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MEMORANDUM OF UNDERSTANDING

Between

MGM MEDICAL COLLEGE & HOSPITAL
(CONSTITUENT UNIT OF MGMIHS)

Sector 1, Kamothe, Navi Mumbai-410209,


Tel.No 022-27432471,022-27432994,Email.mgmmcnb@gmail.com Website: www.mgmuhs.com

AND

MORE-YA BIOSCIENCES Limited Liability Company(LLP)

Sr.No.71/72,Sneh Park Co.op.Hsg.Society


Baner, Pune, Maharashtra 411045


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M.G.M. Medical College & Hospital
Kamothe, Navi Mumbai - 410209



This Memorandum of Understanding (“MOU”) made on this 3rd of August, 2020 by and between the **Mahatma Gandhi Mission Institute of Health Sciences** through its constituent Institute, MGM Medical College & Hospital (**MGMIHS/MGM Medical College**) having its office at MGM Educational Campus, Sector 1, Kamothe, Navi Mumbai, 410209 and **MORE YA BIOSCIENCES Limited Liability Company(LLP)** having its registered office at Sr.No.71/72, Sneh Park Co.op. Hsg. Society, Baner, Pune, Maharashtra 411-045 (hereinafter referred to as the “MYB”) which expression shall, unless it be repugnant to the context or meaning thereof, includes its successors and permitted assigns) of the Second Part. **MGMIHS** and **MYB** each individually and collectively referred to as "Party" and "Parties" respectively herein.

- (A) **Whereas** MGMIHS is a deemed to be University, recognized under the University Grants Commission Act. MGMIHS runs and administers educational institutions and medical colleges in Navi Mumbai and Aurangabad including the Mahatma Gandhi Missions Medical College and Hospital at Kamothe, Navi Mumbai. The aims and objects of MGMIHS are to establish educational institutes and hospital with the required modern facilities and infrastructure, to provide good quality education, medical education/facilities etc to the society and public at large, to help promote education, medical education and provide good quality medical facilities at reasonable rates etc.
- (B) **And Whereas** MYB is a LLP founded and headed by Mr Varunraj More. MYB is a limited liability company registered in India MYB though being a startup company has developed a software by the name “AI Tool” which helps detect and reliably diagnosing COVID-19 cases by use of X-Ray images. The validation process of the said software is required to be done.
- (C) **And Whereas** COVID-19 which began with the reporting of unknown causes of pneumonia in Wuhan, Hubei province of China on December 31, 2019, has rapidly become a pandemic. This new virus spread from Wuhan to most countries in the world by March 2020. The ongoing pandemic is expected to be the most severe pandemic in recent history. The disease is named COVID-19, and the virus is termed SARS-CoV-2.


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(D) **And Whereas** India has seen more than 15,00,000 confirmed cases and more than 34,000 deaths from this disease as of July 29, 2020. This virus's name SARS-CoV2 describes its most common symptom: "**Severe Acute Respiratory Syndrome,**" where patients' lungs are usually the first to suffer damage. The typical clinical features of COVID-19 include fever, cough, sore throat, headache, fatigue, muscle pain, and shortness of breath. The most accurate test for COVID-19 is a real-time reverse transcription-polymerase chain reaction (RT-PCR). However, its use is limited by low availability, high costs, and longer delays in getting the diagnosis. Chest radiological imaging such as computed tomography (CT) and X-ray have vital roles in early diagnosis and treatment of this disease. The Chest radiological imaging method if validated and used will serve as an cost effective alternative to the other test, help in early detection and prevention of damage to the lungs.

(E) **And Whereas** MYB has developed an **AI tool** in reliably diagnosing COVID-19 cases by use of X-Ray images. MYB is looking to collaborating/associating itself with reputed universities, institutes having the required infrastructure, facilities and know how to validate the AI tool. MYB has requested MGMIHS to *validate the software tool.*

(F) **And Whereas** MGMIHS is a reputed institute having the required facilities, infrastructure etc and has been in and associated with the medical field and medical research. MYB has approached MGMIHS, through the MGM Medical College and Hospital with a request to validate the AI tool at the MGM Medical College and Hospital with the help of the retrospective data available with the MGM Medical College and Hospital Kamothe navi Mumbai.

