MEMORANDUM OF AGREEMENT (MOA)

Between

INDIAN COUNCIL OF MEDICAL RESEARCH

And

XXXX

Ministry of Health & Family Welfare,
Government of India

FOR VALIDATION OF TECHNOLOGY

MEMORANDUM OF AGREEMENT

THIS MEMORANDUM OF AGREEMENT ("MoA/Agreement") is formalized and effective on DD/MM/YYYY "Effective Date"

By and Between

The INDIAN COUNCIL OF MEDICAL RESEARCH, an apex body in India for formulation, coordination and promotion of biomedical research under the Department of Health Research, Ministry of Health & Family Welfare, Government of India, registered as a Society under the Societies Registration Act, 1860, having its registered office at V. Ramalingaswami Bhawan, Ansari Nagar, Post Box 4911, New Delhi – 110029, India (hereinafter referred to as "**ICMR**" which expression shall wherever the context so admits include its successors and permitted assignees), the **PARTY OF THE FIRST PART; (FIRST PARTY)**

AND

XXXX, a company registered and incorporated under the Companies Act 1956 (or Companies Act, 2013) and having its registered office at _____(hereinafter referred to as 'COMPANY' which expression shall wherever the context so admits include its successors in interest, liquidators, administrators and permitted assignees) / _____ (Mention the name of Society / University/Research Institute/ College wherein the Research / development is being conducted)_____(hereinafter referred to as "INSTITUTE") the **PARTY OF THE SECOND PART; (SECOND PARTY)**

The FIRST PARTY and SECOND PARTY are hereinafter collectively referred to as the "Parties".

WHEREAS:

1. SECOND PARTY has developed a device/ diagnostic kit/ digital data tool etc. _____" etc. (hereinafter referred to as the **"PRODUCT")** with potential for screening and diagnosis of tuberculosis/ drug resistance (RIF/INH/FQ etc.) and is interested in evaluating the _____activity of the same (hereinafter called **"VALIDATION");**
2. Considering that the PRODUCT has the potential for_____ and therefore may have large scale societal impact, the FIRST PARTY through its institutes/TB validation network/ affiliated centers etc. has agreed to support the validation of the PRODUCT and has expressed its willingness to undertake this VALIDATION for commercialization and/or translation

potential for the PROJECT**.**

3. FIRST PARTY while extending its support shall be the nodal coordination centre for **"Validation"** undertaken by the its institutes/TB validation network/ affiliated centers and requested by the SECOND PARTY as mentioned in Clause 3 below, herein after referred to as the **"PROJECT".**

NOW THEREFORE, Parties, each in consideration of the covenants and agreements of the other and intending to be legally bound, agree as follows:

1. REPRESENTATIONS AND WARRANTIES OF THE SECOND PARTY

SECOND PARTY represents and warrants the following:

1.1 The SECOND PARTY has all requisite authority to enter into this Agreement and to perform and fulfil its obligations under this Agreement;

1.2 The execution and delivery of this Agreement and the performance or fulfillment of the SECOND PARTY obligations under this Agreement will not conflict with, or result in breach of, or constitute a default under, or require the consent of any third party under any applicable laws, Agreement, or instrument to which the SECOND PARTY is bound;

1.3 There are no pending or threatened lawsuits, actions, or any other legal or administrative proceedings against the SECOND PARTY, its promoters, or directors, or dean/heads which, if adversely determined against them, would have a material adverse effect on the ability of the SECOND PARTY to perform its obligations under this Agreement.

2. DEFINITIONS

2.1 **Background Intellectual Property** ("BGIP") shall mean any Intellectual Property/IP that is created or owned by the Party prior to the Effective Date of this Agreement between the Parties.

2.2 **"Disclosing Party"** shall mean the Party to the MoA, or its employees, agents and other authorized representatives disclosing the Confidential Information to the other Party to The MoA, or its employees, agents, and other authorized representatives.

