

MEMORANDUM OF UNDERSTANDING

THIS Memorandum of Understanding (MOU) made and entered into on this 14th day of May Two Thousand Nineteen [2019] by and between:-

Council of Scientific and Industrial Research (CSIR), a Society registered under the Societies Registration Act (XXI of 1860), having its registered office at Anusandhan Bhavan, 2, Rafi Marg, New Delhi – 110 001 through its constituent laboratory **CSIR-Institute of Microbial Technology**, Sector 39A, Chandigarh 160036 (herein after, referred to as "CSIR-IMTECH"), which expression shall where the context so admits include its successors and permitted assigns) of the one part

And

Institute of Liver and Biliary Sciences, an autonomous institute under Government of National Capital Territory of Delhi (A-Deemed-to-be-University) having its registered office at D-1, Vasant Kunj, New Delhi 110070, India (hereinafter, referred to as "ILBS"); which expression shall where the context so admits include its successors and permitted assigns)

(**CSIR-IMTECH** and **ILBS** are wherever the context so requires, hereinafter, collectively referred to as "the Parties" and individually as "Party")

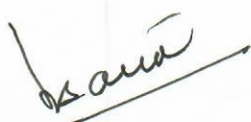
PURPOSE

This Memorandum of Understanding ("MOU") and Annexure(s) herein sets out the mutual understanding and intention of the Parties to collaborate in "**Development of Gut Microbiome Consortia for management of Severe Alcoholic Hepatitis (SAH)**" ("The Collaboration")

BACKGROUND

WHEREAS, it is imperative to state that in the last decade, there have been intensive and sustained efforts in understanding the role of gut microbiota in various disease mechanisms and explore their potential as therapeutics. Most liver related deaths in India are caused by consumption of alcohol and the gut microbiota has emerged as one of the most prominent modifiable factors in disease progression.

WHEREAS, CSIR- IMTECH is a premier R&D lab in the area of microbiology and biotechnology, proposes to establish itself as a 'Centre of Excellence for Microbiome Research' to cater to the needs of human microbiome research in healthcare through high-end technology platforms.



WHEREAS, CSIR-IMTECH's Microbial Type Culture Collection (MTCC) division has the necessary expertise, competence and experience in different areas of microbiome research important for the collaboration such as culturomics, metagenomics, whole cell genomics, metabolomics, antimicrobial resistance, big data analysis and cell biology.

WHEREAS, ILBS is a premier institute established for specialized healthcare in liver and biliary disorders and has the largest liver set-up for treating in Asia. ILBS has done pioneering work in undertaking the first human trials in patients with severe alcoholic hepatitis and has a large stool bank consisting of nearly 600 healthy donors as well as patients with various liver diseases.

WHEREAS, CSIR-IMTECH, on behalf of the Ministry of Science and Technology and the Government of India is collaborating with ILBS for developing a clinical, translational and basic biology hub in the field of modulation of gut microbial flora for the management of patients with severe alcoholic liver disease.

Now therefore, in consideration of the premises and mutual covenants hereinafter contained the parties hereto agree as follows:-

Clause I.SCOPE OF INTENDED COLLABORATION

It is understood between the Parties that this MOU signed for "**Development of Gut Microbiome Consortia for management of Severe Alcoholic Hepatitis (SAH)**" would set out the detailed structure of the collaboration, scope of work and other terms and conditions as described in this document.

The main objectives of this Collaboration are:-

- Identification of the core microbial consortia based on available donor-recipient pair and related family members of patients with severe alcoholic hepatitis.
- High-throughput culturomics and meta-genomics to understand the microbiome structure-function of healthy donor fecal samples for FMT (Fecal Microbiota Transplant).
- Defining the most appropriate route and mode [capsule formulations versus fresh preparations], the dose and the duration of FMT therapy.
- Examining the efficacy of the microbial consortia in animal models.
- Formulation and clinical testing of the final microbial consortium with the potential for altering the gut dysbiosis due to alcoholic hepatitis, based on the results from the above objectives.
- To discuss any other related scientific issue emerging during the course of the studies.



Clause II. RESPONSIBILITIES OF ILBS

- ILBS shall provide faecal bank samples stored at its facility for microbiome analysis/storage to CSIR-IMTECH.
- ILBS shall be responsible for conducting clinical trials & obtain requisite ethical clearances for conducting clinical trials.
- ILBS shall allow research personnel of CSIR-IMTECH to visit its labs for sample collection and usage of their equipment's/facilities for research purposes within the scope of the collaboration.

