

Memorandum of Understanding

This Agreement is made on 07 Feb 2022, by and between **Clinical Pharmacokinetics & Biopharmaceutics (CPB) Department, Wockhardt Research Center, Wockhardt Limited** having its Office at D-4, MIDC Area, Chikalthana, Aurangabad-431 006 referred as a party- A

And

Mahatma Gandhi Mission (MGM) Medical College & Hospital, N-6, CIDCO, Aurangabad, Maharashtra 431 003 referred as a party-B

The two parties, in a spirit of business cooperation, agree to sign this contract and pledge to fulfill conscientiously all the obligations stipulated in it.

NOW, THEREFORE, in consideration of the promise and mutual covenants herein contained and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, it is mutually covenanted and agreed by and between the parties here to as follows.

MGM Medical College & Hospital signs this agreement with Party for a period of **05 years w. e. f 07 Feb 2022 to 06 Feb 2027. (Will be reviewed and updated accordingly)**

Obligations of Party A:

- Party A is a pharmaceutical company based in Aurangabad that conducts BABE studies in all therapeutic areas.
- Party A is desirous of working with party B for the purpose of obtaining ethic committee approval from MGM's Ethics committee for Research on Human Subjects (MGM-ECRHS) for BABE studies conducted at their site.
- Party A shall submit their proposal to MGM-ECRHS at least 15 days prior to the scheduled EC meeting in the prescribed format.
- Party A shall facilitate monthly postings of students pursuing MD pharmacology, MSc Medical Pharmacology and MSc Clinical Research in MGM Medical College, Aurangabad to acquire practical perspective of theoretical concepts relevant to their domain.
- After obtaining EC approval from MGM-ECRHS, Party A shall notify regarding initiation of the study and shall submit final study update at the end of the study.
- Party A shall perform all trial related activities following ethical principles in strict adherence to ICH- GCP guidelines and Clinical Trial Act 2019.
- Part A shall ensure protocol & applicable regulatory guidelines compliance and adherence.
- Party A shall report all AE/SAEs to MGM-ECRHS within 24 hours. Moreover, the SAEs reported by other centers should also be reported from time to time with comments, if any action is required in the current study.
- Party A shall document any protocol deviation as appropriate and communicate any impacting subject safety to MGM-ECRHS.

- Party A shall also notify premature termination of study with reasons along with.
- Party A shall extend all the co-operation for monitoring the conduct of the study by MGM-ECRHS.

This agreement will last for 05 (five) years and can be renewed further on mutual agreement.

B. Obligations of Party B

- The ethics committee of Party B i.e. MGM-ECRHS is entrusted with the initial review of the proposed research proposals prior to initiation of the projects.
- A **50% discount in EC fees** shall be provided for each submitted protocol and other services related to EC (SAE, Amendment to protocol) which are paid.
- **As per current version of EC SOP, EC fees**
 - For routine review of a protocol – Rs 75,000
 - For expedited review of a protocol - Rs 85,000
 - For Amendment to protocol – Rs 30,000
 - SAE review fees – Rs 30,000
- MGM-ECRHS shall also have a continuing responsibility of regular monitoring of the approved projects to foresee the compliance of the ethics during the period of the project in accordance with the regulatory guidelines wherever applicable.
- MGM-ECRHS members may perform on-site inspection of Party A “for cause” or for a routine audit.
- “For cause” monitoring will be performed, in any of the following conditions:
 - for high number of protocol violations,
 - Remarkable SAE reports,
 - High recruitment rate,
 - Non-compliance or suspicious conduct, and
 - Any other cause as decided by MGM-ECRHS member.

C. Term of Agreement

The term of this Agreement shall be for a period of 05 years commencing on the effective date 07 Feb 2022. However, this Agreement shall be reviewed annually by both parties if needed.

D. Confidentiality


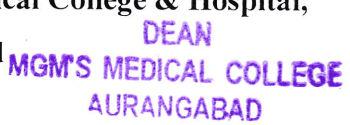

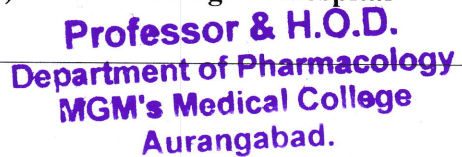
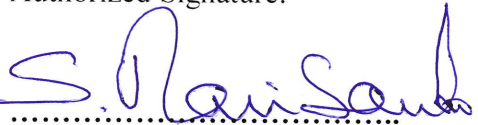
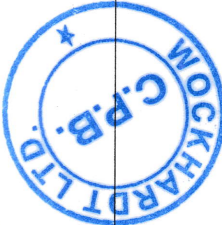
- The parties here recognize and agree that due to the complex and competitive nature of the business, the confidentiality of information concerning both parties is of critical importance. Either party shall not, either during or after the term of this Agreement, disclose to any third

party any confidential information and all Information or information relative to the work or the business of either party without the written consent of either party.

