INDIAN COUNCIL OF MEDICAL RESEARCH
Serving the nation since 1911

भारतीय आयुर्विज्ञान अनुसंधान परिषद
स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research
Department of Health Research, Ministry of Health and Family Welfare, Government of India

File No-S/3/Tech.trans/2021-IT

Date: 1st June, 2021
07

Office Memorandum

Subject- ICMR-Guidelines for Technology Transfer and Revenue Sharing

Please find enclosed herewith the ICMR-Guidelines for Technology Transfer and Revenue Sharing for Information and for further compliance, while entering into the different types of Memorandum of Agreement (MOA).

While finalizing MOA, the draft may be sent to ICMR for final approval.

07/06/2021

Dr. R Lakshminarayanan
Deputy Director General (Admn)

To,

1) All Directors & Officer-in-charge of Institutes /Centers
2) PS to DG/Sr. DDG (A)/Sr. FA
3) Heads of Divisions/Sections
4) DDG/ADG (A)
5) Head BMI- Please upload this on ICMR website.
6) Addmn.II, ICMR

वी. रामलिंगस्वामी भवन, पोस्ट बॉक्स नं. 4911,
अंसारी नगर, नई दिल्ली - 110 029, भारत
V. Ramalingaswami Bhawan, P.O. Box No. 4911,
Ansari Nagar, New Delhi - 110 029, India

Tel: +91-11-26588895 / 26588980 / 26589794
+91-11-26589336 / 26588707
Fax: +91-11-26588662 | icmr.nic.in

INDIAN COUNCIL OF MEDICAL RESEARCH (ICMR)

GUIDELINES FOR TECHNOLOGY TRANSFER AND REVENUE SHARING

DEPARTMENT OF HEALTH RESEARCH

MINISTRY OF HEALTH AND FAMILY WELFARE,

GOVERNMENT OF INDIA

सत्यमेव जयते

प्रोफेसर (डा.) बलराम भार्गव, पदम श्री
एमडी, डीएम, एफआरसीपी (जी.), एफआरसीपी (ई.), एफएसीसी,
एफएएचए, एफएएमएस, एफएनएएस, एफएएससी, एफ.एन.ए., डी.एस.सी.
सचिव, भारत सरकार
स्वास्थ्य अनुसंधान विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय एवं
महानिदेशक, आई सी एम आर

Prof. (Dr.) Balram Bhargava, Padma Shri
MD, DM, FRCP (Glasg.), FRCP (Edin.),
FACC, FAHA, FAMS, FNASc, FASc, FNA, DSc
Secretary to the Government of India
Department of Health Research
Ministry of Health & Family Welfare &
Director-General, ICMR

भारतीय आयुर्विज्ञान अनुसंधान परिषद
स्वास्थ्य अनुसंधान विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
भारत सरकार
वी. रामलिंगस्वामी भवन, अंसारी नगर
नई दिल्ली - 110 029

Indian Council of Medical Research
Department of Health Research
Ministry of Health & Family Welfare
Government of India
V. Ramalingaswami Bhawan, Ansari Nagar
New Delhi - 110 029

FOREWORD

The Indian Council of Medical Research (ICMR), with the vision of translating research into action for improving the health of the population strives to encourage innovation and translational research for meeting public health objectives. Since the inception of Innovation and Translational Research Division at ICMR Headquarters, ICMR has been developing and transferring multiple technologies to various industry partners for commercialization. ICMR has also endeavored to facilitate knowledge transfer nationally and internationally for societal benefit through collaborations, licensing, publications, patents and dedicated symposiums.

With huge surge in the innovation and translational activities of ICMR, a need was felt to create an enabling innovation ecosystem across its 27 institutes which can catalyze, accelerate and upscale technology development and commercialization. Recognizing the need for having a standard document which can be referred to by various stakeholders, the Technology Transfer and Revenue Sharing Guidelines have been drafted to provide the blueprint and broader framework for Science, Technology and Innovation landscape of ICMR. It is envisaged that these guidelines will act as a catalyst in making India 'AtmaNirbhar' by developing *Make in India* technologies and making them accessible to the masses through multi-stakeholder partnerships. With these guidelines, ICMR resonates with the motto of our Hon'ble Prime Minister to "Innovate, Patent, Produce and Prosper". The purpose of these guidelines is to provide equal opportunity, inbuilt utmost transparency and a level playing field in making technology and IP opportunities at ICMR accessible to all in public interest.

These guidelines are forward looking and provide all encompassing framework for facilitating smooth material transfers, validation, technology- transfer and collaborations. These guidelines will go a long way to strengthen the framework for the royalty determination, its reporting and monitoring. I am extremely hopeful that these guidelines will further ease and facilitate the process of transfer of technology to industries with more efficiency and build many national and international collaborations. ICMR will keep striving to promote Global Affordable Need Driven Healthcare Innovations (GANDHI) for a wider societal impact.

We hope that this document will serve as a practical guide for reference by ICMR Institutes, Industry, beneficiaries, national and international organizations while dealing with licensing/ collaboration with ICMR.

I congratulate the committee for bringing out such an excellent document.

With regards

Yours sincerely,

Balram Bhargava

(Balram Bhargava)

Tele.: 26588204, 26589620, Fax (Off.) : 91-11-26588662, E-mail: secy-dg@icmr.gov.in

Contents

GUIDELINES FOR TECHNOLOGY TRANSFER AND REVENUE SHARING

BACKGROUND

The Indian Council of Medical Research (ICMR) is a premier organization of the Department of Health Research, Government of India with the mandate of planning, promoting, coordinating, and conducting bio-medical research in the country. The ICMR (established in 1911) is one of the oldest medical research organisation in the world with a broad mandate to create new knowledge by conducting and supporting bio-medical research in all areas that would have a bearing on improving the health of Indian people. As a part of its mandate, ICMR is actively involved in innovation and translation research activities. Many of the scientific technologies under research and development through ICMR funding support are commercially viable and are transferred to companies for further development and commercialisation. ICMR develops biomedical technologies through in-house R&D at its network of 27 Institutes across the country and also through extramural research grants. The technologies so developed, having market and commercialisation potential are transferred to the industry for further development and commercialisation for societal benefit. Thus, Transfer of ICMR Technologies to Industry contributes significantly to Self-Reliance in Technology, Industrial Growth and National Development and thus nurture AatmaNirbhar Bharat.

The Government of India emphasizing on the monetization aspects of public funding has set up monetization pipeline for imbibing the monetization of research leads to facilitate the research institution/departments for revenue generation and is urging the public funded Institutes to have suitable mechanisms in place for monetisation of their research leads. As the government is moving ahead with the mantra of “monetise and modernize”, ICMR endeavours to promote technology transfer and commercialization of technologies developed through its funding support to create large scale societal impact. In this context, there is a need to develop technology transfer guidelines with defined revenue sharing framework to ensure that a revenue pipeline is generated through ICMR. This policy document incorporates guidelines of ICMR for technology-transfer with an objective to bring utmost transparency and provide equitable opportunity to all Industries/ stakeholders for licensing ICMR technologies/ Materials and join hands with ICMR for bringing them to the market for larger societal impact. These guidelines endeavour to disseminate ICMR technologies through a framework that ensures seamless transfer of technology to industry leading to indigenous product development and commercialization as per “Make in India” initiative of the Government.

The guidelines also include a basic framework for the Royalty determination, its reporting and monitoring structure to ensure uniformity, transparency, and larger societal impact through commercialization. These guidelines may be referred to by the ICMR Institutes, Industry, Academic institutes, and beneficiaries/ prospective beneficiaries of ICMR while dealing with Technology-Transfer, collaborations, material transfer etc. of ICMR Technologies.

I. Objective

The objective of the Technology Transfer and Revenue Sharing Guidelines is to disseminate Technologies developed by ICMR support through a framework that ensures seamless transfer of technology(ies) to industry(ies) to boost the growth and capabilities of manufacturing sector of the country leading to development of "Make in India" products for the envisioned AatmaNirbhar Bharat.

II. Types of License

Broadly, the technology(ies) developed through ICMR funding support can be Licensed to suitable Licensee(es) in the following ways:

1. Non-Exclusive License

All technologies developed through ICMR support shall be transferred on a non-exclusive basis to ensure maximum public access.

2. Exclusive License

To be given on exceptional circumstances on recommendations of appropriate Advisory Committee and approval of the Competent Authority of ICMR. Start-up companies coming out from fully supported ICMR programs may be given exclusive license on approval by the Competent Authority in-line with Start-up India Program.

III. Eligibility of Applicants for Technology Transfer

Applicants meeting the following eligibility criteria shall be eligible to apply for licensing/material transfer:

1. Company (Start-up, Small, Medium or Large) incorporated under the Companies Act 2013 having a minimum of 51% of the shares of the Company to be held by Indian Citizens.

2. Limited liability Partnership (LLP) incorporated under the Limited Liability Partnership Act, 2008 having a minimum half of the persons who have subscribed their names to the LLP document as its Partner should be Indian citizens.
   *(NOTE: The applicant Company/LLP should have adequate in-house facility to address the project implementation and manufacturing of the product as per cGMP/regulatory requirements) The Company should have a DSIR (*Department of Scientific and Industrial Research) *certificate or should be incubated with any of the recognized incubation facility with suitable tie-ups for product manufacturing.*

3. Technology transfer to Foreign Entity or to an Entity with Foreign Equity shall be subject to due approval by the Competent Authority of ICMR. Technology transfer to

Foreign Entity or to an Entity with Foreign Equity shall be purely on a non-exclusive basis with the provision of making the product accessible at an affordable/negotiated price to people most in need within India, as determined by ICMR/Government of India.

4. The applicant should have demonstrated capabilities of product development and scale-up.

5. The Company should have been in existence for the last 3 years working in the area of Technology to be licensed.

Note: Such provisions (4 and 5 above) may be waived-off for start-up companies.

IV. Equitable Opportunity for Technology Transfer

ICMR shall provide equal opportunity to all the Companies, Persons, prospective Licensees for exploring and exercising Licensing opportunity for the Technologies developed through ICMR funding support. ICMR shall ensure complete transparency and openness during the call for application, short listing of applicants, and selection of applicant company(ies) for technology transfer. To ensure this, ICMR shall:

1. Advertise the details of technology to be transferred through the publications/bulletins/newsletters/journals/magazines etc. of ICMR.

2. Technology briefs shall be posted on the website of ICMR; and shall also be circulated through agencies engaged by ICMR for facilitating bilateral technology transfers/ collaborations.

3. Expression of interest on a case-to-case basis shall also be invited through ICMR website and other appropriate channels.

V. Applicable Agreements

During the process of Transfer of Technology, several Agreements are required. Before exchanging any confidential information, **Non-Disclosure Agreement (NDA)** is entered into with the potential Licensee for providing confidential information regarding the Technology for enabling due-diligence by the potential Licensee. Another agreement is **Material Transfer Agreement (MTA)**. Under MTA, lab/ Institute can transfer relevant materials such as molecules, protocols, reagents, antibodies etc., the materials so transferred generally play an important role in technology development and commercialization. **License Agreement (LA)** for Transfer of Technology is entered between ICMR and the Licensee for enabling transfer of technology. **Memorandum of Understanding (MoU)** to initiate discussions regarding transfer of material(s) and/or transfer of technology.

The details of the Legal Agreements to be entered are as follows: -

1. Non-disclosure Agreement (NDA)

Prior to taking a decision regarding Licensing of technology from ICMR, the prospective licensee may desire to carry out a 'due-diligence' for comprehensive understanding of the technology. Thus, in order to safeguard the Intellectual Property of ICMR, it is essential to enter into NDA with the prospective licensee as a prerequisite for permitting the prospective licensee to carry out the 'due-diligence' for validating the claims about the technology.

2. Material Transfer Agreement (MTA)

ICMR also transfers material(s) such as molecules, protocols, reagents, antibodies etc.to various Government and Private institutes/organizations for research and development purposes. Also, very often the prospective licensee is interested in obtaining the sample of the product/technology developed for carrying-out 'due-diligence' so that it can study and assess the nature of technology. In such a situation, in order to safe-guard the Intellectual Property of ICMR, it is essential to enter into Material Transfer Agreement as a pre-requisite for providing the material for carrying out research, development, and due-diligence.

3. Licensing Agreement (LA) for Transfer of Technology

This is the Agreement executed between ICMR and the Licensee covering the terms of Licensing of Technology. The terms of the License Agreement shall be drafted in accordance with the present guidelines.

4. Memorandum of Understanding (MoU)

As a starting point for negotiations on transfer of material(s) and/or transfer of technology(ies), it is sometimes essential to execute a Memorandum of Understanding (MoU) at very initial stages so as to define the scope and purpose of the collaboration. The understanding developed between the parties by MoU is then implemented through a detailed Agreement defining the specific terms and conditions.