(G) **Whereas** the parties propose to undertake the validation process of the AI Tool with the help of the Chest radiological imaging of X-ray of patients affected with the COVID 19 virus. *Under the MOU , MGMIHS through the MGMMCH will validate the "AI tool" developed by MYB in reliably diagnosing COVID-19 cases by use of X-Ray images. The parties propose to use the X-Ray images available with the MGM Medical College and Hospital, Navi Mumbai (the retrospective data).*

(H) **And Whereas** pursuant to various meetings and discussions the MGMIHS and MYB have agreed to execute and enter in this MOU with a objective to spell out and define the scope of work, duties, responsibilities etc of both the parties and specific role of each party in testing, developing and validating the AI tool developed by MYB and the work to be undertaken in respect thereof in the future.


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NOW THEREFORE THESE PRESENTS WITNESSETH AND IT IS AGREED BY AND BETWEEN THE PARTIES HERETO AS FOLLOWS:

1. SCOPE, OBJECTIVES AND BENEFITS OF MOU:

- (a) The MGM Medical College and Hospital Navi Mumbai will test and validate the AI tool developed by MYB, in reliably diagnosing COVID-19 cases by use of X-Ray images (the retrospective data) from the MGM Medical College and Hospital, Navi Mumbai and the MGM College and Hospital Aurangabad. MGMIHS will validate the software developed by MYB. The validation will be in the form of A Performa (Annexure 1 hereto) which has been approved in the Ethics committee. Further the parties agree and accept that MGMIHS can utilize the validation/ soft ware for patients diagnosis, for academic, research and publication purposes etc.
- (b) The parties agree and accept that the MOU, will able MYB to gets its AI Tool software validated from MGMIHS and MYB may provide access at the discretion of MYB to MGMIHS to use the software for its research purposes, hospitals and patients diagnosis etc.


2. TERMS AND CONDITIONS OF THE MOU AND TERMINATION:-

- (a) The MOU is for a period of -5 /years. The parties may renew/extend the MOU for a further period upon such terms and conditions which are mutually agreeable to the parties.
- (b) **Termination:** Either party shall have the right to terminate the MoU by giving a 30 days (notice period) notice to the other party. Once the termination notice is given no activity will be conducted by and between the parties.

3. Responsibilities/Duties/Obligations of Parties :

(A) Responsibility of MGM Medical College & Hospital, Navi Mumbai:

- (i) MGM Medical College & Hospital will provide data (retrospective data) of covid-19 patients which will be collected from the patient's medical record. The same will include basic demography data, clinical data-symptoms, any signs of lung involvement on auscultations, SPO2, Standard X-Ray chest obtained as per the site operating procedure to ensure data collection and Site radiologist report and the RT PCR reports.


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Navi Mumbai - 410206



(ii) Data collection will be the responsibility of the investigating team of MGMIHS. The Investigating team consists of the Principal investigator and the Co-investigators of the MGM Medical College & Hospital of MGMIHS. The investigators will be responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported. All source documents will be completed in a neat, legible manner to ensure accurate interpretation of data. Hardcopies of the study visit worksheets will be provided for use as source document worksheets for recording data.


(iii) The Clinical data will be entered into the MYB supported web based data platform. The data system includes password protection and internal quality checks, such as automatic range checks to identify data that appear inconsistent, incomplete, or inaccurate. The clinical data will be entered directly from the source documents. Investigating team of MGM will enter the data.

(iv) To compare the accuracy of COV-Ai tool vs site radiologist vs. blinded independent radiologist to classify COVID-19 related lung involvement correctly.

(v) To assess the accuracy of COV-Ai tool to classify COVID-19 related lung involvement in various patient subgroups based on triaging in the hospital. MGM will validate the soft ware too depending on the various levels of Covid 19 i.e patients will be divided according to their severity so the tool will validate it for the various levels of severity.

