
72	National Institute of Technology, Jamshedpur, Jharkhand
73	National Institute of Technology, Kurukshetra, Haryana
74	Visvesvaraya National Institute of Technology, Nagpur, Maharashtra
75	National Institute of Technology, Patna Patna Bihar

DHR/ICMR Research Instituions

1	National JALMA Institute for Leprosy & Other Mycobacterial Diseases (https://www.jalma-icmr.org.in/)
2	National Institute of Cancer Prevention and Research (https://nicpr.icmr.org.in/)
3	National Institute of Occupational Health (http://nioh.org/)
4	National Centre for Disease Informatics and Research (https://ncdirindia.org/)
5	Bhopal Memorial Hospital & Research Centre (http://bmhrc.ac.in/)
6	National Institute for Research in Environmental Health (https://nireh.icmr.org.in/)
7	National Institute for Research in Tuberculosis (http://www.nirt.res.in/)
8	National Institute of Malaria Research (https://nimr.org.in/)
9	National Institute of Pathology (http://instpath.gov.in/)
10	National Institute of Medical Statistics (http://icmr-nims.nic.in/)
11	National Institute of Nutrition (https://www.nin.res.in/index.html)

12	National Institute of Cholera and Enteric Diseases (http://www.niced.org.in/)
13	National Institute for Research in Reproductive Health (http://nirrh.res.in/)
14	National Institute of Immunohematology (https://www.niih.org.in/)
15	National Institute of Virology (https://www.niv.co.in/)
16	National AIDS Research Institute (https://nari-icmr.res.in/)
17	Rajendra Memorial Research Institute of Medical Sciences (http://www.rmrims.org.in/)

DRDO INSTITUTES

1	Defence Bioengineering & Electro-medical Laboratory (https://www.drdo.gov.in/labs-and-establishments/defence-bio-engineering-electro-medical-laboratory-debel)
2	Defence Institute of Bio-Energy Research (https://www.drdo.gov.in/labs-and- establishments/defenceinstitute-bio-energy-research-diber)
3	Defence Institute of High-Altitude Research (https://www.drdo.gov.in/labs-and-establishments/defenceinstitute-high-altitude-research-dihar)
4	Defence Institute of Physiology & Allied Sciences (https://www.drdo.gov.in/labs-and-establishments/defence-institute-physiology-allied-sciences-dipas)
5	Defence Institute of Psychological Research (https://www.drdo.gov.in/labs-and-establishments/defence-institute-psychological-research-dipr)
6	Institute of Nuclear Medicine and Allied Sciences (https://www.drdo.gov.in/labs-and-establishments/institutenuclear- medicine-allied-sciences-inmas)

AYUSH INSTITUTES

1	Central Council for Research in Ayurvedic Sciences (http://www.ccras.nic.in/)
2	Central Council for Research in Homoeopathy (https://www.ccrhindia.nic.in/)
3	Central Council for Research in Unani Medicine (https://ccrum.res.in/)
4	Central Council for Research in Siddha (http://siddhacouncil.com/home/)
5	Central Council for Research in Yoga and Naturopath (http://www.ccryn.gov.in/)

Appendix III

For the purpose of the scheme, TRL as defined by DBT-BIRAC are taken as the standards. Please refer to DBT-BIRAC TRL webpage for latest definitions

1. Drugs (including Drug Delivery)

Stage	Technology Readiness Level	Definition
Ideation	TRL-1	Need identified, Basic principles observed and reported (Scientific research begins to be translated into applied research and development)
Proof of Principle	TRL-2	Research ideas developed, hypothesis formulated, and protocols developed (Idea proven on initial level by *In-vitro studies i.e.* biochemical studies etc)
Proof of Concept demonstrated	TRL-3	Hypothesis testing and initial proof of concept (PoC) is demonstrated in a limited number of in vitro models and limited in-vivo efficacy studies (Studies proven by *In-vitro* model studies i.e. relevant Cell based models, ex-vivo, organoid cell model and In-vivo efficacy in minimum number of animals)
Proof of concept established	TRL-4	Efficacy & safety of candidate drug formulation is demonstrated in a defined animal model (Results of formulation studies, pharmacokinetic studies & ADME, PD , safety of candidate formulations at preliminary level and efficacy in i*n-vivo* disease model)
Early stage validation	TRL-5	Pre-clinical studies, including GLP efficacy, acute and chronic toxicity in animal model producing sufficient data for DCGI application for clinical trials. DCGI approval for Phase- 1 trial
	TRL-6	Material produced in GLP facility for clinical trials. Phase-1 Clinical trials done and results submitted to DCGI. Investigative new drug application reviewed by DCGI for approving Phase-II Clinical trials
Late stage Validation	TRL-7	Phase-II Clinical trials completed and data reviewed by DCGI and Phase-III Clinical trial plan approved
Pre-commercialization	TRL-8	Phase-III Clinical trials completed successfully. DCGI approves the New Drug Application and provides commercial manufacturing license for market introduction
Commercialization & post market study	TRL-9	Commercial launch of the new drug, Post marketing studies and surveillance