VI. Handholding Support by ICMR

Handholding support would be provided by ICMR Scientists for enabling successful transfer of the Technology including its know-how to the Licensee to ensure its further development and commercialisation. If travelling by the ICMR Scientists is required for facilitating technology-transfer and providing handholding support, such travel expenses, including boarding and lodging charges for ICMR/ non-ICMR and support staff, would be borne by the Licensee as per actual and as permitted by Government rules.

VII. Technology Transfer Document (TTD)

TTD is essential to facilitate smooth technology transfer to the Licensee. Following transfer of the ICMR technology, essential documents covering the know-how of the technology shall be provided to the Licensee. Such documents shall include essential details of know-how, relevant drawings if any, Product details, Essential process details, Process parameters, Details of Packaging/ handling etc.

VIII. Technology Transfer Fees and Royalty Sharing

1. Technology Transfer Fees

An upfront payment shall be applicable on licensing of technologies as decided on case-to-case basis on technology valuation. The upfront payment shall be made as one-time payment based on Technology Readiness Level (TRL) of technology being licensed or as staggered payment based on the achievement of certain milestones.

2. Royalty from Net Sales

All Grantees/Licensees of ICMR commercializing ICMR technologies shall make royalty payments from 'Net Sales' wherein 'Net Sales' shall mean gross sales made by the company/ its licensee/ its sub-licensee based on the MRP of the product excluding applicable excise duty, Goods and Services Tax (GST) or any other levies, as defined by the Indian Accounting Standards and certified by the Chartered Accountant.

IX. Categories wherein Royalty shall be applicable and Applicable Agreements

The provisions of sharing royalty with ICMR shall be applicable in the following categories:

S. No.	Categories	Applicable Agreements
1.	Grant-in-aid funding	Undertaking by Principal Investigator (PI) regarding Royalty sharing by Licensee as per ICMR's Technology Transfer and Revenue Sharing Guidelines
2.	Licensed Technology	License Agreement
3.	Validation by ICMR	Validation Certificate or Letter of Award
4.	Material transfer of molecules, protocol, reagents, antibody etc.	Material Transfer Agreement (MTA)

X. Broad Principles for Licensing Fees and Royalty Determination

ICMR provides grant-in-aid funding support to its beneficiaries to conceptualize, develop, validate, and commercialise the technologies for societal benefit. The technologies developed by its beneficiaries through ICMR funding support are at different stages of development. If technology so developed has been validated and shows promising technical results in terms of safety and efficacy, and is up on the scale of technology readiness level a higher Royalty can be expected to be paid by the Grantee/Licensee.

The determination of Royalty shall be purely based on the Technology Readiness Level (TRL) at the time of licensing the technology. TRL is a type of measurement system used to assess the maturity level of a particular technology. Each technology project shall be evaluated against the parameters for each technology readiness level and shall be assigned a TRL rating based on the project progress. There are nine technology readiness levels. TRL 1 is the lowest and TRL 9 is the highest. TRL for different categories of products/Technologies is defined in **Annexure 2**.

The following Royalty Structure is proposed to serve as a reference guide for Royalty payment by Licensee/prospective beneficiary based on the TRL.

<table>
<tr><th colspan="2">Technology Readiness Level (TRL)</th><th>Royalty on Net Sales</th></tr>
<tr><td>TRL-1</td><td>Ideation</td><td rowspan="3">1%-2%</td></tr>
<tr><td>TRL-2</td><td>Proof of Principle</td></tr>
<tr><td>TRL-3</td><td>Proof of Concept demonstrated</td></tr>
<tr><td>TRL-4</td><td>Proof of concept established</td><td rowspan="3">3%-5%</td></tr>
<tr><td>TRL-5</td><td rowspan="2">Early-stage validation</td></tr>
<tr><td>TRL-6</td></tr>
<tr><td>TRL-7</td><td>Late-stage Validation</td><td rowspan="3">*5%</td></tr>
<tr><td>TRL-8</td><td>Pre-commercialization</td></tr>
<tr><td>TRL-9</td><td>Commercialization and post market studies</td></tr>
</table>

***Royalty of more than 5% may be considered in exceptional circumstances when significant contribution has been made by ICMR in developing/co-developing the Technology(ies) till TRL-7, 8 or 9. In such cases, Royalty Rates of more than 5% shall be applicable on approval by the Competent Authority of ICMR.**

1. Grant-in-aid funding

The Grant-in-aid funding is given by the ICMR to the Principal Investigator (PI) accordingly, PI shall execute an undertaking regarding Revenue sharing by Licensee to whom the technology will be licensed later, as per ICMR's Technology Transfer and Revenue Sharing Guidelines. Each technology project shall be evaluated on technology readiness level at the time of licensing and royalty of 1%-5% on Net Sales shall be applicable based on TRL rating of the technology at the time of Licensing.

2. Licensing

Each technology that shall be licensed by the ICMR shall be evaluated on technology readiness level at the time of licensing and royalty of 1%-5% on Net Sales shall be applicable based on TRL rating of the technology.

3. Validation by ICMR

ICMR facilitates validation of technologies at different stages of the technology development cycle including at early stages to establish the proof-of-concept and also at advanced stages of technology readiness for validating the sensitivity and specificity, safety and efficacy claims prior to commercialisation. Accordingly, for both these cases, different royalty rates shall be applicable, as given below:

i. Validation of Proof-of-Concept

ICMR has unique experience and expertise in providing validation support through cell line based evaluation and/or conducting animal studies including non-human-primate studies in its specialised BSL-3 and BSL-4 facilities. Such studies are critical for validating the proof-of-concept of the technology under the purview of pre-clinical studies. In cases wherein ICMR has assisted in validation of the Technology through pre-clinical studies, Royalty rates of 2%-3% on Net Sales shall be applicable. If ICMR is involved in taking the product/Technology to advanced stages of validation including clinical validation, higher Royalty rates may be applicable, based on the TRL Level.

ii. Validation of Commercially Ready Product(s)/Technology(ies)

ICMR also facilitates validation of technologies that are at advanced stages of technology readiness and require validation in terms of safety and efficacy for validating the claims for such product made by the applicant. Accordingly, in such cases higher TRL rating and Royalty of 5% on Net Sales shall be applicable.

4. Material Transfer

ICMR also transfers material(s) such as molecules, protocols, reagents, antibodies etc. to various Government and Private institutes/ organizations for research and development purposes. The materials so transferred generally play an important role in technology development and commercialization. In such cases, the technology is anticipated to be at initial stages of technology readiness, accordingly, in MTAs lower TRL rating and Royalty, i.e., 1%-2% on Net Sales shall be applicable.

5. Discounted Royalty

A discounted royalty of 1%-2% on Net Sales shall be considered in certain scenarios. Such discounts shall be applicable only after getting requisite approval from the competent authority of ICMR or in cases where specific orders are issued by the competent authority of ICMR.

i. Nationally Important Projects/National Emergency

If certain Projects are determined as nationally important Projects by the Government of India or in case of declaration of national emergency by the Government of India, then competent authority of ICMR will issue a specific "Order" mentioning that discounted royalty shall be applicable on such products.

ii. Government to Government

ICMR shall consider the provision of discounted royalty on a case-to-case basis wherein the Grantee/Licensee is selling the ICMR's licensed products to a Government organization/institute/agency.

6. Staggered Royalty Payment

The Royalty expectations from the Licensee/Company may be reasonably increased at regular intervals, based on the Net Sales of the Licensed Technology/product.

7. Determination of Licensing Fees/ Upfront Payment

An upfront payment shall be applicable on licensing of technology (ies) as decided on a case-to-case basis on technology valuation. The upfront payment shall be made as one-time payment based on TRL Level of Technology being licensed or as staggered payment based on the achievement of certain milestones.

The upfront payment/Licensing Fees for each Technology shall be determined by a Committee constituted by ICMR having representatives from Technical Experts of the Institute (Technology Developer), ICMR Hqrs-ITR Division, Sr. (FA) or Nominee, Officer(s) Sr. Administration and External Expert(s). The upfront payment value(s)

recommended by the Committee shall be approved by the Competent Authority of ICMR.

XI. Provisions Regarding Change in Royalty Structure

Any change in the royalty structure may be considered, on a case-to-case basis, if needed, only at the level of DG, ICMR with financial concurrence of Sr. FA, ICMR on the basis of recommendations of 3-membered Committee duly constituted for the purpose by DG, ICMR.

XII. Approval and Agreement Execution Process

1. Applicable Agreements and its Revenue sharing terms shall be proposed by ITR Division of ICMR in-line with these guidelines.

2. Applicable Agreements with any Grantee/Licensee shall only be signed and executed by ICMR-Hqrs after approval of the Competent Authority of ICMR. In certain cases, ICMR-Hqrs may authorize the Director(s) of the ICMR Institute(s) to execute the Agreement, following approval by the ICMR-Hqrs.

XIII. Royalty Reporting

1. Grantee/Licensee shall pay the royalties due based on Net Sales made by the Grantee/Licensee, Sub-licensee, or other associates in India and foreign countries on a quarterly basis and within 30 (Thirty) days at the end of each Royalty Period. The Royalty due for each financial year shall be payable to ICMR within 30 (Thirty) days of closing of corresponding financial year.

2. Before 30 days from the last day of a Royalty Period due, Grantee/Licensee must send to ICMR a written statement for the Royalty Period to which the statement relates including the role made by Licensee in India, Foreign sales and through its Sub-Licensee(s), in the following format:

Product name	Unit Sale Price (Country-wise)	Unit of Measurement (Country-wise)	Quantity Sold (Country-wise)	Sales Value (INR)	Gross Sales value	% of Royalty Payable	*Royalty Amount (INR)

***** Goods and Services Tax (as applicable) shall be paid on Royalties due.

Sublicensing Fee (To be paid by Licensee in Addition to Licensing Fees/Royalty)			
Sub-licensing fees received by Grantee/Licensee		Total (A +B) = C	*Amount due to ICMR @ of 10% of C
Lump sum (INR)	Royalty (INR)		

(A)	(B)		

***** Goods and Services Tax (as applicable) shall be paid on amount due.

3. The Royalty Reports submitted by the Licensee shall be certified by the Chartered Accountant.

XIV. Royalty Monitoring &Audit Rights

1. Accounts to be maintained by the Grantee/Licensee

i. Grantee/Licensee must keep, and must ensure that Grantee/Licensee itself and its each Sub-Licensee keeps true and accurate accounts and records of the quantities of the Product manufactured, sold, and in stock, Gross Sales Price of the Products in relation to each of the sub-territories comprising the Territory, All other accounting, stock, ordering, purchasing invoicing, and delivery records in relation to the Products as are required by good accounting practice, Sub-License Fees received and due to be received,

ii. Sub-License Agreements entered into; if any or any other documents that may be reasonably requested by the ICMR specifically shall be submitted by the Licensee within 15 days of such request.

2. Inspection of Accounts by ICMR

i. ICMR may at any time, appoint a person or reputed auditing firm to inspect the Licensee's and sub-licensee's books and records so maintained.

ii. Cost of such Audit shall be borne by the Grantee/Licensee.

XV. General Provisions including Revenue sharing from Sub-Licensing & Foreign Sales

1. Grantee/Licensee shall pay royalty to ICMR at the rate of 1-5per cent (determined on the basis of TRL Level of the technology) on quarterly Net Sales of the product(s) developed with ICMR's assistance. Payment of royalty shall fall due beginning with the first sale of the product(s).

2. Royalties shall be payable on a quarterly basis and within 30 (Thirty) days at the end of each Royalty Period. Royalty for each financial year shall be payable to ICMR within 30 (Thirty) days of closing of corresponding financial year.

3. If the Grantee/licensee intends to transfer/sell/ sub-license/Assign the Product's interests to any third party, it shall take prior written permission from ICMR. Grantee/licensee shall pay 10% (Ten Percent) of all Sub-Licensing Fees (Lump sum

and royalties) along with Goods and Services Tax (as applicable) received by the Grantee/licensee by virtue of any Sub-License Agreement(s).

4. If the Grantee/licensee intends to sell the Product in foreign countries, a 1%-2% higher royalty rate on Net Sales of the product sold, shall be applicable.

5. Goods and Services Tax and any other Taxes (as applicable) shall be provided by Grantee/Licensee on License Fee and Royalty Amount at the time such Payments are being made by Grantee/Licensee to ICMR.

6. In cases, wherein ICMR provides Grant-in-aid Assistance to same Grantee (PI) for more than one project, in such cases:

   i. If the Grantee gets Grant-in-aid assistance for more than one Project that will culminate into the same Product(s), then the Grantee shall pay royalty to ICMR at a cumulative rate[1] on annual Net Sales of the product(s) developed with ICMR's assistance.

   ii. If the Grantee gets Grant-in-aid assistance for more than one Project that will culminate into the distinct Product(s), then the Grantee shall pay additional royalty to ICMR at the rate of 2-5 per cent (determined on the basis of TRL Level of the technology) on annual Net Sales of each such distinct Product(s) developed with ICMR's assistance.