2.3 **"Effective Date"** shall mean the date of signing of this MoA or the date of issuance of Sanction Order by the FIRST PARTY (as applicable). In the event the Parties affix their signatures to this Agreement on separate dates, the Agreement shall be effective from the date on which the last set of signatures is affixed thereto. Three copies of the Agreement shall be signed by each of the Parties and one copy each shall remain in the custody of each Party.

2.4 **Intellectual Property** shall mean and include the following (a) Invention (as defined herein) or discovery (whether patentable or not); manner, method or process of manufacture; method or principle of construction; chemical composition or formulation; biological material; computer program; integrated circuit, circuit layout or semi conductor chip layout or design; plan, drawing; or scientific, technical or engineering information or document; (b) Invention(s), improvement,

modification or development of any of the foregoing; (c) patent, application for grant of a patent, right to apply for grant of a patent or similar rights for or in respect of any subject matter referred to in sub-paragraphs (a) or (b) above; (d) trade secret, know-how, or right of secrecy or confidentiality in respect of any information or document or other Intellectual Property referred to in sub-paragraphs (a) or (b) above; (e) copyright or other rights in copyright subsisting in any works or other subject matter referred to in sub-paragraphs (a) or (b) above; (f) circuit layout rights.

2.5 **Net Sales** shall mean Revenue from sales of goods or services by all ICMR Grantees/ Licensees/ Sub-licensee(s) based on the net sales realization from operations, net of discounts and indirect taxes, as defined by the Cost Accounting Standards - 24 and certified by the Chartered Accountant.

2.6 **PRODUCT** shall mean each product under development/ expected to be developed under this PROJECT or _____.

2.7 **PROJECT** shall mean the research proposal entitled _____.

2.8 **Project Review Committee (PRC)** shall mean a Monitoring Committee comprising of eminent experts from the relevant field(s) which will be constituted by FIRST PARTY to monitor the progress of the objective(s) of the PROJECT.

2.9 **Receiving Party** shall mean the Party, its employees, agents, or other authorized representatives, receiving Confidential Information from the other Party, its employees, agents, or other authorized representatives.

2.10 **Royalty term** shall mean Royalty payable from the net sales for a period of 10 years from the date of commercialization of product.

2.11 **Scope of Work** shall mean, in respect to the PROJECT, the scope as detailed in this MoA, including any document or agreement executed pursuant to this MoA or as mutually agreed and executed between the Parties.

2.12 **Technology** shall mean any and all discoveries, inventions, processes, methods, techniques, know-how, 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 for the purpose of this PROJECT.

2.13 **Term** shall mean the term or duration of this MoA commencing from the Effective Date and continuing for _____ () years thereafter, or extended with the agreement of the Parties in writing, unless terminated earlier in accordance with Clause 21 (Termination) of this Agreement.

3. SCOPE OF WORK

This Agreement is being done for undertaking validation for the use of the **"PRODUCT"** for at the validation centers of the TB validation network of the FIRST PARTY:

4. OBLIGATIONS OF THE FIRST PARTY

4.1 FIRST PARTY shall be the nodal agency for coordination of the Validation and shall oversee the progress of the PROJECT.

4.2 The FIRST PARTY will provide logistic support (monitoring/administrative) or financial support as approved by the PRC/Competent Authority. The FIRST PARTY reserves the right to extend the PROJECT as and when required, FIRST PARTY approval for PROJECT, Sanction Order/Letter is placed at Schedule-1.

4.3 The FIRST PARTY shall validate the claims for the Product/batches (as the case may be), made by the SECOND PARTY, as required under mandatory regulatory compliances in India, as per the requirements of the PROJECT, under this Agreement.

4.4 There will be no financial or other obligation(s) on the FIRST PARTY after the proposed duration of this Agreement and/or premature termination (under Clause 20) of this agreement.

4.5 The FIRST PARTY through its Project Review Committee (PRC) shall evaluate the reports of the Validation and give recommendations on its successful completion for extension of the PROJECT, if recommended by PRC and approved by the Competent Authority.