2. Vaccines

Stage	Technology Readiness Level	Definition
Ideation	TRL-1	Need identified, Basic principles observed and reported (Scientific research begins to be translated into applied research and development)
Proof of Principle	TRL-2	Epidemiologic study, Research ideas developed, hypothesis formulated and protocols developed (Initial level *in vitro studies*, Development of working Cell Bank)
Proof of Concept demonstrated	TRL-3	Hypothesis testing and initial proof of concept (PoC) is demonstrated in a limited number of *in vitro* models and limited *in vivo* efficacy studies (Formulation development, complete in-house testing of the formulated vaccine by *in vitro* model studies and *In vivo* efficacy in limited number of animals)
Proof of concept established	TRL-4	Efficacy & safety of vaccine candidate is demonstrated in a defined animal model (Results of serological studies in different animals at preliminary level and efficacy in defined *in vivo* model, Manufacturing and QC release of vaccine for Studies, Scale up Development)
Early stage validation	TRL-5	Pre-clinical studies, including GLP efficacy, acute and chronic toxicity, all the studies mandatory for safe exposure to humans such as repeat dose toxicity (RDT) and safety in animal model producing sufficient data for DCGI application for clinical trials
	TRL-6	Material produced in GMP facility of clinical trials. Phase I Clinical trials done and results & safety of the vaccine candidate reviewed by DCGI for approving Phase II Clinical trials.
Late stage Validation	TRL-7	Phase II Clinical trials completed and data reviewed by DCGI and Phase III Clinical trial plan approved.
Pre-commercialization	TRL-8	Phase III Clinical trials completed successfully. DCGI approves the vaccine and provides commercial manufacturing license for market introduction.
Commercialization and post market studies	TRL-9	Commercial launch of the new vaccine, Post marketing studies and surveillance (Phase IV clinical trial)

3. Biosimilars

Stage	Technology Readiness Level	Definition
Ideation	TRL-1	**Review of Scientific Knowledge Base** Scientific findings are reviewed, including patent status and assessed as a foundation for conceptualizing new technologies
Proof of Principle	TRL-2	**Development of Hypotheses and Experimental Designs** Scientific studies to identify the innovator molecule. Development of Biosimilar along with assays to test activities of candidate molecules *in vitro.* High expression Clone available
Proof of Concept demonstrated	TRL-3	**Identification and Characterization of Preliminary Product** Expression of biosimilar product, studeis for efficacy and toxicities *in vitro*. Comparative evaluation of product for Biosimilarity with innovator molecule • Physiochemical • Biological - *in-vitro* and *in-vivo* Cell line characterization of Master Cell bank and Working Cell Bank & process development Biosimilarity demonstrated, *in vitro* efficacy and preliminary efficacy demonstrated *in vivo* in appropriate small animal model
Proof of concept established	TRL-4	**Process development, optimization, demonstration of biosimilarity and generation of consistency data** Optimization of process development for performing preclinical studies. Generation of three consistent batches. Formulation development, Appropriate formulation finalized for the route of administration. Draft Product Profile. Process optimized and regulatory approvals for preclinical candidate compound from the relevant body (RCGM/GEAC).
Early stage validation	TRL-5	**Advanced Characterization of Product and Initiation of Manufacturing** Conduct pre-clinical studies *(in vivo* toxicity and efficacy in relevant *in vivo* models; PK/PD studies, ADME characteristics and/or immune responses) as necessary for

Stage	Technology Readiness Level	Definition
		regulatory filing. Identify manufacturing partners. Submission of pre-clinical data to RCGM
	TRL-6	**Regulated Production, Regulatory Submission** Manufacture GMP-compliant pilot lots. Begin stability testing on biosimilar. Develop assays/analytical methods for product characterization and release (potency, purity, sterility and identity).
Late stage Validation	TRL-7	**Scale-up, Completion of GMP Process Validation and Consistency Lot Manufacturing and Regulatory Approvals** Develop a scalable and reproducible manufacturing process amenable to GMP. Determine dosing and treatment population for Phase 3 study. Complete stability studies of the GMP drug product in a formulation, dosage form, and container consistent with Target Product Profile. Finalize GMP manufacturing process. Identify clinical sites and begin contract negotiations. DCGI Approval for the Phase 3 Clinical study
Pre-commercialization	TRL-8	**Clinical Trials Phase 3 and Approval or Licensure** Complete clinical efficacy trials (e.g., Phase 3), and/or expanded clinical safety trials as appropriate. Prepare and submit Biologics Licensing Application BLA.
Commercialization and post market studies	TRL-9	**Full commercial application.** The technology has been fully developed and can be distributed/marketed. Post-marketing surveillance.