- Party A agrees that it shall not during, or at any time after the termination of this Agreement, directly or indirectly disclose or use any information for any reason whatever, without the prior written consent of party B.
- Party B shall not disclose to any third party any information about new studies received from Party A.

E. Termination of Agreement

This Agreement shall be terminated by mutual agreement by giving sixty (60) days prior written notice by either party after the completion of any ongoing trials.

<p>Authorized Signature:  Name: Dr. Rajendra Bohra Designation: Dean Date:..... Hospital Name: Mahatma Gandhi Mission's (MGM) Medical College & Hospital, Aurangabad </p>	<p>Authorized Signature:  Name: Dr. Deepak Bhosle Designation: Professor & Head, Department of Pharmacology Date:..... Hospital Name: Mahatma Gandhi Mission (MGM) Medical College & Hospital </p>
<p>CPB Dept. Wockhardt Limited Authorized Signature:  Name: Dr. S. Ravisankar Designation: Vice President, CPB department, Wockhardt R & D Date: 07 Feb 2022 Address: CPB department, Wockhardt R & D, D-4, MIDC Area, Chikalthana, Aurangabad-431 006</p> 	



MGMMCHA-WOCKHARDT COLLABORATION



Date : 15/12/2020

ACADEMIA-INDUSTRY COLLABORATION

BETWEEN

MGM-MCH AURANGABAD AND WOCKHARDT RESEARCH CENTER, AURANGABAD

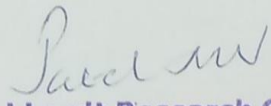
Collaboration activity proposed and initiated by Incharge, CRL-MGM-MCHA (Amol Shindikar)
(through emails, personal visit and telephone)


Architects of collaboration: Senior Vice President – Wockhardt Research Center. (Dr.Sachin Bhagwat) and Incharge, CRL-MGM-MCHA (Amol Shindikar).

Supporters of Collaboration: Dean-MGM-MCHA (Dr.Rajendra Bohra)
Dy.Dean – MGM-MCHA (Dr.Pravin Suryavanshi)
Medical Director –MGM-MCHA (Dr.Ajit Shroff)
Vice Chairman –MGM Trust (Dr.P.M. Jadhav)
Director, ICU and Dept.of Medicine (Dr.Anand Nikalje)

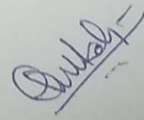
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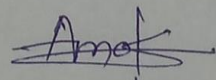
Chief Scientific Officer - Wockhardt Research Center. (Dr.Mahesh Patel).


Wockhardt Research Centre
D-4, MIDC Area, Chikalthana,
Aurangabad-431006.


Wockhardt Research Centre
D-4, MIDC Area, Chikalthana,
Aurangabad-431006.




Dr. Anand Nikalje
M.D. (Medicine)
Associate Professor & Intensivist
MGM Medical College & Hospital A'bad
Reg. No. 67939


Amol V. Shindikar
INCHARGE
CENTRAL RESEARCH LABORATORY,
INCUBATION AND INNOVATION CENTER
MGM's MEDICAL COLLEGE
AND HOSPITAL, AURANGABAD.

Regarding Academia-Industry Collaboration- MGM Medical College and Hospital,Aurangabad-Request for Appointment

Inbox



Central Research Lab Incubation and Innovation Centres <miic@mgmcha.org>

2020, 9:31 PM

to ssbhagwat.bhagwat, sbhagwat, ssbhagwat, PRAVIN, rajbohra, mgmmca, Registrar, dyr

Respected Sir,

Greetings from MGM Medical College and Hospital,Aurangabad.Thanks for giving me your another email ID.

Myself is Amol Shindikar-Incharge - Central Research Laboratory,Incubation and Innovation Center, MGM Medical College and Hospital,Aurangabad. MGM is an reputed and well known organisation across India.

Recently we have established an Central Research Laboratory in MGM-MCHA with great support of MGM trust.