Clause III. RESPONSIBILITIES OF CSIR-IMTECH

- CSIR-IMTECH shall provide the required space/facilities/equipment's as per institute's policy to the research personnel of ILBS for undertaking work pertaining to the collaboration.
- CSIR-IMTECH shall arrange for manpower/logistics for transporting the faecal samples from ILBS, New Delhi during the tenure of the project.
- CSIR-IMTECH shall take responsibility for obtaining ethical clearance before processing fecal samples for research purpose under the scope of collaboration.
- CSIR-IMTECH shall provide the microbes/consortia isolated from the faecal samples to ILBS for achieving the objectives of the collaboration.
- CSIR-IMTECH shall facilitate for formulation of the selected microbial consortia in a capsule format for conduct of clinical trials.
- CSIR-IMTECH shall deposit the microbial cultures isolated from the faecal samples at MTCC and would be accessible to research personnel of ILBS for purposes within the scope of collaboration.
- CSIR-IMTECH shall provide full access to ILBS scientists for microbial isolates stored at MTCC deposited under the collaboration for future research and development. Publications and patents arising out of such investigations would incorporate names of investigators of both parties based upon mutual understanding and best international practices.

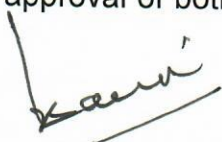


Clause IV.FINANCIAL ARRANGEMENTS

- For the work to be done as per the scope of collaboration, CSIR-IMTECH & ILBS shall explore various funding sources including CSIR for achieving the desired objectives.

Clause V. CONFIDENTIALITY, PUBLICATIONS AND INTELLECTUAL PROPERTY RIGHTS

- Each Party hereby undertake to observe the secrecy of confidential information received from or supplied to the other party during the period and for the purpose of implementation of this MOU or any other agreement's made pursuant to this MOU.
- For the purposes of this MOU, "confidential information" means any information whether prior to or hereinafter, disclosed by a party (the disclosing party) to the other party (the receiving party) of this MOU involving technical, business, marketing, policy, knowhow, planning, project management and other information, data and/or solutions in any form, including but not limited to any information which is designated in writing to be confidential or by its nature intended to be for the knowledge of the Receiving Party or if orally given, is given in the circumstances of confidence.
- The Parties agree that the provisions of this clause shall continue to be binding between the parties notwithstanding the termination of this MOU.
- Parties agree that any intellectual property pertaining to the products or know-how owned by Parties prior to effective date of the MOU shall remain the property of the respective Parties.
- If any, Intellectual Property(IP) that is [knowhow/ process/ design/ technique/ patents/ products/ copyrights] generated during the course of collaboration, it shall be jointly owned by ILBS and CSIR-IMTECH; the extant of ownership shall be decided mutually depending upon the relative inputs(Intellectual/technical/financial/physical/clinical/microbial) made by the parties hereto for the collaboration.
- If any results are obtained during the course of collaboration that has a commercial value attached to it and is not patentable, their terms and conditions would be addressed via separate MoU(s) based on input assessment.
- Any publication pertaining to the results of collaboration, their credit and affiliations will be jointly shared between CSIR-IMTECH and ILBS as per mutually agreed terms.
- Where both ILBS and CSIR-IMTECH agree to write a joint publication or where either party wishes to publish the results of their collaboration, such publication shall be subject to the approval of both parties not to be unreasonably withheld and shall



in no event include either party's business or trade secrets or any other Confidential Information that would enable competitors to confer an advantage.

- However, during the tenure of the MOU and 5 years thereafter both parties undertake on their behalf and on behalf of their subcontractors/ employees/ representatives/ associates to maintain strict confidentiality and prevent disclosure thereof, of all the information and data exchanged/ generated pertaining to work under this MOU for any purposes other than in accordance with this MOU.

Clause VI. EFFECTIVE DATE, DURATION, COMPLETION, RENEWAL, TERMINATION OF THE ASSIGNMENT

- The MOU shall be effective from the date of signing of this MOU and shall remain in force for a period of three years from the date of its signing.
- This MOU could however be extended to such further periods as may be mutually agreed to in writing by the parties, between the parties without any liability on the part of CSIR-IMTECH.
- During the tenure of the MOU, parties hereto can terminate the MOU either for violation of any of the clause of the MOU or other work by giving one month's advance notice in writing to the defaulting party. Failure of either party to terminate the MOU on account of breach of default by the other shall not constitute of waiver of that party's right to terminate this MOU.
- In the event of termination of the MOU vide (Clause VIc) the rights and obligations of the parties hereto shall be settled by mutual decisions, the financial settlement shall take into consideration not only the expenditure incurred but also the expenditure committed by CSIR-IMTECH.

Clause VII. GENERAL PROVISIONS

CSIR-IMTECH, shall not be responsible for any damage to property/ plant/ material/ personnel of ILBS or loss to ILBS during the course of or consequent to jobs taken up under this MOU. The provisions of this MOU shall be deemed severable, and the invalidity or unenforceability of anyone or more of the provisions hereof shall not affect the validity or enforceability of the other provisions hereof.

ILBS shall not be responsible for any damage to property/ plant/ material/ personnel of CSIR-IMTECH or loss to CSIR-IMTECH during the course of or consequent to jobs taken up under this MOU. The provisions of this MOU shall be deemed severable, and the invalidity or unenforceability of anyone or more of the provisions hereof shall not affect the validity or enforceability of the other provisions hereof.

At a time to be mutually agreed upon by the Parties each may issue a press release and make public statements regarding the MOU collaboration, the content of which will be subject to the good faith agreement, which will not unreasonably be withheld or delayed.