7. All donations of product developed with ICMR's assistance by the Grantee/Licensee shall be counted for Revenue sharing.

XVI. Mode of Payment of Revenue Share

1. The amount of Revenue share payable by the Grantee/Licensee shall be paid by way of account payee crossed cheque OR Demand Draft drawn in favour of "Director General-Indian Council of Medical Research" payable at "New Delhi".

XVII. Delay in Payment of Royalty and Non-Payment

1. In case of delay in payment of Royalty, the Grantee/Licensee shall be liable to pay simple interest at the rate of 12 (twelve) per cent per annum, on the amount of default in payment of royalty for the period of delay.

2. In cases where three consecutive Royalty payments have not been made by the Licensee, it will result in Automatic termination of License with prior notice of 30 days to remedy the breach and make the payment.

[1] Cumulative rate shall be lower than sum of individual royalty rate applicable for each project.

XVIII. Mandatory Provisions of Applicable Agreements

1. Branding and Acknowledgement

i. Support of ICMR must be suitably acknowledged in the publications (papers, reports, advertisements, brochures, websites, flyers etc.) and products (labels, leaflets, package inserts etc.) by the Grantee/Licensee.

ii. Use of ICMR Logo on Product packages:

a. Grantee/Licensee shall at its own cost affix a label or plate or inscribe in a conspicuous manner upon every box or packet containing the Product its components and spares the legend or inscription Technology(ies)developed at .....Technology Source Institute....., with support from ICMR with ICMR logo. Similarly, every advertisement, publicity material/customer literature/hoardings etc. in respect of the Product shall include the same legend in bold letters as aforesaid, at a conspicuous place in such advertisements/publicity material/customer literature/hoardings, etc.

b. The Grantee/Licensee shall be permitted to use the ICMR Logo only post approval by the Competent Authority of ICMR and as per the guidelines of ICMR.

2. Press Release and Public Announcements

i. Prior written permission must be taken by the Grantee/Licensee from ICMR prior to any press releases, public announcements, or media statement with respect to the technology that has been given grant-in-assistance by ICMR or licensed by the ICMR for commercialization.

ii. ICMR reserves the rights to make any modifications for incorporation by the Grantee/Licensee in the Proposed Publication/Press Release.

3. Responsibility of Grantee/Licensee

i. Regulatory Approvals

a. Grantee/Licensee shall be responsible to apply for the required certifications and approvals necessary for commercialization of the technology nationally and internationally and have them in order at their own cost.

ii. Commercialization for Societal Impact

a. It shall be the responsibility of Grantee/Licensee to make every effort to commercialize the technology at reasonable price.

b. March-in-Rights - ICMR shall retain a Royalty-free, non-exclusive, irrevocable license to the Product, after taking into consideration the Grantee/Licensee requirement for reasonable expansion and the demand supply gap at the appropriate time, shall have the right to require the Grantee/Licensee to transfer the technical know-how of the Product developed under the Project to other entrepreneur(s)/Person and train them, on such terms and conditions as may be mutually agreed among ICMR, Grantee/Licensee, and such other entrepreneur(s)/Person.

iii. Mandatory GeM Registration and Discounted Pricing for Government

a. Grantee/Licensee is required to register its novel product derived from the Patents, on GeM portal of the Ministry of Commerce and Industry, Government of India, at a discounted price for all government hospitals/departments/bodies.

4. Saving Provisions for ICMR

i. Release &Indemnification

a. Release

i) Grantee/Licensee unconditionally releases ICMR, and its officers, employees, sub-contractors and agents absolutely from and against all actions, claims, proceedings or demands and in respect of any loss, death, injury, illness or damage (whether personal or property, and whether special, direct, indirect or consequential, including consequential financial loss) suffered by the Licensee, its affiliates, any sub-licensee(s) or any third party arising out of such party's Commercialization or use of the Intellectual Property, or the Products.

ii) To the full extent permitted by law, ICMR and its officers, employees, sub-contractors and agents will not be liable to the other Party/Licensee for any special, indirect or consequential damages, including consequential financial loss arising out of the Commercialization or use of the Intellectual Property, by the Grantee/Licensee, its affiliates, or any sub-licensee(s), or the Products derived from the Intellectual Property, by the Grantee/Licensee, its affiliates, or any sub-licensee(s).

b. Indemnification

i) Grantee/Licensee indemnifies and agrees to keep the ICMR, and its officers, employees, sub-contractors and agents indemnified from and against: (i) all actions, claims, proceedings or demands (including those brought by third parties) which may be brought against any of them, whether on their own or

jointly, in respect of any loss, death, injury, illness or damage (whether personal or property, and whether special, direct, indirect or consequential, including consequential financial loss) arising out of the Commercialisation or use of the Intellectual Property, or any Products; (ii) any breach of any provisions, including of the representations and warranties, any and all misrepresentation, liabilities, obligations, commitments; and/or (iii) any violation of the applicable laws.

ii. No-warranty Clause

a. ICMR shall makeno warranty, express or implied about the workability of the technology/IPR/Data/Records being transferred by ICMR. The same are being transferred by ICMR on an *"as is where is"* basis.

b. ICMR will not have any liability to the Grantee/Licensee or any other person resulting from the use of the Records or any other information supplied or for any opinions expressed by any of them or for any errors, omissions or misstatements.

c. Among other things, ICMR disclaims any express or implied warranty of merchantability, of fitness for a particular purpose, 1. of non-infringement or 2. arising out of any course of dealing.

5. ICMR Rights (Societal Benefit)

ICMR shall retain rights, on behalf of itself and all other ICMR supported non-profit academic research institutions/centres,

i. To use the technology and associated inventions or technology for educational and research purposes.

ii. Non-exclusive license to commercialize in public interest.

iii. March-in-Rights where demand supply gap is not being met on reasonable price, or the technology has not been commercialized by the Grantee/Licensee within 2(Two) years from Licensing.

iv. ICMR and Institutes/Centres of ICMR shall have equal rights on IP and on data sharing.

XIX. Non-performance

1. In the event the Grantee/Licensee is unable to commercialize the Product within 2 (Two) years from the date of grant-in-aid assistance received or licensing of the

technology, ICMR shall have the March-in-Rights and the Grantee/Licensee shall be obligated to transfer the know-how to as many third-parties as ICMR may advise.

2. In the event the Grantee/Licensee is unable to commercialise the Product within the stipulated period, due to unavoidable circumstances and causes beyond the control of the Grantee/Licensee, the Grantee/Licensee shall make a request in writing for extension of the time limit before the expiry of the date giving detailed reasons. This request will be carefully examined and considered on merit by the ICMR.

3. Upon expiration or termination of Agreement for any reason, the rights granted to Licensee shall terminate immediately. The Licensee may however be allowed using the knowhow for period not exceeding more than 30 days to complete such orders that are in production at the time of termination and also existing stock lying on the date of termination shall be allowed to be liquidated.

XX. Other Provisions

1. Confidentiality

i. The grantee/Licensee to protect the 'Confidential Information' owned by ICMR.

2. Dispute Resolution Mechanism

i. To be resolved amicably and in good faith by mutual consultation.

ii. If no resolution is reached within 30 (Thirty) days following the date on which one party first notifies in writing to the other of its request that such a meeting be held, then, the Dispute shall be resolved by arbitration as per the provisions of the Arbitration and Conciliation Act, 1996 and the Rules there under, as amended from time to time.

iii. The unresolved dispute or difference whatsoever arising between the Parties out of or relation to the construction, meaning, scope, operation or effect of this agreement or the validity the breach thereof or in respect of any defined legal relationship associated therewith or derived there from dispute shall be submitted for arbitration to International Centre for Alternate Dispute Resolution (ICADR), an autonomous organization working under the aegis of the Ministry of Law & Justice, Department of Legal Affairs, Government of India. The Authority to appoint the arbitrator(s) shall be the ICADR. The Arbitration under this Clause and provision of administrative services by ICADR shall be in accordance with the ICADR Arbitration Rules, 1996 and as per Indian Arbitration & Conciliation Act, 1996. The award made in pursuance thereof shall be binding on the Parties. The venue of arbitration shall be New Delhi and the arbitration proceedings shall be conducted in English Language. The provision of this Clause shall not become

inoperative notwithstanding the Agreement expiring or ceasing to exist or being terminated or foreclosed.

iv. The venue of arbitration shall be New Delhi.

3. Foreclosure and Termination

i. Automatic Termination

Automatic termination for default in payment of amounts due and non-payment of royalties due for payment for three consecutive Royalty reporting periods.

ii. Termination by ICMR

ICMR shall notify the Grantee/Licensee regarding the breach of provisions under which Grant-in-aid assistance/license was given, thereby, invoking the provisions of termination giving one month notice to remedy the breach. ICMR shall have the right to foreclose and terminate if the default prevails even after serving notice, under following circumstances:

a. for failure to achieve milestones within the timelines agreed between ICMR and the Grantee/Licensee,

b. on account of submission of false reports or misrepresentations by the Grantee/Licensee,

c. for non-fulfilment of obligations pursuant to the Grant-in-assistance or license,

d. If the Grantee/Licensee suspends or discontinues manufacture of the Product for a period exceeding 1 year without obtaining prior written permission or extension in this regard from the ICMR, except for reasons beyond the control of the Grantee/Licensee and that are agreed by the ICMR.

iii. Termination by Grantee/Licensee

Grantee/Licensee may at any point of time choose to terminate the applicable agreements after giving reasons, by giving prior notice of at least three months. Under such circumstances, the Grantee/Licensee shall

a. Meet all the financial liabilities including Royalty payments due till that point of time,

b. Submita confidential report detailing the status of Technology development till that point of time, and;

c. Cooperate with the ICMR in transferring the Technology to third party.

4. Survivability

Notwithstanding the termination or foreclosure, Grantee/Licensee shall continue to be bound by the following provisions:

- General provision for Payment of Royalty (Section VII)
- Branding and Acknowledgement (Section X (1))
- Press release and public announcements(Section X (2))
- Saving Provisions of ICMR(Section X (4))
- ICMR Rights (Societal Benefit) (Section X (5))
- Confidentiality (Section XII(1))
- Dispute Resolution (Section XII(2))

XXI. Definitions

*(Please refer **Annexure 1** for Definitions)*

LIST OF ABBREVIATIONS

Abbreviations	Full Form
CDSCO	Central Drugs Standard Control Organisation
CIB	Central Insecticide Board
DCGI	Drugs Controller General of India
DFM	Design for Manufacture
DSIR	Department of Scientific & Industrial Research
GEAC	Genetic Engineering Approval Committee
GeM	Government-e-Marketplace
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GST	Goods and Services Tax
IBSC	Institutional Biosafety Committee
ICADR	International Centre for Alternative Dispute Resolution (ICADR)
ICMR	Indian Council of Medical Research
ICMR-Hqrs	ICMR Headquarters, New Delhi
IND	Investigational New Drug
IPR	Intellectual Property Rights
ITR	Innovation & Translation Research
IVD	In-Vitro Diagnostics
LA	License Agreement
LLP	Limited Liability Partnership
MoU	Memorandum of Understanding
MTA	Material Transfer Agreement
NDA	Non-Disclosure Agreement
NIB	National Institute of Biologicals
OT&E	Operational Test and Evaluation
PD	Pharmacodynamics
PI	Principal Investigator
PK	Pharmacokinetics
PoC	Proof of Concept
PRI	Public Research Institute

QC	Quality Control
QSR	Quality System Regulation
RCGM	Review Committee on Genetic Manipulation
TPP	Target Product Profile
TRL	Technology Readiness Level
TTD	Technology Transfer Document
VAT	Value-added Tax

MEMBERS OF DRAFTING COMMITTEE

- Dr. G S G Ayyangar, SrDDG (Admin), ICMR, New Delhi (Chairperson)
- Shri Rajeev Roy, Sr Financial Advisor, ICMR, New Delhi
- Dr.Samiran Panda, Scientist 'G' & Head, Division of ECD, ICMR, New Delhi
- Dr. R S Dhaliwal, Scientist 'G' & Head, Division of NCD, ICMR, New Delhi
- Dr. Sadhana Srivastava, Scientist 'F', IPR Unit, ICMR, New Delhi
- Dr. R Lakshminarayanan, DDG (Admn), ICMR, New Delhi
- Dr. Suchita Markan, Scientist ‘E’, Division of ITR,ICMR, New Delhi
- Dr.Prakamya Gupta, Scientist ‘C’, Division of ITR, ICMR, New Delhi

ANNEXURE 1

DEFINITIONS

1. **"Applicable Agreements"** shall mean an agreement that needs to be executed by the Grantee or Licensee under different categories on whom the provisions of Revenue sharing shall be applicable;

2. **"Commercialization"** shall mean in relation to the Intellectual Property, to use, make, manufacture, have made or manufactured, sell, advertise, promote, distribute, hire, supply or otherwise dispose of any Product (being manufactured using the Intellectual Property), or to keep it for the purpose of doing any of those things in each country and area and space throughout the universe and to assign, license or sub-license it to any third party to do the same;