(B) Responsibilities of MORE-YA BIOSCIENCES :-

- (i) MYB will provide the software COV-Artificial intelligence-based tool (COV-Ai) to predict COVID-19 related lung involvement.
- (ii) To assess the accuracy of COV-Ai to classify COVID19 related lung involvement in suspected cases.
- (iii) To assess the accuracy of COV-Ai in patients with laboratory-confirmed COVID-19 infection.


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(C) Responsibilities of both the Parties:

Confidentiality/secretcy

- (i) The confidentiality and privacy of the data of the Covid-19 patients will be strictly held in trust by the parties, the participating investigators, the staff of both the parties and all participants or people involved in the project.
- (ii) The data collected under this project or the data used under this project shall be the property of the MGMIHS and the same ought to be kept confidential by the parties. The parties shall be bound by the terms of confidentiality in respect of all the data (main or incidental) to the studies under this MOU or studies under this MOU. MYB agrees and undertakes not to use the data for any other purpose whatsoever.

All case report forms and other data (including without limitation, written, printed, graphic, video and audio material, and information contained in any computer data base or computer readable form) generated by the Study Site in the course of conducting the Study (the "Data") shall be the property of the study sponsor, which may utilize the Data in any way it deems appropriate, subject to and in accordance with applicable privacy laws. Any copyrightable work created in connection with performance of the Study and contained in the Data (except any publication by the Principal investigator) shall be property of the study sponsor

- (iii) The parties agree and undertake to hold in strict confidence the data that could be used to identify a specific study participant within the research team.
- (iv) The parties agree that no personally identifiable information from the study or any document used during the study will be released to any unauthorized third party. Release if required for the purpose of the study shall be made after receiving written approval and prior consent of both the parties. The parties agree and undertake that all the research activities, work will be carried out/conducted in MGM Hospital, Kamothe, Navi Mumbai & MGM Hospital Aurangabad. The same shall be a private and confidential set up. Any deviation or relaxation as regards the confidentiality clause or any matter affecting (directly or indirectly) the confidentiality shall need the prior written approval of the MGM Ethical Committee.
- (v) The parties agree and undertake that the study participant's contact information will be securely stored at each clinical site for internal use during the study. The same shall be under the control and in the custody of Electronic Data Processing (EDP) section of MGM.

4. **Fees:** MGMIHS has agreed to do the validation without charging any fees and considers the same as a contribution of MGMIHS towards the fight against COVID-19 pandemic.

5. **General Conditions :**

- (i) There will be quarterly meetings between the parties to audit the work to ensure that the aims and objects of the MOU are met and the issues/ difficulties if any are addressed. A report of the meetings shall be filed with the Scientific Advisory Committee (SAC) of the MGM Hospital Navi Mumbai and MGM Hospital Aurangabad. The decision of the committee in respect thereof shall be final and binding.
- (ii) **Data/Records:-**At the end of the study, all data and records will be kept/stored in a secure location i.e Electronic Data Processing (EDP) section of MGM. The data will be stored for a period of 5 years and shall be under the review of the Scientific Advisory Committee.
- (iii) The study documents will be retained for a minimum of 2 years or until at least 2 years have elapsed since the formal discontinuation of clinical development of the study intervention. The said documents shall be retained by and in custody of MGMIHS. The parties agree that no records/data will be destroyed without the written consent of both the parties.
- (iv) **Protocol deviations:** The parties agree that it shall be the responsibility of the Principal investigator to use continuous vigilance to identify and report protocol deviations within 7 working days of identification of the protocol deviation. The deviations if any from the planned protocol, shall be placed before the Ethics committee of MGMIHS. If any adverse effects are noticed the adverse effects need to be informed to the Ethics committee for research on human subjects. The decision of the Ethics Committee shall be final.
- (v) All deviations will be addressed in study source Documents/protocol.
- (vi) **Publication and data sharing policy:** The parties agree that all publication shall be a joint publication and due weightage shall be given to both the parties.
- (vii) The data collected from the MGM Hospital of Navi Mumbai, will be the sole property of the MGMIHS. At the end of the study, one or more manuscripts for joint publication may be prepared in collaboration between the Investigator(s) MGMIHS and the MYB.

