MEMORANDUM OF UNDERSTANDING
BETWEEN

INDIAN COUNCIL OF MEDICAL RESEARCH

AND

GARDP FOUNDATION

ON ANTIMICROBIAL RESISTANCE RESEARCH AND INNOVATION

The Memorandum of Understanding (hereinafter referred to as the 'MOU') is being entered into on 31.3.21 (hereinafter referred to as the 'Effective Date') by and between:

GARDP Foundation, a not-for-profit organisation established under the laws of Switzerland having its office at 15 Chemin Camille Vidart (formerly Louis-Dunant), 1202 Geneva, Switzerland, (hereinafter referred to as "**GARDP**"),

and

INDIAN COUNCIL OF MEDICAL RESEARCH, a medical research council having its offices at Ansari Nagar, New Delhi 110029, India (hereinafter referred to as **"ICMR").**

ICMR and GARDP shall individually be referred to as "Party" and collectively as "Parties".

WHEREAS ICMR is one of the oldest medical research bodies in the world which was founded by the Government of India as the Indian Research Fund Association in as early as 1911. It was re-designated in 1949 as the Indian Council of Medical Research. It is funded by the Government of India through the Department of Health Research (DHR), Ministry of Health and Family Welfare. It is the apex body in India for formulation, coordination and promotion of biomedical research in the country. The ICMR's research priorities coincide with the national health priorities of the Government of India towards prevention of communicable diseases, non-communicable diseases, improving Reproductive and Child Health and Nutrition, promoting Basic Medical Sciences and Drug research including Traditional medicines. The ICMR promotes biomedical research in the country through intramural and extramural research.

WHEREAS GARDP is a not-for-profit research and development organization that addresses global public health needs by developing and delivering new or improved antibiotic treatments, while endeavouring to ensure their sustainable access. Initiated by the World Health Organisation (WHO) and The Drugs for Neglected Diseases initiative (DNDi) in May 2016, GARDP is an important element of WHO's Global Action Plan on Antimicrobial Resistance that calls for new public-private partnerships to encourage research and development of new antimicrobial agents and diagnostics. GARDP was registered as an independent legal entity in Switzerland in July 2018, and was incubated by DNDi until March 2019 and subsequently fully operational. GARDP's mission is to bring together the public and private sectors to develop new treatments for bacterial infections and ensure responsible and sustainable access, addressing the public health impact of antibiotic/antimicrobial resistance ("**AMR**").

WHEREAS, ICMR has on-going collaborations with DNDi which, prior to the establishment of GARDP, hosted the AMR work now independently located in and managed by GARDP as a separate entity. DNDi, is a not for profit research and development organization, and is a partnership model that maintains neglected patients' needs as the guiding principle in research and development work. ICMR is a key partner of the DNDi initiative, guiding priorities and the development of activities worldwide. In India DNDi has partnered with ICMR and other partners to develop new treatments in visceral leishmaniasis. This new treatment has treated several thousands of kala-azar patients

through the national programme in India. DNDi activities in the AMR landscape (prior to the transfer of the mandate to GARDP) have included neonatal sepsis observational work as per a memorandum of understanding between DNDi and ICMR dated 4 October 2018 which was assigned by DNDi to GARDP on 12 June 2019 (hereinafter referred to as the "**Neonatal Sepsis Initial Collaboration**").

DNDi continues to provide important assistance to GARDP for activation of AMR projects and has, in particular, a critical support role in India.

WHEREAS GARDP and ICMR share common aims, concerns, and interests and have identified a common interest in addressing antimicrobial resistance research and treatment regimen access for bacterial infections in adults and children in India.

WHEREAS, the Parties wish to further develop their strategic partnership to other antibiotic treatment research and development projects beyond the Neonatal Sepsis Initial Collaboration.

THEREFORE, the Parties wish to set out in this document some non-binding overarching aims and principles agreed between the Parties to provide a holistic framework which will allow for the optimal development of collaborations on specific projects.

HAVE REACHED the following understanding:

1. Purpose, scope and contributions of Parties

1.1. This MoU provides the foundation for a strategic partnership to maximise the impact of each Party's activities in the field of AMR by collaborating on mutually agreed projects (the "**ICMR-GARDP Collaboration**").

In particular, the ICMR-GARDP Collaboration may potentially include the following activities:

(a) Support by ICMR of the establishment of clinical trial sites in India with the capacity to undertake controlled/protocol regulated trials for serious bacterial infections in adults and children, with prior informed consent of the adults and parent(s)/guardian(s) of the children involved in the clinical trials. Support may include providing technical expertise, staff and training programmes and making effort to facilitate funding from Indian sources. ICMR may also support and enable product registration and stewardship strategies to allow responsible and sustainable access to new treatments.