3. **"Competent Authority"** shall mean an officer, employee, or any person that has been legally delegated or vested authority, capacity, or power to perform a designated function by the ICMR;

4. **"Confidential Information"** shall mean any and all information and know-how in any form, whether of a technical, financial, business or other nature, including, without limitation, the terms of this Agreement, information relating to the Parties' research, development, inventions, products, production, manufacturing, finances, marketing, business plans, trade secrets, know-how, data or other confidential communications, that is or has been disclosed to or otherwise received or obtained by either Party, whether or not in connection with or pursuant to this Agreement;

5. **"Exclusive License"** shall mean that no person or business other than the named licensee has right to make, use, or sell the licensed technology/ IP for commercial purposes;

6. **"Grantee"** shall mean a person, Institute, or organization private, public, or Government that receives grant-in-aid funding or any other support from ICMR at any stage from ideation to the commercializing of the technology;

7. **"Intellectual Property or IP or IPR or Intellectual Property Rights"** shall mean patents, rights to inventions, copyright and related rights, moral rights, rights in designs, rights in trademarks, rights to preserve the confidentiality of information (including know-how and trade secrets) and any other intellectual property rights, in each case whether registered or unregistered and including all applications (or rights to apply for and be granted), divisional, continuations, continuations-in-part, reissues, renewals or extensions of, and rights to claim priority from, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world regarding subject matter disclosed in Licensed patents; and shall

include without limitation, the Technology, Licensed Patents and Licensed Trademarks, developed/ created through ICMR support;

8. **"Licensee"** shall mean any business, organization, institute, or individual that has been given legal permission in form of a license, by ICMR to commercialize the technology;

9. **"Net Sales"** shall mean the gross sales made by the company/ its licensee/ its sub-licensee based on the MRP of the product excluding excise duty, GST or any other levies, as defined by the Indian Accounting Standards and certified by the Chartered Accountant;

10. **"Non-exclusive License"** shall mean that the licensee has the right to make, use, or sell the technology for commercial purposes, but ICMR remains free to grant any number of other licensees the same rights to make, use, or sell the technology for commercial purposes or any other purposes;

11. **"Person"** shall mean and includes a legal or natural person or a partnership, firm, trust, company, government or local authority and shall also include the legal representative or successor in interest of such person;

12. **"Principal Investigator or PI"** shall mean the individual responsible for the preparation, conduct, and administration of a research grant, cooperative agreement, training or public service project, contract, or other sponsored project;

13. **"Royalty Period"** shall mean each consecutive period ending 31st March, 30th June, 30th September, and 31st December respectively each year;

14. **"Sub-License"** shall mean a person to whom the Licensee grants a Sub-License to Commercialize the Licensed Patents, its Improvements, and associated IP;

15. **"Technology"** shall mean any and all discoveries, inventions, processes, methods, techniques, know-how, and Intellectual Property and proprietary rights, expressed in whatever form including technical information, processes, procedures, material for trials, methods, formulae, protocols, software, specifications, instructions, data, documents, drawings, images, prototypes and materials encompassing the Licensed Patents and Improvements there upon developed under ICMR Programs.

ANNEXURE 2

TEHNOLOGY READINESS LEVEL (TRL)

ICMR - Technology Readiness Levels (TRLs)

1. New Chemical Entity (New Drug molecule including Drug Delivery)

TRL	Status	Definition	Key Indicator(s)
TRL-1	**Ideation**	Lowest level of technology readiness. Maintenance of scientific awareness and generation of scientific and bioengineering knowledge base. Scientific findings are reviewed and assessed as a foundation for characterizing novel product with new technology.	1. Scientific literature reviews and initial market surveys are initiated and assessed. 2. Potential Scientific Application to defined problems is articulated. 3. Need identified. 4. Basic principles observed and reported (Scientific research begins to be translated into applied research and development)

TRL-2	**Proof-of-Principle**	Intense intellectual focus on the problem, with generation of scientific "paper studies" that review and generate research ideas, hypotheses, and experimental designs for addressing the related scientific issues. Concept formulation.	1. Research ideas developed and hypothesis formulated. 2. Plans and protocols are developed, peer reviewed, and approved 3. Concept formulated. 4. Technology review leading to understanding market position of technology completed. (Idea proven on initial level by *in-vitro studies i.e.*, biochemical studies etc.).
TRL-3	**Proof-of-Concept demonstrated**	Basic research, data collection, and analysis begin in order to test hypothesis, explore alternative concepts, and identify and evaluate critical components. Initial tests of design concept and evaluation of candidate(s) study endpoints defined. Animal models (if any) are proposed. Analytical and experimental proof of concept of the essential functions and/ or characteristics. Initiation of Proof-of-Concept for NCE product development is described through limited researches whether *in vitro or in vivo* on model animals (Preclinical study).	1. Hypothesis testing and initial Proof-of-Concept (PoC) is demonstrated in a limited number of in vitro models and limited in-vivo efficacy studies. 2. Analytical studies supporting the predicted performance are available. 3. Characteristics/nature and performance capacity have been identified and predicted; 4. In vitro laboratory experiments have been conducted; and 5. In vivo laboratory experiments on model animals have been conducted. 6. Research results support concept. (Studies proven by *in-vitro* model studies, i.e., relevant cell based models, ex-vivo, organoid cell model and i*n-vivo* efficacy in minimum number of animals).

TRL-4	**Proof-of-Concept established**	Initiation of animal model development. Non-GLP *in-vivo* toxicity and efficacy demonstration in accordance with the product's intended use. Initiation of experiments to identify markers, correlates of protection, assays, and endpoints for further non-clinical and clinical studies. **Animal Models**: Initiate development of appropriate and relevant animal model(s) for the desired indications. **Assays**: Initiate development of appropriate and relevant assays and associated reagents for the desired indications. **Manufacturing**: Manufacture laboratory-scale (i.e., non-GMP (Good Manufacturing Practice) quantities of bulk product and proposed formulated product.	1. Animal model defined. 2. Safety and efficacy of candidate drug formulation is established in a defined animal model. 3. Value proposition stated. 4. Laboratory-scale prototype of Good Laboratory Practice (GLP) has been created for Preclinical test material 5. 'Key' processes for production have been identified and reviewed in the laboratory (Results of formulation studies, pharmacokinetic studies & ADME (Absorption, Distribution, Metabolism, and Excretion), Pharmacodynamics (PD), safety of candidate formulations at preliminary level and efficacy in i*n-vivo* disease model ready).
TRL-5	**Early-Stage Validation**	Continue non-GLP *in-vivo* studies, and animal model and assay development. Develop a scalable and reproducible manufacturing process amenable to GMP. **Animal Models:** Continue 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. Questions of shelf life, storage	1. Target Product Profile (TPP) has been determined, comprising substance administration, substance content, indication, dosage, dose ranging, method of administration, benefits, possible side effects, type of substance; and Initial pre-clinical test in the form of safety and efficacy completed. 2. Competitive advantages of technology specified. 3. Pre-clinical studies, including GLP efficacy, acute and chronic toxicity biological immunology/activities and efficacy of the

		conditions, and packaging should be considered to ensure that anticipated use of the product is consistent with the intended use for which approval will be sought from DCGI.	GLP substance, 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. Pre-clinical tests on the safety completed. 4. DCGI approval for Phase-1 trial received 5. Preparation for production and facilities of GMP ready; 6. Pilot-scale production has been designed and conducted. 7. Substance master formula has been reviewed by the Quality Assurance and has complied with GMP convention. 8. Design for stability test and restrictive stability test have been completed. 9. Design for clinical test on human(s) has been prepared based on the pre-clinical test.
TRL-6		Manufacture GMP-compliant pilot lots. Prepare and submit Investigational New Drug (IND) package to DCGI and conduct 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. **Manufacturing**: Manufacture, release and conduct stability testing of GMP-compliant bulk and formulated product in support of the IND and clinical trial(s). **Target Product Profile**: Update Target Product Profile as appropriate.	1. Material produced in GLP facility for clinical trials. 2. Phase-1 Clinical trials done and results submitted to DCGI has met the safety requirements and demonstrated the expected pharmacokinetics (PK) and pharmacodynamics (PD). 3. Data about phase 1 clinical test result which supports the preparation of protocol for clinical test phase generated. 4. Candidate reviewed by DCGI for approving Phase-II Clinical trials.

TRL-7	**Late-Stage Validation**	Conduct animal efficacy studies as appropriate. 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 at a scale compatible with USG requirements. 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. **Target Product Profile**: Update Target Product Profile as appropriate.	1. Phase-II Clinical trials completed and data reviewed by DCGI. 2. Phase-III Clinical trial plan approved. 3. Scale-up and initiated validation of GMP manufacturing process.
TRL-8	**Pre-Commercialization**	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 New Drug Application with DCGI. **Manufacturing**: Complete validation and manufacturing of consistency lots at a scale compatible with Regulator requirements. Complete stability studies in support of label expiry dating. **Target Product Profile**: Finalize Target Product Profile in preparation for DCGI approval.	1. Phase-III Clinical trials completed successfully. 2. Certification by regulator. DCGI approves the New Drug Application and provides commercial manufacturing license for market introduction. 3. Customer acceptance. 4. R&D ceased.

TRL-9	**Commercialization and post market studies**	Actual application of the new drug in its final form and under mission conditions, such as those encountered in operational test and evaluation (OT&E). Examples include using the system under operational mission conditions. • Product launched. • Post-marketing studies and surveillance	1. Regulatory approval received /licensed labelling received. 2. Commercial launch of the new drug. 3. Product on sale. 4. Post marketing studies and surveillance

2. Vaccines

TRL	Status	Definition	Key Indicator(s)
TRL-1	**Ideation**	Lowest level of technology readiness. Maintenance of scientific awareness and generation of scientific and bioengineering knowledge base. Scientific findings are reviewed and assessed as a foundation for characterizing novel antigen with new technologies.	1. Scientific literature reviews and initial market surveys are initiated and assessed. 2. Potential Scientific Application to defined problem is articulated. 3. Epidemiologic study. 4. Need identified. 5. Basic principles observed and reported 6. Scientific research begins to be translated into applied research and development.
TRL-2	**Proof-of-Principle**	Intense intellectual focus on the problem, with generation of scientific "paper studies" that review and generate research ideas, hypotheses, and experimental designs for addressing the related scientific issues. Concept formulation.	1. Research ideas developed and hypothesis formulated. 2. Plans and protocols developed, peer reviewed, and approved 3. Concept formulated. 4. Technology review leading to understanding of market position of technology completed. (Development of working Cell- Bank and idea proven on initial level *in-vitro* studies, i.e., biochemical studies etc.).

TRL-3	**Proof-of-Concept demonstrated**	Basic research, data collection, and analysis begin in order to test hypothesis, explore alternative concepts, and identify and evaluate critical components. Initial tests of design concept and evaluation of candidate(s) study endpoints defined. Animal models (if any) are proposed. Analytical and experimental proof of concept of the essential functions and/or characteristics. Initiation of Proof of Concept for vaccine product development is described through limited researches whether *in vitro or in vivo* on model animals.	1. Hypothesis testing and initial Proof-of-Concept (PoC) is demonstrated in a limited number of in vitro models and limited *in-vivo* efficacy studies. 2. Analytical studies supporting the predicted performance are available; 3. Characteristics/nature and performance capacity have been identified and predicted; 4. *In-vitro* laboratory experiments have been conducted; and 5. *In-vivo* laboratory experiments on model animals have been conducted. 6. Research results support concept. (Formulation development, complete in-house testing of the formulated vaccine by *in-vitro* model studies and *in-vivo* efficacy in limited number of animals done)
TRL-4	**Proof-of-Concept established**	Initiation of animal model development. Non-GLP in vivo toxicity and efficacy demonstration in accordance with the product's intended use. Initiation of experiments to identify markers, correlates of protection, assays, and endpoints for further non-clinical and pre-clinical studies. **Animal Models**: Initiate development of appropriate and relevant animal model(s) for the desired indications. **Assays**: Initiate development of appropriate and	1. Animal model defined. 2. Efficacy & safety of vaccine candidate is demonstrated in a defined animal model. 3. Value proposition stated. 4. Laboratory-scale prototype of Good Laboratory Practice (GLP) has been created for Preclinical test material 5. 'Key' processes for production have been identified and reviewed in the laboratory (Results of serological studies in different animals at preliminary level and efficacy is

		relevant assays and associated reagents for the desired indications. **Manufacturing**: Manufacture laboratory-scale (i.e., non-GMP (Good Manufacturing Practice)) quantities of bulk product and proposed formulated product.	defined *in vivo* model, Manufacturing and QC release of vaccine for Studies, Scale-up Development)
TRL-5	**Early-Stage Validation**	Continue non-GLP *in-vivo* studies, and animal model and assay development. Intensive period of nonclinical and pre-clinical studies is performed by involving parametric data and analysis is performed of a validated system, and. Develop a scalable and reproducible manufacturing process amenable to GMP. **Animal Models:** Continue 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 for Pilot-scale production of vaccine candidate **Target Product Profile:** Perform GLP toxicity	1. Target Product Profile (TPP) has been determined, comprising substance administration, substance content, indication, dosage, dose ranging, method of administration, benefits, possible side effects, type of substance; and Initial pre-clinical test in the form of safety and efficacy. 2. Competitive advantages of technology specified. 3. Pre-clinical studies, including GLP efficacy, acute and chronic toxicity biological immunology/activities and efficacy of the GLP substance, 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.. 4. DCGI approval for Phase-1 trial received 5. Preparation for production and facilities of GMP; 6. Pilot-scale production has been designed and conducted. 7. Substance master formula has been reviewed

		test on the test animal, determine the markers for clinical test prediction on human, and proof of immunogenicity and potential, as well as PK and PD and initiation of study on substance stability. Draft preliminary Target Product Profile. Questions of shelf life, storage conditions, and packaging should be considered to ensure that anticipated use of the product is consistent with the intended use for which approval will be sought from DCGI.	by the Quality Assurance and has complied with GMP convention. 8. Design for stability test and restrictive stability test have been completed. Design for clinical test on human has been prepared based on the pre-clinical test.