4. Regenerative Medicine

Stage	Technology Readiness Level	Definition
Ideation	TRL-1	Scientific findings are reviewed and assessed as a foundation for conceptualizing new technologies.
Proof of Principle	TRL-2	**Development of Hypotheses and Experimental Protocol Designs** - Hypothesis (es) generated, research plans and/or protocols are developed.
Proof of Concept demonstrated	TRL-3	**Target/Candidate Identification and their Characterization** Mandatory registration of Institutional Committee for Stem Cell Research (ICSCR) and Institutional Ethics Committee (IEC), with National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT) and CDSCO respectively Begin research, data collection, and analysis in order to test hypothesis. Explore alternative concepts, identify and evaluate critical technologies and components. • Sample collection after informed consent from the voluntary donor and begin characterization of candidate(s). • Preliminary efficacy demonstrated *in vitro* and *in vivo.* – Identify target and/or candidate. – Demonstrate *in vitro* activity of candidate(s) – Generate preliminary *in vivo* as proof-of-concept efficacy data (non-GLP).
Proof of concept established	TRL-4	**Candidate Optimization and Non-GLP *In Vivo* Demonstration of Activity and Efficacy** **Animal Models:** Initiate development of appropriate and relevant animal model(s) for the desired indications and perform non-GLP in vivo toxicity and efficacy **Assays:** Initiate development of appropriate and relevant assays and associated reagents for the desired indications. **Manufacturing:** Manufacture laboratory-scale (i.e. non-GMP) quantities of bulk product and proposed formulated product.

Stage	Technology Readiness Level	Definition
		• Demonstrate non-GLP *in vivo* activity and potential for efficacy consistent with the product's intended use (i.e. dose, schedule, duration, route of administration, and route). • Conduct initial non-GLP toxicity studies and determine pharmacodynamics and pharmacokinetics and/or immune response in appropriate animal models (as applicable). • Initiate experiments to determine assays, parameters, surrogate markers, correlates of protection, and endpoints to be used during non-clinical and clinical studies to further evaluate and characterize candidate(s).
Early stage validation	TRL-5	**Advanced Characterization of Candidate and Initiation of GMP Process Development** **Animal Models:** Development of animal models for efficacy and dose-ranging studies. **Assays:** Initiate development of in-process assays and analytical methods for product characterization and release, including assessments of potency, purity, identity, strength, sterility, and quality as appropriate. **Manufacturing:** Initiate process development for small-scale manufacturing amenable to GMP. **Target Product Profile:** Draft preliminary Target Product Profile including shelf life, storage conditions, packaging and transport should be considered to ensure that anticipated use of the product is consistent with the intended use • Demonstrate acceptable absorption, distribution, metabolism and Elimination characteristics and/or immune responses in non-GLP animal studies as necessary for IND filing (wherever required). • Continue establishing correlates of protection, endpoints, and/or surrogate markers for efficacy for use in future GLP studies in animal models. Identify minimally effective dose to facilitate determination of "humanized" dose

Stage	Technology Readiness Level	Definition
		Application submitted to Cell Biology Based Therapeutic Drug Evaluation Committee (CBBTDEC) constituted by CDSCO for conduct of cell therapy based clinical trials.
	TRL-6	**GMP Pilot Lot Production, IND Submission, and Phase 1 Clinical Trial(s)** **Animal Models:** Continue animal model development via toxicology, pharmacology, and immunogenicity studies. **Assays:** Qualify assays for manufacturing quality control and immunogenicity, if applicable. **Target Product Profile:** Update Target Product Profile as appropriate. • Conduct GLP non-clinical studies for toxicology, pharmacology, and immunogenicity as appropriate. **Manufacturing:** Manufacture GMP-compliant pilot lots. Manufacture, release and conduct stability testing of GMP-compliant bulk and formulated product in support of the IND and clinical trial(s) and submit Investigational New Drug (IND) package to DCGI and conduct Phase 1 clinical trial(s) to determine the safety and pharmacokinetics of the clinical test article. • Complete Phase 1 clinical trial(s) that establish an initial safety, pharmacokinetics and immunogenicity assessment as appropriate.
Late stage validation	TRL-7	**Scale-up, Initiation of GMP Process Validation, and Phase 2 Clinical Trial(s)** Scale-up and initiate validation of GMP manufacturing process. Conduct animal efficacy studies as appropriate for Conduct Phase 2 clinical trial(s). **Animal Models:** Refine animal model development in preparation for pivotal GLP animal efficacy studies. **Assays:** Validate assays for manufacturing quality control and immunogenicity if applicable. **Manufacturing:** Scale-up and validate GMP manufacturing process. Begin stability studies of the GMP product in a formulation, dosage form, and container consistent with Target Product Profile. Initiate manufacturing process validation and consistency lot production.