4.6 The FIRST PARTY shall be responsible to co-ordinate with validation centers/ conduct the Validation and successful completion of the PROJECT under this Agreement.

4.7 The FIRST PARTY shall nominate a Project Investigators (PIs) of the validation centers who shall be responsible for rendering timely deliverables under this PROJECT and co-ordination with the validation sites/ its institutes for complying with the terms and conditions of this Agreement.

4.8 The PI shall ensure that the activities for this PROJECT are executed in timely manner for successful completion of the PROJECT within the stipulated Term of this Agreement.

4.9 The PI shall ensure the use of the PRODUCT is strictly for the intended purpose of the PRODUCT for which the Agreement is being made and not for any other purposes. The validation study has to be conducted as per the agreed protocol and will share the anonymized findings with FIRST PARTY to be shared to the SECOND PARTY.

4.10 The FIRST PARTY though its validation centers agrees to return the PRODUCT(s) after the termination of the Agreement if/whenever asked by the SECOND PARTY. There is no obligation on any party to enter in to a purchase process after the Agreement is over.

4.11 The validation centers shall maintain and provide complete and accurate records and all supporting documentation as sufficient and necessary as may be provided under this Agreement in such connection.

4.12 The validation centers shall take all measures necessary to ensure secrecy and confidentiality of confidential and / proprietary information relevant to the SECOND PARTY as well as the patients, including such other or additional measures as may be required while conducting the study.

4.13 The validation centers shall be responsible for the proper and intended usage of the

PRODUCT(S) provided by the SECOND PARTY under this Agreement.

4.14 The FIRST PARTY agrees to abide by the confidentiality obligations as per Clause 10, defined hereafter.

5. OBLIGATIONS OF THE SECOND PARTY

5.1 In consideration of the mutual covenants hereunder, the SECOND PARTY hereby agrees to provide adequate number of PRODUCTS as per the requirements of the PROJECT, along with_____ and other essential items for the PRODUCT to use/ validate/ test for at no Cost to validation centers of the FIRST PARTY;

5.2 The SECOND PARTY agrees to cover the maintenance and accidental damage by appropriate insurance and will repair/ replace the unit(s) immediately when so needed and provide complete backup support to enable FIRST PARTY to successfully complete the Validation study.

5.3 The SECOND PARTY agrees to provide the necessary safety items for the operator/ technician for ensuring patient care and safety with each PRODUCT.

5.4 The SECOND PARTY will depute trained personnel with each PRODUCT for managing and controlling the PRODUCT at each site;

5.5 The SECOND PARTY hereby, declares that the PRODUCT has certified quality and safety standards as per the requirements of the PROJECT (to be defined on case-to-case basis);

5.6 The SECOND PARTY shall provide undertaking that no extraneous substance has been added to the PRODUCT(s) provided for VALIDATION.

5.7 In case, the SECOND PARTY fails to accomplish the requirements (e.g., documents/validation charges) stated by the FIRST PARTY, the PRODUCTs under consideration/PRC- approved PRODUCT under validation would be rejected at any stage of VALIDATION.

5.8 The SECOND PARTY shall notify FIRST PARTY of any material change in its incorporation status, shareholding, entity status, Project Coordinator, implementation site or any such changethatwouldimpacttheperformanceofitsobligationsunderthePROJECTand this Agreement.

5.9 The SECOND PARTY shall not assign or transfer the PRODUCT/ PROJECT interests/ rights to any third party directly or indirectly without prior written consent from FIRST PARTY till full and final settlement of all dues as mutually agreed by the Parties.

5.10 The SECOND PARTY 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.

5.11 The SECOND PARTY is required to register its novel PRODUCT if it is co-developed with FIRST PARTY under this Agreement, on GeM portal of the Ministry of Commerce and Industry, Government of India.

5.12 The SECOND PARTY must ensure to strictly abide/comply with all the obligations provided under the “ICMR Guidelines for Technology Development Collaboration” (as amended from

time to time).