We have state of art laboratory equipped with Cell culture, RT-PCR facility as well as specific pathogen free (SPF) facility for animal expts.Currently our lab is engaged in diagnosis of COVID 19 as well.

Our lab's thrust areas are drug discovery and evelopment , translational research and to study the role of miRNAs in the pathogenesis of various types of diseases.

We are open for signing an Academia-Industry collaboration and work closely with pharma research industry on various projects. Governments funding agencies like ICMR/DBT are willing to support and provide the funds for such projects and collaborations.

Incase Wockhardt Research Center is interested, MGM Medical College and Hospital,Aurangabad is willing to go ahead for the same.

May I request you to give me your appointment so that I can meet you for discussion in person for the same.

Looking forward.

Thanking you in anticipation,
Best regards.

Amol V. Shindikar (9325148181)
(M.Pharm.Pharmacology)
Incharge- Central Research Laboratory,Incubation and Innovation Center,

MGM Medical College and Hospital,Aurangabad.Maharashtra.
MGM Institute of Health Sciences (MGMIHS),
Deemed to be University u/s UGC act 1956,
Kamothe,Navi Mumbai,Maharashtra,.INDIA.

Sachin Bhagwat <sbhagwat@wockhardt.com>

Oct 6, 2020,
12:00 PM

to mgmmca@themegmgroup.com, Mahesh, me, drspravin22@gmail.com, dyr@mgmmcha.org

Dear Amol

Thanks for your mail.

We can discuss the feasibility and scope of potential academia-industry collaboration and for that we need to understand your thoughts on Drug Discovery and Development and Translational Research and the role you envisage for your centre to play in such research work.

We can meet in person at our R &D Centre on coming Friday Oct 9th if fine with you.

Best regards
Sachin S Bhagwat, Ph.D.
Senior Vice President – Drug Discovery Research
Wockhardt Research Center
Aurangabad, India

Central Research Lab Incubation and Innovation Centres <crlic@mgmmcha.org>

Oct 6, 2020,
1:14 PM

to Sachin, drspravin22@gmail.com, mgmmca@themegmgroup.com, dyr@mgmmcha.org, Mah

Dear Dr.Bhagwat,

Greetings.

Thank you very much for your reply and giving me your appointment.I hereby confirm that 9th October would be an absolutely fine date for me to meet you.May I request you to let me know also the time for our meeting so that I can arrange my visit to you accordingly.

Just for introduction, I have attached my CV herewith for your perusal.

Looking forward.

Thanking you once again.

Best regards.

Amol V. Shindikar (9325148181)

(M.Pharm.Pharmacology)

Incharge- Central Research Laboratory, Incubation and Innovation Center,
MGM Medical College and Hospital, Aurangabad, Maharashtra.
MGM Institute of Health Sciences (MGMIHS),
Deemed to be University u/s UGC act 1956,
Kamothe, Navi Mumbai, Maharashtra, INDIA.

Central Research Lab Incubation and Innovation Centres <crlic@mgmcha.org>

10:11 AM

to Sachin, ssbhagwat.bhagwat, PRAVIN, Mahesh, Registrar, dyr, rajbohra, mgmmca

Dear Dr. Bhagwat,

Greetings. (This email is sent again to Dr. Bhagwat sir as he informed me that he has not yet received the same.)

Thank you very much for your reply and giving me your appointment. I hereby confirm that 9th October would be an absolutely fine date for me to meet you. May I request you to let me know also the time for our meeting so that I can arrange my visit to you accordingly.

Just for introduction, I have attached my CV herewith for your perusal.

Looking forward.

Thanking you once again.

Best regards.

Amol V. Shindikar (9325148181)

(M.Pharm.Pharmacology)

Incharge- Central Research Laboratory, Incubation and Innovation Center,
MGM Medical College and Hospital, Aurangabad, Maharashtra.
MGM Institute of Health Sciences (MGMIHS),
Deemed to be University u/s UGC act 1956,
Kamothe, Navi Mumbai, Maharashtra, INDIA.

Sachin Bhagwat <ssbhagwat.bhagwat@gmail.com>

Oct 7, 2020,
10:47 AM

to me, Sachin, PRAVIN, rajbohra, mgmmca, Mahesh, Registrar, dyr

We can meet at 11 am on coming Friday, Oct 9th.