Stage	Technology Readiness Level	Definition
		Target Product Profile: Update Target Product Profile as appropriate. Conduct GLP animal efficacy studies as appropriate for the product at this stage. Complete expanded clinical safety trials as appropriate for the product (e.g., Phase 2)
Pre- commercialization	TRL-8	**Completion of GMP Validation and Consistency Lot Manufacturing, Pivotal Animal Efficacy Studies or Clinical Trials3, and DCGI Approval or Licensure** Finalize GMP manufacturing process. Complete pivotal animal efficacy studies or clinical trials (e.g., Phase 3), and/or expanded clinical safety trials as appropriate. Prepare and submit NDA/BLA. **Manufacturing:** Complete validation and manufacturing of consistency lots at a scale compatible with DCGI requirements. Complete stability studies in support of label expiry dating. **Target Product Profile:** Finalize Target Product Profile in preparation for FDA approval. Complete pivotal GLP animal efficacy studies or pivotal clinical trials (e.g., Phase 3), and any additional expanded clinical safety trials as appropriate for the product. Prepare and submit New Drug Application (NDA) or Biologics Licensing Application (BLA) to the DCGI. Obtain FDA approval or licensure
Commercialization And post market studies	TRL-9	**Post-Licensure and Post-Approval Activities** • Commence post-licensure/post-approval and Phase 4 studies (post-marketing commitments), such as safety surveillance, studies to support use in special populations, and clinical trials to confirm safety and efficacy as feasible and appropriate.

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 demons-trated	TRL-3	Individual modules/Components/PCBs/Software s/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 *in vitro* cytotoxicity assays.

Stage	Technology Readiness Level	Definition (Medical Devices including diagnostic devices)	Definition (In vitro Diagnostic Kits & reagents)	Definition (Biomedical implants)
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 serial dilution or ELISA or spiked biological sample studies.	Material safety and or imaging compatibility proven in *in vivo* 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.
Early stage validation	TRL-5	Relevant IEC & ISO tests (Electromagenetic 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	*In vivo* 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

Stage	Technology Readiness Level	Definition (Medical Devices including diagnostic devices)	Definition (In vitro Diagnostic Kits & reagents)	Definition (Biomedical implants)
	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

Stage	Technology Readiness Level	Definition (Medical Devices including diagnostic devices)	Definition (In vitro Diagnostic Kits & reagents)	Definition (Biomedical implants)
Commerci-alization 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

6. Artificial intelligence, Big Data Analysis, IoT's, software development & Bioinformatics

Stage	Technology Readiness Level	Definition
Ideation	TRL-1	• Need identified • Development of basic use, basic properties of software architecture, Mathematical formulations, and general algorithms.
Proof of Principle	TRL-2	• Research ideas developed • Technology concept or application formulated. • To carry out analytics studies and coding starts & comparing competing technologies
Proof of concept demonstrated	TRL-3	• Concept/Pre-alpha script is ready and working draft is created.
Proof of concept established	TRL-4	• Development of limited functionality environments to validate critical properties and analytical predictions using nonintegrated software components and partially representative data • Laboratory results showing validation of critical properties.
Early stage validation	TRL-5	• Developed Software technologies to integrate with different aspects of existing system • Developed Software technologies implementations conform to target environment/interfaces. Experiments with realistic problems • Rigorous alpha testing
	TRL-6	• Feasibility of the software technology is demonstrated on full-scale realistic problems • Technology validation in a relevant end to- End environment. • Rigorous Beta testing
Late stage Validation	TRL-7	• Rigorous testing & validation by third parties
Pre-commercialization	TRL-8	• ISO/IEC 9126 software quality as per the international standards

Stage	Technology Readiness Level	Definition
		• Data Privacy & Protection as per international standards (may be complied as per HIPAA Norms) • Launch of the software
Commercialization and post market studies	TRL-9	• Continuous improvement (New versions) as per user demand and feedbacks. • Continuous incorporation of new features as per user demand and feedbacks.