5.13 The SECOND PARTY agrees to obtain any other required compliances of Government, as amended from time-to-time.

5.14 The SECOND PARTY agrees to abide by the confidentiality obligations as per clause 10, defined hereafter.

6. INTELLECTUAL PROPERTY RIGHTS (IPR) OR INTELLECTUAL PROPERTY (IP)

6.1 Intellectual Property (I.P) shall mean and includes the following (a) an idea or invention or discovery (whether patentable or not); manner, method or process of manufacture; method or principle of construction; chemical composition or formulation ; biological material; computer program; integrated circuit; circuit layout or semiconductor chip layout or design; plan, drawing; or scientific, technical or engineering information or document(a) product(s)/ prototype(s) (b) improvement, modification or development of any of the foregoing; (c) patent, application for a patent, right to apply for a patent or similar rights for or in respect of any subject matter referred to in sub-paragraphs (a) or (b) above; (d) trade secret, know-how, or right of secrecy or confidentiality in respect or confidentiality in respect of any information or document or other Intellectual property referred to in sub paragraphs (a) or (b); (e) copyright or other rights in the nature of copyright subsisting in any works or other subject matter referred to in sub-paragraphs or (b); (f) circuit layout rights.

6.2 Background Intellectual Property ("BGIP") shall remain the sole and exclusive property of the respective Parties generating the BGIP.

6.3 All forms of Intellectual Property such as 'Patents', 'Copyrights' or 'Trademarks' developed from the PROJECT study, if any shall be jointly owned by Indian Council of Medical Research and the SECOND PARTY.

6.4 The PRODUCTs and know-how generated through VALIDATION as per this Agreement may be utilized by the FIRST PARTY and its validation centers for research purposes, depending on its research potential.

6.5 Any improvement which claims priority from or which are obvious modifications of the jointly owned I.P. (as evidenced by potential application of Improvements and improvements to the inventions) it is agreed that the FIRST PARTY and the SECOND PARTY shall jointly own all Intellectual Property in such Improvements throughout the Territory of India and abroad and in perpetuity and any IP Rights in such Improvements shall be deemed to fall within the scope of this Agreement. In case of modifications and improvements which do not claim priority from and are substantially different from the inventions, the party conceptualizing shall exclusively and absolutely own all Intellectual Property in such Improvements, throughout the Territory and in perpetuity, wherein 'Improvements' shall mean, any and all improvements, enhancements, variations, or modifications of the Technology and all inventions, designs, information, know-how, specifications, formulae, data, processes, methods, techniques arising in connection with the development, manufacture, and production of any products used in, generated or otherwise created

using the Technology; and 'Field of use' shall mean in the domain of "PROJECT."

6.6 The SECOND PARTY shall be responsible for suitable protection including filing and prosecution of 'Jointly owned IP', if so generated. Further, the transfer of jointly developed IP and associated sharing of revenue shall be governed as per 'ICMR Guidelines for Technology Development Collaboration'.

7. COMMERCIALIZATION FOR SOCIETAL IMPACT

7.1 Indian Council of Medical Research, New Delhi shall provide the funding for carrying out the PROJECT and shall be the apex body to oversee the progress of the PROJECT. All Intellectual Property rights developed from the PROJECT study shall be jointly held by the Indian Council of Medical Research and SECOND PARTY.

7.2 It shall be the responsibility of the SECOND PARTY to make every effort to commercialize the PRODUCT at discounted price to the Government of India/ as declared in National Interest and the final decision will be that of the Government of India.

7.3 The SECOND PARTY agrees to keep the price of the PRODUCT fixed at the discounted prices mentioned in Clause 7.2 above for supplies in the national TB elimination program.

8. ROYALTY PAYOUTS

8.1 Royalty remittance obligations to the SECOND PARTY shall be applicable as per the "ICMR Guidelines for Technology Development Collaboration", as amended from time-to-time.

8.2 The SECOND PARTY agrees that the Royalty @1% (one percentage) on Net Sales of the PRODUCT shall be paid for the royalty term on half yearly basis as entered in the books of account maintained by the SECOND PARTY, up to 30th September and 31st March respectively every year regularly and punctually.