(b) GARDP may seek to identify new treatments including via co-development agreements with public and private partners and provide technical expertise through its international network to deliver those new treatments for bacterial infections in adults and children of public health interest to India. This may include involvement in the design and conduct of epidemiological, observational and interventional studies to determine the needs, efficacy and safety of new treatments, and participation in appropriate collaborations seeking to enable global registration and sustainable access for suitable candidates.

1.2. This MoU is non-binding but provides the framework for the Parties to discuss opportunities to collaborate on specific projects (the "**Projects**" and each a "**Project**") that align with their common interests to maximise the potential for impact in the AMR field. All Projects shall be the subject of separate legally binding agreements that will provide for the rights and obligations of each Party and the terms for funding and implementation of the Project, as well as provisions regarding Intellectual Property which may be generated under such Projects. In case of conflict between a Project agreement and this MoU, solely the terms of the Project agreement are binding and shall prevail.

2. General Principles and Modalities of Operation

2.1. Each Party shall identify one permanent nominee/point of contact (hereinafter referred to as the '**Nominee**') who shall organise strategic meetings with relevant participation from both Parties to be held as required to exchange on programmes of mutual interest in antimicrobial drug development, discuss potential Project opportunities, and facilitate a written binding agreement for new Projects.

2.2. ICMR and GARDP agree that the Nominee will help ensure that each Party supports and encourages the Collaboration and any agreed Projects. Additional meetings or discussions may be coordinated by the Nominees as necessary as the Collaboration evolves.

2.3. It is the intent of ICMR to provide information and advice to GARDP wherever possible in all matters within its scope of competence. ICMR shall continue to have the opportunity to recommend an expert as candidate for potential election to GARDP's Scientific Advisory Committee.

2.4. GARDP recognises that ICMR's extensive networks and institutes can be a source of important technical assistance for clinical and scientific research programmes for GARDP.

2.5. Each Party may assist the other Party in terms of supporting clinical development programmes, joint site feasibility and selection assessments, clinical and microbiology surveillance and supportive research, capability training, regulatory and ethical approval support, study, site and project management approaches and tools, and identifying and assessing patients' needs.

3. Funding and Resources

3.1. The ICMR-GARDP Collaboration may include establishing a strategy and modalities for financial and in-kind contributions by both Parties to ensure the success of the joint objectives. Funding may be provided directly to the other Party or to third parties engaged in Projects. All financial and in-kind contributions will be the subject of separate legally binding agreements.

4. Communication and Advocacy Activities

4.1. The Parties may cooperate as relevant to optimise each Party's advocacy activity for antimicrobial research as well as to generate public support for innovative drug research.

4.2. The Parties will actively work together to promote the ICMR- GARDP Collaboration and highlight the contributions made by each Party. In order to ensure positive and effective public communications with respect to the ICMR- GARDP Collaboration, modalities for promotion (including agreement on media channels together with appropriate use of each Party's brand and logo, with prior written consent of each Party) will be agreed as part of the regular meetings established pursuant to paragraph 2.1 above. The use of the name, logo and/or official emblem of the Parties on any publication, document and/or paper shall require prior written permission of both Parties. Each Party acknowledges the status of the other Party (ICMR as medical research council established by government and GARDP as a not-for-profit entity with public health objectives) and will not use the other Party's brand and logo in any manner that could compromise the other Party's objectives and mission.

5. Data Sharing and Scientific Publications

5.1. Wherever appropriate the Parties will, in accordance with their respective mission statements, and subject to any requirements for confidentiality or third party rights, encourage scientific publications. Any publication prepared as part of joint work conducted by the Parties pursuant to this MoU will recognize each Party's contribution.

6. Intellectual Property

6.1. The Parties acknowledge that they have aligned interests in ensuring the appropriate use of intellectual property relevant to the combat of AMR including for the benefit of the people of India, and for work in the public sphere. For this purpose, during the Term of this MoU, as defined under Clause 14 of this MOU, the Parties will explore possibilities for mutually beneficial sharing of relevant intellectual property on terms to be agreed, in writing. In particular, the Parties shall seek to ensure that intellectual property developed pursuant to collaborative Projects entered into under this MoU using Indian public funds is protected, managed and commercialised so as to benefit in particular patient populations in India.