- (viii) Any publication of results must acknowledge all sites/centers, this being the multicentre project. The other site/center being MGM Medical Hospital Aurangabad. The results from other site must be reported in entirety in a responsible and coherent manner and results from subsets should not be published in advance or without clear reference to the primary publication of the entire study.
- (ix) The parties agree and accept that MGMIHS and MYB have the right to publish data of the study independently. MGMIHS will include name of MYB in its publications and MYB will include the name of MGMIHS in their publication.
- (x) If the matter considered for publication is deemed patentable by the MYB due weightage should be given to MGMIHS the name of MGMIHS will be in the Patent as a co-investigator however they will not share any revenue with MGMIHS as it a soft wear that has been put together by MYB , MGMIHS is only validating. The soft wear MYB will give the soft wear free for use to MGM Group Of Hospitals for covid -19 Patient diagnosis.
- (xi) MGMIHS retains its ownership of the data related with patients of Covid19 for the use by MGMIHS stake holders for the research and other purposes.

6. NOTICES

Any notices given under this Agreement will be in writing and delivered by e-mail or speed post or by hand addressed to the parties as follows:

MGMIHS:-

Address: Sector 1, Kamothe Navi Mumbai-410209, Tel No: 022-27432471 / 27432994
Fax: 022-27431094
Email: mgmuniversity@mgmuhs.com / mgmuniversity@yahoo.co.in

MORE-YA BIOSCIENCES

Director of More-YaBiosciences.
Sr.No.71/72, Sneh Park Co-operative Hsg.Society, Baner, Pune,
Maharashtra - 411045, INDIA,
TEL.: 9890765555 E-MAIL: vgore@more-ya.com

7. MISCELLANEOUS

a) Assignment

Neither party may assign this MOU or the rights their under without the prior written consent of the other party.

b) Severability

If any provision of this MOU becomes or is declared illegal, invalid, or unenforceable, such provision will be divisible from this MOU and will be deemed to be deleted from this MOU. If such deletion substantially alters the basis of this MOU, the parties will negotiate in good faith to amend the provisions of this MOU to give effect to the original intent/object of the parties under this MOU.

c) Order of Precedence.

In the event of any inconsistency between the terms of this MOU and the documents referenced or incorporated herein or any other document, correspondence or MOU concerning this Project between the Parties and/or their employees, the terms of this MOU will prevail.

d) Entirety.

This MOU represents the entire agreement and understanding between the parties with respect to its subject matter and supersedes any prior and/or contemporaneous discussions, representations, or agreements, whether written or oral, of the parties regarding this subject matter.

e) Amendments.

The Amendments or changes to this MOU must be in writing and signed by duly authorized representatives of both the parties. 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 agreement. The modification/changes shall be effective from the date on which they are made / executed unless otherwise agreed to.



f) Independent Entities.

MGMIHS and MYB are independent parties and neither is an agent, joint venture partners, or partner of the other.

g) Dispute Resolution.


In event of dispute or claim between the parties concerning the interpretation of any provision of this agreement or the performance of any of the terms/obligations of/under this Agreement, such matter or matters in dispute shall be first settled amicably by mutual discussion between the Vice Chancellor / Registrar of MGMIHS and MYB failing which through the Arbitration process. Both the parties after due discussion shall appoint an Arbitrator for resolving the dispute arising out of this Agreement. The Arbitration shall take place in Navi Mumbai.

Now, therefore, for and in consideration of the foregoing premises the parties have signed the Memorandum of Understanding on 30th Nov., 2020. **PARTIES**

 Dean	 Director
MGM MEDICAL COLLEGE & HOSPITAL CONSTITUENT UNIT OF MGM Institute Of Health Sciences, (Deemed to be University u/s 3 of UGC Act 1956) Grade "A" Accredited by NAAC Sector 1, Kamothe, Navi Mumbai – 410209	Varun Gore MORE-YA BIOSCIENCES Sr.No.71/72, Sneh Park Co-operative Hsg. Society, Baner, Pune, Maharashtra - 411045. E-mail: vgore@more-ya.com Website: www:more-ya.com


Registrar

MGM Institute of Health Sciences
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