8.3 To pay royalty under and in terms of this sub-clause shall accrue upon the commencement of the commercial sale of the PRODUCT ("Royalty"). These reports shall show for the period in question based on Net Sales made by the SECOND PARTY and its Affiliates, if any, of the PRODUCT(S), details of the quantities of the PRODUCT sold, Net Sales made by the SECOND PARTY and the royalty due to the FIRST PARTY from both Government and Non-Government sales.

8.4 Royalty Reporting

8.4.1 The SECOND PARTY shall pay the royalties on half yearly basis. Royalty due upto 31st March must be paid before the last working day of April and for royalty due up to 30th September by last working day of October.

8.4.2 SECOND PARTY must submit to the FIRST PARTY a CA Certified account statement for the Royalty Period in the following format:

Product Name	Unit Sale Price	Total Quantity Sold	Gross Sales Value (INR)	Net Sales value (INR)	% of Royalty Payable	*Royalty Amount (INR)

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

8.5 Mode of Payment of Royalty to the FIRST PARTY

The Royalty on the Net sales shall be paid by the Grantee 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" or by electronic mode in favour of ICMR.

8.6 Delay in Payment of Royalty and Non-Payment

8.6.1 In case of delay in payment of Royalty, the SECOND PARTY shall be liable to pay simple interest at the rate of 12 (twelve) percent per annum, on the amount of default in payment of royalty for the period of delay.

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

8.7 Royalty Monitoring & Audit Rights

8.7.1 Grantee must keep, and must ensure that SECOND PARTY itself and each of its Sub-Licensee keeps true and accurate accounts and records of the quantities of the PRODUCT manufactured, sold, and in stock, Gross Sales Price and Net sales of the PRODUCT(s) 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 PRODUCT(s) as are required by good accounting practice.

8.7.2 The SECOND PARTY must ensure to strictly abide/comply with the Termination Clause mentioned in this Agreement, which shall include strict compliance with the Royalty remittance obligation provided under the "ICMR Guidelines for Technology Development Collaboration," non-compliance of the same by the SECOND PARTY shall result in the Termination of this Agreement.

8.8 Inspection of Accounts by the FIRST PARTY

8.8.1 The FIRST PARTY may at any time, appoint a person or reputed auditing firm to inspect the SECOND PARTY books and records so maintained for ensuring royalty compliance.

8.8.2 Cost of such Audit shall be borne by the SECOND PARTY.

9. CONFIDENTIALITY

9.1 "Confidential Information" means all information (whether in oral, written or electronic form) relating to the minutia of research and development proposals, presentations, Intellectual Property stated in the research and development proposals, due diligence reports, in-house analysis reports and Freedom to operate reports, information on business and finances, unpublished data, organizational and individual information, proposed technology or intended inventions/ procedures, nature of research and/or plans for prioritizing research, commercialization strategy, technical validation, budgets and strategies, minutes of the meeting(s) or other agnate materials including any notes or summaries derived from those materials of the Disclosing Party and confidential information received by the Disclosing Party from third parties. All information under the MoA shared between the parties shall be treated as confidential information and shall be subject to restrictions on disclosure other than for the purpose of this MoA.

9.2 During the tenure of the Agreement, the Parties, undertake to maintain strict confidentiality and refrain from disclosure thereof, of all or any part of the information and data exchanged/generated from the PROJECT under this Agreement for any purpose other than purposes in accordance with this Agreement. It shall be the responsibility of the Parties to ensure maintenance of such confidentiality including on behalf of their employees, representatives and associates involved in the PROJECT.

9.3 The Parties shall not have any obligation of confidentiality with respect to any information that is proved with documentary evidence that it:

a. Is in the public domain by use and/or publication at the time of its disclosure by the disclosing party; or

b. Was already in possession of the recipient prior to receipt from the disclosing party;or

c. Is properly obtained by the recipient from a third party with a valid right to disclose such information and such third party is not under confidentiality obligation to the disclosing party; or

d. Was disclosed to any third party on a non-confidential basis prior to commencement of the PROJECT; or

e. Was developed by the recipient, as established by acceptable written record, independently of the disclosure of information by the disclosing party; or

f. Is required by public authority, by law or decree.