Regards

Sachin Bhagwat

Central Research Lab Incubation and Innovation Centres <crlic@mgmmcha.org>

11:20 AM

to Sachin, Sachin, PRAVIN, rajbohra, mgmmca, Mahesh, Registrar, dyr

Dear Sir,

Sure.I will be there at 11 am on friday.

Thanks and regards.

Amol Shindikar (9325148181)

Central Research Lab Incubation and Innovation Centres <crlic@mgmmcha.org>

3:18 PM

to Sachin, Sachin, PRAVIN, rajbohra, mgmmca, Mahesh, Registrar, dyr

Dear Sachin Sir,

Greetings.

First of all I would like to thank again for giving me your valuable time and listening to my thoughts about collaboration.

Your suggestions, opinions and directives are very much important and valuable for us to develop the research approach in developing antibacterials/antibiotics.We completely agree with you start from small work but with serious and best quality of scientific research.

I am very much overwhelmed for the same.

I have briefed about our meeting to my immediate bosses, Dr.Bohra (Dean) and Dr.Suryawanshi (Dy.Dean and CEO of MCHA and MCRI). Marked them in the CC of email.

As you suggested, we would again meet 15/20 days later alongwith Dean and Dy.Dean sir for detailed discussion. I have informed them about the immediate possible research study of 100 patients, Isolation of microorganisms from secondary infections of COVID 19 patients/ repository and performing efficacy of your compounds on those sample.

Hopefully everything goes well as per our discussion.

Looking forward for long term association with Wockhardt Research Center.

I will keep in touch with you regularly.

Thanking you once again.

Best regards.

Amol Shindikar (9325148181)

Central Research Lab Incubation and Innovation Centres  critic@mgmmcha.org

3:56 PM

to Sachin, Sachin, PRAVIN, rajbohra, mgmmca, Mahesh, Registrar, dyr

Dear Dr. Bhagwat,

Greetings.

Thanks for your todays call.

As you said, I have requested Dr. Suryawanshi to come with me to your research center alongwith a Critical care specialist/Intensivist who is treating the COVID 19 patients. We will be there at your research center at 4 PM on friday.

Keep you posted.

Thanking you,

Best regards.

Amol Shindikar (9325148181)

Central Research Lab Incubation and Innovation Centres  critic@mgmmcha.org

11:10 AM

to anandnikalje, Sachin, Sachin, PRAVIN, rajbohra, mgmmca, Mahesh, Registrar, dyr

Dear Dr. Bhagwat,

Goodmorning and Greetings from MGM-MCHA.

As per our discussion, this is to inform you and confirm again about our tomorrows (friday) scheduled meeting at 4 O'clock at your research center.

Following will be the team from MGM medical college and Hospital visiting and meeting you tomorrow.

- 1) Dean, Dr.Rajendra Bohra.(M.S. E.N.T.)
- 2) Dy.Dean and CEO, Dr.Pravin Suryawanshi (MGM-MCHA and MGM-MCRI) (DNB Surgery-Gastroenterologist)
- 3) Dr.Anand Nikalje (M.D.Medicine) - Intensivist/Incharge- Critical care specialist for COVID 19.

4) Amol Shindikar - Incharge-Central Research Laboratory, Incubation and Innovation Center.

See you tomorrow.

Thanking you,
Best regards.

Amol Shindikar (9325148181)

Central Research Lab Incubation and Innovation Centres qcrlic@mgmmcha.org
10:01 AM

to Sachin, Sachin, PRAVIN, rajbohra, mgmmca, Mahesh, Registrar, dyr, anandnikalje

Dear Dr. Bhagwat,

Good morning.

I would like to thank you and Dr. Patel for Friday's meeting. As you suggest, we would go for further discussion and activities soon such as writing study design for a project.

Please let me know as per your convenience.

Sachin Bhagwat <sbhagwat@wockhardt.com>

Nov 6, 2020,
12:50 PM

to Mahesh, Registrar, dyr@mgmuhs.com, anandnikalje@rediffmail.com, me, Sachin, PRAVIN,

Dear Amol

Please find attached the 1st draft of the protocol outline for the planned study to assess the prevalence of bacterial infection in COVID patients. Request to review and finalize. Inputs from Dr. Nikalje and other critical care specialist needs to be sought.

Regards

Dr Sachin S. Bhagwat, Ph.D.
Senior Vice President – Drug Discovery
Wockhardt Research Centre
Aurangabad, India
Phone: + 91 240 6694185