TRL-6		Manufacture GMP-compliant pilot lots. Prepare and submit Investigational vacine package to DCGI and conduct 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. **Manufacturing**: Manufacture, release and conduct stability testing of GMP-compliant bulk and formulated product in support of the IND and clinical trial(s). **Target Product Profile**: Update Target Product Profile as appropriate.	1. Material produced in GMP facility of clinical trials. 2. Phase I Clinical trials on a limited number of humans have been performed and have met the safety requirements and demonstrated the expected result of immunogenicity and pharmacokinetics (PK) and pharmacodynamics (PD). 3. Data about phase 1 clinical test result which supports the preparation of protocol for clinical test phase generated. 4. Candidate reviewed by DCGI for approving Phase II Clinical trials.
TRL-7	**Late-Stage Validation**	Conduct animal efficacy studies as appropriate. 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 at a scale compatible with USG requirements. Begin stability studies of the GMP product in a formulation, dosage form, and container consistent with Target Product Profile. Initiate manufacturing process validation and	1. Phase-II Clinical trials completed and data reviewed by DCGI. 2. Phase-III Clinical trial plan approved. 3. Scale-up and initiated validation of GMP manufacturing process.

		consistency lot production. **Target Product Profile**: Update Target Product Profile as appropriate completed.	
TRL-8	**Pre-Commercialization**	Finalize GMP manufacturing process. Complete pivotal animal efficacy studies or clinical trials (e.g., Phase 3), and/or expanded clinical safety trials as appropriate. **Manufacturing**: Complete validation and manufacturing of consistency lots at a scale compatible with Regulator requirements. Complete stability studies in support of label expiry dating. **Target Product Profile**: Finalize Target Product Profile in preparation for DCGI approval.	1. Phase-III Clinical trials completed successfully. 2. Certification by external regulator. DCGI approves the New Vaccine and provides commercial manufacturing license for market introduction. 3. Customer acceptance. 4. R&D ceased.
TRL-9	**Commercialization and post market studies**	Actual application of the technology in its final form and under mission conditions, such as those encountered in operational test and evaluation (OT&E). Examples include using the system under operational mission conditions. • Product launch • Post-marketing studies and surveillance	1. Regulatory approval received/ licensed labeling. 2. Commercial launch of the new vaccine. 3. Product on sale. 4. Post marketing studies and surveillance

3. Biosimilars

TRL	Status	Definition	Key Indicator(s)
TRL-1	**Ideation**	Lowest level of technology readiness. Maintenance of scientific awareness and generation of scientific and bioengineering knowledge base. Scientific findings are reviewed and assessed as a foundation for characterizing new biologic medical product with technologies.	1. Scientific literature reviews and initial market surveys are initiated and assessed. 2. Potential Scientific Application to defined problems is articulated. 3. Need identified. 4. Basic principles observed and reported (Scientific research begins to be translated into applied research and development)
TRL-2	**Proof-of-Principle**	Scientific studies to identify the biologic medical product or molecule. Sequence identification. Experimental designs established, Assays to test activities of candidate molecules *in vitro*, Development of Biosimilar.	1. Innovator/ Reference molecule identified and selected. 2. Experimental designs, plans, and protocols are developed, peer reviewed, and approved. 3. Biosimilar development initiated. 4. Assays to test activities of candidate molecules by *in-vitro* tests established. 5. High expression clone available. 6. Institutional Biosafety Committee (IBSC) established at the host institute.
TRL-3	**Proof-of-Concept demonstrated**	Development of Biosimilar, Analytical and experimental Proof-of-concept of the essential functions and/ or characteristics. Initiation of Proof-of-Concept for Biosimilar product development is described through limited researches whether *in vitro or in vivo* on animal models.	1. Identification and Characterization of Preliminary Product done. 2. Expression of biosimilar product, studies for efficacy and toxicities *in vitro*. Comparative evaluation of product for Biosimilarity with innovator molecule a. Physiochemical *b.* Biological-*in-vitro* and *in-vivo*

			3. 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 models)
TRL-4	**Proof-of-Concept established**	Process development, optimization, demonstration of biosimilarity and generation of consistency data Manufacture laboratory-scale (i.e., non-GMP (Good Manufacturing Practice) quantities of bulk product and proposed formulated product.	1. Appropriate formulation finalized for the route of administration. 2. Product Profile defined (identity, purity and potency) 3. 'Key' processes for production have been identified and reviewed in the laboratory. A complete description of the manufacturing process from development and characterization of cell banks, stability of clone, cell culture/ fermentation, harvest, excipients, formulation, purification, primary packaging interactions (if different from Reference Biologic), etc. and the consequences on product characteristics determined. 4. Process Optimized- Generation of three consistent batches 5. Laboratory-scale prototype of Good Laboratory Practice (GLP) has been created for Preclinical test material. Product characterization and product specifications data generated. 6. Submission of data generated along with the following basic clinical information and

			preclinical study protocols to the relevant body (RCGM/GEAC) for obtaining permission.
TRL-5	**Early-Stage validation**	Intensive period of nonclinical and pre-clinical studies is performed by involving parametric data and analysis is performed of a validated system, and pilot-scale production of biosimilar. Research result shows appropriate potential test, proposed production will comply with GMP convention on a pilot scale, identification and proof of concept on the test animals may predict tests on human, through appropriate markers. Perform GLP toxicity test on the test animal, determine the markers for clinical test prediction on human, and proof of immunogenicity and potential, as well as PK and PD and initiation of study on substance stability. Advanced Characterization of Product and Initiation of Manufacturing.	1. Results of 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 regulatory filing available. 2. Identify manufacturing partners. Submission of pre-clinical data to RCGM.
TRL-6		Regulated Production, Regulatory Submission	1. RCGM approval received 2. Manufactured GMP-compliant pilot lots 3. Stability testing on biosimilar commenced. 4. Assays/analytical methods for product characterization and release (potency, purity, sterility and identity) developed.

TRL-7	**Late-Stage Validation**	Scale-up, Completion of GMP Process Validation and Consistency Lot Manufacturing and Regulatory Approvals	1. A scalable and reproducible manufacturing process amenable to GMP developed. 2. Dosing and treatment population through multi-centric clinical study, if required by DCGI. Completed stability studies of the GMP drug product in a formulation, dosage form, and container consistent with Target Product Profile (if required by DCGI). 3. Finalized GMP manufacturing process. 4. Identifiedclinicalsitesandbegancontractnegotiations.DCGIApproval for Clinical study
TRL-8	**Pre-Commercialization**	Clinical Trials Phase III and Approval or Licensure	1. Completed clinical efficacy trials and/or expanded clinical safety trials as appropriate. 2. Prepared and submitted Biologics Licensing Application.
TRL-9	**Commercialization and post market studies**	Actual application of the technology in its final form and under mission conditions, such as those encountered in operational test and evaluation (OT&E). Examples include using the system under operational mission conditions. • Product launch. • Post-marketing studies and surveillance	1. Regulatory Approval Received/ Licensed Labeling. 2. Commercial launch of the new Biosimilar. 3. Product on sale. 4. Post marketing studies and surveillance

4. Medical Devices including Diagnostic devices

TRL	Status	Definition	Key Indicator(s)
TRL-1	**Ideation**	Lowest level of technology readiness. Maintenance of scientific awareness and generation of scientific and bioengineering knowledge base. Scientific findings are reviewed and assessed as a foundation for characterizing new medical diagnostic with technologies. An idea or a concept is generated based in this scientific awareness and knowledge.	1. Scientific literature reviews and initial market surveys are initiated and assessed. 2. Potential Scientific Application to defined problems is articulated. 3. Need identified. 4. Basic principles observed and reported (Scientific research begins to be translated into applied research and development) 5. Idea or concept is generated
TRL-2	**Proof-of-Principle**	Intense intellectual focus on the problem, with generation of scientific "paper studies" that reviews and generates research ideas, hypotheses, and experimental designs for addressing the related scientific issues. Concept formulation. The idea is validated to be scientifically possible.	1. Research ideas developed and hypothesis formulated. 2. Plans and protocols are developed, peer reviewed, and approved 3. Concept formulated. 4. Technology review leading to understand market position of technology completed.

TRL-3	**Proof-of-Concept demonstrated**	Basic research, data collection, and analysis begin in order to test hypothesis, explore alternative concepts, and identify and evaluate component technologies. Initial tests of design concept and evaluation of concept(s). Study endpoints defined. Animal models (if any) are proposed. Design verification, critical component specifications, and tests (if a system component is necessary for device test and evaluation [T&E]).	1. Hypothesis testing and initial proof of concept (PoC) of device is demonstrated in a limited number of in vitro models and limited in-vivo efficacy studies. 2. Research results support concept. 3. A physical POC is made.
TRL-4	**Proof-of-Concept established**	Non-GLP laboratory research to refine hypothesis and identify relevant parametric data required for technological assessment in a rigorous (worst case) experimental design. Exploratory study of candidate device(s)/systems (e.g., initial specification of device, system, and subsystems). Candidate devices/systems are evaluated in laboratory and/or animal models to identify and assess potential safety problems, adverse events, and side effects. Procedures and methods to be used during non-clinical and clinical studies in evaluating candidate devices/systems are identified. The design history file, design review, and, when required, a Device Master Record (DMR), are initiated to support Regulatory Approval.	1. 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) 2. Device Master Record (DMR) prepared. 3. Functional POC testing completed.

TRL-5	**Early-Stage Validation**	Further development of selected candidate(s). Devices compared to existing modalities and indications for use and equivalency demonstrated in model systems. Examples include devices tested through simulation, in tissue or organ models, or animal models if required. All component suppliers/vendors are identified and qualified; vendors for critical components are audited for cGMP/Quality System Regulation (QSR) compliance. Component tests, component drawings, design history file, design review, and any DME are verified. Product Development Plan is drafted. Pre-Investigational Device Exemption (IDE) meeting is held with external stakeholders (Institutional Ethical Committee and/or CDSCO) for proposed devices, and the IDE is prepared and submitted to CDSCO. Determine substantially equivalent devices and their classification, validate functioning model, ensure initial testing is complete, and validate data and readiness for cGMP inspection. The pre-clinical trial stage or pre human studies completed.	1. 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. 2. Quality management certification (ISO13485) in place. 3. Design iterated prototype ready to go for clinical validation. Clinical study plan approved by Institutional Ethical Committee and/or CDSCO. 4. Preliminary findings confirm that the device is equivalent to predicate device in term of performance, through bench-studies/ pre-clinical studies.

TRL-6		Clinical trials are conducted to demonstrate safety of candidate medical device in a small number of humans under carefully controlled and intensely monitored clinical conditions. Component tests, component drawings, design history file, design review, and any DMR are updated and verified. Production technology demonstrated through production-scale cGMP plant qualification. For Regulatory Approval (CDSCO), component tests, component drawings, design history file, design review, and any DRM are updated and verified.	1. Fully functional clinical grade device ready with regulatory dossier (DRM) for use on human subjects/patients. 2. Quality assurance certification (like CE/PMA/510(k)) applied. 3. Pilot clinical study/trials on limited number of subjects/patients to prove safety and substantial equivalence/ efficacy/ performance conducted. 4. Data submitted to CDSCO for Pivotal study approval, if applicable. 5. Manufacturing facility is ready for cGMP inspection.