9.4 Notwithstanding anything contained herein, the provisions of Confidentiality shall survive early termination or expiration of this Agreement for a period often (10) years from early termination or expiration, as the case may be.

10. PUBLICATION

10.1 In case of Co-development, the Parties shall have equal rights on the manuscripts/ scientific publications (joint publication/acknowledgment/other credits as applicable) and in accordance

with guidelines of International Committee of Medical Journal Editors (ICMJE.org).

10.2 Support of ICMR must be duly acknowledged in all publications.

10.3 ICMR Scientists and Scientist/officials of the validation site may be given due advantage of authorships in the publications arising out of the validation study.

11. BRANDING AND ACKNOWLEDGEMENT

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

11.2 Use of ICMR Logo on PRODUCT packages:

11.2.1 The name/logo of ICMR shall suitably be displayed on each and every PRODUCT by the SECOND PARTY at its own cost.

11.2.2 The SECOND PARTY shall be permitted to use the ICMR Logo following approval by the Competent Authority of ICMR and as per the Brand Guidelines of ICMR.

12. DATA RIGHTS AND DATA PRIVACY

12.1 The FIRST PARTY shall have joint and equal rights on the data generated during the collaboration and shall be free to use the data for any purpose, including for further research and teaching purposes. SECOND PARTY shall take reasonable steps to prevent the FIRST PARTY data, documents or other the FIRST PARTY confidential and proprietary information from unauthorized usage or falling in to unauthorized hands. SECOND PARTY shall ensure that its personnel working on such assignment shall sign appropriate agreements (acceptable to the FIRST PARTY) to prevent unauthorized usage and disclosure of specific data, documents or other FIRST PARTY confidential and proprietary information thereof.

12.2 Data rights in cases where Artificial Intelligence is involved shall be dealt with separately.

12.3 In case patient data is being used by the SECOND PARTY it must ensure that the data is anonymized, and it must ensure to strictly abide by the provision of Information Technology (IT) Act, 2000 and The Digital Personal Data Protection Act, 2023 while dealing with such data.

13. PRESS RELEASE AND PUBLIC ANNOUNCEMENTS

13.1 Prior written permission must be taken by the SECOND PARTY from ICMR before making any press releases, public announcements, or media statement with respect to the PRODUCT that has been given grant-in-assistance by the FIRST PARTY as per this Agreement.

13.2 The FIRST PARTY reserves the rights to make any modifications for incorporation by the SECOND PARTY in the Proposed Publication/Press Release.

14. NO LIABILITY

In case of any legal or tax related issues arising related to sales, etc. or any other terms of this Agreement, the FIRST PARTY will have no bearing on the same and such matters shall be exclusively dealt by the SECOND PARTY.

15. NO-WARRANTY CLAUSE

15.1 The FIRST PARTY shall make no warranty, express or implied about the workability of the technology/IPR/Data/Records being transferred by the FIRST PARTY. The same shall be transferred by the FIRST PARTY on an "as is where is" basis.

15.2 The FIRST PARTY will not have any liability to the SECOND PARTY 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.

15.3 Among other things, the FIRST PARTY shall disclaim 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.

16. RELEASE AND INDEMNIFICATION

16.1 Release

16.1.1 The SECOND PARTY unconditionally releases ICMR including its Institutes, study sites, 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 SECOND PARTY, its affiliates, any sub-licensee(s) or any third party arising out of such party's Commercialization or use of the PRODUCT(s), or the Intellectual Property.

16.1.2 To the full extent permitted by law, the FIRST PARTY, its Institutes, study sites, and its officers, employees, sub-contractors, and agents will not be liable to the other for any special, indirect or consequential damages, including consequential financial loss arising out of the Commercialization or use of the PRODUCTs or the Intellectual Property, by the SECOND PARTY.