Except as provided in this MOU, or to the extent otherwise required by applicable law, no Party will issue any press release or promotional material, hold any press conference or make any public announcement concerning this MOU, the relationship of the Parties hereunder without obtaining the written approval of the other Parties.

Unless otherwise agreed to, all information-sharing between the Parties described in this MOU will flow between these points of contact. The Parties agree to share a contact list with their point of contact for implementation of this MOU, and to notify the Parties of any changes to their points of contact as soon as practicable.

Each Party shall bear its own costs in relation to the negotiations and other tasks contemplated in this MOU, including any costs related to experts, consultants and lawyers or travel expenses.

This MOU may be executed in any number of counterparts, each of which, when executed and delivered, shall be deemed an original, but all of which shall constitute one and the same instrument. Delivery of an executed counterpart by facsimile transmission or by email delivery in portable document format (PDF) shall be equally effective as delivery of a manually executed counterpart thereof. Any Party delivering an executed counterpart of this MOU by facsimile or PDF shall also deliver one manually executed counterpart thereof, but failure to do so shall not affect the validity, enforceability or binding effect of this MOU.

Clause VIII. FORCE MAJEURE

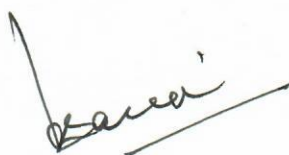
Neither party shall be held responsible for non-fulfillment of their respective obligations under this MOU due to the exigency of one or more of the force majeure events such as but not limited to Acts of God, war, flood, earthquakes, strike, lockouts, epidemics, riots, civil commotion, etc. provided on the occurrence and cessation of any such events, the party affected thereby shall give a notice in writing to the other party within one month of such occurrence or cessation. If the force-majeure conditions continue beyond six months, the parties shall then mutually decide about the future course of action.

Clause IX. NOTICES

All notices and other communications required to be served on the PARTY under the terms of this MOU shall be considered to be duly served if the same shall have been delivered to left with or posted by registered mail to the PARTY at its last known address of business. Similarly, any notice to be given to the CSIR shall be considered as duly served if the same shall have been delivered to, left with or posted by registered mail to the CSIR at its registered address in New Delhi.

Clause X. AMENDMENTS TO THE MOU

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



Clause XI. GOVERNING LAW & ARBITRATION

All disputes and differences arising out of, or in any way, concerning this agreement (except those, the decision whereof is otherwise, hereinbefore provided for) shall be referred for sole arbitration by any person to be nominated jointly by the Director, ILBS & Director, IMTECH. The award of the arbitrator so appointed shall be final and binding on both the parties. The existence of any dispute(s) or difference(s) or the initiation or continuance of the arbitration proceedings shall not permit the Parties to postpone or delay the performance by the parties of their respective obligations pursuant to this agreement. The venue of the arbitration shall be New Delhi, India.

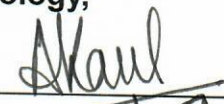
Clause XII. JURISDICTION

Notwithstanding any other court or courts having jurisdiction to decide the question(s) forming the subject matter of the reference if the same had been the subject matter of a suit, any and all actions and proceeding arising out of or relative to the agreement (including any arbitration in terms thereof) shall lie only in the Court of Competent Civil jurisdiction in this behalf at Delhi/New Delhi and only the said Court(s) shall have jurisdiction to entertain and try any such action(s) and/or proceeding(s) to the exclusion of all other Courts.

SEAL OF PARTIES

In witness whereof the parties hereto have signed this MOU, in two originals on the day, month and year mentioned hereinbefore.

Agreed and accepted on behalf of
CSIR- Institute of Microbial Technology,



Name: DR. ANIL KOUL
Title: DIRECTOR, CSIR-IMTECH
Date: 14 May 2019

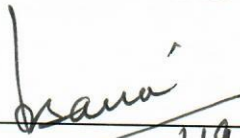
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Witness:

1. MANUJ TRIPATHI 
2. Rashmi Kumar 

Agreed and accepted on behalf of
Institute of Liver and Biliary Sciences,



Name: DR. SHIV KUMAR SARIN
Title: DIRECTOR, ILBS
Date: 14 May 2019

Institute of Liver and Biliary Sciences
Sector D-1, Vasant Kunj
Seal New Delhi-110 070

Witness:

1. Vijay Kumar 
14/5/2019
2. Nishu 
14/5/2019

ANNEXURE - I**PROJECT SCOPE OF WORK**

	Objectives	Timeline (In months)
Phase - 1	Determination of route of administration and best possible Fecal microbiota transplant protocol	1-12
	Identification of healthy donors	

	Objectives	Timeline (In months)
Phase- 2	Comparison of Encapsulated FMT vs Liquid FMT	13-36
	Determining FBC and MBC	
	Determination of Route of Administration of Minimal Bacterial Consortium (MBC) and Encapsulation	
	Comparison of Liquid FMT with Encapsulated Minimal Bacterial Consortium (MBC)	