TRL-7	**Late-Stage Validation**	Clinical safety and effectiveness trials are conducted with a fully integrated medical device prototype in an operational environment. Continuation of closely controlled studies of effectiveness and determination of short-term adverse events and risks associated with the candidate product. Functional testing of candidate devices is completed and confirmed, resulting in final down-selection of prototype device. Clinical safety and effectiveness trials are completed. Final product design is validated, and final prototype and/or initial commercial scale device is produced. Data are collected, presented, and discussed with CDSCO in support of continued device development. For Regulatory Approval (CDSCO), final prototype and/or initial commercial-scale device are produced and tested in a military operational environment.	1. Manufacturing lines established. 2. Design for manufacture (DFM) finalized and devices manufactured. 3. Documentation on design history file (DHF) ready. 4. Clinical end points and test plans are agreed to by CDSCO. 5. Pivotal clinical study/trials completed (if applicable) and clinical performance data submitted to CDSCO for manufacturing license.
TRL-8	**Pre-Commercialization**	Implementation of clinical trials to gather information relative to the safety and effectiveness of the device. Trials are conducted to evaluate the overall risk-benefit of using the device and to provide an adequate basis for product labeling. Confirmation of QSR compliance, the design history file, design review, and any DMR are completed and validated, and device	1. Regulatory approval received / Licensed labeling. 2. Manufacturing license obtained from CDSCO. 3. Commercial batch manufacturing initiated 4. Pilot batch manufacturing completed 5. Product Pilot launch 6. Early adoption

		production is followed through lot consistency and/or reproducibility studies.	
TRL-9	**Commercialization and post market studies**	Actual application of the technology in its final form and under mission conditions, such as those encountered in operational test and evaluation (OT&E). Examples include using the system under operational mission conditions. • Product launch. • Post-marketing studies and surveillance	1. Commercial launch of the new device. 2. Product on sale 3. Post marketing studies and surveillance

5. In-Vitro Diagnostics (Kits and Reagents)

TRL	Status	Definition	Key Indicator(s)
TRL-1	**Ideation**	Lowest level of technology readiness. Maintenance of scientific awareness and generation of scientific and bioengineering knowledge base. Scientific findings are reviewed and assessed as a foundation for characterizing new technologies.	1. Scientific literature reviews and initial market surveys are initiated and assessed. 2. Potential Scientific Application to defined problems is articulated. 3. Need identified. 4. Basic principles observed and reported (Scientific research begins to be translated into applied research and development). 5. Idea or concept is generated
TRL-2	**Proof-of-Principle**	Intense intellectual focus on the problem, with generation of scientific "paper studies" that review and generate research ideas, hypotheses, and experimental designs for addressing the related scientific issues. Concept formulation. The idea is validated conceptually to be scientifically possible.	1. Research ideas developed and hypothesis formulated. 2. Plans and protocols are developed, peer reviewed, and approved. 3. Concept formulated. 4. Market surveillance data and competitor analysis available to support idea. 5. Technology review leading to understand market position of technology completed. 6. Individual core components of kit/reagents (Antibodies/ Antigens/Aptamers/Nanoparticles) finalized, developed/ procured for testing.

TRL-3	**Proof-of-Concept demonstrated**	Basic research, data collection, and analysis begin in order to test hypothesis, explore alternative concepts, and identify and evaluate component technologies. Initial tests of design concept and evaluation of candidate(s). Study endpoints defined. Design verification, critical component specifications, and tests (if a system component is necessary for device test and evaluation [T&E]). Explore assay components via prototypes and screening; identify and evaluate critical technologies and components, and begin characterization of lead design. Initiate user feedback. Demonstrate preliminary assay with simplified sample/artificial matrices. Demonstrate sensitivity and specificity with spike/recovery studies in the appropriate matrices.	1. Hypothesis testing and initial proof of concept (PoC) of device is demonstrated in a limited number of in vitro models and limited in-vivo efficacy studies. 2. Research results support concept. 3. Individual core components optimized at lab scale. 4. Demonstrated the limit of detection/Sensitivity with metabolite serial dilution or ELISA or spiked biological sample studies. 5. A physical PoC is made
TRL-4	**Proof-of-Concept established**	Integration of critical technologies and components (including hardware and software). Select appropriate candidate reference and QC (quality control) reagents. Assay/ test method validation in accordance with the product's intended use (Sample type, volume, assay components). Establish Draft Product Profile. Determine Regulatory and reimbursement strategy.	1. 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. 2. Functional Prototype developed by integration of different modules. 3. Integrated system tested in house with metabolite serial dilution or ELISA or spiked biological sample studies. 4. Functional PoC testing completed.

TRL-5	**Early-Stage Validation**	Design freeze. Develop a scalable and reproducible manufacturing process aligned with regulatory guidelines (as needed). Finalize QC criteria. Identify supply chain and/or manufacturing partners. Demonstrate acceptable performance as necessary for regulatory filing.	1. Integrated system tested in-house extensively with clinical samples (Blood, Urine, Sputum etc.) before taking it for clinical validation. 2. Analytical validation of the kit completed. Shelf life, stability data of the kit reagents available. 3. Quality management certification (ISO13485) in place. 4. Clinical study plan approved by Institutional Ethical Committee and/or CDSCO. 5. Preliminary findings confirm that the IVD kit is equivalent to its predicate in terms of safety and efficacy through bench studies/ pre-clinical studies.
TRL-6		Clinical study is conducted to demonstrate safety specificity and sensitivity of the Assay/kit under carefully controlled and intensely monitored conditions. Component tests and design review are updated and verified. Production technology demonstrated through production-scale cGMP plant qualification. Assays used to assess product quality are validated. Assays used to assess critical outcomes in clinical trials and in animal efficacy studies are validated.	1. Clinical study performed on statistically significant number of samples at one or two centers to define the specificity and sensitivity of the Assay/kit. 2. Quality assurance certification for the product obtained. 3. Pilot clinical study on limited number of subjects to prove safety and efficacy/ performance conducted.

TRL-7	**Late-Stage Validation**	Functional/Performance testing of candidate devices is completed and confirmed, resulting in final down-selection of prototype device. Final product design is validated, and final prototype and/or initial commercial scale device is produced. Data are collected, presented, and discussed with CDSCO in support of continued device development. For Regulatory Approval (CDSCO), final prototype and/or initial commercial-scale device are produced and tested. Based on regulatory classification (e.g., CLIA vs IVD route), submit regulatory package. For Regulatory Approval (CDSCO), component tests, component drawings, design review, and Manufacture product compliant with quality protocols.	1. Clinical end points and test plans are agreed to by CDSCO. 2. Pivotal clinical study/ Multi-Centric Trials completed (if required, by DCGI) at NABL accredited centers and performance evaluation report submitted to CDSCO for manufacturing license. 3. Performance evaluation report of notified products (IVD for HIV, HCV, HBV and Blood grouping sera) obtained from National Institute of Biological (NIB), Noida.
TRL-8	**Pre-Commercialization**	Confirmation of QSR compliance and device production is followed through lot consistency and/or reproducibility studies.	1. Manufacturing license obtained and commercial scale manufacturing set up/Packing/labeling ready etc. 2. Commercial batch manufacturing initiated. 3. Pilot batch manufacturing completed 4. Product pilot launch for early adoption.

TRL-9	**Commercialization and post market studies**	Actual application of the technology in its final form and under mission conditions, such as those encountered in operational test and evaluation (OT&E). Examples include using the system under operational mission conditions. • Product launch. • Post-marketing studies and surveillance	1. Regulatory approval received/ licensed labeling. 2. Commercial launch of the new IVD. 3. Product on sale. 4. Post marketing studies and surveillance.

6. Implants

TRL	Status	Definition	Key Indicator(s)
TRL-1	**Ideation**	Basic principles observed. Maintenance of scientific awareness and generation of scientific and bioengineering knowledge base. Scientific findings are reviewed and assessed as a foundation for characterizing new medical diagnostic with technologies.	1. Scientific literature reviews and initial market surveys are initiated and assessed. 2. Potential Scientific Application to defined problems is articulated. 3. Need identified. 4. Basic principles observed and reported(Scientific research begins to be translated into applied research and development). 5. Idea or concept is generated.
TRL-2	**Proof-of-Principle**	Intense intellectual focus on the problem, with generation of scientific "paper studies" that reviews and generates research ideas, hypotheses, and experimental designs for addressing the related scientific issues. Concept formulation.	1. Research ideas developed and hypothesis formulated. 2. Plans and protocols are developed, peer reviewed, and approved 3. Concept formulated. 4. Technology review leading to understanding of market position of technology completed. 5. Material research completed and material properties of the finalized material/composites compared against benchmarks.

TRL-3	**Proof-of-Concept demonstrated**	Basic research, data collection, and analysis begin in order to test hypothesis, explore alternative concepts, and identify and evaluate component technologies. Initial tests of design concept and evaluation of key concept(s). Study endpoints defined. Animal models (if any) are proposed. Design verification, critical component specifications, and tests (if a system component is necessary for device test and evaluation [T&E]).	1. Relevant ASTM standard tests (strength, ductility, corrosion, surface properties, antimicrobial activity, usability, shelf life etc.) on the material performed successfully. 2. Material sterilization method finalized. 3. Research results support concept. 4. Biocompatibility (ISO 10993) proven in *in-vitro* cytotoxicity assays. 5. Hypothesis testing and initial proof of concept (PoC) of device is demonstrated in a limited number of *in-vitro* models and limited *in-vivo* efficacy studies. 6. A physical PoC is made.
TRL-4	**Proof-of-Concept established**	Non-GLP laboratory research to refine hypothesis and identify relevant parametric data required for technological assessment in a rigorous (worst case) experimental design. Exploratory study of candidate device(s)/systems (e.g., initial specification of device, system, and subsystems). Candidate devices/systems are evaluated in laboratory and/or animal models to identify and assess potential safety problems, adverse events, and side effects. Procedures and methods to be used during non-clinical and clinical studies in evaluating candidate implants are identified. The design history file, design review, and, when required, a Device Master Record (DMR), are initiated to support Regulatory Approval.	1. Functional Prototype implant device developed as per the design in a near GMP condition. 2. Sterilization and packaging established. 3. Material safety and/or imaging compatibility proven in *in-vivo* small animal model study (with Institutional Animal Ethics Committee approvals). 4. Functional PoC testing completed

TRL-5	**Early-Stage Validation**	Further development of selected candidate(s). Devices compared to existing modalities and indications for use and equivalency demonstrated in model systems. Examples include devices tested through simulation, in tissue or organ models, or animal models if required. All component suppliers/vendors are identified and qualified; vendors for critical components are audited for cGMP/Quality System Regulation (QSR) compliance. Component tests, component drawings, design history file, design review, and any DME are verified. Product Development Plan is drafted. Pre-Investigational Device Exemption (IDE) meeting is held with external stakeholders (Institutional Ethical Committee and/or CDSCO) for proposed devices, and the IDE is prepared and submitted to CDSCO. Determine substantially equivalent devices and their classification, validate functioning model, ensure initial testing is complete, and validate data and readiness for cGMP inspection.	1. *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. 2. Quality management certification (ISO13485) in place. 3. Design iterated, prototype ready to go for clinical validation. 4. Preliminary findings confirm that the device is equivalent to predicate device. 5. Clinical study plan approved by Institutional Ethical Committee and/or CDSCO
TRL-6		Clinical trials are conducted to demonstrate safety of candidate medical device in a small number of humans under carefully controlled and intensely monitored clinical conditions. Component tests, component drawings, design history file, design review, and any DMR are updated and verified. Production	1. Clinical level implant device fabricated using clinical grade material in GMP facility with safety dossier for use on human subjects/patients. 2. Quality assurance certification (like CE/PMA/510(k)) applied. 3. Pilot clinical trials performed on statistically

		technology demonstrated through production-scale cGMP plant qualification. For Regulatory Approval (CDSCO), component tests, component drawings, design history file, design review, and any DRM are updated and verified.	significant number of patients against the predicate implant device to prove safety, substantial equivalence/ efficacy/ performance. 4. Data submitted to CDSCO for Pivotal study approval. 5. Manufacturing facility is ready for cGMP inspection.
TRL-7	**Late-Stage Validation**	Clinical safety and effectiveness trials are conducted with a fully integrated medical device prototype in an operational environment. Continuation of closely controlled studies of effectiveness and determination of short-term adverse events and risks associated with the candidate product. Functional testing of candidate devices is completed and confirmed, resulting in final down-selection of prototype device. Clinical safety and effectiveness trials are completed. Final product design is validated, and final prototype and/or initial commercial scale device is produced. Data are collected, presented, and discussed with CDSCO in support of continued device development. For Regulatory Approval (CDSCO), final prototype and/or initial commercial-scale device are produced and tested in a military operational environment.	1. Manufacturing lines established. 2. Design for manufacture (DFM) finalized and devices manufactured. 3. Documentation on design history file (DHF) ready. 4. Clinical end points and test plans are agreed to by the CDSCO. 5. Pivotal clinical study/trials completed (if required) and clinical performance data submitted to CDSCO for manufacturing license.