16.2 Indemnification

16.2.1 The SECOND PARTY shall indemnify and shall agree to keep 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 Commercialization 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.

16.2.2 The SECOND PARTY shall, always, indemnify and keep indemnified ICMR against all claims/damages etc. by any infringement of any Intellectual Property Rights (IPR) while fulfilling their responsibilities/work under the PROJECT and this Agreement.

16.2.3 The provision under this Agreement by the FIRST PARTY does not create any liability, explicit or implicit, on the FIRST Party including, its validation centers, in respect of the workforce engaged in the PROJECT.

17. FORCE MAJEURE

Neither Party shall be liable hereunder by reason of any failure or delay in the performance of its obligations hereunder on accounts of riots, fires, flood, storm, explosions, act of God, war, governmental action, lockdown, epidemic, pandemic, labor conditions, earthquakes or any other cause which is beyond the reasonable control of such Party provided the affected Party gives the other Party prompt written notice of the occurrence of any Force Majeure event and the nature and extent to which the affected Party will be unable to perform its obligations under this Agreement. The affected Party agrees to use commercially reasonable efforts to correct the Force Majeure event as quickly as possible. Performance shall be excused only to the extent of and during the reasonable continuance of such Force Majeure event, provided that either Party may terminate this Agreement if such Force Majeure event continues for a period of 30 (thirty) days or more. Any deadline or time for performance specified in this Agreement which falls due during or subsequent to the occurrence of a Force Majeure event shall be automatically extended for a period of time equal to the period of the Force Majeure event.

18. TENURE OF THE AGREEMENT

The Agreement will be valid from the Effective Date for a period of thirty six (36) Months. In case of Foreclosure/Termination of the PROJECT as per terms of this Agreement, the Agreement shall be valid till the date of the Foreclosure/Termination Letter issued by the FIRST PARTY.

19. AMENDMENTS TO THE AGREEMENT

No amendment or modification of this Agreement shall be valid unless the same is made in writing by the Parties or their authorized representatives specifically stating the same to be an amendment of this Agreement. The modifications shall be effective from the date on which they are made/executed unless otherwise agreed to.

20. FORECLOSURE AND TERMINATION

20.1 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.

20.2 Termination by the FIRST PARTY

The FIRST PARTY shall notify the SECOND PARTY regarding the breach of provisions under this Agreement, thereby, invoking the provisions of termination giving one-month notice to remedy the breach. The decision of the FIRST PARTY shall be final in all respects. The SECOND PARTY shall immediately refund any amount unutilized out of the FIRST PARTY's disbursements to the FIRST PARTY. The FIRST PARTY shall have the right to foreclose and terminate if the default prevails even after serving notice, under following circumstances:

20.2.1 For failure to achieve milestones within the timelines agreed between the FIRST PARTY and the SECOND PARTY.

20.2.2 On account of submission of false reports or misrepresentations by the SECOND PARTY.

20.2.3 For non-compliance with the royalty remittance obligation.

20.2.4 Failure to submit CA audited documents (upon royalty remittance) certifying the actual sales made by the SECOND PARTY.

20.2.5 For non-fulfilment of obligations pursuant to the Grant-in-assistance.

20.2.6 If the SECOND PARTY 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 FIRST PARTY, except for reasons beyond the control of the SECOND PARTY and that are agreed by the FIRST PARTY.

20.3 Termination by the SECOND PARTY

The SECOND PARTY may at any point of time choose to terminate this Agreement after giving reasons, by giving prior notice of at least three months. On serving such notice to FIRST PARTY, the SECOND PARTY shall be bound to complete the following obligations for effective termination.

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

20.3.2 Submit a confidential report detailing the status of Technology development/ validation till that point of time.

For effective Termination, the above obligations shall be subject to approvals by the Competent Authority, ICMR.