The Parties agree that ownership of intellectual property arising out of Projects will take into account contributions made by a Party and other third parties related rights. Subject to paragraph 6.3 and the terms and conditions of each specific Project agreement, it is understood by the Parties that, wherever possible and appropriate, joint ownership of intellectual property and inventions generated through commonly undertaken program should be the principle.

6.2. The Parties shall ensure, as part of each Project agreement, appropriate protection of intellectual property rights generated from cooperation pursuant to MoU, consistent with their respective laws rules and regulations and multilateral agreements to which countries of the Parties are party to.

6.3. Notwithstanding paragraph 6.1 above, nothing in this MoU will be construed as a transfer or grant to the other of any of the Parties' intellectual property rights and interests, unless specifically agreed upon in writing by the Parties. Furthermore, the Parties acknowledge that third party rights may influence or restrict any future agreements for sharing or generating intellectual property.

7. Confidentiality

7.1. Parties shall maintain confidentiality regarding the information shared under this MOU and under Projects that will be undertaken and governed by Project specific Agreements. The Parties will not use the information for purposes other than that specified without the prior written consent of the other Party.

7.2. All confidential information shall remain the exclusive property of the disclosing Party. The Parties agree that the sharing of confidential information does not grant or imply and licence, interest or right to the recipient in respect to any intellectual property right of the other Party.

8. Non exclusivity

8.1. The Parties agree that this relationship is not exclusive and that entering into this MOU will not prevent either Party from associating with any other third party for the purpose of similar cooperation.

9. Amendment

9.1. This MOU may be amended in writing at any time by mutual consent of the Parties.

10. Nature of this MOU

10.1. The Parties agree to understand that this MOU shall not create or give rise to any legally binding rights or obligations. Any dispute concerning the interpretation, implementation or application of this MOU shall be settled amicably between the Parties.

11. Neonatal Sepsis Initial Collaboration

11.1. The terms of the Neonatal Sepsis Initial Collaboration remain unchanged by this MoU.

12. Independence of Parties

12.1. No Party shall have any authority to act for or bind the other Party in any way, or to represent that it has such authority. Nothing in this MoU shall be deemed to create an employer-employee, agency relationship or joint venture between the Parties.

12.2. Each Party shall be solely responsible for the conduct of its officials, employees and any consultants or subcontractors it may engage in relation to activities it may pursue within the framework of the ICMR-GARDP Collaboration. A Party is neither responsible nor liable for any action, omission, negligence or misconduct of the other Party's officials, employees, consultants or subcontractors, nor for any insurance coverage for such aforementioned persons or entities, nor for any costs, expenses or claims associated with any illness, injury,

disability, death or other claims of any nature (including claims for taxes, social security or pension contributions, or similar) of aforementioned persons or entities.

13. Compliance with Laws and Ethical Standards

13.1. Each Party will comply with all laws, regulations and guidelines applicable to it. Disputes, if any, between the Parties may be resolved amicably and if required as per law prevailing in India, without reference to its conflict of laws provisions..

13.2. The Parties agree that all activities carried out pursuant to this MOU must be executed in accordance with the highest possible ethical standards. Fraud and misconduct will not be tolerated by either Party.

13.3. Each Party warrants for itself that no official or employee of the other Party, directly or indirectly, has received or will be offered any personal benefit arising from the execution of this MOU or activities that may be carried out in relation thereto.

13.4. Both Parties acknowledge the importance of the protection of human and animal subjects in any health program. Matters related to the transfer of biological material and research projects should receive prior approval on each side according to the existing rules and regulations applicable to each Party.

14. Term and Termination

14.1. This MOU comes into force on the date of its signing by both Parties and shall continue for a period of five years (hereinafter referred to as the 'Term'). This MOU shall be renewed for successive five-year terms subject to mutual written consent of the Parties.

14.2. Either Party may terminate this MOU with six months prior written notice. Termination of this MOU shall not terminate any other agreement between the Parties unless specifically stated.

14.3. The termination of this MoU shall not absolve the Parties from the obligation undertaken in para 7 of this MoU.

IN WITNESS WHEREOF, GARDP and ICMR hereto have caused this MOU to be duly executed on their behalf by their representatives

Authorized Representative
GARDP Foundation

Signature: 

Name: Dr Manica Balasegaram

Title: Executive Director

Date: 12/4/2021

Authorised Representative
INDIAN COUNCIL OF MEDICAL RESEARCH

Signature:

Name: Prof Dr Balram Bhargava

Title: Director General

Date: 31/3/2021