TRL-8	**Pre-Commercialization**	Pilot batch manufacturing, Implementation of clinical trials to gather information relative to the safety and effectiveness of the device. Trials are conducted to evaluate the overall risk-benefit of using the device and to provide an adequate basis for product labeling. Confirmation of QSR compliance, the design history file, design review, and any DMR are completed and validated, and device production is followed through lot consistency and/or reproducibility studies.	1. Manufacturing license obtained from CDSCO. 2. Commercial batch manufacturing initiated. 3. Pilot batch manufacturing completed.
TRL-9	**Commercialization and post market studies**	Actual application of the technology in its final form and under mission conditions, such as those encountered in operational test and evaluation (OT&E). Examples include using the system under operational mission conditions. • Product launch. • Post-marketing studies and surveillance	1. Regulatory approval received/ licensed labelling. 2. Commercial launch of the new device. 3. Product on sale 4. Post marketing studies and surveillance

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

TRL	Status	Definition	Key Indicator(s)
TRL-1	**Ideation**	• Need identified, • Development of basic use, basic properties of software architecture, Mathematical formulations, and general algorithms. • Basic Principles observed	1. Scientific articles published on the principles of the new technology. 2. Goal Oriented Research Designed 3. Concrete ideas with sound maths, to pursue through experimentation in the next stage ready. 4. The basic principles, hypotheses, and research plans stated and referenced with relevant papers to design and run experiments to analyse model/algorithm properties for the planned application.
TRL-2	**Proof-of-Principle**	• Research ideas developed • Technology concept or application formulated. • To carry out analytics studies and coding starts & comparing competing technologies	1. Active R&D initiated 2. The models run in test beds: simulated environments and/or surrogate data that closely matches the conditions and data of real scenarios.

TRL-3	**Proof-of-Concept demonstrated**	• Concept/Pre-alpha script is ready and working draft is created.	1. Experimental Proof-of-Concept established 2. Checkpoints to push code development towards interoperability, reliability, maintainability, extensibility, and scalability developed.
TRL-4	**Proof-of-Concept established**	• 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.	1. Demonstration in a real scenario 2. Results of tests carried out in the laboratory. 3. Demonstration of utility towards one or more practical applications, taking care to communicate assumptions and limitations.

TRL-5	**Early-Stage Validation**	• 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	1. Technology including its components validated in a relevant environment. 2. The R&D to product handoff. 3. Machine Learning Capability developed 4. Transitioning the model or algorithm from an isolated solution to a module of a larger application with technology push to productization
TRL-6		• Feasibility of the software technology is demonstrated on full-scale problems • Technology validation in a relevant end to- End environment. • Rigorous Beta testing	1. Technology demonstrated in relevant environment. 2. Software engineering to bring the code up to product-caliber, as well as defining product-specific requirements and data pipelines spec. ready
TRL-7	**Late-Stage Validation**	Rigorous testing & validation by third parties	1. Result of the prototype level tests carried out in the operating environment. 2. AI infrastructure, product platform, data pipes, security protocols made ready. 3. Validation by third party demonstrates workability of the Technology based on specific parameters.

TRL-8	**Pre-Commercialization**	• ISO/IEC 25010:2011 software quality as per the international standards • Data Privacy & Protection as per international standards (may be complied as per HIPAA Norms)	1. Results of system tests in final configuration. 2. System complete and qualified marking the end of system development 3. The technology is demonstrated to work in its final form and under expected conditions. 4. Pilot Launch of the software
TRL-9	**Commercialization and post market studies**	• Continuous improvement (New versions) as per user demand and feedbacks. • Continuous incorporation of new features as per user demand and feedbacks.	1. Product deployed successfully 2. Final reports in working condition proven in operational environment and collated 3. Monitoring the current version, improving the next based on feedback. 4. Post-Marketing studies and surveillance

8. Regenerative Medicines

TRL	Status	Definition	Key Indicator(s)
TRL-1	**Ideation**	Basic principles observed. Maintenance of scientific awareness and generation of scientific and bioengineering knowledge base. Scientific findings are reviewed and assessed as a foundation for characterizing novel medicine with new technologies.	1. Scientific literature reviews and initial market surveys are initiated and assessed. 2. Potential Scientific Application to defined problems is articulated. 3. Need identified. 4. Basic principles observed and reported (Scientific research begins to be translated into applied research and development). 5. Idea or concept is generated.
TRL-2	**Proof-of-Principle**	Intense intellectual focus on the problem, with generation of scientific "paper studies" that review and generate research ideas, hypotheses, and experimental designs for addressing the related scientific issues. Concept formulation.	1. Research ideas developed and hypothesis formulated. 2. Plans and protocols are developed, peer reviewed, and approved 3. Concept formulated. 4. Technology review leading to understand market position of technology completed.

TRL-3	**Proof-of-Concept demonstrated**	Registration at 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. Basic research, data collection, and analysis begin in order to test hypothesis, explore alternative concepts, and identify and evaluate critical components. Sample collection after informed consent from the voluntary donor and begin characterization of candidate(s). Initial tests of design concept and evaluation of candidate(s) study endpoints defined. Animal models (if any) are proposed. Analytical and experimental proof of concept of the essential functions and/or characteristics. Initiation of Proof of Concept for regenerative medicine development is described through limited researches whether *in-vitro or in-vivo* on model animals.	1. Study Registered at 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. 2. Sample collected after informed consent from the voluntary donor. 3. Characteristics/nature and performance capacity have been identified and predicted. 4. Preliminary efficacy demonstrated *in vitro* and *in-vivo*. a. Target identified. b. *In-vitro* activity of candidate(s) demonstrated c. Preliminary *in-vivo* as proof-of-concept efficacy data (non-GLP) generated. 5. Research results generated which supports concept.

TRL-4	**Proof-of-Concept established**	Initiation of animal model development. Non-GLP in vivo toxicity and efficacy demonstration in accordance with the product's intended use. Initiation of experiments to identify markers, correlates of protection, assays, and endpoints for further non-clinical and pre-clinical studies. **Animal Models**: Development of appropriate and relevant animal model(s) for the desired indications. **Assays**: Development of appropriate and relevant assays and associated reagents for the desired indications. **Manufacturing**: Manufacture laboratory-scale (i.e., non-GMP (Good Manufacturing Practice)) quantities of bulk product and proposed formulated product.	1. Animal model defined for the desired indications and to perform *in vivo* toxicity and efficacy test. 2. 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) conducted and established for the desired indications. 3. Efficacy & safety of candidate is demonstrated in a defined animal model consistent with the product's intended use (i.e., dose, schedule, duration, route of administration, and route).
TRL-5	**Early Stage Validation**	Continue non-GLP *in-vivo* studies, and animal model and assay development. Intensive period of nonclinical and pre-clinical studies is performed by involving parametric data and analysis is performed of a validated system, and. Develop a scalable and reproducible manufacturing process amenable to GMP. **Animal Models:** Continue development of animal models for efficacy and dose-ranging studies. **Assays:** Initiate development of in-process assays and analytical methods for product characterization	1. Target Product Profile (TPP) has been determined, comprising substance administration, substance content, indication, dosage, dose ranging, method of administration, benefits, possible side effects, type of substance. 2. Initial pre-clinical test in the form of safety and efficacy including GLP efficacy, acute and chronic toxicity biological immunology/activities and efficacy of the GLP substance, all the studies mandatory for safe exposure to humans such as repeat dose toxicity (RDT) and safety in animal model

		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 for Pilot-scale production of regenerative medicine candidate. **Target Product Profile:** Perform GLP toxicity test on the test animal, determine the markers for clinical test prediction on human, and proof of immunogenicity and potential, as well as PK and PD and initiation of study on substance stability. Draft preliminary Target Product Profile. Questions of shelf life, storage conditions, and packaging should be considered to ensure that anticipated use of the product is consistent with the intended use for which approval will be sought from DCGI.	producing sufficient data for IND filing available. 3. Competitive advantages of technology specified. 4. Preparation for production and facilities of GMP initiated. 5. Continue establishing correlates of protection, endpoints, and/or surrogate markers for efficacy for use in future GLP studies in animal models. 6. Identify minimally effective dose to facilitate determination of "humanized" dose. 7. Application submitted to Cell Biology Based Therapeutic Drug Evaluation Committee (CBBTDEC) constituted by CDSCO for conduct of cell therapy based clinical trials.
TRL-6		Manufacture GMP-compliant pilot lots. Prepare and submit Investigational Regenerative Medicine package to DCGI and conduct Phase I 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.	1. Target Product Profile updated as appropriate. 2. Material produced in GMP facility for clinical trials. 3. Phase I Clinical trials on a limited number of humans has been performed and has met the safety requirements and demonstrated the expected result of immunogenicity and pharmacokinetics (PK) and pharmacodynamics (PD). 4. Data about phase 1 clinical test result which

		Manufacturing: Manufacture, release and conduct stability testing of GMP-compliant bulk and formulated product in support of the IND and clinical trial(s). **Target Product Profile**: Update Target Product Profile as appropriate.	supports the preparation of protocol for clinical test phase II generated. 5. Candidate reviewed by DCGI for approving Phase II Clinical trials.
TRL-7	**Late-Stage Validation**	Conduct animal efficacy studies as appropriate. 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 at a scale compatible with USG requirements. 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. **Target Product Profile**: Update Target Product Profile as appropriate.	1. Target Product Profile updated as appropriate. 2. Phase-II Clinical trials completed and has met the safety requirements and demonstrated the expected result of immunogenicity and pharmacokinetics (PK) and pharmacodynamics (PD). 3. Data reviewed by DCGI. 4. Phase-III Clinical trial plan approved by DCGI. 5. Scale-up and initiated validation of GMP manufacturing process.

TRL-8	**Pre-Commercialization**	Finalize GMP manufacturing process. Complete pivotal animal efficacy studies or clinical trials (e.g., Phase III), and/or expanded clinical safety trials as appropriate. **Manufacturing**: Complete validation and manufacturing of consistency lots at a scale compatible with Regulator requirements. Complete stability studies in support of label expiry dating. **Target Product Profile**: Finalize Target Product Profile in preparation for DCGI approval.	1. GMP Validation completed. 2. Consistent Lot Manufacturing achieved. 3. Phase-III Clinical trials completed successfully. 4. Application to obtain DCGI approval or licensure submitted for commercial manufacturing and market introduction. 5. Commercial batch manufacturing initiated. 6. R&D ceased.
TRL-9	**Commercialization and post-market studies**	Actual application of the technology in its final form and under mission conditions, such as those encountered in operational test and evaluation (OT&E). Examples include using the system under operational mission conditions. • Product launch. • Post-marketing studies and surveillance	1. Regulatory approval received/licensed labelling. 2. Commercial launch of the new regenerative medicine. 3. Product on sale. 4. Post marketing studies and surveillance underway

9. Veterinary Drugs and Vaccines

TRL	Status	Definition	Key Indicator(s)
TRL-1	**Ideation**	Lowest level of technology readiness. Maintenance of scientific awareness and generation of scientific and bioengineering knowledge base. Scientific findings are reviewed and assessed as a foundation for characterizing novel drugs and antigen with new technologies.	1. Scientific literature reviews and initial market surveys are initiated and assessed. 2. Potential Scientific Application to defined problems is articulated. 3. Need identified. 4. Basic principles observed and reported (Scientific research begins to be translated into applied research and development)
TRL-2	**Proof-of-Principle**	Intense intellectual focus on the problem, with generation of scientific "paper studies" that review and generate research ideas, hypotheses, and experimental designs for addressing the related scientific issues. Concept formulation.	1. Research ideas developed and hypothesis formulated. 2. Plans and protocols are developed, peer reviewed, and approved 3. Concept formulated. 4. Technology review leading to understand market position of technology completed. (Idea proven on initial level by *in-vitro studies, i.e.*, biochemical studies etc.).

TRL-3	**Proof-of-Concept Demonstrated**	Basic research, data collection, and analysis begin in order to test hypothesis, explore alternative concepts, and identify and evaluate critical components. Initial tests of design concept and evaluation of candidate(s) study endpoints defined. Analytical and experimental proof of concept of the essential functions and/ or characteristics. Initiation of Proof of Concept for product development is described through *in vitro* studies.	1. Hypothesis testing and initial proof of concept (PoC) is demonstrated in in-vitro models/studies. 2. Analytical studies supporting the predicted performance are available. 3. Characteristics/nature and performance capacity have been identified and predicted; 4. *In vitro* laboratory experiments have been conducted. 5. Research results support concept. (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).
TRL-4	**Proof-of-Concept established**	Demonstration of proof of concept (PoC) in limited number of animals (by serological studies). Working on feasible formulation development and conducting safety and efficacy studies)	1. Key processes for production have been identified and reviewed in the laboratory. 2. Studies to assess safety and efficacy study of candidate drug formulation initiated *in-vivo* in limited number of animals. 3. Value proposition stated and Competitive advantages of technology specified.

TRL-5	**Early-Stage Validation**	Target Product profile, Establishment of Shelf life of the drug. Conducting the toxicity studies in the laboratory animal model.	1. Target Product Profile (TPP) has been determined, comprising substance administration, substance content, indication, dosage, dose ranging, method of administration, benefits, possible side effects, type of substance. 2. Design for stability test and restrictive stability test have been completed. 3. Preparation for production and facilities of GMP underway. 4. Results of formulation studies, pharmacokinetic studies & ADME, PD, safety of candidate formulations at preliminary level and efficacy in i*n-vivo* disease model available.
TRL-6		Scale up under cGMP conditions and Conduct extensive field trials. Further confirm by Challenge studies where ever possible., Third Party Validation preferably government agencies	1. Material produced in cGMP conditions for clinical trials. 2. Field Clinical trials conducted on increased number of animals and has met the safety requirements and demonstrated the expected pharmacokinetics (PK) and pharmacodynamics (PD).

TRL-7	**Late-Stage Validation**	Scale-up, validation, and Regulatory Submission	1. Scale-up and initiated validation preferably government agencies 2. Application submitted for regulatory approval and Manufacturing license to appropriate Regulatory authority (DCGI).
TRL-8	**Pre-Commercialization**	Finalize GMP manufacturing process. Finalize Target Product Profile Regulatory Approval and manufacturing license.	1. Regulator approved/licensed labeling. 2. Manufacturing license obtained. 3. Commercial batch manufacturing initiated.
TRL-9	**Commercialization and post market studies**	Product launched. Post-marketing studies and surveillance	1. Commercial launch of the new drug. 2. Product on sale level. 3. Post marketing studies and surveillance

10. Veterinary Medical Devices and Diagnostics

TRL	Status	Definition	Key Indicator(s)
TRL-1	**Ideation**	Lowest level of technology readiness. Maintenance of scientific awareness and generation of scientific and bioengineering knowledge base. Scientific findings are reviewed and assessed as a foundation for characterizing new medical device and diagnostic with technologies.	1. Scientific literature reviews and initial market surveys are initiated and assessed. 2. Potential Scientific Application to defined problems is articulated. 3. Need identified. 4. Basic principles observed and reported(Scientific research begins to be translated into applied research and development)
TRL-2	**Proof-of-Principle**	Intense intellectual focus on the problem, with generation of scientific "paper studies" that review and generate research ideas, hypotheses, and experimental designs for addressing the related scientific issues. Concept formulation.	1. Research ideas developed and hypothesis formulated. 2. Plans and protocols are developed, peer reviewed, and approved 3. Concept formulated. 4. Technology review leading to understand market position of technology completed.

TRL-3	**Proof-of-Concept demonstrated**	Basic research, data collection, and analysis begin in order to test hypothesis, explore alternative concepts, and identify and evaluate component technologies. Initial tests of design concept and evaluation of candidate(s). Study endpoints defined. Design verification, critical component specifications, and tests (if a system component is necessary for device test and evaluation [T&E]).	**Device** 1. Hypothesis testing and initial proof of concept (PoC) of device is demonstrated in *in vitro* models. 2. Analytical and laboratory studies to physically validate the analytical predictions of separate elements of the technology. 3. Research results support concept. **Diagnostics** 1. Expression and Purification of the diagnostic agent, its characterization and initial validation at lab level using standard immune assays completed.
TRL-4	**Proof-of-Concept established**	Exploratory study of candidate device(s)/systems (e.g., initial specification of device, system, and subsystems). Candidate devices/systems are evaluated in laboratory to identify and assess potential problems. Procedures and methods to be used during non-clinical in evaluating candidate devices/systems are identified. The design history file, design review, and, when required, a Device Master Record (DMR), are initiated to support Regulatory Approval.	**Device** 1. Functional Prototype developed by integration of different modules and safety, efficacy and performance of candidate device or system demonstrated in a defined laboratory and Simulated Environment. 2. Device Master Record (DMR) Prepared. **Diagnostics** 1. Data on physical and biological Characterization of candidate antigen/s produced in different batches (around 5 batches) available.

TRL-5	**Early-Stage Validation**	"High-fidelity" laboratory integration of components. Study of candidate device(s)/systems (e.g., initial specification of device, system, and subsystems) to evaluate safety and efficacy in animals and to identify and assess potential problems, adverse/side effects etc.	**Devices** 1. Target Device Profile defined. 2. 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. 3. Safety, efficacy, and performance of candidate device or system demonstrated in relevant environment and limited number of animals. **Diagnostics** 1. Diagnostic kits having desired specificity & sensitivity based on the data generated is established.

TRL-6		Clinical trials are conducted to demonstrate safety of candidate medical device in a small number of animals under carefully controlled and intensely monitored clinical conditions. Component tests, component drawings, design history file, design review, and any DMR are updated and verified. Production technology demonstrated through production-scale cGMP plant qualification. For Regulatory Approval (CDSCO), component tests, component drawings, design history file, design review, and any DRM are updated and verified.	**Device** 1. Fully functional clinical grade device ready. 2. Quality assurance certification applied. 3. Manufacturing facility is ready for cGMP inspection. 4. Clinical trials conducted on increased number of animals and has met the safety requirements and demonstrated the expected workability. **Diagnostics** 1. Data on reliability from extensive field evaluation available. 2. Fully functional clinical grade product ready. 3. Quality assurance certification applied. 4. Manufacturing facility is ready for cGMP inspection.
TRL-7	**Late-Stage Validation**	Scale-up, validation, and Regulatory Submission	**Device/Diagnostics** 1. Manufacturing lines established. 2. Design for manufacture (DFM) finalized and devices manufactured. 3. Scale-up and initiated validation preferably government agencies 4. Application submitted for regulatory approval and Manufacturing license to appropriate Regulatory authority (CDSCO).

TRL-8	**Pre - Commercialization**	Finalize GMP manufacturing process. Finalize prototype Regulatory Approval and manufacturing license.	**Device/Diagnostics** 1. Regulator approved/licensed labelling. 2. Manufacturing license obtained. 3. Commercial batch manufacturing initiated.
TRL-9	**Commercialization and post market studies**	Product launched. Post-marketing studies and surveillance	**Device/Diagnostics** 1. Commercial launch of the new device. 2. Product on sale level. 3. Post marketing studies and surveillance

11. Biopesticides

TRL	Status	Definition	Key Indicator(s)
TRL-1	**Ideation**	Maintenance of scientific awareness and generation of scientific and bioengineering knowledge base. Scientific findings are reviewed and assessed as a foundation for characterizing novel product with new technologies.	1. Scientific literature reviews and initial market surveys are initiated and assessed. 2. Potential Scientific Application to defined problem is articulated. 3. Need identified. 4. Basic principles observed and reported (Scientific research begins to be translated into applied research and development)
TRL-2	**Proof of Principle**	Intense intellectual focus on the problem, with generation of scientific "paper studies" that review and generate research ideas, hypotheses, and experimental designs for addressing the related scientific issues. Concept formulation.	1. Research ideas developed and hypothesis formulated. 2. Plans and protocols are developed, peer reviewed, and approved 3. Concept formulated. 4. Technology review leading to understand market position of technology completed.
TRL -3	**Proof-of-Concept demonstrated**	Collection, Isolation, and purification of microbial samples	1. Samples of microorganisms or infected arthropods collected from natural environments. 2. Colonies formed from the collected samples.

TR L-4	**Proof-of-Concept established**	Characterization, taxonomic identification, and selection Optimization of media for mass multiplication and development of delivery systems for the selected efficient isolates	1. Individual colonies of interest have been selected. 2. Colonies which have potential human health implications or may negatively impact non-targets organism eliminated. 3. Delivery systems formulated for the selected efficient isolates
TRL-5	**Early-Stage validation**	*In vitro* evaluation and screening of local strains against target pathogens or insects	1. *In vitro* laboratory tests performed. 2. Preliminary screening data against a number of potential targets available. 3. Target product profile defined.
TRL-6		Testing bio-efficacy of the formulations against select phytopathogens / insects inside greenhouse/net house, storage and shelf life and stability studies	1. Data from lab scale bio-efficacy studies and toxicity (skin, mucus membrane irritation etc.) studies available. 2. Analytical assays based on bioactive chemistry developed to ensure quality control during the manufacturing process. 3. Data from stability test and restrictive stability studies available 4. Shelf-life determined.

TRL-7	**Late-Stage Validation**	Conduct extensive field trials (Multi-location or hotspots) or other technology performance experiments to determine the potential yield,product quality Validation & Regulatory submission (chemistry, bio-efficacy, toxicology, packaging)	1. Data from field trails available on a. Bio-efficacy in terms of product quality and product yield. b. Toxicity and effect on non-target organisms from single exposure studies. c. Phytotoxicity 2. Packaging and labeling finalized. 3. Design for manufacture finalized and product manufactured. 4. Application for regulatory approval and registration (provisional) submitted to appropriate regulatory authority, i.e., Central Insecticide Board (CIB)/ICAR/FSSAI along with data. 5. Validation preferably by government agencies such as Central Insecticides Laboratory (CRL).
TRL-8	**Pre-Commercialization**	Produce certified planting materials or other kinds of technologies and ensure that these can be sourced or are workable for full-scale production. Also, operational efficiency, costs and returns or resource quality improvements that would result from the innovation are established. Commercial-scale production by producers or manufacturers occurs with delivery of products to producers, handlers, processors, distributors, or other supply chain participants to market outlets and for meeting user demand.	1. Regulator Certification - Approved/licensed labeling received 2. Manufacturing license obtained. 3. Commercial batch manufacturing initiated.

TRL-9	**Commercialization and post market studies**	Product launched. Post-marketing studies and surveillance	1. Regulator approved/licensed labelling. 2. Commercial launch of the new drug. 3. Product on sale. 4. Post marketing studies and surveillance

REFERENCES

1. Biomedical and Line DoD Technology Readiness Levels (TRLs), [April 27 2018] (https://tier7.us/biomedical-line-dod-trls/)

2. Lavin A. & Renard G., Technology Readiness Levels for AI & ML [16 December 2020] (https://arxiv.org/abs/2006.12497)

3. Technology Readiness Level (TRL) by British Council (https://www.britishcouncil.id/sites/default/files/annex_2_technology_readiness_level_trl_033020_final.pdf)

4. DMTC Guideline - Technology Readiness Levels, Medical Countermeasures (https://dmtc.com.au/wp-content/uploads/2019/04/DMTC-TRL-Guideline-MCM-2019.pdf)

5. Gustav Notander, EIT Health, European Union (Technology Readiness Levels -TRL - NASA's contribution to Horizon 2020) (https://www.wmahsn.org/storage/resources/documents/EIT_Health_KIC_A_guide_to_TRL-EIT_health.pdf)

6. Technology Readiness Levels – (TRL): Technology Compendium Biomedical Technology Wing 2017.

7. TRLs for Product Development Tools for Medical Countermeasure Product Development Tools (PDTs) (https://www.medicalcountermeasures.gov/trl/trls-for-product developmenttools/#:~:text=TRLs%20for%20Product%20Development%20Tools&text=Consider%20availability%20of%20animal%20models,must%20begin%20at%20TRL%201)

8. Crop Research Technology Readiness Level (TRL) (2016) – United State Department of Agriculture National Institute of Food and Agriculture Institute of Food Production and Sustainability (https://longevity.technology/about/)

9. Technology Readiness Assessment (TRA) Guidance, U. S. Department of Defense (2011).

10. Biomedical Technology Readiness Levels (TRLs), Deputy for Research and Development, Commander, U.S. Army Medical Research and Material Command ATTN: MCMR-ZC, 504 Scott Street, Fort Detrick, MD 21702-5012.

11. TRL- BIRAC (https://www.birac.nic.in/desc_new.php?id=443)

12. Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India (2016), Department of Biotechnology, India. (http://dbtindia.gov.in/sites/default/files/uploadfiles/Guidelines_on_Similar_Biologics%2C2016.pdf)

13. The TRL Scale as a Research & Innovations Policy Tool – EARTO Recommendations (2014) (https://www.earto.eu/wp-content/uploads/The_TRL_Scale_as_a_R_I_Policy_Tool_-EARTO_Recommendations_-_Final.pdf)

14. Banke J., August 20, 2010, Technology Readiness Levels Demystified, NASA (https://www.nasa.gov/topics/aeronautics/features/trl_demystified.html)

15. Medical Devices Classifications (https://sctimst.ac.in/About%20SCTIMST/Organisation/BioMedical%20Technology%20Wing/R%20&%20D%20Activities/Technologies%20for%20Transfer%20-%20Archive/Technology%20Compendium%20-%20Archive/resources/Medical%20devices%20classification%20-%20TRL.pdf)

16. JRC Technical Report- AI Watch Assessing Technology Readiness Levels for Artificial Intelligence. (https://ec.europa.eu/jrc/en/publication/ai-watch-assessing-technology-readiness-levels-artificial-intelligence)

******

Indian Council of Medical Research (ICMR)

Department of Health Research

Ministry of Health and Family Welfare, Government of India

New Delhi