21. NO JOINT VENTURE

Nothing contained in this Agreement will be construed as creating a joint venture, agency, partnership, or employment relationship between the Parties hereto, nor will any Party have the right, power or authority to create any obligation or duty, express or implied, on behalf of the other Party.

22. ENTIRE AGREEMENT

This Agreement as well as any exhibits attached shall for all considerations be the entire Agreement for the properties listed. Furthermore, this Agreement will take precedence over all previous communications

including, but not limited to, any oral or written understandings & other correspondence between the Parties.

23. SEVERABILITY

In case any one or more of the provisions or parts of a provision contained in this Agreement shall, for any reason, be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provision or part of a provision of this Agreement; and this Agreement shall, to the fullest extent lawful, be construed as if such invalid or illegal or unenforceable provision, or part of a provision, had never been contained herein.

24. SURVIVABILITY

If, at any point one or more terms and conditions within this Agreement are deemed to be unenforceable or void, the Parties agree to substitute a similar term or condition to replace the defective one.

25. WAIVER

The failure to enforce or uphold any aspect of this Agreement shall not constitute a waiver of any other aspect of the Agreement.

26. REGULATORY COMPLIANCE

The SECOND PARTY shall primarily be responsible for complying with all applicable laws, regulatory approvals and obtaining such regulatory approval shall be read as integral part to this Agreement.

27. GOVERNING LAW, JURISDICTION AND DISPUTES SETTLEMENT

27.1 The MoA shall be considered, interpreted, and governed by the laws of India and Courts at Delhi shall have exclusive jurisdiction in all such matters.

27.2 In the event of any dispute or difference between the Parties hereto upon or in relation to or in connection with this Agreement, such dispute or difference, shall be resolved amicably and in good faith by mutual consultation. 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.

27.3 If such resolution is not possible, then 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 read with New Delhi International Arbitration Centre Act, 2019 (NDIAC) 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.

28. NOTICES

Any notice to be given to the FIRST PARTY shall be considered as duly served if the same shall have been delivered by registered mail to the FIRST PARTY and the SECOND PARTY at their addresses as stated below:

FIRST PARTY

Director General, ICMR

V. Ramalingaswami Bhawan, Ansari Nagar, Post Box 4911, New Delhi–110029

All notices and other communications required to be served on the SECOND PARTY including for violation of the terms of this Agreement shall be considered to be duly served if the same shall have been delivered either in person, via courier, or via registered mail to the SECOND PARTY at its address as stated below.

SECOND PARTY

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29. SURVIVAL

Notwithstanding the termination or completion of the term of this Agreement, as per terms of the clause twenty-seven above, the following clauses shall survive and continue to have effect:

29.1 Clause 6 (‘IPR’)

29.2 Clause 7 (‘Commercialization for Societal Impact’)

29.3 Clause 8 (‘Royalty payouts’)

29.4 Clause 9 (‘Confidentiality’)

29.5 Clause 10 (‘Publication)

29.6 Clause 11 (Branding and Acknowledgement’)

29.7 Clause 12 (‘Data Rights and Data Privacy’)

29.8 Clause 13 (‘Press Release and Public Announcements’)

29.9 Clause 14 (‘No Liability’)

29.10 Clause 21 (‘No Joint Venture’)

29.11 Clause 23 (‘Severability’)

29.12 Clause 24 (‘Survivability’)

29.13 Clause 27(‘Governing Law, Jurisdiction and Disputes Settlement’)

IN WITNESS WHEREOF, the FIRST PARTY, and the SECOND PARTY have signed this Agreement on the day, month, and year mentioned herein before

For and on behalf of the FIRST PARTY:	
(Signature & Stamp)	
Name:	
Date:	
WITNESSES	
Signature:	Signature:
Name:	Name:
Date:	Date:

For and on behalf of the "SECOND PARTY" duly authorized vide Board Resolution No _____dated _____of its Board of Directors/duly authorized/vide Authority Letter Dated _____by its concerned Authority:	
(Signature & Stamp)	
Name:	
Date:	
WITNESSES	
Signature:	Signature:
Name:	Name:
Date:	Date: